EXTENDED CAUDAL ANALGESIA USING CAUDALLY ADMINISTERED NALBUPHINE AS AN ADJUVANT FOR LEVOBUPIVACAINE IN TODDLERS UNDERGOING HYPOSPADIAS REPAIR: A RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT:

Background: *Caudal anesthesia is the most reliable neuraxial anesthetic practice in pediatric population and is increasingly performed in pediatric regional anesthesia practices.*

Aim of the study: *This prospective randomized double blind study was done to compare the effects of caudally administered plain levobupivacaine versus Levobupivacaine plus nalbuphine as single-shot for postoperative pain relief in toddlers undergoing hypospadias correction surgery.*

Patients and Methods: *A total of 64 pediatrics were prospectively randomized into two groups: Group L: Patients received caudal levobupivacaine only. Group LN: Patients received caudal levobupivacaine plus nalbuphine. Postoperative analgesia indicated by Face, Leg, Activity, Cry, Consolability (FLACC) pain scale, time to first analgesic request, total consumption of rescue analgesic and occurrence of complications were all recorded.*

Results: *There was statistically significant higher FLACC score in group L than group LN at 30 min and up to 8 hours. The difference between the two groups regarding time to first analgesic request was significantly longer in group LN with significantly lower analgesic consumption. No patients in both groups had respiratory depression, xerostomia or pruritis. Few patients had postoperative nausea and vomiting with no statistically significant difference between the two groups.*

Conclusion: *The combination between nalbuphine and Levobupivacaine was valuable as regarding efficacy and safety profiles in caudal analgesia in toddlers. The intensity and duration of analgesia were remarkable compared to levobupivacaine alone with negligible side effects.*

Keywords: *levobupivacaine; nalbuphine; caudal analgesia*

INTRODUCTION:

Caudal analgesia (CA) is considered the most reliable regional anesthetic technique in pediatric population. It is easy to perform with an excellent safety profile [1]. CA is most effectively used along with general anesthesia to offer the anesthesiologist the opportunity to decrease intraoperative volatile anesthetic use and to follow an intravenous narcotic-sparing approach that ultimately benefits the patient allowing faster and smoother recovery from anesthesia [2] with more satisfying postoperative course and less nausea and vomiting [3].

Being the most favorable technique for postoperative analgesia in surgeries below the umbilicus, single shot CA has the drawback of being of limited duration [4]. Insertion of caudal catheters is rarely done to avoid soiling and infection [5]. Analgesia can be prolonged by addition of a variety of adjuncts, including opioids as, fentanyl or morphine and non-opioids as, dexmedetomidine, ketamine, midazolam, clonidine with variable success rates [6]

Undesirable adverse consequences, including pruritis, nausea and vomiting or most seriously the risk of respiratory depression, made the use of opioids as adjuvants in pediatrics unpopular [7]**.** Nalbuphine is a synthetic opioid and a partial agonist–antagonist analgesic. Its structure resembles those of naloxone and oxymorphone. It exhibits an agonistic action of kappa receptors and partial antagonistic action of mu receptors providing both analgesia and sedation, while protecting against the risk of respiratory depression. Nalbuphine shows a ceiling effect; that's, once its maximum plasma concentration has been achieved, no more analgesic effect or increased risk of respiratory depression can result by incremental doses [8]. Neuraxial opioids acts on activation of mu opioid receptors (presynaptic& postsynaptic) situated in the substantia gelatinosa of the spinal cord dorsal horn as well as the C and A fibers [9]. Thus, inhibiting excitatory neurotransmitters, substance P and glutamate presynaptic release, and stimulating postsynaptic spinal adenosine release. Also, activation of the delta and kappa receptors can take a share in spinal analgesia [10].

AIM OF THE STUDY:

This study was conducted to study the results of adding nalbuphine 0.1 mg/kg to levobupivacaine 0.25% in single-injection caudal analgesia for pain control in toddlers undergoing hypospadias repair in the postoperative period up to 24 hours.

PATIENTS AND METHODS:

This prospective, randomized, double blinded clinical trial was conducted at Ain Shams university hospitals.

64 American society of Anesthesiologists (ASA) physical status I, II toddlers aged 1-3 years scheduled for hypospadias correction surgeries were included in this study. Exclusion criteria included ASA III, IV pediatrics, signs of infection at site of injection, known coagulopathy disorder, mental and / or developmental retardation.

Randomization and allocation concealment were achieved using the method of numbered, opaque, sealed envelopes, and the patients were allocated into two groups as follows:

(Group L): Caudal block was done in this group using levobupivacaine 0.25% with the volume of 1 ml /kg plus one ml normal saline after induction of general anesthesia.

(Group LN): Caudal block was done in this group using levobupivacaine 0.25% with the volume of 1 ml /kg + nalbuphine 0.1 mg /kg in one ml normal saline after induction of general anesthesia.

The study was double blinded; neither the parents of the patients nor the investigator who collected the data were aware of the group allocation.

A preoperative visit was done at the night of surgery for careful history taking and identification of bleeding tendency, regular drug intake, past history of allergy or sensitivity to any drugs or previous anesthetic experience. General clinical examination and inspection of caudal area were done. Checking of routine preoperative investigations in the form of Complete blood count (CBC), coagulation profile (PT, INR,

and PTT) was done. The parents were instructed about the fasting hours of the children being 8 hours for food, 6 hours for milk and 2 hours for clear fluids.

At the operating room, children were connected to the monitor including ECG, non-invasive blood pressure and pulse oximeter. Then, initiation of general anesthesia by inhalational route using sevoflurane 4% was done followed by intravenous line insertion. Atropine 0.01 mg/kg, atracurium 0.5 mg/kg were administrated and an appropriate size endotracheal tube was inserted. Maintenance of anesthesia was done with sevoflurane 2-3% and 100% oxygen and pressure controlled mechanical ventilation. During surgery, children received Lactated Ringers solution 4 ml/kg/h. An intraoperative decrease of MAP or HR by > 20% was defined as hypotension or bradycardia, respectively, and was treated by fluid bolus, ephedrine and or atropine as necessary. Sedatives and opioids were omitted throughout the intraoperative period.

After establishment of general anesthesia, child was positioned in lateral decubitus with knee flexed to the chest, povidone iodine solution was used to clean the skin over the sacrum. Under complete aseptic conditions the coccyx was palpated then cephalad sliding of the palpating finger till feeling a skin depression was done. The site of the hiatus was confirmed by drawing a triangle made by the posterior superior iliac spines and the sacral hiatus. A 22 - gauged short, beveled needle was inserted in perpendicular fashion. The needle was inserted just below the spinous process S4. After feeling a slight snap during advancement of the needle indicating piercing the sacrococcygeal ligament and on reaching the ventral wall of the canal, the needle was slowly withdrawn and redirected cranially into the canal. A negative aspiration test was done to exclude intravascular or intrathecal placement then a "whoosh" test was done by the injection of approximately 2 ml of air through the caudal needle, then injection of the study volume was done slowly [11]**.**

Group L: received levobupivacaine 0.25% only 1 ml/kg plus 1 ml normal saline.

Group LN: received levobupivacaine 0.25% 1 ml/kg plus nalbuphine 0.1 mg/kg in 1 ml normal saline.

Adequate analgesia in the intraoperative period was indicated by the stability of hemodynamics, as any increase in heart rate (HR) or mean arterial blood pressure (MAP) more than 15% of the baseline values within 15 minutes of skin incision was considered as failure of caudal anesthesia, and the child received an analgesic in the form of fentanyl 0.5 µg/ kg and consequently excluded from the study.

After skin closure, discontinuation of inhalational anesthesia and reversal of muscle relaxant was done using neostigmine 0.05mg/kg plus atropine 0.02/kg following extubation the child was transported to the post anesthetic care unit with routine basic monitoring of hemodynamics and pain assessment.

Quality of pain control was evaluated by**:** The FLACC (face, leg, activity, crying, and consolability) scale as children were evaluated and scored either 0, 1 or 2 in each category based on their behavior. A total score was calculated (0 = no pain; 1–3 = mild pain; 4–7 = moderate pain; 8–10 = severe pain). On obtaining a score of greater than 3 was identified the child was first managed non pharmacologically (position changing, tactile stimulation, etc), if no effect after 5 minutes intravenous acetaminophen 15 mg/kg was given. Then, after another 30 minutes, if pain score still exceeding 3 a rescue analgesic meperidine was given in a dose 1 mg/kg was given. Duration of analgesia indicated by time to first analgesic request and, total consumption of rescue analgesic/24 hours were recorded.

Occurrence of complications as PONV, pruritis, xerostomia and or respiratory depression were also documented.

Ethical considerations:

This study obtained approval from the Ethics Committee of Ain Shams Faculty of Medicine. All participants gave informed, written consents. The study was registered at the clinicalTrials.gov (Date: November 16, 2022; ID: NCT05617976).

Statistical analysis:

Data were collected, revised, coded, and entered to the Statistical Package for Social Science (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations and ranges when their distribution found parametric. Mann Whitney U test was used for two-group comparisons in non-parametric data. Also, qualitative variables were presented as number and percentages. The comparison between groups with qualitative data were done by using Chi-square test and Fisher exact test instead of the Chi-square only when the expected count in any cell found less than 5. The comparison between two groups with quantitative data and parametric distribution were done by using independent t-test. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the P-value was considered significant at $P < 0.05$ and highly significant at $P < 0.001$.

Sample size justification:

MedCalc® version 12.3.0.0 program "Ostend, Belgium" was used for calculations of sample size, statistical calculator based on 95% confidence interval and power of the study 80% with α error 5%. A previous study [12] showed that the mean of FLACC scale at 24 h in fentanyl group was 2.1±1.29 compared to 0.95±0.89 for nalbuphine group. So, based on this assumption, the sample size was calculated according to these values. A minimal samples size of 58 cases was enough to find such a difference, but the number was increased to 64 (32 per group) to show appropriate results and to increase the strength of the study.

RESULTS:

Sixty four patients were enrolled in the study. Thirty two patients in each group. Groups were compared as regarding demographic data in terms of (age, ASA, weight & height and duration of surgery) and there were no statistically significant differences between groups (Table 1).

Table (1): Comparison between the two groups regarding demographic and characteristic data

		Group L (N = 32)	Group LN (N = 32)	Test value	P-value
Age (years)	Mean ± SD	2.03 ± 0.62	2.21 ± 0.69	-1.136	0.260
	Range	1 – 3	1 – 3		
ASA	I	24 (75.0%)	27 (84.4%)	0.869	0.351
	II	8 (25.0%)	5 (15.6%)		
Weight (kg)	Mean ± SD	12.88 ± 2.05	13.30 ± 1.47	-0.946	0.348
	Range	9.5 – 16	11 – 15		
Height (cm)	Mean ± SD	91.84 ± 6.31	94.88 ± 7.84	-1.704	0.093
	Range	76 – 105	79 – 105		
Duration of surgery	Mean ± SD	92.81 ± 7.00	91.53 ± 5.30	0.826	0.412
	Range	80 – 100	85 – 100		

N: number; SD: standard deviation; ASA: American society of Anesthesiologists

On comparing the two studied groups as regarding postoperative FLACC score, the score was significantly lower all over the study time points and up to 8 h postoperatively. Then, the difference turned to be non-significant afterwards (**Table 2**).

Table (2): Comparison between the two studied groups regarding FLACC sore

FLACC scale		Group L (N = 32)	Group LN (N = 32)	Test value	P-value
At 30 min	Median (IQR)	1 (1-2)	1 (1-1)	-2.527	0.011*
	Range	1 – 2	1 – 2		
At 1 h	Median (IQR)	1 (1-2)	1 (1-1)	-2.708	0.007*
	Range	1 – 3	1 – 2		
At 2 h	Median (IQR)	2 (2-3)	2 (1-2)	-3.155	0.013*
	Range	1 – 3	1 – 3		
At 4 h	Median (IQR)	3 (2-4)	2 (2-3)	-1.966	0.049*
	Range	2 – 5	2 – 4		
At 8 h	Median (IQR)	4 (3-5)	3 (2-4)	-2.906	0.004*
	Range	2 – 7	2 – 5		
At 12 h	Median (IQR)	5 (4-6)	5 (3-6)	-1.180	0.238
	Range	4 – 8	3 – 7		
At 16 h	Median (IQR)	5 (4-6)	5 (4-6)	-1.127	0.260
	Range	3 – 7	3 – 7		
At 24 h	Median (IQR)	4 (3-6)	4 (3-5)	-1.383	0.167
	Range	3 – 7	1 – 6		

N: number; SD: standard deviation; FLACC: Face, Leg, Activity, Cry, Consolability; *Significant at P<0.05

A significant difference was found between the two studied groups as considering time to first analgesic requirement being remarkably longer in LN group with a significant lower total analgesic consumption in the same group (Table 3).

Table (3): Comparison between the two groups regarding time to first analgesic request and total consumption of rescue analgesic

		Group L (N=32)	Group LN (N=32)	Test value	P-value
Time to first analgesic requirement (h)	Mean ± SD	7.28 ± 1.07	11.59 ± 2.54	-8.857	0.000**
	Range	4 – 8	6 – 14		
Total consumption of rescue analgesia (mg)	Mean ± SD	23.47 ± 8.17	19.23 ± 7.31	2.192	0.032*
	Range	9.5 – 36	11 – 30		

N: number; SD: standard deviation; *Significant at P<0.05; ** Highly significant at P<0.001

There were no significant differences between the studied groups regarding any of the possible expected complications (Table 4).

DISCUSSION

CA is a favorable, feasible and safe technique for pediatric pain control and is frequently applied following the stabilization of general anesthesia to induce intraoperative and postoperative analgesia in pediatrics undergoing infra-umbilical surgical procedures [13]. It facilitates an enhanced, smooth recovery with excellent postoperative pain control but for a short duration of action. Extending the effect of caudal analgesia has been obtained by adding of variable adjuncts. Recently, anesthetists tried nalbuphine for this aim. Nalbuphine hydrochloride is an opioid with mixed agonist-antagonist activity. It exerts its action on spinal and supraspinal opioid receptors , leading to adequate analgesia with minimal sedation, mild nausea and vomiting and less respiratory depression with cardiovascular stability [13]. In our study we performed a prospective double blinded

randomized clinical trial in Ain Shams university hospitals, on sixty four toddlers aged 1-3 years old. Patients were randomly divided into two groups to evaluate the effect of adding nalbuphine to levobupivacaine (group LN) versus levobupivacaine alone (group L) in caudal analgesia as regarding quality of postoperative analgesia (indicated by FLACC score), duration of the block (indicated by time to first analgesic request), total postoperative analgesic consumption and, occurrence of complications in the first 24 hours postoperative after hypospadias repair. We intended to avoid the use of narcotics at induction of anesthesia so that we can assess the success of CA at the beginning of the operation by hemodynamic changes in response to surgical stimulation which can be masked using narcotics with strong analgesic effect. Also, the use of intravenous narcotics may affect the quality of postoperative analgesia or duration of the block. Instead, stress response to intubation can be blunted in toddlers by deep anesthesia with full relaxation. Patients who required intraoperative analgesia were excluded from the study for failure of caudal block. Our data showed that caudal anesthesia supplemented with low dose of nalbuphine 0.1 mg/kg added to 0.25% levobupivacaine 1ml/kg body weight during single dose injection significantly improved the quality of analgesia with a significantly lower FLACC score in group LN up to 8 h postoperatively compared with patients who received a routine caudal block. It also prolonged the duration of analgesia indicated by significantly longer time to first analgesic request in group LN with overall significantly lower total analgesic consumption in the same group, without significant increase in occurrence of complications as there was no incidence of respiratory depression or pruritis in the caudal nalbuphine group patients.

Mok *et al.*[14] first, reported the effectiveness of nalbuphine when used in epidural anesthesia. They added 10 mg nalbuphine to 10 ml isotonic saline instead of the same volume of plain isotonic saline in the epidural space through the postoperative period after complete emergence from anesthesia only at suffering of marked discomfort. They found that pain scores were significantly lower in the nalbuphine group. There was neither pruritis nor respiratory depression detected in any patient.

Shin *et al.*[15] then evaluated caudally administered nalbuphine for postoperative pain control after a perianal surgery. Caudal analgesia was achieved using 1.5% lidocaine 25 ml in one group and mixed with nalbuphine 3 mg in the second group, nalbuphine 5 mg in the third group, and nalbuphine 10 mg in the fourth group. Analgesia was indicated by the lack of need for intravenous analgesic in the form of pethidine. The fourth group showed significantly reduced analgesic consumption for the first 24 hours postoperatively. Complications did not correlate with the dose of nalbuphine.

Culebras *et al.* [16] compared the effects of morphine to nalbuphine when given in the subarachnoid space, for cesarean section, they used morphine 0.2mg and nalbuphine in three doses (0.2, 0.8, 1.6 mg) in 1ml added to 10mg of bupivacaine 0.5% (total volume 3ml) as single intrathecal dose. No significances were recorded between any of the groups considering the overall satisfaction of patients at 24 hours, indicated by VAS scores, but adverse effects were less observed in the nalbuphine groups.

Malinovsky *et al.*[17] studied the effects of nalbuphine when given in epidural space. They used nalbuphine 0.1mg/kg of nalbuphine in 12ml of normal saline in comparison to 12mL of solution saline with 15 mg of bupivacaine alone both administered in the epidural space. Their conclusion was that nalbuphine is highly effective to achieve labor analgesia and is

ultimately safe for both the mother and the newborn.

Gomaa *et al.*[18] observed the post-operative analgesic profile of nalbuphine plus bupivacaine versus fentanyl plus bupivacaine injected intrathecally for a cesarean section. Nalbuphine showed adequate intra and post operative pain control with less adverse effects.

Kumar *et al.*[19] studied the effect of nalbuphine with bupivacaine compared to bupivacaine alone for post-operative epidural analgesia. Nalbuphine significantly prolonged postoperative analgesia without causing significant adverse effects.

Mohamed *et al.* [20] compared the effectiveness of caudal nalbuphine plus bupivacaine versus caudal bupivacaine alone. The quality of analgesia was assessed using pain discomfort scale for the first postoperative 24 h. The duration of analgesia as well as time to first need of analgesia were prolonged in the group of nalbuphine. Using an objective score based on eye opening they assessed postoperative sedation, and they recorded that more sedation scores were obtained at 30 min and 1 h in the nalbuphine group. While no respiratory depression was recorded.

Salama[21] added nalbuphine to levobupivacaine in single-shot CA compared to levobupivacaine alone. They recorded that the quality of analgesia was better in nalbuphine group indicated by significantly lower FLACC pain score after 2 h and afterwards till the end of the study period. The postoperative analgesic free time before asking for supplementary analgesic in the nalbuphine group was significantly longer. Also, there was significantly less consumption of intravenous paracetamol in the first 12 h in the nalbuphine group compared to levobupivacaine only group. They recorded no serious complications for the first 12 h in both groups.

Salama *et al.* [22] then compared nalbuphine, dexmedetomidine and bupivacaine alone in three separate groups in single-shot CA. They found that either dexmedetomidine or nalbuphine can be considered as safe additives in caudal block in pediatrics to increase and prolong CA. They also found that the postoperative pain scores were significantly lower in dexmedetomidine group and slightly lower in nalbuphine group than in bupivacaine group with no adverse effects observed in the first 24 h in all 3 groups.

Murthy *et al.*[23] compared nalbuphine versus dexmedetomidine when added to ropivacaine to induce postoperative analgesia in pediatrics undergoing surgeries below the umbilicus using CA. The results of this study confirmed the effect of nalbuphine as an adjunct to local anesthetic to elevate the intensity of caudal block without significant complications.

Sanaa *et al.*[24] compared the effects of adding nalbuphine or fentanyl to bupivacaine versus bupivacaine alone in children scheduled for hernia repair operations under general anesthesia combined with single shot CA. Significant differences were found regarding postoperative analgesia and sedation as there were more prolonged analgesic and sedation times in the nalbuphine group in comparison to fentanyl and bupivacaine groups with considerably less adverse effects. They concluded that addition of nalbuphine 0.2 mg/kg to bupivacaine 0.125% provides higher quality of postoperative analgesia than adding fentanyl 1 µg/kg to bupivacaine in the same concentration with marked decrease in the rate of occurrence of complications.

When talking about failure, nalbuphine was disappointing as an adjuvant for bupivacaine in epidural analgesia only in a study done by **Camann *et al.***[25], as they tested the analgesic property of epidural nalbuphine and the effect of local anesthetic choice. They investigated 58 patients

undergoing elective Caesarean section using epidural anesthesia. Patients classified to receive either lidocaine 2% with 1:200,000 epinephrine or chloroprocaine 3% in the epidural space intraoperative, followed by either 10, 20, or 30 mg of nalbuphine administered at epidural space at first complain of postoperative pain. They concluded that nalbuphine prolonged the analgesia of lidocaine for a maximum of four hours following caesarean section, with no or only minimal analgesia with chloroprocaine. This might be due to delaying administration of epidural nalbuphine.

Conclusion:

The combination between nalbuphine and Levobupivacaine was valuable as regarding efficacy and safety profiles in toddlers analgesia. The intensity and duration of analgesia were remarkable compared to levobupivacaine alone. Fortunately, there were no side effects of systemic hazards recorded from systemic absorption of nalbuphine. We recommend considering nalbuphine as one of the valuable adjuvants to levobupivacaine in caudal analgesia according to its efficacy and safety profile.

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Conflicts of interest:

None.

The authors confirm that this paper has not been published in its current form or substantially similar form elsewhere including on a web site and also, it has not been accepted for publication elsewhere.

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التسكين الذيلي الممتد بإستخدام عقار النالوفين كعامل مساعد لليفوبيوبيفاكين في الأطفال الذين يخضعون لإجراء إصلاح الإحليل التحتي: تجربة سريرية عشوائية ذات شواهد

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قسم التخدير كلية الطب جامعة عين شمس

الخلفية: يعتبر التخدير الذيلي هو الطريقة الوحيدة الأكثر أهمية للتخدير المحوري العصبي في الأطفال ويتم إجراؤه بشكل متزايد في ممارسات التخديرالموضعي للأطفال. تم إجراء هذه الدراسة المرتقبة العشوائية مزدوجة التعمية لمقارنة تأثير الليفوبيوبيفاكين العادي مقابل الليفوبيوبيفاكين بالإضافة إلي النالوفين في التخدير الذيلي أحادي الحقن لتسكين الألم الناتج عن جراحة إصلاح الإحليل التحتي في الأطفال.

الطريقة: تم إدراج عدد ٦٤ طفل بشكل عشوائي وتقسيمهم في إحدي المجموعتين. مجموعة ل: سيتلقي الأطفال فيها عقار الليفوبيوبيفاكين فقط. مجموعة ل ن: سيتلقي الأطفال فيها الليفو بيوبيفاكين بالإضافة إلي النالوفين. تم تقييم مدي تسكين الألم ما بعد الجراحة بإستخدام مقياس الوجه، الأرجل، النشاط، البكاء و التعزية. كما تم تسجيل المدة الزمنية قبل ان يطلب المريض لمسكن منقذ، الإستهلاك الكلي من هذا المسكن، أو حدوث أية مضاعفات.

النتائج: وجد أن هناك اختلاف ذو دلالة احصائية فيما يخص مقياس الألم حيث كانت نسبته أعلي في المجموعة ل عند ٣٠ دقيقة وحتي ٨ ساعات، كما كانت المدة الزمنية قبل طلب مسكن إنقاذ هي الأقصر في نفس المجموعة، وكذلك الإستهلاك الكلي لمسكن الإنقاذ كان أعلي في المجموعة ل، بينما لم يكن هناك فرق ذو دلالة إحصائية فيما يخص حدوث مضاعفات في كلا المجموعتين.

الإستنتاج: إن المزج بين عقاري الليفوبيوبيفاكين والنالوفين هو طريقة فعالة وآمنة في التخدير الذيلي للأطفال، حيث أن شدة تسكين الألم ومدته أعلي عند إستخدام المزيج بالمقارنة ب عقار الليفوبيوبيفاكين العادي دون أي مضاعفات تذكر.