

Nerve Stimulator–guided Paravertebral Blockade Combined with Sevoflurane Sedation versus General Anesthesia with Systemic Analgesia for Postherniorrhaphy Pain Relief in Children

A Prospective Randomized Trial

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Background: Improvement of the duration of postoperative analgesia is desirable in children undergoing inguinal hernia repair.

Methods: Fifty children aged 5–12 yr were prospectively randomized to receive either paravertebral nerve blockade or general anesthesia (sevoflurane–fentanyl–nitrous oxide–oxygen) combined with standardized postoperative systemic analgesia, both combined with light sevoflurane anesthesia, for inguinal hernia repair.

Results: Mean pain scores were significantly lower in paravertebral nerve blockade patients compared with patients treated with systemic analgesia during the entire 48-h observational period ($P < 0.05$). Analgesic consumption was significantly higher in the systemic analgesia group (88%) compared with the paravertebral nerve blockade group (32%) ($P < 0.001$). Parental satisfaction was significantly higher (80 vs. 48%; $P < 0.05$) and same-day discharge was possible in a higher proportion of patients in the paravertebral blockade group (80% vs. 52%; $P < 0.05$).

Conclusions: Paravertebral nerve blockade was associated with improved postoperative pain relief; reduced analgesic consumption, and faster hospital discharge compared with a systemic analgesia protocol in children undergoing herniorrhaphy.

INGUINAL hernia repair represents one of the most frequent surgical interventions performed in children.¹ A variety of different regional anesthetic techniques (e.g., caudal blockade, ilioinguinal/iliohypogastric nerve block, local infiltration)^{2–7} and systemic analgesics^{8,9} are currently used and are associated with good immediate postoperative analgesia. Further improvement of the duration of postoperative analgesia is still clearly desirable, especially considering the increasing number of patients being treated on an outpatient basis.

The use of paravertebral blockade (PVB), either in combination with general anesthesia¹⁰ or as a technique only supplemented by light sedation,^{11–13} has recently been reported in adults and has been found to produce excellent and surprisingly long-lasting postoperative pain relief after unilateral inguinal hernia repair. Despite these positive adult findings, only very limited data on this technique are currently available in children,¹⁴ and to the best of our knowledge, no prospective randomized pediatric data has so far been published for inguinal hernia repair. However, because the surgical intervention for hernia repair is considerably less extensive in children, it is currently not clear whether the excellent adult results of PVB also can be reproduced in children. Therefore, the aim of the current study was to conduct a prospective, randomized, observer-blinded comparison between light sevoflurane anesthesia combined with nerve stimulator–guided PVB or general anesthesia combined with standardized postoperative systemic analgesic in children undergoing pediatric hernia repair, with the primary hypothesis being that PVB would result in better and more prolonged postoperative analgesia.

Materials and Methods

After approval of the Research Ethical Committee at Makassed General Hospital, Beirut, Lebanon, and written parental consent were obtained, 50 children, aged 5–12 yr, admitted to undergo elective herniorrhaphy were included in this study conducted from January 2003 to December 2003. Exclusion criteria consisted of bilateral inguinal hernia, a known history of allergic reactions to the local anesthesia, bleeding diathesis, and preexisting or obvious spinal diseases of the lower back as determined by physical examination. According to the randomization, the children were assigned to receive either general anesthesia alone (GA) or a nerve stimulator–guided PVB. Trained nurses blinded to patient's treatment collected the various postoperative data. Thus, neither the anesthetist nor the surgeon performing the procedure was involved in data collection.

Protocol of the General Anesthesia

No premedication was given; eutectic mixture of local anesthetics cream was applied 1 h before GA induction

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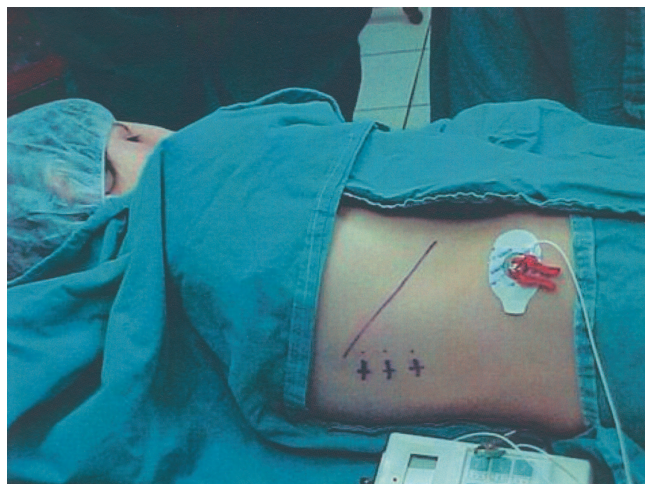


Fig. 1. Nerve stimulator–guided paravertebral technique. Patient in left decubitus position. The oblique line corresponds to D12. Sites of injection are marked 1.5 cm lateral to the midline at D12–L1, L1–L2, and L2–L3 levels.

by intravenous fentanyl (1.5 $\mu\text{g}/\text{kg}$) and thiopental (3–5 mg/kg) followed by tracheal intubation facilitated by atracurium (0.5 mg/kg). Anesthesia was subsequently maintained with 1–3% sevoflurane, 70% nitrous oxide, and 30% oxygen. The sevoflurane concentration was adjusted with the intention of keeping hemodynamic values within 25% of preinduction values.

Paravertebral Block Technique

After induction of 3–4% sevoflurane by facemask and placement of regular anesthetic monitors, unilateral PVBs were performed at the T12–L1, L1–L2, and L2–L3 levels by three separate injections while the child was in the lateral decubitus position, with the side to be operated on in the upper position. Sites of injection were marked 1.5–2 cm lateral to the midline, depending on the age and the body mass index of the child¹⁵ (fig. 1).

After aseptic preparation of the skin, the injection sites were each infiltrated with 0.1 ml lidocaine, 1%. A nerve stimulator (Stimuplex; B. Braun AG, Melsungen, Germany) was used to identify a muscular response appropriate for the T12–L3 levels. A 50-mm 21-gauge insulated needle (Stimuplex) was introduced perpendicularly to the skin at the site of the upper injection point using the following nerve stimulator settings: 5 mA, 9 V, and 1 Hz. Initially, contractions of the paraspinal muscles were seen as a result of direct muscle stimulation. After the paravertebral space had been entered, the stimulating needle was gently manipulated into a position to allow an adequate muscular response with a stimulating current of 0.4–0.6 mA. The manipulation of the needle tip within the paravertebral space is not an in-out movement; rather, it is an angular manipulation and circumferential rotation around the axis of the needle to orient the tip of the needle into close proximity of the corresponding nerve root. Adequate muscle responses were

low abdominal, inguinal, and cremaster contractions for the T12–L1, L1–L2, and L2–L3 levels, respectively. At this point, 0.1 ml/kg of a local anesthetic mixture was injected at each level (total volume of 0.3 ml/kg). After the PVB was achieved, sevoflurane was maintained at 0.4–0.8%.

Each 20 ml of the mixture contains 6 ml lidocaine, 2%; 6 ml lidocaine, 2%, with 1/200,000 epinephrine; 6 ml bupivacaine, 0.5%; 1 ml fentanyl, 50 $\mu\text{g}/\text{ml}$; and 1 ml clonidine, 75 $\mu\text{g}/\text{ml}$. This PVB technique and local anesthetic mixture have previously been used by our group.^{11,16–19}

Important Anesthetic Difference between the Study Groups

In summary, the main differences in anesthetic technique between the two study groups were the following: in the general anesthesia with systemic analgesia group (GA/SA), an intravenous induction was performed in all patients. Airway management consisted of tracheal intubation and fentanyl, plus nitrous oxide was administered instead of a regional anesthetic block. In the PVB group, an inhalational induction with sevoflurane was performed in all children. Because of the expected light level of sevoflurane sedation necessary after the performance of the PVB, airway management was by facemask only, and these patients were not given intraoperative fentanyl or nitrous oxide.

Intraoperative Monitoring

Noninvasive mean arterial blood pressure, heart rate, and oxygen saturation were recorded preoperatively (baseline), intraoperatively (incision of skin, dissection of hernia, traction over the sac, and closure of incision), and immediately postoperatively (recovery room). During the operation, any hemodynamic changes in excess of 25% from baseline values resulted in a stepwise increase or decrease of the sevoflurane concentration.

Protocol for Postoperative Systemic Analgesia

Tramadol hydrochloride (Tramal drops; Laboratoire, Grunenthal, Aachen, Germany), 1–2 mg/kg, was given when the visual analog scale (VAS) score was greater than 5 (one drop of Tramal contains 2.5 mg tramadol hydrochloride); 30 mg/kg intravenous propacetamol hydrochloride (Pro-Dafalgan; Laboratories UPSA, Agen, France) was given if the VAS score was 4 or 5. A 350-mg paracetamol suppository (Tylenol CILAG SA, Schaffhouse, Switzerland) was prescribed when children or parents requested analgesics despite a VAS score of less than 4. At discharge from the hospital, 350-mg paracetamol suppositories were prescribed as needed (maximum 4 times/24 h).

Postoperative Pain Assessment

During hospitalization, trained nurses, blinded to the randomization, collected the VAS scores, and after hos-

pital discharge, VAS scores were assessed by parents through phone calls made by the same nurses. Postoperative pain at rest (in bed), during movement (flexing the hip), and during activity (walking inside the room) were assessed during the first 2 postoperative days at predetermined time intervals (6, 12, 24, 36, and 48 h) using a VAS (0–10 cm) where 0 represents no pain and 10 represents the worse possible pain. Pain scores were always assessed before giving the patient supplemental analgesics. Patients discharged from the hospital were contacted by telephone to assess their postoperative pain.

Discharge from the Hospital

The decision to discharge the patient from hospital was made entirely by the surgeon according to previously established clinical routine. Thus, none of the investigators were involved with or could influence this decision making. The criteria for hospital discharge were pain score less than 4, hemodynamic stability, ability to drink water, micturition, and absence of nausea and vomiting.

Surgeon and Parents' Satisfaction

The surgeon's satisfaction was based on the overall postoperative clinical status of the patient. The parents' satisfaction was also assessed postoperatively based on their children's comfort and activity.

Statistical Analysis

Based on clinical observations and to detect a difference between the VAS scores at rest, 48 h postoperatively, with the mean (SD) equal to 0.84 (0.96) and 0.1 (0.04) for the GA/SA and PVB groups, respectively, with a 5% significance level and 95% power, a sample size of 25 patients in each study group was deemed adequate. Patients were randomly assigned using computer-generated random number tables and allocated to one of the two groups using the sealed opaque envelope technique. Data are reported as mean (SD) or percentage. Two-way analysis of variance for repeated measurement was used to indicate a significant difference between the two groups over the follow-up time period comparing the average pain scores. The *t* test was used to compare significant differences between the two groups for pain scores at rest, during activity, and during movement.

Results

The two study groups were similar with regard to age, sex, weight, and height (table 1).

In five PVB patients, the inspired sevoflurane concentration had to be adjusted because of an intraoperative increase of hemodynamic parameters as a result of the surgical stimulation. However, most PVB patients (80%) only required inspired sevoflurane concentrations in the

Table 1. Patient Characteristics and Postoperative Data

	GA/SA	PVB	P Value
Number of patients	25	25	
Age, yr	7.92 (1.75)	8.16 (1.82)	NS
Sex			
Male	19 (76%)	20 (80%)	NS
Female	6 (24%)	5 (20%)	
Weight, kg	26.11 (4.49)	25.7 (5.68)	NS
Height, cm	127.08 (8.59)	128.52 (10.57)	NS
Duration of surgery, min	38.16 (4.39)	37.72 (4.72)	NS
PONV incidence	3 (12%)	0 (0%)	NS
Duration of hospital stay			
Same-day discharge	13 (52%)	20 (80%)	
Overnight stay	8 (32%)	5 (20%)	< 0.05
> 1 day	4 (16%)	0 (0%)	
Postoperative surgeon satisfaction			
Excellent	13 (52%)	22 (88%)	
Good	7 (28%)	2 (8%)	< 0.05
Unsatisfied	5 (20%)	1 (4%)	
Postoperative parent satisfaction			
Excellent	11 (44%)	20 (80%)	
Good	8 (32%)	3 (12%)	< 0.05
Unsatisfied	6 (24%)	2 (8%)	

Data are presented as mean (SD) or number of patients (%).

GA/SA = general anesthesia with systemic analgesics; NS = no significant difference at $P = 0.05$; PONV = postoperative nausea and vomiting; PVB = paravertebral blockade.

range of 0.4–0.8% during the intraoperative period. In the GA/SA group, 10 children needed an increase in sevoflurane concentration because of an intraoperative increase of blood pressure.

Pain scores at rest, during movement, and during activity for the two groups during the first 48 postoperative hours are displayed in table 2. The two-way analysis of variance for repeated measurements of pain scores within the entire follow-up period showed a significant difference in favor of the PVB group ($P < 0.05$). At each assessment time point, all three VAS pain scores (at rest, during movement, and during activity) were found to be lower in the PVB group compared with the GA/SA group ($P < 0.05$ – 0.001 ; table 2 and fig. 2).

The majority of children in the PVB group (80%) left the hospital the same day (outpatients) compared with only 52% in the GA/SA group ($P < 0.05$; table 1). Both the surgeon and the parents expressed greater postoperative satisfaction in the PVB group compared with the GA/SA group ($P < 0.05$; table 1). No complication except mild local tenderness at the PVB injection sites (in three patients) was noted in the PVB group.

Discussion

The main finding of the current prospective, randomized study was a significant improvement of postoperative pain relief after herniorrhaphy, both at rest and during activity, in children treated with nerve stimula-

Table 2. Average Pain Scores during the Follow-up Period*

	6 h	12 h	18 h	24 h	36 h	48 h
GA/SA						
At rest	5.05 (2.41)	4.65 (2.52)	4.0 (2.29)	2.55 (1.93)	1.45 (1.55)	0.84 (0.96)
During movement	5.41 (2.57)	5.25 (2.57)	4.71 (2.19)	3.09 (1.77)	2.31 (1.51)	1.65 (1.18)
During activity	5.81 (2.81)	5.35 (2.49)	4.81 (2.31)	3.29 (1.89)	2.51 (1.77)	1.85 (1.23)
PVB						
At rest	1.95 (1.90)	1.90 (1.77)	1.55 (1.67)	1.15 (1.09)	0.1 (0.44)	0.1 (0.04)
During movement	2.56 (2.16)	2.43 (1.98)	2.06 (1.57)	1.59 (0.77)	1.01 (0.68)	0.56 (0.46)
During activity	2.76 (2.36)	2.63 (2.09)	2.26 (1.87)	1.79 (0.94)	1.15 (0.88)	0.76 (0.66)

Data are presented as mean (SD). An overall statistically significant difference is present during the entire observation period for all three parameters ($P < 0.05$). Consumption of supplemental analgesics was significantly higher in the general anesthesia with systemic analgesics (GA/SA) group compared with the paravertebral blockade (PVB) group during the entire follow-up period ($P < 0.001$). Only 8 patients (32%) in the PVB group required additional analgesics vs. 22 patients (88%) in the GA/SA group (table 3 and fig. 3). Number of patients needing tramadol, proparacetamol, and paracetamol are given in table 3.

* Statistically significant differences at each individual time point for all three parameters, with $P < 0.01-0.001$.

tor-guided paravertebral nerve blockade compared with subjects receiving systemic analgesia. Use of the paravertebral technique resulted in less than one third of the patients requiring supplemental analgesics during the first 48 postoperative hours and also allowed for significantly earlier hospital discharge (80% same-day discharge vs. 52%).

Prospective case series and proper randomized clinical trials in adults have shown PVB to provide excellent postoperative anesthesia after a variety of surgical interventions,^{10-13,16-19} and the PVB technique has been the focus of a number of recent review articles.^{20,21} The PVB technique has also been shown to produce favorable results when used for inguinal hernia repair in adults,¹⁰⁻¹³ and it has also been suggested that this technique can be used in children.¹⁴

Despite a number of pediatric publications relating to the use of PVB, to our knowledge, no proper prospective randomized trial has been published for inguinal hernia repair. Against this background, we believed that it was essential to perform a basic prospective randomized trial against regular general anesthesia and systemic postoperative pain relief to verify a true beneficial effect of the PVB technique also in children, because the surgical technique for hernia repair is considerably different in children as compared with adults.

With regard to the primary endpoint of the study, PVB was found to provide superior pain relief both at rest and during activity throughout the 48-h observational period, compared with a general anesthetic technique with a well-defined postoperative analgesic protocol. Not surprisingly, the better postoperative analgesia as judged by parental VAS recordings was also associated with a significantly reduced need for supplemental postoperative analgesia in the PVB group.

Pain relief associated with PVB in the current study seems to substantially outlast the expected duration of the local anesthetics. However, this finding is in accord with previous publications.^{11,16,17,19,22} Because of the prolonged analgesic effect achieved by the use of a local anesthetic mixture also containing a synthetic opioid and an α_2 -adrenergic agonist that we have observed in previous studies,^{11,16-19,23,24} we decided that it would be ethically questionable not to use this solution also in this pediatric study. Not using plain local anesthetics may make the interpretation of the initial postoperative data more difficult because systemic absorption of fentanyl and clonidine could possibly influence these obser-

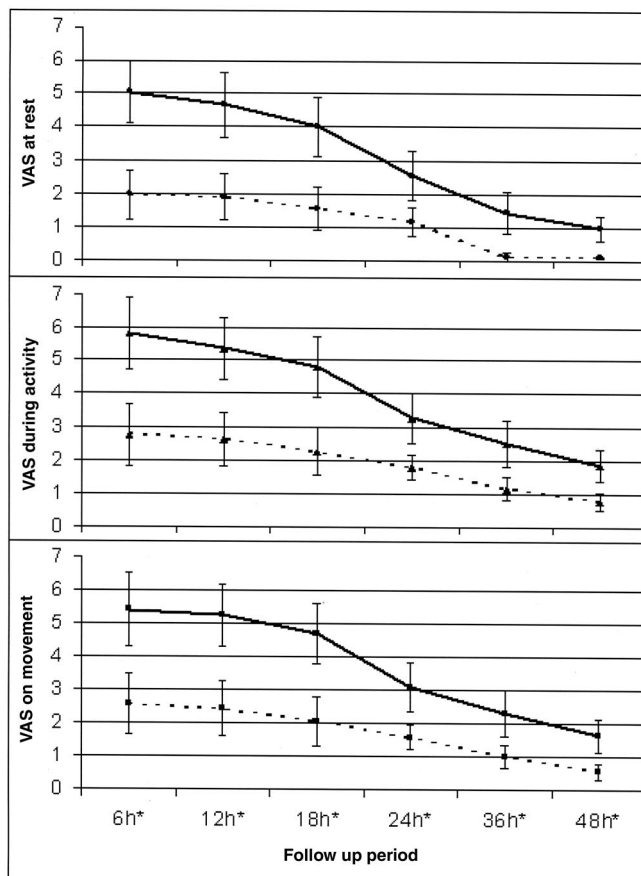


Fig. 2. Means and 95% confidence intervals for visual analog scale (VAS) scores at rest, during activity, and during movement through the postoperative follow-up period. *Solid line* = general anesthesia with systemic analgesics group; *dotted line* = paravertebral blockade group. * Statistically significant difference between general anesthesia with systemic analgesics and paravertebral blockade groups for all three VAS scores.

Table 3. Number of Patients Consuming Analgesics during the Follow-up Period*

	6 h	12 h	18 h	24 h	36 h	48 h
GA/SA						
Tramadol	13	9	6	3	1	0
Propranolol	7	3	3	3	3	0
Paracetamol	2	10	13	15	12	12
Total	22 (88%)	22 (88%)	22 (88%)	21 (84%)	16 (64%)	12 (48%)
PVB						
Tramadol	2	1	1	0	0	0
Propranolol	3	4	3	0	0	0
Paracetamol	3	3	3	5	1	0
Total	8 (32%)	8 (32%)	7 (28%)	5 (20%)	1 (4%)	0 (0%)

* Statistically significant difference between the general anesthesia with systemic analgesics (GA/SA) group and the paravertebral blockade (PVB) group with regard to total number of patients requiring supplemental analgesia ($P < 0.001$).

vations. Such systemic absorption cannot, however, explain the prolonged effects observed in this study. Prolonged analgesia (up to 23 h) has also been reported after the use of plain bupivacaine for breast surgery,²⁵ indicating that paravertebral administration of plain local anesthetics seems to result in more long-lasting analgesia compared with most other anatomical locations.

Whether the choice of parental VAS scores to assess postoperative pain is optimal can be debated but was chosen for two main reasons. First, this method allows scoring of the entire age span of inguinal hernia patients, whereas the use of more age-specific pain assessment tools would have necessitated the use of at least two different methods, which would have made both the assessments and statistical analysis of the data overly complicated. Second, because the 48-h observational period required a telephone follow-up, it was deemed that parental VAS scoring was the only possible tool to use to obtain reliable assessments after hospital discharge. Even if parental VAS scoring is not an optimal choice, the method is well described and validated.²⁶

The substantially better pain relief associated with PVB could also be translated into earlier hospital discharge, with 80% of the patients being treated as outpatients. This beneficial effect of PVB might not be considered as a very relevant finding by some clinicians because the majority of pediatric inguinal hernia patients are treated as outpatients in many industrialized countries, regard-

less of the anesthetic technique used. However, under less developed and less affluent circumstances, this beneficial effect of PVB might be able to reduce overall cost and to save limited hospital resources for more complicated cases.

Because PVB is not a widely known regional technique, it may be appropriate to discuss briefly the complications associated with the technique. In two previous publications from our group, including both adults and children, we have found that the incidence of complication is low,^{19,27} and the use of a nerve stimulator-guided technique seems to improve success rate significantly.¹⁹ The risk for inadvertent pleural puncture and pneumothorax, possibly the most significant complication of this technique, only exists at the thoracic levels and therefore is not a concern at the levels used in this study. The occurrence of hypotension is rare in children because of the strict unilateral sympathetic blockade associated with PVBs performed on only one side. Unintentional vascular puncture may occur, and aspiration tests and fractional injection of local anesthetic should be performed as with other regional techniques. In the current study, we did not observe any of the above-described complications, but local tenderness at the injections points was observed in some patients.

In conclusion, PVB associated with light sevoflurane sedation resulted in prolonged and improved postoperative analgesia, increased the possibility of same-day discharge, and provided better parent and surgeon satisfaction compared with general anesthesia and systemic postoperative pain relief. Whether PVB also provides better and more long-lasting pain relief compared with other regional anesthetic techniques used for inguinal hernia repair remains to be studied.

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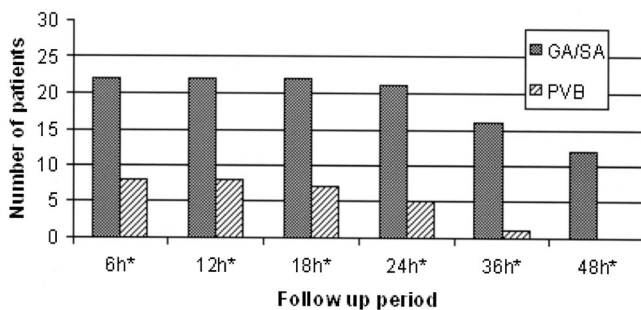


Fig. 3. Number of patients consuming analgesics during postoperative follow-up period. * Statistically significant difference between general anesthesia with systemic analgesics (GA) and paravertebral blockade (PVB) ($P < 0.001$).

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