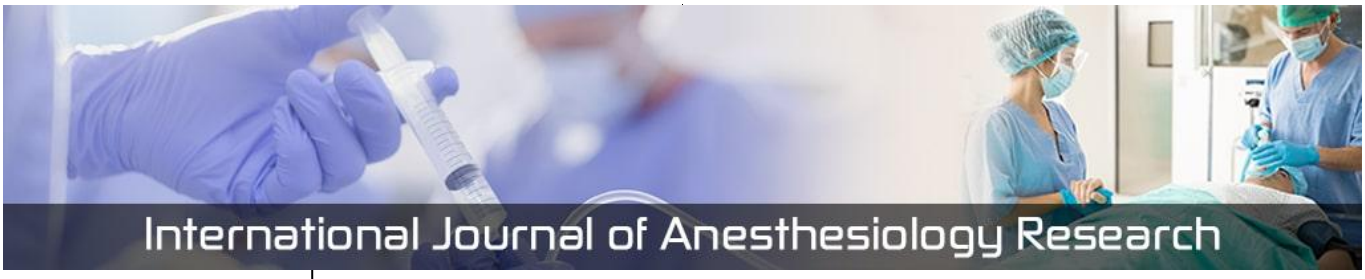

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Stress response and hemodynamic changes associated with intrathecal anesthesia versus caudal epidural anesthesia in infants undergoing laparoscopic inguinal herniorrhaphy: Prospective randomized control study

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Abstract
Introduction: Intrathecal and caudal blocks regulate hemodynamics, reduce neuroendocrine responses, enhance recovery, improve pain relief, and minimize opioid side effects.
Objective: To evaluate the influence of intrathecal anesthesia on infants' stress responses and hemodynamics compared to caudal epidural anesthesia for laparoscopic inguinal herniorrhaphy.
Methods: This prospective randomized control study involved 120 patients aged from full term one month to year, both sexes, with laparoscopic inguinal herniorrhaphy, allocated into three groups. Control Group (C): General anesthesia (GA) group, intrathecal Group (I) and caudal block group (E).
Results: Groups I and E had significantly reduced sevoflurane consumption intraoperatively than Group C, and Group I had a lower consumption than Group E (p<0.001). Groups I and Group E had significantly lower total analgesic intake and rescue analgesia needs in comparison to Group C (p<0.001), while no substantial variation in Groups I and E had considerably lower FLACC scores immediately after surgery than Group C, and Group I had a lower score than Group E (p<0.001). Groups I and E exhibited significantly lower FLACC scores at 6, 12, and 24 hours than Group C (P <0.001).
Conclusions: Intrathecal anesthesia is effective and safe in providing intraoperative analgesia in infants undergoing laparoscopic inguinal herniorrhaphy with lower stress response in the form of decrease in serum glucose and serum cortisol level, intraoperative anesthetic consumption, total analgesics consumption, need for rescue analgesia post operative, pain score and better hemodynamics intra operative compared to caudal epidural anesthesia (CEA) and GA.

Keywords: Stress response, hemodynamic changes, intrathecal anesthesia, caudal epidural anesthesia, laparoscopic inguinal herniorrhaphy

Introduction
Intrathecal anesthesia and caudal blocks, first introduced decades ago, have proven to be safe and effective for various laparoscopic abdominal surgeries. These techniques provide total muscle relaxation and analgesia in conscious patients, reducing the need for opioids and anesthetic drugs, while minimizing airway manipulation [1].
Between 1990 and 2000, the use of intrathecal anesthesia in neonates and preterm infants rose from 2.1% to 3.6% in regional anesthesia [2]. Today, intrathecal anesthesia is commonly used in pediatric anesthesia, accounting for up to 95.4% of cases, particularly in preterm infants. It helps prevent perioperative complications such as hypoxemia, bradycardia, and hypotension associated with general anesthesia [3, 4].
Caudal blocks are frequently employed for intraoperative and postoperative analgesia in pediatric surgery. In children, central neuraxial blocks are critical for acute postoperative pain management, aiming to eliminate pain, ensure rapid recovery, and prevent chronic pain or hyperalgesia [5]. Acute postoperative pain can evolve into chronic pain in 10%–50% of adults and 20% of children who undergo major surgeries. So caudal block has an important advantage in controlling acute postoperative pain [6]. Another advantage of intrathecal anesthesia and caudal blocks is that they use significantly lower opioid doses compared to

traditional general anesthesia, reducing side effects such as ventilatory depression, reduced gut motility, and immune function modulation [7, 8]. This allows for enhanced recovery, improved pain control, and fewer respiratory complications and dysrhythmias [9].

The aim of this work was to assess stress response and hemodynamic changes associated with intrathecal anesthesia versus caudal epidural anesthesia in infants undergoing laparoscopic inguinal herniorrhaphy.

Methods

This prospective randomized control study involved 120 cases aged from full term one month to year, both sexes, with clinical criteria of laparoscopic inguinal herniorrhaphy. This study was carried out following the approval of the Ethical Committee (Approval code: 35680/8/22). The case's relatives gave their signed, informed consent.

The exclusion criteria were diseases of the central nervous system, metabolic and coagulation defects, pre-term infant, infection at site of injection, congenital anomaly in vertebral column, use of corticosteroids and respiratory dysfunction

Patient randomization

To create a random list, an internet randomization program (http://www.randomizer.org) was utilized. cases were randomly allocated with a 1:1:1 allocation ratio into three groups in a parallel manner. The following groups were assigned to each patient at random: control group (C): GA group, intrathecal group (I), and caudal block group (E).

The patients' medical and surgical histories were obtained, and they underwent a clinical examination that included vital signs, cardiovascular, respiratory, abdominal, neurological, and airway evaluation. A complete blood count, coagulation profile, diagnostic testing for the liver and kidneys, and other standard laboratory evaluations were also performed.

The pre-operative fasting guidelines of ASA permit the consumption of clear liquids for up to 2 hours, unclear fluids for up to four hours, non-human milk and light meals for up to 6 hours, and prepared food and meat for up to eight hours before the procedure [10].

Intraoperatively, on entering the operating room, monitoring: ECG, noninvasive BP, pulse oximetry, capnogram, and temperature probe were used.

Throughout the procedure, important health indicators such as peripheral O_2 saturation, heart rate (HR), and noninvasive measurements of systolic, diastolic, and Mean Arterial Pressure (MAP) were taken every 5 minutes. Basic vitals like temperature, $ETCO_2$, serum cortisol, and glucose were measured before and after the operation. For cases with clinically significant hypotension, which is characterized as a 20% drop in systolic arterial blood pressure from baseline values, 1.2 mg/kg of ephedrine was given IV [11]. Atropine, at a dosage of 0.02 mg/kg, was injected in response to a decrease in HR to less than a hundred beats per minute or a decrease of more than 20% from baseline [12].

In group (I), 2% sevoflurane was administered through a Jackson-Rees modification of the Ayre's T-piece and a well-fitting face mask in oxygen (total flow 6 liters per minute). The cumulative dose of any medications and fluid requirement during the operation were recorded. Every four to six breaths, the sevoflurane concentration was raised by 2%, up to a maximum of 8%. Once the eyelid reflex was lost, the dosage of sevoflurane was lowered to 5% until the level of anesthesia was determined to be enough for intravenous cannulation. The utilization of an endotracheal tube of the right size was made possible by administering atracurium with dose 0.5 mg/kg [13].

End tidal expiratory sevoflurane (2%), a mix of 50% O_2 and 50% air, was employed to maintain anesthesia. Atracurium additional doses of 0.1 mg/kg were carried out 20-45 minutes after the initial dosage to keep up neuromuscular block and keep the muscles relaxed during the procedure. The cases were classified into three groups: those given GA, those given a caudal block, and those given intrathecal oxygen therapy. The goal of the ventilator adjustments was to keep the $ETCO_2$ level around 35 mm Hg. Following administration of the anesthesia in accordance with the patient's assigned group, surgical intervention commenced.

In group (C), GA inducted as described before and all patient in this group received fentanyl in a dose (1 µg/kg).

In group (I): received GA as described before.

Position: A dural puncture in the lumbar region was required, as was sterilizing the infant's skin with 10% povidone iodine and placing him on his side with his back curved. Considering that the spinal cord terminates at L3 in most neonates and possibly lower, the optimal weight for the patient informed the calculation of the needle placement at both the L4/5 or L5/S1 interspace [5, 6], dose of heavy Marcaine 0.5%: 0.5 mg/ kg [14] starting at around 6 mm at birth, the gap in the skin and the epidural space increases to 10-12 mm after one year. One milligram per kilogram is another estimate. Spinal needles for children are Rap ID, with a pencil point, a length of 90 mm, and a gauge of 27G [5].

In group (E): received GA as described above.

Position: A significant cephalad shift of the dural sac is associated with the lateral placement of cases with their pelvis, neck, and knees fully extended.

When palpated, the sacral cornus and sacral hiatus were both marked. After immersing the skin in 10% povidone iodine for sterilization, a 22-gauge needle was placed at an angle of 60 to 80 degrees until the sacrococcygeal ligament was pierced, as indicated by a bursting feeling. Once the results of the aspiration were negative for blood and CSF, in order to make it easier to penetrate the sacral canal, A reduction of 20 to 30 degrees was made to the needle's position. and its insertion depth was raised by 2 to 3 mm. The LA solution, which contained 0.25% bupivacaine and had a total volume of 1 mL/kg, was injected over a 1-minute period being subjected to tight hemodynamic and ECG monitoring. In the event that the needle came into contact with bone, aspirated blood, or caused subcutaneous tissue bulging, the intervention operation would have to be redone., and the needle's angle was altered. The dose of bupivacaine was 0.25% at a volume of 1 ml/kg, assuming a healthy weight [15], a supine position was adopted by the infants following the injection of the LA mixture in all procedures. The position was adjusted in accordance with the surgical approach, and the surgery commenced, the same surgical team, which was qualified and experienced in these types of operations, performed all surgical procedures. Following the procedure, the patient was given a mix of neostigmine (0.04 mg/kg) and atropine (0.01 mg/kg) to mitigate the effects of the muscle relaxers. Once all the

necessary conditions were satisfied for extubation, the case was transported to the recovery room [16], HR or MAP increase of more than 20% from the baseline during surgery would indicate a failure of block performance and require the administration of Intravenous (IV) opioid analgesic in the form of fentanyl (1 µg/kg) [17], records were maintained for any episodes of bradycardia or hypotension. Bradycardia (HR less than 100 b/min) was managed with an IV injection of atropine (0.01-0.02 mg/kg), which may be given again if necessary. Patients experiencing hypotension (defined as a drop in MAP of 20% or more from the initial measurement) were given intravenous saline in addition to a shot of vasopressor (0.3 mg/kg Ephedrine). If no response was observed, the treatment may be repeated [18]. If Local Anesthetic Systemic Toxicity (LAST) manifested as seizures, tachyarrhythmia, apnea, or cardiovascular collapse, it would be promptly addressed through the administration of oxygen, control of airway, and the management of seizures with midazolam and thiopental. A bolus of intralipids 1.5 ml/kg of 20% emulsion of lipid was given IV within a 1min period to resolve the cardiovascular toxicity. This procedure may be repeated as necessary [19].

Blood collection and preparation, blood samples of 2 ml were obtained in a plain tube and transported to the Department of Clinical Pathology for analysis. The samples were analyzed using Konilab for glucose and Chemiluminecence TOSO for cortisol. The standard laboratory procedures were followed to analyze all blood samples in the same biochemical laboratory. The normal serum glucose level was 70:170 mg/dl, and the laboratory reference indicates that the normal serum cortisol level ranged from 120 to 360 nmol/L.

Measures to maintain normothermia perioperative [20]

During transport: During anesthesia, all infants are dressed and covered with blankets for as long as feasible. The operating room is heated to a temperature within the thermoneutral range to ensure that the children remain warm before the induction of anesthesia. Esophageal or nasopharyngeal probes are employed. For infants, an ambient temperature of 24 °C to 30 °C is suitable.

Active warming therapy before induction of anesthesia: During anesthesia, all infants are dressed and covered with blankets for as long as feasible. The operating room is heated to a temperature within the thermoneutral range to ensure that the children remain warm before the induction of anesthesia. Esophageal or nasopharyngeal probes are employed. For infants, an ambient temperature of 24°C to 30°C is suitable.

During anesthesia and surgery: Active warming therapy was maintained through the utilization of forced-air warmer irrigation solutions to elevate body temperatures. Devices that transfer heat and moisture to lessen the rate of heat loss by evaporation from the airways. Blood and fluid warmers are employed to warm fluids and blood. Following anesthesia, each neonate is returned to a preheated bed in the postoperative phase. Postoperatively, the cases were relocated to the PACU. If the Face, Legs, Activity, Cry, Consolability (FLACC) score was between 2 and 4 within a 6-hour time interval, a highest daily dose of 60 mg/kg of IV paracetamol was given. IV Tramadol 1 mg/kg is administered intravenously in the event that the FLACC score exceeds 4 within the first 24 hours following surgery.

The FLACC scale is a pain assessment tool for children aged one month to 7 years, specifically created for those who cannot articulate their pain. Five categories of behavior are included in this scale, each of which is from 0 to 2, leading to total score of 0-10. A score of 0 determines no pain, while a score of 10 determines the greatest degree of pain [21], Patients were removed from the PACU upon meeting the standards criteria: normal consciousness, stable vital signs, signs of motor block regression (Bromage 0 to 2), no analgesia required within the previous 20 minutes. During the postoperative period, the time to self-void urine was notated.

During the postoperative period, patients were evaluated for pain using the FLACC scale. In addition to the postoperative assessment of serum glucose and cortisol at 6, 12, and 24 hours, the ingestion of any analgesics was recorded and compared [22, 23].

The primary outcome was stress response to surgery (cortisol and glucose) in infant patients who undergoing laparoscopic inguinal herniorrhaphy. The secondary outcomes were hemodynamic changes, anesthetic requirements intraoperative and analgesic requirements post operatively.

Sample size calculation

The sample size and power analysis were determined by the Epi-Info software statistical application, which was developed by the World Health Organization and the Center for Disease Control and Prevention in Atlanta, Georgia, USA in 2002. The following criteria were employed for the sample size calculation: The 95% confidence limit, 80% power of the study, and anticipated elevated stress response in the best treatment group are 90%, while the least favorable treatment group is at 65%. The sample size for each cohort was indicated to be N > 37, as per the aforementioned criteria. The sample size was increased to 40 by the researcher to account for the incomplete results.

Statistical analysis

The IBM SPSS software program version 20.0 (Armonk, NY: IBM Corp) was employed to analyze the data that was inputted into the computer. Percentages and numbers were employed to characterize qualitative data. The distribution normality was confirmed by the Kolmogorov-Smirnov test. Range (minimum and maximum), mean, standard deviation, median, and Interquartile Range (IQR) were employed to describe quantitative data. The chi-square test ($\chi 2$) was employed to compare categorical variables in distinct groups. Comparing quantitative variables that were distributed normally among distinct groups, the one-way ANOVA test (F) was implemented. To compare non-parametric quantitative variables between distinct groups, Kruskal-Wallis's test (H) was implemented. A significant level of 5% was utilized to evaluate the results.

Results

One hundred thirty-eight patients were considered for the trial; Twelve participants were ineligible, and six rejected to take part. We divided the left 120 cases into three equal groups (40 in each). Full statistical analysis and follow-up was performed on all assigned patients. Figure 1

In terms of demographic data and operating time, none of the 3 groups differed significantly. Table 1

No substantial variation found in the three groups' serum glucose and cortisol levels either before or at 24h. Groups I

and E had significantly lower levels of serum glucose and cortisol at 6 and 12 hours post-operatively than Group C, and Group I had lower levels than Group E (p<0.05). The use of intraoperative sevoflurane consumption was reduced in Groups I and E in comparison to Group C and I relative to Group E (p<0.001). Table 2

There is no considerable difference in HR and MAP in the 3 groups at baseline and after induction. Groups I and E had considerably lower HR at 15, 30, 45, and 60 minutes than Group C, and Group I had a lower HR than Group E (p<0.05). Figure 2

The intraoperative intake of sevoflurane was considerably decreased in Groups I and E in comparison to Group C, and in Group I in comparison to Group E, with (p<0.001) Group I also had lower levels of serum glucose and cortisol. Groups I and E had significantly lower total analgesic intake and rescue analgesia needs in comparison to Group C (p<0.001), No considerable difference in Groups I and E. Table 3

In comparison to Group C, the FLACC score was markedly lower in Groups I, E immediately postoperatively, and in Groups I in comparison to E (p<0.001). Groups I and E exhibited significantly lower FLACC scores at 6, 12, and 24 hours than Group C (p<0.001), while there was no substantial difference in Groups I and E. Table 4

Table 1: Comparison of studied groups as recorded by as recorded by operation time according to demographic data and operation time

		Group C (n=40)	Group I (n=40)	Group E (n=40)	p-value
Age (months)		6.15±3.11	6.2±3.16	5.9±3.07	0.899
Sex	Female	8(20.0%)	11(27.5%)	6(15.0%)	0.383
	Male	32(80.0%)	29(72.5%)	34(85.0%)	
Weight (kg)		6.38±2.02	6.71±1.97	6.86±1.85	0.528
Operation time (min)		69.45±9.4	70.58±9.2	71.45±8.66	0.616

Data are presented as mean ± SD or frequency (%).

Table 2: Comparison in studied groups as regards serum glucose and cortisol level

	Group C (n=40)	Group I (n=40)	Group E (n=40)	p-value	Post Hoc
Serum glucose level (gm/dl)					
Pre-operative	109. ±18.09	105.2±15.48	111.5±14.14	0.216	
Post-operative	124.5±11.1	106.3 ± 20.12	115.3±16.67	<0.001*	P1<0.001* P2=0.037* P3=0.04*
6h	113.1±14.65	89.9±12.86	99.6±18.31	<0.001*	P1<0.001* P2<0.001* P3=0.016*
12h	111±17.09	88.7±14.62	97.9±19.28	<0.001*	P1<0.001* P2=0.002* P3=0.047*
24h	95.4±17.53	87.1±17.71	92.9±14.84	0.080	
Serum cortisol level					
Pre-operative	447.6 ± 108.88	466.5±107.16	445.9±114.43	0.652	
Post-operative	633.6 ± 116.71	467.1±145.44	537.2±119.02	<0.001*	P1<0.001* P2=0.003* p3=0.041*
6h	602.3 ± 132.36	459.1±117.96	535.1±120.45	<0.001*	P1<0.001* P2=0.044* P3=0.019*
12h	589.7±93.38	414.2±147.18	510.5±135.43	<0.001*	P1<0.001* P2=0.017* P3=0.003*
24h	493.7 ± 117.89	446.4±112.02	468.6 ± 119.21	0.196	

Data is presented as mean ± SD. * Significant as P value <0.05, P1: P value between Group C and Group I, P2: P value between Group C and Group E, P3: P value between Group I and Group E.

Table 3: Comparison in studied groups as indicated by intraoperative anesthetic consumption of sevoflurane, total analgesics consumption and need for rescue analgesia

	Group C (n=40)	Group I (n=40)	Group E (n=40)	p-value	Post Hoc
Intraoperative anesthetic consumption of sevoflurane (ml)	32.8±4.52	23.6±1.88	29.2±5.98	<0.001*	P1<0.001* P2=0.002* P3<0.001*
Total analgesics consumption	360.7 ± 114.05	177.2 ± 67.44	191.7 ± 55.8	<0.001*	P1<0.001* P2<0.001* P3=0.714
Need for rescue analgesia	17 (42.5%)	7 (17.5%)	3 (7.5%)	<0.001*	P1=0.015* P2<0.001* P3=0.176

Data are presented as Mean ± SD or frequency (%). * Significant as P value <0.05, P1: P value between Group C and Group I, P2: P value between Group C and Group E, P3: P value between Group I and Group E.

Table 4: Comparison in studied groups in terms of FLACC score

	Group C (n=40)	Group I (n=40)	Group E (n=40)	p-value	Post Hoc
FLACC score					
Immediately postoperative	7 (6-8)	2 (1-2)	3 (3-4)	<0.001*	P1<0.001 P2<0.001* P3<0.001*
6h	5 (4-5)	4 (3-5)	3 (3-5)	<0.001*	P1<0.001* P2=0.016* P3=0.180
12h	4 (4-5.75)	3 (3-4)	4 (3-4)	<0.001*	P1<0.001* P2 <0.001* P3=0.146
24h	4 (3-5)	3 (3-4)	3(3-4)	<0.001*	P1<0.001* P2<0.001* P3=0.276

Data are presented as Median (IQR) or frequency (%). FLACC: score The Face, Legs, Activity, Cry, Consolability. *Significant as P value <0.05, P1: P value between Group C and Group I, P2: P value between Group C and Group E, P3: P value between Group I and Group E.

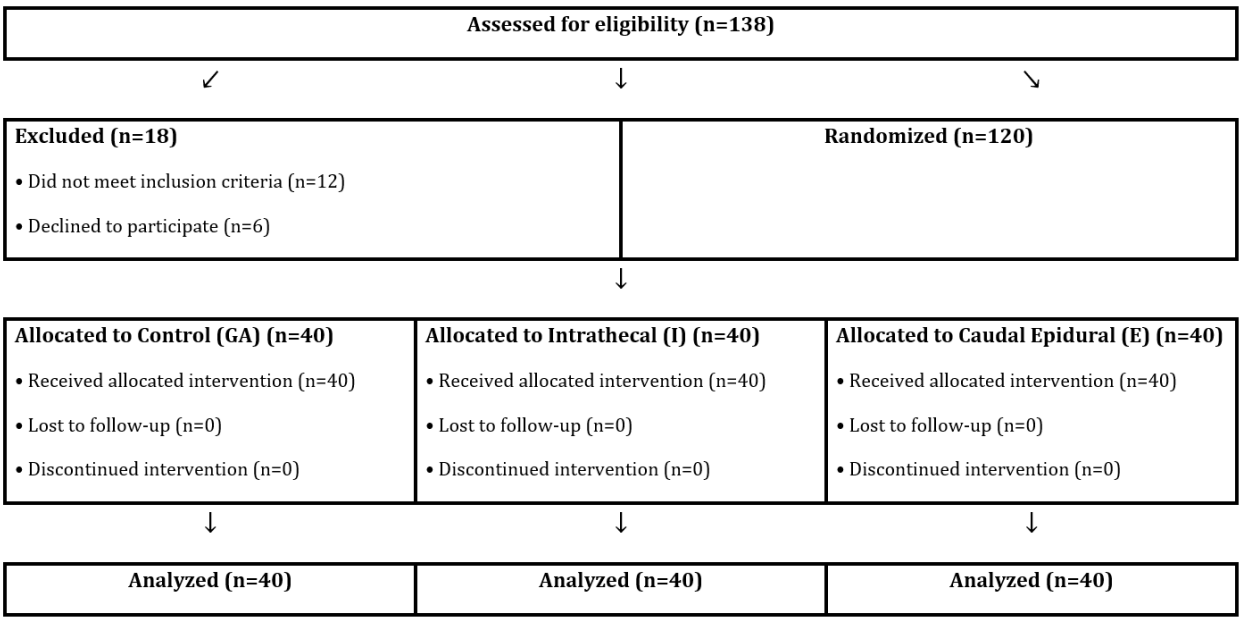
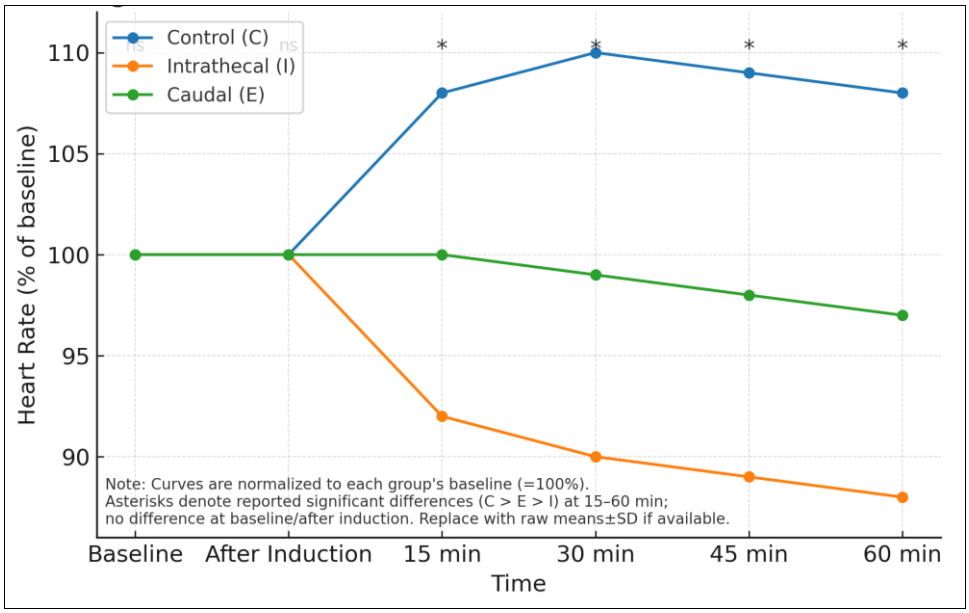
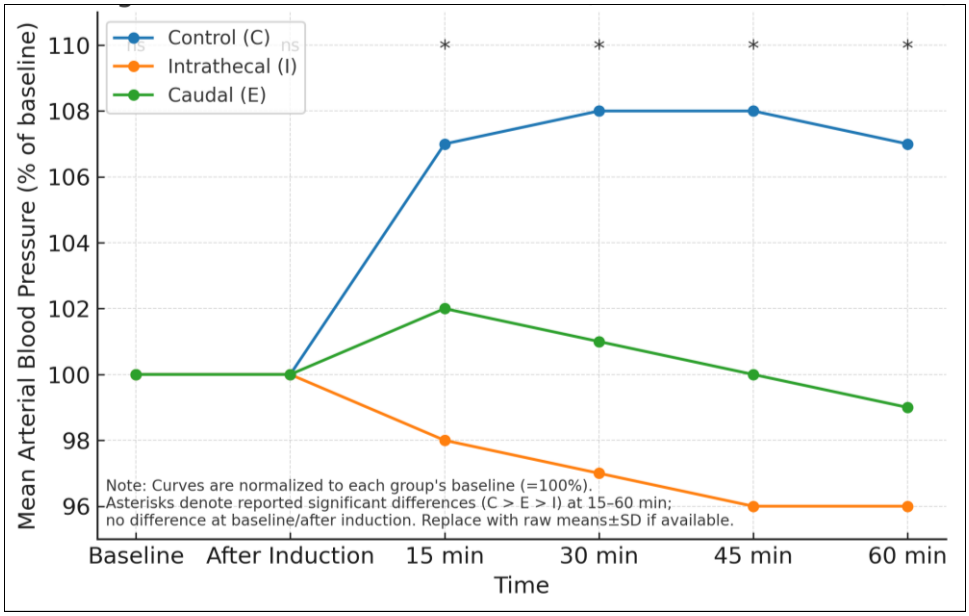


Fig 1: CONSORT flow chart of the studied patients



A) Heart rate over time (normalized to baseline



B) Mean ABP over time (normalized to baseline)

Figure 2: Comparison among the three groups as regard (A) HR and (B) mean ABP

Discussion

In the neonate and infant, the hormonal and metabolic responses to surgery are severe and potentially detrimental during surgical procedures. Surgical procedures cause an increase in β-endorphins, catecholamines, growth hormone, cortisol, and glucagon levels in infants, leading to a significant catabolic drive both during and after the procedure. This is marked by increased oxygen consumption, glucose, lactate, pyruvate, tissue glycogen, and protein catabolism, all of which a sensitive infant has a hard time coping with [24].

Taking high doses of opiates can help alleviate some of the severe metabolic and hormonal stress reactions to operation and the pain that follows it. The additional benefits of high-dose opiates include an increased threshold for ventricular fibrillation; however, opiates cause severe respiratory depression, necessitating a period of breathing apparatus. Furthermore, high-dose opiates reduce pulmonary hypertensive crises and blunt pulmonary vascular reactivity in neonates with pulmonary hypertension [25].

In the current study, the serum glucose level was considerably decreased in intrathecal and caudal block groups than control cases at 6 and 12 hours postoperatively, and in intrathecal group when compared to caudal block group.

In comparison the findings, Samuel et al. [26] reported that the amount serum glucose at beginning and five minutes after induction were not substantially different in the spinal and GA groups. However, the mean blood glucose amounts in spinal anesthesia group were markedly lower compared to those in GA group at the termination of the surgery and 60 minutes following the last surgical procedure. The outcomes are conforming to those of Vakamudi et al. [27] who also found that the caudal block group had substantially lower serum glucose levels than the intravenous analgesia group. Our findings are supported by the work of Benka et al. [28] revealed that children who underwent caudal block, their serum glucose levels were significantly lower than those who underwent GA alone. In addition, Milosavljevic et al. [29] discovered a significantly lesser serum glucose value in the spinal anesthesia group in comparison to GA group.

Our results revealed no substantial difference in serum cortisol levels in the 3 groups at either the pre- or post-operative during 24-hour. Both the intrathecal and caudal block groups had serum cortisol levels that were markedly lower in comparison to control group at 6 and 12 hours post-operatively; the intrathecal group also had lower levels than the caudal block group.

Benka et al. [28] confirmed our findings by demonstrating that the serum cortisol level was statistically considerably lower in caudal block group when comparison to GA group at 30 minutes postoperatively. Vakamudi et al. [27] revealed that the serum cortisol level was markedly decreased in caudal block group than intravenous analgesia cases. In accordance with our findings, Milosavljevic et al. [29] established that the serum cortisol level was considerably lower in spinal anesthesia group than GA group. Contrasting to our findings, Pangasa et al. [30] demonstrated that the intrathecal group had substantially greater cortisol of serum range than caudal block group at 6 and 24 hours postoperatively. The difference might be because the two groups' surgeons and anesthesiologists utilized separate kinds of local anesthetics combining morphine and bupivacaine, but, in our trial, the intrathecal group received Marcaine while the caudal block group received bupivacaine.

In comparison to the control group, the intraoperative anesthetic consumption of sevoflurane was considerably lower in intrathecal and caudal block groups, and in intrathecal cases when compared to caudal block cases in this current study. This came consistent with our results, Pandurov et al. [31] revealed that intraoperative anesthetic talking was considerable lower in caudal block group compared to in GA group. Similarly, to our findings, Gawe et al. [32] discovered that the intraoperative anesthetic intake was markedly decreased in caudal epidural block cases than the GA only cases. In addition, Lin et al. [33] showed that the intraoperative anesthetic taking was notably decreased in caudal block cases compared to the GA cases. Comparable

with our results, Kim et al. [34] revealed that sevoflurane taking was substantially decreased in caudal group than in control group.

In this study, the HR and MAP were notably decreased in intrathecal and caudal block cases in comparison to control group at 15, 30, 45, and 60 minutes, and in intrathecal cases compared in caudal block cases. According to Pandurov et al [31] found that the caudal block group had considerably lower HR and MAP than the general anesthetic group, which is in keeping with our results. Our investigations are in line with those of Lin et al. [33] who additionally observed a statistically significant decrease in HR and no change in MAP between the caudal block and general anesthetic groups. This discrepancy could be explained by the fact that our group employed 0.25% bupivacaine with volume of 1 ml/kg, whereas caudal block group used 0.15% ropivacaine and 1.0% lidocaine with dose of 0.8 ml/kg.

This work's single-center design was one of its key limitations. Because of this, the sample size was small. Duration of the research was short. We did not use different types of anesthetic drugs. We did not compare intrathecal anesthesia with other anesthetic procedures rather than caudal epidural anesthesia.

Conclusions:

Compared to caudal epidural anesthesia (CEA) and GA, decrease intrathecal anesthesia is safe and effective in reducing the need for postoperative analgesia in infants undergoing laparoscopic inguinal herniorrhaphy. It also leads to lower levels of serum glucose and cortisol, less consumption of intraoperative anesthetics and total analgesics, less pain scores, and better hemodynamics.

Abbreviations

C: Control Group
GA: General anesthesia
I: intrathecal Group
E: caudal block group
HR: heart rate
MAP: mean arterial pressure
LAST: local anesthetic systemic toxicity
FLACC: Face, Legs, Activity, Cry, Consolability
IQR: interquartile range
CEA: caudal epidural anesthesia

Declarations:

Ethics approval and consent to participate:

This study was carried out following the approval of the Ethical Committee (Approval code: 35680/8/22). The case's relatives gave their signed, informed consent.

Consent for publication: Not applicable

Availability of data and materials: Data is available upon reasonable request from the corresponding author.

Conflicts of Interest: Not applicable

Funding: No funding was received for conducting this study.

Author contribution: All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by MMIH, MAEB, AAY and JMED. The first draft of the manuscript was written by SMR and all authors commented on previous versions of the manuscript. All authors read and approved of the final manuscript.

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