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Postoperative outcomes in the Pyloromyotomy Procedure under Spinal Anaesthesia : A retrospective study of 100 cases

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Abstract : *Background* : Infantile hypertrophic pyloric stenosis is one of the most common gastro-intestinal emergencies in the first 2 months of life, and can be treated by pyloromyotomy. Challenges in inducing general anesthesia have led to the development of spinal anesthetic techniques. The purpose of this study is to evaluate the outcomes of pyloromyotomy performed under spinal anesthesia.

Method s: A retrospective study of 100 infants who underwent open pyloromyotomy under spinal anesthesia between 2005 and 2015 at Bnai Zion Medical Center was performed. The primary outcome measures were: time to postoperative full enteral feeding, total operating time, and postoperative length of hospital stay. The secondary outcome measures were: incidence of postoperative respiratory adverse events and spinal anesthesia complications.

Results : Ninety-two infants underwent pyloro-myotomy under spinal anesthesia. The median time to full enteral feeding was 19 hours. Median operating time was 45.0 minutes. Median length of hospital stay was 2 days. No respiratory or spinal-anesthesia complications were reported.

Conclusions : This study suggests that spinal anesthesia is effective and safe in open pyloromyotomy and may improve surgical outcomes.

Key words : infant ; paediatric ; pyloric stenosis ; pyloromyotomy ; spinal anaesthesia ; surgical outcomes.

Introduction

Infantile hypertrophic pyloric stenosis (HPS) is one of the commonest gastrointestinal emergencies that occurs during the first 2 months of life. It is associated with dehydration, electrolyte imbalance, and metabolic alkalosis, requiring surgical intervention (1, 2) .

There is an increase in the incidence of premature infants diagnosed with HPS (3). These infants are prone to postoperative apnea following general anaesthesia and an increased risk of developing intracranial hypertension during endotracheal intubation (4, 5). Despite the correction of systemic metabolic alkalosis, cerebrospinal fluid can remain alkalotic. In this context, hyperventilation and opioids may increase the risks of postoperative central apnea (6). Conversely, sleep studies in full-term infants (n = 30) have not demonstrated a risk of postoperative after pyloromyotomy under general anaesthesia (7). However, a randomised trial of full-term infants (n = 60) undergoing halothane vs. remifentanil induction observed a postoperative apnea rate of 16% (8).

Anaesthetic induction and airway management of infants with HPS can be challenging because of the accumulation of significant volumes of gastric content, predisposing these patients to pulmonary aspiration prior to the establishment of a secured airway (9). Rapid-sequence induction (RSI) and cricoid pressure in HPS remain controversial and are associated with complications such as failure to intubate at first attempt, and hypoxia, especially in the absence of a pediatric anesthetist (10,11). The above-mentioned risks associated with classic RSI have led many anesthetists to use a modified RSI approach (gentle bag-valve-mask ventilation with gentle cricoid cartilage pressure) (12). However, correct application of cricoid pressure may be difficult in infants and inappropriate use of this manoeuvre may render both bag-valve-mask

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ventilation and endotracheal intubation more difficult (13). As demonstrated by Cook-Sather et al., awake endotracheal intubation is non-superior to standard or modified RSI for HPS patients (14). Inhalation anesthetic induction after stomach suctioning has also been described, but the risk of gastric content aspiration still remains (15, 16).

Due to the risks mentioned above, some anesthetists have adopted spinal anesthesia (SA) for pyloromyotomy in infants (17-19). We first started using SA in high-risk premature infants, as reported in our previous study, (18) and subsequently started performing SA in full-term infants as well.

The main outcomes of this retrospective study were to evaluate the postoperative full enteral feeding time, total operating time, and length of hospital stay in infants undergoing open pyloromyotomy under spinal anesthesia. The incidence of postoperative respiratory adverse events and spinal anesthesia complications were evaluated as secondary outcomes.

Methods

The study described below is registered at ClinicalTrials.gov with Identifier NCT02879292.

Following approval by the Bnai Zion Medical Center Ethics Committee, the medical records of infants diagnosed with HPS between 2005 and 2015 at Bnai Zion Medical Center, Haifa, Israel, were retrieved and examined. Data of 100 infants who underwent open pyloromyotomy under SA were collected by a certified research assistant and analysed by a Pediatric Anesthetist.

Patients were considered ready for surgery if they were well hydrated, and had normal skin turgor, moist mucus membranes, normal urine output and normal serum electrolyte values (i.e., serum bicarbonate < 2 7mmol l^{-1} and serum chloride > 100mmol l^{-1}).

The stomach was suctioned through an orogastric or nasogastric tube whilst tilting the patient to the left and right until no further gastric fluid was obtained. SA was then provided, followed by gastric tube withdrawal prior to the beginning of surgery.

In all cases, SA was provided by the same group of eight Consultant Anesthetists, all of whom were experienced in this technique. The infant's back was scrubbed with chlorhexidine. Lumbar puncture was performed in the sitting position with the head extended in a midline approach through either the fourth or fifth lumbar space using a 22 or 25–gauge 4 cm disposable styletted needle. Spinal isobaric bupivacaine 0.5%, 0.8-1.0 mg.kg^{-1} without epinephrine was injected using a 1ml tuberculin syringe.

Standard monitoring during anesthesia included: heart rate (HR), blood pressure by non-invasive means (NIBP), skin temperature and blood oxygen saturation (SpO_2) using the AS/3® monitor (Datex, Engestrom, Helsinki, Finland). These parameters were recorded before performing the spinal block, and subsequently every 5 minutes after the spinal block until the end of surgery.

Effective SA was defined by lack of movement in the lower extremities. The sensory level of anesthesia was determined by observing the patient's segmental response to a tetanic stimulus of 10-30 mA, delivered by a peripheral nerve stimulator (Innervator® NS252, Fisher and Pajkel Healthcare Electronics Ltd, Auckland, New Zealand). Attainment of sensory block was indicated by the lack of crying or flexure of the upper extremities, and by a heart and respiratory rate within 15% of baseline.

Ten minutes after performing the spinal puncture, the site of the skin incision was tested by the surgeon, and in the absence of crying or other pain signs (i.e. a 15% increase in NIBP, HR and respiratory rate), the operation begun. For inadequate relaxation or in cases of persistent movement in the upper extremities without signs of pain, infants were first comforted with glucose solution on a pacifier. If sufficent relaxation was not achieved, intravenous propofol was administered at increments of 1 mg.kg^{-1} to a maximum of 5 mg.kg^{-1}. Alternatively, intravenous midazolam was administered at increments of 0.05 mg.kg^{-1} to a maximum of 0.2 mg.kg^{-1}.

All pyloromyotomies were performed by the same group of two Consultant Pediatric Surgeons, using the open Fredet-Ramstedt technique through a transverse right-upper-quadrant incision. Intraoperatively, infants were hydrated with 5% dextrose in a 0.45% NaCl solution at a rate of 5 ml.kg^{-1}.$h.^{-1}$ using an infusion pump. Intravenous sodium chloride 0.9% was added to replace the gastric fluid losses. Preoperative hypokalemia was corrected with intravenous potassium chloride.

Our pediatric surgical department protocol for enteral feeding after pyloromyotomy involves early feeding with 20-30 ml of Pedialyte® (Abbott Laboratories) on the pediatric surgical ward, which commences when infants demonstrate signs of hunger (i.e., crying or sucking on a pacifier). This is followed by ad-libitum full-strength breast milk or formula as tolerated up to 130ml.kg^{-1} (20, 21).

Total operating room (OR) time was defined as the time between entrance to the operating room until transport to the post-anesthesia care unit (PACU) or the neonatal intensive care unit (NICU).

Postoperative hospital length of stay (LOS) was defined as the number of days between surgery and when infants were discharged home after tolerating 2-3 full enteral feeds without complications.

Surgical time was defined as the time between the surgical incision and the application of wound dressings.

Significant respiratory adverse events included apnea, desaturation and the need for endotracheal intubation, aspiration, and laryngospasm.

All 12 premature infants who were lower than 46 weeks of post-conceptual age (PCA) at time of surgery were monitored in the NICU for the high risk of postoperative apnea (22) using Vitalmon® 5010 (Kontron Instruments, France), with the nursing staff recording occurrences of apnea, desaturation, and bradycardia.

A long apnea was defined as a respiratory pause of at least 15s, or any apnea that coincided with bradycardia. Bradycardia was defined as a heart rate lower than 100 bpm, and hypoxia was defined as O_2 saturation <95% for more than 30s. An increase or decrease in blood pressure and heart rate more than 15% from baseline was considered clinically significant.

Statistical analysis

For the demographic continuous variables (age, weight and height at surgery) and the surgical continuous variables (duration of spinal anesthesia, surgical time, total operating room time, time to full enteral feeding, length of stay) means, standard deviations, medians, ranges and interquartile ranges (IQR; the difference between Q3 and Q1) were calculated. For the categorical variables (number of spinal attempts and sedation required), numbers and percentages were calculated.

For the continuous repeated measures of respiratory rate, oxygen saturation, mean blood pressure and heart rate at six time intervals, the means and standard deviations were calculated, and the results were analysed by the ANOVA repeated measurements with the Box correction of the F test was used.

All statistical tests were analysed to a significance level of 0.05. Statistical analysis was performed using the STATA 12.0 software package (StataCorp. 2011. Stata Statistical Software : Release 12. College Station, TX: StataCorp LP.).

Results

Demographic data are presented in Table 1. Twelve infants were born prematurely and were still considered high-risk at the time of surgery, at lower than 46 weeks of PCA (Table 1). Thus, these infants were monitored for 24 h postoperatively in NICU.

Spinal anesthesia data are presented in Table 2. A satisfactory condition for beginning surgery was achieved in 92 infants. In eight infants the spinal puncture was unsuccessful after a third attempt. They underwent general anesthesia and were excluded from the study. The duration of the spinal motor block was 40-90min (Table 2). The sensory levels achieved ranged between the T3 and T5 spinal segments.

Table 1
Demographic data

	Mean ± SD, median n = 92	IQR, Range
Age at surgery (weeks)	4.4 ± 0.9, 4.0	(4-5), (3-6)
Weight at surgery (kg)	4.21 ± 0.59, 4.05	(4.0-4.5), (3.0-5.6)
Height (cm)	49.3 ± 4.4, 49.5	(45-53), (40-58)
Full term/Premature (%)	80/12, 87/13	

SD = Standard Deviation, QR = Interquartile Range ; the difference between Q3 and Q1.

Table 2
Spinal Anaesthesia Data

	n = 92	Range
Duration (min)	61.9 ± 9.5, 60.0	(55-65), (40-90)
Rate of spinal success / failure	92 / 8*	
Sensory level	T3 – T5	
Spinal attempts (1/2/3) (%)	58/31/3, 63/34/3	
Sedation required (yes/no) (%)	33/59, 36/64	

Values are presented as mean ± SD, medians. Sedation agent (n = 33) : Propofol -25 infants, Midazolam -8 infants
*Excluded from study.

Table 3, shows the cardiorespiratory variables measured at baseline, at 5min after spinal anesthesia, and at 5, 15, 20 and 30 min after the surgical incision. The respiratory rate at 5min after spinal anesthesia was significantly higher vs. the other five time-points ($p = 0.0222$). The heart rate and mean blood pressure however did not vary significantly across the six time-points ($p = 0.353$ and $p = 0.390$ respectively).

Overall, 33 infants received IV sedation (25 received IV propofol, and 8 received IV midazolam). Of the infants receiving propofol, 10

Table 3
Cardiorespiratory variables

	Baseline (n =9 2)	5 min after spinal anesthesia	5 min after incision	15 min after incision	20 min after incision	30 min after incision	p value
RR	34.0 ± 12.6	35.7 ± 6.5*	33.1 ± 4.6	33.7 ± 5.3	34.1 ± 2.2	33.5 ± 2.5	0.0222
O_2 saturation	96.2 ± 1.1	96.4 ± 1.2	96.3 ± 1.1	96.6 ± 1.0	96.4 ± 0.9	96.5 ± 0.9	0.1581
MBP	48.5 ± 7.0	47.4 ± 6.3	46.8 ± 5.0	46.5 ± 5.5	46.4 ± 5.7	46.0 ± 6.8	0.353
HR	151 ± 12.6	147.7 ± 11.5	149.2 ± 12.2	144.5 ± 9.4	144.4 ± 10.3	145.3 ± 8.9	0.390

Data are presented in mean ± standard deviation (SD). RR= Respiratory rate. MBP = mean blood pressure. HR = Heart Rate
* = statistically significantly different with respect to other interval measurements.

Table 4
Summary of surgical outcomes

	Mean ± SD, median	IQR, Range
Surgical time (min)	27.4 ± 4.2, 28.0	(25-30), (20-35)
Total OR time (min)	43.8 ± 7.9, 45.0	(38-50), (28-60)
Time to full enteral feeding (h)	19.3 ± 2.4, 19.0	(18-21), (16-27)
LOS (days)	2.6 ± 0.8, 2.0	(2-3), (2-6)

SD = Standard deviation. IQR = Interquartile Range ; the difference between Q3 and Q1. OR = Operating room. LOS = Length of stay.

required a maximum dose 1 mg.kg^{-1}, and 15 were administered 0.5mg.kg^{-1} of propofol in incremental doses. Of the infants receiving midazolam, three received a maximum dose of 0.15 mg.kg^{-1}, and received 0.10 mg.kg^{-1} in increments. All 33 infants were maintained at light-to-moderate sedation, with none reaching deep sedation. No intraoperative vomiting or aspiration occurred. Fifteen infants (16%) experienced at least one episode of postoperative vomiting. No apnoeic episodes were detected in NICU, and no respiratory complications were detected during surgery, in PACU or on the surgical ward.

Table 4 presents the surgical time, as well as the primary outcome measures (time to postoperative full enteral feeding, total OR time, LOS). Surgical time ranged between 20-35 min. Full enteral feeding was achieved at 16-27 h postoperatively (median = 19 h), and total OR time ranged between 28-60 min. LOS ranged between 2 and 6 days. Three premature infants who suffered pre-existing neonatal respiratory distress syndrome (NRDS) (requiring supplemental oxygen) were discharged at 6 days.

Discussion

All infants in this study began early enteral feeding, and there are no previous studies describing the full enteral feeding time after pyloromyotomy under spinal anesthesia. There is much controversy regarding full enteral feeding times in infants undergoing pyloromyotomy under general anesthesia (GA). Our finding of a 19h median is comparable to the time reported by Hall et al., who found a significantly shorter full feeding time in laparoscopic vs. open surgery (18.5 h *vs*. 23.9 h, p = 0.002) (23).

In their retrospective study published in French, Kretz et al. compared two regimens of enteral feeding after pyloromyotomy under GA and found a shorter full feeding time with the ad-libitum regimen vs. the progressive feeding regimen (35.6 h *vs*. 69 h) (21).

Although Kretz et al. observed a shorter full feeding time with the ad-libitum regimen, an even lower median time (19 h) was observed in our cohort. This could be due to a higher tolerance of milk-containing enteral feeding regimens at incremental ad-libitum dosing when pyloromyotomy is performed under spinal anesthesia.

Our mean OR time of 43.8 ± 7.9 min can be considered relatively short when compared to pyloromyotomy under GA, as found in previous retrospective studies. Katcko et al. compared OR time in 60 infants divided into two groups: pyloromyotomy under SA (n = 24) and pyloromyotomy under GA (n = 36). The authors found a significantly shorter mean OR time in the SA vs. the GA group (50.9 min *vs*. 69.5 min; p = 0.001), and attributed this to the difference in "wake-up" times. (19)

In a recent study involving full-term and premature infants, Ing et al. also found a shorter mean OR time in the SA (n = 218) *vs*. the GA (n = 206) groups (69 ± 18.3min *vs*. 87.7 ± 22 min; p < 0.0001) (24).

The median postoperative LOS in our study was 2 days, which was longer than the LOS found by Ing et al., where the authors found LOS to be 1.19 times longer in the GA *vs*. the SA group (p < 0.02) (24). Our LOS results were however comparable with those of Van der Bilt et al., who investigated

infants undergoing laparoscopic pyloromyotomy with a mean LOS of 55.4 ± 42.7 h (25).

Prematurely born infants are particularly susceptible to postoperative apnea, desaturation and bradycardia when undergoing surgery under GA *vs*. SA, as found by cohort studies (26-28). These infants constitute 10% to 12% of infants with HPS undergoing pyloromyotomy under GA (1, 29). Pediatric anesthesiologists still prefer the use of SA in these high-risk infants despite the lack of convincing evidence to support the routine use of SA in ex-premature infants undergoing inguinal hernia repair, as concluded in a metanalysis by Craven et al. (30).

Of the 12 premature infants in this study who were monitored in the NICU, none experienced apnea. The same result was obtained in our previous study in pyloromyotomy under spinal anesthesia in the four infants who were born prematurely and were still considered high-risk at the time of surgery, with 39-45 weeks postconceptional age.

In their recent prospective study with large numbers of premature and ex-premature infants undergoing infaumbilical surgery, Davidson et al. found that apnea in the first 30 min of recovery was lower in the regional anesthesia (n = 363) *vs*. the GA (n = 359) group (1% *vs*. 3%; p = 0.0367). However, the authors found no significant differences after the 30 min threshold (2% in both groups), and concluded that the main risk factor for postoperative apnea was prematurity itself (31).

The immediate postoperative complications in the pediatric population after GA are related to the respiratory system (i.e., laryngospasm, bronchospasm, pulmonary aspiration). These adverse events can be predicted in patients who are lower than 1 year old, in children whose American Society of Anesthesiologists (ASA) physical status is high, and in patients who are mechanically ventilated (32, 33).

No postoperative respiratory adverse events, and no aspiration or high spinal anesthesia events requiring endotracheal intubation occurred in this study, even in patients requiring intravenous sedation. In comparison, Ing et al. identified 2 infants out of 218 who received SA, and who experienced respiratory adverse events (laryngospasm, apnea), and one infant requiring endotracheal intubation (24). However, these rates are still considered low, when the denominator and the high-risk status of premature infants is considered. We postulate that spinal anesthesia as implemented in the present study, together with appropriate preoperative preparation, contributed to the absence of of intra- and postoperative respiratory complications.

Earlier studies concluded that spinal anesthesia does not influence blood pressure in small infants. This was attributed to the immaturity of the sympathetic nervous system, and to the lower venous capacitance in the lower extremities (34, 35). A more recent study of 12 pre-term infants receiving SA demonstrated a significant reduction in cerebral blood flow velocity, as well as in systemic blood pressure variables (36). This corresponded to an increased cerebral artery resistance index and led the authors to conclude that SA significantly affects systemic arterial and cerebral hemodynamics, with (as of yet) undetermined clinical implications (36). The authors recognised that previous groups used hyperbaric tetracaine as opposed to bupivacaine, which may account for the discordance in hemodynamic findings. Returning to our study, hemodynamic stability was observed in all 92 patients following 0.5% isobaric bupivacaine at doses comparable to those reported by Bonnet et al. (0.8-1.0 $mg.kg^{-1}$ *vs*. 1.0 $mg.kg^{-1}$). It would be informative in the future to stratify patients according to bupivacaine dose and to measure systemic and cerebral hemodynamic variables as per Bonnet et al. This could potentially establish whether hemodynamic outcomes are subject to sample-size or other sources of bias, and may elucidate clinical effects in sufficiently large numbers of participants. Another avenue of future research may involve the prospective comparison of SA vs. GA in laparoscopic pyloromyotomy. This has been studied in small numbers (n = 24) with no significant difference in physiological variables, but with a significantly reduced time to leave the operating theatre in the SA group (37).

Overall, the results of this retrospective study suggest that spinal anesthesia is effective and safe. Specifically, spinal anesthesia in pyloromyotomy is associated with short time to full enteral feeding, a short operating room time, and a short length of hospital stay. Furthermore, it carries a very low risk of respiratory complications. Finally, we suggest that randomised trials should be undertaken comparing SA and GA in patients undergoing open pyloromyotomy for HPS.

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