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**Standard stapled transanal rectal resection vs stapled transanal rectal resection with only one high volume stapler in the prevention of complications in old patient: our experience**

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**Abstract**

**BCEMI TQWPF:** The causes of obstructed defecation syndrome (ODS) can actually be either functional or mechanical (primary or secondary deficit of the sensitivity, slow bowel transit, pelvic floor dys-synergia, internal and external rectal prolapse, recto-anal intussusceptions, anterior or posterior rectocele and pelvic prolapse of the bladder, uterus, bowel or sigma). The aim of our study was evaluate the safety, efficacy and feasibility of Transanal Rectal Resection (STARR) procedure performed by a single or double stapler through clinical and functional outcomes for transanal stapled surgery.

**MGVJ QFU:** From January 2016 to October 2017, ninety patients with ODS secondary to rectal prolapse, anal-rectal intussusception and anterior rectocele, that underwent to a STARR procedures were enrolled. Thirty of these underwent a STARR procedure with double circular stapler PPH-01 (Group A); 30 with single circular stapler CPH34HV with a purse string suture (Group B); and 30 with single circular stapler CPH34HV with a "parachute technique" (Group C). All patients were selected with clinical examination, Wexner score for fecal incontinence and ODS score for constipation. Patients also underwent a Defeco RMN for an anatomical and dynamic evaluation of the pelvic floor.

**RGUWNVU:** No recurrence rates were observed in the three groups. The mean operative time was 46,3 minutes in group A; 34,5 minutes in group B; and 37,6 minutes in Group C. The volume of the resected specimen was 17 ml in group A; 15 ml in group B; and 16 ml in Group C. Complications were bleeding (3.3% in group A); fecal urgency (6.6% in group A, 10% in group B and 3.3% in group C); rectal hematoma (3.3% in group A). all symptoms significantly improved after the operation without differences between groups.

**EQPENWUQP U:** The STARR technique performed with a single stapler CPH34HV is safe, faster and less expensive than the STARR performed by a double PPH01. Besides, with the parachute technique, it is possible to resect asymmetric prolapses.

**Keywords:** Stapled Transanal Rectal Resection (STARR); Obstructed Defecation Syndrome (ODS); stapler; stapler complications

## Background

The Stapled Transanal Rectal Resection (STARR) technique was introduced at the beginning of 2000 (1-3) for the treatment of the Obstructed Defecation Syndrome (ODS), caused by internal or external rectal prolapse, recto-anal intussusception and anterior or posterior rectocele.

This procedure was originally performed using two circular staplers, PPH01 and then PPH03, <sup>(4-6)</sup> with the same technique. <sup>(7)</sup>

Later, a semicircular stapler called CCS-30 Contour Transtar was introduced in order to treat larger prolapses, with a different surgical technique. <sup>(8-10)</sup>

Nowadays, new devices (with a larger case –high volume-, with an improvement of the haemostatic effect) are being developed to reduce some important complications highlighted by the use of the staplers, such as bleeding, strictures, total rectal obliteration, rectal wall hematoma and perforation and most of all to simplify the technique. <sup>(11)</sup>

The aim of our study was to evaluate clinical and functional outcomes of the STARR performed with single or double stapler.

## Methods

From January 2016 to October 2017, at the Department of Surgical Sciences, Umberto I in Rome, “Sapienza”, ninety patients with ODS secondary to rectal prolapse, anal-rectal intussusception and anterior rectocele, that underwent to a STARR procedures were enrolled. We excluded patients with previous proctological or pelvic surgery or with an associated functional pelvic pathology.

A block randomization method was adopted to design patients in three groups to ensure the balance in sample sizes.

30 of these underwent a STARR procedure with double circular stapler PPH-01 (Group A), 30 with single circular stapler CPH34HV by pulling the prolapse and the rectocele with a purse string suture

(Group B) and 30 with single circular stapler CPH34HV by pulling the prolapse and the rectocele by a "parachute technique" (Group C). All the patients were prospectively observed.

Preoperatively, all patients were assessed with a detailed medical history (previous abdominal or rectal surgery, natural or cesarean childbirths), proctological and urogynecological examination.

Patients also underwent a Defeco RMN for an anatomical and dynamic evaluation of the pelvic floor, in order to diagnose a rectocele, a rectal prolapse, a rectoanal intussusceptions, an abdominopelvic dyssynergia and possible prolapses of the anterior and/or middle compartment.

If they were older than 40 or referred rectal bleeding, underwent to colonoscopy, in order to exclude a coexisting organic colorectal pathology.

The Wexner score for fecal incontinence and the Obstructed Defecation Syndrome (ODS) score for constipation were performed before and one, six and twelve months after surgery. <sup>(12)</sup>

Antibiotic prophylaxis was administered by metronidazole 500 mg, three times daily for 2 days. All operations were performed in the lithotomy position under general (sedation + local anesthesia) or regional anaesthesia (subarachnoid anaesthesia).

After the operation, the patients took two spoons of lactulose once a day for 3 days and then fiber plus water.

The administration of painkillers drugs, antibiotics and laxatives, complication symptoms and postoperative hospital stay in all the patients were recorded after surgical treatment.

The follow-up was performed by ambulatory visits after a week, 4 weeks and 6 months from the surgical treatment and then annually by phone contact. The mean follow up was 20 months (range 12-36).

The outcome of the intervention was assessed with a physical examination and considering patients' reported symptom and satisfaction.

### ***Surgical techniques* STARR with double circular stapler PPH-01**

The procedure typically involves the sequential use of two conventional PPH circular staplers. The patient is placed in the lithotomy position. The Circular anal dilator (CAD) is inserted into the anal

canal. Three 2-0 vicryl stitches are placed at the apex of the prolapse at 10, 12, and 2 o'clock traversing the mucosa, submucosa, and rectal muscle wall over half the rectal circumference. The first PPH-01 stapler is inserted and the posterior rectal wall is protected with a spatula. The ends of sutures are delivered through the specific holes of the stapler, and tension is applied to prolapse into the stapler housing, making sure that the posterior vaginal wall had not been incorporated; the stapler is closed and fired. Check of the section and of the fibrous residual lateral bridge. By the same procedure, three 2-0 vicryl stitches are placed at 4,6 and 8 o'clock and a second PPH-01 stapler is performed on the posterior rectal wall. 2-0 Vicryl stitches are positioned on the staple line in order to improve haemostasis and consolidate the anastomosis. <sup>(13,14)</sup>

### **STARR with single circular stapler CPH34HV by pulling the prolapse and the rectocele with a purse string suture**

The patient is placed in the lithotomy position. The Circular anal dilator (CAD) is inserted into the anal canal . Rotating the anoscope, a purse-string suture with 2-0 polypropylene around the entire anal circumference, approximately 2 to 3 cm above the dentate line, is performed. It includes only the rectal mucosa and the submucosa. The haemorrhoidal circular stapler is completely opened. Then, its head is introduced and positioned beyond the purse string, which is then tied with a closing knot. The ends of the suture are knotted externally. With traction on the purse string, the prolapse is pulled into the casing of the circular stapling device. In female patients, the posterior vaginal wall is checked to avoid entrapment in the agraphes line. The stapler is screwed on and fired to excise a ring of mucosa and submucosal and then examined by anoscopy. We usually put on the resection line additional absorbable 2/0 vicryl stitches in order to obtain an accurate haemostasis and an additional prolapse lifting. The case of high capacity allows to accommodate a greater amount of prolapse, compared to the case of PPH.

## **STARR with single circular stapler CPH34HV by pulling the prolapse and the rectocele by a "parachute technique**

The single stapler parachute technique (SSPT) allows with the use of only one stapler a bigger resection of the prolapse in terms of weight, volume and length and, when required, an asymmetrical resection. It is possible, thanks to the application of traction stitches instead of a purse string. The patient is placed in the lithotomy position. Circular anal dilator is inserted into the anal canal. Six separated Vicryl 2/0 stitches are placed at hours 1, 3, 5 (left side), 7, 9, 11 (right side) proximal to the dentate line. The single suture threads are secured to each other in two groups. The prolapsed is pulled into the stapler case. The stapler is then fired. <sup>(15)</sup>

We check the suture line and we usually additional absorbable stitches, in order to obtain an accurate haemostasis and an additional prolapse lifting.

### ***Statistical Analysis***

$\chi^2$  test including Yates' continuity correction and Anova was used as appropriate. A significant difference was considered when the p value was  $p < 0.05$ . All analyses were performed using GraphPad Prism Version 7. The follow-up was performed in the outpatient clinic at 1 week, 4 weeks and 6 months from the surgical treatment and yearly thereafter.

### **Results**

90 patients, 8 males (mean age 67.5 years, age range 58-77 years) and 82 females (mean age 65,7 years, age range 55-89 years) were randomly divided into three groups. Table 1 summarizes the patients' demographic and clinical data.

The mean operative time was 46,3 minutes (range 30-100) in group A, 34,5 minutes (range 20-65) in group B and 37,6 minutes (range 20-80), in Group C.

The volume of the resected specimen was 17 ml (range 12-25) in group A, 15 ml (range 12-22) in group B and 16 ml (range 12-22) in Group C.

The mean postoperative hospital stay was 3,2 days (range 2-6) in group A, 3 days (range 2-4 ) in group B and 3,4 days (range 2-4) in Group C.

Early postoperative complications (during 7 days after procedure) are summarized in table 2.

In group A, there was a case of bleeding in the fourth postoperative day, that required a surgical revision of the hemostasis. There was also a case of rectal hematoma, which was treated conservatively with antibiotic therapy.

In group B and in group C, instead, there were, respectively, 3 cases and 1 case of urgency, but it was resolved after about a month.

The Wexner Score for Fecal Incontinence is summarized in table 4, at 1 month after surgery was 1,8 (range 0-4) in group A, 2,3 (range 1-4) in group B and 2 (range 0-4) in group C. At 6 months was 1,6 (range 0-4) in group A, 2 (range 0-4) in group B and 1,3 (range 0-3) in group C. At 12 months follow-up was 1,3 (range 0-3) in group A, 1,5 (range 0-3) in group B and 0,8 (range 0-3) in group C.

The Wexner Constipation Scores is summarized in table 5. The scores were 13,8 (range 5-24) in the group A, 15,4 (range 7-25) in the group B and 16,8 (range 6-25) in group C preoperatively and decreased significantly to 2,8 (range 2-5), 2,6 (range 2-4) and 3,4 (range 2-6) 1-month after surgery. After 12 months the Wexner Constipation Score were 1 (range 0-2) in group A, 0,9 (range 0-2) in group B and 1 (range 0-2) in group C.

The pain was measured with a VAS scale from 0 to 10 (table 5). In early postoperative time was 4,3 (range 0-9) in group A, 5 (range 0-10) in group B and 3,1 (range 0-8) in group C. At 1 month follow-up was 1,4 (range 0-6) in group A, 1,5 (range 0-7) in group B and 0,5 (range 0-4) in group C. After 6 months the VAS was 0,2 (range 0-2) in group A, 0,1 (range 0-1) in group B and 0,03 (range 0-1) in group C.

No recurrence rates were observed in the three groups.



In our experience we observed longer operative time and more complications in the group treated with double circular stapler PPH-01. We had no differences regarding the volume of the resected specimen and post-operative hospital stay. Patients in all three groups solved the symptoms of ODS.

## Discussion

The ODS is characterized by the feeling of incomplete evacuation, fragmented defecation, the need to perform digitations in the rectum and/or vagina and perineum to facilitate the evacuation, the use of enemas and laxatives which result ineffective, pain during defecation. The causes can actually be either functional or mechanical.

The former include: primary or secondary deficit of the sensitivity, slow bowel transit, pelvic floor dyssynergia.

The latter include: internal and external rectal prolapse, recto-anal intussusceptions, anterior or posterior rectocele and pelvic prolapse of the bladder, uterus, bowel or sigma.

Nowadays, a variety of surgical techniques, including different approaches (Transanal, transvaginal, transperineal, transabdominal (laparoscopy or laparotomy), allows the treatment of the ODS.

Surgery is indicated in a percentage between 10% and 30% when medical treatment and rehabilitation failed. <sup>(16)</sup>

The transanal treatment is recommended when the ODS is secondary to morphological abnormalities, such as internal and external rectal prolapse, recto-anal intussusceptions, anterior or posterior rectocele.

The STARR technique, introduced by Longo, has been widely spreading ever since. Many reviews highlight the positive results obtained with the STARR, whereas other authors point out some major complications. <sup>(17, 18, 19)</sup>

New devices are currently being developed with the aim of reducing some crucial complications caused by the use of the aforementioned technique and in order to simplify the technique.

The first device used was the PPH01. Some major drawbacks, related to the PPH01, have been reported: limited capacity of the casing (approximately 15 cm<sup>3</sup>) and hence the need of making a double (anterior and posterior) resection to remove a maximum volume of 30 cm<sup>3</sup>, the formation of two residual lateral flaps, the impossibility to control the correct positioning of the rectal wall in the casing with the risk of creating a rectal diverticulum or a perforation. <sup>(20)</sup>

The amount of the resected prolapse depends on the volume of the case. In order to resect a larger prolapsed, Longo realized a rechargeable circular stapler, the CCS30- Transtar, which makes it possible to realize a larger rectal resection, through a longitudinal incision of the prolapse and a circumferential resection of the prolapsed rectal wall. However, this technique can lead to an inadequate and spiralling resection of the prolapse, thus enhancing the risk of a stapler line dehiscence. <sup>(21)</sup>

STARR with Contour Transtar has an increased risk of urge symptoms. <sup>(22, 23, 24, 25)</sup> Major complications have been described, e.g. a large hematoma in the mesorectum extending up to both kidneys and solved by a laparotomy <sup>(26)</sup>, a hemoperitoneum treated with a colostomy, a rectal perforation with a recto-vaginal fistula. <sup>(27,28)</sup> Other related disadvantages are also the prolonged surgical times, the high costs of the device and the longer learning curves.

Due to the only partially satisfactory correction of the prolapse obtained by starr performed by double pph01, and also in view of the technical complexity and the high costs of the Transtar, a novel device has been recently introduced in order to perform larger rectal resections.

In particular, we focus here on the new circular staplers CPH (Circular stapler for Prolapse and haemorrhoids) according to size CPH32 and CPH34. These staplers, especially the CPH34, provide noteworthy advantages described below: the case features a higher capacity, is transparent and also allows to control the pulling of the prolapse in its interior, it has four longitudinal grooves to let the passage of the traction wires of the prolapsed.

Moreover, the CPH34 is also characterized by a higher number of agraphes that reduces the risk of dehiscence and bleeding.

The CPH34HV permits a greater resection with a single firing, simplify the technique, reduces the operating time, prevents the formation of lateral “ears” and also allows to reduce the costs since only one stapler is used. In addition, if the resection is performed with the parachute technique, a calibrated resection of asymmetric prolapse (in which for example the front part is larger than the rear) is feasible. However we prefer to perform a symmetrical prolassectomy. In our series 5 of 30 patients in the group B are males.

The mechanical cause of the ODS is the internal/external rectal prolapse, recto-rectal and ano-rectal intussusception, anterior and posterior rectocele. There is no scientific evidence that the ODS symptoms depends on the amount of the prolapse. A bigger prolapse may not imply nor is implied by worse symptoms. We believe that the amount of prolapse to be removed must be actually tailored to the patient.

An inadequate resection may not resolve the symptoms due to the mechanical obstruction. On the contrary, an excessive resection may give rise to defecatory urgency or gas/fecal incontinence caused by a volume reduction of the rectum. The surgeon may hence choose the one which is the most suitable for the patient.

It is important to exclude from the transanal treatment the patients with associated prolapse of the anterior or the middle compartment. Patients with abdominopelvic dyssynergia are recommended to undergo a biofeedback treatment, prior to being later assessed again for surgery. The surgeon is expected to perform a preoperative interview with the patient. It is worth remarking that the correction of the anatomical defect is not always linked to a correction of the function.

In our study Wexner Score for fecal Incontinence showed better results in group C but not statistically significant at 12 months after surgery.

The Wexner Score for Constipation it was equivalent between all techniques at 12 months after surgery but better in the first year with those of the group A and B.

The pain measured with VAS Score showed less pain for the patients in group C preoperative and 6 months after surgery, but not statistically significant.

The high volume technique seems safe and faster, less expensive and with quicker recovery.

Moreover, the effectiveness of the operation, though achievable in most cases, is not certain.

It is also important, finally, to emphasize that the STARR technique represents a major surgical intervention which can be affected by complications, even when performed by expert hands. The surgeon is hence expected to have acquired a specific training, allowing him to give the right indication, to choose the most suitable device for the patient and to treat possible complications.

### **Conclusion**

The STARR procedure performed by a single stapler with CPH34HV is safe and faster, less expensive and complex than using double stapler. It also allows better results in terms of pain and continence.

In addition the STARR technique performed by CPH34HV with “parachute technique” it is possible to resect asymmetric prolapses.

**List of abbreviations**

Stapled Transanal Rectal Resection (STARR)

Obstructed Defecation Syndrome (ODS),

Circular anal dilator (CAD)

single stapler parachute technique (SSPT)

Circular stapler for Prolapse and haemorrhoids (CPH)

Wexner Constipation Score (WCS)

Wexner Fecal Incontinence Score (WFIS)

Visual Analog Scale (VAS)

**Authors' contributions**

DM: co-wrote the paper and co-made literature research, gave final approval of the version to be published.

AP: : made finale revisions, gave final style to the paper, gave final approval of the version to be published.

CE: co-collected data and draft tables, gave final approval of the version to be published.

GG: collected and interpreted data, gave final approval of the version to be published.

SP: made finale revisions, gave final style to the paper, gave final approval of the version to be published.

SS: made finale revisions, gave final style to the paper, gave final approval of the version to be published.

DP: conception and co-designed of the study, made revisions, gave final style to the paper, gave final approval of the version to be published.

**Ethics approval and consent to participate**

Written informed consents were obtained from all patients and ethics approval was issued by the Clinical Trial Centre Umberto I Hospital Sapienza University of Rome.

**Consent for publication**

Not applicable

**Availability of a data and materials**

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

**Financial competing interests**

There are any non-financial competing interests to declare in relation to this manuscript.

**Competing interests**

The authors declare that they have no competing interests

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## Tables

**Table 1-** The patients' demographic data.

|  | <b>GRUPPO A</b>   | <b>GRUPPO B</b>    | <b>GRUPPO C</b>    | <b>p Value</b> |
|--|-------------------|--------------------|--------------------|----------------|
| Number of patients                     | 30                | 30                 | 30                 |                |
| Mean age (years)                       | 65 (range 45-89)  | 64,8 (range 46-85) | 65,2 (range 49-83) | <b>0,99</b>    |
| Male                                   | 1                 | 5                  | 2                  |                |
| Wexner Constipation Score preoperative | 13,8 (range 5-24) | 15,4 (range 7-25)  | 16,8 (range 6-25)  | <b>0,093</b>   |

**Table 2-** Operative data and early postoperative complications

|                                      | GRUPPO A            | GRUPPO B           | GRUPPO C           | p Value        |
|--------------------------------------|---------------------|--------------------|--------------------|----------------|
| Mean operative time (min)            | 46,3 (range 30-100) | 34,5 (range 20-65) | 37,6 (range 20-80) | <b>0.00053</b> |
| Volume of the resected specimen (ml) | 17 (range 12-25)    | 15 (range 12-22)   | 16 (range 12-22)   | <b>0.30</b>    |
| Postoperative hospital stay          | 3,2 (range 2-6)     | 3 (range 2-4)      | 3,3 (range 2-4)    | <b>0.428</b>   |
| Bleeding                             | 1                   | 0                  | 0                  |                |
| Urgency                              | 2                   | 3                  | 1                  |                |
| Anal abscess                         | 0                   | 0                  | 0                  |                |
| Hematoma                             | 1                   | 0                  | 0                  |                |
| Suture dehiscence                    | 0                   | 0                  | 0                  |                |

**Table 3-** Wexner Constipation Score

| Wexner Constipation Score | GRUPPO A        | GRUPPO B        | GRUPPO C        | p Value      |
|---------------------------|-----------------|-----------------|-----------------|--------------|
| 1 month                   | 2,8 (range 2-5) | 2,6 (range 2-4) | 3,4 (range 2-6) | <b>0.005</b> |
| 6 month                   | 2,7 (range 2-5) | 2,9 (range 2-5) | 3,4 (range 2-5) | <b>0.048</b> |
| 12 month                  | 1 (range 0-2)   | 0,9 (range 0-2) | 1 (range 0-2)   | <b>0.98</b>  |

**Table 4-** Wexner Fecal Incontinence Score

| Wexner Fecal Incontinence Score | GRUPPO A         | GRUPPO B        | GRUPPO C        | P Value     |
|---------------------------------|------------------|-----------------|-----------------|-------------|
| 1 month                         | 1,8 (range 0-4)  | 2,3 (range 1-4) | 2 (range 0-4)   | <b>0.09</b> |
| 6 month                         | 1,6 (range 0-4)  | 2 (range 0-4)   | 1,3 (range 0-3) | <b>0.06</b> |
| 12 month                        | 1,3 (range 0-39) | 1,5 (range 0-3) | 0,8 (range 0-3) | <b>0.01</b> |

**Table 5-** Pain measured with VAS score

| VAS Score           | GRUPPO A        | GRUPPO B        | GRUPPO C         | p Value      |
|---------------------|-----------------|-----------------|------------------|--------------|
| Early postoperative | 4,3 (range 0-9) | 5 (range 0-10)  | 3,1 (range 0-8)  | <b>0.033</b> |
| 1 month             | 1,4 (range 0-6) | 1,5 (range 0-7) | 0,5 (range 0-4)  | <b>0.043</b> |
| 6 months            | 0,2 (range 0-2) | 0,1 (range 0-1) | 0,03 (range 0-1) | <b>0.179</b> |
| 12 months           | 0               | 0               | 0                |              |