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SIUD Abstracts

1 - INTRAVESICAL PROSTATIC PROTRUSION INFLUENCES THE EFFICACY OF ALPHA-BLOCKERS IN MEN WITH LOWER URINARY TRACT SYMPTOMS (LUTS) AND BENIGN PROSTATIC ENLARGEMENT (BPE)

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INTRODUCTION AND AIM OF THE STUDY

Intravesical Prostatic Protrusion (IPP) has been found to be correlated to reduced efficacy of alpha blockers in patients with IPP and mild/moderate (<40 ml) prostate volume (PV) [1]. No data are available, to our knowledge, on patients with PV≥40 ml [2]. Aim of this study was to investigate the efficacy of an alpha-blocker (Tamsulosin) in patients with lower urinary tract symptoms (LUTS) and benign prostatic enlargement (BPE) with IPP.

MATERIALS AND METHODS

This is an observational prospective study, performed accordingly to the STROBE statement. Patients with BPE (defined as trans-rectal ultrasound (TRUS) estimated PV≥30 ml, in whom Tamsulosin had been prescribed for Lower Urinary Tract Symptoms (LUTS), were considered eligible for the study. IPP (estimated by TRUS) was graded as grade 1 (IPP< 5 mm), grade 2 (IPP≥5<10 mm) and grade 3 (IPP≥10 mm). Patients were enrolled in a single center in one year and were treated with Tamsulosin (0,4 mg/day) for twelve weeks. Evaluation was performed before/after treatment by means of International Prostate Symptom Score (IPSS) and uroflowmetry. Patients were considered responders (treatment success) if showing a reduction of IPSS >3 points. Univariate logistic regression was used to evaluate relationships between IPP grade and treatment success. Multivariate logistic regression was used to evaluate relationships between IPP grade and the treatment success, after correction for other possible confounding factors (PV, PSA, age, IPSS at baseline, Qmax at baseline). A p value <0.05 was considered statistically significant. All analyses were performed by means of the software STATA 13.0.

RESULTS

One hundred fourtytwo patients were included in the study. Their mean age was 64 ± 8,9 years; their mean PV was 50 ± 18,4 ml; their mean PSA was 3,1 ± 2,3 ng/ml; their mean IPSS was 18,8 ± 4,6; their mean Qmax was 10 ± 2 ml/s. Twelve patients presented incomplete data, thus were excluded from the evaluation. Of the remaining 130 patients, 50 showed an IPP grade 1 (group 1), 52 an IPP grade 2 (group 2) and 28 an IPP grade 3 (group 3). Treatment success was obtained in 82%, 38,5% and 7,1% of patients, in group 1, 2 and 3, respectively; these differences (group 1 vs 2-3 and group 2 vs. 3) were highly significant (p<0.001 and p=0.008 respectively). The odd ratio to obtain a treatment success was of 59 and 8.1 in group 1 and group 2 respectively, in comparison to group 3. After multivariate regression the relationship between IPP grade and treatment success remained significant (group 1 vs 2/3, p=0.000; group 2 vs 3, p=0.009). In particular, PV seems not influence this relationship.

INTERPRETATION OF RESULTS

According to our observational study, IPP seems significantly and inversely correlated with treatment success in patients with LUTS and BPE, treated by means of alpha-blockers (Tamsulosin). Alpha blockers odd ratio of success is 59 times higher in patients with a low grade IPP in comparison to patients with a high grade IPP.

CONCLUSIONS

This is, to our knowledge, the first study showing a negative correlation between IPP and alpha-blockers success rate, excluding PV as an influencing factor.

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2 - THE ROLE OF EXTERNAL URINARY SPHINCTER IN THE ONSET OF INCONTINENCE AFTER SURGERY FOR BENIGN PROSTATIC OBSTRUCTION: MAXIMUM URETHRAL CLOSURE PRESSURE AS A POTENTIAL PREDICTOR OF INCONTINENCE

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INTRODUCTION AND AIM OF THE STUDY

Data about incontinence after surgery for benign prostatic obstruction (BPO) are scant and consider only permanent incontinence, which is about 2% in the literature. However temporary incontinence is relatively common after open prostatectomy and holmium laser enucleation of prostate (HOLEP), infrequent but still present after vaporization and transurethral resection of prostate (TURP).

It is commonly believed that some mistake in surgical procedure could cause damage to external urinary sphincter (EUS). The estimation of the tone of EUS is the maximum urethral closure pressure (MUCP), measured during urethral pressure profile (UPP).

Aim of our study was to verify if differences exist in MUCP before surgery and after surgery in continent and incontinent patients (pts), as well as to compare the MUCP before surgery in continent and incontinent pts.

MATERIALS AND METHODS

Retrospective analysis of urethral pressure profile before and after surgery in pts undergone surgery for BPO. One researcher had to review the urodynamics archive, exporting those patients undergone BPO surgery where both exams before

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and after surgery were available, and included UPP. Another independent researcher consulted the files of the selected patients, in order to observe if temporary incontinence was evident postoperatively. The intent was to have 3 distinct groups of pts: continent, urge incontinent and stress incontinent. The analysis consisted in evaluating if differences existed between MUCP before and after surgery, and then if differences among the 3 groups were evident in preoperative MUCP. Parametric test were used if the distribution of the whole pool of urodynamics showed normal distribution, otherwise non parametric tests could be employed.

RESULTS

We found 110 pts undergone urodynamics before and after surgery, whose clinical data about continence after surgery were available. The dimension of the sample permitted to use parametric tests.

Pts were divided in 3 groups as follows:

- continent: 52 pts;
- Urge incontinence: 28 pts;
- Stress incontinence: 30 pts.

The values of MUCP before and after surgery were:

CONTINENT	Mean	Standard error (se)	Confidence interval (C.I.)
Before surgery	135,423	36,340	121,455-149,391
After surgery	107,385	30,808	95,543-119,227

URGE INCONTINENCE	Mean	se	C.I.
Before surgery	99,714	27,0453	85,547 - 113,881
After surgery	83,857	25,17281	70,671 - 97,043

STRESS INCONTINENCE	Mean	se	C.I.
Before surgery	69,333	20,67665	58,869 - 79,797
After surgery	60,133	21,89542	50,053 - 71,213

In all the groups of pts the values of MUCP before and after surgery did not show any statistically significant difference (t-student test for paired data: $P > 0,05$).

The ratio of reduction of MUCP after surgery resulted quite similar in the 3 groups, as shown in the following table:

	Ratio	se ratio	C.I. ratio
CONTINENT	0,177	0,217	0,094 - 0,26
URGE INCONTINENCE	0,150	0,139	0,077 - 0,223
STRESS INCONTINENCE	0,114	0,183	0,022 - 0,206

We have employed the t-student test for independent data in order to compare the preoperative MUCP of the 3 groups.

The difference between continent and stress incontinent patients resulted statistically significant ($P < 0,05$), while no statistical significant difference was obtained when comparing continent and urge incontinent pts, as well as urge and stress incontinent pts ($p > 0,05$).

INTERPRETATION OF RESULTS

Even if there is a trend toward reduction of MUCP after surgery, we failed to show any statistically significant variation of the tone of external urethral sphincter before and after surgery. The ratio of reduction resulted similar in all the 3 groups.

Data showed a statistically significant difference in preoperative MUCP between continent and stress incontinent pts. However no statistically significant difference was observed between continent and urge incontinent pts, as well as between urge incontinent and stress incontinent pts.

In our experience, surgery does not look to cause relevant damage to external urethral sphincter. However the ablation of the central adenoma of the prostate implies demolition of the bladder neck and removal of the fibromuscular network known as internal urethral sphincter. After surgery, then, continence mostly relies on EUS. By our data, stress incontinence could be justified by lower tone of EUS (lower MUCP), which can be evaluated before surgery. Our data suggest that preoperative MUCP can be a good candidate as a predictor of temporary urinary stress incontinence.

The case of urge incontinence is more tricky. Also urge incontinence is temporary in most cases, otherwise curable with medical treatment, botulinum toxin or sacral neuromodulation. Detrusor overactivity (DO) is involved in etiopatogenesis of this form of incontinence. However it appears de novo after surgery in patients affected by DO even before the operation. Our data show lower values of preoperative MUCP in urge incontinent pts compared to continent group, even if statistical analysis failed to show any significant difference. Significant difference was observed between MUCP of continent and stress incontinent pts, but this was not the case of comparison between urge incontinent and stress incontinent pts. We believe that MUCP values of urge incontinence are realistically in between continence and stress incontinence. In other words slight reduction in preoperative MUCP could cause overt urge incontinence after surgery.

CONCLUSIONS

Our data suggest that preoperative MUCP is a good candidate as a predictor of temporary incontinence after surgery for BPO, and justify further research. Damage to EUS after surgery is probably overestimated, while the ablation of IUS and reduced preoperative MUCP values could be responsible of postoperative iatrogenic incontinence.

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3 - LONG-TERM, SUSTAINED SAFETY AND EFFICACY OF REPEAT ONABOTULINUMTOXINA TREATMENT IN MULTIPLE SCLEROSIS PATIENTS WITH NEUROGENIC DETRUSOR OVERACTIVITY

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INTRODUCTION AND AIM OF THE STUDY

Multiple sclerosis (MS) patients often have neurogenic detrusor overactivity (NDO), which can result in urinary incontinence (UI)[1]. Intradetrusor onabotulinumtoxinA (BOTOX®; Allergan, Inc.) has been shown to be well tolerated and effective in the treatment of NDO due to MS or spinal cord injury in two phase 3, randomized, double-blind, placebo-controlled trials in patients who were not adequately managed by an anticholinergic[2,3]. A large, multicenter, extension study was conducted to investigate the long-term efficacy and safety of repeat onabotulinumtoxinA treatments. Here we present the final long-term efficacy and safety results of repeat onabotulinumtoxinA in the cohort of MS patients.

MATERIALS AND METHODS

Patients who completed a phase 3 trial of onabotulinumtoxinA were invited to continue to receive multiple intradetrusor onabotulinumtoxinA injections (200U or 300U) in the extension study. Patients were treated 'as needed' for control of symptoms (based on patient request and fulfilment of predefined retreatment criteria [≥12 weeks since previous treatment and ≥1 UI episode within the 3-day diary]), so the number of treatments needed during the study differed between patients. Change from study baseline in UI episodes/day, proportion of patients with 100% reduction in UI, duration of effect (defined as time to patients' request for retreatment and calculated from each patient's individual median duration of effect from all completed treatment cycles), adverse events (AEs), and initiation of CIC were assessed.

RESULTS

A total of 231 MS patients received ≥1 onabotulinumtoxinA treatment over 4 years. At baseline, patients reported a mean of 4.8 UI episodes/day in the onabotulinumtoxinA 200U group. Repeat onabotulinumtoxinA treatments consistently reduced the number of UI episodes/day; mean reductions from baseline at week 6 following onabotulinumtoxinA 200U were consistent, ranging from -3.6/day to -3.9/day over 5 treatments. 45.2-61.9% of patients achieved complete continence at week 6 following onabotulinumtoxinA 200U over 5 treatments. Median duration of effect was 36.3 weeks in MS patients (200U). Efficacy results for onabotulinumtoxinA 300U were comparable. Most common AEs over the complete cycle (onabotulinumtoxinA 200U) were uncomplicated urinary tract infection (58.3, 47.4, 47.6, 40.2, and 34.4%; cycles 1-5, respectively) and urinary retention; rates were higher in the 300U group. De novo CIC rates were 28.8, 4.2, 7.1, 0, and 0% in the 200U group (cycles 1-5, respectively) and were higher with 300U. Annualized MS exacerbation rates ranged from 0.03-0.15 (200U). Discontinuation rates due to AEs/lack of efficacy were low (3.3%/1.7%).

INTERPRETATION OF RESULTS

These results demonstrate that in patients with multiple sclerosis and NDO, onabotulinumtoxinA consistently reduces urinary incontinence during long-term treatment (up to 4 years). At week 6 after each treatment, approximately half of patients achieved complete elimination of incontinence episodes, and duration of treatment effect was (on average) 9 months (200U group). The 300U dose of onabotulinumtoxinA provided no additional efficacy benefit compared to 200U. The rate of de novo CIC, which was highest during the first treatment and was greatly reduced in all subsequent treatments, indicates that patients who do not need CIC after their first treatment have a much lower risk of needing it in subsequent treatments.

CONCLUSIONS

Repeat onabotulinumtoxinA treatment consistently reduced UI in MS patients with NDO who were not adequately managed by an anticholinergic, with no new safety concerns identified over 4 years' follow-up.

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4 - LONG-TERM RESULTS OF REPEATED ONABOTULINUMTOXIN- A INTRADETRUSOR INJECTIONS FOR REFRACTORY OVERACTIVE BLADDER

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INTRODUCTION AND AIM OF THE STUDY

Onabotulinumtoxin- A (Onabot/A) intradetrusorial injection has been recently licensed for the treatment of idiopathic overactive bladder syndrome (IOAB) refractory to conventional anticholinergics. Over the last years, results from different randomised, placebo- controlled trials showed the efficacy and safety of Onabot/A after one single injection, but there have been only few small series reporting the outcomes of repeated injections in patients with IOAB.

The aim of the present study was to evaluate the long term efficacy of intravesical Onabot/A, as alternative option for patients with IOAB, refractory to standard anticholinergics. We also evaluated the long- term compliance and side effects.

MATERIALS AND METHODS

Between January 2000 and September 2014 sixty- four patients suffering from IOAB were prospectively included in the study. Baseline evaluation included 3-day voiding diary, urinalyses and culture, urodynamics and/or uroflowmetry with post-void residual volume (PVR) and Visual Analog Scale (VAS) about patients' perception of their urinary condition. All patients received repeat intradetrusorial injections of 100 U of Onabot/A (≥1) and treatment schedules were individualised based upon patient request/ need for retreatment and required at least 12 weeks since previous treatment. Follow up was performed at 15 days and 1, 3, 6 months after treatment and then once per year, and included clinical evaluation, urinalyses and cultures, VAS and uroflowmetry with PVR. The need to perform intermittent catheterization (IC) was also evaluated.

RESULTS

59 patients were females and 5 males. Median age at first injection was 54.4 ± 5.6. Clinical results related to baseline evaluation and to the last follow up have been here reported. Overall, 31 patients had 2 injections, 18 had 3 injections, 10 had 4 injections, 2 had 5 injections, 1 had 7 injections and 2 had 10 injections. Mean number of injections for each patient was 3.01 ± 1.6. Mean interval between two consecutive injections was 7.2 ± 2.1 mos. Mean ± SD values of day-time and night-time urinary frequency significantly changed: from 12.9 ± 4.5 and from 4.3 ± 1.6 to 6.9 ± 3.2 and to 1.7 ± 1.4, respectively. Also urgency and UI episodes/ day significantly improved (Table 1) This improvement was maintained in all patients along time. Four patients had an increase of PVR ≥ 200 ml but none required to perform IC. Mean episodes of bleeding during or soon after treatment was 0.7 ± 0.3. Finally, mean annual frequency of UTI/patient was 4.1 ± 1.6. No systemic side effects.

INTERPRETATION OF RESULTS

The literature provides data with a high level of evidence in terms of fficacy/tolerability profile of the Onabot/A, allowing the onabotulinum toxin A to be included in the therapeutic algorithm for the IOAB.

Our results demonstrate that re- treatment with Onabot/A is a valid alternative to control IOAB symptoms along time. No systemic side effects have been reported and also, the rate of complications (haematuria) during treatment and after it (PVR, UTI) are very low. Worth of nothing adherence and persistence to treatment were high.

CONCLUSIONS

To our knowledge this study is one of the longest longitudinal follow-up for the treatment of IOAB. Our results showed that repeated injections of Onabot/A are able to significantly reduce OAB symptoms and improve UI without inducing any serious adverse effects. Rates of minor com'plications are lower than those reported by others.

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Table 1

	Baseline (mean ± SD)	Last follow up (mean ± SD)
Day- time urinary frequency	12.9 ± 4.5	6.9 ± 3.2
Night- time urinary frequency	4.3 ± 1.6	1.7 ± 1.4
Urgency episodes/day	9.7 ± 2.6	5.2 ± 1.8
UI episodes/ day	5.9 ± 1.4	2.4 ± 1.5
VAS (about urinary condition)	3.7 ± 1.4	8.8 ± 1.2
Qmax (ml)	28.5 ± 2.2	21.7 ± 3.5
PVR	18.60 ± 12.4	60.2 ± 44.5

5 - EVALUATION OF SAFETY, TOLERABILITY AND EFFICACY ON URINARY CONTINENCE AND QUALITY-OF-LIFE OF A NEW TITANIZED INSIDE-OUT TRANSOBTURATORY SLING FOR MALE STRESS INCONTINENCE

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INTRODUCTION AND AIM OF THE STUDY

To evaluate safety, tolerability and efficacy on urinary continence and quality-of-life of a new titanized sling for male post-surgical stress incontinence.

MATERIALS AND METHODS

Interventional single-armed prospective study. From 11/2012 to 10/2014, 23 patients with stress urinary incontinence after radical prostatectomy (19) or TURP (4) underwent transobturator sling implantation with the inside-out DeLeval technique [1]. The implanted sling was the TiLoop® (pfmmedical, Köln, Germany), a polypropylene mesh coated with titanium to improve biocompatibility, 40 × 1,5 cm in dimension. Patients were assessed preoperatively and every three months after surgery with uroflowmetry, pads use/day, urodynamic study (pre-operatively), International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and Patient-reported Global Impression of Improvement (PGI-I; score 1-7) and Satisfaction (yes/no). The success was defined as no pad use, while a reduction of at least 50% of the number of pads has been considered as an improvement. Complications and postoperative adverse effects have been prospectively collected.

RESULTS

Final evaluation included 21 patients (90.5%), excluding two (previous radical prostatectomy) lost to follow-up. Preoperatively, 10 (48%) and 11 (52%) patients used two or three to five diapers, respectively. Two patients were previously treated with pelvic radiotherapy. After a median follow-up of 12 months (4-26 months), 12 (57%) patients were cured, 5 (24%) were improved and 4 (19%) reported no benefit (patients with use of 4-5 pads/day, two had radiotherapy). The mean ICIQ-SF score improved from 17.2 preoperatively to 7.6 postoperatively ($p < 0.01$), whereas the QoL score (question 5: "Overall, how much does leaking urine interfere with your everyday life?", score 0-10) improved from 8.8 to 3.1 ($p < 0.01$). At PGI-I, 17 (81%) patients reported an improvement and 15 (71%) patients were completely satisfied. The Qmax and the post-voiding residual volume were statistically unchanged postoperatively. There were no perioperative complications and no patient experienced urinary retention requiring catheterization. Ten (48%) patients reported mild perineal pain which resolved spontaneously within maximum 3 months.

INTERPRETATION OF RESULTS

These preliminary results on TiLoop® transobturator sling are satisfactory and consistent with those reported in literature for similar fixed male sling. The inside-out technique is safe and well tolerated. Failure has been associated with severe incontinence or previous pelvic radiotherapy suggesting that patient selection may further improve these results.

CONCLUSIONS

These preliminary results on TiLoop® transobturator sling are satisfactory and consistent with those reported in literature for similar fixed male sling. The inside-out technique is safe and well tolerated. Failure has been associated with severe incontinence or previous pelvic radiotherapy suggesting that patient selection may further improve these results. Prospective long-term and larger studies are needed to confirm these results.

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6 - TRANS-LABIAL ULTRASOUND IN THE DIAGNOSIS OF FEMALE URETHRAL DIVERTICULA: OUR EXPERIENCE

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INTRODUCTION AND AIM OF THE STUDY

Urethral diverticulum (UD) is difficult to diagnose and often the investigations are not successful. Symptoms associated with UD, when present, however, are variable and the classic clinical presentation (dribbling after voiding, dysuria, peri-urethral mass and expression of pus from the urethra on physical examination) is uncommon. Thus, imaging is a necessary support for clinicians. The aim of this study is to demonstrate

effectiveness of trans-labial ultrasound (TL-US) in the evaluation of female UD.

MATERIALS AND METHODS

In the study period, 20 UD were diagnosed and treated. All data on demographic characteristics, presenting symptoms, physical examination findings, diagnostic and operative procedures, were considered. Patients were referred to TL-US for diverticular evaluation, using a 2D 7.5-MHz endfire probe.

For each UD, size, complexity, echogenicity content, and presence of diverticular neck were considered. Follow-up controls were carried out at 1, 6 and 12 months after surgery, to evaluate outcome and need for further intervention.

RESULTS

Mean patient age was 46 years (range, 35–55 years) and mean parity was 1 (range, 0–3). The principal symptoms associated with the diverticular mass was dysuria (25%). In all evaluated cases, UD was single (simple in 15 cases and complex in 5). The mean size of the diverticula was 28 mm (range, 8–50 mm). Nineteen diverticula were diagnosed on TL-US, and urethrocystoscopy was carried out for confirmation. Treatment consisted of diverticulectomy. No intraoperative or postoperative complications occurred. At 1-, 6- and 12-month follow up after surgery, TL-US showed no recurrence of UD in any of the patients.

INTERPRETATION OF RESULTS

While careful clinical examination is clearly important, imaging is essential for accurate diagnosis and characterization of UD and, subsequently, for adequate preoperative surgical planning. Since 1990, TL-US has been used as a valid technique in disorders of the lower urogenital tract. In the present series, 95% of the UD were identified in an outpatient setting, with TL-US and without the help of level II diagnostic methods. Only in one case was urethrocystoscopy necessary to confirm US diagnostic suspicion.

Given the present data, we suggest that a skilled sonographic operator perform TL-US as a first-line method for the diagnosis and evaluation of urethral masses, especially when UD is suspected on objective exam; the use of urethrocystoscopy should be limited to dubious cases, which, in the diverticular neck, are not visible during US.

CONCLUSIONS

TL-US is a valid, mini-invasive and reproducible method to diagnose UD.

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7 - ABDOMINAL SACRAL COLPOPEXY: A LONG-TERM FOLLOW-UP STUDY

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INTRODUCTION AND AIM OF THE STUDY

Sacrocolpopexy (SC) represents the gold standard in the surgical treatment of vaginal vault prolapse. Pelvic Organ Prolapse (POP) alters significantly women's quality of life and can lead to withdrawal from social activity due to urinary, anorectal, and sexual symptoms. It is estimated that 30% of women aged 50–89 yr will seek consultation for pelvic floor disorders. The aim of POP surgery is not only to restore anatomy but also to improve or relieve symptoms. Long term results are mandatory for patients perspective and counselling and this study aims to evaluate anatomic and functional outcomes up to 4 years after abdominal sacrocolpopexy (ASC).

MATERIALS AND METHODS

71 consecutive patients referred to our Department for symptomatic vault prolapse and who underwent ASC between June 1996 and January 2013, were assessed and 67 out of 71 who attended follow-up visits for at least 4 years were included in this study (4 pts excluded for inadequate follow up). All patients signed an informed consent. Preoperative evaluation included detailed medical and urogynecological surgery history, evaluation of voiding symptoms, storage symptoms, urinary incontinence (ICS standardization) and sexual activity, clinical examination with POP classified on the basis of POP-Q system, uroflowmetry with PVR measurement, urodynamic study, trans-perineal ultrasonography. Patients completed self-administered Urinary Distress Inventory Short Form (UDI-6), Incontinence Impact Questionnaire–Short Form (IIQ-7), Female Sexual Function Index questionnaire (FSFI). All patients underwent ASC using 2 rectangular polypropylene meshes, fixed with 1 or 2 nonabsorbable sutures to sacral promontory after a wide preparation of anterior and posterior vaginal walls. All procedures were performed by 2 senior surgeons. Patients were followed up at 1, 3, 6, and 12 months after surgery, and then annually. At each visit, patients underwent clinical examination, evaluation of urinary and sexual symptoms, uroflowmetry with PVR measurement and Patient Global Impression of Improvement (PGI) questionnaire. Furthermore patients completed self-administered UDI-6 and IIQ-7 questionnaires annually and FSFI at 1 and 2 years. All the data present in our database were collected and recorded along the f-up period. The following outcomes were recorded: a) anatomic outcomes b) symptoms outcomes, c) functional outcomes d) global patient perceptions. Statistical analysis was performed by using X2 test for categorical data comparisons.

RESULTS

All patients had a vaginal vault prolapse (stage III-IV), a mean age 65.6 ± 8.18 years, mean BMI 26.40 ± 3.50, median parity 2 (range 1- 4) Median follow-up was of 60 months (range 48-144 months). Anatomical success rates was 100% for apical prolapse, 74.6% and 69.4% for anterior and posterior compartment respectively (recurrences $<$ stage I-II). Post-operative overall urinary symptoms were significantly improved: voiding and storage symptoms disappeared in 95.1% and 85.4% respectively. The time trend curve for both symptoms is represented in fig. 1. De novo voiding symptoms were present in only 1 patient. The novo storage symptoms tend to increase till 21% at 1 year follow-up and then they improve within the third year (20% after urinary tract infection treatment, 40% spontaneously, 40% after anticholinergic therapy). Patients preoperatively incontinent were 31.34% (17.94% urgency incontinence and 13.40% stress incontinence). After ASC, SUI disappeared in 79.2% of the patients and UUI in 92.2% of patients. The time trend curve of UI is represented in Fig. 2. De novo SUI and UUI appeared in 9.3% and 1.8% respectively in the first months after surgery. De novo UUI disappeared 1 year after surgery, while SUI tend to disappear during the second year

(50%for physiokinesitherapy and 50% for anti-incontinence surgery). After surgery 62.5% of patients with preoperatively sexual difficulties improved, 25% showed persistent symptoms, 12.5% had not sexual intercourse. The incidence of de novo sexual disorders was 20% and in 70% of the cases they appeared within 2 years after surgery (33.33% for mesh erosion, 66.67% for vaginitis) . Mesh erosion rate was 3%. Post-operative uroflowmetry data (Qmax baseline 14,62 ± 9,13 vs Qmax end-point 25.45 ± 14,89 $p<0.001$), IIQ7 and UDI6 scores showed significant improvement. PGI was 1 or 2 in 73.13% and 26.87% of the cases respectively.

INTERPRETATION OF RESULTS

The results confirm ASC is an excellent procedure for the treatment of vaginal vault prolapse, not only for the anatomical results but also for functional results and patient satisfaction. The anatomical success rate of 100%, 74.6% and 69.4% (for apical, anterior and posterior compartment) is an optimal result taking into account that all the persistences were asymptomatic, of low stages (I-II) and remained stable in the time. Finally no patient needed reoperation. Voiding and storage symptoms significantly improved (95.1% and 85.4% respectively). Only 1 patient presented de novo voiding symptoms while de novo storage symptoms, present at 1 year in 21% of the cases tend to improve in the time. UUI and SUI significantly improved after surgery (92.2% - 79.2%) with 1.8% and 9.3% appeared the novo respectively. The time trend curve for SUI showed a 20% of patients incontinent in the first year and then an improvement due to the patients who underwent anti-incontinence surgery (50%) or physiokinesitherapy (50%). On the contrary UUI, persisted in the first months after surgery and then improved in the time. These excellent functional outcomes are confirmed by the high PGI scores (1 in 73.13% and 2 in 26.87% of the cases)

CONCLUSIONS

This study confirms the excellent outcome of ASC in the treatment of vaginal vault prolapse in the long term follow-up. Anatomical results and functional outcomes showed significant improvements which persisted after 4 or more years. These data are confirmed by the high subjective patient satisfaction. On these basis it is possible to justify the actual trend in the treatment of vaginal vault prolapse which more and more is moving toward SC performed with mini-invasive techniques (laparoscopic or robotic assisted procedures) awaiting for long-term results.

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Figure 1: The time trend curve of Urinary Symptoms

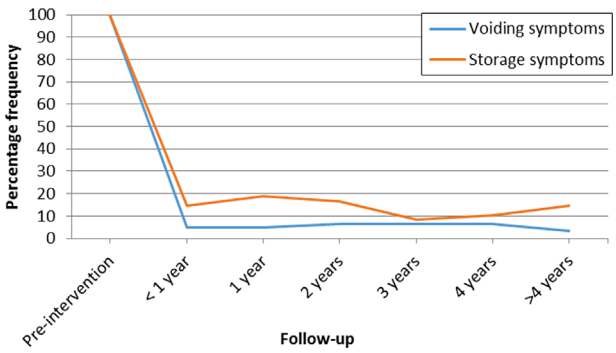
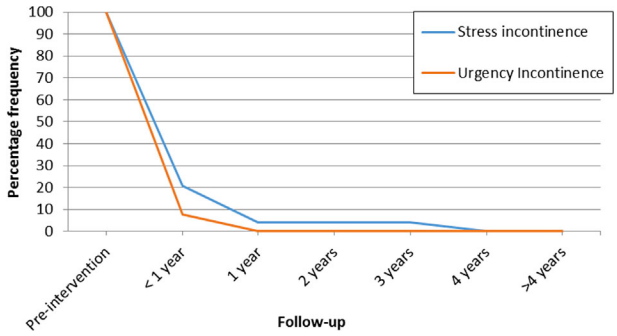


Figure 2. The time trend curve of Urinary Incontinence



8 - SURGICAL AND CLINICAL OUTCOMES OF POP SURGERY IN WOMEN WITH PREOPERATIVE STRESS URINARY INCONTINENCE

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INTRODUCTION AND AIM OF THE STUDY

The urinary incontinence commonly co-exists with POP and the inverse relation is just as possible [1]. At present, on the basis of the available conflicting data, it seems not desirable to combine a transvaginal surgical correction of pelvic organ prolapse with a midurethral sling for stress urinary incontinence, preferring a two-step approach. It was demonstrated that the clinical outcome of midurethral sling does not change is if it's inserted in combination with prolapse surgery or if it's positioned some months after prolapse surgery; however, the reduction in the rate of adverse events with a two-step surgical approach makes it recommended this strategy rather than a combined approach [2]. Aim of this study is to assess 1-year outcomes of surgery for POP in women with anterior POP and concomitant SUI, in terms of: how the symptoms of SUI have changed 3, 6 and 12 months after POP surgery, studying the average difference in the Visual Analogic Scale (VAS) score and the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) score. Secondary outcomes were: to evaluate the change in the average scores of the defined points of POPQ system (Ba, C, Bp, TVL); the assessment of the impact of the POP surgery on the patients' quality of life, comparing the average of the scores POP-QoL before and 12 months after surgery.

MATERIALS AND METHODS

We considered patients from January 2011 to January 2013 subjected to surgical repair of anterior vaginal prolapse with or without repair of central and/or posterior compartment (depending on the presence or absence of the uterus or bowel's prolapse). We included women with anterior vaginal prolapse $\geq$ stage II according to the POP-q and with concomitant diagnosis of symptomatic or occult SUI at preoperative urodynamic study. All women underwent the same fascial surgical procedure for the anterior compartment repair, performed by the same surgical team. Exclusion criteria were: prior continence surgery, prior POP surgery and diagnosis of detrusor overactivity at urodynamic. The patients were examined at time 0 and 3, 6 and 12 months after surgery. At

time 0 (preoperative) we collected medical history, we explored the severity of symptoms with a simple Visual Analogic Scale (VAS) but also in a standardized manner with validated self-assessment questionnaires such as the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) and Pelvic Organ Prolapse-Quality of Life (POP-QoL). The stage of prolapse was also assessed with POP-Q system and the bladder function investigated through the urodynamic study. Patients were revaluated 3, 6 and 12 months after surgery: both the VAS for USI and Prolapse' symptoms and the stage of prolapse with POPQ-system were recalculated. Finally, 12 months after surgery for prolapse, the patients have filled out again the ICIQ-SF and POP-QoL questionnaires.

RESULTS

We selected 42 women who respected our inclusion and exclusion criteria. Baseline characteristics of the population: age: 64.7 ± 8.28 (mean ± SD) BMI: 24.8 ± 4.08. At time 0 (preoperative) 100% of the women was symptomatic for prolapse (VAS of prolapse at time 0: 8.6 ± 1.69) and 24 of them (57%) were symptomatic also for SUI, while 18 of them (43%) had a negative history for SUI (VAS of SUI at time 0: 3.9 ± 2.09) but they showed during urodynamics a potential SUI. In any way, all the patients received a diagnosis of clinical or potential stress urinary incontinence during urodynamic examination conducted with the use of the vaginal pessary. In particular 9 of the 24 women with a history of SUI (37.5%) had a mild stress urodynamic incontinence; 13 women (54.2%) had a severe stress urodynamic incontinence; 2 patients (8.3%) had a moderate stress urodynamic incontinence. Of the 18 women without symptoms of stress urinary incontinence 11 patients (61.1%) had mild stress urodynamic incontinence, one woman (5.6%) had moderate stress urodynamic incontinence and 6 women (33.3%) had severe stress urodynamic incontinence. In the 42 patients, UDS results were: mild SUI 47.6% (20 woman), moderate SUI 7.2% (3 woman), severe SUI 45.2% (19 woman). The results of POPQ system at time 0 were: about the anterior compartment 71% (30/42 women) had a stage II, 26% (11/42 women) had a stage III and only one woman (0,02%) had a stage IV; about the central compartment 62% (26/42 woman) had a stage I, 26% (11/42 woman) had a stage II and 12% (5/42 woman) had a stage IV; about the posterior compartment 45% (19/42 woman) had a stage I, 0.07% (3/42 woman) had a stage II, while most of the patients (20/42 woman) hadn't posterior prolapse (table Stage of POP). Regarding the type of surgery, 55% of patients received only fascial repair of cystocele, 45% of women received cystocele repair, vaginal hysterectomy and McCall culdoplasty. We found statistically significant differences in the score of the VAS scale for stress urinary incontinence before and 1 year after surgery: 3.9 ± 2.09 vs 1.2 ± 2.11, p=0.0001. Finally, the comparison between the mean score of the ICIQ-SF pre and post-surgery was statistically significant: 11.7 ± 7.6 vs. 4:18 ± 2.25 (mean ± SD), p <0.0001. The difference between the mean preoperative and 1 year after surgery of the points C and Ba of the POP-Q system was statistically significant: the point Ba, at time 0 and at 1 year, was respectively: +1.0 ± 1:25 vs. −1.5 ± 1.17 (mean ± SD), p value <0.0001; the point C, at time 0 and at 1 year, was respectively: −1.9 ± 3.70 vs −4.9 ± 1.93 (mean ± SD), p value <0.0001. There was no significant difference between the mean of the total vaginal length (TVL) preoperative and 1-year: 8.8 ± 1.32 vs 8.3 ± 1.38 (mean ± SD), p value = 0.06. The relationship between vaginal prolapse severity and quality of life was investigated by the questionnaire POP-QoL at preoperative and 1-year: a statistically significant difference was for the average scores of all items, with p value <0.0001 for Prolapse Impact, Role limitations, Physical limitations, Emotions, Sleep/Energy and Severity Measures items. In addition, the average difference in VAS score for prolapse at time 0 and at 1-year was statistically significant: 8.6 vs 1.3 ± 2:45 ± 2:22 (mean ± SD), p value <0.0001.

POP-Q	Pre-surgery	After 3 months	After 6 months	After 12 months
TVL (mean ± SD)	*8.8 ± 1.32*	*8.3 ± 1.38*	*8.3 ± 1.38*	*8.3 ± 1.38*
Ba (mean ± SD)	*+1.0 ± 1.25*	*−2.3 ± 0.68*	*−2.1 ± 0.68*	*−1.5 ± 1.17*
C (mean ± SD)	*−1.9 ± 3.70*	*−6.2 ± 1.23*	*−5.7 ± 1.41*	*−4.9 ± 1.93*

	Pre-surgery	After 3 months	After 6 months	After 12 months
VAS prolapse (mean ± SD)	8.6 ± 2.45	0.9 ± 1.39	0.8 ± 1.56	1.3 ± 2.22
VAS SUI (mean ± SD)	3.9 ± 2.09	1.1 ± 1.70	1.0 ± 1.73	1.2 ± 2.11

ICIQ-SF Pre-surgery	ICIQ-SF after 1 years	p Value
11.7 ± 4.18	7.6 ± 2.25	<0.0001

INTERPRETATION OF RESULTS

Our survey has shown that fascial surgery for anterior prolapse can ensure high cure rates and high scores of QOL and subjective satisfaction, even in the presence of SUI (clinical or occult) at baseline. At 1-year follow-up, no patients required a sling procedure for the treatment of SUI.

CONCLUSIONS

In women with anterior POP (with or without prolapse of the other vaginal compartments) and concomitant clinical or occult SUI, the fascial surgical repair of the anterior compartment without slings procedure appears to be at 1-yr follow-up highly effective also on the symptoms of SUI.

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9 - FECAL AND URINARY INCONTINENCE: SACRAL NEUROMODULATION AND A LONG-TERM FOLLOW-UP

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INTRODUCTION AND AIM OF THE STUDY

The purpose of this study is to evaluate improvement in symptoms of fecal incontinence (FI) and urinary incontinence (UI) in a group of patients who were successfully implanted with the sacral neuromodulation (SNM) device. FI is defined as

involuntary loss of feces solid or liquid at inopportune times. It is a serious problem especially for the elderly. The epidemiology of incontinence is not well described in the literature although it is often used as an endpoint for treatment evaluation in clinical trials. It's estimated that in Europe, between 4.4 and 6.7% of the population (age > 18 years), has incontinence for solid and liquid feces[1]; 35% of these have severe incontinence[2] and 52% have a strong impact on the quality of the life[2]; 30% do not respond to conservative treatment[2]. The prevalence of UI in middle-aged adults is reported to be between 14% and 41% with urge incontinence accounting for 22% of cases in women and 73% in men[3]. Urinary and fecal incontinence are common conditions that are frequently associated, when they coexist is referred to as double incontinence (DI). Approximately 40% of men and women with anal incontinence also have UI[3]. The causes of incontinence are varied: idiopathic, neurological, obstetric trauma, sphincter defects, iatrogenic (post hemorrhoidectomy, after resection for rectal prolapse, after anal fistula or after low anterior resection). Sacral neuromodulation (SNM) has led to a change in the diagnostic and treatment of incontinence. It's indicated in patients, after failure or intolerance to treatment more conservative due to dysfunction important anatomical, physiological or neurological.

MATERIALS AND METHODS

All our data were obtained from patients (pts) referred to the our center of significant regional interest in rehabilitation therapy before and after operation of the digestive system, the pelvic floor and neuromodulation at the University of Naples, Federico II. From 2002 to 2009, we have selected 21 pts with DI [3 men (mean age 46 - SD 16.37) and 18 women (mean age 54.83 - SD 9.42)] were subjected to definitive implant of SNM. Before treatment and during follow up, all patients were investigated with clinical evaluation (history/examination), pathophysiological and semeiological studies. The duration of symptoms ranged from 2 to 6 years with a median of 3,2 years. Patients candidates for SNM, have been subjected to percutaneous nerve evaluation test and all had a positive outcome. Subsequently, we have implanted the definitive device. The SNM procedure was performed after failure of conservative treatment, after failure of rehabilitation therapy (FKT, BFB, ES) . All pts, in fact, were treated by pharmacological agents and behavioral techniques such as biofeedback training. Incontinence etiology was classified but not significantly. All patients were followed over time constantly until today. The first pts have a follow up of 12 years, the last have a follow-up of 5 years (mean follow-up 9.04 years, SD 2.35). Wexner score incontinence (WSI) was used to compare the degree of incontinence of the pts. Incontinence Impact Questionnaire (Short Form IIQ-7) is used to evaluate the influence of the UI in the life of pts. Status of health (SF36) is the test used to assess quality of life (QoL) of pts. Questionnaires were completed by all patients before and after implantation of neurostimulator.

RESULTS

The WSI is statistically improved in all patients treated with SNM (from an average of 13,47 to 6,57, $P< 0.001$). Incontinence for solid feces decreased (from an average of 2,89 to 0,89, $P<0.001$) as well as incontinence to liquid feces (from an average of 3,42 to 1,71, $P< 0.001$). Incontinence gas is reduced (from an average of 3,52 to 1,80, $P< 0.001$). The request to pad has declined (from an average of 3,14 to 1,33, $P<0.001$). The lifestyle is improved (from an average of 2,80 to 0,95, $P< 0.001$). Also, IIQ-7 shows a statistically significant improvement in symptoms of UI (from an average of 15,04 to 8,76, $P<0,01$). The neuromodulator was implanted under local anesthesia. The intervention lasted on average 15 minutes. The postoperative hospital stay has been one day. There were neither complications nor infections. The level of the test SF 36 confirms the improvement statistically significant of the QoL of pts after the implantation of a neuromodulator. In fact, SF 36 questionnaire showed a significant increase in the physical functioning score of the whole population 48,9 + 31,2 to 67,0 + 22,3 ($P<0,05$).

INTERPRETATION OF RESULTS

This study has confirmed the beneficial effect of SNM in the management of incontinence, it's statistically reduced. The use of pad is decreased and the quality of the social life of patients improved. SNM is a safe treatment modality for incontinence, with no major complications. The procedure for implanting of device is rather easy in experienced hands and requires specific training for general surgeons. The adverse events associated with the procedure are low. In our experience SNM is associated with minimal post-operative morbidity. Using an antibiotic prophylaxis similar to that of the other units, infections are rare. A follow up accurate is fundamental to the success of therapy. Are sufficient periodic ambulatory visits, also considering the patient's clinical diary (number of losses daily; type and severity of losses) and change the parameters of the neurostimulator programming if necessary. All patients are satisfied with their results.

CONCLUSIONS

This study demonstrates that SNM offers significant improvement in patient symptoms and quality of life on medium and long term follow-up. Furthermore, it is associated with low morbidity. The authors believe that further research should be conducted to better understand the complex mechanism of continence and in order to develop new devices ever more reliable and efficient.

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10 - TRANSVERSE CYSTOCELE REPAIR AND UTERINE PRESERVATION IN WOMEN WITH ANTERIOR AND CENTRAL COMPARTMENT PROLAPSE: IS IT POSSIBLE?

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INTRODUCTION AND AIM OF THE STUDY

Pelvic organ prolapse (POP) is a condition that involves a large percentage of patients between 60-69 years old (1) but also a segment of population somewhat younger. Traditionally the surgical correction of uterovaginal prolapse has included hysterectomy. However, without a real uterine disease and especially if the uterus is not the "active" protagonist of the POP, why take a hysterectomy? The evidence shows a wide variety of surgical options to preserve the uterus in women with uterine prolapse, but data on efficacy and safety of these procedures are lacking (2). Aim of the present study was to assess prospectively surgical outcomes in women with anterior

vaginal prolapse and concomitant uterine prolapse, undergoing to uterine preservation and fascial repair with transverse cystocele repair.

MATERIALS AND METHODS

Between January 2013 and December 2014, data of consecutive women of a single centre study were collected in an IRB approved database. All the women affected by uterovaginal prolapse, in particular with stage II or III of anterior compartment and stage II of central compartment with -1>C≤ 0, according to the ICS classification, were enrolled in this prospective study. Before surgical correction, each patient was assessed about personal and surgical history, physical examination of prolapse according to the Pelvic Organ Prolapse Quantification scoring system and urodynamic study. Subjective assessment was based on symptoms of uterovaginal prolapse like pelvic pressure or ''sense of vaginal bulge'' recorded using a visual analogue scale (VAS). Each patient was asked to record the disturbance given by genital prolapse as quality of life expectancy on a 0 to 100-mm horizontal VAS, with 0 being no disturbance and 100 the worst disturbance imaginable. The surgical procedures included a transverse cystocele repair with uterine preservation suspending the plicated pubocervical connective tissue to cervical stroma; this procedure was performed as previously described by Shull et al (3) and by a single surgeon, with an extensive background in urogynecologic surgery. Follow-up evaluations were scheduled at 3 and 12 months after surgery. Subjective outcomes were assessed by the Patient Global Impression of Improvement (PGI-I) (a 7-point scale, with a range of responses from 1, ''very much improved,'' through 7, ''very much worse''). Subjective success was indicated in case of ''very much improved'' or ''much improved'' (PGI-I ≤2). Objective success was indicated by POP< II stage in all the compartments. Exclusion criteria were: presence of endometrial disease, family oncological history, point C >0. Statistical significance was assumed when p< 0.05. Statistical analysis was performed with GraphPad version 5 (GraphPad Software, San Diego CA).

RESULTS

Twenty-four patients fulfilled the inclusion criteria. Baseline characteristics are shown in Table1. Anterior prolapse was of II stage in 66,6% (16/24) while (8/24) 33,3% was of III stage. The median of disturbance given by genital prolapse was 8,5 (8-9,25) at VAS. The median of symptoms of prolapse at VAS after surgical fascial repair were 0 (0-3). After the follow-up at 3 moths the subjective success based on PGI was 83,3%. Preoperative and postoperative data of prolapse quantification were summarized in Table 2 (POP-Q simplified). Only one patient had a postoperative complication (urinary tract infection).

Tab.1 n° pt	24 pt
AGE (median)	63,5 (55,25-70,75)
HRT %	20.83
P>4000%	25
P.OP %	4,16
BMI (median)	26,5 (23,3-32,4)
Parity (median)	2 (1,25-2,75)
Previous surgery %	8,30

Tab.2	Median	Median	P value
POP-Q staging	*preoperatory*	*postoperatory*	
Ba	0,5 (0,25-1)	−2 (-3 - -2)	<0.0001
C	−1 (-1 - - 1)	−6 (-6 - -4)	0.0002
Tvl	9 (9-10)	9 (8-10)	n.s

INTERPRETATION OF RESULTS

Our results showed that this surgical procedure is safe and effective, and it assures uterine preservation, when the anterior defect is more relevant and the uterine prolapse is < stage III. This procedure could reduce the surgical time and the possible complications of a hysterectomy when it is not necessary. Limitations of the present study include the relative small sample size of the population included and the short follow-up of evaluation. Additionally, a single skilled surgeon performed all the procedures, thus making our results not reliable in a setting without advanced urogynecological experience.

CONCLUSIONS

This surgical procedure, based on a tansverse cystocele repair, allows preserving the uterus in women with anterior and central compartment prolapse but with a moderate uterine descensus. Our reported experience suggests that patients with good surgical and subjective result at the 12-week postoperative visit will maintain good support also at one year. Additional follow-up, however, needs to be performed to assess the durability of this specific repair.

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11 - SEVERE PERINEAL LACERATIONS IN AN ITALIAN OBSTETRIC REFERRAL UNIT: A PROSPECTIVE OBSERVATIONAL STUDY

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INTRODUCTION AND AIM OF THE STUDY

Vaginal birth can be accompanied by complications such as vaginal tears, cervical lacerations and perineal lacerations. Perineal lacerations are commonly classified in four categories with ano-rectal involvement starting from the IIIrd degree: IIIrd and IVth degree tears are commonly considered as severe[1]. The incidence of severe perineal lacerations shows a big variability in the literature, according to the different settings and populations[2,3]. Demography and obstetrical practice can differ from one context to another: this is why data analysis of risk factor for each particular setting is so important to drive clinical approach in this particular field.

The objective of this study is to analyze the incidence of severe perineal lacerations and to identify possible risk factors within a tertiary Obstetric Italian referral Unit.

MATERIALS AND METHODS

This was a prospective observational cohort study based on women ≥ 32 weeks gestational age who delivered in an Italian Tertiary Referral Maternity Hospital between July 2014 and December 2014.

All the staff working in the Unit was involved in entering data on pregnancy history, labour and delivery in an electronic

database. Relevant parameters (table 1) were then anonymously extracted from the original database to build-up a specifically designed one.
An univariate analysis for categorical and continuous parameters in relation to severe perineal tears was performed with *Fisher* and parametric *t-Student* tests respectively. A logistic stepwise multivariate analysis was then also performed including all the parameters that resulted significant at univariate analysis. $p<0.05$ was considered for significance and software Stata 9.0 was adopted(Stata Corporation, College Station, Texas, USA).

RESULTS

A total of 1677 women delivered in the period considered: 430 women were excluded, due to gestational age < 32 weeks (6 women) or because of abdominal delivery (424 C-Sections, 25% of all deliveries). Finally 1247 women were included in the study. Nulliparous women significantly differed from multiparous for all parameters. As only one multiparous women sustained a severe laceration, an unique statistical analysis was performed on all eligible women.

Table 1. Demographics and obstetrical parameter with univariate analysis.

Parameter	No perineal lacerations $+I^{st}$ and II^{nd} degree (n=1232)	Severe perineal lacerations ($\geq III^{rd}$ degree) (n=15)	*p-value*
Ethnicity			*0.048*
Caucasian	979 (79.8%)	9 (60%)	
Asiatic	99 (8.1%)	5 (33.3%)	
South American	81 (6.6%)	1 (6.7%)	
Middle-Eastern	35 (2.9%)	0	
African	33 (2.7%)	0	
Age Average ± SD	32.8 ± 5.3	29.7 ± 6.9	*0.013* §
BMI Average ± SD	26.1 ± 3.8	26.1 ± 3.1	*0.499* §
Nulliparity	694 (56.3%)	14 (93.3%)	*0.002* *
Mode of Delivery			*0.248* *
Vaginal	1022 (83.0%)	11 (73.3%)	
Vacuum extractor	210 (17.1%)	4 (26.7%)	
GA (weeks) Average ± SD	39.4 ± 1.3	39.7 ± 1.1	*0.183* §
Onset of labour			*0.152* *
Induction	354 (28.7%)	2 (13.3%)	
Spontaneous	878 (71.3%)	13 (86.7%)	
Lenght of induction (h)			
≤24 h	277 (83.2%)	1 (50%)	*0.312* *
>24 h	56 (16.8%)	1 (50%)	
Pushing second stage > 1h	216 (17.7%)	3 (20.0%)	*0.514* *
Oxytocin augmentation	296 (24.0%)	7 (46.7%)	*0.048* *
Epidural analgesia	462 (37.5%)	6 (40.0%)	*0.519* *
Maternal position			
Orthostatic	77 (7.6%)	3 (27.3%)	*0.047* *
Lithotomic	941 (92.4%)	8 (72.7%)	
Neonatal birth weight			
Average ± SD	3333 ± 437	3367 ± 223	*0.385* §

* *Fisher's exact test;* § *t-Student test*

Integrum perineum was found in 233 women (18.7%), while 676 (54.2%) sustained a perineal tear and 338 (27.1%) had an episiotomy. Only 15 women (1.2%) had a severe laceration, among which one IV degree. Results from multivariate logistic stepwise analysis are reported in table 2.

Table 2 results of multivariate logistic stepwise analysis

	univariate		multivariate	
Risk Factor	OR (95% IC)	*p*	OR (95% IC)	*p*
Age	0.90 (0.83–0.99)	*0.028*	0.90 (0.81 – 1.01)	*0.071*
Mother's position at delivery	0.22 (0.06 – 0.84)	*0.027*	0.20 (0.05 – 0.79)	*0.022*
Nulliparity	0.09 (0.01 – 0.70)	*0.021*	0.16 (0.02 – 1.26)	*0.082*

INTERPRETATION OF RESULTS

Our data reflect the results reported in the literature, in fact the severe lacerations' rate of 1.2% in our study agrees with the average values commonly observed. The risk factors emerging in this cohort of women are similar to the ones found in several works, such as ethnicity, younger age, nulliparity, oxytocin augmentation and orthostatic maternal position at delivery. However our data on maternal position at delivery has to be cautiously considered due to the small number of severe lacerations and some missing data in our sample size. In the literature both lithotomic and squatting position at birth are associated with an increased risk for severe lacerations and in our series squatting was included in the orthostatic group. Moreover this is the only independent risk factor emerging as significant in our multivariate logistic stepwise analysis, even though both younger age and nulliparity are close to significance, being therefore relevant in the prediction model.

CONCLUSIONS

In an Italian tertiary referral Center an incidence of 1.2% of severe perineal laceration was observed. Orthostatic maternal position at delivery emerged as significant risk factor for severe lacerations, with younger age and nulliparity to be also considered. Further data are needed to clarify our results, since considering orthostatic maternal position at delivery as a risk factor would have an impact on midwifery practice.

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12 - PERISTEEN TRANSANAL IRRIGATION SYSTEM FOR THE TREATMENT OF NEUROPATHIC BOWEL DYSFUNCTION AND ABDOMINAL PAIN

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INTRODUCTION AND AIM OF THE STUDY

Transanal irrigation of the rectum (TAI) and colon is designed to assist the evacuation of faeces from the bowel by introducing water into these compartments via the anus. Patients with neurologic bowel disease experience not only the discomfort of an irregular bowel clearance but also very often chronic abdominal pain which limits social activities. Data from literature have already shown the efficacy of TAI on improving bowel emptying but there is a lack regarding the contribute of this system on reducing abdominal

pain. The aim of this study was to evaluate if the use of TAI for neuropathic constipation could also relief symptoms in those subjects with associated chronic abdominal pain.

MATERIALS AND METHODS

A prospective study was conducted on the first cohort of adult patients affected with spinal cord lesions and neuropathic bowel dysfunction referred to our centre for Peristeen TAI treatment between July 2013 and November 2014. Patients with neurogenic bowel disturbance who did not satisfactorily respond to conventional bowel management were enroled. In particular, patients were selected following the directions of consensus review of best practice of TAI in adults [1]. After providing informed written consent, a previously described and validated Neurogenic Bowel Dysfunction score (NBD) (fig. 1) was used to assess bowel function. Abdominal pain was evaluated by a Visual Analogic Scale (VAS), from 0=no discomfort to 10=severe discomfort (fig. 2). This questionnaires were administered before and after treatment. Peristeen TAI composed of a coated rectal balloon catheter, manual pump and water container [2]. After the first visit in which it was determined if the patients could receive treatment and trained, they performed treatment every day per 10 days, then on alternate days.

The number of points for each possible answer is given in parenthesis

(1) Frequency of defecation — Points
Daily ☐(0) 2–6 times every week ☐(1) Less than once a week ☐(6) ___

(2) Time used for each defecation
0–30 min ☐(0) 31–60 min ☐(3) More than one hour ☐(7) ___

(3) Uneasiness, headache or perspiration during defecation
No ☐(0) Yes ☐(2) ___

(4) Regular use of tablets against constipation
No ☐(0) Yes ☐(2) ___

(5) Regular use of drops against constipation
No ☐(0) Yes ☐(2) ___

(6) Digital stimulation or evacuation of the anorectum
Less than once every week ☐(0) Once or more every week ☐(6) ___

(7) Frequency of faecal incontinence
Less than once every month ☐(0) 1–4 times every month ☐(6)
1–6 times every week ☐(7) Daily ☐(13) ___

(8) Medication against faecal incontinence
No ☐(0) Yes ☐(4) ___

(9) Flatus incontinence
No ☐(0) Yes ☐(2) ___

(10) Perianal skin problems
No ☐(0) Yes ☐(3) ___

Total NBD score (range 0–47) ___

NBD score	Bowel dysfunction
0–6	Very minor
7–9	Minor
10–13	Moderate
14 or more	Severe

Fig. 1

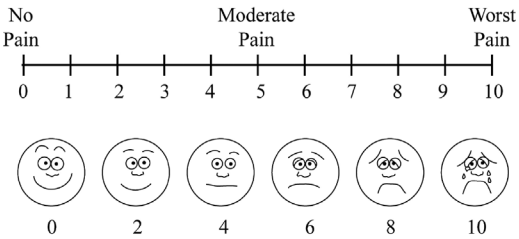

Fig. 2

RESULTS

Twenty patients were referred for Peristeen TAI during the study period. Mean time of using Peristeen TAI was 10 months and mean length of follow-up was about 3 months. All patients were noted to have an improvement in their chronic neuropathic constipation and abdominal pain, increasing in quality of life scores. VAS and NBD score were significantly different before and after. In particular, before treatment patients scored at VAS a mean value of 7.64 ± 0.29, while after-treatment they scored a mean 3.64 ± 0.29 (fig. 3); NBD score before treatment showed a mean value of 23.28 ± 3.14 and post-treatment of $1{,}92 \pm 0.76$ (fig. 4).

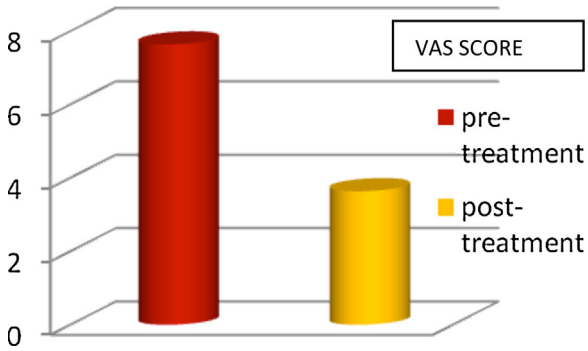

Fig. 3

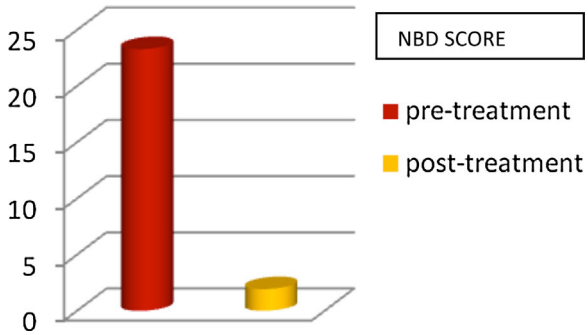

Fig. 4

INTERPRETATION OF RESULTS

Spinal cord lesions affect colorectal motility, transit times and bowel emptying, with consequent constipation leading to abdominal pain, faecal incontinence, or a combination of both. Although these symptoms are not life-threatening, they may have a severe impact on quality of life and increase levels of anxiety and depression. Many methods are used to deal with constipation and faecal incontinence, including conservative and surgical approaches. Intake of high rates of fibers by the diet and administration of laxatives are used in the prevention and treatment of constipation and overflow faecal pseudoincontinence. TAI is a system that helps to achieve a regular evacuation. The effect of water administration is provided by a simple mechanical wash-out effect because the administration of water generates colonic mass movements. The results of this experience confirm the efficacy of TAI on improving faeces evacuation but allow us to show that this outcome is also associated with a statistically significant reduction of VAS scores relative to chronic abdominal pain. This data should enforce clinicians to investigate and treat possible bowel dysfunctions in neurogenic individuals and identify those subjects who can benefit from TAI with the aim to obtain a regular bowel clearance, preventing possible complications, and to improve quality of secondary to abdominal pain reduction.

CONCLUSIONS

In this study, TAI appears to be a safe and effective bowel management system, which improves bowel function and

quality of life in patients affected with chronic neuropathic constipation.
Abdominal pain, evaluated through VAS, decreases significantly with satisfaction of the patients. Comprehensive training of the patient is central to a safe and efficient longterm use of TAI.

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13 - PELVIC ORGAN PROLAPSE WITHOUT URINARY SYMPTOMS: THE ROLE OF URODYNAMICS BEFORE SURGERY

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INTRODUCTION AND AIM OF THE STUDY

Pelvic organ prolapse (POP) is common among the female population. It is present in up to 50% of parous women. A woman's life-time risk of having a surgery for prolapse is about 11%. The International Continence Society recommends UDS as part of pre-operative assessment in order to detect concomitant stress urinary incontinence (SUI), occult SUI and detrusor overactivity (DO). However, the value of urodynamic studies (UDS) before the prolapse surgery is still unclear [(1)]. A number of studies suggest that preoperative UDS may be beneficial in planning surgery for women who have POP with lower urinary tract symptoms (LUTS) [(2)]. On the other hand, the value of UDS in women having POP without LUTS has not been assessed. In view of its invasive nature, the importance of UDS in such women needs to be evaluated to recommend this investigation to them.
The aim of this study is to assess the value of preoperative UDS in women with POP without LUTS and to assess relationship between urinary symptoms assessed by the King's Health Questionnaire (KHQ) and urodynamic diagnosis.

MATERIALS AND METHODS

This is an observational study carried out in the department of Urogynaecology at a tertiary level hospital. Women having surgery for prolapse were routinely assessed with 3 day bladder diary, KHQ and UDS as part of their preoperative work up. We conducted a retrospective analysis of UDS of 800 women with moderate to severe POP who underwent the investigation from December 2000 to April 2014. Women were selected if they reported no urinary symptoms on direct questioning. The data were analysed using SPSS Statistics package (SPSS 19, Chicago, IL, USA and GraphPad Prism 5.0, CA, USA).

RESULTS

Ninety eight women described themselves as asymptomatic for urinary symptoms. The mean age was 56 years (s.d. 14) and the mean parity was 2,7 (range between 0 and 10). Out of 98, 82 patients completed the self-reported KHQ. On UDS investigation, 47 patients were found to have normal bladder function. 30 patients were diagnosed to have systolic or provoked DO, urodynamic stress incontinence (USI) was reported in 17 women. DO and USI were coexistent in 3 patients. UDS findings are summarised in table 1.

Table 1 UDS specific parameters found in women with prolapse not reporting urinary symptoms.

UDS findings	N	Rate
Reduced BC (<400 ml)	13	13,3%
Low First Desire (<100 ml)	9	9,2%
Low Compliance (Detrusor Pressure/BC > 0,03)	21	21,4%
Max Detrusor Pressure >40 cmH20	18	18,4%
Poor flow rate (PFR < 15 ml/s)	28	28,6%
High PVR (>100 ml)	9	9,2%

BC: bladder capacity; PFR: Peak flow rate; PVR: post void residual

Although all the patients were reported to be asymptomatic on clinical history, only 63% of them confirmed being asymptomatic on the symptom score of the KHQ. 21% patients reported mild symptoms and 15% of the patients reported moderate to severe symptoms. 57% of the patients denied any SUI and the proportion of patients reporting mild, moderate and severe SUI were 20%, 10% and 12% respectively. Interestingly, the symptoms reported by the patients and the UDS diagnosis did not always coincide. The results of the study showed that out of the 56 patients who denied any UUI, 18 patients were diagnosed to have DO on UDS. Similarly, out of 70 patients who denied SUI, 12 were found to have USI. Moderate to severe degree of nocturia was reported by 33 patients in KHQ and DO was diagnosed in 15% of those patients. (Chi square test: $P = 0.026$).

INTERPRETATION OF RESULTS

A lot of patients with POP, although not reporting urinary symptoms, show abnormal UDS patterns and validated questionnaires don't have the power to detect latent LUTS.

CONCLUSIONS

Most patients with POP frequently suffer from LUTS. Clinical history appears to be insufficient to exclude LUTS from patients with POP. Validated urinary symptom questionnaires have not been shown previously to be useful in patients with pelvic floor prolapse. UDS has a crucial role in comprehensive assessment of patients who need surgery for prolapse in order to counsel them appropriately and to avoid the pre-existing problems getting labeled as post-operative complications. We therefore recommend urodynamics should be used in all patients prior to POP surgery.

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14 - CHANGES IN THE HOFFMANN REFLEX DURING BLADDER FILLING PROVIDE CLUES TO THE PATHOPHYSIOLOGY OF BLADDER DYSFUNCTION IN THE PATIENTS WITH MULTIPLE SCLEROSIS

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INTRODUCTION AND AIM OF THE STUDY

Previous studies with neurophysiological techniques showed that in healthy subjects bladder filling inhibits spinal motor neuron excitability, as tested by the soleus reflex size, which

decreases at maximum cystometric capacity (MCC) during urodynamics. While some information exist on the H reflex behaviour in patients with Parkinson's disease and spinal cord injury, there are no studies in patients with neurogenic detrusor overactivity (NDO) due to MS. Aims of the study were: to investigate whether testing H reflex during urodynamics helps understand whether bladder dysfunction depends on suprapontine or spinal lesions; to investigate the mechanisms underlying intradetrusor botulinum toxin A-induced effects on NDO in patients with MS and whether botulinum toxin A-induced improvement in bladder function in these patients depends on changes in the viscero-somatic reflex.

MATERIALS AND METHODS

25 MS patients with overactive bladder symptoms (OAB) and NDO refractory to anticholinergics were studied. 18 healthy subjects acted as control. Preliminary evaluation included neurological and urological physical examinations, 3-day voiding diary, standardized Quality of Life questionnaire on incontinence (I-QoL) and urodynamics with the recording of the H reflex. Electrical stimuli were delivered to the right tibial nerve with an EMG device. Patients then underwent intradetrusorial injections of 100 U of one commercially available neurotoxin A (BoNT/A), diluted in 10 ml normal saline, under cystoscopy. Clinical assessment, voiding diary, I-QoL, urodynamics with H reflex measurement were repeated 1 month after treatment.

RESULTS

At baseline, MS patients presented with OAB symptoms and with DO on urodynamics: mean $\pm$ SD first volume and maximum pressure of uninhibited detrusor contractions were 161 ± 45 ml and 33 ± 12 cmH_2O, respectively. Mean $\pm$ SD MCC was reduced (267 ± 39 ml). One month after treatment, day-time and night-time urinary frequency significantly decreased, from 8.5 ± 1.2 to 5.2 ± 0.3 ($p = 0.02$) and from 2.42 ± 0.4 to 0.5 ± 0.2 ($p < 0.001$) respectively. There was also a significant increase in volumes at first, normal and strong desire to void. All patients spontaneously emptied their bladder with a low post-void residual volume (PVR: 56 ± 18 ml). Conversely, DO was not observed in healthy subjects. None of the patients complained of systemic adverse events during or after BoNT/A treatment.

H reflex size was significantly inhibited in healthy subjects at MCC ($p < 0.001$), whereas it remained almost unchanged in MS patients ($p = 0.71$). BoNT/A intradetrusorial injections induced no significant effect on the H reflex size in MS patients.

INTERPRETATION OF RESULTS

The new finding in this study is that whereas in healthy subjects the H reflex size at MCC decrease, in patients with vescico- sphincter dysfunction, and detrusor overactivitu related to MS it remains unchanged. In the patients who received BoNT/A injection, clinical and urodynamic investigations showed a significant improvement in drug- refractory OAB symptoms. Despite its efficacy in improving bladder symptoms, BoNT/A had no significant effect on the H reflex. Why it did so remains conjectural.

CONCLUSIONS

While H reflex significantly changed at MCC in healthy subjects, it remained unchanged in MS patients. H reflex during urodynamics therefore helps understand that in MS patients, despite the prominent suprapontine lesion load, OAB symptoms mainly reflect spinal cord dysfunction. Additionally, despite the efficacy of BoNT/A in improving OAB symptoms and DO in MS patients, the neurotoxin produced no significant effect on the H reflex. The observation that in our MS patients BoNT/A modulates bladder filling sensation but leaves urodynamic variables testing muscle strength unchanged support the hypothesis that BoNT/A injected into the detrusor muscle modulates bladder afferent information.

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15 - IS MULTICOMPARTMENT REPAIR ALWAYS REQUIRED AT THE TIME OF PRIMARY PROLAPSE SURGERY?

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INTRODUCTION AND AIM OF THE STUDY

Pelvic organ prolapse is defined as the descent of vaginal walls, uterus (cervix), or vaginal vault (after hysterectomy) [1]. It is a common clinical condition affecting the 50% of parous women older than fifty years [2]. The cornerstone of primary surgical treatment is restoring vaginal apical support in order to avoid prolapse recurrence [3]. Additional procedures can be adopted to support anterior and posterior repair. We aimed to define the outcomes of anterior and posterior repair associated to apical suspension as a part of primary prolapse treatment.

MATERIALS AND METHODS

Between 2008 and 2012 patients who underwent vaginal hysterectomy and high utero-sacral ligaments suspension for pelvic organ prolapse were retrospectively analyzed. Anterior and/or posterior repairs were additional procedures performed according to clinical examination. Exclusion criteria were use of mesh (with exception of suburethral slings) and previous prolapse surgery. All the patients included in our analysis were divided into four, not mutually exclusive groups, according to surgical procedures performed in addition to vaginal hysterectomy and high utero-sacral ligaments suspension (anterior repair: yes/no, posterior repair: yes/no). Comparison was made in order to assess if concomitant compartment repair is effective in preventing the site recurrence. Preoperative and postoperative evaluation included medical interview and clinical examination according to POP-Q system.

RESULTS

According to the inclusion/exclusion criteria 351 patient were considered. Twelve patients (3.4%) were lost at follow-up visit, so we analyzed 339 patients. Surgical procedures are defined in Table 1. Mean follow up was 28.7 ± 15.3 months without differences among groups. Perioperative complications were similar among groups. Postoperative incidences of considered site $\geq$ II stage prolapse are described in Table 2. Postoperative dyspareunia, voiding and bowel dysfunctions are listed in Table 3.

Table 1 Surgical Procedures

	Site repaired	Site not repaired
Anterior repair	296 (87.3%)	43 (12.7%)
Posterior repair	246 (72.6%)	93 (27.4%)

Table 2 Incidence of recurrence

	Site repaired	Site not repaired	p-value
Anterior repair	32 (10.8%)	9 (20.9%)	0.0763
Posterior repair	9 (3.7%)	15 (16.1%)	0.0002

Table 3 Functional outcomes

Anterior repair	Site repaired	Site not repaired	p-value
Bowel dysfunction	71 (24%)	14 (32.6%)	NS
Voiding dysfunction	47 (15.9%)	10 (23.3%)	NS
Dyspareunia	19 (6.4%)	5 (11.6%)	NS
Posterior repair	Site repaired	Site not repaired	p-value
Bowel dysfunction	59 (24%)	26 (28%)	NS
Voiding dysfunction	40 (16.3%)	17 (18.3%)	NS
Dyspareunia	17 (6.9%)	7 (7.5%)	NS

INTERPRETATION OF RESULTS

Posterior repair showed to be effective in reducing posterior recurrence. For anterior repair there is a trend of anatomical outcome improvement when procedure is performed. Both procedures do not affect negatively functional outcomes but should be not considered mandatory.

CONCLUSIONS

In our series multicompartment repair was safe and effective in reducing site recurrence rate, even without significant change in functional outcomes.

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16 - CORPUS, A NOVEL TECHNIQUE: COMPLETE RECONSTRUCTION OF THE POSTERIOR URETHRAL SUPPORT AFTER ROBOTIC RADICAL PROSTATECTOMY. A URODYNAMIC COMPARISON WITH THE ROCCO STITCH TECHNIQUE

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INTRODUCTION AND AIM OF THE STUDY

Urinary incontinence is one of the most common and bothersome side effects after radical prostatectomy and severely worsens the quality of life of patients. Between 84% and 97% patients recover continence within 12 months from robotic radical prostatectomy (RARP). The main variables that affect continence after RARP are the patient age, BMI, comorbidity, LUTS, prostate volume, experience of the surgeon. The use of a nerve sparing technique and preservation of the bladder neck increase the probability to recover continence as well as muscle-fascial reconstruction. The latter may also reduce the time required to recover continence [1]. One of the most common techniques of muscle-fascial reconstruction has been described by Rocco and is also currently being used in our institute. Nevertheless the urinary continence recovery after RARP is not yet achieved in all patients; therefore a number of surgical techniques may be adopted. For example, the AdVance retrourethral transobturator male sling (American Medical Systems) has shown a high efficacy in the short to medium term. The AdVance technique is based on the concept that repositioning the posterior urethra in a more proximal position plays an important role in continence. From this idea we have recently introduced an innovative technique that provides the complete reconstruction of the urethral support that we have called COmplete Reconstruction of the Posterior Urethral Support (CORPUS). We use this technique alternatively with that called Rocco Stitch. We have shown that the CORPUS technique allows to obtain a significant improvement in early urinary continence recovery compared the one of Rocco. In particular the greatest difference was observed at a distance of 30 days from surgery with an average ICIQ-SF of 4.5 ($\pm$ 1.9) for CORPUS against 6.7 ($\pm$ 2.9) for Rocco [2]. The reason of this difference is not clear, thus we tried to investigate this difference comparing urodynamic parameters in patients underwent both techniques in the short term.

MATERIALS AND METHODS

In the frame of time between 15/09/2014 and 31/12/2014, 25 patients underwent RARP at our institution. They were alternately assigned to two groups. In the first one an experienced surgeon used Rocco Stitch as reconstructive technique, on the contrary in the second group an experienced surgeon used the CORPUS technique. We evaluated as preoperative parameters the BMI, PSA, IPSS, previous prostate surgery. We also considered if a nerve sparing technique was performed, number of days before removing the catheter, post-operative complications. The following histological characteristics were considered: prostate weight, Gleason Score, extraprostatic extension (EPE) and surgical margins (R). A written consensus was obtained. We asked patients to bring us a 72 hours voiding diary and the last 24 hours used pads. We also asked them to complete a ICIQ-SF questionnaire. A free uroflowmetry was obtained if possible. The urodynamic study was done in a standing position with a 8-Fr bladder catheter. The filling rate was 40 ml per minute. We started injecting 200 cc of iodinated contrast medium, after that we injected saline solution until the maximum cystometric capacity (CC) was reached. We evaluated the first sensation of bladder filling (FS), the bladder compliance, the presence of a detrusor overactivity (DO), the maximum cystometric capacity (CC) the maximum flow (Qmax), the detrusor pressure at maxiumum flow (Pdet@Qmax), the post void residual volume (PVR). The results of the pressure-flow study were classified according to the ICS normogram. A urethral pressure profile (UPP) was recorded, using a sterile puller system, through a micro-transducer catheter withdrawn at 60 a speed of mm/min, with the bladder filled to 150 cc of saline solution. The maximum urethral closing pressure (MUCP) and the functional length (FL) were measured.

RESULTS

Of the 25 patients underwent RARP, 9 were evaluated through urodynamics, three were in the Rocco group and 6 in the CORPUS group. The median age was 64.9 years (62.6-65.7) for Rocco and 67.5 (53.8-73.6) for CORPUS. The other results are presented in the table 1.

INTERPRETATION OF RESULTS

The preoperative parameters (BMI, PSA, age) were comparable. The median IPSS score was worse in CORPUS group, extraprostatic extension was found in 4 patients (66.7%) of the CORPUS group and 1 (33%) in the Rocco group. In several studies [1] the use of a nerve-sparing technique has shown to allow an early recovery of continence, on the contrary, in these set of patients, a wider use of a nerve sparing technique (66.7% in the Rocco's

group against 16.7% in the Corpus group), did not lead to better results. ICIQ-SF and 24 hours PAD test seem to support a better recovery of continence for CORPUS. In the CORPUS group the median MUCP and functional length were better than in the Rocco's one (42.5 cm H2O Vs 34 cm H2O and 36 mm Vs 28 mm). These data could partially explain the best performance of the CORPUS technique, however, we have no pre-surgical data and the number of patients is limited to find statistical evidence.
Voiding phase parameters seems to be worst in the CORPUS group (figure 1), with a median maximum flow of 13.5 ml/sec (7-18) vs 15 ml/sec (12-20), and a median Pdet@Qmax of 58.5 cm H2O (22-88) compared to 32 cm H2O (2-54). Likewise as reported in the experience with bulb-urethral sling [3] it appears that an increased MUCP and an increased FL could be associated with better continence at the price of a more obstructive voiding pattern.

CONCLUSIONS

The low number of patients was not sufficient for a statistical analysis. However, the data we have collected appear to confirm the advantage for the CORPUS technique in comparison with the Rocco technique in the early recovery of continence, even in non nerve-sparing patients.
The explanation for this improved performance could be due to a greater functional length of the urethra and a greater maximum urethral closing pressure. Apparently the CORPUS technique worsens the emptying phase parameters with a weaker maximum flow and a greater Pdet@Qmax. Nevertheless, all patients were able to empty the bladder without significant post-voiding residual urine. It could be useful to study a larger number of patients, both before and after radical prostatectomy.

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Table 1

	Rocco	CORPUS
Median BMI	25.5 (25.3-26.0)	26.6 (22.1-30.7)
Median PSA (ug/L)	4.24 (2.7-5.2)	7.20 (4.5-10.8)
Median IPSS	4 (1-5)	8.5 (7-12)
Previous TURP	1 (33%)	0 (0%)
Median age	64.9 (62.6-65.7)	67.5 (53.8-73.6)
Nerve sparing	2 (66.7%)	1 (16.7%)
Median n. of days with catheter	6 (6)	7 (6-10)
Postoperative complications	0	0
Median prostate weight (g)	38.5 (38-39)	50 (19.5-52)
Median GS	6 (6-7)	7
Positive EPE	1 (33%)	4 (66.7%)
Positive R	3 (100%)	2 (33.3%)
Median ICIQ-SF	11 (5-17)	7.5 (4-17)
Median 24hr pad test weight (g)	289 (5-852)	105.5 (6-1400)
Median time RARP-SVUD	74 (45-92)	31.5 (23-114)
Median bladder capacity (cc)	380 (350-460)	255 (230-360)
DO	1 (33.3%)	2 (33.3%)
Median compliance (ml/cm H20)	16.6 (10-23.7)	18.4 (7.7-76.6)
Median MUCP (cm H2O)	34 (24-72)	42.5 (16-84)
Median FL (mm)	28 (20-66)	36 (32-63)
Median Qmax (ml/sec)	15 (12-20)	13.5 (7-18)
Median Pdet@Qmax	32 (2-54)	58.5 (22-88)
Obstructed (ICS nomogram)	0	2 (33.3%)
PVR (cc)	0	0 (0-50)

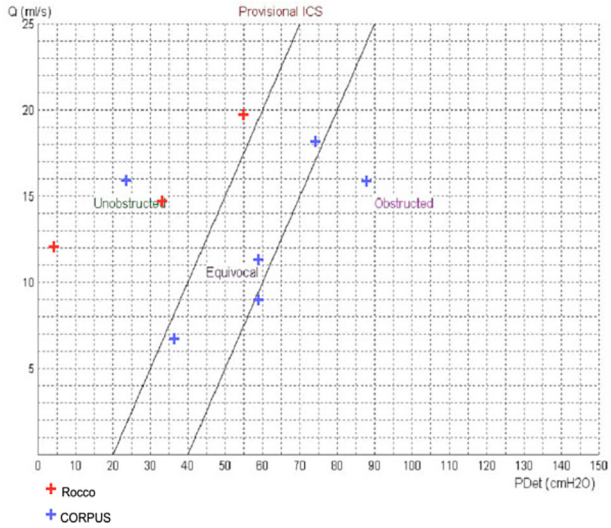

Fig 1.

17 - MANAGEMENT OF MALE AND FEMALE NEUROGENIC STRESS URINARY INCONTINENCE IN SPINAL CORD INJURED (SCI) PATIENTS BY ADJUSTABLE CONTINENCE THERAPY (PROACT® /ACT®)

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INTRODUCTION AND AIM OF THE STUDY

Neurogenic stress urinary incontinence (nSUI) is the consequence of congenital or acquired lesions at sacral or sub sacral level (e.g. spinal disraphysm, conus injury, tumour) determining incompetence of urethral closure mechanisms. Most patients perform intermittent self catheterization to empty their bladder and are at higher risk for complication of any prosthetic implant used for incontinence. The most frequently used surgical option for nSUI is an artificial urinary sphincter. AUS had a high rate percentage of success (61-93%), but It must be evidenced that complications and re-operation rates are higher than in non-neurogenic patients (mean values 31% and 51% respectively) [1]. The aim of our study is to evaluate the effectiveness of a less invasive continence device in neurogenic population.

MATERIALS AND METHODS

The ProACT/ACT® is an adjustable continence support for male and female incontinence. It consist of 2 inflatable balloons that are implanted in minimally invasive fashion on each side of the urethra; small subcutaneous titanium ports allow refilling or deflation at any time. We retrospectively included in this study patients with sacral and sub sacral spinal lesions and complaining of neurogenic stress urinary incontinence and treated at our Institution with Pro-ACT/ACT® implantation. Diagnosis of stress urinary incontinence was achieved with clinical history data collection and video-urodynamic testing. All patients were discharged from the hospital after one day. The first refilling of the balloons was done at one month with 1ml of isotonic contrast medium solution for each side. Further fillings were done after at least one month from the previous refilling, until the patient was dry or was satisfied with the continence result achieved. In case of erosion, malfunctioning

or displacement of the balloon, its removal was done in an outpatient office.

RESULTS

We treated, at our clinic, a total of 12 patients (10 males and 2 females) with diagnosis of nSUI due to sacral or sub sacral spinal cord lesions. Mean age at implantation was 51,6 years (from 27,6 to 74,5 years). Six patients had paraplegia due to spinal cord injury between T12 and L2, two at T5 and T7 respectively, three had a cauda equine syndrome and finally one suffered form extensive ischemic myelopathy (below D7). All patients had already undergone surgical procedures for the treatment of urinary tract-related pathologies: one intravesical electrical stimulation for severe detrusor impairment contractility, eight bladder neck and urethral bulking therapy for nSUI, two intra-detrusor botulinum toxin injection and two sacral dorsal rhizotomy (SDR) because of concomitant non-responder NDO. nSUI in this patients appeared after SDR. Four patients with NDO and incomplete SCI were also treated successfully only with oral oxybutinin. All patients performed intermitted self-catheterization to empty their bladder. Every patient had received preventive video-urodynamic testing evidencing mean maximum cystometric capacity of 430 ml, bladder compliance always >20 ml/cmH2O, mean urethral closure pressure of 52,3 cmH2O. NDO, even if present at previous examinations, was not present at the moment of implant (adequate management with continuous antimuscarinic or botulinum toxin and SDR). Eleven implantations were performed bilaterally, without or under spinal anaesthesia and under fluoroscopic control. In one case it was technically impossible to correctly implant the left device, so only the right balloon was implanted; the rate and severity of leakage significantly decreased, and this patient, in the follow up always refused a second intervention to place a left balloon. Mean hospital recovery from the intervention was 2-3 day. We had no short term complications: no labial/scrotal hematoma and no intraoperative urethral perforation requiring longer Foley catheter placement. Patients were followed up for a minimum time of three months to one year. The continence device did not interfere in any case with voiding modalities. Mean refilling times is 2,25 and mean final balloon volume is 3,12 cc. Two were dry and used only a safety pad during the day, eight were improved (urine loss reduced > 50%), two were unvaried (urine loss reduced < 50%) and none worsened incontinence. Long term complications were: two episodes of erosion/migration of the balloons, two episodes of device infection, one episode of device failure (balloon deflate). None of the patient had any difficulty in self catheterization. The device was explanted in four patients and re-implanted only in one case.

INTERPRETATION OF RESULTS

Overall continence results are encouraging: all patients, before the comparison of any complication, decreased the number of urinary incontinence episodes and the number of pads used. Only 16,6% of patients were completely dry, but 83,3% of patients achieved a significant reduction in urinary leakage (at least >50%). Furthermore, at the last office examination, patients were asked about their subjective perception of the benefits reached: all patients having a significant reduction in urinary loss (83,3%) were subjectively satisfied with this treatment. The overall complication (41,7%) and explanation rate (33,3%) is quite high, but is comparable to that of artificial urinary sphincter in neurogenic population. The most common complications are erosion and infection. The advantage of this technique is that it is cheaper than other techniques, less invasive and adjustable. It may not guarantee good results to neurogenic patients, but offers a small invasive first-line alternative, that in some cases can ameliorate the quality of life of the patient.

CONCLUSIONS

Implantation of proACT/ACT® device is safe and minimally invasive procedure [2} also in neurological patients [3], with a relative low rate of intra and post-operative complications. Efficacy is good although slightly lower when compared with the results in non-neurological patients, probably due to severity of neurogenic sphincter deficiency, high incidence of urinary tract infections and tissues weakness. ProACT/ACT ® are a reasonable therapeutic option in neurological patient (i.e spinal cord injured) who are at high risk of complications in case of more invasive surgery (urethral sling, artificial urinary sphincter)

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18 - PERCUTANEOUS TIBIAL NERVE STIMULATION FOR LOWER URINARY TRACT SYMPTOMS IN MULTIPLE SCLEROSIS PATIENTS

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INTRODUCTION AND AIM OF THE STUDY

Percutaneous tibial nerve stimulation (PTNS) showed to be an effective treatment on several low urinary tract functional disorders, such as overactive bladder syndrome and other voiding dysfunctions, both in neurogenic and non-neurogenic populations. In particular, some recent papers have investigated the efficacy of PTNS in patients affected with multiple sclerosis (MS) (1,2). Aim of this retrospective study was to evaluate improvement in low urinary tract symptoms (LUTS) in patients affected with MS treated by PTNS.

MATERIALS AND METHODS

We prospectively evaluated patients affected with MS, complaining with LUTS and non-responders to first line treatments, consecutively treated by PTNS in a single centre between years 2012 and 2014.

The patients underwent a 30-minute PTNS weekly stimulation for 12 weeks; evaluation was performed by means of bladder diaries and questionnaires. ''Over-Active Bladder questionnaire short form'' (OABq-sf) or an ''International Prostate Symptoms Score'' (IPSS) were administered at first admission and at the end of the last PTNS session, depending on their predominant LUTS (storage or voiding). Success of the treatment was defined as the will of the patients to continue PTNS after the 12 weeks, because they considered their LUTS consistently improved. Information about comorbidities were collected. Patients with pelvic organ prolapse major than grade II or previous pelvic surgery were excluded. A statistical analysis by t-test was performed.

RESULTS

We evaluated 17 patients (15 female, 2 male) aged between 33 and 65 years (mean 49.6 years). Three of them were affected with diabetes mellitus type II.

At the preliminary interview, 13 patients complained with storage symptoms (group 1) and 4 with voiding symptoms (group 2).

Group 1 showed a mean OABq-sf score of 45% (range 13-80%) before the treatment and a mean score of 35% (range 7-80%) after the treatment. A t-test was performed, showing a p-value of 0.08.

85% of patients in group 1 asked to continue the treatment and were considered successfully treated. According to bladder diaries, an improvement in daily micturition frequency was recorded (mean -20%).

Group 2 showed a mean IPSS score of 16.75 (range 16-18) before the treatment and a mean score of 11.75 (range 10-13) after the treatment. A t-test was performed, showing a p-value lower than 0.05.

An improvement in voided volume for each micturition was recorded (mean +15%). 100% of patients in group 2 asked to continue the treatment and were considered successfully treated. No adverse effects were reported.

INTERPRETATION OF RESULTS

All patients generally except two in group 1 showed LUTS improvement at the evaluation by OABq-sf even if the reduction of the score failed to reach a statistically significance, probably due to the reduced number of patients included in the study. All the patients in group 2 showed a LUTS improvement, with a better IPSS score. In our opinion, the high p-value score in group 1 patients could be related to the small sample size.

Data from bladder diaries showed improvement in both groups as well. It is worthy to note that around 85% of patients in group 1 and 100% of patients in group 2 decided to continue PTNS treatment, because they considered their LUTS consistently improved. These data are in agreement with the data coming from the most recent literature, confirming the efficacy and safety of PTNS in treating storage and voiding LUTS in MS patients. The study has several limitations: it focuses on a small sample size (no power calculation) and it lacks both a control group and a long-term follow-up.

CONCLUSIONS

Despite some limitations, this study shows that PTNS can be effective in MS patients complaining with either storage or voiding LUTS.

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19 - CHILDBIRTH AND MODE OF DELIVERY: AN INFLUENCING FACTOR ON WOMEN SEXUAL WELL-BEING?

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INTRODUCTION AND AIM OF THE STUDY

Sexual well-being changes significantly in the postpartum period; different causes from endocrine to psychological alterations are concerned. Few studies have analyzed until today the effects of the type of delivery on sexual well-being in primiparous women in the postpartum period using objective parameters (questionnaires validated by international scientific societies) and a sample of population homogeneous for age, parity, and psychological well-being.

MATERIALS AND METHODS

A retrospective observational study has been performed. The labour group has identified and examined 650 heterosexual and primiparous women afferent to the general and to family planning ambulatory present at our department between March 2013 and March 2014. These patients were divided into 3 groups according to the type of delivery: 1) Vaginal delivery without episiotomy or vaginal tears <2 grade. 2) Vaginal delivery with episiotomy or vagino-perineal lacerations ≥ 2 grade or operative delivery. 3) Urgent or planned caesarean section.

Sexual well-being was investigated using a validated questionnaire (the female sexual function index questionnaire FSFI) administered and filled in by the patients at the beginning of pregnancy, at the time of resumption of sexual activity after birth and at 6 and 12 months.

The FSFI questionnaire evaluates six domains of female sexual satisfaction: desire, arousal, lubrication, orgasm, satisfaction and pain; each domain has a scale of evaluation and the full scale score range from 2.0 to 36.0 with higher scores associated with a good sexual function. Score less than 65% of maximum achievable score were consedered as sexual dysfunction.

Inclusion criteria were primiparity, uncomplicated pregnancy, maternal age between 20 and 30 years, absence of note chronic disease, same partner by a period ≥ 2 years, absence of psychological-psychiatric pathology, delivery at gestational age $\geq$ 39 weeks.

Exclusion criteria were presence of fetal disease or macrosomia, reduction of fetal growth $\leq$ 10pc, maternal chronic diseases, obesity (BMI $\geq$30 kg / m2), pregnancy related disorders.

RESULTS

Among all patients who began the study, 41 (1%) did not complete it reporting that the questionnaire was related to a too intimate and personal sphere or lamenting the lack of sufficient time to spare for it, 609 (99%) completed the study.

The 609 women were divided into 3 groups according to the type of delivery: Group 1) 122pz (20%). Group 2) 195pz (32%) . Group 3) 292 pts (48%).

Women of all three groups have resumed sexual activity after an average period of three months after delivery.

The analysis of the results of the questionnaires on sexual function shows that in Group 1 the 52.5% of women had an average FSFI score of 27, the 53.3% in Group 2 had an avarage FSFI score of 24 and in Group 3 the 54.7% had an avarage FSFI score of 30. We also noticed that in the group 2, patients undergoing operative delivery showed FSFI mean score of 22.

INTERPRETATION OF RESULTS

We found that the difference results of FSFI questionnaires between Groups 1, 2 and 3 is not statistically significant ($P > 0.05$).

Analyzing the questionnaires in their different domains and overall we highlight that there is a worsening of sexual well-being in patients of Group 2 than women in Group 3 and Group 1 ($P > 0.05$). This deterioration becomes statistically significant if we consider only women undergoing vaginal operative delivery or with vagino-perineal lacerations $>$ 2 grade ($P < 0.05$).

Comparing the results of the questionnaires of the patients in Group 1 with Group 3, there is not statistical difference ($P > 0,05$) for the benefit of patients undergoing cesarean section; that difference tends to decrease with time.

CONCLUSIONS

As far as the results of the study are concerned, we can say that the sexual well-being of women is not influenced by the delivery mode. To improve the maternal sexual intercourse routine episiotomy should be avoided

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20 - ULTRALATERAL COLPORRHAPHY AS A VALID ALTERNATIVE FOR ANTERIOR VAGINAL WALL PROLAPSE IN THE MESH ERA : OUR EXSPERIENCE

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INTRODUCTION AND AIM OF THE STUDY

The anterior vaginal wall is the most common segment of the vagina to prolapse, with up to 81% of POP surgery involving this compartment. Anterior colporrhaphy has been used as a surgical technique to correct this defect since 1914 when Kelly and Drum first described it. Using strict anatomic criteria this procedure appears to have an unacceptably high failure rate that is reported in primary surgery as high as 40%. Therefore the anterior compartment is the most common site for recurrence and its repair is one of the most challenging issues in reconstructive pelvic surgery. The traditional technique used to repair anterior vaginal wall descent consists in a midline plication of the pubovesicocervical fascia, placing one or two rows of plication sutures or a purse-string suture followed by plication sutures. A modification of this standard repair performed in our Unit is ultralateral anterior colporrhaphy in which the dissection and mobilization of the vaginal flaps is extended laterally to the ischiopubic rami on each side. The paravaginal connective tissue is then plicated in the midline under tension.

The aim of this study is to show the better anatomic efficacy and the lower failure rate of this modified technique compared to standard colporrhaphy.

MATERIALS AND METHODS

Consecutive women referred to our tertiary level urogynaecological unit, symptomatic for prolapse and presenting with stage II or greater anterior vaginal wall descent (point Ba -1 or greater) according to the POP-Q System were included. Data on medical, pharmacological and surgical history were collected. All women had a urogynaecological evaluation including symptoms assessment, a physical examination and a preoperative urodynamic testing. Women with previous reconstructive pelvic surgery were excluded. After evaluation women were referred for surgical correction and underwent anterior vaginal wall repair (using ultralateral colporrhaphy) preceded by colpohysterectomy if necessary. At 12 months after surgery we recorded the anatomical results. Using the POP-Q system a symptomatic cystocele of stage II or higher on follow-up examination was considered recurrence.

RESULTS

A total of 100 women who underwent anterior vaginal wall repair between January 2012 and January 2014 at our Unit were enrolled. All women were matched for age, menopause state, parity and obstetric history. For all patients after 12 months since surgery a physical examination was performed in order to evaluate the anatomic success rate and prolapse-related symptoms were assessed. Eighty-six out of these 100 patients (86%) had anterior vaginal wall descent $\leq$ stage I at 1 year; in particular anatomic outcome was ''optimal'' (stage 0) in 22 women and ''satisfactory'' (stage I) in 64 women. The prevalence of recurrence at 1 year (stage II or more) was 14%. At follow-up examination, subjects completed a prolapse symptom visual analog scale (VAS 0-100 mm; clinically relevant prolapse symptom as VAS $>$ 20 mm). Ninety-two out of these 100 women (92%) denied prolapse symptoms at 1 year and no patient required retreatment for prolapse during the study follow-up period.

INTERPRETATION OF RESULTS

Many previous studies reported that anterior colporrhaphy is associated with poor success rate based on anatomic outcome. This high rate of anatomic failure, up to 40%, was often quoted as the underlying reason for performing mesh-augmented prolapse repair that ensures a better long-term correction of the vaginal descent. Placement of mesh is likely to be associated with increased complication rates compared to native tissue repair, such as de novo dyspareunia, mesh exposure etc. requiring surgical management in approximately 10–15% of cases. Moreover, according to contemporary definitions of success after prolapse surgery such as the absence of vaginal bulge symptoms and the absence of retreatment in addition to anatomic outcome, various papers reported that there is no difference in the overall success rate between mesh-augmented and native tissue prolapse repair.

Our findings show that ultralateral anterior colporrhaphy is associated with a better objective anatomic outcome comparing our data to those from literature relative to the standard technique, with similar results to augmented repairs in terms of treatment success but without the typical complications of meshes, including additional surgeries.

The main weakness of our study is that this is a retrospective observational study in which our surgical results are compared to data from other studies. Another limiting factor is that the surgical procedures were not performed exclusively by one single surgeon but at least three surgeons with the involvement of multiple trainees, as we are in a university hospital.

CONCLUSIONS

On the basis of our results, native tissue repair for anterior compartment prolapse using ultralateral colporrhaphy combines good objective and subjective cure rates with an excellent safety profile and no mesh complications. Therefore, ultralateral anterior colporrhaphy appears a valid alternative to mesh-reinforced repair for a successful correction of the vaginal descent and, in our opinion, it should be considered the surgery to prefer for the primary treatment of symptomatic anterior vaginal prolapse.

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21 - VAGINAL TREATMENT OF HIGH GRADE POP: PROGRESS WITH AN INNOVATIVE MESH SPARING THE UTERUS

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INTRODUCTION AND AIM OF THE STUDY

Surgical correction of uterovaginal prolapse usually includes hysterectomy also if the uterus is believed to be passive in the disease. Now women tend to uterine preservation because concerned about risks of hysterectomy, or seeing the uterus as affecting sexual function or self-identity(1).

Since 2005, we have used a self-designed single-piece polypropylene mesh, inserted by a vaginal procedure, to correct anterior and apical defects, simultaneously obviating hysterectomy. Results were good from the start (90.9% success rate) because our pelvic floor repair recreates De Lancey's first two support levels, thanks to the shape of our mesh and how we anchor it (Fig A).

This prospective study aims to assess the effectiveness of our original uterus-sparing technique for the correction of high-grade anterior and apical defects in terms of anatomical correction, safety, resolution of symptoms and effect on quality of life (QoL).

MATERIALS AND METHODS

From May 2008 to December 2013 we enrolled 66 pts with high grade anterior (Point Ba) and apical (Point C) defects, POP-Q stage$>$2

Occult stress incontinence: 21 pts*

Mean age: 69.5 $\pm$ 7.8 yrs

Mean BMI: 24.9 $\pm$ 5.2

Median parity: 2 (IQR 1-2)

Post-menopausal: all

Previous POP surgery: none

Patient assessment comprised history, pelvic examination, urodynamics (uroflowmetry, filling cystometry with and without prolapse reduction, pressure/flow studies), and King's Health questionnaire for QoL evaluation.

Surgical Technique**:**

A longitudinal colpotomy is performed in both anterior and posterior vaginal walls (Fig B). The mesh is introduced in the anterior space to support the cystocele. Its anterior wings are fixed with a trans-obturator technique. The shape of the mesh allows us to then place it around the cervix, passing its posterior halves (Fig C) into the posterior space through a tunnel on either side of the cervix. The uterus and enterocele thus are supported by the mesh when its posterior halves are self-joined behind the cervix with 2 stitches. Lastly, the posterior wings are fixed by stitches to the sacrospinous ligaments. The final position of the mesh is shown in Fig D.

(*Patients with occult stress incontinence required a mini sling.)

We define objective anatomical cure when points Ba, and C are POP-Q stage $<$ 2.

We performed a descriptive analysis and compared pre- and postoperative results using three statistical tests: paired t-test, McNemar Chi squared test, and Mann-Whitney test. We considered $p<0.05$ as statistically significant.

RESULTS

Mean operating time: 82 $\pm$ 20 min

All patients had a Foley catheter removed on second post-op day

Hospital recovery: 3 days

Postop complications Clavien I/II : 4 pts (6%) (1 pelvic haematoma, 1 *de novo* urge incontinence treated with antimuscarinics, 1 urinary retention requiring 2 weeks self-catheterization, 1 late vaginal erosion treated with removal of the exposed part of the mesh)

Average follow-up: 45,8 $\pm$ 15,1 mos

Anatomical findings:

Post op Point Ba stage $<$ 2 rate 90.9% ($p<0.0001$)

Post op Point C stage $<$ 2 rate 92.4% ($p<0.0001$)

No unsuccessful patient required operation

LUTS:

storage symptoms (urgency, urge incontinence) preop 42.4%; postop 18.2% ($p<0.0001$)

voiding symptoms (hesitancy/incomplete emptying) preop 22.7%; postop 4.5%

($p<0.0001$)

Prolapse symptoms (heaviness): preop 96,7%; postop 3,0% ($p<0.0001$)

De novo SUI: no pts

QoL: significantly improved

INTERPRETATION OF RESULTS

These results are due to: 1) the position of the mesh, 2) the fact that it is held taut by secure anchoring points (transobturator at the front and sacrospinous at the back), and 3) the innovative mesh shape that encompasses the cervix. Thus the uterus is lifted up to its normal anatomical position, obviating hysterectomy.

CONCLUSIONS

Our technique is easy to perform; outcomes show that it is safe and offers a remarkable anatomical correction of anterior (90.9%) and apical defects (92.4%), and statistically significant improvements in urinary symptoms and QoL.

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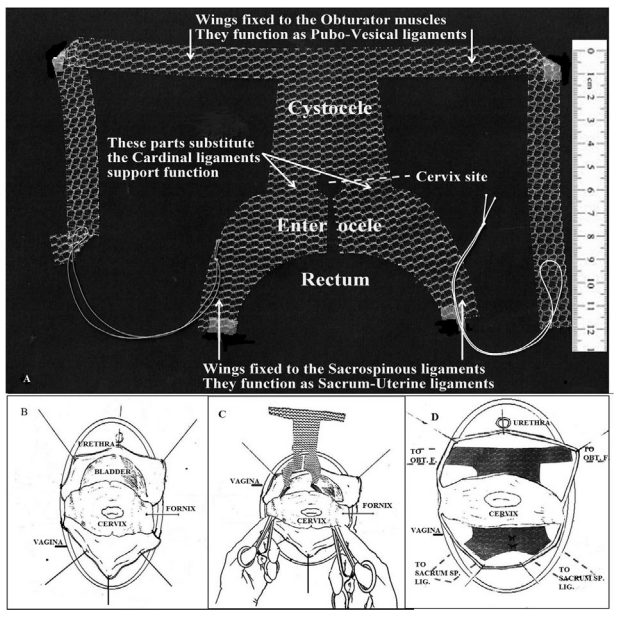

22 - EFFECTS OF BOTULINUM TOXIN TYPE A ON THE CELL GROWTH OF NORMAL HUMAN PROSTATE EPITHELIAL CELLS: PRELIMINARY RESULTS OF AN ''IN VITRO'' STUDY

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INTRODUCTION AND AIM OF THE STUDY

Botulinum toxin A injection has been recently investigated as a potential treatment for benign prostatic enlargement (BPE), due to its ability to reduce the volume of the prostate in the rat, in the dog and somewhat in humans. Cytotoxic effects interfering with cell survival in the prostate gland have been postulated to be responsible for this ability, but the real mechanism by which BoNT/A reduces the prostate volume remains still unclear.

In an ''in vitro'' study we investigated the activity of a purified botulinum toxin A (BoNT/A) to inhibit the cell growth of normal human prostate epithelial cells.

MATERIALS AND METHODS

Normal Human Prostate Epithelial Cells' lines (PrEC- Cloneticsᵀᴹ , Lonza, USA) were cultured at 37°C in a 5% CO_2 (v/v) in air, supplemented with growth factors and the media were replaced every 48 h.

Then PrEC cultures were treated for four days with a purified BoNT/A (lacking non toxic component), at increasing doses of 100 U/ml; 1000 U/ml; 2500 U/ml; 25000 U/ml.

Cell proliferation of PrEC was determined before and four days after the purified BoNT/A administration, by using the MTS-CellTiter 96® assay (Promega Corporation, USA), that measures the mitochondrial conversion of tetrazolium salt to a blue formazan salt. The samples with MTS reagent were read at 490 nm in a microplate reader after 3 hours of incubation.

RESULTS

Our results showed that treatment with [100 U/ml] of purified BoNT/A seems to not affect PrEC lines proliferation; on the other hand, high concentration of purified neurotoxin A for 4 days caused a significant dose-dependent decrease of PrEC proliferation

INTERPRETATION OF RESULTS

At the conditions imposed in this study, our preliminary results show that low doses of purified BoNT/A did not change the levels of cell growth of PrEC lines, while very high concentrations significantly affected the cell growth of these cells. These results support the hypothesis that BoNT/A activate apoptotic pathways in ''in vitro'' studies with normal prostate epithelial cells, as previously observed in animals.

To date no information exists about these cytotoxic mechanisms in humans.

CONCLUSIONS

The fact that low doses of purified BoNT/A did not affect cell proliferation in our PrEC lines, may explain, at least in part, the contrasting clinical results obtained with the neurotoxin A injected in the prostate gland of men affected by BPE.

Further investigations are needed to study the effect of the neurotoxin A in the different cellular components of the prostate gland.

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23 - PELVIC PAIN AFTER CHILDBIRTH - MITH OR REALITY? OUR EXPERIENCE

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INTRODUCTION AND AIM OF THE STUDY

Chronic pelvic pain (CPP) is a common condition among women of reproductive age; however, the reported prevalence varies greatly because of diverse study settings, designs, and definitions. Apart from being common, CPP is a multifactorial disease that makes it difficult to establish a definite diagnosis, and it is difficult to treat.

Several previous studies have suggested that mode of delivery may have an impact on the development of pelvic pain. During a vaginal delivery, descent of fetal head and stretching of the perineum can cause direct tissue and neuromuscular injury. Stretching of the tissues to accommodate the fetal head may result in tears of the levator ani muscles as well as the perineum.

It has been postulated that labour and vaginal delivery, and in particular the second stage of labour, might have a negative effect on nervous structures supplying pelvic organs and the pelvic floor.

The aim of our study has been to assess the effects of vaginal delivery and time since birth on chronic pelvic pain and Health-related quality of life (HRQoL) among primiparous women.

MATERIALS AND METHODS

The our retrospective study was conducted from October 2013 to April 2014. The target population included primiparous women aged 18–40 years who had given birth at least 6 months previously. Time since birth was divided into the following three periods: less than 1 year, 1-3 years, and more than 3 years. The following obstetrical exposures were recorded: vaginal birth, prolonged second stage (>2 hours), vaginal delivery with birthweight $\geq$ 4000 g, perineal laceration, episiotomy, anal sphincter laceration and operative vaginal delivery (vacuum or forceps).

The women completed a self-administered questionnaire (SF-36) and EQ-VAS, and information about pelvic pain was obtained via interview.

Moreover, we have studied the effects of childbirth on the pudendal nerve. We have used an invasive technique, concentric needle electromyography (CN-EMG) to investigate these issues.

RESULTS

The study included a total of 531 participants. The data were incomplete for 33 women.

Overall, 214 (43%) women developed CPP after delivery. Among those, moderate to severe dyspareunia was more common among those who experienced a vaginal delivery of a baby $\geq$4 kg (32%-27/86) and those who had a operative vaginal delivery (25%-29/118).

The rate of CPP increased with increasing time since birth [2.3%,9.3% and 10.7% for the 3 specified time periods, respectively ($P < 0.001$)]

EMG showed that changes in pudendal nerve function were seen in 358 (72%) women.

INTERPRETATION OF RESULTS

Operative delivery, length of second stage and birthweight are the main predictor of CPP after vaginal delivery.

Increased fiber density (via EMG) after vaginal delivery is evidence of nerve injury and repair.

Women who had a long active second stage of labour and heavier babies showed the most EMG evidence of nerve damage. Perineal tears and episiotomy did not affect the degree of nerve damage seen.

CONCLUSIONS

Despite the fact that a number of important questions remain to be answered, there seems little doubt that vaginal childbirth can have significant negative effects on the pudendal nerve and its branches in some women. It causes partial denervation of the pelvic floor (with consequent re-innervation) in most women having their first baby.

Vaginal delivery is a major risk factor for developing pelvic floor dysfunction. Pudendal nerve damage is found in women with pelvic floor dysfunction, and has been documented as occurring with vaginal birth.

The extent of the resulting deterioration in nervous function seems to be associated with length of second stage and the mode of delivery.

The clinical relevance of these findings however, remains to be defined.

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24 - EXTERNAL VALIDATION OF THE NEUROGENIC BLADDER SYMPTOM SCORE IN MULTIPLE SCLEROSIS PATIENTS WITH LOWER URINARY TRACT DYSFUNCTION

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INTRODUCTION AND AIM OF THE STUDY

Multiple sclerosis (MS) is a chronic neurological disorder characterized by disseminated demyelination of nerve fibers of the brain and spinal cord.

Multiple Sclerosis (MS) is a chronic disease that has a negative impact on sexually active adults. However, there are no patient-reported measures (PROMs) for assessing urological symptoms and their relationship with sexual dysfunction or urodynamic parameters. Recently, the Neurogenic Bladder Symptom Score (NBSS) has been introduced as a valid tool to quantify the symptoms and consequences of neurogenic bladder dysfunction. Its 24 questions cover incontinence, storage and voiding symptoms, and urinary complications associated with neurogenic bladder dysfunction, but it was only internal validated without a relation to urodynamic parameters or sexual function.

The aim of this study was to externally validate the NBSS in a cohort of MS patients with lower urinary tract dysfunction (LUTD) and to investigate its relationship urodynamic parameters and with other patients reported outcomes of sexual dysfunction, anxiety, depression and disability.

MATERIALS AND METHODS

From January 2011 to September 2013,122 consecutive patients with multiple sclerosis in remission phase and LUTD, recruited from the MS outpatient clinic, underwent first urodynamic examination. Criteria for inclusion were: diagnosis of MS according to the McDonald Revised criteria, "stable sexual relationship" defined as the presence of the same partners for six or more consecutive months. Indication for urodynamic examination was defined as following: frequency $\geq$8 micturitions per day or $\geq$1 during the night, urgency and/or urinary incontinence.

Exclusion criteria were as follows: hysterectomy or vaginal surgery, those receiving oral or vaginal estrogen therapy, history of antidepressant, anticonvulsant, and anxiolytic drug use, existence of a major psychiatric disease, inflammatory disease such as ankylosing spondylitis and chronic rheumatoid arthritis, bowel incontinence, restricted function of hand, knee, or hip joints, chronic alcohol consumption, nitrite-positive urinary tract infection, previous surgical treatment for benign prostatic obstruction or therapy with 5-alpha reductase inhibitors, anti-cholinergics or phosphodiesterase type 5 inhibitors, life expectancy $<$2 years, current diagnosis of bladder stones, patients with indwelling catheter or with an episode of acute retention of urine in the last 4 weeks, poorly controlled diabetes and hypogonadism.

Baseline examination included urinalysis, ultrasonography of the upper urinary tract, post-void ultrasonography and a full urodynamic study according to the 2002 ICS. Definition of DO, DSD or DU comply with the 2002 ICS Standardization Report on terminology of lower urinary tract function.

Depression and anxiety were evaluated by the Hamilton Depression Scale (HAM-D) 17 and the Hamilton Anxiety Scale (HAM-A) while neurological impairment was assessed using the Expanded Disability Status Scale (EDSS). Sexual function was assessed with the Italian Female Sexual Function Index (FSFI) and the International Index of Erectile Function (IIEF-15). Bladder symptoms were investigated with the Neurogenic Bladder Symptom Score (NBSS) as reported by Welk B. et al.

RESULTS

Of all subjects, 72 (59.0%) were female and 50 (41.0%) were male. Median age was 46.0, median NBSS was 20.0. After urodynamic examination, NDO was diagnosed in 69 (56.6%). The concordance between patients with DO and PdetMax $\geq$ 20.0 cmH20 was 0.89 ($p<0.05$).

Ninety-five (77.9%) had bladder management with spontaneous voiding while 27 (22.1%) used clean intermittent catheterization. Patients with EDSS $\geq$ 4.5 (more serious impairment) had greater (worse) mean NBSS (25.41 vs. 20.19; $p<0.05$), NBSS-incontinence (8.73 vs 4.71; $p<0.05$), NBSS-consequence (4.51 vs. 3.13; $p<0.05$) and NBSS-QoL (2.14 vs. 1.65; $p<0.05$).

With Anova test, the means of MCC, bladder compliance and PdetMaxIDC were significantly impaired with increasing values of NBSS-QOL. The Spearman's correlation analysis showed positive association between NBSS and EDSS, HAM-A HAM-D and negative between NBSS, IIEF-EF and FSFI (Table 1). The linear regression analysis showed significant association between NBSS-Qol and MCC ($r= -0.18$; $p<0.05$), Compliance ($r= -0.19$; $p<0.05$) but not with PdetMaxIDC ($r= 0.15$; $p=0.09$). With multivariate logistic regression analysis, the NBSS did not independently predict PdetMaxIDC $\geq$ 20 cmH20 ($p=0.77$) but weakly predicted maximum cystometric capacity (MCC) $<$ 212

Table 1 Spearman's correlation between variables.

	SPEARMAN'S RHO								
NBSS	**MCC**	**PdetMax**	**Pdet MaxIDC**	**Compliance**	**HAM-A**	**HAM-D**	**EDSS**	**FSFI**	**IIEF-15**
Total score	−0.213†	−0.401‡	−0.005	−0.086	0.447‡	0.389‡	0.278‡	−0.228†	−0.194†
Incontinence	−0.154	−0.472‡	−0.050	0.009	0.326‡	0.302‡	0.332‡	−0.149	−0.219
Storage + Voiding	−0.097	−0.200†	0.033	−0.127	0.369‡	0.312‡	0.121	−0.206	−0.186
Consequence	−0.197†	−0.197†	−0.028	−0.060	0.379‡	0.384‡	0.254‡	−0.446‡	−0.102
QoL	−0.291‡	−0.229†	0.076	−0.229†	0.474‡	0.408‡	0.398‡	−0.329‡	−0.457‡

†$p<0.05$ $p<0.01$

cc (OR: 0.95 [95%CI: 0.91-0.99; $p<0.05$) after adjusting for age, EDSS, gender, duration and variants of MS.
The AUC values of the base models for predicting PdetMaxIDC $\geq$20 cmH20 was 0.80 without gaining in accuracy when adding NBSS. The AUC values of the base models for predicting MCC < 212 cc was 0.77 and 0.79 when adding NBSS with not statistical significance in gaining accuracy.
The bootstrapping calculations generally confirmed the p-values of the conventional logistic regression analysis with larger ranges of 95% CI of the ORs.

INTERPRETATION OF RESULTS

The external validity of the NBSS showed a correlation with the EDSS but a weak correlations with some urodynamic parameters. Bladder symptoms appear to coexist with sexual dysfunction and depression and anxiety in this population.

CONCLUSIONS

Urodynamic studies still provide important information about bladder function that cannot be completely assessed with patient reported outcomes such as the NBSS.

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25 - ABDOMINAL VS LAPAROSCOPIC SACROCOLPOPEXY: A RANDOMIZED CONTROLLED TRIAL, FINAL RESULTS

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INTRODUCTION AND AIM OF THE STUDY

Aim of this prospective randomized controlled trial is to compare Abdominal (AS) versus Laparoscopic sacropexy (LS) in women with advanced pelvic organ prolapse (POP) to demonstrate the effective role of LS in POP repair.

MATERIALS AND METHODS

Consecutive patients affected by symptomatic POP stage>II according to the POP-q classification were prospectively randomized using a predetermined computer-generated randomization code (4 blocks). IRC approval was obtained, and the trial was registered as Clinical trial NCT01182090. The primary objective was to test the clinical equivalence of AS and LS in terms of subjective and objective outcomes. The primary outcome was the quantitative description of point C/D. The secondary outcome was assessment of how much better LS was than AS in terms of complications, morbidity assessed using the Clavien-Dindo surgical complications classification, operating time, intra-operative blood loss, length of hospital stay and post-operative complications. A sample size of **60** patients per group, at $p=0.05$, two-sided t test was estimated to have **90**% power to reject the null hypothesis that the laparoscopic and open methods are not equivalent (with a pre-specified tolerance limit margin of **0.5** cm for equivalence with a common SD of 0.8 cm). The Mann-Whitney and Chi square tests were used for statistical analysis

RESULTS

121 patients have been randomized. 1 patient from the LS group and 1 from AS group were lost to f-up, 1 patient in the LS group was converted so finally we evaluated 58 pts in the LS arm and 60 in the AS arm. The median follow-up was 32,53 months (range 16-56 months). No significant inter-group differences emerged in the pre-operative evaluations. Operating time was longer for LS (mean 121 min for A**S** vs 219 min for LS, $p<0.001$). Intra-operative blood loss was higher in AS (mean 245 ml for A**S** vs 99,13 ml for LS, $p<0.001$) and hospital stays were longer (mean 5.8 days for A**S** vs 4.4 days for LS, $p<0.001$). The complications according to the Clavien-Dindo classification were 14 in the AS arm and 13 in the LS arm for the grade I ($p=0,15$), 11 in the AS group Vs 1 in the LS group for the grade II ($p=0,02$) and 1 in the AS group Vs 4 in the LS group for the grade III ($p=0,017$). Tab I shows the mean post-operative point C/D evaluation for both techniques which demonstrates their equivalence. No apical prolapse in both groups recurred, asymptomatic stage I-II recurrence was reported in 10% in AS vs 24.1% in LS ($p=0.051$). Mesh exposure were 1 in the AS arm and 3 in the LS arm, all conservatively treated.

INTERPRETATION OF RESULTS

These preliminary results showed LS provided outcomes as good as **AS** with decreased morbidity, less blood loss, less pain and shorter recovery times at a median follow-up of 32 months. Subjective and objective outcomes were not significantly different. Recurrency in anterior and posterior compartment POP showed a difference in the two groups which, although not statistically significant, need to be evaluated in the long-term.

CONCLUSIONS

As the laparoscopic approach is becoming more popular with surgeons and patients, the results from this prospective trials

Tab 1. Post-operative C/D point (POP-Q system)

type	C/D pre	C/D post	p
AS	−1,9	−7,4	<0.001
LS	−1,52	−7,36	<0.001
Total	−1,7	−7,38	<0.001

could define the definitive role of laparoscopic sacropexy in the treatment of high grade POP thanks to the benefits of a minimally invasive approach.

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26 - DECREASE OF BLADDER CONTRACTILITY IS SLOWER THAN INCREASE OF FLOW AFTER PROSTATIC OBSTRUCTION SURGERY

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INTRODUCTION AND AIM OF THE STUDY

Since we adopted a non invasive urodynamic technique (1) before and after surgical treatment of bladder outlet obstruction (BOO) in order to check the feasibility of the procedure and to find a predictive value for the outcome of the surgery, we found that shortly after surgery for prostatic obstruction the flow rate significantly improved but the detrusor contraction only slightly decreased. We now want to check what is happening after at least one year from the operation when many variants as inflammation or slow adaptation of the bladder to the new situation no more interfere with the results of these studies.

MATERIALS AND METHODS

Patients waiting in our clinic for surgical intervention for Lower Urinary Tract Symptoms and prostatic enlargement were evaluated with a non-invasive pressure/flow measurement using a uroflowmeter and a penile cuff before surgery and 3 months and 1 year after the operation. We excluded from the study patients with indwelling catheter, bladder stones, high volume diverticula or reflux. We asked patients to fill in an International Prostatic Symptom Score (IPSS) questionnaire on the occasion of the examinations. We also took account of prostate volume before surgery (with abdominal or transrectal ultrasound) and the amount of tissue removed during surgery. The cuff was placed around the penis and the subject asked to void without straining into the uroflowmeter connected to the cuff machine. Once voiding commenced the cuff was automatically inflated at 10 cm H2O/sec until flow was interrupted or a safety cut off of 200 cmH2O was reached. The cuff pressure (Pcuff) at which flow was interrupted provides a valid and reproducible estimate of isovolumetric bladder pressure, that is a measure of detrusor contraction strength. The cuff then automatically rapidly defleated with resumption of flow, allowing the process to be repeated until voiding was complete. Maximum values of Pcuff and maximum urinary urine flow rate (Qmax) were read from the continuous plot of flow rate and cuff pressure obtained for each void (1). The test together with IPSS (from which we extrapolated the question about quality of life QOL) and postvoiding residue (PVR) evaluations were repeated 3 months and at least 1 year after surgery in order to check the change of clinical and non invasive urodynamic parameters on short and long term using the pressure-flow nomogram.

RESULTS

19 patients completed the 3 months follow-up, 17 completed the 1 year follow-up (1 patient is lost at follow-up and 1 patient died). So we used 17 patients for the statistical analysis. Results appear in the following table.

Surgery performed was TURP in 9 cases and retropubic prostatic adenomectomy (Millin) in the other 8. Before surgery average IPSS was 19, 3 months and 1 year after surgery was 5, with highly significant difference ($p<0,001$). Average QOL improved from 4 to 1 with a highly significant difference ($p<0,001$) and remained stable after 1 year. Post-voiding residue reduced from an average of 142 ml before to 52 ml 3 months after surgery ($p<0,01$) and 36 ml 1 year after surgery ($p=0,002$).

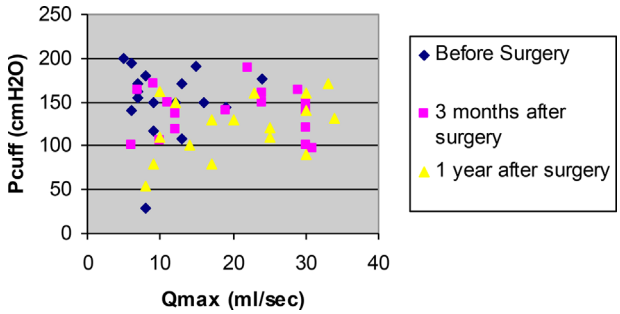
Average Pcuff and Qmax before surgery were respectively 152 cmH2O and 11 ml/sec; 3 months after surgery were respectively 138 cmH2O ($p=0,24$) and 20 ml/sec ($p=0,001$); 1 year after surgery were 122 cmH2O ($p=0,02$) and 20 ml/sec ($p<0,001$).

Eventhough detrusor contraction did not reduced significantly 3 months after removal of BOO, it decreased significantly 1 year after. Highly significant improvement of IPSS and QOL score remained the same after 3 months and 1 year later. Unchanged improvement was also seen for PVR and Qmax.

	Before								3 months					1 year				
N°	IPSS	QoL	Prostatic vol	PVR	Pcuff	Qmax	Type of surgery	Grams removed	IPSS	QoL	PVR	Pcuff	Qmax	IPSS	QoL	PVR	Pcuff	Qmax
1	24	4	113	174	150	12	MILLIN	90	1	0	115	140	19	1	0	250	130	17
2	23	5	150	182	200	5	MILLIN	75	3	1	159	118	12	2	1	0	90	30
3	29	6	30	191	190	15	TURP	10	17	4	23	189	22	5	0	0	80	17
4	17	5	69	121	170	7	MILLIN	50	7	1	4	164	29	5	1	40	171	33
5	13	3	98	50	140	6	TURP	70	7	2	128	170	9	8	2	6	100	14
6	8	6	127	487	180	8	MILLIN	90	4	1	20	107	10	16	2	100	54	8
7	9	2	40	300	108	13	TURP	15	7	1	80	97	31	4	1	0	131	34
8	22	5	90	97	162	7	MILLIN	20	6	4	50	163	7	14	5	0	162	10
9	21	5	117	119	150	9	MILLIN	70	1	1	60	136	12	0	0	0	130	20
10	29	4	63	180	29	8	TURP	30	7	2	58	120	30	9	3	0	80	9
11	10	0	28	80	155	7	TURP	50	2	0	0	140	30	2	0	0	120	25
12	18	3	93	70	149	16	MILLIN	80	6	1	0	150	24	4	0	100	110	25
13	19	5	80	80	177	24	TURP	30	2	1	0	160	24	1	1	0	160	23
14	15	3	65	70	143	19	TURP	30	4	1	0	150	30	4	0	0	160	30
15	13	4	70	40	117	9	TURP	20	5	1	160	150	11	4	1	86	110	10
16	15	5	120	80	170	13	MILLIN	90	6	2	0	100	6	2	1	0	150	12
17	31	5	40	100	194	6	TURP	10	4	0	25	100	30	1	0	26	140	30

INTERPRETATION OF RESULTS

Symptoms improvement and reduction of PVR occurred already 3 months after surgery and remained stable after 1 year. Concerning urodynamic parameters as it is shown in the following nomograms, plotting Qmax against Pcuff, Qmax improvement is seen immediately after 3 months from surgery for prostatic obstruction and remain stable after 1 year. Decrease of bladder contractility is happening much more slowly, reaching statistical significance only after 1 year. The rapid improvement of Qmax is certainly due to the release of the obstruction, while bladder contractility is reducing slowly probably due to intravesical slow change of many chemical factors influencing the detrusor fiber contraction.



CONCLUSIONS

Non-invasive urodynamic evaluation of BOO has been shown to improve outcome prediction for men undergoing prostatic adenomectomy (2). Our study also shows that traditional clinical outcome of BOO surgery is in agreement with the changes of the non-invasive urodynamic evaluation. Among these changes, we observed major and more rapid improvement of Qmax while the bladder pressure reduced significantly only after a follow up of at least 1 year. Therefore the slope of the equivocal area distinguishing obstructed from unobstructed patients using the ICS plot for definition of obstruction should be thinner and steeper when using Pcuff or isovolumetric bladder pressure.

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27 - URODYNAMIC STUDY IN THE EVALUATION OF ELDERLY MALE WITH CHRONIC RETENTION OF URINE : ASSESSMENT OF THE RESULTS AND PROGNOSTIC VALUE

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INTRODUCTION AND AIM OF THE STUDY

Chronic urinary retention (CUR) is a poorly defined entity, although is common in the elderly. Benign prostatic hyperplasia (BPH) is highly prevalent in those older than 60 years and, therefore, CUR is often attributed to consequent bladder outlet obstruction (BOO). However, in older adults the cause of urinary retention is often multifactorial and inadequate voiding may persist, despite outflow–tract surgery. The aim of this study is to examine the urodynamics analysis in a cohort of outpatients aged 65 years or more with CUR. Furthermore, we would like to evaluate if urodynamics could be helpful in identifying patients who may especially benefit from outflow–tract surgery.

MATERIALS AND METHODS

This was a retrospective review of urodynamic data collected from January 2010 to December 2013 in a cohort of 50 elderly outpatients with BPH and lower urinary tract symptoms, including storage-voiding, postmicturition symptoms and incomplete or complete urinary retention. We included only patients age 65 years and over. Patients were divided into two groups, according to postvoid residual urine (PVR) volume of CUR (more or less than 1000 ml). Urodynamic investigations were carried out according to the good practice guidelines for urodynamics. As an index of detrusor contractility, we chose the following parameters: Watts Factor, its value at peak flow (WF Q max) and bladder contractility index (BCI). BOO was defined by the ICS nomogram. A detailed clinical history was taken from each patient and clinically examination was performed (uroflowmetry and post void urine volume) We excluded patients with co-occurring neurological diseases.

RESULTS

Twenty-two patients were young-old (65-74 years) and 28 were old-old (75 years and over). Thirthy-eigth patients underwent outflow-tract surgery, 9 did not undergo surgery and 3 were lost at follow up. Main comorbidities were hypertension, heart and vascular disease (n= 24), diabetes (n= 9), and dementia (n=2). Four patients were prescribed with anticoagulants. Those with CUR <1000 ml were 17 while those with CUR >1000 ml were 33 (66%). Hydronephrosis (n=10), renal failure (n=7) and urinary tract infections (n=9) were the most frequent complications. Nineteen patients (38%) had overactive bladder syndrome with 4 being incontinent. The urodynamic findings, the clinical features of patients who underwent post outflow –tract surgery and the urodynamic findings in patients in whom surgery failed are reported in Tables,2 and 3 , respectively. Overall successful surgery was found in 33/38 patients (87%). Six out of 9 patients who did not undergo surgery, received alpha–blocker therapy but they showed persistent inadequate voiding. In 3 patients active voiding was not possible and indwelling catheter was replaced.

INTERPRETATION OF RESULTS

Elderly men may present several urodynamic abnormalities associated with CUR: BOO, Underactive Detrusor Activity (UDA), Overactive Detrusor Activity (ODA) or Detrusor Hyperactivity Impaired Contractility (DHIC). Despite BOO is quite frequent in our cohort (40%), CUR seems to be more commonly associated with UDA (74%) especially in the old-old. The findings that ageing, decreased bladder sensitivity, high PVR (>1000 ml), severe UDA (WF Q max < 5 and/or BCI < 40) may suggest that these factors need to be considered as possible predictors of unsuccessful surgery.

Table 1 Urodynamic reports of 50 elderly males

	Young old (22 pts)	Old (28 pts)
Bladder outlet obstruction (BOO) (20/50pts)	8	12*
Underactive detrusor activity (UDA) (37/50pts)	15 **	22
Overactive detrusor activity (ODA)(29/50 pts)	13	16
Detrusor hyperactivity		
Impaired contractility (DHIC) (18/50pts)	7	11
Elevated detrusor compliance	8	8
First voiding desire (> 500 ml)	4	6

* (5/12 pts BOO+DHIC) ; ** (6/15 severe UDA)

Table 2 Clinical features post outflow –tract surgery of 38 elderly patients

Retake of normal voiding pattern with not PVR	26 pts
Retake of normal voiding pattern with < 500 ml PVR	7 pts
Placement indwelling catheter for > 500 ml PVR	5 pts

Table 3 Urodynamic reports of 5 elderly males with replacement indwelling catheter post outflow –tract surgery.

WF Q max	BCI	ODA	BOO (ICS-A/G)	pre surgery - PVR - post surgery
1,9	26	/	19	3000 ml 900 ml
2	29	/	25	2500 ml 700 ml
2,3	15	/	3	2800 ml 700 ml
1,9	28	/	1	2500 ml 600 ml
2,7	39	/	2	3100 ml 500 ml

CONCLUSIONS

Urodynamic study in elderly males may play an important role in establishing the underlying causes of CUR and may help in predicting patients who may benefit from prostatectomy.

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28 - OBSERVATIONS ON URODYNAMIC FINDINGS OF THE FEMALE OVERACTIVE BLADDER SYNDROME : TEN YEARS OF EXPERIENCE

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INTRODUCTION AND AIM OF THE STUDY

Overactive bladder (OAB) is a common in the urological and gynaecological practice. OAB is a diagnosis of exclusion, intuitively considered to be related to detrusor overactivity (DO). However, it is well know that the correlation between clinical features and urodynamics findings is often poor and that the bladder is a not very reliable witness in women. In this observational study urodynamic findings of our ten years OAB population have been retrospectively analysed with the aim to identify the characteristics of the urodynamic results in order to improve evidence regarding this puzzling syndrome.

MATERIALS AND METHODS

Urodynamics executed between January 2005 and January 2015 have been retrospectively analysed. Female patients presenting characteristics of OAB syndrome according to International Continence Society (ICS) definition were identified. Exclusion criteria were a concomitant genital prolapse, metabolic and neurologic diseases (i.e. diabetes mellitus, dementia, ictus cerebri, Parkinson's disease). Urodynamic investigations have been carried out according to the good practice guidelines for urodynamics. Each exam included uroflowmetry and measurement of residual volume through catheterisation, multichannel cystometry, pressure-flow study and urethral pressure profile. Urodynamic investigation of urethral function was conduced during a traditional pressure –flow study. A circumferential air –charged T-DOC, 7 F. was used for this purpose. During uroflowmetry the voided volume was at least 150 ml and a 20% residual of voided volume was considered significant. The Blaivas-Groutz cut off for female urinary obstruction was used to detect voiding dysfunction.

RESULTS

According to the selection criteria 132 patients presenting OAB syndrome have been considered eligible to join the study. 20 patients were young adults (18-39 age), 41 middle adults (40- 65 age) and 71 (66-85 age) elderlies. 56 patients presented OAB without urge incontinence, 76 with urge incontinence .Besides, 35 women (26%) had associated stress incontinence and 7 reported enuresis. Patients' clinical features detail and urodynamic parameters are show in table 1 and 2.

Table 1 Clinical features of patients with Overactive Bladder Syndrome

	Young adult pts	Middle adult pts	Elderly pts
Patients (132)	20	41	71
Mean age	31	48	84
Urge incontinence	7	20	49
Stress Urinary Incontinence	0	15	20
Enuresis	0	2	5
Significant Postvoidal residual	3	4	12

Table 2 Urodynamic parameters of patients with Overactive Bladder Syndrome

	Young adult pts	Middle adult pts	Elderly pts
Patients (132)	20	41	71
Hypersensitive Bladder (HB)	3	17	13
Detrusor Overactivity (DO)	5	8	25
Detrusor Underactivity (DU)	0	4	24
Detrusor Overactivity with impaired contractile (DHIC)	0	1	11
Detrusor Normal (DN)	4	7	1
Bladder Outlet Obstruction (BOO) (Overactive Urethra /Pseudo-dyssynergia)	13	8	21

INTERPRETATION OF RESULTS

This study confirmed that symptomatic diagnosis of OAB does not correlate with a urodynamic DO (38%) . Moreover it showed that the urodynamic results can be significantly different and include a combination of sensory and motor dysfunctions regarding not only bladder but also the urethra . In fact we found hypersensitive bladder(HB,25%), detrusor underactivity-(DU,22%), detrusor overactivity with impaired contractile performance(DHIC 9%), detrusor sphincter pseudo-dyssynergia including bladder neck dysfunction (BOO, 32%). Urinary incontinence is an important contributor to the complication of OAB women with DHIC, especially in elderly patients, because it can be mistakenly diagnosed with simple mixed

urinary incontinence. In these cases a post void residual and low urinary flow rate were correlated. A more thorough urodynamic observation is probably necessary in such patients. Urodynamic investigation of urethral function can be essential for those patients because voiding dysfunctions can occur. In fact voiding dysfunctions, though relatively uncommon in women, can cause suggestive OAB symptoms. Overactive urethra can be associated either with sphincter hyperactivity (muscular component) or fibrosis of the distal part (connective component). Sacral reflex arc disorders in absence of neuropathologies can lead to perineal hyperreflexia and bladder sphincter pseudo-dyssynergia. In this study such condition has been observed in younger patients with a 9% prevalence.

CONCLUSIONS

The diagnosis of OAB symptoms-based can be inadequate . Urodynamic testing is still essential because the underlying causes can be different and include a combination of sensory and motor dysfunctions regarding not only bladder but also the urethra, especially in young and elderly patients.

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29 - FEATURES OF PELVIC FLOOR DYSFUNCTION AFTER DELIVERY: A PREVALENCE AND DESCRIPTIVE PRELIMINARY ANALYSIS

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INTRODUCTION AND AIM OF THE STUDY

Pelvic Floor Dysfunction (PFD) are quite common after delivery, being claimed of up to 48%[1]. Data on Italian population are scarcely reported and based on telephone interview or multicentric data collection[2,3]. We aimed at prospectively describe the features of PFD observed at a 3 months postpartum clinical assessment after delivery in an Italian tertiary Obstetric referral Unit.

MATERIALS AND METHODS

This was a prospective observational cohort study based on women $\geq$ 32 weeks gestational age who delivered in an Italian Tertiary Referral Maternity Hospital between July 2014 and December 2014. All the eligible women, who accepted to take part to the study, were invited for a clinical PFD assessment 3 months after delivery. At that time the presence of PFD was detected according to the criteria reported in table 1.

Table 1 Selection criteria (symptoms and physical evaluation) for PFD 3 months after delivery [1]

PFD	Measurement tool	Cut off
Urinary incontinence (UI)	ICI-Q SF	≥ 1
Anal Incontinence (AI)	Wexner score	$\geq$1solid/liquid &/or $\geq$2 gas
Prolapse	POP q staging criteria	≥ 2
Pain/Dyspareunia	Pain &/or dyspareunia VAS	> 0
Perineal Testing	Oxford score (0-5)	≤ 2

Women complaining of Urinary Incontinence (UI) and Dyspareunia were also administered a specific QoL Questionnaire (IQOL and FSFI Italian validated versions respectively). All the data were collected in a specifically designed database and descriptive statistical analysis performed.

RESULTS

This is an ongoing study. We are presenting our preliminary data concerning the 3 months follow-up consultation on women who delivered between the beginning of July and beginning of October 2014.

Of the 812 deliveries occurred in that period 151 (18,6%) were not enrolled: 51 because of refusal and 100 because of linguistic difficulties or missing data. Demographics and obstetrical features of the 661 women actually enrolled are reported in Table 2.

Table 2 Demographics and obstetrical parameters of 661 women enrolled

Parameter	
Etnicity: Caucasian n (%)	554 (83.2)
Age Mean $\pm$ *SD*	33.7 $\pm$ 5.2
BMI Mean $\pm$ *SD*	26.3 $\pm$ 3.9
Nulliparity n (%)	433 (65.5)
Mode of Delivery n (%)	
Vaginal	410 (62.1)
Obstetric Ventouse	79 (11.9)
Cesarean Section	172 (26.0)
Pushing second stage $>$ 1h n (%)	87 (13.2)
Epidural analgesia n (%)	196 (29.7)
Neonatal birth weight (gr) *Media* $\pm$ *SD*	3297 $\pm$ 520
Episiotomy n (%)	125 (18.9)
Severe perineal lacerations ($\geq$ *III°*) n (%)	7 (1.1)

Three-hundred-and-eighteen women (48.1%) actually came to the 3 months PFD clinic. Ninety-nine women (31.1%) presented a PFD according to the adopted criteria. Among them 53 complained of UI and 16 referred AI which is 16.6% and 5% of the general population respectively. Other findings are reported in table 3.

Table 3 PFD at 3 months postpartum§: symptoms distribution, combinations and scoring

PFD	Total n (%)	Isolated PFD n (%)	PFD Combin. n (%)	Score Mean (min-max)
*Urinary Incontinence (UI)**	*53 (54.6)*	*36 (37.1)*	*17 (17.5)*	ICIqSF 8.9 (1-20)
Urinary Stress I.	37 (38.1)	26 (70.3)	11 (29.7)	
Urinary Urge I.	12 (12.4)	7 (58.3)	5 (41.7)	
Mixed I.	4 (4.1)	3 (75)	1 (25)	
Anal Incontinence (AI)	*16 (16.5)*	*6 (6.2)*	*10 (10.3)*	*Wexner 5.1 (2-20)*
Gas I.	13 (13.4)	6 (46.2)	7 (53.8)	Wexner gas 2.5 (2-3)
Fecal I.	3 (3.1)	0	3 (100)	Wexner FI 13.1 (8-20)
Pelvic Organ Prolapse (POP)	*2 (2.1)*	*0*	*2 (100)*	
Pain/Dyspareunia #	*29 (29.9)*	*12 (41.4)*	*17 (58.6)*	
PF Muscle Dysfunction Modified Oxford grading (0-5)	*27 (27.8)*	*14 (51.9)*	*13 (48.1)*	*Grade 2: 19 (70.4%) <Grade 2: 8 (29.6%)*

§ Data calculated on 97 patients (2 missing data); *IQOL questionnaire; # FSFI questionnaire

The IQOL questionnaire on Urinary incontinent women (normalized to100; higher values worse QoL) scored 81 (Mean ± 16 SD). Only 2 (9.9%) out of the 22 women with dyspareunia who actually filled in the FSFI questionnaire could be classified as having a sexual dysfunction.

INTERPRETATION OF RESULTS

In this preliminary report 31.1% of women who delivered in an Italian Tertiary Referral Maternity Hospital complain of PFD 3 months after delivery. The overall rates of UI and AI within our population are respectively 16.6% and 5%. UI is the most prevalent symptom (54.6%) among PFD symptomatic women. AI, POP, Pain and PF Muscle Dysfunction are mostly observed in combination with other symptoms as expression of a complex PF dysfunctional involvement. To be noticed the difference in scoring between gas and fecal incontinence, being the second one the most bothering symptom.

CONCLUSIONS

To the best of our knowledge this is the first single-center study reporting clinical data on PFD at 3 months postpartum, including physical examination, on an Italian population.

Our data confirm that post-partum PFD affects around 1/3 of women delivering in an Italian referral center. This represents an increasing issue for health care providers, especially in the light of the growing evidence of pelvic floor rehabilitation as an efficacious treatment in this subset of population. Unfortunately the availability of this kind of treatment is scant in our country. Descriptive studies are of value for better tailoring health services.

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30 - POSITION IN THE SECOND STAGE OF LABOUR AND DE NOVO ONSET OF POST-PARTUM URINARY INCONTINENCE

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INTRODUCTION AND AIM OF THE STUDY

At present, with the possible exception of increased blood loss, no negative, maternal or fetal, effects of delivery in the upright position have been demonstrated [1,2]. Few data on this topic are available in the literature; however, in light of the existent studies, it is suggested that women should be encouraged to deliver in whichever position is most comfortable for them. The available findings on the impact of the position at delivery on the pelvic floor showed in the upright positions a significant reduction in the episiotomy rates, with a higher rate of 2nd degree tears. However, no data on the impact of the upright positions on the de novo onset of urinary incontinence post-partum exist. Aim of this study was to evaluate for the first time in the literature the role of the maternal position at the time of delivery, on the post-partum onset of de novo symptoms of urinary incontinence (UI).

MATERIALS AND METHODS

Between January 2014 and July 2014, consecutive women who underwent labour and delivery at our Department were considered for this prospective study. On admission to labour, women were asked for their consent to participate in the study. They answered questions about urinary function during hospitalization, and at 12 weeks after delivery via a telephone interview. We included only women with a physiological single pregnancy, with a spontaneous onset of the labour or an inducted labour for post-term pregnancy, with a spontaneous delivery. Exclusion criteria were: the presence of urinary symptoms prior to delivery; women delivered by caesarean section or operative vaginal delivery; twin pregnancy. A standardized protocol for obstetric management was used [3].All these patients chose to deliver in the position that they considered the most comfortable. Telephone interviews were carried out by a trained urogynaecologist, blinded to the previously collected data for each woman, at 12 weeks after delivery. Interviews were based on questions present in the International Consultation on Incontinence Questionnaire short form (ICIQ-sf).

RESULTS

During the study period 716 primiparous women, who fulfilled the inclusion and exclusion criteria, were included in the study. A total of 60 women refused the 12-wks post-partum interview (8.4%). Therefore, we included in the final analysis 656 patients. Women were divided in two groups: 296 (45.1%) women that chose an upright position during delivery (group 1) and 360 (54.9%) women that chose a supine position (group 2). The group 1 presented a significantly lower episiotomy rate but a higher rate of perineal tears > II degree. In the group 1 we found a significantly lower rate of de novo urinary incontinence (40.5% vs 48.9%, p=0.03) (table 1). Comparing women that referred at 3-mo follow up de novo onset of UI with continent women, at univariate analysis we observed that incontinent women presented a higher BMI, a higher perineal tears>2 degree and a higher rate of supine position at delivery (table 2). Via multivariate analysis birth position was the only factor correlating with the occurrence of urinary incontinence in the post-partum period (OR: 1.52; 95%CI: 1.06, 2.18; p=0.02). Increase in BMI was associated with a slightly, non significative, increase in the risk of developing incontinence (OR: 1.04 per 1-unit increase in BMI (95%CI: 0.99 1.08) and OR: 1.25 per 5-unit increase in BMI (95%CI: 0.96, 1.53); p=0.10). Instead, the occurrence of third-degree perineal tears did not influence the risk of developing urinary incontinence in the post-partum (p=0.99).

Table 1 characteristics anamnestic and of labour and delivery in the two groups

	Group 1: upright positions (n = 296)	Group 2: supine positions (n=360)	p value
Age (yrs)	32 (29.5-35)	31 (28-34)	0.17
Gestational age (weeks)	39+1 (37+2–40+5)	39+4 (37+5 – 40+5)	0.89
BMI	26.60 (25-28.95)	26.40 (24-29.30)	0.49
Duration 1th stage delivery (min)	150 (86-280)	160 (90-290)	0.69
Duration 2nd stage delivery (min)	50 (27-120)	47 (30-120)	0.56
Episiotomy	90/296 (30.4%)	146/360 (40.6%)	**0.007**
Perineal tears > 2nd degree	4/296 (1.35%)	0/360 (0%)	**0.04**
Fetal weight (gr)	3300 (3010-3590)	3250 (3020-3580)	0.92
Fetal pH at birth	7.321 (7.199-7.450)	7.298 (7.210-7.460)	0.56
Apgar < 7 at 1 min	7/296 (2.4%)	9/360 (2.5%)	1.000
Apgar < 7 at 5 min	1/296 (0.3%)	1/360 (0.3%)	1.000
Blood loss (ml)	350 (150-400)	350 (150-450)	0.88
No. with blood loss > 500 ml	4/296 (1.3%)	5/360 (1.4%)	1.000
Post-partum Urinary Incontinence	120/296 (40.5%)	176/360 (48.9%)	**0.03**

Table 2 association between obstetric risk factors and urinary incontinence

	incontinent (n = 296)	Continent (n=360)	p value
Age (yrs)	32 (29-35)	31 (28-35)	0.52
Gestational age (weeks)	39+4 (37+5–41+5)	39+2 (37+1 – 41+5)	0.89
BMI	27.05 (24.95-29.40)	26.10 (24.3-28.5)	**0.01**
Duration 1th stage delivery (min)	160 (90-290)	165 (75-260)	0.35
Duration 2nd stage delivery (min)	50 (30-117)	49 (27-120)	0.85
Episiotomy	104/296 (35.1%)	132/360 (36.7%)	0.74
Perineal tears > 2nd degree	4/296 (1.35%)	0/360 (0%)	**0.04**
Fetal weight (gr)	3280 (3020-3585)	3250 (3015-3480)	0.27
Supine positions	176/296 (59.5%)	184/360 (51.1%)	**0.03**

Data are expressed as absolute number (%) or median (interquartile range)

INTERPRETATION OF RESULTS

In agreement with previously published data the upright positions at delivery are related with a lower episiotomy rate and a higher rate of perineal tears>II degree. However, we found that the supine positions are an independent risk factor for the onset of de novo post-partum UI.

CONCLUSIONS

The supine positions at delivery appears to be an independent risk factor for the onset of de novo post-partum UI.

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31 - THE PUBOVAGINAL CYSTOCELE SLING: CYSTOCELE REPAIR BY AUTOLOGOUS RECTUS FASCIA GRAFT

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INTRODUCTION AND AIM OF THE STUDY

The autologous rectus fascia pubovaginal sling has been a safe and effective means of correcting stress urinary incontinence (SUI). In this study we tested the feasibility of using a larger graft for correcting cystocele with or without SUI.

MATERIALS AND METHODS

30 patients with symptomatic cystocele underwent the Pubovaginal Cystocele Sling (PCS) procedure, between January 2006 and October 2010; 14 were with concomitant SUI and 16 without. The technique is a modification of the standard pubovaginal sling procedure. A large trapezoidal (major base 6cm, minor base 4cm, height 5cm) rectus fascia graft is used, with four instead of two sutures to suspend the graft corners (fig. 1). The two sutures at the level of mid urethra are tied above rectus muscles in a tension-free manner, whereas the two at the level of the cervical fold are tied with tension (fig. 2). Data on anatomical outcomes (Baden-Walker classification), functional outcomes (Pelvic Floor Impact Questionnaire, PFIQ-7-short form), postvoid residual urine volume (PVR), and urinary tract infection (UTI) were prospectively collected.

RESULTS

At mean follow-up of 62.6 months (range 46-98 months), there was no recurrence in anterior compartment but one involving both apical and posterior compartments. All patients reported a statistically significant improvement in PFIQ-7 score. When present preoperatively, PVR, UTI, and SUI ceased in all cases. There was only one complication, a donor-site wound dehiscence without fascial involvement. Results are shown in the table.

	Preoperative	Postoperative 1 year	Postoperative last follow-up	p-value''
PFIQ-7 score	193.5 ± 45.66	38.2 ± 37.29	36.2 ± 21.14	<0.0001
PVR (mL)	56 ± 48.12	0	0	<0.001
UTIs (%)	30	0	0	0.2
Pads/day§ (#)	3.2 ± 1.30	0	0	<0.0001
POP degree (HWS*)				
Anterior vaginal defect degree	30/30 3.3 (range: 2-4)	1/30^ 1	1/30^ 1	<0.001
Apical vaginal defect degree	10/30 1.9 (range: 1-3)	0/30	1/30 1	0.007
Posterior vaginal defect degree	1/30 1	1/30 1	2/30 1.5 (range: 1-2)	0.9

Data expressed as mean ± standard deviation or rate.
§Patients with SUI. *HWS: Half Way Classification System. ^Redundant vaginal wall rather than recurrent prolapse. ''Preoperative vs. postoperative 1 year or postoperative last follow-up (Student's t-test for means; Chi square test for rates); Postoperative 1 year vs. postoperative last follow-up: p-value: ns (> 0.05) for all.

INTERPRETATION OF RESULTS

The described PCS procedure provided anatomical success in 96.7% (29/30) of cases, as only one patient had a de novo apical and posterior compartment defect 66 months after surgery. All patients had functional improvement in PVR, UTI, and SUI when present. Current literature suggests defining success after POP surgery on the basis of urological symptoms and patient's satisfaction rather than on anatomical correction only. According to PFIQ-7 scores, the PCS provided significant symptoms improvement in all patients; also in the patient with postoperative redundant vaginal wall had a significant, though lower, reduction in PFIQ-7 score. Complications were only minor, as we had a 30% rate of postoperative urinary retention that, however, disappeared within one week, and no case of de novo detrusor overactivity/urge incontinence.

The use of any autologous substitute may be limited by the possibility of donor-site complications. Risks potentially associated to the creation of a large fascial defect could have been difficulty in fascial closure, postoperative pain and wound dehiscence. Fortunately, there was none of these problems and

the case of wound dehiscence was probably due to patient's risk factors (diabetes mellitus) rather than the procedure itself. It is likely that a wide and accurate mobilization of rectus muscle fascia and closure of the isosceles trapezoid fascial gap into a figure of Y were effective in reducing tension up to preventing significant postoperative pain and fascial dehiscence.

CONCLUSIONS

The autologous PCS seems to be a safe and effective technique for correcting cystocele, with or without SUI.

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Figure 1 - A large trapezoidal (base 6cm, apex 4cm, height 5cm – picture in picture) rectus fascia graft is harvested through a Pfannenstiel incision.

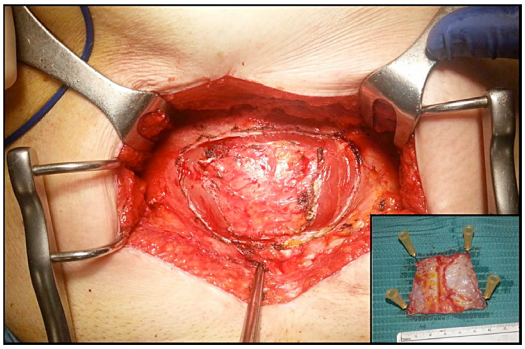
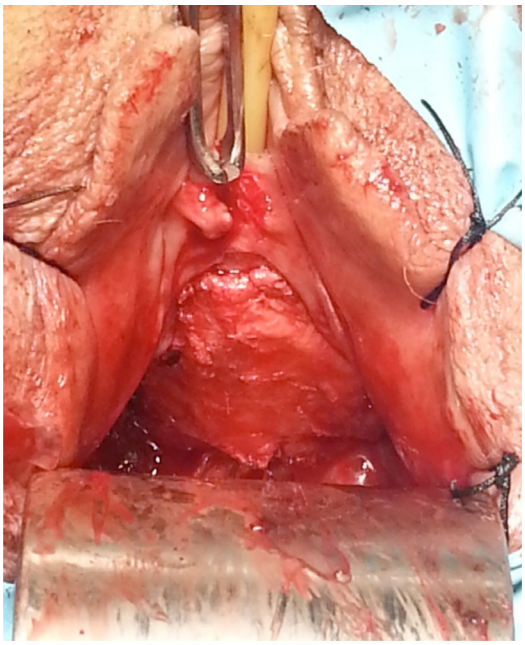


Figure 2 - Using 3/0 polyglactin stitches, the apical part of the graft is fixed to mid urethra whereas the basal one is fixed at the level of the cervical fold



32 - OUTCOMES AND POST-OPERATIVE COMPLICATIONS OF ROBOT-ASSISTED LAPAROSCOPIC HYSTEROSACROPEXY: INITIAL EXPERIENCE

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INTRODUCTION AND AIM OF THE STUDY

Pelvic organ prolapse (POP) is a common condition, affecting about 50% of women with children. It has been estimated that one in nine women will undergo a hysterectomy in their lifetime, and up to 10% of these women may need surgical repair of a major vaginal prolapse. [1]

Since the da Vinci robotic system (Intuitive Surgical, Sunnyvale, California, USA) gained US Food and Drug Administration approval for use in gynaecological surgery in April 2005, the number and variety of gynaecological cases performed continued to expand. Many women are now increasingly requesting uterine preservation, and hysterosacropexy (HSP) may be a viable option for those patients who need or desire a uterus-sparing surgery. [2]

Until now, only few studies have been addressed to assess the outcomes of robot assisted histero-sacrocolpopexy and no randomized controlled trials or meta analysis have been conducted.

The aim of our study is to evaluate the results and complication rate with standardized criteria in a series of female patients undergoing robot assisted laparosocpic histerosacropexy (RALHSP).

MATERIALS AND METHODS

A medical record review of all female patients consecutively undergone RALHSP for hysterocele $>$ stage II from February 2010 to November 2013 was performed.

All patients were evaluated with history, and a complete urogynaecological examination with vaginal inspection and, in case of sign and/or symptom of stress urinary incontinence (SUI), with urodynamics.

Operative outcomes included: operative time, intraoperative complications, estimated blood loss, length of hospital stay, conversion to laparotomy, time to catheter removal, post operative complications.

Patients' comorbidity was evaluated using the Charlson comorbidity index and ASA score; POP was assessed using the POP-Q system and all complications within 90 days of surgery were recorded and graded according to the Clavien Dindo system.

After a minimum follow-up of 3 months a check-up was performed, including clinical examination and a 0-10 point scale (VAS) to achieve information about patient satisfaction.

RESULTS

Mean age was 58.26 $\pm$ 11.08 years and Charlson score was 0 in 13 patients (86.6%) and ASA score was 2 in eleven patients (73.3%).

Four patients (26.6%) underwent previous uro-gynaecological surgery, respectively two anterior colpoplasty, one Perigee and Monarc positioning and one removal of ovarian cysts.

All patients had uterine or vaginal prolapse stage $>$ II and 2 patients showed urodynamic stress incontinence (USI).

Median total operative time was 110 minutes (range: 75 - 205 minutes) and median estimated blood loss was 0 cc (range: 0–50 cc).
There was no intraoperative complication and no need of intra or post operative blood transfusion.
The median catheterization time was 3 days (range: 1- 4 days) and mean hospitalization time was 4 days (range: 3-6 days); more than 50% of the patients were discharged within post operative day (POD) 4.
According to Clavien-Dindo system, grade I early complications occurred in 26.6% of cases (4/15): two nausea episodes, one asymptomatic hypocalcemia and one asymptomatic hypokaliemia (treated with electrolyte infusion); one patient (6.6%) had a grade II complication (diarrhoea treated with antibiotic therapy); no higher grades were observed.
At a median follow up of 36 months (IQR: 32–43) median VAS score was 9 (IQR: 5.5–9.5). Overall, we observed 4 totally unsatisfied patients: three because of POP recurrence (hysterocele: VAS score 4, 0, 0, respectively) and one due to the persistence of dyspareunia, urgency and recurrent urinary tract infections (VAS score 1). POP Q evaluation showed a significant improvement in patient undergoing RALSHP.
At the last check- up, no patient showed evidence of cervical dysplasia or tumor.

INTERPRETATION OF RESULTS

The intra and post operative results of our study are significantly in favour of our technique, with absence of conversions, low blood loss and low operative time and complication rate.
The results of our study are better or at least overlapping, with regards to intraoperative outcomes, to the literature data, with the limitation of a small number of patients, however higher than literature, and slightly worse results with regard to functional outcome, although with a longer follow up.

CONCLUSIONS

RALHSP seems to be a safe and effective procedure, offering a low complication rate, low estimated blood loss, rapid recovery, preserving fertility in young patients.
Prospective randomised clinical trials with long-term follow-up are needed, in order to compare the outcomes of RALSHP with traditional procedures.

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33 - QUALITY OF LIFE IN WOMEN WITH A 10-YEAR MINIMUM FOLLOW UP AFTER ANTERIOR VAGINAL PROLAPSE REPAIR WITH MESH

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INTRODUCTION AND AIM OF THE STUDY

Transvaginal polypropylene mesh (TVPM) implantation is one of the techniques used for pelvic organ prolapse (POP) repair. (1)
The aim of our study was to evaluate long-term results and quality of life using Patient Global Impression of Improvement (PGI-I) and Patient Perception of Bladder Condition (PPBC) questionnaires in patients with TVPM implantation for anterior vaginal prolapse repair.

MATERIALS AND METHODS

Files from 36 women aged 64.67 ± 7.59 years (at time of surgery) with anterior pelvic organ prolapse (POP-Q≥2) who underwent anterior TVPM implantation alone or associated to other surgery to treat concomitant stress urinary incontinence (SUI) and/or other POP, having a 10-year minimum follow-up, were evaluated (mean 11.5 ± 1.4 years).

RESULTS

Thirteen out of 36 (36.11%) were lost to follow-up. The remaining 23 ladies were investigated (mean follw-up 11.30 ± 1.29 years). Table 1 shows demographic data of the survivors at a 10-year minimum follow-up.

Table 1 Demographic data from survivors at a 10-year minimum follow-up.

N° of patients 8pts)	23
Mean age (yrs) ± SD	63.3 ± 6.59
Anterior prolapse (POP-Q≥2) n° of pts (%)	23 (100%)
Posterior prolapse n° (%)	5 (21.74%)
SUI n° (%)	8 (34.78%)
Storage symptoms n° of pts (%)	1 (4.34%)
Urge urinary incontinence n° of pts (%)	2 (8.69%)
Systemic comorbidities n° of pts (%)	10 (43.47%)

No difference in terms of age and preoperative comorbidity was found between survivors and lost at follow-up. An anterior TVPM implantation alone was performed in 10 out of the 23 survivors (43.47%); in the remaining patients it was associated to a posterior vaginal repair (5/13) and/or a mid-urethral sling placement (9/13). The mean PGI-I score was 1.33 (± 0.82) and the mean PPBC score was 2.21 (± 1.65). We did not find any correlation between increasing age or comorbidity at surgery and either PPBC or PGI-I scores.

INTERPRETATION OF RESULTS

Although the few number of patients survived at a 10-year minimum follow-up after anterior vaginal prolapse repair with mesh, the long term impact of this procedure on patient-s'quality of life was satisfying with a high level of improvement (up to 69.5% of cases).

CONCLUSIONS

Transvaginal polypropylene mesh (TVPM) implantation shows a satisfactory quality of life improvement in patient with anterior compartment prolapse.

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34 - SACRAL NEUROMODULATION AND FEMALE SEXUALITY. REVIEW ARTICLE

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INTRODUCTION AND AIM OF THE STUDY

Pelvic floor dysfunctions (PFDs) are associated in varying degrees with female sexual dysfunctions (FSD). Concomitant

clinical benefits of the SNM implant on females suffering from urinary and bowel dysfunctions were reported[1,2,3].

The primary end-point of the present critical review is to determine if sufficient data exist on the therapeutic effect permanent SNM may have on FSD, and then to gather information on the possible mechanism of action of SNM on female sexual function (FSF).

MATERIALS AND METHODS

Methods, definitions, and units conform to the standards jointly recommended by the International Urogynecological Association and the International Continence Society. This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement. A MEDLINE and OVID search was done using the following terms: "sacral neuromodulation" (AND) "female sexual dysfunction" (OR) "female sexual function". Search criteria were limited to humans, adults, English full-text articles. Reviews and case reports were excluded. Studies reporting results of other neuromodulation techniques (e.g. pudendal) were also not included. All relevant papers published in English from 2001 to 2014 were retrieved. REFERENCES of selected articles and international guidelines were hand searched to identify additional reports. All identified studies were screened for eligibility, in accordance with the Cochrane Handbook for Systematic Reviews of Interventions. Data from eligible reports were extracted by one author and discrepancies were resolved by discussion.

Various outcome measures were used to evaluate the efficacy of permanent neuromodulation procedures on FSF. These may be divided into 3 categories: self-general assessment of global efficacy, patient-recorded event log of sexual activity, and more specific assessments on sexuality such as the Female Sexual Function Index (FSFI). A full FSFI scale score lower than 26.55 was indicative of female sexual disorder.

RESULTS

Overall, 10 articles were selected. Of those, 9 were prospective clinical studies. Of the 260 females initially eligible pre-SNM, only 184 (70.8%) were included post-SNM evaluation. Fig. 1

The majority of females included were of menopause ages. Three authors included sexually inactive women. Two authors incorporated females with LUTS related to neurological illness. One-hundred-forty-eight out of 184 (80.4%) females underwent unilateral sacral third (S3) permanent implant with an InterStim system (Medtronic, Minneapolis, MN, USA) using the tine-lead technique. Overactive bladder (OAB) symptoms in 73 females (39.7%) constituted the most frequent reason for permanent neuromodulation implant; 43 (23.4%) showed concomitant faecal incontinence and unspecified urinary symptoms; 31 (16.8%) had concomitant OAB symptoms and pelvic pain; 18 (9.8%) unspecified micturition symptoms; 10 (5.4%) faecal incontinence and 9 (4.9%) showed urinary retention.

Overall 15 (8.2%) women were never assessed post-SNM. Follow-up post-SNM varied from 3 to 36 months. The range of women who appropriately completed the questionnaires during follow-ups were between 143 (77.7%) and 161 (87.5%). The most specific questionnaire assessing FSF was the Female Sexual Function Index (FSFI) used by six authors. During follow-ups all six authors showed statistically significant improvement ($p<0.05$) in at least one FSFI domain compared to baseline. In one study statistically significant improvement ($p<0.05$) in the FSFI pain domain was exclusively detected in the group of neurological females. Responders were categorised as women with an increase of at least 60% in their baseline score for each FSFI domain, including the total FSFI score. Fig 1.

Two studies, however, using the questionnaire to screen for sexual dysfunction did not find any statistically significant differences after SNM. The most severe FSF drawback concerns loss of libido and reduction of vaginal lubrication which was resolved in one female following the removal of the SNM implant.

Table 1 sub-analysis of the FSFI score

	Results
Zahibi et al	Statistically significant improvement ($p= 0.029$) in the overall satisfaction domain for only 15 patients with urinary symptoms alone
Signorello et al	Total FSFI score > 26.55: 4/16 in 2-year follow-up, and 2/12 in around 3-year follow-up Statistically significant improvement ($p=0.046$) in the pain domain for 6 neurological females at the final follow-up (3 years)
Gill et al	4/8 females reached total FSFI score > 26.55
Lombardi et al	4/11 "neurogenic responders" in two domains; three out of 4 in arousal domain. 2/8 "non-neurogenic responders"; one in arousal *plus* desire and one in lubrication. Mean duration of sexual improvement around 2 years

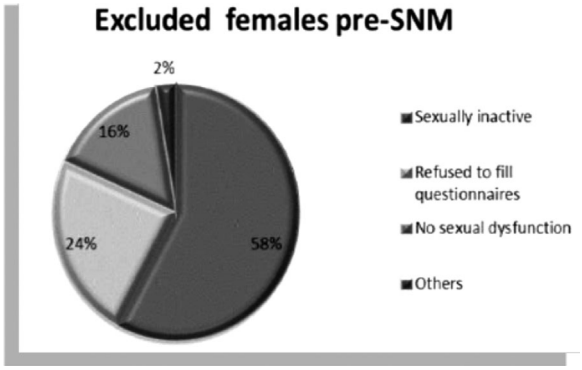

Fig.1. rates and reasons of exclusion

INTERPRETATION OF RESULTS

Most authors reported statistically significant improvement using validated questionnaires mainly through the FSFI for women who underwent a permanent SNM implant. The most relevant limit concerns the small patient sample of the present studies. Two authors using the FSFI simply reported which patients reached a total FSFI score $\geq$ 26.55 after SNM surgery, without providing supplementary information such as their baseline FSFI scores, ages, or type of voiding disorders. The improvement of sexual function in females with urinary symptoms was mainly justified by the reduction in urinary symptoms after SNM. However, a statistically significant correlation between improvement in bladder symptoms in females affected with OAB symptoms and sexual function was demonstrated only by one author.

CONCLUSIONS

Actual data are still insufficient to definitely assert the positive role of SNM on FSF. Further studies should clarify whether an improvement after SNM might be correlated to an amelioration in overall pelvic floor function.

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35 - PELVIC FLOOR REHABILITATION FOR TREATMENT OF PREMATURE EJACULATION

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S.C. Urologia, Don Tonino Bello, Molfetta, Italia [(1)]

INTRODUCTION AND AIM OF THE STUDY

Premature ejaculation (PE) is the most common male sexual disorder. The International Society for Sexual Medicine (ISSM) recommends the following definition of PE: 'a male sexual dysfunction characterized by ejaculation which always or nearly always occurs before or within about 1 min of vaginal penetration, and the inability to delay ejaculation on all or nearly all vaginal penetrations, and negative personal consequences, such as stress, bother, frustration and/or the avoidance of sexual intimacy'. Intravaginal ejaculatory latency time (IELT) is defined as the time from vaginal intromission to intravaginal ejaculation and it is often used as a parameter to quantify clinical response to therapy and as a standardized method to compare different treatment modalities in clinical trials. In the present study, men with lifelong PE underwent pelvic floor muscle (PFM) rehabilitation, including physio-kinesiotherapy, electro-stimulation and biofeedback. The primary objective of our study was to evaluate the effectiveness of PFM rehabilitation by measuring changes in IELT after 12 weeks of therapy.

MATERIALS AND METHODS

Between November 2012 and September 2014, 49 male patients were enrolled in this study. PE was diagnosed by applying the ISSM definition of PE. All of the subjects had lifelong PE with a baseline IELT $\leq$ 60 s (mean: 36.7 s, range: 18.6–52.4 s). Pretreatment IELT was measured during a 4-week baseline period. In particular only 9 patients reported previous use of local anaesthetic cream applied to the glans penis and penile shaft 30 min before sexual intercourse without any significant benefit in IELT. No other therapy was reported. The patients were all treated with PFM rehabilitation. To evaluate the effectiveness of PFM rehabilitation, we compared the mean IELT values of the patients after 12 weeks of treatment. On physical examination, none of the patients presented with phimosis (6 patients were circumcised), frenulum breve, erectile dysfunction or a history of chronic prostatitis. The PFM rehabilitation protocol consisted of physio-kinesiotherapy to achieve a muscle contraction that allowed the patient to be aware of motor activity; electro-stimulation of the perineal floor to stimulate directly the pudendal nerve and biofeedback, in which the patient learns to control the muscle contractions of the perineal floor and the genitourinary sphincter. The patients had two 60-min therapy sessions each week, during which the three techniques were applied for 20 min each. The results were measured after the first 20 sessions (6 weeks) and then again at the end of therapy (12 weeks). Statistical analysis was performed by using the computer statistical package SPSS version 10.0 and SAS version 6.4. A $p < 0.05$ was considered statistically significant.

RESULTS

At the end of 12 weeks of treatment, 26 (65%) of 40 patients gained control of their ejaculation reflex, optimizing the latency time to ejaculation from the start of intravaginal intercourse (IELT before therapy: $\leq$ 60 s). Nine patients were nonresponsive to the treatment and opted to drop out of the study. For patients who responded favourably to the PFM rehabilitation, the results were maintained throughout the follow-up time (until 5 months after the 12-week treatment). None of the patients reported adverse effects that could have led to discontinuation of the treatment. At the end of week 12 of the PFM rehabilitation, the mean IELT was 124.2 ± 31.3 s (range: 86.6–215.5 s).

INTERPRETATION OF RESULTS

Ejaculation is neuromodulated by the spinal control centre, which coordinates sympathetic, parasympathetic and somatic activities, leading to emission and expulsion. The spinal control centre is influenced by the supraspinal centres with the control mechanisms responsible for inhibition of ejaculation descending from the supraspinal level and involving a number of regulatory neurotransmitters, of which the most widely studied is 5-hydroxytryptamine, or serotonin. The pelvic floor undoubtedly plays an important role in sexual function; evidence suggests active roles of the ischiocavernous and bulbocavernous muscles, and sphincters, with a significant increase in electromyographic activity during the entire ejaculatory period. The PFM rehabilitation protocol used in the present study addresses both of these possibilities; physio-kinesiotherapy and electro-stimulation are designed to improve the contractile strength of the perineal muscles, whereas biofeedback trains the patient to recognize and contract the muscles to increase the closing strength of the urethral sphincter. Only a few studies have reported pelvic floor exercises as a possible treatment option for PE, and no rehabilitation protocol has been standardized. After the end of our treatment, 65% of the patients learned to control their ejaculatory reflex.

CONCLUSIONS

The limitations of our study include the small sample of patients enrolled, the short follow-up time, and the lack of another self-administered questionnaire such as the premature ejaculation diagnostic tool. In any case the PFM rehabilitation protocol is easy to perform, with no reported adverse effects. Although it has not yet been standardized, the results obtained in our patients with lifelong PE suggest that it may be considered as a therapeutic option for patients with PE.

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36 -OnabotulinumtoxinA FOR NON NEUROGENIC OVERACTIVE BLADDER : OUR EXPERIENCE

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INTRODUCTION AND AIM OF THE STUDY

Onabotulinumtoxin-A (BoNT-A) has been approved for neurogenic detrusor overactivity (NDO) and more recently also for idiopathic detrusor overactivity (IDO). BoNT-A injection is a safe and effective therapeutic option as demonstrated by large randomized clinical

trials, nevertheless data from "real life" studies are lacking. This study evaluates the efficacy and safety of repeated intravesical BoNT-A injections in consecutive unselected patients with non-neurogenic detrusor overactivity treated in our center.

MATERIALS AND METHODS

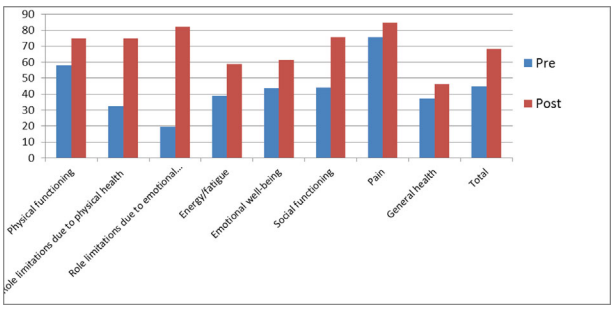
From January 2008 to October 2014, patients with non-neurogenic detrusor overactivity refractory to anticholinergics (ACH) were enrolled. After the signature of a specific informed consent for the off label use of drugs (until 2014), all patients received an initial 100-150U of intravesical BoNT-A injection followed by repeated injections when the clinical benefit of previous injection diminishes.

Assessments included the following parameters: medical/surgical history, number of urinary incontinence and urgency episodes, nocturia, number of PAD used, baseline multichannel urodynamics (UD), the SF-36 and the OAB screener and the Treatment benefit scale (TBS).

RESULTS

Seventeen patients were enrolled (M/F=4/13; mean age: 64y). Ten patients already received pelvic surgery (TURP/TOT/TVT). The mean duration of overactive bladder symptoms was 69.9months and all patients had been inadequately managed by ACH therapy for 23.3 months. The baseline UD confirmed the presence of detrusor overactivity in 94.1% of the cases. The mean number of injection was 1.8 per patient (range: 1-6). At first injection, 9 patients received 150U and 8 100U of toxin. No intraoperative complications occurred, whereas one patients developed a temporary urinary retention treated by clean intermittent catheterization. A significant reduction of number of urinary incontinence and urgency episodes, nocturia, number of PAD used from baseline to 12 weeks follow-up visit was observed ($p<0.05$). The quality of life measured by SF-36 score showed a significant improvement in almost all domains (physical function and social functioning, limitation due to emotional and physical health, energy and general health) and smaller changes in the pain domain.

The OAB screener questionnaire showed a significant reduction from 36.6 to 18.4 at week 12 ($p<0.05$). The patients' perception of change in their condition using the TBS demonstrated that 82.3% of patients had a great improvement of symptoms after treatment.



INTERPRETATION OF RESULTS

BoNT-A treatment in patients with non-neurogenic detrusor overactivity refractory to ACH resulted in improvements in urinary incontinence and urgency episodes, even in this real life study.

CONCLUSIONS

The general health status, as measured by SF-36, and the bother of storage bladder symptoms, as measured by OAB screener, confirmed the true clinical benefits of BoNT-A injections supporting its wider adoption. The optimal high acceptance by the patients motivates surgeons and caregivers to use this approach with great attention to the patients needs and the quality of life.

37 - OUTCOMES OF RETROPUBIC TENSION-FREE VAGINAL TAPE FOR THE TREATMENT OF URODYNAMIC STRESS INCONTINENCE AT 13-YEAR FOLLOW-UP

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INTRODUCTION AND AIM OF THE STUDY

Nowadays, it has been widely demonstrated as Tension-Free Midurethral Slings are the most effective and safe surgical procedures for the management of female stress urinary incontinence (SUI), with excellent subjective and objective cure rates. Prospective studies, reviews and meta-analyses have evaluated the efficacy and safety of TVT at medium term, however only few studies reported its long-lasting benefits. The aim of the present study is to report the long-term subjective, objective outcomes of women subjected to TVT with a follow-up of at least 13 years.

MATERIALS AND METHODS

Between January 1999 and December 2001 we have enrolled all consecutive women who complained about symptoms of pure SUI with Urodynamically proven Stress Incontinence (USI). All the patients candidate to surgery were scheduled for a retropubic TVT procedure. Exclusion criteria were as follows: women with previous history of anti-incontinence or radical pelvic surgery, psychiatric and neurological disorders, concomitant vaginal prolapse >1st stage according to the POP-Q system; Overactive Bladder (OAB) symptoms, urodynamically proven detrusor overactivity (DO) and post-void residual >100mL. Preoperative evaluation included medical history, physical examination, a frequency-volume chart, urine analysis and complete urodynamic testing. Follow-up evaluations were scheduled at three and 12months, and once per year thereafter, including anamnestic and physical examination, cough test, evaluation of subjective satisfaction with validated questionnaires. A cough test was performed in lithotomic and upright positions with a full bladder (ultrasonographic measurement of at least 400 cc). The objective cure was defined as the absence of urine leakage during a cough test. The subjective satisfaction was defined by using Visual analogue scale (VAS) from 1 to 10-point symptom assessment scale (where 0 represented unbearable urinary and 10 no urinary problems) and by Patient Global Impression of Improvement (PGI-I) (a 7-point scale, with a range of responses from 1, "very much improved," through 7, "very much worse"). Subjective success was indicated in case of "very much improved" or "much improved" (PGI-I ≤ 2) and VAS scale ≥ 8. Secondary outcome was to evaluate the changes of Urogenital Distress Inventory (UDI) and International Consultation on Incontinence Questionnaire Short Form (ICQ-SF).

RESULTS

During the study period a total of 26 women with proven USI, who fulfilled the inclusion and exclusion criteria, underwent the TVT procedure. At 13-year follow-up, 24 (92.3%) cases were available for evaluation whereas 2 patients (6.7%) were lost to follow-up or no-more evaluable; one of them died for medical reasons not related to the TVT procedure and the other patient was lost to follow-up. Patient's demographic characteristics are summarized in Table 1. No bladder perforation, severe bleeding or other complications occurred during surgery procedures. Table 2 summarizes subjective satisfaction and objective cure rate across the follow-up period. No significant deterioration of both subjective, and objective outcomes was observed over time (all p values >0.99). No differences in terms of onset OAB symptoms were observed pre- and post-TVT [0/26 (0%) vs 2/26

(7%); p value 0.49 [a]] at 3, 12 months and 13 years [7/24 (29.1%); p value 0.06 [b]]. We found statically significant difference between UDI stress incontinence [60 (40-80) vs 0 (0-15); p value < 0.0001 [a]] and ICQ-SF pre- and post-TVT [17 (16-17) vs 0 (0-8); p value < 0.0001 [a]]. No differences about UDI irritative symptoms pre- and post-TVT [0 (0-0) vs 0 (0-8); p value < 0.16 [a]]. (Table 3)

Table 1

	n=26 (%)
Age, yr	65.5 (51-75)
BMI, kg/m2	25.9 (17-35)
Obese: BMI ≥ 30 kg/m2	3 (11.5)
Sexually active	20 (77)
Menopausal	24 (92.3)
HRT	11 (42.3)
Recurrent UTI	0 (0)
Previous vaginal deliveries	3 (1-7)
Macrosome (≥ 4000 g)	2 (7.7)
Operative delivery (vacuum/forceps)	4 (15.4)
Previous hysterectomy	12 (46.1)
Urethral hypermobility	22 (84.6)
VLPP <60 cm H2O	14 (53.8)
ICQ-SF	17 (16-17)
UDI stress incontinence	60 (40-80)
UDI irritative	0 (0-0)

Table 2

	3 months	1 year	13 years	p value
Subjectively cured	92.3% (25/26)	92.3% (25/26)	91.6% (22/24)	0.99 a 0.59 b
Objectively cured (at stress test)	92.3% (25/26)	92.3% (25/26)	87.5% (21/24)	0.99 a 0.54 b
Onset of OAB	7.7% (2/26)	7.7% (2/26)	29.1% (7/24)	0.06 b

Table 3

	3 months	1 year	13 years	p value
UDI postoperatively Stress incontinence	0 (0-15)	0 (0-15)	0(0-18)	0.61[b]
UDI postoperatively irritative symptoms	0 (0-40)	0 (0-40)	0(0-50)	0.20[b]
ICQ-SF postoperatively	0 (0-8)	0 (0-8)	0(0-12)	0.04[b]

[a] Chi-square test [b] Chi square test for trend

INTERPRETATION OF RESULTS

In agreement with previously published data on retropubic sling procedure, our results demonstrated that this procedure is a highly effective and safe procedure, with a long lasting effectiveness over time. In our series, we recorded a growing trend of de novo overactive bladder, although this is not statistically significant. This could be reflect the aging of the patients rather than the consequence of surgery.

CONCLUSIONS

The long-term results of this study seem to demonstrate that the TVT is a highly effective option for the treatment of female SUI. Indeed, we recorded very high cure rates and low complication rate over the 13-year observation.

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38 - MIXED URINARY INCONTINENCE: A PROSPECTIVE STUDY ON THE EFFECT OF TRANS-OBTURATOR MID-URETHRAL SLING

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INTRODUCTION AND AIM OF THE STUDY

Mixed urinary incontinence (MUI) is defined as the complaint of involuntary loss of urine associated with urgency as well as with efforts or physical exertion or on sneezing or coughing.

Some authors have suggested that urethral dysfunction has a central role in MUI. The latest and most fascinating theory on the pathogenesis of MUI suggests stress urinary incontinence (SUI) as the origin of the disease: during increased intra-abdominal pressure, in the presence of bladder neck incompetence, urine enters the proximal urethra provoking an involuntary detrusor contraction through an urethro-detrusorial reflex. Following this theory, mid-urethral slings have been proposed in patients with MUI.

Primary objective of this study was to evaluate, at a mean follow-up of 59 months, the subjective and objective outcomes on continence using a trans-obturator mid-urethral sling (TOT) in patients with MUI. Secondary objective was to determine the impact on Quality of Life (QoL) as well as which factors potentially influence the success of the procedure.

MATERIALS AND METHODS

This is a prospective, single-arm, observational study on female patients with MUI and predominant SUI conducted at a high-volume urogynaecological centre between April 2008 to December 2011. SUI was diagnosed using both the Cough Stress Test and urodynamics. All patients had unsuccessfully undergone pelvic floor training and antimuscarinic therapy. Inclusion criteria: age >18 years, no previous SUI surgery, no POP>stage II, unresponsive to conservative therapies, no neurological diseases. All patients provided informed consent to participate in our study. The study was approved by the ethical committee of the institution. All patients underwent surgical insertion of a trans-obturator mid-urethral sling (Monarc®). Post-operative work-ups were planned for 6 months, 1 year and then annually. The post-operative assessment was carried out by different authors to those who operated. The correction of SUI was evaluated objectively using the standardised Cough Stress Test (CST) and the 1-hour PAD test. The subjective cure rates for both SUI and UUI were evaluated using ICIQ-SF and the Patient Global Impression of Improvement (PGI-I). The King's Health questionnaire was used to evaluate Quality of Life (QoL). For the overall results, we defined patients as 'dry' when they had no urinary leakage and no use of pads; as 'improved' with at least a 50% reduction in use of pads and a declaration of "satisfaction with the results of the operation"; as 'failed' in all other cases.

Statistical analysis: the McNemar chi-square test, the paired t-test for continuous parametric variables, and the Fisher exact test. We considered $p<0.05$ to be statistically significant. A

logistic regression model and odds ratios (with 95 percent confidence intervals) were used to assess the independent prognostic value of six variables for the outcome. A p value of <0.05, using the Chi-square test, was considered statistically significant. No financial assistance was received from any company in the design or execution of this study.

RESULTS

Eighty six consecutive patients with MUI that met all the study criteria were included and evaluated. Mean age was 60 years, mean BMI 27.07, median parity 2; 64 patients were post-menopausal. The mean follow-up was 59 months (36-84 months). We evaluated the results for SUI and UUI separately. We had an objective cure rate for SUI in 83.7% (72 patients) and a subjective cure rate in 87.2% (75 patients). UUI disappeared in 64 patients (74.4%).

The PGI-I data are shown in Table 1.

Table 1 PGI-I values

Very much better	60 patients (69.8%)
Much better	15 patients (17.4%)
A little better	6 patients (6.9%)
No difference	4 patients (4.7%)
A little worse	1 patients (1.2%)
Much worse	0
Very much worse	0
Total	86 patients

The overall continence rate (for SUI and UUI together) was 66.3% (57 patients). The King's Health Questionnaire indicated a statistically significant improvement in QoL in all domains. The analysis of urodynamic data showed a statistically significant post-operative increase of detrusor pressure at maximum flow (PdetQmax) ($p=0.02$) and a reduction of Maximum flow ($p=0.03$) (Table 2). No obstruction, according to Blaivas and Groutz nomogram, was observed.

Table 2 Pre- and post-operatively urodynamic data

	Pre-op	Post-op	P
Cystometric capacity	mean 398.2 (222-593 ml)	mean 370 (237-520ml)	0.22§
Detrusor overactivity	68 patients (79.1%)	63 patients (73.3%)	0.87*
PdetQmax	mean 16.2 (1-46 cmH2O)	mean 25.3 (9-57 cmH2O)	0.02§
Qmax	mean 25.3 (9-57 ml/sec)	mean 18.4 (7-28ml/sec)	0.03§
Urodynamic SUI	86 patients (100%)	14 patients (16.3%)	0.0000*

*MacNemar test
§ t-test

Using the univariate analysis, we looked at the performance of 6 variables (age, parity, BMI, menopausal status, pre-op. detrusor overactivity and pre-op PdetQmax) and we found no significant risk factor for failure (Table 3).

Table 3 Univariate logistic regression

Variables	Cure rate	Failure rate	p value*	Odds ratio
Age (years)			0.114	0.474
36-59	27/57 (47.4%)	10/29 (34.5%)		
>60	30/57 (52.6%)	19/29 (65.5%)		
Parity			0,547	0.730
0-2	18/57 (31.6%)	7/29 (24.1%)		
3	39/57 (68.4%)	22/29 (75.9%)		
Body mass index			0.234	
21-29 kg/m2	40/57 (70.2%)	24/29 (82.8%)		2.100
>30 kg/m2	17/57 (29.8%)	5/29 (17.2%)		
Menopause				
yes	39/57 (68.4%)	25/29(86.2%)	0.082	0,347
not	18/57 (31.6%)	4/29 (13.8%)		
PdetQmax				
<20 cmH2l	49/57 (85.9%)	21/29 (72.4%)	0.876	0.917
>20 cmH20	8/57 (14.1%)	8/29 (27.6%)		
DO			0.113	0.338
yes	42/57 (73.7%)	26/29 (89.7%)		
not	15/57 (26.3%)	3/29 (10.3%)		

*Chi-square test

INTERPRETATION OF RESULTS

Our study demonstrates that transobturator mid-urethral slings correct SUI in 83.7% of the sample, and UUI in 74.4%, with an overall correction of incontinence in 66.3%. According to the univariate analysis, we did not find clinical or urodynamic parameter correlated with the outcome.

Our data seem to confirm the theory that, in some patients, MUI could be mainly due to an urethral rather than to a detrusorial dysfunction. This hypothesis could be confirmed by the lack of pre-operative response to the antimuscarinic drugs in our sample, considering that these drugs act on the detrusorial component of incontinence.

CONCLUSIONS

Our study demonstrates that transobturator mid-urethral slings can be used effectively in patients with MUI with 87.2% of patients satisfied of the results of the operation, as confirmed by PGI-I. More studies are needed to identify pre-operative selection criteria that could be predictive of the outcome of surgical treatment in patients with MUI.

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39 - VIDEOURODYNAMIC EVALUATION OF ORTHOTOPIC "U-SHAPED" ILEAL NEOBLADDERS ACHIEVED BY TOTALLY INTRACORPOREAL LAPAROSCOPIC TECHNIQUE

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INTRODUCTION AND AIM OF THE STUDY

Laparoscopic radical cystectomy (LRC) with intracorporeal reconstruction of an orthotopic neobladder was not performed until 2002 and consequently data are lacking in the literature with regard to the post-operative function of these econstructed neobladders. Aim of this study was to evaluate the functional outcomes achieved in our first 30 cases of LRC with

intracorporeal orthotopic U-shaped ileal neobladder reconstruction by Videourodynamic (VUDM)

MATERIALS AND METHODS

Patients - 30 consecutive patients were enrolled in this study. Inclusion criteria were: (1) muscle-invasive urothelial bladder cancer T2–4a, N0–Nx, and M0; (2) high-risk and recurrent non–muscle-invasive tumours; (3) multifocal T1G3; and (4) T1G3 with concomitant carcinoma in situ (CIS). Exclusion criteria included: (1) patient refusal of LRC with orthotopic diversion; (2) contraindications to LRC including distant metastases, an American Society of Anaesthesiologists (ASA) score >3, and severe heart and/or respiratory failure and (3) the presence of contraindications to neobladder diversion.

U-shaped neobladder configuration technique

LRC with bilateral pelvic lymphadenectomy was performed using a five-port, fan-shaped transperitoneal approach. Then, a 35-cm ileal segment, 20 cm from the ileocecal junction was isolated. Bowel continuity was restored using Endo-GIA staplers. A globular, U-shaped, ileal neobladder was constructed with two 18-cm, 3-0 barbed sutures then anastomosed to the urethra using the Van Velthoven technique with the same suture. Each ureter was spatulated for a length of 1 cm and separately anastomosed to the terminal ends of the U-shaped ileal segment by using the Bricker technique with continuous 4-0 Vicryl sutures. Two single-J 7 Ch 40-cm ureteral stents were inserted via the Seldinger technique through the abdominal wall in the midline just above the symphysis using a 2-mm MiniPort trocar.

Videourodynamic evaluation

Methods were based on Good Urodynamic Practices. VUDM was performed using a Medtronic urodynamic equipment combined with a digital angiographic device. A double-lumen 6 Fr transurethral catheter was inserted into the neobladder. A rectal balloon 10 Ch was used to record abdominal pressures. Surface electrodes were applied to the perineal floor to assess muscular behaviour under stimulus (coughing or Valsalva manouvre) and during micturition. The neobladder was filled with contrast medium at room temperature through the catheter (30 mL/min). Patients were evaluated either in the standing and sitting position. The following parameters were evaluated: 1) neobladder capacitY; 2) presence of residual peristaltic activity; 3) neobladder compliance; 4) Valsalva leak point pressure value in subjects with urinary stress incontinence; 5) neobladder pressure during voiding phase; 6) post-micturition urinary residue; 7) perineal floor behaviour. The following radiologic data were collected: morphology of the neobladder, evidence of ureteral passive or active refluxes, and any urinary leakage either during residual peristaltic activity or during active manouvres.

RESULTS

Patient demographic and operative data: median age of the patients was 67 years (range: 62–79), median BMI 22.3 (16–26.1), and mean ASA score was 2.2 (1–3). No patient had prior radiation; 3 patients had received neoadjuvant chemotherapy, and 9 patients had failed intravesical bacillus Calmette-Guérin instillation. No case required conversion to open surgery, no perioperative mortalities were reported. The median operating time was 365 min (range: 270–605). Median blood loss was 290 mL (range: 50–800), with a transfusion rate of 26.6%. The mean number of lymph nodes removed was 16 (range: 5–28). Overall median time to regular diet, ambulation, and hospital length of stay were six days (range: 4–11), two days (range: 1–4), and nine days (range: 7–37), respectively. **Pathologic data:** all tumours were transitional cell carcinoma; 30% of patients (9 of 30) had concomitant carcinoma in situ. Incidental prostate cancer was detected in 26.6% (8 of 30) of the patients. All surgical margins were negative. Eight patients with non – organ-confined disease or positive lymph nodes received adjuvant chemotherapy. **Complications**: according to Clavien classification system 11, early complications occurred in 11 patients (33.3%), including 8 patients with low-grade complications (1–2) and 2 patients with high-grade complications (3–5). Late complications occurred in 6 patients (3 with grade 1, 2 with grade 2, and 1 with grade 3b). However, no early complications involved the neobladder

Functional outcomes and VUDM results

Hundred and eighty days postoperatively, 22/30 (73%) of patients were continent by day with intervals between micturitions ranging from 3.5 to 4.2 h. The remaining 8 patients reported occasional urinary leakage during cough, sneezing, or secondary to an urgent desire to void. Night time micturition intervals ranged from 2 to 4.4 h, and 11/30 (36%) patients reported urine leakage between night micturitions. VUDM revealed a mean maximal neobladder capacity of 227 mL (190–285). Residual peristaltic activity was observed in all individuals evaluated but only 9/30 (30%) displayed severe peristaltic activity (>35 cmH2O, maximum value: 44 cm H2O). Six of these nine (66.6%) individuals experienced urinary leakage during these neobladder contractions. Mean post-void residual volume was 44 mL (0–105), and peak flow rate was 13.9 mL/s (9.7–29.2). Six patients (20%) needed intermittent self-catheterisation for chronic urinary retention (>100 mL). The Valsalva manoeuvre was positive in 5/30 (17%) subjects at maximum neobladder filling with a radiologic leak point pressure varying from 44 to 82 cmH2O. The analysis of the voiding phase revealed that 25/30 (83%) of subjects employed the activation of abdominal straining. Of these subjects, 12/25 (48%) individuals showed a complete relaxation of the pelvic floor on electromyographic evaluation, while 13/25 (52%) showed a concomitant activation of abdominal straining and pelvic floor musculature. However, these patients urinated easily against the resistance of the contracted pelvic floor. In five (17%) cases, voiding was achieved without abdominal straining, by maintaining the tone of the neobladder wall and relaxing the pelvic floor muscles.

Bladder morphology assessed during contrast cystography showed the desired U-shape in all cases. Ureteral reflux was observed in 7/30 (23.3%) of individuals, but was incomplete and monolateral in all cases, except for one subject, who developed monolateral hydronephrosis and required ureteral stenting. All subjects with ureteral reflux displayed a relatively low neobladder capacity (mean value, 212 mL), and their residual peristaltic activity varied from 28 to 44 cmH2O.

INTERPRETATION OF RESULTS

There are no specific data regarding functional results of orthotopic ileal neobladders performed by totally intracorporeal technique and there is no evidence in literature of post-operative follow-up based on VUDM which has already proven to be the best tool to investigate neobladder function in patients submitted to RC. In this experience, VUDM showed a good morphologic aspect of the neobladders associated with satisfying functional results. Mean neobladder volume and compliance were adequate. Urinary incontinence, ureteral reflux and significant post-voiding residue were represented in very low rate of subjects. These data support the evidence that the neobladder configuration achieved by intracorporeal technique using mechanical laparoscopic devices does not negatively affect the anatomic and functional outcome of the urinary diversion, with consequent low risk of post-operative complications and good satisfaction for the quality of life of the patients.

CONCLUSIONS

This experience further shows that VUDM represents the best tool to investigate neobladder function, cause it allows a synchronus evaluation of anatomic and functional aspects under dynamic study, differently from CT and MRI. Moreover, VUDM overcomes the low sensitivity and scarce accuracy of the traditional cystography in the evaluation of functional problems and spares most of the patients a second invasive examination.

40 - ORGASM ASSOCIATED INCONTINENCE (CLIMACTURIA) AND PELVIC FLOOR MUSCLE TRAINING AFTER ROBOT RADICAL PROSTATECTOMY.

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INTRODUCTION AND AIM OF THE STUDY

Orgasm associated urinary incontinence or climacturia, that is the inadvertent leakage of urine during sexual activity is a common clinical entity. Stress incontinence is more often related to patients with climacturia and the degree of incontinence is higher than in those without it. Climacturia is present in 20%-40% of men after radical prostatectomy, and adversely affects sexual satisfaction. Although several strategies have been proposed for the treatment of climacturia, none have been systematically studied to date.

The mechanism of incontinence during sexual activity after prostatectomy is poorly understood and some authors argues against climacturia as simply a variation of stress urinary incontinence that is triggered by increased intra-abdominal pressure during orgasm.

Pelvic floor muscles exercises seem to result in an improved urinary continence and erectile function after radical prostatectomy: the aim of this observational study evaluate the effect of a complete pelvic floor rehabilitation program on both incontinence and climacturia.

MATERIALS AND METHODS

We retrospectively reviewed 416 patients who had undergone nerve sparing robotic assisted radical prostatectomy, consecutively admitted to an outpatient rehabilitation clinic for the assessment of pelvic floor muscle strength and function after surgery. The median age at the time of surgery was 60 (range 49–71) years. All were provided advice concerning the modification of incorrect lifestyles and personalized exercises aimed at awareness and training of pelvic floor muscles, focusing on the bulbocavernosus and ischiocavernosus muscles. After three months, 136 patients were reassessed as at baseline: the outpatient rehabilitation clinic evaluates patients after robotic surgery at a hub center and therefore many patients are unable to take part in follow-up due to geographical distance.

102 out of the 136 patients evaluated were taken into outpatient care for persistent urinary incontinence, while the other 34 continued the exercises without physiotherapy supervision. 69 out of the 102 patients (68%) were sexually active and 37 (53%) complained of climacturia. Before rehabilitation treatment all patients completed a protocol that included ICI-Q, IIEF, ICIQ-mLUTSsex and a multiple choice questionnaire for climacturia. We used a nonvalidated questionnaire developed by the authors because there is a lack of validated survey instruments to address issues of orgasm function and climacturia. The same protocol has been repeated after six months.

For ICI-Q, IIEF, ICIQ-mLUTSsex and multiple choice questionnaire for climacturia results, P-values have been calculated using Wilcoxon test for continuous variables and the $\chi 2$-test for categorical ones.

RESULTS

The severity of urinary incontinence during sexual activity has been shown to decrease in time since surgery. At the nine-months follow up 95 patients were reassessed: 9 were still incontinent and of the 69 sexually active, climacturia persists in 8 patients; 5 patients were continent day and night and only had orgasm associated urinary incontinence.

At the nine-months inspection the persistence of climacturia was related only to the number of urine leakage present after three months ($F=6.01$ d.f.$=1.35$ $p=0.019$) and to the ICIQ - mLUTS score after three months ($F=6$ d.f.$=1.35$ $p=0.019$) . The reduction in the frequency of climacturia is related to the improvement of urinary incontinence assessed with ICI-Q ($F=23.4$ d.f.$=1.72$ $p<0.001$) and also the stress of people with persistent climacturia seems to be reduced at item 5 of ICIQmLUTS-sex ($F=22.05$ d.f.$=1.72$ $p<0.001$). Moreover, at the nine-months follow up there would not appear to be any change in the behaviour adopted to prevent climacturia.

INTERPRETATION OF RESULTS

Pelvic floor rehabilitation implemented in subjects with post-prostatectomy urinary incontinence appears to be effective also on climacturia, even if there is no certainty about the onset mechanism of urinary incontinence related to sexual activity. Post-prostatectomy urinary incontinence and orgasm associated urinary incontinence may have different underlying mechanisms; this was also suggested by Choi et al. and damage of the autonomic nerves during surgery may be of importance.

CONCLUSIONS

Climacturia is a common clinical entity, occurring in almost half of all patients after radical prostatectomy.

Conservative treatment, such as pelvic floor muscle training, may help men control post-prostatectomy orgasm associated urinary incontinence

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41 - RADICAL PERINEAL PROSTATECTOMY: FUNCTIONAL EVALUATION IN THE SHORT TERM

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INTRODUCTION AND AIM OF THE STUDY

Urinary incontinence is a complication observed in 2,5 to 57% of cases after Radical Prostatectomy (RP). This wide variability

depends on perception of incontinence by patients as well as different assessment methods used in the literature. Moreover, reports relate to radical retropubic prostatectomy (open, laparoscopic or robotic), while few data exist about the recovery of continence after Radical Perineal Prostatectomy (RPP).
Incontinence improves gradually over time, therefore it is wise to wait at least 6 -12 months before planning invasive treatments.
Aim of our study was to evaluate the ratio of continent and incontinent patients (pts) undergone RPP six months after surgery. using validated questionnaires (ICIQ-UI Short Form) and 24 hours pad test.

MATERIALS AND METHODS

Retrospective analysis of the pts undergone RPP at our Institution, in order to evaluate the percentage of incontinence at six months after surgery. Inclusion criteria were the availability of the 24 hour pad test and the ICI-UI short form Inventory, both administrated at 6 months after surgery. Patients selected for RPP had clinically localized prostate cancer, with Gleason score (GS) lower than 7, preoperative PSA lower than10 ng/ml,and prostate volume not exceeding 50 g.
Subjective Evaluation was quantified using the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF).
Objective quantification of urine loss was obtained using the 24h pad test, and pts were categorized as follows: continent (0-1g), moderate (2-49g), severe: >50g

RESULTS

19 patients aged 58-74 years (mean 66), undergone RPP in a period between September 2013 and June 2014 by a single surgeon, matched the inclusion criteria of the study.
11/19 patients (57,9%) were continent at 6 months from surgery (no loss of urine) hte patients reported an initial modest urine loss at the time of catheter removal, resolved in 4-6 weeks in all the cases.
8/19 patients (42,1%), reported incontinence.
The 24h pad test confirmed that continent patients were effectively dry: the pts wore and weighted 2 pads in the day, highlighting no more than 1g weight difference before and after wearing.
Incontinent patients (8/19), referred to use 2 pads/day in daily life.
In 6 patients (31,57%) urine leakage at pad test was moderate, ranging 5-20g, especially during physical efforts, without a urge component. In 2 patients urine loss was severe, 50 and70g respectively; mixed incontinence could be supposed in both. Pts did not undergo urodynamics to confirm the symptoms, while anticholinergics were administered, and both pts referred reduction of incontinence.
Mean and mode of pad test results were 18,5g and 10g respectively.
With regard to questionnaires results, incontinent patients presented a mean value of 7,4 (range 5-11), considering a maximum value of 21.
we Also report complete erectile function recovery in 5 patients, penile tumescence in 6 and erectile dysfunction in 8 at six month.

INTERPRETATION OF RESULTS

Our data showed good short term continence recovery, preserved in over 50%of cases soon after catheter removal. In 31,5% of pts incontinence was moderate and did not show huge interference with daily life. In 2 cases only (10,52%), incontinence was significant. In complex our data are similar to reports of the literature about robotic RRP. Compared to robotic procedure, RPP is more mininvasive (one perineal incision no more than 7cm lenght) and of course more cost effective.

CONCLUSIONS

Urinary incontinence following RP is a common complication. In our experience , RPP is an advantageous surgical approach as regards the recovery of continence.

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42 - NEUROGENIC BOWEL MANAGEMENT WITH TRANSANAL IRRIGATION:PROPOSAL OF A CUSTOMIZED PATIENT PROCEDURE

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INTRODUCTION AND AIM OF THE STUDY

Patients suffering spinal cord injury (SCI) almost experience bowel disfunction and usually manifest one or more symptoms including abdominal pain, costipation, fecal incontinence. By now, the entity of gastrointestinal problems has been relatively ignored without respect to its high incidence; those are almost associated with patient's own management of social activities with implication on emotional issues and quality of life.(1)
The aim of this study is to evaluate clinical results and patient's satisfaction with a new customized method of transanal irrigation with Peristeen® device. It consists in a continuous radiological evaluation at the first administration of the transanal irrigation (TAI) to obtain a patient sized bowel evacuation plan.
We consider this radiological investigation to be an useful method to evaluate the degree and the distribution of feces at the descending colon; it also permits to investigate the presence of either megacolon or obstruction of the large bowel due to strictures, tumours, acute inflammatory bowel disease, diverticulitis.

MATERIALS AND METHODS

A total of 68 patients affected by SCI (38 man and 30 women; mean age 18-75 years; 40 patient with complete injury and 28 incomplete injury; 64% of population with supraconal SCI) were admitted to the our Spinal Injury Unit between April 2013 and April 2014. At the first TAI administration all study partecipants were evaluated with a radiological examination to estabilish colon transit. Iodine contrast was diluited and the irrigation fluid was introduced with progressive increases of 100 ml, under scopic controls. Macrogol® was administered the day before the procedure to assure bowel free from chronic faecal impaction. Patients proceeded with daily TAI with Peristeen® for the first week. Later TAI was performed at alternate days, always associated with Macrogol® consumption the night before. All patients were trained by a specialized nurse and were strongly invited to refer about issues and queries regarding the procedure.
Bowel function was assessed at baseline (T0), after four weeks (T1) and after six months (T2) using the Bristol Stool Chart (type

3-4:normal stool) and the Neurogenic Bowel Dysfunction score (NBD; 0-47, 47 severe symptoms). Quality of life was evaluated at the same intervals with the modified American Society of Colonrectal Surgeon fecal incontinence scores (for each subscale, range 0-4, 4=high quality of life).
Patients with a story gastrointestinal surgery or pre-existent desease were excluded. Patients were invited to observe a regular diet and ordinaly lyfestyle during the period of evaluation.

RESULTS

Among the 48 enrolled patients, one was lost secondly to a recent diagnosis of diverticulitis; 4 patients discontinued for recurrent catheters expulsion during irrigation at the first week. The baseline Bristol Stool Chart values, showed constipation with type 1-2 feces in 40% of patients and diarrhea with type 6-7 feces in 52%. Only the 8% of our population had 3-4 type feces with normal stool. At one month, 60% of the population showed a progressive normalization of the type of feces. At six months,84%of patients showed type 3-4 feces, confirming the initial results. Only 8% of patients continued to complain about constipation and was treated with both reduction of daily fiber supply and intake of osmotic laxatives.
The mean NBD score at the baseline was 13, such as a moderate level of bowel dysfunction. At T1 and T2 follow up, mean values was respectively of 8 and 7, showing a significative improvement of bowel dysfunction.
The modified American Society of Colonrectal Surgeon fecal incontinence scores at baseline were as follows: lifestyle 2.0, coping/behavior 1.0; depression/self perception 2.8; embarassment 1.5. At six month (T2) the scores were: lifestyle 3.5; coping/behavior 3.8; depression/self perception 3.2; embarassment 3.6.

INTERPRETATION OF RESULTS

Although bowel dysfunction secondary to neurogenic bowel is a common complication in patients affected by SCI, there have been relatively few studies compared with neurogenic bladder ones. Bowel dysfunction after SCI is both difficult to be properly treated and also requires continuous management. Thus, it is one of the most common and important problem that reduce the quality of life and delay social adjustments in patients. Prior to the management of bowel dysfunction, it is important to accurately evaluate it. Radiological examination when performing initial TAI procedure is a saving and easy method to properly define bowel dysfunction, consenting to customize the irrigation fluid dose on the basis of the morphofunctional characteristics of each patient bowel. However patient selection and instruction is categorical to obtain satisfactory results. In our study, TAI was finally associated with both early and later satisfactory results. The neurogenic bowel dysfunction score, that correlates clinical symptoms patient's quality of life, resulted significantly lower at four weeks and six months follow up. Furthermore, symptom-related quality of life showed improved scores at T1 and T2.
An additional interesting finding was that the frequency of urinary tract infection resulted significantly lower during the time of the study.

CONCLUSIONS

A bowel program is a comprehensive individualized treatment plan focused on preventing incontinence, achieving effective and efficient colonic evacuation, and preventing the complication of neurogenic bowel dysfunction. TAI is a therapeutic method for reducing symptoms and improving quality of life. In SCI patients candidated to TAI procedure, initial radiological investigation is a simple and fast technique to better evaluate and properly manage bowel dysfunction.

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43 - THE ROLE OF NON-INVASIVE URODYNAMIC ASSESSMENT IN CHILDREN WITH LUTS AND FUNCTIONAL COSTIPATION.

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INTRODUCTION AND AIM OF THE STUDY

Children with Lower Urinary Tract Symptoms (LUTS) are widely represented in a school age population (15-20%). More than 50% of children with LUTS are affected by Functional Constipation (FC). Constipation alone is responsible of 25% of visits in a paediatrician gastroenterologist. Up to a third of these children will develop chronic constipation. In 2006, the Rome III pediatric criteria for constipation and non-retentive fecal incontinence, were presented to improve and standardize gastroenterologic diagnosis in these patients.
The aims of this study was to investigate with a non invasive integrated urodynamic studies (according to ICCS), the voiding parameters in children with LUTS and constipation, following at the same time a non invasive urodynamic method and Rome III criteria.

MATERIALS AND METHODS

This study included 25 patients (16 male and 9 female), aged 4 to 14 years (mean age 8,28 years) with LUTS and constipation referred to our hospital between January 2014 and December 2014.
All these patients received a non-invasive integrated study, compilation of frequency volume chart and gastroenterologic approach with Bristol stool form scale (Rome III criteria), completed from uroflowmetry with dynamic ultrasonography (US) of the bladder and the diameter of the rectum. The cut-off value for the rectum was 3 cm of transverse diameter, where >3 cm indicated constipation.
After the child consumed adequate fluids in an appropriate setting, natural filling of the bladder occurred. At the first need to void, detrusor of the anterior bladder wall was measured using high-frequency US to determine the capacity of the bladder and to estimate post-void residual urine volume (PVR). We also described the presence of eventual dilated ureters.
The maximum cystometric capacity (MCC) was considered to be the volume estimated by measuring the bladder when the patient reported the second desire to void. Total time spent in each exam had an average of 5 hours. As the need to void is influenced by the emotional state of the child, it was very important that the examinations were carried out in a comfortable environment and that the child was distracted by recreational activities (in all the exam there was the collaboration of volunteers to play children). The uroflowmetry with US evaluation was performed twice for each patient.

RESULTS

17 children out of 25 (68%, 12 male and 5 female), had constipation (bristol stool chart score < 3).
Out of children with constipation, 4/17 pts (23,5%) had encopresis, 13/17 pts (76,5%) had the diameter of the rectum

> 3 cm, and in only 2/17 pts (11,75%) the measurement obteined was between 2,5-3 cm.
In the 13 children with dilatation of the rectum > 3 cm, the MCC was 112% of the expected (p=0.03).
Of the 17 children with constipation, 10 pts (59%) had a bladder volume above normal for age.
More over, 9 pts out of 25 (36%) had a detrusor-sphincter dyssynergia; of these 9, 7 pts (77.7%) had a PVR higher than 10%.
In a total of 25 pts, 12 had a low Bristol stool form scale (score 1-2). In this group of pts, 8/12 pts (66,6%) had a abnormal voiding frequency (< 4 times a day) (p=0.024).
Finally, 10/25 children (40%) had recurrent urinary tract infections (UTIs) and the 40% of them had a dilatation of the upper urinary tract (p=0.017).

INTERPRETATION OF RESULTS

We obtain a significantly correlation between pts with rectum dilation (> 3 cm) and pts with abnormal MCC (p=0.03).
This aspect could confirm what reported in the literature according a condition of same neuropathology of rectum and bladder. At the same time the main symptoms, low voiding frequency and constipation are strongly correlated (p=0.024).

CONCLUSIONS

The non invasive urodynamic integrated approach is an inexpensive, sensitive and well accepted method that can be used to diagnose and follow any children with LUTS and constipation.
This study with both, simultaneous urologic and gastroenterologic approach, could better explain in future the etiology and physiopathology of dysfunctional elimination disorders, from children to adult age.

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44 - PELVIC-FLOOR THERAPY IN CHILDREN AND ADOLESCENT WITH GIGGLE INCONTINENCE

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INTRODUCTION AND AIM OF THE STUDY

Giggle Incontinence (GI) is a rare syndrome in which apparently complete voiding occurs specifically during or immediately after laughing; bladder function is normal when the child is not laughing[1]. Since laughter suddenly induces uncontrollable urgency immediately followed by urinary leakage, GI expose patients to embarrassing social situations. Although pathophysiological relationships to cataplexy and detrusor overactivity were suggested, pathophysiology of GI remains unclear[2,3]. Various therapeutic approaches have been proposed including parasympatholitic, anticonvulsivant, anthicholinergic agents, botulin toxin, methylphenidate and biofeedback. Since reports on treatment outcome are rare, a standard treatment for GI is not established. Aim of the present study is to evaluate efficacy of pelvic-floor therapy (PFT) in children and adolescent with GI, believing that knowledge and control of pelvic floor and striated sphincter can help these patients to prevent and control loss of urine during laughing.

MATERIALS AND METHODS

In the last 3 years, 15 (5 male and 10 female) patients with GI were observed at our Urodynamic Laboratory (tab 1). Average age at observation was 10.6 year in males and 12.1 years in females. Before to start PFT, all patients underwent bladder diary, flowmetry with EMG of the pelvic floor and ultrasound postvoiding residual urine evaluation (PVR). Methods of non-invasive urodynamics tests and definitions of lower urinary symptoms (LUTS) and dysfunction (LUTD) were in agreement with the ICCS standardization document[1]. PFT consisted in, at least, 3 sessions (1 session/month) of *cognitive and behavioural therapy* (explanation of bladder function; patient education to: correct fluid intake, normal voiding frequency and correct posture during voiding) and *physical therapy* to learn sensation and use of pelvic floor muscles by means of exercises to develop ability to isolate, contract and relax perineal muscles. Patients were instructed to perform daily exercises to contract and relax pelvic floor at home between sessions.Bowel management was added in children with associated constipation. Results on GI were assessed at the end of PFT. Student t test and Chi square test were applied for statistical comparison.

RESULTS

All patients underwent PFT. Three (2 males and 1 female) patients had been previously treated with anthicholinergics

Table 1.

PTS	SEX	Age (year)	LUTS	Flowmetry/ EMG	PVR (ml)	PFT sessions	GI unchanged	GI improved	GI Cured
1	M	13	Retention	Voiding postponement	no	6	yes	-	-
2	M	12	no	Normal	no	6	yes	-	-
3	M	10	no	Normal	no	6	yes	-	-
4	M	7	Retention	Voiding postponement	no	6	yes	-	-
5	M	11	Retention	Normal	no	6	-	-	yes
6	F	8	no	Normal	no	6	yes	-	-
7	F	10	no	Normal	no	3	-	-	yes
8	F	10	Retention	Normal	no	3	-	-	yes
9	F	13	Retention	Dysfunctional voiding	80	6	-	-	yes
10	F	13	Retention	Dysfunctional voiding	no	6	yes	-	-
11	F	14	no	Normal	no	3	-	-	yes
12	F	15	Retention	Dysfunctional voiding	no	3	-	-	yes
13	F	12	Retention	Dysfunctional voiding	no	3	-	yes	-
14	F	15	Increased frequency	Normal	no	6	-	-	yes
15	F	11	Retention	Dysfunctional voiding	no	3	-		yes

without results. Results are shown in table 1. Average age at PFT was 10.6 (range:7-13) years in male and 12.1 (range:8-15) years in female patients (p=0.45). Mean number of PFT sessions was 6 in male and 4.2 in female patients (p=0.01). Ten (3 males and 7 females, p=0.02) patients had LUTS; in none, types of urinary incontinence different from GI were found. Non invasive urodynamic evaluation showed LUTD in 7 (2 males and 7 females, p=0.03) patients. Ten (1 male and 8 females, p=0.003) patients showed improvement of GI after PFT.

INTERPRETATION OF RESULTS

In the present series, PFT was effective to treat GI in 60% of patients: 53% of children completely resolved and 9% improved. Even if LUTS and LUTD were more represented in girls than in boys, cure rate of GI was significantly higher in female (70%) than in male (20%). Moreover, the number of PFT sessions to obtain results was significantly lower in girls than in boys. Results obtained in females could be explained by the greater ease in obtaining knowledge and control of the pelvic floor than males. Furthermore, shorteness of female urethra enable more easily control of GI through perineal contraction. Differently from Chandra[3], we did not found clear symptoms or flowmetry pattern of detrusor instability in our patients; on the contrary, we found disorders of bladder emptying associated with GI which can explain ineffectiveness of anthicholinergics.

CONCLUSIONS

PFT is useful in children and adolescent with GI to strengthen their pelvic floor muscles and allow them to remain continent during laughing. Therefore, PFT should be incorporated in the treatment algorithm for GI. Since PFT seems to be more effective in girls than in boys, it should be considered before pharmacotherapy especially in female patients.

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45 - QUALITY OF LIFE OF 171 PATIENTS WITH BLADDER CANCER UNDERGOING ILEAL ORTHOTOPIC NEOBLADDER: A MULTICENTRE STUDY AMONG LONG-TERM SURVIVOR

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INTRODUCTION AND AIM OF THE STUDY

Patients undergoing urinary radical cystectomy (RC) and urinary diversion for bladder cancer had some limitations in health-related quality of life (HRQOL). At present there are not sufficient studies to evaluate the levels of discomfort caused by different urinary diversion in survivors[(1)]. In the present study we used the validated Italian version of QLQ-BLM30 to assess bladder cancer-specific HRQOL in patients with ileal orthotopic neobladder (IONB) after RC.

MATERIALS AND METHODS

From June 2007 to September 2012, a total of 171 consecutive patients with bladder cancer (156 males and 15 females), who underwent RC with IONB from five urological academic centres, were included in this study. All patients had no evidence of tumor recurrence and were actively followed-up. Clinical and pathological data as well as clinical outcomes were retrospectively analyzed. HRQOL was analyzed using Italian versions of the EORTC BLM30 questionnaires. Questionnaire results were analyzed in order to evaluate the HRQOL in patients with IONB at different times of follow-up (1-18, 19-36, 37-72 and $\geq$73 months). Mean values with standard deviations ($\pm$ SD) were computed for all items. Wilcoxon rank test was used to verify differences by comparing the short follow-up (1-18 months, first quartile) with subsequent quartiles of follow-up. Statistical significance was achieved if p-value was $\leq$0.05.

RESULTS

The median age of the patients was 66 years. The pTNM–UICC stages were 36.8% (0-I), 46.2% (II), and 17.0% (III-IV stage). Patients underwent adjuvant chemotherapy were 17 (9.9%). The median of follow-up was 38 months. The numbers of patients for each quartile of follow-up were: 43, 42, 35, and 51, respectively for 1-18, 19-36, 37-72, and $\geq$73 months. Our data showed that patients with a long-term follow-up ($\geq$73 months) had an improvement in HRQOL in urinary symptoms in comparison with patients with short-term follow-up (1-18 months) (34.1 ± 23.6 Vs.18.9 ± 21.1 - p=0.0004) as well as in sexual life (96.9 ± 8.5 Vs. 83.7 ± 25.2 - p=0.005). Conversely we found a worse HRQOL in patients with long-term follow-up regarding the abdominal bloating and flatulence (8.9 ± 22.2 Vs. 17.6 ± 20.9 - p=0.003). In addition in patients with an intermediate follow-up (37-72 months) we found a poor HRQOL in body image (23.8 ± 27.6 Vs 35.6 ± 27.5 - p=0.02), and sexual functioning (13.8 ± 23.8 Vs 21.9 ± 24.5 - p=0.04).

INTERPRETATION OF RESULTS

The patients with IONB show a progressive decrease of limitations of HRQOL during the years demonstrating a high adaptability to the new body image.

CONCLUSIONS

Our study based on long-term follow-up in patients undergoing RC with IONB showed improvement in HRQOL with regards to the role of urinary symptoms and sexual life.

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46 - A COMPARATIVE MULTICENTER QUESTIONNAIRE SURVEY ON QUALITY OF LIFE IN ELDERLY PATIENTS AFTER RADICAL CYSTECTOMY FOR BLADDER CANCER: A COMPARISON BETWEEN ORTHOTOPIC NEOBLADDER AND ILEAL CONDUIT.

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INTRODUCTION AND AIM OF THE STUDY

Bladder Cancer (BC) is the most common malignancy of the urinary tract and the seventh most common cancer in men and the 17th in women [1]. In the literature, several surgical options of urinary diversion after RC have been described, from simply diverting the urine through a conduit to orthotopic reconstruction

The number of elderly patients candidates for radical cystectomy (RC) as treatment for bladder cancer is now increasing. Although for younger patients orthotopic neobladder after RC has gained popularity, this type of diversion can be suitable for elderly adults with no additional morbidity compared with an ileal conduit. Sparse data have been published on the comparison of these two types of diversion in elderly patients focusing the attention on QoL.

The aim of the study was to evaluate QoL in elderly patients with bladder cancer who received an orthotopic neobladder of an ileal conduit after radical cystectomy (RC).

MATERIALS AND METHODS

A cross-sectional study analyzing files from 77 patients aged 75 or older (median age 77), who had received an orthotopic neobladder (n. 26, group 1) or an ileal conduit (n. 51, group 2) after RC at 5 Italian institutions was performed.

QoL was evaluated by using the Italian version of the European Organisation for Research and Treatment of Cancer (EORTC) instruments quality of life questionnaire C30 (QLQ-C30), a 30-item questionnaire that incorporates five functional scales (physical, role, cognitive, emotional, and social), three symptom scales (fatigue, pain, and nausea/vomiting), and a global health and quality-of-life scale [2] and QLQ muscle invasive bladder cancer module (QLQ-BLM).

RESULTS

Patients' groups were comparable except for gender (0.029), pT stage (0.022), and long term complications (0.005). The scores of all the QLQ multi-item scales and single-item measures were comparable in the two groups except for the following domains in favor of group 1 patients: cognitive functioning (0.008), sleep (0.048), appetite loss (0.033), constipation (0.001), financial difficulties (0.043). Using the propensity score matching, patients with orthotopic neobladder showed better but not significant QOL scores for the domains of cognitive functioning (0.069) and financial difficulties (0.065).

INTERPRETATION OF RESULTS

The results of our study suggest that an orthotopic neobladder in elderly male patients with a low pT stage without long-term complication rate can offer better scores for some aspects of QoL when comparing to ileal conduit

CONCLUSIONS

Orthotopic neobladder in elderly patients may offer a better quality of life aspects, when compared to ileal conduit.

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47 - HRQOL IN 112 MEN AND 33 WOMEN UNDERGOING ILEAL CONDUIT: EVALUATION IN LONG-TERM SURVIVORS

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INTRODUCTION AND AIM OF THE STUDY

Patients undergoing urinary radical cystectomy (RC) and urinary diversion for bladder cancer had some early and late complications, and experience substantial limitations in health-related quality of life (HRQoL). At present, there are sparse studies that evaluated the levels of discomfort in long-terms survivors$_{(1\text{-}3)}$. In the present study, we used the validated Italian version of QLQ-BLM30 and QLQ-C30 from EORTC to assess bladder cancer-specific HRQOL in men and women with ileal conduit (IC) after RC and with long term follow-up.

MATERIALS AND METHODS

From June 2007 to September 2013, a total of 145 consecutive patients with bladder cancer (112 males and 33 females), who underwent RC with IC from five urological academic centres, were included in this study. All patients had no evidence of tumor recurrence and were actively followed-up. Clinical and pathological data as well as clinical outcomes were retrospectively analyzed. Quality of life was analyzed using Italian versions of the EORTC BLM30 and QLQ-C30 questionnaires. Mean values with standard deviations ($\pm$ SD) were computed for all items. Wilcoxon rank test was used to verify differences by sex in the long-term follow-up. Statistical significance was achieved if p-value was $\leq$0.05 (two-sides).

RESULTS

The median age of men was 72 years (range:49-95) and 71 years (range:52-86) in women undergoing IC. The median of follow-up was 34 months (range:49-95) in 112 men and 40 months (range:6-153) in the 33 women with IC. Our data showed that women with IC had greater problems than men in cognitive functioning (higher score means a better functionality) (77.3 ± 27.9 and 87.8 ± 18.6 respectively; $p=0.04$) as well in future perspective (lower score means a low level of symptomatology/problems) (42.4 ± 34.4 and 21.9 ± 24.6 respectively; $p=0.001$). Instead men undergoing IC had more problems in sexual functioning than women (23.3 ± 24.5 and 7.0 ± 20.3 respectively; $p=0.001$).

INTERPRETATION OF RESULTS

Our study based on long-term follow-up in women and men undergoing RC with IC showed a better cognitive functioning and a more optimistic vision of the future in men than in women, and a worse sexual function in men in comparison with women.

CONCLUSIONS

RC and IC have a different impact in men and in women in relation to HRQoL in long-term.

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48 - ENDOSCOPIC RENDEZVOUS PROCEDURE FOR URETERAL IATROGENIC DETACHMENT: LONG-TERM FOLLOW-UP OUTCOMES

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INTRODUCTION AND AIM OF THE STUDY

Injury to the ureter is the most common urologic complication of pelvic surgery, with an incidence that ranges from 1% to 10%. Most cases of ureteral injuries are related to gynecologic

procedures. The ureter is particularly vulnerable to detachment or ligation during hysterectomy due to its position from the lateral edge of the cervix. Here, we report a case series of female patients who underwent the ureteral rendezvous procedure for ureteral detachment.

MATERIALS AND METHODS

Between January 2009 and April 2013, 18 ureteral rendezvous procedures were performed for cases with complete detachment. We assessed the operative and clinical outcomes of these patients over a mean follow-up duration of 26.5 months, and describe the three most representative cases.

RESULTS

The endoscopic rendezvous technique was performed in all cases to manage ureteral detachment. Computed tomography urography at discharge, and 6 and 12 months after discharge, confirmed the restoration of ureteral integrity without any leakage in 66% (12/18) cases, indicated ureteral stenosis in 22% (4/18) cases, and indicated ureteral leakage in 12% (2/18) cases. The overall long-term success rate for all 18 patients was 78% (14/18) at a mean follow-up of 26.5 months.

INTERPRETATION OF RESULTS

The antegrade-retrograde endoscopic rendezvous procedure is a minimally invasive technique that enables the restoration of ureteral integrity, thus avoiding an invasive procedure. In some cases, this can be a challenging maneuver, and requires an integrated radio-urological approach. The advantage of the rendezvous procedure includes its combined ureteroscopic/fluoroscopic approach, which makes it a relatively non-invasive procedure compared to major surgical repair. Thus, patients may be offered a long-term solution, instead of long-term nephrostomy treatment that may potentially result in complications and gradual renal deterioration, and may thus require future nephrectomy. Our results suggested that complete ureteral detachment could be effectively restored using the aforementioned radio-endoscopic approach. The technique yielded encouraging results with a short hospital stay (mean, 3.8 ± 1.2 days) and no perioperative complications, thus avoiding the need for open surgery. Based on the reported outcomes, we believe that most of the patients with complete ureteral transection injuries should undergo endoscopic rendezvous realignment as a first option, as soon as possible. Although some patients may develop secondary ureteral strictures after the rendezvous procedure, as observed in the present case series, the technique appears to prevent the complete ureteral obstruction associated with iatrogenic injuries. In case of failure of the procedure, open surgical repair can still be performed.

CONCLUSIONS

The rendezvous technique is an effective, combined radiological and endourological procedure that can be used to manage ureteric injuries in the early postoperative period in cases with appropriate indications. This minimally invasive maneuver can restore the continuity of the ureter and reduce the need for open surgical repair that is associated with higher morbidity. We believe that this procedure may represent the optimal initial solution in patients with iatrogenic ureteral lesions, before attempting invasive procedures.

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49 - ADJUSTABLE CONTINENCE THERAPY (PROACT™) FOR TREATMENT OF STRESS URINARY INCONTINENCE IN MEN: 12 YEARS-SINGLE CENTRE EXPERIENCE AND LONG-TERM RESULTS

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INTRODUCTION AND AIM OF THE STUDY

Post-operative stress urinary incontinence (SUI) and erectile dysfunction are common problems following pelvic surgery, in particular for prostate cancer. Literature data show 12-mo continence rates ranging between 60%- 93% after RRP, 66%-95% after LRP, and 79%-96% after RALP. ProACT™ is an adjustable continence therapy implant for post-prostatectomy incontinence (PPI). This device consists of two silicone balloons, each attached to a port by short tubing. The balloons are positioned either by fluoroscopic or ultrasonographic control at the proximal urethra neck and can be postoperatively adjusted through percutaneous injection of the port with the aim of compressing the urethra and thus augmenting resistances. The aim of our study is to retrospectically evaluate the long-term follow-up of male patients suffering of SUI and treated with ProACT at our Institution.

MATERIALS AND METHODS

We retrospectively included in our study all patients complaining of stress urinary incontinence and treated at our Institution with ProACT implantation. Diagnosis of SUI was achieved with anamnestic data collection, 24-hours pad test and video-urodynamic testing. All patients were discharged from the hospital after one day. The first refilling of the balloons was done at one month with 0,5-1ml of isotonic contrast medium solution for each side. Further fillings were done after at least one month from the previous refilling, until the patient was dry or was satisfied with the continence result achieved. In case of complication of the device, its removal was done in an outpatient office.

RESULTS

We treated 398 male patients suffering of SUI from 2002 to 2014. Mean age at intervention was 68,2 years. The cause of SUI was RRP in 70,9%, LPR/RALP in 5,1%, TURP in 8,9%, prostatic open adenomectomy in 7,5%, neurosurgery in 5,6%, HIFU in 0,9% and radical cystectomy in 0,9%. We excluded cases of neurogenic bladder that have been assessed in our separate study.

In case of prostate cancer, 10,4% of patients had received adjuvant RT and 9,2% needed bladder anastomosis or urethral incision due to post-RP stenosis. 45% of patients underwent pelvic floor rehabilitation as first therapeutic option, without significative success. 49,4% of patients suffered of severe incontinence (more than 4 pads/day and 24-hours pad-test>250g), 39,9% of moderate incontinence (three to four pads/day and 24-hours pad-test 50-250g), and 10,7% of mild incontinence (one or two pads/day and 24-hours pad-test<50g). 92% of balloons were positioned under fluoroscopic control, whether 8% were positioned under ultrasonographic

control. Every patient received preventive cystoscopic evaluation. Mean final balloon volume is 4,43 cc. 25,9% were dry, 9,9% used only a safety pad during the day, 26% were improved (urine loss reduced > 50%), 14,9% had minimal benefit (urine loss reduced < 50%) and 23,2% % had no benefit. Long-term complications were: 3% erosion/migration of the balloons, 2% device infection and 2% device failure. The device was explanted in 29% of patients and re-implanted in 10% with good continence results.

INTERPRETATION OF RESULTS

Our population is characterized by a very severe grade of incontinence, with almost half of the patients using more than 4 pads/day. If we consider the percentage of completely dry patients (25,9%), it may seem low, but if we consider the sum of dry patients and the patients that achieved a subjective and objective good result in daily pad reduction, this percentage reaches 61,8%. After the first years of experience we noticed that the majority of patients having the worse results were those who had undergone pelvic radiotherapy or HIFU and those affected by bladder anastomosis or urethral sclerosis. During the last six years (2009-2014) we limited the indication of ProACT placement considering radiotherapy, HIFU and bladder neck/urethral sclerosis as relative contraindications to ProACT placement. We analysed the results during the last six years following the exclusion criteria over-mentioned: 185 patients were treated, 42,9% were dry, 32,4% improved more than 50%, 17% had limited benefit (<50%) and 7% had no benefit. Data show a significant improvement in result. The total of patients who are dry or using only a safety pad raised to 42,9% and the total of patients having a subjective benefit raised to 75,3%. In this cohort, we assisted to dislocation of the device only in two patients and to erosion phenomena only in one patient, giving a proof that the quality of urethral tissue influences the complication rate. Follow-up of patients ranges from 1 month to 76,3 months. In almost 50% of cases, results have been evaluated with at least a 5-years long follow-up from implantation.

The current standard for the surgical treatment of this condition is still the artificial urinary sphincter, but these encouraging results make ProACT placement a first step in the treatment of stress urinary incontinence in selected patients. Its positioning is minimally invasive, requires a short hospital stay and in case of malfunctioning its removal can be done in an outpatient office. The volume of balloon filling is adjustable, so it is less likely to cause refractory obstruction to voiding and urinary retention.

CONCLUSIONS

The ProACT is an acceptable first step alternative surgical treatment for stress urinary incontinence in men. To our knowledge this experience represents one of the longest follow-up series available in the medical literature. In our cohort continence results are not linked to the severity of preoperative incontinence, but are conditioned by the selection of patients and by the quality of urethral tissue, thus pelvic radiotherapy and bladder neck/urethral sclerosis can be considered as relative contraindications. This device has proven to ensure durable results in time as long as the devices are implanted properly in selected cases.

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50 - A NEW ARTIFICIAL URINARY SPHINCTER WITH CONDITIONAL OCCLUSION FOR TREATMENT OF STRESS URINARY INCONTINENCE IN MEN: SINGLE CENTRE EVALUATION AND PRELIMINARY RESULTS

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INTRODUCTION AND AIM OF THE STUDY

Post-operative stress urinary incontinence (SUI) is common problem following pelvic surgery, in particular for prostate cancer. The Artificial Urinary Sphincter (AUS) AMS800 is widely accepted as the gold standard for the treatment of male urodynamic stress urinary incontinence. Nevertheless a surgical revision rate of over 30% has been reported. A number of these revisions are secondary to urethral atrophy, erosion, mechanical failure and infection. We aimed to evaluate the use of a new alternative Artificial Urinary Sphincter (FlowSecure®) that has been recently introduced at our Institution.

MATERIALS AND METHODS

The FlowSecure is a new silicone hydraulic urinary sphincter that has an extra pressure transmission balloon to transfer increased intra-abdominal pressure directly to the cuff. The pressure of the urethral cuff is low (<40cm H2O) to maintain continence at rest. In the event of an effort, intra-abdominal pressure peaks will be transferred to the cuff. Furthermore it provides the possibility of adjusting the pressure within the system post-operatively. We evaluated male patients who presented with SUI following prostate surgery to establish feasibility and short-term efficacy of the procedure. Patients were assessed at baseline using 24-hours pad testing, which was repeated post operatively. Perioperative details were recorded. All patients were discharged from the hospital after three days. Any complications were noted.

RESULTS

Eight male patients have been implanted from May 2013 to May 2014. Median age 70.5 years (range 65-76) with a mean follow up of 6.2 months. Previous prostate surgery included retropubic Prostatectomy in all patients, 4 patients had received adjuvant Radiotherapy. All patients had failed conservative therapy. Most patients had undergone a previous surgery for their incontinence including: ProACT (3), Argus-T Sling (1) and AMS800 (1). Mean operative time was 90 mins (54-116). Five patients required almost 1 adjustment. At last follow up, 2 patients were dry, 2 patients continued to wear 1 safety pad per day, and 4 patient had no benefit. Post void residual was negligible (< 50ml). Per operative complications included 1 device inadvertently destroyed by the surgeon. Postoperative complications included depressurisation of the device in 3 patients; one explantation was undertaken due to cuff too wide compared to the urethra. Two patients went into retention, but were managed by deflation of the cuff in an outpatient office.

INTERPRETATION OF RESULTS

The FlowSecure artificial sphincter incorporates many characteristics that aim to overcome some of the disadvantages of the AMS800. The principal design features of the new implant include the following: a self-sealing port in the pump

assembly for in-situ pressure adjustment, a stress relief mechanism providing low resting occlusion pressure and conditional occlusion of the urethra, one-piece assembly to facilitate implantation and minimise mechanical failures, improved cuff design to reduce potential for creasing and fracture and patient-activated rapid cuff re-inflation facility. As the pressure around the urethra is low at rest and increase according to the intra-abdominal pressure, the risk of urethral atrophy and erosion may be reduced. Implantation of the device is technically feasible and would appear to be safe and effective in the short term for the treatment of SUI in male in the absence of mechanical complications. Prior anti-incontinence surgery and radiotherapy does not appear to be an impediment to implantation. The FlowSecure AUS is an easily implantable prosthesis, which allows for adjustability when needed. Satisfactory continence rates can be achieved operating at a lower pressure. We have had no erosions but we have identified increased risk for system depressurisation probably due to pump puncturing during the pressurisation procedure or mechanical failures due to the manufacturing process.

CONCLUSIONS

The FlowSecure is an interesting device as incorporates many innovative features. Further controlled evaluation of the use of the device is warranted. A revision of the mechanical system or the pump design is desirable to prevent mechanical failures in the future.

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51 - ADJUSTABLE CONTINENCE THERAPY (ACT™) FOR TREATMENT OF STRESS URINARY INCONTINENCE IN FEMALE: 14 YEARS-SINGLE CENTRE EXPERIENCE AND LONG-TERM RESULTS

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INTRODUCTION AND AIM OF THE STUDY

Stress urinary incontinence (SUI) is a significant problem in the female population. Aging, vaginal delivery, pelvic surgery and organ prolapse are among the risk factors. The main mechanism involved is the sphinteric deficiency, which can be associated with urethral hypermobility. The implant of a periurethral adjustable device represents a valid alternative for the mini-invasive correction of SUI due to severe intrinsic sphinteric deficiency (ISD) or in cases of contraindication to TVT slings. The ACT™ system consists of two silicone balloons, which are surgically implanted at the sides of the urethra under the bladder neck through a mini-invasive procedure; they can be filled with isotonic contrast medium solution though a titanium port implanted in the mayor labia.

MATERIALS AND METHODS

We retrospectively included in our work all patients complaining of stress urinary incontinence and treated at our Institution with ACT implantation. Diagnosis of stress urinary incontinence was achieved with anamnesis data collection, physical examination, 24-hours pad test and urodynamic testing. All patients were discharged from the hospital after one day. The first refilling of the balloons was done at one month with 1ml of isotonic contrast medium solution for each side. Further fillings of 0,5-1ml were done after at least one month from the previous refilling, until the patient was dry or was satisfied with the continence result achieved. In case of complication of the balloon, its removal was done in an outpatient office.

RESULTS

We treated 103 female patients suffering of SUI due to severe intrinsic sphinteric deficiency (ISD) from 2000 to 2014. Mean age at intervention was 60,7 years (from 28 to 90 years). We could collect a complete clinical history in 49% of patients: among them 21 patients had undergone hysterectomy, 6 major abdominal oncologic surgery, 3 urethral surgery and 2 reported pelvic trauma. We excluded cases of neurogenic bladder, which have been assessed in our separate study. 25% of patients underwent pelvic floor rehabilitation as first treatment modality, without significative success. 64% of patients had already undergone SUI surgical treatment: 70% urethral bulking therapy, 25% TVT/TOT sling positioning, 28% Burch colposuspension, 5% sacral neuromodulation and 5% botulinum toxin injection. 70% of patients suffered of pure intrinsic sphinteric deficiency and in 30% sphinteric deficiency was associated with urethral hypermobility. 59,5% of patients suffered of severe incontinence (more than 4 pads/day), 39,8% of moderate incontinence (three to four pads/day), and 0,7% of mild incontinence (one or two pads/day). All balloons were positioned under fluoroscopic control. Every patient received preventive cystoscopic evaluation. Mean refilling times is 1,9 (from 0 to 10 refilling times) and mean final balloon volume is 4,3 cc. 27,9% were dry, 18% used only a safety pad during the day, 17,9% were improved (urine loss reduced $>$ 50%), 6,6% had minimal benefit (urine loss reduced $<$ 50%) and 29,6% had no benefit. Long-term complications were: 10 erosion/migration of the balloon, 5 device infection, 10 device failure. The device was explanted in 25 patients and re-implanted in 10 patients with good continence results.

INTERPRETATION OF RESULTS

Our population is characterized by a very severe grade of incontinence, with almost half of the patients using more than 4 pads/day. At a first glance only 27,9% of patients were completely dry, but if we sum the rates of patients being dry or using only a safety pad, having a significative benefit (>50%), we reach 63,8% of positive results. Follow up ranges from 3 months to 68 months with at least one third of patients having a follow up of more than 36 months. This device has demonstrated to be simple to implant with limited complications rates and little discomfort to the patient. It represents an extra-urethral bulking therapy, acting with a compressive mechanism. In case of necessity of removal of the device, it can be easily done in an outpatient office. Furthermore, the device is adjustable to the needs of the patients, limiting the incidence of obstruction.

CONCLUSIONS

In selected cases, represented by severe ISD or in cases of contraindication to TVT sling placement or in complex cases such as after multiple pelvic surgical procedures, the placement of ACT device can represent a good mini-invasive option to treat stress urinary incontinence in female. To our knowledge this experience represents one of the longest follow-up series

available in the literature. Data collected show that the efficacy seems to be long lasting as long as the devices are implanted properly in selected patients. The complication rate is limited and complications can be resolved in an outpatient office.

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52 - MODIFIED TRANSOBTURATOR RETROLUMINAL REPOSITIONING SLING SUSPENSION. A NEW TREATMENT OPTION FOR MALE URINARY INCONTINENCE AFTER RADICAL PROSTATECTOMY

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INTRODUCTION AND AIM OF THE STUDY

Urinary incontinence (UI) is a major concern for patient undergoing radical prostatectomy (RP). New surgical approaches have been recently investigated. The AdVance male sling, introduced in 2007, is a polypropylene mesh placed retrourethrally under the proximal part of the urethral bulb, passing bilaterally through the obturator fossae. Preliminary results showed immediate cure rate of 80%. Because of a failure rate as high as 30% over time, in mid 2010 a new version of this retrourethral transobturator male sling (RTS) was launched, replacing the former AdVance sling in clinical practice: the AdVanceXP®. We report our experience with the AdVanceXP since its introduction in 2011.

MATERIALS AND METHODS

From January 2011 to December 2014 we treated 48 patients affected by UI after RP. The degree of incontinence was based on pad usage over a 24-h period and a 24h-pad test. Residual sphincter function and luminal closure of sphincter region by perineal compression was evaluated during urethroscopy (repositioning test). The wet pad usage per day and 24h-pad test were assessed in all patients at 1, 6 months and 1 year post-operatively. Patient were considered cured if using no pads or a security pad, improved if using one pad or more but reduced pad use for more than 50% and failed otherwise

RESULTS

Mean operating time was 22 minutes. All procedures were done by the same surgeon. No intra-operative complications were observed. Follow-up ranged from 1 to 45 months. Our data showed a cure/improving rate of 87,5% (72% cured and 15.5% improved). Six patients failed after the procedure (12,5%). Four of these six patients had a 24h Pad test >700 ml; the others underwent radiotherapy after RP.

INTERPRETATION OF RESULTS

Male UI with residual sphincter function is associated with urethral descent because of a laxity of levator ani due to iatrogenic causes or to aging. Positioning a retrourethral sling via a transobturator approach should relocate the posterior urethra into a more proximal position restoring the changed anatomy, caused by RP, to the former pre-operative condition. The second generation of RTS provided additional feature with the aim of incresead stability of the sling during the healing period after implantation. Our results with the AdVanceXP confirm both the efficacy and durability of the treatment. In fact all patients cured or improved after 1 month still remains dry or improved during follow-up. Our previous experience with the former AdVance showed similar cure rate after 1 month but incontinence cure and improvement rate appeared to decrease over time (80% after 1 moths vs 49.6% at one year of follow-up).

CONCLUSIONS

Our result showed that AdVanceXP is a safe and effective procedure in patient with UI after RP. Cure rate remains stable over time. The amelioration of the results in term of stability could be a consequence of improvement of the surgical technique also. AdVanceXP may be considered the first-treatment option in patient with UI after RP. In our experience, risk factors for failure of RTS seemed to be severe urinary incontinence and radiotherapy. In these patients, artificial urinary sphincter should be considered.

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53 - A NEW SELF-ANCHORING ADJUSTABLE TRANSOBTURATOR SYSTEM FOR TREATMENT OF STRESS URINARY INCONTINENCE IN MEN: SINGLE CENTRE EVALUATION AND PRELIMINARY RESULTS

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INTRODUCTION AND AIM OF THE STUDY

Post-operative stress urinary incontinence (SUI) is common problem following pelvic surgery, in particular for prostate cancer. The Artificial Urinary Sphincter is widely accepted as the gold standard for the treatment of male urodynamic stress urinary incontinence. Nevertheless a surgical revision rate of over 30% has been reported. In recent years, various minimally invasive sling systems have been investigated as treatment options for post-prostatectomy SUI. We aimed to evaluate the use of the adjustable transobturator male system (ATOMS®) that has been recently introduced at our Institution.

MATERIALS AND METHODS

The ATOMS device has two components: the mesh implant with integrated adjustable cushion, and the implantable titanium port for adjusting the volume of the cushion. The silicone cushion is located in the middle of the mesh tape and filled via the low-profile port and catheter both intra- and postoperatively. The mesh is built of macroporous, monofilament polypropylene. The implant is inserted using an outside-in technique by passing the obturator foramen. We evaluated male patients who presented with SUI following prostate surgery to establish feasibility and short-term efficacy of the procedure. Patients were assessed at baseline using 24-hours pad testing, which was repeated post operatively. All patients were discharged from the hospital after one/two days. Perioperative details were recorded. Any complications were noted.

RESULTS

Five male patients have been implanted to date. Median age 68.5 (range 65-74) years with a mean follow up of 5.2 months. Previous prostate surgery included retropubic Prostatectomy (4) and TURP (1). Two patients had received adjuvant

Radiotherapy. All patients had failed conservative therapy. Most patients had undergone a previous surgery for their incontinence including: ProACT (4) and AMS800 (1). Mean operative time was 55 mins (40-70). Three patients required almost 1 adjustment. At last follow up, 4 patients were dry, 1 patient continued to wear 1 safety pad per day. Post void residual was negligible (< 50ml). No intraoperative complications occurred. Two patients went into retention post-operatively, but were managed by deflation of the device. Two patients referred pain and numbness of the perineum, scrotum or glans penis, which disappeared spontaneously after treatment with analgesics within 1-3 months after surgery.

INTERPRETATION OF RESULTS

One of the drawbacks of using male slings is the lack of ability to make postoperative adjustments. To resolve the problems associated with postoperative adjustment of male sling systems, the adjustable transobturator male system was designed. The basic component of this new hydraulic system is the trans-obturatoric mesh implant with integrated adjustable cushion. Connected with an implantable titanium port, the cushion volume is adjustable at any time postoperatively. Implantation of the device is technically low invasive and would appear to be safe and effective in the short term for the treatment of SUI in male. Prior anti-incontinence surgery and radiotherapy does not appear to be an impediment to implantation. In our cohort we have had no erosions. The most frequently reported complications in the present study were transient pain or numbness referred to the perineum, scrotum or thighs, and urinary retention; no system had to be explanted for this reason.

CONCLUSIONS

The ATOMS sling is an interesting device as incorporates many innovative features. The device is a low invasive implantable sling, which allows for adjustability when needed. The option of long-term, minimally invasive adjustment to respond to patient needs is a significant advantage of this device. In our cohort of patients the treatment was found to be safe and effective. Further controlled evaluation of the use of the device is warranted.

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54 - ARGUS-T DEVICE IN MALE URINARY INCONTINENCE: SHORT-TERM RESULTS IN 182 PATIENTS

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INTRODUCTION AND AIM OF THE STUDY

The quality of life (QoL) in presence of urinary incontinence is significantly decreased after radical prostatectomy. ARGUS-T sling are currently employed for the treatment of stress urinary incontinence (SUI) after radical prostatectomy but data on this device remain still limited[1-2].

We report the short-term results of SUI treatment after radical prostatectomy with ARGUS-T.

MATERIALS AND METHODS

From June 2008 since March 2013 161 patients affected by post-prostatectomy SUI and 21 patients affected by post-TURP SUI were treated with ARGUS-T.

The population was divided in 3 groups according to the incontinence degree: mild (1-2 pads/die), moderate (3-5 pads/die) and severe (>5 pads/die). The result was considered as satisfactory when the SUI was cured or improved.

21/182 patients (11.5%) were affected by mild SUI, 96/182 patients (52.7%) were affected by moderate SUI and 65/182 patients (35.7%) were affected by severe SUI. 49/182 patients (26.9%) were previously treated with adjuvant radiotherapy.

In our study the QoL was evaluated using specific questionnaires (VAS score scale/QoL score scale) and the daily pad number was compared before and after ARGUS positioning.

RESULTS

Median age of patients was 71 years old (range 50-86 years) and median follow-up was 22 months (1-59 months).

In our study the results was satisfactory in 157/182 patients (86.2%), 60/182 patients (33%) were cured and 97/182 patients (53.2%) were improved respectively. 37/49 patients (75.5%) previously treated with adjuvant radiotherapy showed satisfactory results.

None complication was occurred during the intra-operative period while we observed in 26/182 patients (14.3%) a post-operative complication, such as infection (9/182), urethral erosion (1/182) and hypercontinence (16/182).

The statistical analysis showed a significant reduction in the use of the number of daily pads and a substantial improvement in QoL after ARGUS-T implant ($p<0.001$).

INTERPRETATION OF RESULTS

Sling procedures seem to be easier and safer than artificial urinary sphincter. In particular trans-obturator approach seems to be affected by lower rates of post-operative complications. This is the first study that represents the outcomes in short period after ARGUS-T positioning.

CONCLUSIONS

In the short-term ARGUS-T sling appears to be safe in the treatment of mild and moderate SUI

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55 - COULD EXIST A LEARNING CURVE FOR THE TVT-O PROCEDURE?

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INTRODUCTION AND AIM OF THE STUDY

Transobturator mid-urethral slings are a very effective and safe anti-incontinence procedure [1]. There is only one available study on learning curve in transobturator MUS and this study

did not find any effect of the surgeon' experience on outcomes [2]. The aim of the present study is to evaluate, for the first time, the learning curve of a single urogynecological surgeon, reporting the effects of levels of expertise on surgical and functional outcomes in a large series of TVT-O

MATERIALS AND METHODS

A prospective observational study was conducted in a tertiary reference center. Consecutive women treated by TVT-O™ performed by one surgeon were included. Data regarding subjective, objective cure rates, and adverse events were collected. Trends, over the number of procedures, were estimated using assay analyses. Number of procedures and variables were interpolating in standard curves using linear lines

RESULTS

A total of 372 procedures were included. Patients' characteristics remained stable over the study period ($p>0.05$). Overall, 309 (83.1%) patients had urethral hypermobility. Median preoperative ICIQ-sf was 17 (interquartile range, 16-17). Only nine patients (2.4%) resulted lost to 12-mo follow-up.

Considering peri-operative parameters we observed that estimated blood loss (from 16 (± 5.1) to 11 (± 3.1) ml; 95% CI: -0,003520 to 0,0004931, p=0.14) and length of hospital stay (from 1.5 (0.5) to 1.4 (± 1.0) days; 95%CI: -0,0007453 to 0,0002978, p=0.40) were not influenced by the number of procedures performed; while operative time decreased significantly with the increase in the level of expertise (from 15.1 (± 2.0) to 9.3 (± 0.5) minutes; 95%CI: -0,007787 to -0,003763, $p<0.001$). Figure 1 reports changes in perioperative results. Additionally we observed that postoperative pain levels decreased with the increase in the level of expertise as reported in Figure 2 (pain levels: 1-day: from 6.6 (± 3.3) to 4.3 (± 3.1); 95%CI: -0,01603 to 0,001235, p=0.04; 2-day: from 5.6 (± 4.1) to 3.6 (± 3.7); 95%CI: -0,02092 to -0,002497, p=0.01; 3-month: from 0.2 (± 0.3) to 0 (± 0); 95%: -0,002621 to 0,0003604, p=0.13; 12-month: from 0.1 (± 0.7) to 0 (± 0); 95%CI: -0,001814 to 0,05019, p=0.07). A significant difference in analgesic rescue dose was observed (p=0.03). Table 1 reports objective and subjective outcomes at 12-month follow-up. Overall, objective cure rate was achieved in 93.5% of patients. Additionally, 88.2% and 88.7% patients reported "much better" feeling at PGI-I scale and 80% reduction in UDI score, respectively. Twelve-month postoperative ICIQ-sf was 0 (interquartile range, 0-2). Median patients' satisfaction scale was 10 (range, 9-10). We observed, that the increased number in procedures did not correlate with PGI (from 1.2 (± 0.4) to 2.2 (± 2.7); 95%CI: -0,0009033 to 0,001532, p=0.61) as well as objective cure (338/362 (93.4%); 95%CI: -0,0002990 to 0,0001928, p=0.62) and Patient Satisfaction Scale score (from 9.2 (± 0.7) to 9.5 (± 1.5); 95%CI: -0,001327 to 0,001499, p=0.90). However delta ICIQ-sf (from 12 (± 8.7) to 14 (± 6.0); 95%CI: -0,0005408 to -0,01622, p=0.04) and delta-UDI (from 91 to 97%; 95%CI: 0,0002634 to 0,02775, p=0.04) improved with the increase in the level of expertise.

INTERPRETATION OF RESULTS

Our finding seems to demonstrate that a long learning curve significantly improves, at 12-mo follow up, the subjective satisfaction of patients undergoing TVT-O procedure (based on the variation of the ICIQ-SF score and of the UDI score) and reduces the groin pain at short- and medium-term follow-up

CONCLUSIONS

TVT-O procedure offers excellent outcomes with high objective and subjective cure rates and low complications rate, even at the beginning of the surgeon's learning curve. However, a learning curve also for this procedure seems to exist.

Figure 1

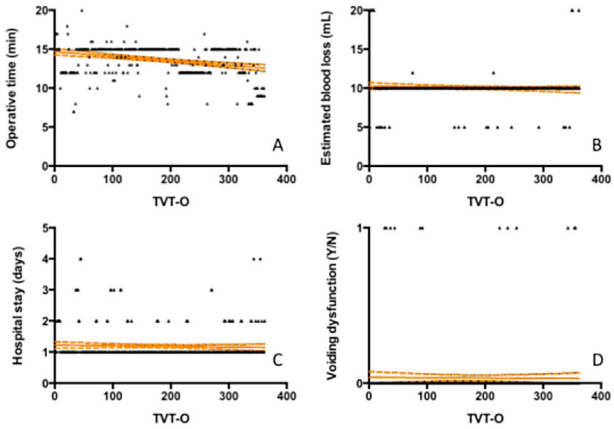

Figure 2

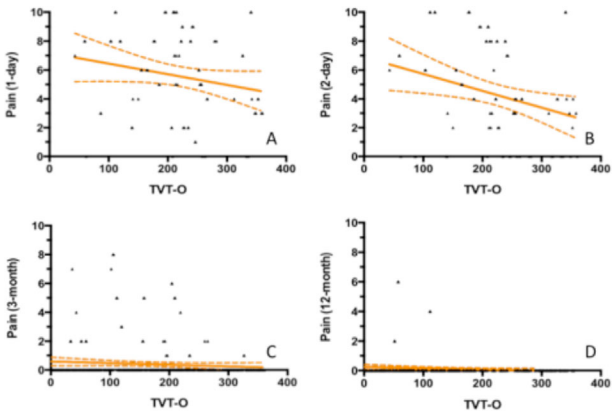

Table 1

	12-mo (N=372)
Negative Stress test	348 (93.5%)
ICIQ-sf	0 (0-2)
"Very much better" or "much better" on PGI-I	328 (88.2%)
Patient Satisfaction Scale	10 (9-10)
80% reduction in UDI score	330 (88.7%)

Data are expressed as absolute number (%) or median (interquartile range)

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56 - ANATOMICAL AND FUNCTIONAL OUTCOMES OF NATIVE TISSUE VAGINAL REPAIR FOR PELVIC ORGAN PROLAPSE: PROSPECTIVE EVALUATION AFTER A 2 YEARS FOLLOW-UP

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INTRODUCTION AND AIM OF THE STUDY

Pelvic organ prolapse (POP) in developed countries has an incidence of approximately 19% (range 3.4 to 56.4%). It has negative effects on women's quality of life and represents one of the main indications for gynecological surgery. The success of vaginal surgery is traditionally assessed according to the cure of anatomical defects and to the rate of recurrence, which is estimated in literature at around 30% . The attempt of improvement of that outcome has led to a progressively increased recourse to prosthetic surgery. The attention to patient's satisfaction and quality of life after surgery is currently high, therefore the debate on outcomes of native tissue repair is extremely actual, given the results of recent reports on mesh-related complications (1). The goal of this study is to assess the anatomical and functional outcomes after native tissue vaginal surgical repair, with a mean follow-up of 2 years, and to analyze the risk factors of anatomic recurrence.

MATERIALS AND METHODS

From June 2011 to May 2014, a cohort of 297 women, admitted at our secondary referral Uro-Gynaecological Unit in order to undergo surgery, were recruited. A standardized questionnaire regarding symptoms of prolapse and urinary or anal incontinence was administered. The pre-operative work-up included for each patient: a) physical examination according to pelvic organ prolapse quantification (ICS POP-Q) staging system of International Continence Society; b) conventional urodynamic study; c) 3D endovaginal ultrasonography (EVUS), performed on basis of a predetermined protocol (2). All patients underwent the validated Italian version of Prolapse Quality of Life (P-QOL) questionnaire (3), before surgery and at 12 months; it includes 20 questions grouped into nine fields (general, health perceptions, prolapse impact, role limitations, physical limitations, social limitations, personal relationships, emotions, sleep / energy, severity measures) with a score of 0 to 4 for each question, with higher scores associated to poorer quality of life. The standardized surgical techniques used were: vaginal hysterectomy, high closure of the peritoneum, colposuspension according to Mc Call modified, or Sacrospinous fixation, reconstruction of pericervical ring to reestablish continuity of the anterior and posterior vaginal fascia at the vaginal apex, anterior colporrhaphy according to Lahodny (1st step), posterior repair according to Richardson, perineal body reconstruction. Medio-urethral sling was applied in 20 cases of 49 patients with stress incontinence. Patients underwent a follow-up examination every six months for the first year and then annually. Statistical analysis of the results using Student's t test or chi-square test, where appropriate, was performed, at a significance level of $p=0.05$.

RESULTS

A total number of 297 patients underwent native tissue vaginal repair, but a complete 2-years follow-up is available for only 142 of them. Age, medical history, concomitant diseases, degree of prolapse, anatomic recurrence and functional symptoms (urinary incontinence -UI, anal incontinence -AI, voiding dysfunctions and sexual activity) were assessed before surgery and after a 2-years time (tab. 1).

The pre-operative P-QOL score of all patients examined was $52.5 + 14.7$ and at 12 months it reduced to $30.3 + 9.3$; the difference was statistically significant ($p < 0.001$). The analysis of potential risk factors related to prolapse recurrence is reported in tab. 2. With the exception of the preoperative POP-Q, stages none of the factors taken into account showed a predictive value for the recurrence of prolapse.

INTERPRETATION OF RESULTS

Data from Preoperative score of Prolapse Quality of Life (P-QOL) questionnaire show that pelvic organ prolapse strongly affects activity of daily living, professional activity as well as social, emotional and sexual functioning. In our series, the prolapse surgical anatomic cure was satisfactory, with a 2-years rate of recurrence of approximately 18% and a reoperation rate of 2.8%. These results are strictly related to the strength points of native tissue repair: restoration of the apical support and reconstruction of the perineal body. We also record satisfactory results regarding functional outcomes, as shown by data on Tab. 1 and by the postoperative P-QOL total score, with a clear improvement of quality of life in patients who underwent surgery.

Table 1 Patients data (n=142)

Age (mean ± SD)	64.2 ± 8.5	Anatomic recurrence at 2 years after surgery		
Parity (mean ± SD)	3.2 ± 1.4	Stage 2		21 (15%)
BMI (mean ± SD)	27 ± 3.3	Stage 3		5 (3.5%)
Diabetes	23 (16%)	Site of recurrence		
Hypertension	54 (38%)	Anterior		19 (73%)
Delivery		Anterior and apical		6 (12%)
spontaneous vaginal	87 (61.5%)	Anterior-apical-posterior		4 (15%)
instrumental	52 (37.4%)	Re-treatment		4 (2.8%)
Caesarean section	3 (2%)			
Newborn weight (mean ± SD)	3743 ± 488	Functional symptoms before/after surgery		
Physiological menopause	111 (79%)		Before	After
Pre-surgery POP-Q stage		UI - stress	49 (34%)	17 (11%)
Stage 2	14 (10%)	UI - urge	14 (10%)	3 (2.3%)
Stage 3	98 (70%)	UI - mixed	18 (13%)	8 (6%)
Stage 4	28 (20%)	Voiding dysfunctions	30 (22%)	3 (2%)
		AI	9 (7%)	3 (2%)
		Poor sexual activity	114 (79%)	28 (21%)
		De novo UI - urge	-	9 (7%)
		De novo UI - stress	-	8 (6%)

Table 2 risk factors related to prolapse recurrence

	Recurrence (26)	no recurrence (116)	test result
age (mean + SD)	64.2 + 8.5	61.6 + 8.2	ns
Parity (mean + SD)	3.2 + 1.4	2.9 + 1.6	ns
BMI (mean + SD)	27 + 3.3	26.8 + 2.1	ns
Diabetes	50%	41%	ns
hypertension	38%	46%	ns
vaginal delivery (n)	28	36	ns
caesarean section (n)	2	5	ns
Newborn weight (mean + SD)	3743 + 488	3788 + 462	ns
Pre surgery POP-Q stage			
Stage 2	7%	20%	ns
Stage 3	45%	56%	ns
Stage 4	**48%**	**24%**	**p<0.05**
Hiatus area (cm2)	19.1 + 3.8	18.0 + 4.6	ns
LAM avulsion	48%	46%	ns

CONCLUSIONS

Given the new goals of pelvic prolapse surgery (absence of bulge symptoms or rate of retreatment), the outcomes of native tissue vaginal POP repair are better than previously thought, with a high patient satisfaction rate and acceptable reoperation rates.

The choice of native tissue surgery rather than prosthetic vaginal surgery needs to be made on a case-to-case basis, according to the individual variables, expectations and anatomical defects. Counseling on risks, benefits and alternatives to pelvic floor surgery is the key for a personalized surgical choice and for the improvement of patient satisfaction

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57 - LONG TERM FOLLOW-UP OF AUGMENTATION CYSTOPLASTY

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INTRODUCTION AND AIM OF THE STUDY

Augmentation cystoplasy (AC) has traditionally been used in treatment of the low capacity, low compliance, or refractory overactive bladder. at present The use of intravesical botulinum toxin and sacral neuromodulation in patient with detrusor overactivity has reduced the number of AC performed. Ileocystoplasty is the most common bladder augmentation procedure, but several other different type of tissue have been used successfully, including sigmoid colon, caecum, stomach and ureter. The post-operative complications associated with AC are mainly those which may occur with any major abdominal surgery, including bowel obstruction. The formation of urinary tract stones, recurrent urinary tract infections, impaired bowel function, metabolic disturbance and malignancy are the main inherent long-term complications after augmentation AC. The aim of this study is to evaluate long term results of AC performed in neurogenic and non-neurogenic dysfunction, in a high volume spinal unit center.

MATEHRIAL AND METHODS

This is an observational retrospective review of the results of 83 AC procedures carried out at our Hospital from January 1976 to December 2012. Indications were based on patients' symptoms in conjunction with urodynamic data demonstrating poor capacity, detrusor overactivity and/or abnormal compliance, and including patients with refractory LUTS who failed less invasive treatments or who were not candidates for those therapies and had high motivation for intermittent catheterization. All patients affected by neurogenic and non-neurogenic bladder dysfunction were included.

Collected data include: patient clinical history, physical examination, pre and postoperative multichannel video-urodynamics performed following International Continence Society guidelines, postoperative early and late surgical related and unrelated complications. We considered indication to surgery a low compliance below or equal to 10 ml/cmH2O.

Data analysis was conducted through inferential statistics with the evaluation of prevalence rates.

46 men and 37 women between 16 and 78 years old with refractory overactive or low compliance bladder, who failed conservative management, underwent AC. 80% were neurogenic, and 20% non-neurogenic. The neurogenic patients were affected mainly by: Myelomeningocele 34 (44%), Spinal cord Injuries 23 (29%). The most common in non-neurogenic disease was idiopathic overactive bladder 4 (30%). Ileocystoplasty 48 (58%), coloncystoplasty 31(37%), gastrocystoplasty 3(4%), uretercystoplasty 1(1%) were performed. In order to reach lower bladder pressure levels, Ileocystoplasty was preferred but in some cases due to specific patients' characteristics colocystoplasy was performed. To achieve better results since 2004 the whole detrusor was removed. In 58 cases (70%) other surgical procedures were combined: 13 (22%) Mitrofanoff; 43 (74%) monolateral ureteral reimplantation; 13 (22%) bilateral ureteral reimplantation. In 18 patients anti-incontinence surgery was performed: 9 artificial urinary sphinter in 9 men and 8 suburetral sling in 2 men and 6 women. The preoperatively urodynamic results are synthetically shown in Tab. 1.

	Overactive bladder	Low compliance
Sphinteric weakness	5 (10%)	9 (26%)
Neurogenic	42 (88%)	25 (71%)
Not neurogenic	6 (12%)	10 (29%)

RESULTS

Minimum follow up is 1 year, maximum is 22 years with an average of 10 years.

We had early complications in only 8% of the cases and late complications in 48% of cases as illustrated in Tab.2

Early complications						**Late Complications**		
Type	N°	%	Type	N°	%	Type	N°	%
None	76	92%	None	43	52%	Sling erosion	1	1%
Bowel obstruction	3	4%	Residual overactivity	9	11%	Prosthesis malfunction	6	7%
Diastase wound	1	1%	Bladder Stones	4	5%	Prosthesis Infection	2	2%
Dyspnea	1	1%	Stress Incontinence	5	6%	Kidney Stones	1	1%
Anemia due to erosive gastritis	1	1%	UTI	4	5%	Stenotic Mitrofanoff	4	5%
			VUR	4	5%			
Retroperitoneal hematoma with hypovolemic shock	1	1%	Toxic hepatitis	1	1%	Stenotic uretero-colic anastomosis	1	1%
			Renal deterioration	3	4%			

A minimum of 6 months after surgery is necessary in order to evaluate the clinical results to allow the new reservoir to accommodate the increasing volume of urine. This is clinically evident with the gradual increase of bladder volume and the disappearance of incontinence between the intermittent catheterizations.

RESULTS INTERPRETATION

Our complication rates are similar to those present in literature. As shown in tab 2 the main early complication was bowel

obstruction (4%) and the main late complication was residual bladder overactivity (OAB) (11%). This percentage is higher compared to the literature(1-2), but Surer et al.(3) had similar results (13%). In order to understand this high numbers of residual OAB we decided to better analyze these cases. We identify residual overactive bladder in 13 cases, 4 patients after coloncystoplasty (30%) and 9 after ileocystoplasty (70%). 100% of the coloncystoplasty had a residual OAB with high pressures (>30 cmH2O) while only 57% of the ileocystoplasty. Since 2004, when a real detrusor substitution with ileum was regularly performed, none of the 8 cases showed significant residual overactive bladder versus the 9 residual OAB in the AC procedures performed before the 2004.

CONCLUSIONS

Even thought botulin toxin has radically reduce the indication, AC remains an essential option in the treatment of bladder overactive and low capacity bladder, refractory to conservative treatments, with excellent and sustained continence rates, and acceptable morbidity. Our experience suggest that better results are obtained if instead of simple augmentation a real detrusor substitution is preferred in order to better reduce intraluminal pressures.

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58 - TREATMENT OF STRESS URINARY INCONTINENCE IN NEUROGENIC PATIENTS BY A NOVEL ELASTOMER PROSTHESIS: PRELIMINARY RESULTS

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INTRODUCTION

Stress urinary incontinence is a common burden which finds many treatments ranging from bulking agents to artificial sphincters. However these options are difficult to transfer to neurological patients where mixed disorders usually coexist. The classic combination in sub-sacral lesion patient consists in underactive bladder and incontinence due to sphincter insufficiency. In this context, hydraulic prosthetics are of difficult management mostly due to the higher risk of erosions and to the frequent need of self catherization. On the other hand classic injectable agents either do not ensure enough bulking, or migrate in time from their infiltration position. Furthermore as all injectable products they can determine allergic inflammatory reactions but can not be removed.

In spite of these considerations new products have been designed with a prime indication in women mild stress urinary incontinence or in male after prostate surgery. According to various studies which analysed over 100 procedures, this new product Urolastic ® is safe, effective, reversible and easy to perform.

The aim of this study is to present preliminary data of this device in the setting of neurological patients.

METHODS

Urolastic ® is composed a Vinyl dimethyl polydimethylsiloxane PDMS, titanium coated, non bioabsorbable elastomer. From a practical point of view it can be defined as an hybrid between bulking agent as it is injected at mid urethra but creates a soft cuff effect as it solidifies around it and therefore remains in the instillation site. Precise injection sites are identified thanks to a dedicated device placed on cystoscope: at level of bladder neck (4 sites) in women at level of membranous urethra in men (2 sites). Injection is the performed under local anesthesia.

5 patients were considered for a preliminary trial: 2 men and 3 women. All patients presented urinary stress incontinence in the context of spinal injury (myelitis, vascular or traumatic). To evaluate the efficacy of the device all patients were evaluated preoperatively and postoperatively monitoring voiding diary data and the use of auxiliary devices as main indicator of continence

RESULTS

Gender	Age (years)	Neurogenic disorder	Incontinence grade	Pre-treament	Post treatment
Female	65	Medullary ischemia	Complete	Diaper	Small pad (1/day)
Female	40	Spina-Bifida	50% of urine loss	Diaper	Small pad (1/day)
Female	45	Myelitis	Complete	Diaper	No progress
Male	40	Spine lesion L1 ASIA C	50% of urine loss	Condom	Dry (phone evaluation)
Male	50	Medullary ischemia	50% of urine loss	Condom	Dry (self cath up to 500 ml)

No complications were registered

Median operative time was 20 minutes

The only treatment failure occurred in a low compliance bladder who then needed detrusor botulinum toxin injection.

CONCLUSION

These preliminary results show that this procedure in feasible, safe and effective in neurological patients. The main advantages in confront to other options are:

1) Creation of a '' soft cuff effect '' easily and completely removable
2) No risk of migration
3) Minimal invasivity

However a larger number of patients is required to fully confirm its indication in this setting.

59 - URODYNAMIC EVALUATION BEFORE AND AFTER CONTINUOUS INTRATHECAL BACLOFEN INFUSION (CIBI) IN PATIENTS ON VEGETATIVE/MINIMALLY CONSCIOUS STATE

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INTRODUCTION AND AIM OF THE STUDY

Spasticity of either spinal or supraspinal origin may compromise patients severely and is associated with the development of pain, limb contractures and immobility. Baclofen is a structural GABA analogue substance acting at the GABA-B receptor subtype. It is assumed to act at the spinal level attenuating mono and polysynaptic conduction, primarily by inhibiting the release of excitatory transmitters. Baclofen

hardly penetrates the blood-brain barrier; therefore, penetration into the cerebrospinal fluid is poor with oral administration. Penn and Kroin were the first to report good results with continuous intrathecal baclofen infusion (CIBI) in patients with severe spinal spasticity. A dramatic clinical improvement was reported. Spasticity of supraspinal origin is much more common than spinal spasticity, but treatment with CIBI has been evaluated far less frequently in this condition. Reports of successful treatment of patients with supraspinal spasticity are limited. Especially patients with severe traumatic and/or hypoxic brain injury often suffer from severe tetraspasticity that is unresponsive to oral medication, physiotherapy or other antispastic therapies. More limited are reports on CIBI use in patients in vegetative or minimally conscious state.

Moreover CIBI has been demonstrated to be effective to improve bladder capacity or to decrease sphincter dyssynergia in patients affected by spinal cord spasticity. Only a few reports have been published on traumatic brain Injury (TBI), especially on the correlation of urodynamic findings, because injured patients commonly have behavioral, cognitive, or communication problems. The injury to the brain itself, impairment of cognitive and behavioral function, may induce voiding problems, such as incontinence. The most commonly expected urodynamic abnormality after TBI is involuntary detrusor contraction, which can be induced by the loss of cortical inhibition caused by suprapontine lesions. Coordinated relaxation of the distal sphincter during detrusor contraction is usually maintained. The incidence of urinary retention after TBI is lower than that after cerebrovascular accident (CVA). Very little is known about changes in urodynamic pattern in patients in vegetative (VS) or minimally conscious state (MCS) after TBI or CVA treated with CIBI. The aim of this study is to urodinamically assess bladder function in patients on VS or MCS before and after CIBI.

MATERIALS AND METHODS

We enrolled for this study 16 patients (13 males and 3 females), all patients were in VS or MCS for CVA (9 extensive brain hemorrhage) or TBI (7 patients). All patients were urodinamically evaluated before and after Baclofen pomp implantation. During urodynamic study were evaluated bladder compliance, presence and amplitude of detrusor overactivity, maximum cystometric capacity, detrusor pressure at opening bladder neck (detrusor leak point pressure) that coincide to detrusor pressure required to void, the presence of impaired contractility. In all patients were applied the Ashworth scale, separately for upper and lower limbs, and the spasm score, before and after implant, to evaluate changes in spasticity. In all patients were evaluated post void residual pre and post CIBI. Statistical analysis were performed using paired t-test and/or paired Wilcoxon test when appropriated to evaluate the difference in Ashworth and spasm scale, and to evaluate the urodynamic results before and after CIBI. We used Fisher's exact test to evaluate the number of patients in clean intermittent catheterization, and the conscious state before and after CIBI. We considered statistical significant when $p<0,05$.

RESULTS

Mean age of patients included in the study was 41.3 ± 13.5 years, coma days were 17.4 ± 5.9, elapsed time between cerebral injury and our centre's admission was 149.5 ± 41.5 days. At admission 3 patients were in MCS and 13 in a VS. Time of catheterization was $117,9 \pm 98.4$ days. At baseline all patients were in spontaneous micturition (reflex urinary incontinence), in 4 out of 16 patients clean intermittent catheterization (CIC) was necessary because high post-void residual. In all patients we observed an improvement of spasticity, especially of lower limbs after CIBI. The mean Ashworth scale pre-implantation was 2.8 ± 0.4 for upper limbs and 3.5 ± 0.5 for lower limbs, spasm score was 1.8 ± 0.7. After CIBI Ashworth scale was reduced, 2.4 ± 0.5 for upper limbs and 2.2 ± 0.4 for lower limbs with a statistical significant difference ($p<0.01$). Also spasm score was improved, after CIBI measuring 1.5 ± 0.5 with a significant statistical difference respect baseline ($p<0.03$).

After CIBI in 8 out of 16 patients was necessary CIC for high PVR (Fisher's exact test $p=0.27$).

At urodynamic evaluation mean baseline bladder capacity was $364,6 \pm 150.1$ ml, after CIBI was 391.9 ± 40.8 ml ($p<0.03$).

Detrusor pressure at opening bladder neck (DLPP) was 98.3 ± 7.4 cmH2O at baseline and 83.8 ± 11.5 cmH2O after CIBI, with a significant statistical difference ($p=0.04$). Mean PVR at baseline was 57.5 ± 21.7 ml, and 100.4 ± 50.9 ml after CIBI ($p=0.01$). At baseline in 10 out of 16 patients a detrusor overactivity was identified, after CIBI detrusor overactivity was present in 3 out of 16 patients ($p=0.02$).

We observed an improvement in conscious state, at hospital admission 13 out of 16 patients were in VS and 3 out of 16 in MCS, at discharge 7 out 16 were in SV and 9 in MCS (Fisher's exact test $p=0.14$).

INTERPRETATION OF RESULTS

The possibility to administer baclofen intrathecally, through a system of programmable infusion pump, has enabled the effective control of spasticity after severe brain injury with fewer side effects compared to oral treatment and with a significant improvement in overall function.

At the level of the urinary system, the γ-aminobutyric acid has an inhibitory action on the detrusor contractility, the origin of this mechanism is both in spinal cord and supraspinal. GABA has been recognized as a neurotransmitter with inhibitory activity on the detrusor. The GABA receptors are involved in the regulation of detrusor contractility through the action carried out on the pelvic ganglia, the sacral parasympathetic nucleus and supraspinal centers. Baclofen has therefore indications for use in the treatment of Lower Urinary Tract Dysfunctions (LUTD) with two main way of action: inhibition of hypertone involving the external urethral sphincter and the increase of detrusor compliance with the consequent increase in the filling capacity of the bladder. The use of intrathecal baclofen in the patients suffering from disorder of consciousness is spreading more and more, and not only for the treatment of spasticity and neurovegetative crisis but also for the possibility to induce a change in positive of consciousness state, many are today reporting in this sense. Another element to be reckoned with in clinical practice is the indication, suggested by some authors, to use early implant in order to prevent the impairment linked with spasticity before it is structured, thus making almost vain the only pharmacological or rehabilitative intervention. This study, even considering the modest numerosity of the sample, allowed to verify that after the implantation of CIBI a significant increase of bladder capacity and a reduction of Detrusor Leak Point Pressure. Also the presence of detrusor overactivity is detected with a significantly reduced frequency respect baseline. Accordingly an increase in PVR was identified. While this data may seem a positive result of the therapy must be related to the type of patient treated, indeed the absence of a detrusor contraction supported and sustained by supraspinal centers can create an increase of the post-void residual. The data therefore indicate the need to monitor PVR closely, in the first weeks after implantation, to avoid the risk of bladder supra-distension in these patients with disturbance of consciousness.

CONCLUSIONS

This is a preliminary pilot study that needs further validation to determine which are the urodynamic implications of CIBI

therapy and which is the best bladder management in patients in vegetative/minimally conscios state after implantation.

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60 - EFFECTS OF ANODAL TRANSCRANIAL DIRECT CURRENT STIMULATION ON BLADDER CONTROL IN INCOMPLETE SPINAL CORD INJURY

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INTRODUCTION AND AIM OF THE STUDY

Transcranial direct current stimulation (tDCS) is a safe noninvasive technique in which a low amplitude electrical current is conducted to the cortex via scalp electrodes. It was found to affect a great variety of brain functions and their range is continuously increasing. Numerous studies have demonstrated that direct current stimulation (tDCS) can modulate brain excitability and behaviour in healthy volunteers, pointing out its therapeutic potential in patients with disease resulting from or leading to abnormalities of brain excitability such as Parkinson's disease, stroke, tinnitus, chronic pain and depression. Studies in humans have linked the effects of tDCS primarily to synaptic modifications within the cortex and plasticity in the operations of cortical neuronal networks.

It has been shown that Anodal transcranial DCS is associated with an increase of cortical excitability that lasts beyond the stimulation period (Nitsche and Paulus, 2001), and seems to have an influence on motor abilities. The results obtained both in healthy subjects and neurologic patients suggest that modulation of motor cortex excitability induced by tDCS affects motor skill learning, raising the hypothesis that tDCS may have an impact on connected structures far from the site of stimulation including the spinal cord networks (N. Roche, 2009). Clancy JA et al. (2014) showed that anodal tDCS over the motor cortex increases sympathetic nerve activity,shifting autonomic nervous system balance toward sympathetic dominance due at least in part to an increase in sympathetic output. As sympathetic nerves inhibit the bladder body and excite the bladder base and urethra (hypogastric and pelvic nerves) we speculated that bladder autonomic function could be modulated by tDCS.

Additionally the motor cortex is important for the voluntary control of pelvic floor muscles (Blok, 2002). Voiding can be intentionally interrupted by contractions of the external urethral sphincter and ancillary pelvic floor muscles (Madersbacher, 2004). Few neuroimaging studies investigated brain activity during voluntary contractions of pelvic floor muscles in healthy subjects. It seems that there is a strong activity of the supplementary motor area (SMA) and other regions (parietal cortex, limbic system, cerebellum, putamen) especially in the full-bladder condition. Areas within supplementary motor area (SMA), the inferior frontal junction (the junction of the inferior frontal sulcus and precentral sulcus; IFJ), superior frontal junction (the junction of the superior frontal sulcus and precentral sulcus; SFJ) and parietal cortex are active in a wide variety of cognitive tasks, and are part of what has been termed the ''task positive network''.

fMRI studes of healthy women (Seseke et al., 2006, J.P. Kuhtz-Buschbeck et al, 2007) found that relaxation and contraction of pelvic floor muscles induced activation patterns which included both the primary motor cortex (M1) and SMA, as well as the frontal cortex, cerebellum and basal ganglia; the strong and consistent activation of the SMA indicates that this region exerts control of pelvic floor muscles either directly or indirectly, possibly via subcortical relays.

The aim of this study was to evaluate the effect of 2 mA anodal/sham transcranial direct current stimulation (20 min per day) over the motor cortex in supplementary motor area applied isolated in 16 patients with neurogenic bladder following incomplete spinal cord injury

MATERIALS AND METHODS

In a sham controlled parallel group design, 16 incomplete spinal cord Injury (SCI, AIS B -D) patients suffering from neurogenic detrusor over-activity (NDO) with or without detrusor sphincter dyssynergia (DSD) were randomized into two groups receiving transcranial direct current stimulation and sham stimulation.

SCI was classified using the International Standards for Neurological Classification of SCI according to neurological level (the most caudal segment of the spinal cord with normal sensory and motor function on both sides of the body) and the American Spinal Cord Injury Association Impairment scale).

Assignment of the patients to the treatment interventions was random, and patients remained blinded to their treatment condition and the specific hypotheses of the study.

Direct current was delivered from a battery-driven, constant current stimulator (BRAINSTIM) using saline-soaked surface sponge electrodes (35 cm2). The anode was placed 1cm before Cz (EEG 10/20 system) to target the motor cortex (SMA) and the cathode over right supraorbital cortex . A constant current of 2mA intensity was applied for 20 min.

For sham stimulation, the electrodes were placed in the same positions as for real stimulation; however, the stimulator was turned off after 20 s of stimulation so that the subjects felt the initial itching sensation, but received no current for the rest of the stimulation period.

Each patient received five consecutive treatment sessions .

Clinical assessment was performed before and after the last day of treatment. Function of the detrusor-sphincter complex was evaluated by urodynamic at three time points: before treatment (baseline), at Day 5 (last day of treatment), 12 weeks after treatment (follow-up). All patients filled out a bladder diary.

The primary outcome measure was the achievement of bladder control and the efficiency of micturition as shown by the decrease of residual urine, reducing of detrusor contraction and development of bladder sensation.

RESULTS

Post-treatment urodynamics studies(at day 5) documented in all treated patients an improved sensation of bladder filling and an increase of cystomanometric bladder capacity. No increase in Qmax ml per sec and no decrease in post-voiding residual urine per ml were documented. At 12 weeks after treatment, the treatment group still presented significant improvement on sensation of bladder filling, whereas no improvements were reported in the other group. The increase in bladder capacity was maintained in 62.5% of the sample

INTERPRETATION OF RESULTS

Supra-sacral SCI eliminates voluntary and supraspinal control of voiding, leading a slow development of automatic micturition and neurogenic detrusor overactivity (NDO); voiding is commonly inefficient owing to simultaneous contractions of the bladder and the urethral sphincter (detrusor–sphincter dyssynergia, DSD).

The bladder guarding reflex is a response which normally helps to maintain continence: throughout bladder filling, the parasympathetic innervation of the detrusor is inhibited and the smooth and striated parts of the urethral sphincter are activated, preventing involuntary bladder emptying.It is aberrant in incomplete SCI, with detrusor-sphincter dyssynergia, but the expression of these disordered reflexes (NDO and DSD) cannot be predicted exactly by the nature and neurological level of SCI. The guarding reflex normally prevents urinary and fecal incontinence through involvement of pontine centers and the integrity of supra-sacral spinal pathways and can be facilitated by voluntary control. In incomplete lesions (iSCI - AIS B–D) it is often preserved but very variable.

Peter H.Ellaway et al. (2014) studied the interaction between reflex and voluntary control of sphincter musculature and showed that 12 of the 23 Incomplete SCI subjects with neurogenic bladder treated by transcranial magnetic stimulation showed facilitation of the pudendo-anal reflex as a surrogate marker for the urethral sphincter guarding reflex.

SMA exerts control of sphincter muscle either directly or indirectly, possibly via subcortical relays. Stimulation of SMA could improve voluntary control of guarding reflex in incomplete SCI patients, leading to an increase of cystomanometric bladder capacity. Urodynamic evaluation showed an objective improvement in the maximum cystometric capacity which increased from 178.6+/−27.2 to 290.5+/−84.8 ml.

No change in detrusor contractility was found, leading to conclusion that tDCS did not significantly
modulate the activity of the brainstem autonomic centres.

Supplementary motor area (SMA) is active in many cognitive tasks, so the awareness of bladder filling could be an effect of electrostimulation of this area.

CONCLUSIONS

Our results demonstrate that transcranial direct current stimulation could increase awareness of bladder emptying and bladder capacity of neurgenic bladder following spinal cord injury. However, due to small number of patients a definite conclusion cannot be derived. No other clinically relevant effect was found on lower urinary tract function.

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