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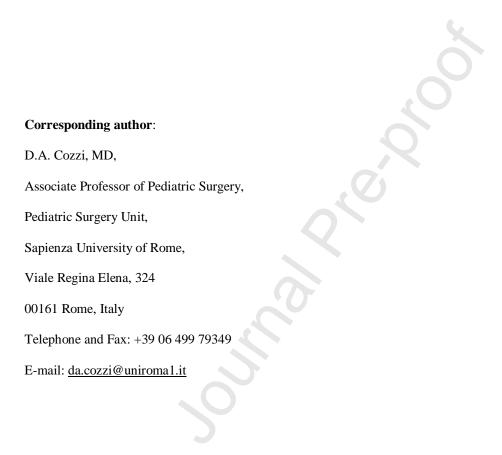
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FEASIBILITY, SAFETY AND OUTCOME OF INGUINAL HERNIA REPAIR UNDER SPINAL VERSUS GENERAL ANESTHESIA IN PRETERM AND TERM INFANTS.

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ABSTRACT

Background: Inguinal hernia repair (IHR) is a common operation in preterm and term infants. Recently, spinal anaesthesia (SA) has been proposed as an alternative to avoid exposure to general anaesthesia (GA) during early life. The aim of this study was to compare surgical outcomes of open IHR performed under SA *versus* GA in neonates and infants, and to detect criteria to predict the success or failure of SA.

Materials and methods: This is a 6-year, single centre, non-randomized interventional study (2013-2019). SA was performed with 0.5% bupivacaine. GA was given using propofol, fentanyl, sevoflurane, and laryngeal mask. Patient demographics, operative time, intraoperative events related to surgery or anaesthesia, and complications were analysed at short and long-term follow-up.

Results: 68 infants (78 IHR) and 37 infants (44 IHR) received SA and GA at the discretion of the anaesthesiologist, respectively. SA failure rate was 9%, and positively correlated with weight at surgery (p=0.001; r_p=0.38). Conversion from SA to GA occurred in 4 (6%) patients due to prolonged operative time (45.75±4.8 vs 23.02±11.3 minutes; p=0.0006). There were no differences regarding operative time, intra- and post-operative complications among the two groups at mean follow-up of 18.53±21.9 months.

Conclusions: This pilot study confirms that SA is safe, effective and not detrimental to surgical outcome of neonates and infants undergoing IHR. Additionally, it may help further define what patients may have a successful SA. Our experience suggests that SA is especially suitable in infants weighing <4000 g, and conversion to GA correlates with prolonged operative time.

LEVEL OF EVIDENCE: Level II

KEY WORDS: Inguinal hernia repair, premature, infants, neonate, spinal anaesthesia, general anaesthesia.

INRODUCTION

Inguinal hernia is one of the most common conditions requiring early surgery in neonates and preterm infants. Prematurity, bronchopulmonary dysplasia, and increased intra-abdominal pressure resulting from chronic lung disease or gastrointestinal dysfunction may be predisposing factors to the development of inguinal hernia [1,2,3]. Surgical repair is conventionally performed under general anesthesia (GA), which may be complicated in approximately 30% to 35% of cases by one apneic episode within the postoperative period, especially in otherwise healthy preterm babies [4,5,6]. Additionally, there is concern on the possibility of long-term deleterious effects of anesthesia exposure on the developing brain structure, especially cognitive function and behavioural outcomes after early exposure to GA [7,8].

Some of the larger risks were age <6 months, GA duration >2-3 hours, and multiple GA exposures.

Recently, awake regional anesthesia (RA) approaches, including caudal or spinal block, have been proposed as safe and efficient alternative anesthesia method in this frail group of patients [9,10]. However, these techniques continue to be highly underutilized for IHR in neonates and infants probably because, from a surgical point of view, there are still concerns on single dose regional block, which may not be able to ensure a fully adequate analgesia for the total length of surgery. Additionally, there are also concerns on potential sac disruption or bowel herniation due to increased intra-abdominal pressure in awake neonates and infants.

The aim of the present study is to investigate the safety, effectiveness, intra- and post-operative surgical outcome of inguinal hernia repair (IHR) performed under spinal anesthesia (SA) only compared to a control group of patients who underwent IHR under GA. Additionally, we made an attempt to develop practical selection criteria for SA in neonates and infants undergoing IHR.

1. MATERIALS AND METHODS

We performed a prospective interventional non-randomized study of all neonates and infants who underwent elective IHR at our Institution between January 2013 and December 2019. Patients who had received SA or GA were selected, recruited, and followed up. Surgery was considered when patients were hemodynamically stable and spontaneously breathing.

One senior surgeon performed or assisted all IHR, using an open inguinal approach without opening the inguinal canal. The hernial sac was gently peeled off the spermatic cord structures as high as possible, ligated and severed at the level of the internal inguinal ring. All patients followed pre-operative fasting thus allowing an eventual conversion from SA to GA. Two senior anesthetists performed or assisted all the anesthetic procedures. The type of anesthetic technique was chosen at the discretion of the senior anesthetists. Additionally, our protocol included conversion to GA after 3 failed attempts at SA. Bilateral IHR was not considered a contraindication to SA, although the onset of agitation or movements during prolonged operative time were considered indications for conversion to GA.

1.1. Spinal anesthesia

The procedure was performed under sterile conditions with the baby in the sitting position and nurse assisting with positioning to accentuate lumbar kyphosis. Topical anesthetic cream (EMLA) was optional. A sucrose-sweetened pacifier was maintained in the baby's mouth. Since in newborns and infants the spinal cord most frequently terminates at the level of L2/L3, we accessed L4-L5 intrathecal space using a 16 mm, 25-gauge spinal needle, to avoid spinal injury. Access to the intrathecal space was considered successful when cerebrospinal fluid is returned. Local anesthetic used in our patients was 0.5% isobaric bupivacaine (1 mg/Kg). Bloody tap was not considered a contraindication for further attempt to SA. Effective motor and sensory block to stimuli was ascertained by gentle pinching of the thigh.

1.2. General anesthesia

All patients were induced with sevoflurane in oxygen-air at 7 L/min flow via facent ask. Fentanyl 2 mcg/kg was given intravenously. Induction was done in slow incremental manner up to 5 vo %. Propofol 2 mg/kg was given intravenously. Ventilation was controlled by positive pressure mask ventilation after apnea occurred, as demonstrated by capnography and respiratory pattern. Laryngeal mask was then positioned. Tracheal intubation was performed in case of difficult face mask ventilation, which was defined as unsatisfactory chest movements and inability to oxygenate the patient ($SpO2 < 90\%$ with $FiO_2 = 1,0$), secondary to either functional or anatomical cause. No muscle relaxants were used.

All patients had an IV placement, regardless of the type of anesthesia received. IV was placed before performing SA and after mask induction in case of GA.

No other block was performed to provide post operative analgesia. Oral or intravenous paracetamol were prescribed pro re nata (PRN) for postoperative pain, which was assessed using a well-validated 10-point FLACC score (Face, Legs, Activity, Cry, Consolability) [11]. Paracetamol was given if FLACC score ≥ 4 (i.e. pain intensity scores in the moderate to severe range). All preterm or < 3 months old infants were kept overnight.

1.3. Outcome measured

Demographics, gestational age, age at surgery, time from placement of the spinal anesthetic to end of operation, success of spinal puncture, success of attaining adequate surgical anesthesia, need for supplemental systemic sedation, and conversion to GA, were prospectively recorded in an electronic database. Measured intra-operative complications included relevant bleeding, bowel injury or rupture of the hernial sac. Additionally, early post-operative complications such as wound infection and hematoma were also recorded. Median arterial pressure (MAP) was measured at skin incision and 15 minutes after beginning of surgery. Any hypotension was defined as MAP of <45 mmHg.

Apnea episodes were monitored until discharge. Apnea was defined as a pause in breathing >15 seconds or >10 seconds if associated with O_2 saturation $<80\%$ or bradycardia (20% fall in heart rate).

We routinely offered clinical assessment at 1 and 6 months' post-operative follow-up. Additionally, we made an attempt to invite patients to a special clinic follow-up, to assess the following surgical outcome measures: testicular size and position, and/or inguinal hernia recurrence, and/or metachronous inguinal hernia.

1.4. Statistical analysis

Continuous variables were expressed as mean (SD). Differences between the two groups were evaluated using two-tailed unpaired t test and Fisher's exact test, as appropriate. Pearson's correlation coefficient was used to evaluate relationship between variables potentially related to failure or conversion of SA. $p < 0.05$ was regarded as significant. Statistical analysis was implemented with SPSS 13.0 statistical software (IBM SPSS Statistics for Windows, Version 22.0. IBM Corp, Armonk, New York, United States). Ethical approval was obtained for this study from our institutional review board (dip.ped.npi: odg n° 9/ 29.01.2013) and informed consent was obtained from all patients.

2. RESULTS

During the study period, we performed 105 surgical procedures for a total of 122 open IHR in preterm or term infants. Table 1 summarizes patient demographics and characteristics. Post conceptional age at surgery was 41.27 ±3.43 and 45.07 ±6.0 days for patients undergoing SA and GA, respectively (p <0.0001; 95%CI: 1.977 to 5.623). Seventy-two patients were electively admitted from home, while the remaining 33 were hospitalized in NICU, without differences between the two groups regarding the associated medical problems as described in table 1.

First-line SA was attempted in 75 infants. However, the initial SA attempt failed (cerebrospinal fluid was not obtained) in 7 (9%) infants weighing between 3790g and 6380g, who were eventually included in the GA group. These patients had a higher mean weight at surgery as compared to the remaining patients undergoing successful SA (4765±0.88g vs 3537±0.91; p=0.001; 95% CI: -1948.3 to -507.62). There was a positive correlation between higher weight and failure of SA (p=0.001; r_p=0.38). Overall, 68 infants finally underwent IHR under SA, including 10 with bilateral inguinal hernia, whereas the remaining 37 infants, 7 with bilateral inguinal hernia, underwent IHR under GA. Three patients of SA group had a concomitant undescended testis, and successfully underwent orchiopexy during the same procedure. There was no difference in laterality of inguinal hernia, mean gestational age and concomitant respiratory, cerebral and cardiac associated problems between the two groups (Table 1).

SA was successful for IHR completed within 29.34 ±10.47 minutes from initial spinal puncture. We found a positive correlation between prolonged operative time and rate of conversion to GA (p=0.001; r_p=0.41). Conversion from SA to GA occurred in 4 (6%) patients because of the onset of agitation and movements during a prolonged operative procedure (43.75±4.78 vs 23.02±11.26 minutes, p=0.0006; 95% CI: -32.12 to -9.35). This prolonged duration of surgery was due to

complicated bilateral IHR (n=2), troublesome repair of Amyand hernia adherent to the sac (n=1), and because of a significant time gap between skin incision and initial spinal puncture (n=1).

One (2.7%) patient undergoing GA experienced bradycardia after anesthetic induction with sevoflurane, which was rapidly reversible after positive pressure ventilation. Additionally, 1 (2.7%) ex-preterm patient developed a laryngospasm at the insertion of laryngeal mask, which required tracheal intubation and intensive care unit observation, thus prolonging his hospital stay. No patient experienced hypotension in either group. However, the MAP measured at skin incision was significantly lower in the GA group (49.94±12.2 vs 62.72±16.8; p=0.009; 95%CI: -22.183 to -3.377), but such difference was no longer significant at 15 minutes after the beginning of surgery (55.83±14.6 *vs*. 48.83 ±12.8; p=0.11; 95%CI: -15.737 to 1.737). No patient in the SA group developed urinary retention.

All patients received full formula soon after the end of surgical procedure. There was no difference within the two groups regarding intra and post-operative complications. There was no bowel injury nor wound complications in both study group. We found no significant difference in the use of postoperative analgesic agents between the two groups. One ex-preterm infant (born at 26 weeks of gestation and operated at 12 weeks of age) included in the GA group, experienced an episode of early post-operative apnea during the first 30 minutes after the end of surgery. No patient in the SA group experienced post-operative apnea. Home discharge was possible within 24 hours for all patients electively admitted (n=72), except one who required prolonged hospital stay because of a laryngospasm during GA. At a median overall post-operative follow-up of 8 months (range 1 to 78), 4 patients of SA group and 2 patients of the GA group presented a metachronous inguinal hernia. One patient of the GA group developed inguinal hernia recurrence 2 weeks after surgery. Finally, 2 patients of the SA group developed testicular atrophy. Of these, 1 patient underwent reduction of incarcerated inguinal hernia before IHR, and the other patient had an associated ipsilateral undescended testis, operated at the same time of IHR.

3. DISCUSSION

Prematurity is the single most important predisposing factor for the development of inguinal hernia [1]. The incidence increases with decreasing birth weight [2], counting around 38% of infants with a birth weight between 751g and 1000g [12], and around 16% of infants with a birth weight between 1001g and 1250g [2,13]. Given the high probability of preoperative incarceration of the inguinal hernia in neonates and infants, occurring in up to 60% of cases within the first 6 months of life [14], prompt treatment immediately after diagnosis is strongly recommended.

Moreover, several studies demonstrated that about 30% to 35% of otherwise healthy ex-preterm infants undergoing IHR under GA at a post conceptual age less than 45 weeks, will experience one or more episodes of apnea in the postoperative period [4,5,6]. This incidence decreases to 5.9% in patients 45-60 weeks post conceptual age. Even though our SA group patients had a significantly lower post conceptual age, none of them developed post-operative apnea. In contrast, the single

episode of post-operative apnea in our series occurred in 1 (2.7%) patient in the GA group. Such incidence was similar to that reported by Davidson et al. [15], who found that the incidence of early apnea (0 to 30 minutes) was higher in the GA group respect to patients undergoing any type of regional anesthesia (RA) (3% vs. 1%; p=0.03). However, in their study, the incidence of late apnea (30 min - 12 hours) was no different between the two groups.

Therefore, the avoidance of post-operative apnea may be a significant advantage of SA over GA, thus potentially allowing earlier home discharge, regardless of the post conceptional age.

Additionally, there is still a concern and debate on GA as potential risk factor for impaired neurodevelopmental outcome in preterm babies and neonates [7,8]. Conversely, a recent multicenter randomized trial comparing GA vs awake-RA in infants (including either SA, caudal anesthetic, or a combined spinal-caudal anesthetic) demonstrated that there is no or very minimal risk of adverse developmental consequences in infants undergoing operations under GA lasting less than 2 hours, such as IHR [16].

However, preterm infants have often different comorbidities such as history of bronchopulmonary dysplasia, which increases the risk of respiratory complications during and after GA. Therefore, the use of SA may be a considerable advantage in this frail group of preterm or ex-preterm patients, giving a more qualitative measure of recovery characteristics.

Additionally, home discharge was possible within 24 hours for all patients electively admitted, but 1 who required prolonged hospital stay because of a laryngospasm during GA. In our experience, SA was feasible and successful in 91% of attempts. Failure in the spinal needle placement was probably due to the greater body weight at operation of a subset of patients, especially at risk if weighing ≥ 5000 g. We hypothesized that the higher is the weight, the more difficult is to access the intrathecal space using a 25 mm needle, as that used in our cohort of patients. Moreover, the bigger the baby, the harder is to hold him and avoid its movements during spinal needle placement, thus making SA more difficult. As far as concerns the sitting position during SA for IHR, this was our anesthetists' preference, merely because they were most familiar with. Notably, both lateral and sitting positions have been successfully used for SA in neonatal and infantile IHR [9], but no outcome comparison between the two positions has been conducted in infants to date.

Additionally, SA failure occurred homogeneously throughout the study period, and independently of whether performed by senior anesthetist or trainee, thus suggesting no correlation with learning curve, although the numbers are too small to extrapolate any firm conclusion.

Frawley G et al. reported that the primary reason for failure of any type of RA was a bloody tap [9], which has been reported as high as 46% in previous studies [10]. In our experience, bloody tap was not considered a contraindication for further attempt to SA, which was successfully performed at the second attempt. Notably, none of our patients requiring conversion to GA presented a bloody tap.

Although spinal complications following SA are rare, we believe that our policy to puncture the L4-L5 intrathecal space may be a safe and effective measure to prevent potential spinal cord injury. Our technique is similar to that already reported by others [9]. Notably, a recently published anatomical study has showed that the conus medullaris in newborns was not found caudal to the L3 vertebral body [17].

An important limitation to SA is that it provides a relatively short duration of surgical anesthesia, generally thought to be less than 60 min for a single spinal block anesthetic injection. Longer time extension may be obtained up to 110 minutes if epinephrine or clonidine is added to the local anesthetic [18,19]. We routinely avoid the addition of epinephrine because our operative time for open IHR, performed without opening the inguinal canal, is usually < 30 minutes, as we believe in many other pediatric surgery centers.

In our experience, single dose SA was enough to obtain analgesia for the duration of the procedure without the need for additional sedation in 94% of cases. The 6% conversion rate from SA to GA in our series was probably due to the prolonged operative time after induction of SA, thus demonstrating that this type of anesthesia is especially suitable for procedures lasting up to 40 minutes from spinal puncture, regardless of the unilateral or bilateral repair. However, complicated inguinal hernia may require longer operative time, thus resulting in the likelihood of conversion to GA, as occurred in 1 patient of our series who had an Amyand hernia adherent to the sac. Therefore, in case of prolonged operative times for any reason, the anesthetist should be ready to convert the procedure into GA or to give a brief supplementation of the SA by mask GA.

To date, the exclusively awake regional anesthetic approach for IHR has not obtained widespread consensus among pediatric surgeons because of the fear that without GA, the child may cry and/or present movements increasing intra-abdominal pressure, which may lead to intestinal herniation during the procedure and/or rupture of the hernial sac. In our experience, these issues did not affect either the operative time nor the post-operative outcome, including the risk of hernia recurrence or testicular damage. In case of intra-operative agitation, crying, or movements of the upper part of the body, gentle manual containment and/or a sucrose-sweetened pacifier maintained in the baby's mouth were successful to obtain control of the baby, instead of switching to GA.

Our outcomes on SA parallel those reported in a previous Cochrane review and in a subsequent randomized study, which did not demonstrate any difference between all types of RA and GA in preterm infants undergoing IHR, in terms of duration of surgery and average length of hospital stay [20,21]. Regarding postoperative pain, we adopted the FLACC score, which is a validated behavioral scale for scoring postoperative pain in young children who are unable to communicate their pain [11]. Notably, a recent randomized study found that FLACC scores were significantly lower in the RA vs the GA group [21]. In our experience, we used simply paracetamol for post-operative pain relief, and we did not find any significant difference between infants receiving SA as compared to those receiving GA. Notably, we do not

use routinely any wound infiltration or caudal analgesia after IHR, and generally paracetamol is prescribed PRN, being required very rarely also in older children. The less postoperative analgesic requirement in our patients may be presumably due to the adopted IHR technique, which does not include opening of the inguinal canal.

Furthermore, in our series we did not experience potential adverse effects described also during RA such as hypotension, bradycardia, or respiratory failure. In contrast, 3 patients in the GA group experienced intraoperative bradycardia (n=1), laryngospasm requiring mechanical ventilation support for 2 days (n=1), and post-operative apnea (n=1).

Of greater importance and impact may be the better hemodynamic stability and preserved cerebral autoregulation of infants during SA vs. GA. McCann et al found that RA reduces the incidence of hypotension and chance of intervention to treat it compared with GA in infants undergoing IHR [22]. Notably, when comparing different types of RA, hemodynamic stability was better after SA vs caudal anesthesia [23]. In our series, there were no significant episodes of hypotension in either group, although GA patients had a lower MAP documented at skin incision.

Recently, Gurria et al. has also reported their successful use of RA in very preterm neonates undergoing IHR [24]. Notably, they found that 17% of their patients undergoing GA experienced prolonged intubation beyond 4 hours after surgery. This was also the case for 1 of our ex-preterm GA patients, who required prolonged intubation following a laryngospasm.

Although there is a large anesthetic literature on SA in infants, limited information is available on this important technique from the surgical standpoint. In our experience, we did not find any difference with regard to surgical outcome between patients who received IHR under GA or SA at a long-term follow-up. Despite the reported fear of rupture of the hernial sac and intestinal herniation disturbing the correct surgical procedure during SA, we did not experience a higher risk of hernia recurrence in this group. The two testicular atrophies occurred in a patient with a previous history of incarcerated ipsilateral inguinal hernia and in a patient with concomitant undescended testis, respectively.

Our 2.8% rate of testicular atrophy parallels the higher incidence of testicular atrophy reported in some specific population of infants undergoing IHR. Conditions predisposing to higher risk of testicular atrophy following IHR include previous hernia incarceration (14%) [25], prematurity (10%) [26], and ipsilateral undescended testis undergoing concomitant orchiopexy (12%) [25].

There are a number of limitations in our study. First, we acknowledge the relatively small sample size of our population, although present series is the largest single center experience using only SA among different types of RA for open IHR. Additionally, there were significant differences in birth weight, weight at surgery and age at surgery among the two study groups, presumably related to the anesthetist's choice of SA for more critical babies, who were

thought to be at higher risk of GA complications. Despite these limitations, our goal with this pilot study was to share our experience, thus contributing to the growing awareness of SA utility and feasibility in infants undergoing IHR.

4. CONCLUSIONS

From our experience, it appears that SA is feasible, safe, and effective in neonates and infants undergoing IHR, without affecting surgical intraoperative or long-term outcomes at specialized pediatric surgical centers. This type of anesthesia has proven to be particularly suitable in small patients with prematurity-related comorbidity, when risks of GA should be weighed against the risks of non-intervention. A body weight of 4000 g and/or expected operative time up to 40 minutes represented our upper limits of predictability for successful SA. However, a prospective randomized control trial with an adequate number of patients may be needed to confirm the results of our pilot study.

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Table 1: Patient demographics and characteristics

	Spinal Anesthesia (n=68)	General Anesthesia (n=37)	p value
M:F	61:7	33:4	1
Bilateral IHR	10	7	0.58
Gestational age (wks)	33.1 ± 4.6	34.5 ± 5.1	0.16
Post conceptional age (wks)	41.27 ±3.43	45.07 ±6.0	0.0002
Birth weight (g)	1178 ± 1.190	2.309 ± 969	<0.0001
Weight at surgery (g)	2174 ± 1.820	4709 ± 1.321	0.002
Age at surgery (mos)	1.9 ± 0.9	2.7 ± 1.4	0.004
Associated problems			
Broncopulmunary dysplasia/RDS	8	6	0.55
Intraventricular hemorrhage	5	2	1
Brain anomalies	2	1	1
Cardiovascular anomalies	17°	8	0.81
Previously incarcerated inguinal hernia	2	3	0.35
Associated undescended testis	3	0	0.55
Intra- and post-operative details			
Operative Time (min)	24.49 ± 13.0	28.40 ± 13.73	0.11
Time from SA puncture to end surgery (min)	29.34 ±10.47	-	-
Inpatients	24 (35%)	7 (19%)	0.11
Intra-operative complications	0	2	0.12
Hernia recurrence	0	1 (2%)	0.39
Testicular atrophy	2 (2.8%)*	0 (0%)	0.53
Post-operative F-U (mos)	18.33 ± 54	18.83 ± 20.65	0.41

RDS: respiratory distress syndrome; °1 patient had a previous surgical repair of patent ductus arteriosus;
* Rate calculated on a total of 71 male IHR; Data are mean ± SD or n.