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Hyperbaric Prilocaine 2% Versus Hyperbaric Bupivacaine 0.5% for Spinal Anaesthesia in Children Undergoing Lower Abdominal Surgeries

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Keywords

Lower abdominal surgeries

Spinal anaesthesia

Prilocaine

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Abstract:

Background: Spinal anesthesia provides a secure and dependable anesthetic approach for children undergoing lower abdominal surgeries. A quick onset of motor and sensory block, predictable rate of regression and minimal incidence of side effects are all characteristics of the ideal spinal anesthetic agent. The aim of this study was to compare spinal anesthesia using hyperbaric prilocaine 2% and hyperbaric bupivacaine 0.5% for children undergoing lower abdominal surgery. **Methods**: This study was conducted at Beni-Suef University Hospital on 50 patients. The patients were divided randomly into two equal groups; group A: received bupivacaine

hydrochloride 0.5% and group B: received prilocaine Hydrochloride 2%. Demographic data, vital parameters, sensory-motor block characteristics, and complications were noted. **Results**: Our study showed there was a highly significant difference regarding the block characteristics, where Prilocaine Group shows faster block onset time than Bupivacaine Group. Time to return to Bromage 0 was significantly shorter in Prilocaine Group than in Bupivacaine Group. Also; There was a significant longer recovery time, ambulation time and time of voiding of urine in the bupivacaine group than the prilocaine group. **Conclusions**: The present study shows that in children undergoing lower abdominal surgeries, Hyperbaric prilocaine provides faster onset time, shorter duration of action than bupivacaine. In addition, prilocaine showed less time for ambulation and voiding of urine with minimal side effects.

1. Introduction:

In addition to being a secure substitute for general anaesthesia, pediatric spinal anesthesia is frequently considered the anesthetic technique of choice for many lower abdomen and lower limb surgical procedures. Its safety and viability are approved, and it is now discovered to be even more affordable. It is a more popular method, especially for day case surgical procedures done most frequently on children. This type of anaesthesia can be readily carried out in regional centers without the need for any additional costly equipment as well **[1]**.

The correct posture along with understanding of neuraxial anatomy are required for administering spinal anesthesia to children. For lower abdominal surgical procedures, the optimum intrathecal anesthetic drug should have a quick motor and sensory blockage onset, predictable rate of regression over acceptable period of time, and minimal side effects **[2]**.

Spinal anaesthesia for pediatric patients have used significantly more frequently during the

past three decades for lower abdomen, perineal, urogenital, and lower extremities surgical procedures **[3]**.

When considering a quick onset and consistent effect, spinal anesthesia produces deep and effective muscle relaxation. It is strongly recommended for pediatrics who might experience postoperative apnea following general anesthesia. Spinal anaesthetic agents are especially recommended for young children who have respiratory tract infections and did not fast before surgical operations **[4]**.

Bupivacaine 0.5% is an amide-based regional anesthetic agent that works by deactivating voltage-dependent sodium channels. Its aromatic ring boosts its lipid solubility and potency **[5]**. Only 15% of it is present in uncharged form at tissue pH since it has a pKa of 8.1. Bupivacaine's uncharged portion crosses the nerve cell membrane and after it is charged, it binds to Na channels and renders them inactive. Due to the delayed bupivacaine release from its binding site, the time of action is prolonged **[6]**.

Bupivacaine may have a wide range undesirable adverse effects. The cardiovascular and nervous systems are the most frequently encountered life-threatening adverse effects. Toxicity of Bupivacaine causes cardiac conduction block [**7]**.

Prilocaine is a regional anesthetic agent with a quick onset of action and intermediate duration and potency. Since its introduction in 1960 and with great effectiveness, it has been utilized as a 5% hyperbaric formulation for spinal anesthesia. In Europe, 2% plain and hyperbaric solution is now offered in a new formulation **[8]**.

In spinal anesthesia for lower abdominal surgeries, prilocaine is recommended as a viable substitute for lidocaine and mepivacaine. Also; it is considered as appropriate alternative to low dosages of long-acting regional anesthetics agents due to its decreased incidence of transient neurological symptoms **[9]**.

The aim of this study was to compare spinal anesthesia using hyperbaric prilocaine 2% and hyperbaric bupivacaine 0.5% for children undergoing lower abdominal surgery.

Subjects & Methods

Setting Study design

2. Patients and Methods:

This study was conducted at Beni-Suef university hospital, approval from the department of anesthesiology, surgical intensive care and pain management at faculty of medicine, Beni-Suef University was obtained, after that; approval from the local research and ethical committee also was

obtained. This study was carried out during the period from October 2022 to March 2023. Written informed consent was gathered from each parent before the surgery.

Subjects:

Fifty patients of both sexes participated in this prospective, randomized controlled trial study. Using a random computer number generator, the randomization schedule was created. The patients were distributed randomly into two equal groups (25 patients each) to receive the study drugs. The study drugs were prepared in identical syringes labeled study drug. Patients in Group (A) was given Bupivacaine 0.5% in doses of 0.4 mg/kg for patients weighing 5 to 15 kg and 0.3 mg/kg for those over 15 kg. Patients in Group (B) was given Prilocaine 2% in doses ranging from 40 mg to 60 mg, with a maximum dose of 4 mg/kg.

Inclusion Criteria:

Patients scheduled for lower abdominal surgery. American Society of Anesthesiology physical status (ASA) I & II of both sexes. Age between 3 and 10 years.

Exclusion Criteria:

Parents refused to give consent, patients with history of allergy to prilocaine or bupivacaine, mental disorders, patient on anticoagulant or antiplatelets, anemic/ sickle cell anemia, patients with advanced cardiac, renal, hepatic disease or methemoglobinemia**.**

Each parent of a child who was enrolled in the study signed an informed permission after receiving information of the study's procedures and objectives. All patients in the study were subjected to the following: complete medical history which include age, previous surgical operations, comorbidities and drug intake &thorough clinical examination & laboratory results which include coagulation profile, complete blood picture (CBC), electrolytes, kidney function tests (creatinine, urea) and liver function tests (ALT, AST, Bilirubin and albumin).

A standardized anesthesia protocol was followed; vital signs as heart rate (HR), respiratory rate(RR), blood pressure(BP), and o^2 saturation was measured and recorded as baseline data. A premedication of atropine injection 0.01mg/kg was given. Midazolam (0.03 mg/kg IV) or ketamine (0.5 mg/kg) were used on the operating table to provide preoperative sedation and to keep the child immobile for lumbar puncture. Lumbar puncture was applied in lateral position via midline approach under aseptic technique. Hyperbaric bupivacaine (0.5%) or Prilocaine (2%) was injected in the subarachnoid space. The end of injection of anesthetic agent was taken into consideration as time zero for

subsequent data recording. The above-mentioned approach is the standard spinal anesthetic procedure used for children at our institute.

A stiff skin pinch to the dermatomal level was used to measure the sensory block level. T10 was set as the desired peak sensory level. Similar to that, the modified Bromage scale was used to evaluate motor block level. **[10]**. The identical stimulus—a firm skin pinch—was applied to the lower limb (thigh) to measure the bromage score. Bromage score was determined as 0 for ability to raise extended leg and move leg & feet freely, 1: reduced knee flexion and inability to lift extended leg,2: able to flex ankle and foot but inability to bend or lift the knees, 3: unable to move leg, knee, ankle or toes. Grade (1) Bromage refers to the onset of motor block, whilst Grade (3) refers to complete motor block.

Sensory block and motor block were evaluated intraoperatively every minute until onset of blockade were noted, and then after 10 min to evaluate the success of spinal anaesthesia and thereafter every 5 min to allocate the time to return to bromage 0. After 10 min of subarachnoid block; if the sensory block level was T10 and Bromage score was 3, spinal block was considered as successful and surgery was permitted to begin. If the sensory block level was under T10 and Bromage score less than 3, spinal block was considered failed and surgery was performed under general anaesthesia and the case was excluded from the study.

2% sevoflurane was used as sedation to maintain the child calm and maintain cooperative environment. Vital signs were monitored throughout the surgical procedure. Supplemental anesthetic agent was given if an intraoperative pain occurred and it was recorded as partial successful block.

Post-surgery, all patients were received intravenous paracetamol (10 15mg/kg) as needed. Until full recovery; The children were monitored closely. Demographic and surgical data of studied children, vital parameters, need for supplemental anesthesia, block characteristics, voiding & ambulation time and occurrence of complications such as shivering or vomiting were observed and recorded.

Ethical considerations:

The research ethics committee of the faculty of medicine at Beni-Suef University gave its approval to the study protocol No. FMBSUREC/02102022/Yousef. The study was conducted in accordance with the Helsinki declarations, and each patient provided their informed consent.

Data collection and analysis:

Statistical presentation and analysis of the present study was conducted, using The statistical software SPSS version 25 (IBM). Data were presented using descriptive statistics in the form of frequencies and percentages. Continuous variables were expressed as mean, range, and standard deviation and compared across the groups. Chi-square, independent t test and Pearson Correlation Coefficient tests were used to compare frequencies between study variables. A significant level of less than 0.05 was used.

3. Results:

The studied groups were randomly assigned into Group (A) Received Bupivacaine 0.5 % and Group (B) Received Prilocaine 2 %. The mean age of patients in prilocaine group was 6.00±2.12 and 68.0 % of them were males. Also, patients in bupivacaine group had a mean age of 5.88±2.13 and 76.0% of them were males. There were no statistically significant differences between the studied groups regarding their age, sex, body weight and duration of surgery (P-value>0.05) (**Table 1)**.

Table (1): Demographic characteristics and surgical data of Studied Subjects. (N=50)

Items	**Bupivacaine Group n_1= 25**	**Prilocaine Group n_2= 25**	**P-value**
Age (mean±SD)	5.88±2.13	6.00±2.12	0.798
Sex **Males** **Females**	 19 (76.0%) 6 (24.0%)	 17 (68.0 %) 8 (32.0%)	 0.529
Weight (kg)	19.12±5.14	19.24±5.08	0.946
Duration of surgery (min) (mean±SD)	40.32±8.73	39.12±8.17	0.919

There was a highly significant difference regarding the block characteristics, where Prilocaine Group shows faster block onset time (4.44±0.51 min) than in Bupivacaine Group (6.44±1.12 min). Sensory Block level after 10min (dermatome) was comparable between the two groups, it was at T6-T8 in Prilocaine Group and at T8-T10 in Bupivacaine Group. Time to return to Bromage 0 was significantly shorter in Prilocaine Group (73.40±3.74 min) than in Bupivacaine Group

(117.00±20.92 min). Also; The success rate of the spinal anaesthesia in both groups was 100% with no need for using anesthetic supplementation (**Table 2)**.

Table (2): Sensory and Motor Block Characteristics among Studied Subjects.

Items	**Bupivacaine Group n1= 25**		**Prilocaine Group n2= 25**		**P-value**
	Mean±SD	**Range**	**Mean±SD**	**Range**	
Block Onset (min)	6.44±1.12	4-8	4.44±0.51	4-5	0.000**
Sensory Block level after 10min	T 9.04±1.02	T8-T10	T6.96±1.02	T6-T8	0.000**
Bromage score after 10min	**No.**	**%**	**No.**	**%**	-
Score 3	25	100%	25	100%	
Using anesthetic supplementation No	25	100%	25	100%	-
Block result after 10 min Success	25	100%	25	100%	-
Time to return to Bromage 0 (min) Mean±SD	117.00±20.92	75-140	73.40±3.74	65-85	0.000**

Test = Independent Samples t Test

- Cannot be computed because at least one of the variables is constant.

There were no statistically significant differences throughout study phases between the studied groups regarding their Systolic BP (**Figure 1),** diastolic BP (**Figure 2),** pulse (**Figure 3)** and O^2 saturation (**Figure 4)**.

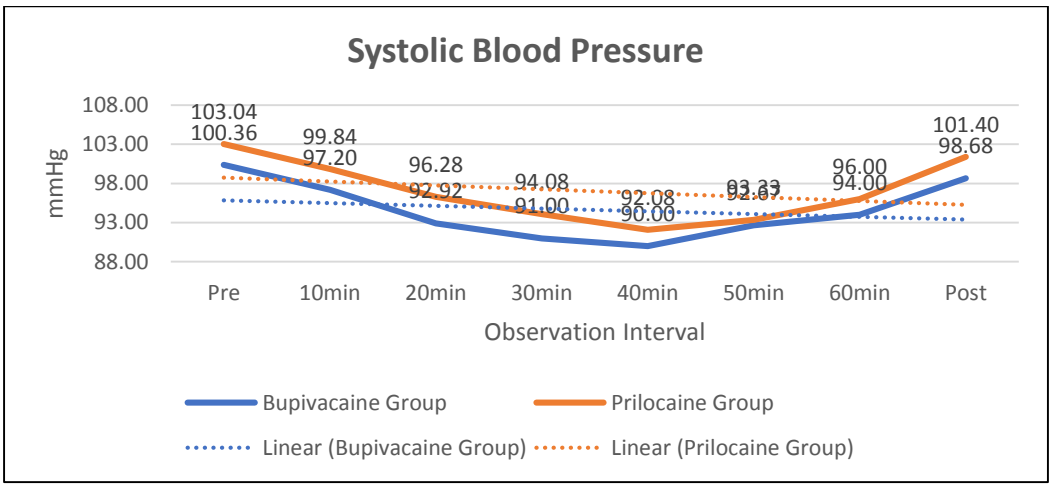

Figure 1. Comparison between both groups regarding the systolic blood pressure throughout study phases.

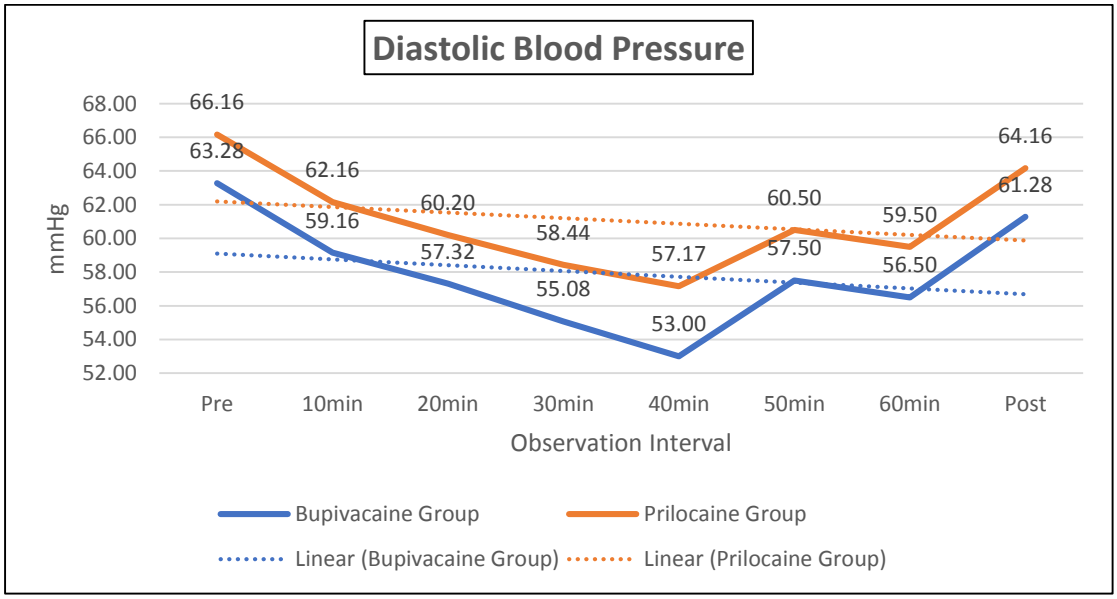

Figure 2. Comparison between both groups regarding the diastolic blood pressure throughout study phases.

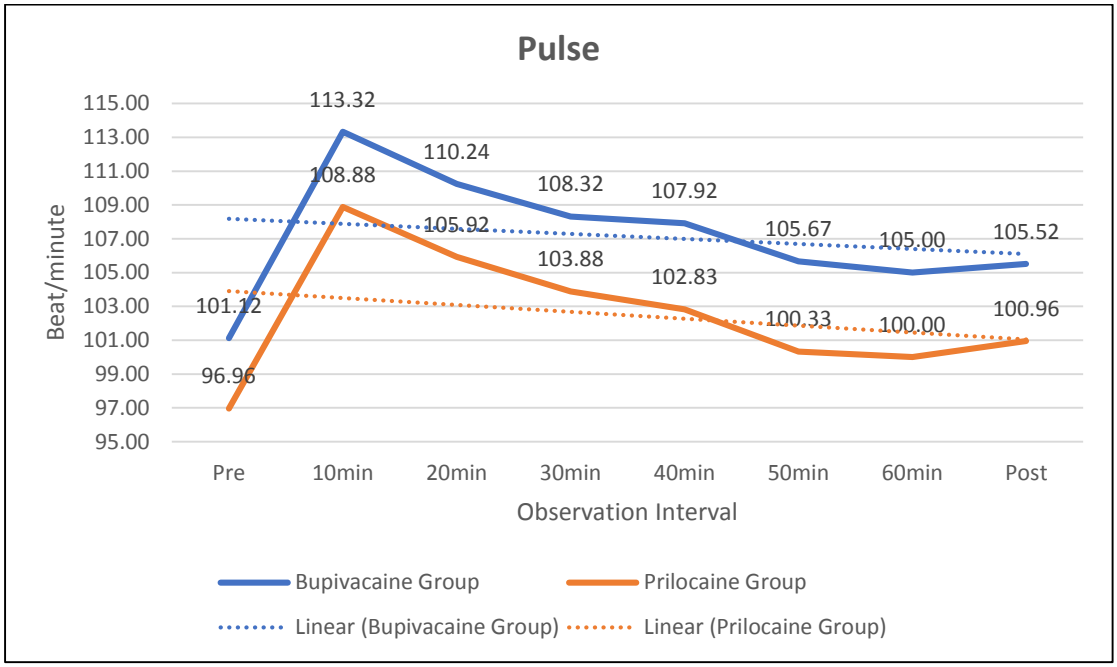

Figure 3. Comparison between both groups regarding the pulse rate throughout study phases.

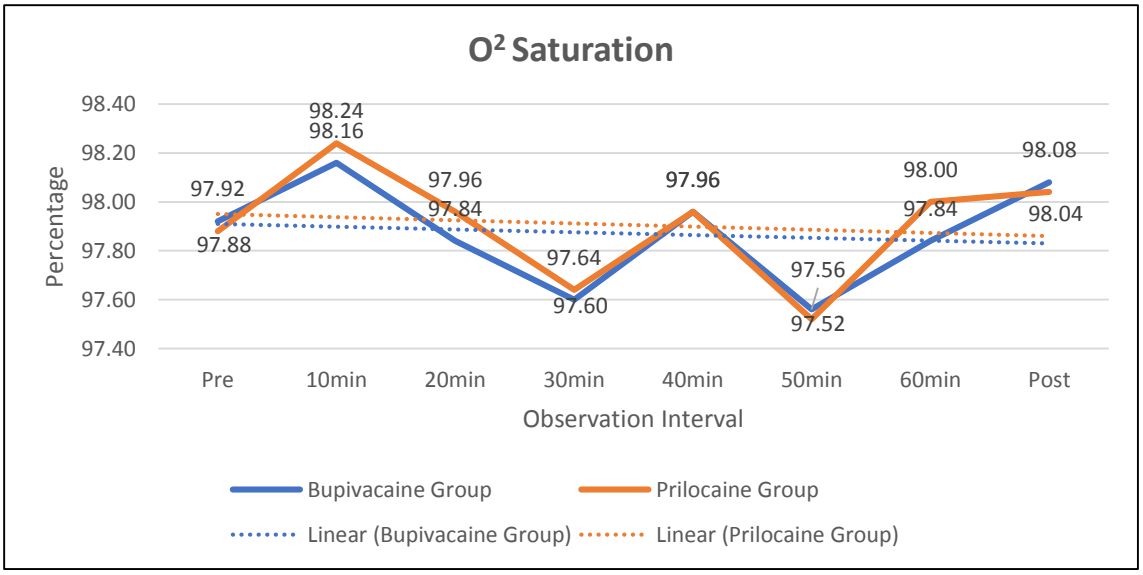

Figure 4. Comparison between both groups regarding the O^2 saturation throughout study phases.

There was a statistically significant shorter time in Prilocaine Group to walk unassisted (78.00±3.82 min) compared to the Bupivacaine Group, where the time to walk unassisted was (122.00±20.92 min). there was a significant longer time to void urine spontaneously in the bupivacaine group than the prilocaine group (P-value 0.000) (**Figure 5)**. There was no statistically significant difference between the studied groups in regard to postoperative surgeon satisfaction (p-value>0.05) but with high postoperative surgeon satisfaction in both groups **(Table 3)**.

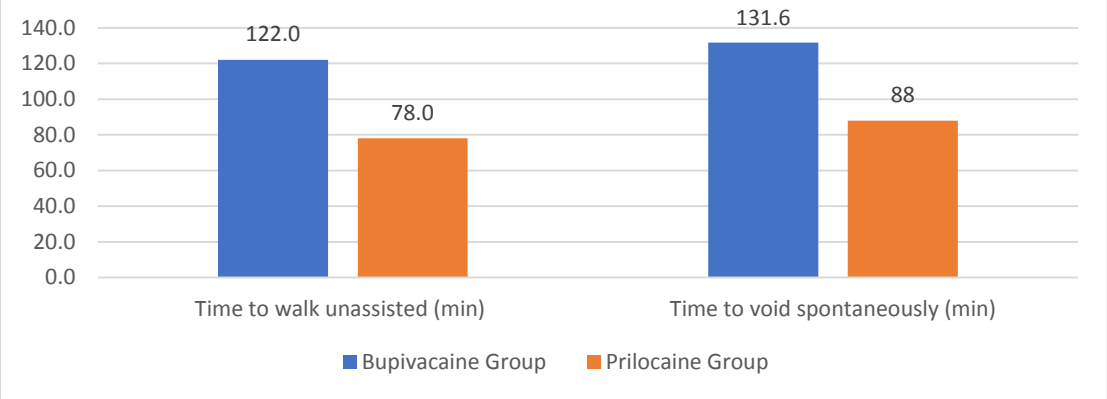

Figure 5. Comparison between both groups regarding the time to walk unassisted and void spontaneously.

Table (3): Postoperative Surgeon Satisfaction among Studied Subjects. (N=50)

Items	**Bupivacaine Group n1= 25**		**Prilocaine Group n2= 25**		**P-value**
	No.	**%**	**No.**	**%**	
Not satisfied	**2**	**8.0**	**1**	**4.0**	**(1.000)**
Satisfied	**23**	**92.0**	**24**	**96.0**	

Test = X^2 Chi square test

FE Expected cell count less than 5, Fisher's Exact test was used.

There was no statistically significant difference between the studied groups regarding intraoperative and postoperative nausea &vomiting, hypotension, bradycardia and shivering (p-value>0.05) **(Table 4)**.

Table (4): Intraoperative and Postoperative Complications among Studied Subjects.

Items		**Bupivacaine Group n1= 25**	**Prilocaine Group n2= 25**	**P-value**
Intraoperative	**Nausea, Vomiting** **Yes** **No**	 **1 (4%)** **24 (96%)**	 **1(4%)** **24 (96%)**	 **(1.000)**
	Hypotension **No**	 **25 (100%)**	 **25 (100%)**	**-**
	Bradycardia **No**	 **25 (100%)**	 **25 (100%)**	**-**
	Shivering **Yes** **No**	 **2 (8 %)** **23 (96%)**	 **1 (4%)** **24 (96%)**	 **(0.561)**
Postoperative	**Nausea, Vomiting** **No**	 **25 (100%)**	 **25 (100%)**	**-**
	Hypotension **No**	 **25 (100%)**	 **25 (100%)**	**-**
	Bradycardia **No**	 **25 (100%)**	 **25 (100%)**	**-**
	Shivering **Yes** **No**	 **1 (4%)** **24 (96%)**	 **25 (100%)**	 **(0.322)**
	Methemoglobinemia **No**	 **25 (100%)**	 **25 (100%)**	**-**

4. Discussion:

Shorten length of stay in hospitals is becoming more crucial, especially for in-patients. Therefore, early ambulation due to a shorter span of motor block is perceived to be preferable in lower abdomen surgeries conducted under spinal anesthesia. Due to worries about cauda equina syndrome and transient neurological symptoms, hyperbaric lignocaine 50 mg/ml has become less popularly used for spinal anesthesia during surgical procedures of short duration **[7]**.

Bupivacaine is a widespread local anesthetic used for spinal anesthesia. Its duration of action is considerably longer than that of other local anesthetics. The usage of other long-acting local anesthetics substitutes has resulted from its toxic effects on the heart when administered in large doses **[11]**.

Prilocaine as an amide-type regional anesthetic agent has a fast onset of action, intermediate duration, and moderate potency. More than twice as much as lidocaine, prilocaine has the most rapid clearance of all amino-amide local anesthetics **[12]**. Compared to the plain solution, the effects of the hyperbaric prilocaine solution diminished more quickly. Due to its substantially lower plasma concentration than that of lidocaine and mepivacaine following regional anesthetic, prilocaine rarely causes toxicity **[13]**.

This study was conducted at Beni-Suef University Hospital to compare spinal anesthesia using hyperbaric prilocaine 2% and hyperbaric bupivacaine 0.5% for children undergoing lower abdominal surgery.

Patients in the prilocaine group had an average body weight of 19.24±5.08 and a mean age of 6.00±2.12. The majority of the patients (68.0 %) were male. Additionally, patients in the bupivacaine group had an average weight of 19.12±5.14 and a mean age of 5.88±2.13. 76.0% of them were male. Age, sex, and body weight did not significantly differ amongst the groups under study.

Similar findings were found in the study by **Talukder et al. (2021)**, which assessed the spinal anesthesia in pediatric patients of district level hospital, Tangail, Bangladesh showed that; The study sample was predominately male (75%), with an average weight of 15.23+7.43 and a mean age of 5.17+2.83 **[14]**.

The mean time of operation for patients receiving bupivacaine was 40.32 minutes, whereas the mean operative time for patients receiving prilocaine was 39.12 minutes. Similar findings were reported by **Gebhardt et al. (2018)** in their study on the analysis of

bupivacaine, prilocaine, and chloroprocaine for low-dose intrathecal anesthesia in outpatient perianal procedures, which showed that the average surgical procedure took about 46 minutes (range: 39–56) for the bupivacaine group and 41 minutes (range: 35–50) for the prilocaine group **[15]**.

The main finding in our study was that spinal anesthesia for lower abdominal surgeries in children with prilocaine 2% provides faster block onset compared with bupivacaine 0.5% spinal anesthesia (4.44±0.51 min - 6.44±1.12 min) respectively. in our study, sensory block level after 10min was significantly higher in prilocaine group (T6.96±1.02) than in bupivacaine group (T9.04±1.02). regarding time to return to bromage 0; the current study demonstrated that it was shorter in prilocaine group than in bupivacaine group (73.40±3.74 min versus 117.00±20.92 min).

In consistence with our study was that performed by **Etriki et al. (2022)** who compared spinal anesthesia using hyperbaric bupivacaine (0.5%) and hyperbaric prilocaine (2%) for day case surgery and revealed that according to sensory block onset values, the Bupivacaine group had statistically significant higher values than the Prilocaine group as the Prilocaine group had a faster motor block onset time (4.87 ± 0.7 min) than the Bupivacaine group (6.1 ± 1.0) and took less time to reach the maximum level of sensory blockade **[16]**.

Also; this is in agreement with **Abdalmegeed et al. (2022**) who applied comparative study between hyperbaric prilocaine (2%) and hyperbaric bupivacaine (0.5%) in spinal anesthesia for saddle area surgeries and found that level of motor block in prilocaine group (T6 - T10) was higher than in bupivacaine group (T8 – T11) **[17]**. Matching with our results regarding the duration of motor block, study by **Verma et al. (2014)** studied Spinal anesthesia in infants and children reported that Mean time to return to Bromage 0 was 111.95 ± 20.54 (70-160) min and all the patients were completely recovered from sensory and motor blockade **[18].**

Also; a study by **Chapron et al. (2021)** compared hyperbaric prilocaine versus hyperbaric bupivacaine for spinal anesthesia in women undergoing elective cesarean section and demonstrated that time to return to bromage zero in prilocaine group was (158 min) which are shorter compared to bupivacaine group that showed a motor block duration (220 min) **[19]**.

In our study it was found that mean duration of block was (73.40±3.74) in Prilocaine group versus (117.00±20.92 min) in Bupivacaine Group which is much less than

adult counterpart as supported by **Ahmed et al. (2010**) who studied the efficacy of spinal anesthesia in children and explained that by; pediatric earlier motor recovery and shorter duration of block may be caused by the cerebrospinal fluid has more rapid turnover in children in addition to the administered local anesthetic becoming more diluted as a result of the larger cerebrospinal fluid volume in children compared to adults in proportion to body weight **[20]**

In the current study; there was a significant longer time for ambulation in the bupivacaine group than the prilocaine group. The mean ambulation time for patients in prilocaine group was 78.00±3.82 min and for patients in bupivacaine group was 122.00±20.92 min. The time of urine voiding was also significantly longer in bupivacaine group to reach a mean 131.60±20.55 min while for patients in prilocaine group it was 88.00±3.82 min.

This is in agreement with **Kaban et al. (2014**) who compared hyperbaric prilocaine versus bupivacaine for day-case intrathecal anesthesia in terms of sensory block offset and time to home discharge and revealed that walk without assistance was different between groups. The mean time to walk unassisted was 136.9 ± 53.6 min in prilocaine group compared to 172.0 ± 82.5 min in bupivacaine group. The mean Time to void was 152.8 ±104.8 min in prilocaine group while it was 172.4 ± 130.8 min in bupivacaine group **[21]**.

In the current study; there was high satisfaction rate for surgeons in both groups. The majority of surgeons in prilocaine group and bupivacaine group (96.0%, 92.0% respectively) were satisfied of anaesthesia. In consistence with our study was that performed by **Goffard et al. (2022**) who compared spinal hyperbaric bupivacaine and hyperbaric prilocaine during elective cesarean sections and concluded that in comparison to hyperbaric bupivacaine 10 mg, spinal anesthesia with hyperbaric prilocaine offers equal qualities of surgical anesthesia and maternal, obstetrician, and midwife satisfaction while enabling faster motor block resolution and greater hemodynamic stability **[22]**.

In contrary to our results was the study of **Rehfuss et al. (2019**) who analyzed medical professionals' suggestions regarding whether using general or spinal anesthesia for common pediatric urological surgical procedures and found that Only 20% of pediatric urologists prefer spinal anesthesia to general anesthesia for common pediatric urology procedures, and they offered possible reasons for this, including the fact

that spinal anesthesia can be technically difficult to apply (and thus lengthen the preoperative period) and the additional challenge of operating on an awake child. Additionally, the time spent under spinal anesthesia is short (around 90 minutes) **[23]**.

In the current study; No variation in respiratory hemodynamics was noted intra-operatively or post-operatively among the children in both groups. no episodes of oxygen desaturation occurred in both groups intra-operatively or post operatively. There were no episodes of hypotension or bradycardia occurred in both groups intra-operatively or post-operatively.

Similarly, **Lönnqvist (2023**) who studied technical aspects, surgical context, potential complications, as well as the potential long-term effects of spinal anaesthesia during infancy and reported that children have spinal anesthesia-related circulatory changes less frequently than adults do. Venous pooling is less common in children under the age of 5-8 due to their undeveloped sympathetic nervous system, small intravascular volume in the lower limbs, and splanchic system **[24]**.

In our study; Heart rate showed observable increase after 10min intraoperatively in both groups as compared to baseline. This can be due to atropine & ketamine which were used as premedication before giving spinal anesthesia.

Similarly, **Bule et al. (2017))** studied the perioperative haemodynamic changes of spinal anesthesia in paediatric patients and reported that Glycopyrrolate and ketamine, which were used as premedication before administering the spinal anesthetic agent, caused heart rate to increase by 11.2% after 5 min of subarachnoid block with 0.5% hyperbaric Bupivaccaine compared to baseline **[25]**.

Shivering was the most common side effects occurs intraoperatively in prilocaine group (4%) and (8%) in bupivacaine group intraoperatively and (4%) postoperatively in bupivacaine group while no case in prilocaine group experienced shivering postoperatively. This is in consistent with **Ahmed et al. (2010**) who studied the efficacy of spinal anesthesia in children and reported that; in neonates and infants, spinal block compromised the central thermoregulatory center and resulted in shivering **[20]**.

Similarly; a study by **Talukder et al. (2021**) assessed the hyperbaric 0.5%. Bupivacaine spinal anaesthesia in paediatric patients of district level hospital, Tangail, Bangladesh showed that Incidence of complications was minimal with shivering in 2 patients (6.25%) & also in 1 patient (3.12%) nausea &

vomiting **[14]**. Also; **Bule et al. (2017**) who studied hyperbaric 0.5% Bupivacaine spinal anaesthesia in paediatric patients of aged 2-8 years found that shivering occurred in 2 patients (5%) also 1 patient (2.5%) had nausea & vomiting **[25]**.

In conclusion, this study shows that in children undergoing lower abdominal surgeries, Hyperbaric prilocaine provides faster onset time, shorter duration of action than bupivacaine. In addition, prilocaine showed less time for ambulation and voiding of urine with minimal side effects.

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