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Levobupivacaine Versus Hyperbaric Bupivacaine in Spinal Anesthesia for Hypospedias Surgery in Children

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Abstract

Background: We have conducted this study to compare between levobupivacaine and hyperbaric bupivacaine in Spinal Anesthesia (SA) for hypospedius surgery in children regarding efficacy, hemodynamics, complications incidence, number of children that needed propofol infusion and surgeon's satisfaction.

Aim of Study: Study comparing between levobupivacaine and hyperbaric bupivacaine in Spinal Anesthesia (SA) for hypospadius surgery in children regarding efficacy, hemodynamics, complications incidence, number of children that needed propofol infusion and surgeon's satisfaction.

Patient and Methods: This study was done in Al-Zahraa University Hospital from January 2019-January 2020. After obtaining Medical Ethical Committee approval and written informed consents from parents of all patients in the study; Thirty patients aged (4-10 years) ASA I and II, scheduled for elective hypospedius surgeries under spinal anesthesia (SA) were divided into two equal groups in a randomized controlled fashion. Group L (n=15) received 0.3mg/kg levobupivacaine (0.5%) and group H (n=15) received 0.3mg/kg hyperbaric bupivacaine (0.5%). Hemodynamics [Mean Arterial Blood Pressure (MAP), Heart Rate (HR)], onset and duration of sensory and motor block, surgeon's satisfaction, number of patients needed propofol infusion and side effects were recorded for each patient.

Results: The results of the present study demonstrated that, levobupivacaine produces definitely rapid regression of unwanted motor blockade and faster onset of sensory blockade compared to hyperbaric bupivacaine with negligible changes regarding other parameters.

Conclusion: We conclude that SA performed with levobupivacaine and hyperbaric bupivacaine are effective in providing adequate quality of SA for hypospedias surgery in children, so, levobupivacaine can be a good alternative in hypospadias surgeries in children.

Key Words: *Spinal Anesthesia in Pediatric – Hyperbaric Bupivacaine – Levobupivacaine.*

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Introduction

IN the developing countries there are a lot of challenges in anesthetic drugs, supplies and monitoring equipments **[1]**. Most of these challenges can be overcame by choice of safe, reliable and effective sole anesthetic technique which can provide both anesthetic and analgesic satisfactory effects for performing the surgical procedure and capable of replacing the General Anesthesia (GA) in these situations. Nowadays regional anesthesia techniques are well established in the practice of pediatric anesthesia **[2]**.

In recent years, SA is used in infants and children for different types of surgery of lower part of body. It can be used as a sole technique with or without sedation or in conjunction with GA in complex surgery **[3]**. Neuraxial anesthesia continues to gain popularity because of rapid onset and profound uniformly distributed sensory and motor block with high success rate **[4]**. SA in pediatric patients was first introduced by August Bier in 1899, however it was not well established in the medical field as anesthesiologists were reluctant to use it in pediatric patients. It was first used by Bainbridge in 1909 to repair strangulated hernia in a neonate. Since then SA was known to be in practice for several years with a series of publications **[5]**.

In 1980's it was reintroduced as an alternate to GA, especially in high risk preterm infants **[6]**. López et al., in 1984 stated that in the modern era of anesthesia practice, SA has been successfully reintroduced in the pediatric age group due to a higher degree of cardiovascular and respiratory stability **[7]**.

The efficacy and safety of SA in pediatric encourage its acceptance as an alternative to GA,

to avoid the risks related to GA such as unpredicted difficult airway, malignant hyperthermia and the procedure can be performed in low resources setting [8].

Among the various drugs approved by Food and Drug Administration (FDA) for pediatric intrathecal use, 0.5% bupivacaine and tetracaine are common and popular. Newer drugs like ropivacaine and levobupivacaine are also safe and effective [9].

Hypospadias is the most common malformation of the male external genitalia (1-300) males, the prevalence of which seems to be increased. There are different types of hypospadias (proximal, distal, and mid-shaft), reconstruction of proximal (posterior) hypospadias remains a rare and disputing problem among pediatric surgeon, especially with concomitant chordee **[10]**.

Hypospadias repair is a challenging topic of urogenital pediatric surgery, many different techniques are currently being used. The optimal surgical technique depends on anatomical factors; one of the main challenges in surgery for crippled hypospadias is the correction of severe ventral curvatures, especially in cases where only a dorsal plication is not sufficient to straighten the penis shaft, and ventral lengthening of the corpus cavernosum is necessary **[11]**.

The time ranging for hypospadias operation from (1-3) hours according to technique and surgeon handing, also hypospadias repair is a one day surgery, post-operative analgesia is mandatory to improve outcome. The prevalence of persistent post-operative pain in children after major surgery remains high. Spinal anasthesia is being increasingly used as part of multimodal analgesic regimens, and has proved to be a valid alternative to conventional opioid-based strategies **[12]**.

This study was designed to compare isobaric levobupivacaine with hyperbaric bupivacaine with respect to intraoperative quality of anesthesia and the post-operative recovery profile in children undergoing hypospadias surgery.

Patients and Methods

After approval of Ethical Committee of Al-Azhar Faculty of Medicine, a prospective, randomized, double blinded study was conducted in the Department of Anesthesia (Al-Zahra) University Hospital. Parents were informed about anesthetic procedure and an informed consent was taken.

Inclusion criteria included:

Thirty patients aged (4-10) years, weight (16-30kg), ASA grade I, II scheduled for hypospedius surgery requiring sensory and motor block below T 10 were included in our study.

Exclusion criteria included:

Any contraindication to regional anesthesia as coagulopathy, infection at the site of block, spine deformity, history of developmental delay, patients with weight >30kg and those with known allergy to local anesthetic drugs, were excluded from the study.

Patients were divided randomly into two groups according to local anesthetic given:

- *Group 1:* (30) child (L): 0.3mg/kg levobupivacaine (0.5%) was injected in intrathecal space.
- *Group 2:* (30) child (H): 0.3mg/kg hyperbaric bupivacaine (0.5%) was injected in intrathecal space.

All patients were evaluated pre-operatively by taking full medical history, physical examination including vital signs, cardiovascular, respiratory, abdominal, neurological, airway evaluation and laboratory investigations as full blood picture, bleeding and coagulation profile.

All the patients were kept NPO for 6 hours for solid meal and 1 hour for clear fluid pre-operatively.

EMLA cream was applied to lumbar puncture area and Intravenous (IV) cannulation site half an hour prior to arrival in the Operating Room (OR).

Children were monitored for ECG, HR, non-invasive blood pressure O_2% saturation with pulse oximetery and the base line values were recorded.

After securing an IV line access with 24G (IV) cannula, atropine 0.01 mg/kg was given as premedication.

In the OR all the children received intramuscular ketamine (5-10) mg/kg 5min before spinal block to achieve immobility of child during block, subsequently all the children were placed in the sitting or lateral decubitus position.

Level of lumbar puncture was obtained through intercristal line (Tuffier's line) which passes through L4-L5 then lumbar puncture was performed using pediatric spinal needle 25G with stylet with the head slightly hyperextended to avoid obstruction of the airway.

When the spinal needle was advanced into the intrathecal space free flow of cerebrospinal fluid was obtained. The local anesthetic syringe was attached and the anesthetic solution was injected over 30 seconds by dose of 0.3mg/kg.

After the puncture, the child was placed supine or with a slight anti-Trendelenburg tilt of 20-30 degrees (2-3 minutes); raising the legs above the height of the trunk was avoided to prevent an unwanted high spinal block.

Assessment of onset of complete block:

In awake children over 8 years, onset of complete sensory block was ascertained by pinprick test (score 0) below level of T10, while onset of complete motor block was assessed by modified Bromage score (score 3). In sedated and younger children (age 4-8 years), onset of complete sensory block was ascertained by FLACC scale (score 0) while complete loss of muscle tone of lower limb muscles after emergence was a good evidence of successful complete motorblock.

Intraoperative sedation was not required if SA was successful because de-afferentiation it self produced sedation, also some children remained sedated by pre-operative ketamine. In some cases, sedation was maintained with propofol infusion (using syringe pump) at the rate of 50-75mcg/ kg/min. Some older children preferred not to be sedated, opting for music or watching a cartoon.

Before shifting the patient to recovery room, one must ensure stable vital signs, intact gag, swallowing and cough reflexes, and adequate respiration. Criteria for discharge included orientation to time, place and person (appropriate for child's age), tolerating oral fluids with minimal nausea, and vomiting. If residual sensory block was present, instruction given to protect the child from hot, cold, or sharp objects given.

Measured parameters:

Primary outcome measured in this study was efficacy of the drug (onset and duration of sensory and motor block). Secondary outcomes included hemodynamics (HR, MAP) at different time interval: Before block, after block (every 5min for 1st 15min then every 15min till the end of operation). Other outcomes measured were satisfaction of surgeons, number of patients needed propofol infusion and complications that occurred.

Statistical analysis:

Recorded data were analyzed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean ± Standard Deviation (SD) and range. Qualitative data were expressed as frequency and percentage.

The following tests were done:

- Independent-samples *t*-test of significance was used when comparing between two means.
- Chi-square (χ^2) test of significance was used in order to compare proportions between qualitative parameters.
- The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the *p*-value was considered significant as the following:
  - *p*-value <0.05 was considered significant.
  - *p*-value <0.001 was considered as highly significant.
  - *p*-value >0.05 was considered insignificant.

Results

The variables in demographic data did not show a statistically significant difference between group.

There was a delay in the onset of complete motor block (Bromage 3, complete loss of muscle tone) of group L compared to group H, while the onset of complete sensory block (pinprick 0, FLACC 0) was faster in group L compared to group H and this was statistically significant Fig. (1).

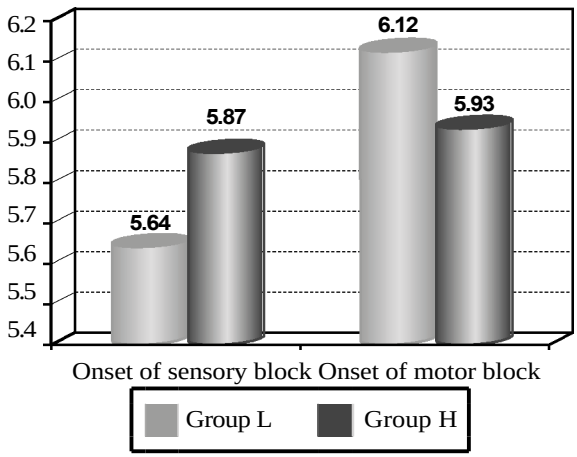

Fig. (1): Comparison between group L and group H according to onset of complete motor and complete sensory block.

As regard regression of block, regression of motor blockade was faster in group L than in group H. Regression of sensory blockade was more rapid in levobupivacaine group than bupivacaine group, and this was statistically significant (Table 1).

Table (1): Comparison between the two groups according to regression of motor and sensory block.

Regression of motor and sensory block	Group L (n=30)	Group H (n=30)	*p*-value
Motor regression(min):			
Mean ± SD	115.00±13.57	130.00±16.86	<0.004*
Range	100-140	100-150	
Sensory regression(min):			
Mean ± SD	98.50±10.40	120.00±12.98	<0.001**
Range	80-120	100-140	

*: *p*-value <0.05 S. **: *p*-value <0.001 HS.

Hemodynamic variables (heart rate and mean arterial blood pressure) showed no statistically significant difference between the two studied groups Figs. (1,2).

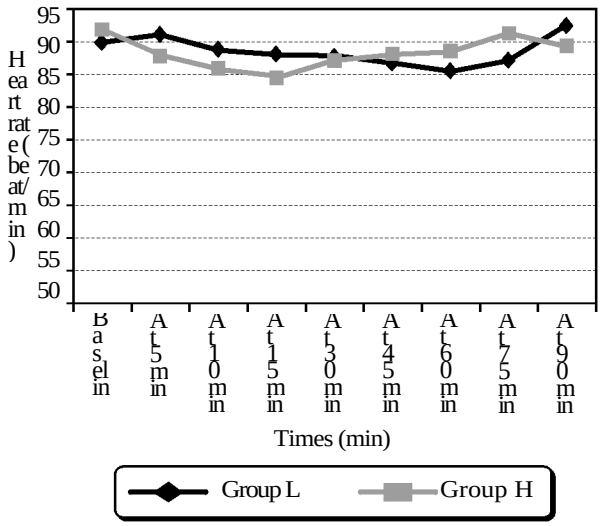

Fig. (2): Comparison between groups according to heart rate.

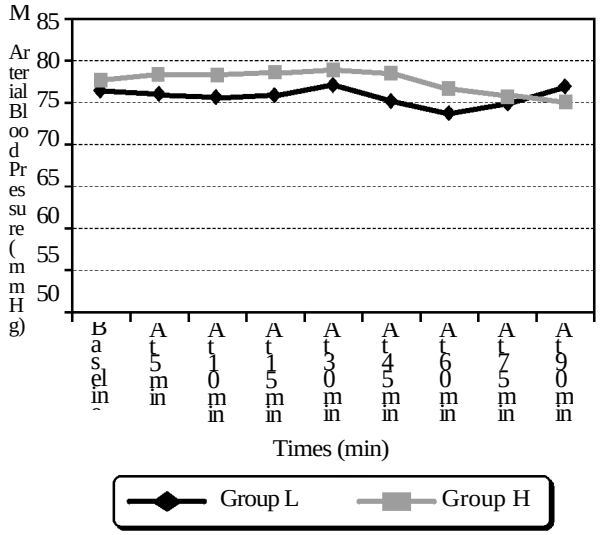

Fig. (3): Comparison between groupaccording to mean arterial blood pressure.

Regarding sedation requirements during surgical procedure, the results are shown in (Table 2).

Table (2): Comparison between the two groups according to sedation requirement during surgical procedure.

	Group 1: L (n=30)	Group 2: H (n=30)	*p*-value
Propofol infusion	2 (6.6%)	4 (13.3%)	>0.05
Under ketamine sedation	10 (33.3%)	8 (33.3%)	>0.05
Watching cartoon	8 (26.6%)	10 (33.3%)	>0.05
Cooperative children	10 (33.30%)	8 (26.6%)	>0.05

Intraoperative adverse effects were recorded in both groups which show no statistically significant differences between them (Table 3).

Table (3): Comparison between the two groups according to adverse effect.

Adverse effect	Group L (n=30)	Group H (n=30)	*p*-value
Bradycardia	2 (6.66%)	4 (13.3%)	>0.05
Shivering	4 (13.3%)	4 (13.3%)	>0.05
Vomiting	4 (13.3%)	2 (6.6%)	>0.05
No	20 (66.6%)	20 (66.6%)	>0.05

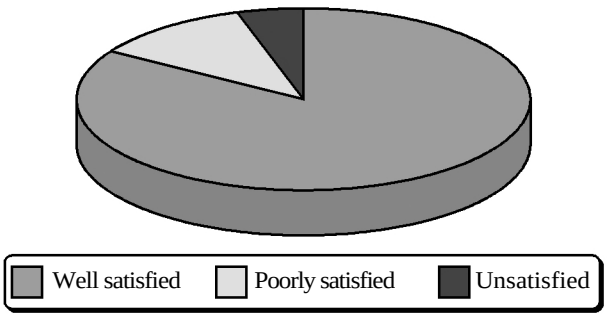

Fig. (4): Surgeon satisfaction.

Table (4): Type of operation done for each

	Group 1: L (n=30)	Group 2: H (n=30)
Tubularized incised plate	10 (33.30%)	12 (40%)
Urethral advancment	10 (33.3%)	8 (26.6%)
Mathuia operation	6 (20%)	8 (26.6%)
Onlay island flap urethroplasty	4 (13.33%)	2 (6.66%)

Discussion

In several studies, SA in pediatric patients showed a decreased incidence of hypotension, hypoxia, bradycardia and postoperative apnea in comparison to GA **[13]** SA is being used frequently in sub-diaphragmatic surgeries to relieve post-operative pain and to achieve sensory block with muscle relaxation and decrease stress response so the recovery is fast in pediatric population **[3].** The demographic profile of our patients were almost

comparable in all groups with no significant statistical difference between the two groups (p>.05).

In this study, the patients remained hemodynamically stable during intraoperative period except a brief increase in HR before performing procedure. This may be because of atropine and ketamine used during procedure. There was no change in blood pressure. This result was agreed with the study done by Gautam et al., **[3]** on 67 pediatric patients aged between 3 to 14 years undergoing lower abdominal surgery.

Troncin and Dadure **[14]** (this reference was corrected here and in the list of references. References are written by surnames not by first names) suggested that the younger children (4-8 years) have a relatively immature sympathetic nervous system and smaller intravascular volume in lower extremities and splanchnic system, which limits the venous pooling. This immaturity of the sympathetic nervous system would make vasomotor tone less dependent on sympathetic nervous system and the smaller capacitance veins in lower extremities causes less blood flows in pediatric. They suggested, in older patients (>8 years old), the sympathetic block can induce bradycardia or hypotension. Supporting this study, authors as Goyal et al. **[15]** suggested that this may be seen even among those aged 8 to 15 years.

In this study as regard the onset of complete sensory blockade (pinprick 0-FLACC 0), it was shorter in levobupivacaine group (4.85±1.04) min than bupivacaine group (5.80±1.20) min, while regression of sensory blockade was more rapid in levobupivacaine group (98.50±10.40) min than bupivacaine group (120.00±12.98) min.

The results of present study run parallel to the study done by Kokki et al., **[16]** who concluded that regression of sensory blockade was faster in levobupivacaine group (90min) than bupivacaine group (103min) in his study on forty healthy children aged 11mo to 14yr, scheduled for surgery below the umbilicus with SA.

Concerning motor blockade in our study onset of complete motor blockade (Bromage 3-complete loss of lower limb muscle tone), it was longer in levobupivacaine group (6.75±1.29) min than bupivacaine group (5.80±1.47) min, while regression of motor blockade was faster in levobupivacaine group after (115.00±13.57) min than bupivacaine group after (130.00±16.86).

Similar to the present study Mahdy et al., **[2]** in their study on fifty patients of both sex, aged 6-12 years, ASA grade I, II, weighed (20-50kg) scheduled for lower abdominal procedures requiring sensory block below T 10 receiving SA using heavy bupivacaine 0.5% in the dose of (0.3mg/kg); they found that the onset of motor blockade of bupivacaine in was (6.8±1.2) min and regression of motor blockade was after (124.5±10.7) min. rapid complete sensory block in levobupivacaine group allow sergeon to start operation early than bupivacaine group, however rapid regression of sensory block of levobupivacaine group enhance rapid use of post-operative analgesics than the bupivacaine group.

Agreeing with present study, Frawley et al., **[17]** in their study found that regression of motor blockade of levobupivacaine in SA in pediatrics was after (90.6±20.1) min which is relatively short duration in comparison to the duration of motor blockade of bupivacaine in SA in pediatrics.

In this study we used intramuscular ketamine as sedation before lumbar puncture. Ketamine is a suitable drug for sedation in pediatric age groups because of its high therapeutic index and ability to produce dissociative anesthesia with intact airway reflex during sedation which has been also reported in similar studies **[5]**.

In this study intraoperative sedation may not be required if SA is successful because deafferentiation itself produces sedation and because of remaining sedation produced by ketamine.

Our observations were similar with a study done by Hermanns et al., **[18]** on 20 child using intrathecal hyperbaric bupivacaine as they proved that intraoperative sedation is not required if SA is successful using bi-spectral index (BIS) in children under SA.

In the present study sedation was maintained with propofol infusion (using syringe pump) at the rate of 50-75mcg/kg/min in 3/40 (7.5%) of children, 20/40 (50%) were under ketamine sedation, 8/40 (20%) preferred to watch cartoon and 9/40 (22.5%) were released from ketamine sedation and they were cooperative preferred not to be sedated.

Against the current study IV sedation with propofol infusion was administered to all children under SA in a study done by Mahdy et al., **[2]** on 50 patients of both sex, aged 6-12 years, ASA grade I, II, weight (20-50kg) scheduled for lower abdominal procedures.

In this study during surgical procedure, the difference in sedation requirement of both groups was statistically insignificant.

Regarding the complications, in general, complications of SA in children are less than in adults **[19]**.

In the present study the levobupivacaine group reported 2/20 (10%) had bradycardia, 3/20 (15.0%) cases had vomiting, and 2/20 (10%) cases had shivering.

Disagreeing with present study, a study done by Kokki et al., **[20]** on 93 children receiving intrathecallevobupivacaine there was (4%) had nausea, (3%) had vomiting, (4%) children had bradycardia, and one (1%) had shivering.

On the other hand, in the present study the bupivacaine group reported 6/20 (30%) had bradycardia, 2/20 (10%) cases had vomiting, and 2/20 (10%) cases had shivering. In contrast Mahdy et al., **[2]** found less incidence of complications with intrathecal hyperbaric bupivacaine as in their study on 50 child aged 6-12 years, scheduled for lower abdominal procedures; they found that 4/50 (8%) had bradycardia and 2/50 (4%) cases had nausea and vomiting.

There was no statistically significant difference between both groups regarding adverse effects in the present study.

In this study bradycardia was treated by atropine 0. 01mg/kg, shivering was controlled by warming and vomiting was treated by antiemetic, while cases of failed block were transferred to GA and were excluded from the study. (This should be first written in the methods).

Regarding satisfaction of surgeons about SA technique during their surgical procedures, in the present study the surgeon were well satisfied in the present study 85% of cases were well satisfied, 10% poorly satisfied, and 5% were unsatisfied, howeveresurgogene recommend also use of SA in hypospadias cases especially crippled or proximal type whose need multiple stages operations.

Conclusion:

SA was a preferred choice either alone or with sedation as an alternate to GA among the pediatric patients especially in high risk cases during hypospadias surgery especially crippled or proximal type whose need multiple stages operations.

From the present study: Levobupivacaine and hyperbaric bupivacaine are effective in providing adequate quality of anesthesia, however levobupivacaine produced definitely rapid regression of unwanted motor blockade and faster onset of sensory blockade compared to hyperbaric bupivacaine.

Conflicts of interest

There are no conflicts of interest.

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دراسة مقارنة تأثير عقار ليفوبيبوفيكان وبيبوفيكان فى التخدير النصفى فى جراحة الأحليل البولى السفلى لدى الآطفال

أهداف البحث: مقارنة تأثير عقار ليفوبيبوفيكان وعقار بيبوفيكان كمخدر نصفى فى جراحات الأحليل لبولى السفلى لدى الأطفال من حيث الكفاءة، ديناميكية الدم، معدل المشاكل، وعدد الحالات التى إحتاجه إضافة عقار بروبوفول كمخدر عام ومعدل رضى الجراح خلال العملية الجراحية.

طريقة البحث: تمت الدراسة فى مستشفى الزهراء الجامعى خلال الفترة ما بين يناير ٢٠١٩ إلى يناير ٢٠٢٠ على ٦٠ حالة مقسمين إلى مجموعتين كل مجموعة مكونة من ٣٠ حالة. تم أخذ موافقة اللجنة العلمية الأخلاقية قبل بداية الدراسة وموافقة الأهل للطفل. تم إختيار الحالات عشوائياً بين سن ٤ إلى ١٠ سنوات يعانون من إحليل بولى سفلى. المجموعة الأولى تم إعطائها عقار ليفوبيبوفيكان بجرعة ٠.٣ مجم لكل كجم والمجموعة الثانية تم إعطائها عقار بيبوفيكان بجرعة ٠.٣ مجم لكل كجم. تنم قياس ديناميكا الدم (ضغط الدم، نبض القلب، بداية إختفاء الشعور الحسى والحركى)، عدد الحالات التى إحتاجت التحويل إلى التخدير العام ومعدل رضى الجراح خلال فترة الجراحة.

النتيجة: عقار ليفوبيبوفيكان له تأثير أسرع على إختفاء الشعور الحسى والحركى مقارنة بعقار بيبوفيكان.

خاتمة البحث: تم إستنتاج أن التخدير النصفى بعقار ليفوبيبوفيكان أو عقار بيبوفيكان له تأثير فعال وقوى خلال جراحات الإحليل البولى السفلى لدى الأطفال، لذى ينصح بإستخدام عقار ليفوبيبوفيكان كبديل لعقار بيبوفيكان كمخدر نصفى للأطفال.