

## ORIGINAL RESEARCH

## ANESTHESIOLOGY

# A randomized controlled trial comparing spinal and general anesthesia in neonates undergoing inguinal herniorrhaphy

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## ABSTRACT

**Background & objectives:** Although spinal anesthesia (SA) has largely replaced general anesthesia (GA) for inguinal herniorrhaphy (IH), the anesthetist might be compelled to go for GA in some special cases, including patient refusal to have SA, or neonates, young children or female patients. We conducted this study to compare the efficacy of SA and GA in neonates undergoing inguinal herniorrhaphy (IH).

**Methodology:** This randomized controlled study was conducted on 74 neonates classified as American Society of Anesthesiology physical status I-II undergoing IH. The patients were randomized equally into two groups. GA group: GA was maintained with 2% sevoflurane. SA group: SA was performed using 0.6 mg/kg of bupivacaine 0.5%. The patients were sedated by administering intermittent injections of ketamine 1 mg, as required. Oxygen was administered through a nasal cannula.

**Results:** The heart rate measurements were significantly higher, and mean arterial blood pressure measurements were significantly lower at 20, 30, 40, 50, and 60min intraoperatively, 30, 60, 90, and 120min in PACU in the SA in comparison to GA group ( $P < 0.05$ ). Oxygen ( $O_2$ ) saturation measurements were significantly higher at 30, 60, 90, and 120 min in PACU in the SA in comparison to the GA group ( $P < 0.05$ ). There was no discernible variation within both groups in the incidence of bradycardia, hypotension, the need for postoperative  $O_2$  supplementation, and hospital stays. The incidence of apnea was substantially decreased in the SA group compared to the GA group (12 (32.43%) vs 4 (10.81%),  $P = 0.045$ ).

**Conclusions:** SA is a viable alternative for GA in neonates undergoing IH, as it offers better hemodynamic and  $O_2$  saturation stability and reduces postoperative apnea.

**Abbreviations:** IH: inguinal herniorrhaphy, GA: general anesthesia, PACU: post-anesthesia care unit SA: spinal anesthesia,

**Keywords:** Spinal anesthesia; General anesthesia; Herniorrhaphy; Neonates; Heart rate

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## 1. INTRODUCTION

Inguinal hernia is a prevalent surgical issue, with a prevalence of 1:3000 births. Early surgery prevents incarceration, bowel ischemia, and gonadal infarction.<sup>1</sup>

The physiology of neonates is distinguished by a high metabolic rate and a restricted cardiac, pulmonary, renal, and thermoregulatory reserve. The neurocognitive development of the neonate may be adversely affected by these metabolic and hemodynamic alterations in the perioperative period. This immaturity generates differences in the pharmacokinetics and dynamics of the drug compared to older children or adults.<sup>2</sup>

With general anesthesia (GA), patients may need positive pressure ventilation assistance. Also, GA impairs cardiovascular function. Either inhalational or intravenous drugs can deliver GA. Neonates are more vulnerable to hypotension, which may impair cerebral perfusion. So, maintaining normotension and normocarbida is highly important intraoperatively.<sup>3</sup> Also, complications of GA are significantly increased in neonates, including apnea and bradycardia.<sup>4,5</sup>

In neonates, regional anesthesia (RA) may be beneficial for many clinical reasons. These include the avoidance of respiratory depression or airway manipulation.<sup>6</sup> Moreover, RA improves perioperative pain management and decreases the possible neurotoxic effects of the drug used in GA.<sup>2</sup>

Spinal anesthesia (SA) is a cost-effective, straightforward, and rapid technique primarily employed in pediatric anesthesia, including infants, neonates, and the preterm.<sup>7-10</sup> SA facilitates the prevention and mitigation of perioperative complications.<sup>11</sup>

A minimal risk of postoperative events was observed in a large observational study of SA for infants undergoing inguinal herniorrhaphy (IH).<sup>12</sup> Compared to GA, SA reduces respiratory morbidity and oxygen (O<sub>2</sub>) desaturation in babies who were born prematurely and had IH postoperatively.<sup>13</sup> This study aims to compare SA and GA in neonates undergoing IH to broaden our understanding of this concept.

## 2. METHODOLOGY

We conducted this open-label, randomized controlled study on a sample of 74 neonates, both sexes, American Society of Anesthesiology (ASA) physical status I-II who underwent IH. The study was done at Tanta University Hospitals, Egypt, after approval from the institutional ethical committee and registration at clinicaltrials.gov (NCT06352606) from February 2024 to July 2024. Informed written consent was obtained from the patient.

The exclusion criteria were obstructed hernia, severe chronic pulmonary disease (e.g., a condition that is associated with recurrent hypercapnia or hypoxemia in ambient air), recognized congenital cardiac defect accompanied with symptoms (such as cyanosis or congestive heart failure), or symptomatic disease of the central nervous system (e.g., seizures).

### 2.1. Randomization and blindness:

Participants were randomly assigned using computer-generated randomization numbers by using an online randomization program (<http://www.randomizer.org>) to generate a random list; every patient had a secret code number. Patients were assigned randomly to two cohorts using a 1:1 allocation ratio in a parallel manner to receive either GA or SA. Because of the variety of approaches used, the research was classified as open-label.

History-taking, clinical examination, and routine laboratory tests were done preoperatively. Patients fast for solid food for 6 hours for artificial milk, 4 hours for nonclear and breast milk, and 2 hours for clear liquids.

Capnography, ECG, non-invasive blood pressure monitoring, pulse oximetry, and temperature probes were utilized to monitor patients' standards.

### 2.2. Spinal anesthesia technique:

The neonates' upper extremities were secured with flexible restraints to prevent abrupt movement. Oral sucrose drips were permissible. The patient was sedated by administering intermittent injections of ketamine 1 mg, as required. O<sub>2</sub> was administered through a nasal cannula at a rate of two L/min when required. The lateral decubitus position was used to administer SA using a 25-gauge spinal catheter at the L3/4 or L4/5 level, and 0.6 mg/kg of bupivacaine (0.5%) was administered. If GA is required, the patient is excluded and replaced by another.

### 2.4. General anesthesia technique:

Induction of GA was performed using sevoflurane 6-8% and 80% O<sub>2</sub>/air. GA was maintained with sevoflurane (2%) and 50% O<sub>2</sub>/air with assisted spontaneous ventilation.

Opioids were not administered intraoperatively. Paracetamol 15 mg/kg was administered in both groups before skin incision. The surgery was done by expert surgeons using the same technique.

The mean arterial blood pressure (MAP), heart rate (HR), and O<sub>2</sub> saturation were recorded at baseline, every 10 min intraoperatively, and then every 30 min in the post-anesthesia care unit (PACU). Babies were carefully observed and continuously observed in the PACU for two hours following the operation. The need for O<sub>2</sub> supplementation was recorded.

**Table 1: Demographic data and duration of surgery of the studied groups**

Parameters	GA group (n = 37)	SA group (n = 37)	P
<b>Gestational age (weeks)</b>	36.78 ± 2.37	37.41 ± 2.19	0.245
<b>Gender</b>	<b>Male</b>	32 (86.49%)	34 (91.89%)
	<b>Female</b>	5 (13.51%)	3 (8.11%)
<b>ASA physical status</b>	<b>I</b>	30 (81.08%)	33 (89.19%)
	<b>II</b>	7 (18.92%)	4 (10.81%)
<b>Duration of surgery (min)</b>	42.57 ± 12.17	43.92 ± 13.08	0.647

*Data are presented as mean ± SD or frequency (%); P < 0.05 considered as significant.*

The term "apnea" refers to a respiratory delay that exceeds 15 sec or 10 sec if it is accompanied by bradycardia (a 20% decrease in HR) or O<sub>2</sub> saturation below 80%.

The interventions required for postoperative apnea included; tactile stimulation, caffeine administration, and the provision of O<sub>2</sub> via a respirator (both with and without positive pressure ventilation).

The primary outcome was hemodynamic parameters including HR and MAP, duration of surgery, incidence of adverse events (bradycardia, hypotension, postoperative apnea), need for postoperative O<sub>2</sub> supplementation, and length of hospital stay.

#### 2.4. Sample Size Calculation:

We calculated the size of the sample utilizing G\*Power 3.1.9.2 (Universitat Kiel, Germany). Based on a prior study<sup>[13]</sup>, the mean ± standard deviation of postoperative HR (the primary outcome) was 108.1 ± 29.7 beats/min with GA and 124.6 ± 15.2 beats/min with SA. The following parameters were used: 95% confidence limit, 0.699 effect size, 80% power of the study, a 1:1 group ratio, and three cases were incorporated into each group to address the drop-out issue. Therefore, we included 37 patients in each cohort.

#### 2.5. Statistical analysis

We utilized SPSS v27 (IBM®, Armonk, NY, USA) for statistical analysis. The Shapiro-Wilks test and histograms were implemented to assess the normality of the data distribution. The quantitative parametric data presented as the mean and standard deviation (SD) were

analyzed using the unpaired student t-test. The qualitative variables, which were presented as frequency (%), were analyzed using the Chi-square test or Fisher's exact test. A two-tailed P less than 0.05 was used to define statistical significance.

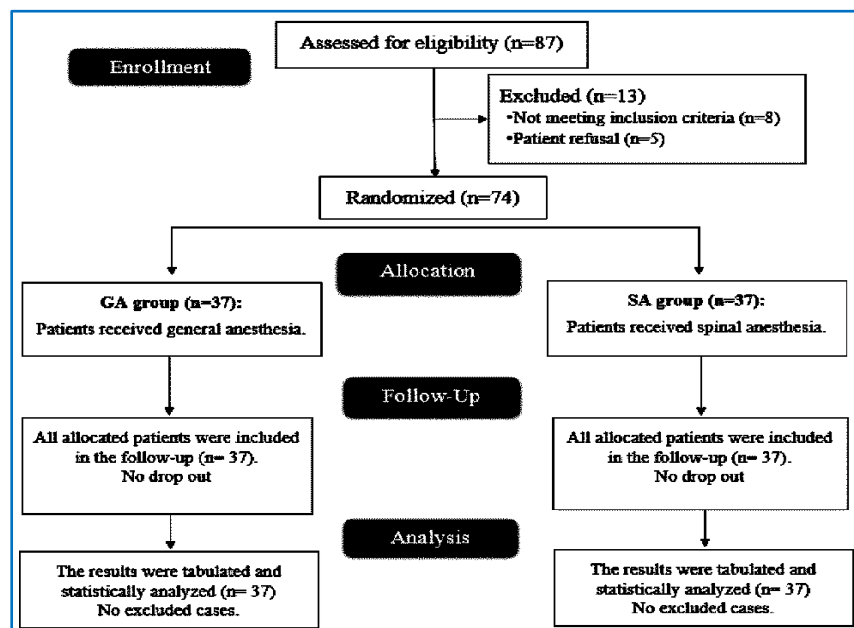
### 3. RESULTS

Eighty-seven patients were evaluated for eligibility in this study; 8 did not satisfy the criteria, and the

guardians of the 5 decided not to participate. All other babies were randomly assigned to one of the two groups, each consisting of 37 babies. The follow-up and statistical analysis of all allocated patients were conducted and there was no drop-outs (Figure 1).

Demographic data and surgery duration did not exhibit statistically significant differences between the two groups. Table 1

HR and MAP measurements did not vary considerably at baseline and 10 min within the grouping. HR



**Figure 1: CONSORT flowchart of the enrolled patients**

**Table 2: Comparative postoperative status and hospital stays of the studied groups**

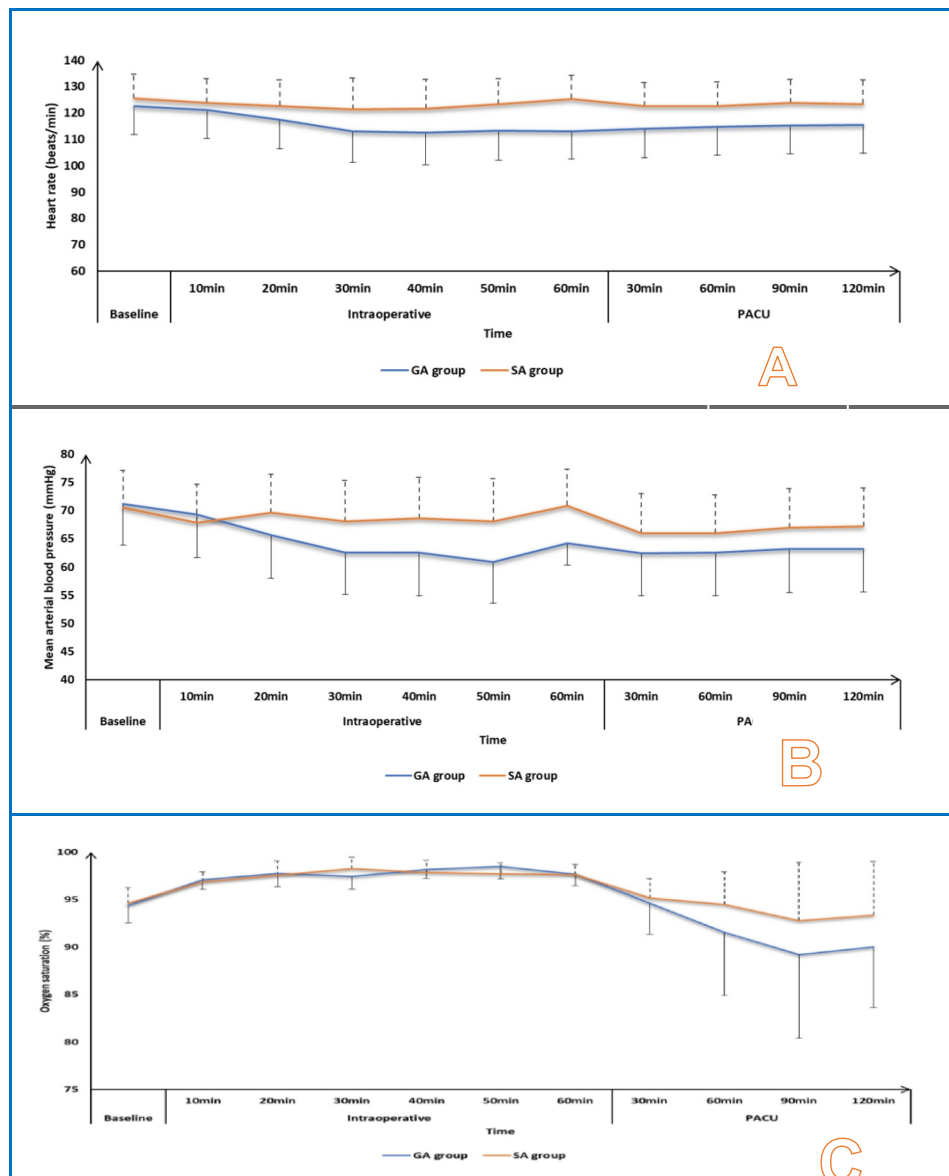
Postoperative status		GA group (n = 37)	SA group (n = 37)	P
Adverse events	Bradycardia	4 (10.81%)	1 (2.7%)	0.357
	Hypotension	7 (18.92%)	3 (8.11%)	0.308
	Apnea	12 (32.43%)	4 (10.81%)	0.045
Need for postoperative O2 supplementation		7 (18.92%)	2 (5.41%)	0.152
Hospital stays (days)		6 (5–15)	6 (3–14)	0.154

*Data presented as median (IQR) or frequency (%); P < 0.05 considered as significant*

measurements were significantly higher, and MAP measurements were significantly lower at 20, 30, 40, 50, 60 min intraoperatively, 30, 60, 90, and 120 min in PACU in the SA in comparison to the GA group (P < 0.05). Figure 2

The O<sub>2</sub> saturation measurements were not significantly different at baseline, 10, 20, 30, 40, 50, and 60 min intraoperatively between both groups and were markedly more elevated at 30, 60, 90, and 120 min in PACU in the SA in comparison to in GA group (P < 0.05).

The two groups did not significantly differ in bradycardia, hypotension, the need for postoperative O<sub>2</sub> supplementation, and hospital stays. The SA group exhibited a substantially lower incidence of apnea than the GA group (12 (32.43%) vs 4 (10.81%), P = 0.045). Table 2



**Figure 2: (A) Heart rate; (B) Mean arterial blood pressure, and (C) SpO<sub>2</sub> changes of the studied groups**

### 4. DISCUSSION

IH repair is frequently performed on preterm and term infants.<sup>14,15</sup> SA is being considered as a potential

substitute for safeguarding against GA during the early phases of life.<sup>16</sup>

HR measurements were significantly higher, and MAP measurements were significantly lower at 20, 30, 40, 50, and 60 min intraoperatively, 30, 60, 90, and 120 min in PACU in the SA in comparison to the GA group. O<sub>2</sub> saturation measurements were markedly more elevated at 30, 60, 90, and 120 min in PACU in the SA compared to the GA group. Similarly to what we discovered, Kim et al. illustrated that the HR and O<sub>2</sub> saturation were notably increased in the SA in comparison to the GA group, while herniorrhaphy in babies that were born prematurely.<sup>13</sup> Also, Davidson et al. informed that the intraoperative heart rate in the RA group (spinal alone, spinal plus caudal, spinal plus ilioinguinal, or caudal alone) was marginally higher than the GA group for IH.<sup>17</sup>

Moreover, Ali et al.,<sup>13</sup> found that blood pressure was notably reduced in the SA in comparison to the GA group in neonates undergoing infra umbilical surgeries. However, the spinal group exhibited significantly reduced heart rate and O<sub>2</sub> saturation than the GA group. This difference is due to our study's high incidence of apnea, which affects HR and O<sub>2</sub> saturation.

In addition, the meta-analysis by Jones et al. explained that O<sub>2</sub> saturation was considerably lower in those who were administered SA than those who were administered GA in preterm neonates undergoing IH in early infancy.<sup>18</sup>

Our results revealed that the incidence of bradycardia, hypotension, and hospital stays was not significantly different in both groups. Aligned with our results, Kim et al. found that the SA and GA groups exhibited no significant differences in bradycardia or hospital stay.<sup>13</sup> Moreover, Lambertz et al. found that hospital stay was insignificantly different between SA and GA groups for IH repair in infants.<sup>19</sup> Also, Jones et al. reported the duration of hospitalization without a substantial distinction between SA and GA.<sup>18</sup> Conversely, Somri et al. discovered that there was a substantial prolonged hospital stay in GA compared to SA with herniorrhaphy in newborns at high risk.<sup>20</sup> This difference may be due to the inclusion of only high-risk (ASA physical status II or greater) infants who suffer from complications other than IH, which may extend the hospital stay compared to our study, which included full-term and preterm neonates.

In our study, the SA group exhibited a significantly reduced incidence of apnea than the GA group, and the need for postoperative O<sub>2</sub> supplementation was insignificant between both groups. This is supported by Frumiento et al.,<sup>21</sup> who showed that the documented apnea rates in neonates after GA are considerably higher than the potential for apnea in premature newborns after SA. In addition, Jones et al.,<sup>18</sup> revealed that the possibility of apnea after surgery was diminished by 47% for preterm infants who did not

receive any sedation when SA was used instead of GA. Additionally, the need for respiratory support was reduced in preterm infants who received SA, although this difference was not statistically significant. Furthermore, Davidson et al. demonstrated that the apnea rate was greatly lower in the RA in comparison to the GA group.<sup>17</sup> In contrast, postoperative O<sub>2</sub> supplementation was insignificantly different between the RA and GA groups. This difference may be due to their larger sample size.

## 5. LIMITATIONS

Our trial has had few limitations including a relatively limited sample size, and it was conducted at a single center. Also, we could not record postoperative pain scores in the neonates, and did not record postoperative analgesic requirements. Further studies are required using various additives, concentrations, volumes, and blocks.

## 6. CONCLUSIONS

Spinal anesthesia is a viable substitute for general anesthesia in neonates undergoing inguinal herniorrhaphy, as it offers hemodynamic stability, satisfactory oxygenation and reduced postoperative apnea.

## 7. Data availability

The numerical data generated during this research is available with the authors.

## 8. Conflict of interest

All authors declare that there was no conflict of interest.

## 9. Funding

The study utilized the hospital resources only, and no external or industry funding was involved.

## 10. Authors' contribution

AEAE and KH: Contributed to the development of the protocol, abstracted data.

MSE and MAEOE: Developed the original idea and the protocol, abstracted and analysed data, wrote the manuscript, and is a guarantor.

MHAE: Prepared the manuscript.

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