Regional Anesthesia and Pain

Incisional self-administration of bupivacaine or ropivacaine provides effective analgesia after inguinal hernia repair

L'auto-administration de bupivacaïne ou de ropivacaïne au site d'incision procure une analgésie efficace à la suite d'une herniorraphie inguinale

Neli Vintar MD,* Gorazd Pozlep MD,* Narinder Rawal MD PhD,† Marija Godec MD,* Slavko Rakovec MD PhD‡

Purpose: To evaluate the safety and applicability of two local anesthetic (LA) solutions self-administered for pain treatment after inguinal hernia repair (IHR) by balloon-pumps via catheters placed in the surgical wound. Effectiveness of analgesia was also compared.

Methods: Two groups of patients for IHR were included in the randomized, double-blind study. An epidural catheter was placed in the surgical wound, tunneled subcutaneously and connected to a balloon-pump containing either 0.25% bupivacaine (B) or 0.25% ropivacaine (R). Postoperatively, the patient self-administered the LA into the wound. Administration could be repeated after 20 min. If moderate to severe pain still persisted, rescue medication (piritramid) was given intravenously. The variables recorded in both groups were: visual analogue scale (VAS), pain scores at rest and with movement, number of applications, wound healing, patients' satisfaction.

Results: During the first 24 hr, median number of LA applications in 26 B patients was 4 (range 1–6) and in 25 R patients 3 (range 1–5). Both groups showed low VAS pain scores: less than 2 at rest, less than 4 with movement. Eighty percent of patients of each group would choose this type of analgesia again. Two patients from B Group and three from R Group needed rescue medication. No wound infection was observed. There were no statistically significant differences between the groups.

Conclusion: Self-administration of the LA solution via a catheter in the surgical wound is an effective method of pain relief after IHR with little side-effects.

Objectif : *Évaluer l'innocuité et l'applicabilité de l'auto-administration de deux solutions d'anesthésiques locaux (AL), pour l'analgésie faisant suite à une herniorraphie inguinale (HI), au moyen d'une pompe et utilisant des cathéters placés dans la plaie chirurgicale. Comparer aussi l'efficacité de l'analgésie.*

Méthode : *Deux groupes de patients qui devaient subir une HI ont participé à l'étude randomisée et à double insu. Un cathéter péridural a été inséré dans la plaie chirurgicale, avec tunnellisation sous-cutanée, et relié à une pompe perfusant soit de la bupivacaïne à 0,25 % (B), soit de la ropivacaïne à 0,25 % (R). Après l'opération, le patient pouvait procéder à l'auto-administration d'AL et répéter après 20 min. Si une douleur modérée ou sévère persistait, une médication de secours intraveineuse (piritramide) était donnée. Les variables enregistrées ont été : les scores de douleur au repos et pendant le mouvement à l'aide de l'échelle visuelle analogique (EVA), le nombre de recours à l'analgésie, l'état de la plaie et la satisfaction des patients.*

Résultats : *Pendant les 24 premières heures, le nombre moyen de recours à l'AL a été de 4 (intervalle de 1–6) chez 26 patients du groupe B et de 3 (intervalle de 1–5) chez 25 patients du groupe R. Les patients des deux groupes ont présenté des scores de douleur faibles à l'EVA : moins de 2 au repos et moins de 4 pendant le mouvement. Quatre-vingt pour cent des patients de chaque groupe choisiraient encore ce type d'analgésie. Deux patients du groupe B et trois du groupe R ont eu besoin d'analgésie de secours. Aucun infection de la plaie chirurgicale n'a été observée. Aucune différence statistique intergroupe significative n'a été enregistrée.*

Conclusion : *L'auto-administration d'une solution d'AL au moyen d'une cathéter implanté au site d'incision constitue une méthode d'analgésie efficace à la suite d'une HI et comporte peu d'effets secondaires.*

From the Departments of Anesthesiology and Intensive Care,* University Medical Centre Ljubljana, Ljubljana, Slovenia; the Department of Anesthesiology and Intensive Care,† Örebro Medical Center Hospital, Örebro, Sweden, and the Clinical Department for general surgery and surgical infections,‡ University Medical Centre Ljubljana, Ljubljana, Slovenia.

Address correspondence to: Dr. Neli Vintar, Clinical Department of Anesthesiology and Intensive Therapy, University Medical Centre, 1000 Ljubljana, Slovenia, Phone and Fax: ++386-01-52-22-234; E-mail: neli.vintar@mf.uni-lj.si

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MOST patients suffer moderate to severe pain after inguinal hernia repair (IHR).[1] Postoperative pain may delay home discharge and prolong postoperative recovery. Various techniques of pain relief have been studied.[1–4]

Postoperative pain is often treated with less potent opiods, non-steroidal anti-inflammatory drugs (NSAIDs) and/or paracetamol given by the oral or *im* route, but these methods are not always effective. Intravenous analgesia is predictable and effective but demands well defined safety measures and cannot be administered at home after day surgery.

Wound infiltration with local anesthetic (LA) has been evaluated in several studies and found to be a good method for postoperative pain relief.[1,2,5,6] Incisional LA analgesia has been shown to diminish the need for opioids. However, these are all single dose studies.

Repeated doses of a LA solution via a catheter placed in the surgical wound have not been studied extensively. This method enables repeated applications of the LA postoperatively by nurses, on the surgical ward, or even by patients at home.[3,7] The catheter can be connected to an elastomeric balloon-pump which delivers a given volume of LA solution determined by opening the clamp for a specific period of time.

The current study was performed to assess the safety and applicability of repeated administrations of LA into the surgical wound after hernioplasty by an elastomeric balloon-pump connected to a subcutaneously placed epidural catheter. The study was undertaken to compare the effectiveness of analgesia during rest and during movement, after the administration of 0.25% bupivacaine (B) or 0.25% ropivacaine (R).

Methods

With Institutional Review Board approval, an informed written consent was obtained from 60 patients scheduled to undergo elective IHR.

Sixty patients, American Society of Anesthesiologists physical status (ASA) I–II, between 16 and 70 yr of age, were randomly allocated to two groups. One group received 0.25% B (Group B) and the other 0.25% R (Group R) for postoperative pain relief.

Intraoperatively, subarachnoid blockade was performed in the lateral position, using a 25-G Sprotte Standard Needle with introducer-cannula (Pajunk), inserted at the L3–L4 interspace. 15 mg of hyperbaric 0.5% B were injected (marcaine spinal 0.5% heavy with glucose; 1 mL contains B hydrochloride 5 mg, dextrose monohydrate 80 mg).

The same surgeon performed all operations. The IHR was performed by the open tension-free suture-less procedure. While in conventional techniques tension is arising from approximation of musculoaponeurotic tissues, the use of a polypropylene mesh prosthesis made it possible to perform the repair without tension. In the procedure used, a plug was inserted in the internal ring and a patch was placed into the subaponeurotic space. The plug was fixed by one stitch to the transverse muscle and no stitch was used to fix the overlay mesh patch. It was sealed in place by the hydrostatic pressure from the surrounding tissues. Thus, absence of traction was achieved.

Before closing the wound, a multihole epidural catheter (Portex clear G 18 epidural catheter with three lateral eyes) was placed subcutaneously alongside the wound through a Tuohy needle inserted at a distance of 4–5 cm from the wound. The catheter was tunneled 4–5 cm subcutaneously by the surgeon, sutured and firmly secured to the skin by a sterile transparent dressing. Using an aseptic technique, the catheter was connected to an elastomeric (balloon) pump (Home pump, I-Flow Corporation, Lake Forest, California, USA) containing 60 mL of 0.25% B (Group B) or 0.25% R (Group R). Postoperatively, when the visual analogue score (VAS) pain score was > 3, the LA infusion was started by opening the clamp. The patient stopped the infusion by closing the clamp after six minutes, so that the pump delivered 10 mL of LA.

The nurses on the ward were taught to use the VAS to determine the intensity of pain at six-hour time intervals. At 6 p.m., patients were requested to stand and walk, at which time pain at rest and during movement was assessed. On the next morning, at 8 a.m., pain was assessed under the same conditions. If the pain score was 3 or more 20 min after the first 10 mL of LA, another 10 mL of LA was self-administered with the pump. If the pain persisted, 3 mg of piritramid were given intravenously as rescue analgesia.

Piritramid is a potent opioid analgesic with hypnotic effect, synthetized in the laboratories of Janssen Pharmaceutica in the early 60's. Compared to morphine, 15 mg of piritramid are equivalent to 20 mg of morphine; naloxone is the antidote.

Each patient was given a form, on which the following variables were recorded by nurses: pain intensity, assessed by nurses every six hours and/or before and after each treatment, pain at rest and upon movement (5 m walk) at 6 p.m. after the operation and at 8 a.m. the next day, the time of day of each LA administration, the use of rescue *iv* analgesic medication. Although the patients self-administered the LA, they called the nurse to record the administrations to facilitate data collection for this study. The total number of times the LA was self-administered, technical prob-

lems with the pump, possible side effects or complications, overall satisfaction/dissatisfaction with analgesia (better than expected, as expected, worse than expected) were recorded by residents at 6 p.m. and 8 a.m. the next morning. The patients were also asked if they would decide in favour of this method of analgesia in case of another operation in the future. The resident removed the catheter 24 hr after insertion and sent the tip for microbiological analysis.

The patients were examined one week after the operation and the surgical wound was evaluated as: healing without complications; inflammation of the skin around the wound. The surgeon reported his observations to the anesthesiologist who recorded them on the patients' forms.

Statistical analysis

Descriptive statistics are reported as mean ± SD. Because the pain scores obtained in both groups at different times were not normally distributed, they were compared using the nonparametric analog to the t test, the Mann-Whitney test. A P value less than 0.05 was considered to be statistically significant. We compared patients' satisfaction with analgesia between the groups using the chi-square test with Yate's correction.

Results

There were no differences between the two groups with regard to age, gender distribution and duration of surgery (Table I). Patients did not require any sedatives or analgesics during surgery. Sixty patients were enrolled in the study, only 51 were evaluated (two patients mistakenly received 60 mL of LA rapidly, seven patients did not require any postoperative analgesic).

Median number of LA administrations was 4 (range 1-6) in Group B and 3 (range 1–5) in Group R patients. The difference between the two groups was not statistically significant (P = 0.08). There were three patients in Group B and four in Group R who needed no analgesia during the first 24 hr after the operation, and these patients were not included in the data analysis.

Table II shows numbers of LA administrations in both groups of patients.

Three patients from Group B needed 20 mL of the LA with the second 10 mL dose repeated after 20 min, so did five patients from Group R. However, for two of Group B patients and for three of Group R, even a repeated dose of LA was not sufficient and they needed *iv* piritramid. Both group B patients needed piritramid twice, all Group R patients needed piritramid once. Table III shows total piritramid consumption in patients of both groups.

TABLE I Patient demographics and surgical data

	Group B	*Group R*
Age (yr)	52.71 ± 15.41	56.17 ± 15.96
Sex (M/F) %	96.7/3.3	94/6
Duration of surgery (min)	59 ± 9.82	64 ± 12.7

Values are mean ± SD; B = bupivacaine; R = ropivacaine.

TABLE II Number of LA administrations in both groups of patients

Number of patients	*Bupivacaine group*	*Ropivacaine group*
Not requiring any analgesia*	3	4
Requiring one bolus*	3	3
Requiring two boluses	4	7
Requiring three boluses	3	8
Requiring four boluses	7	4
Requiring five boluses	8	4
Requiring six boluses	2	0

*TABLE II shows results for all 60 patients enrolled in the study. Patients who did not require any postoperative analgesia and two patients who accidentally received one bolus of 60 mL of the local anesthetic (LA) were not included in the data analysis.

TABLE III Piritramid consumption

Intravenous piritramid	*Group B*	*Group R*
First dose (3 mg)	2 × 6 mg	3 × 3 mg
Repeated dose (3 mg)	2 × 6 mg	0
Total consumption	12 mg	9 mg

B = bupivacaine; R = ropivacaine.

Pain assessment

The VAS scoring of pain was obtained at rest and with movement. The mean VAS score at rest at 6 p.m. on the day of operation was 1.69 cm in Group B and 1.86 cm in Group R patients. Although mean higher pain scores were obtained on mobilization: 4.17 cm in Group B and 3.8 cm in Group R, no statistically significant differences between the LA treatments were found. VAS scores showed similar trends in both groups at 8 a.m. the morning after the operation (Figure 1).

Patient satisfaction

Patients from both groups were very satisfied with pain relief: in 70% of patients from Group B, and 50% of patients from Group R pain relief was better than expected. Eighty percent of patients of Group B would decide again in favour of this technique of postoperative analgesia, and so would 83.3% of patients of Group R (Figure 2).

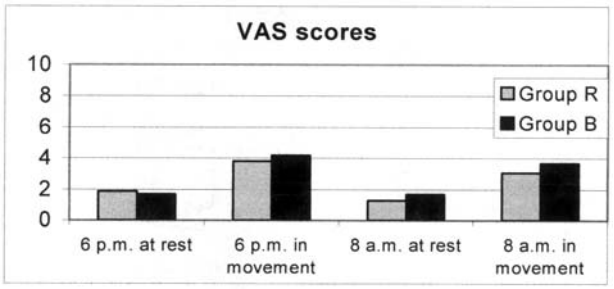

FIGURE 1 VAS scores at 6 p.m. on the day of surgery and the next morning at 8 a.m. No significant differences between R (ropivacaine) and B (bupivacaine).

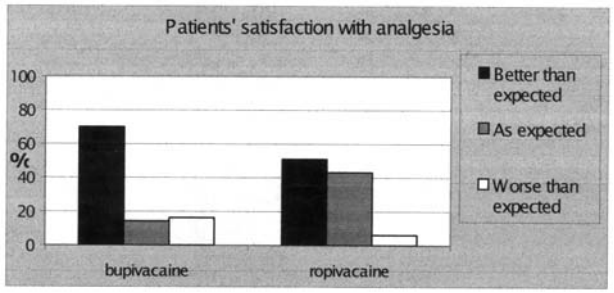

FIGURE 2 Patient's satisfaction with analgesia.

Side-effects

During our study, we did not observe any side effects such as nausea and vomiting.

Complications

In two cases, one from Group B and one from Group R, the clamp of the balloon-pump was not closed properly after self-administration of the LA. As a result, 60 mL of 0.25% B or 60 mL of 0.25% R were infused in the patient's wound in about 35 min. Both patients were monitored carefully (electrocardiograph, noninvasive blood pressure measurements in ten-minute intervals, pulse oxymety) and asked regularly for any clinical signs of systemic toxicity, such as tinnitus, metallic taste, numbness of the tongue. No clinical signs of LA toxicity were observed.

Microbiological analysis of catheter tips and wound healing

Staphylococcus epidermidis was isolated on the tips of three catheters in Group R and on four in Group B, while the remaining were sterile.

No signs of local inflammation were noted in any of the patients. Wound healing assessed by the surgeon was considered normal in all patients.

Discussion

Our double-blind randomized study shows that incisional analgesia by self-administration of a LA on demand is an effective method of pain treatment after hernioplasty. An elastomeric ballon-pump connected to an epidural catheter inserted in the wound provides a simple method of applying a predetermined volume of the LA solution. We did not observe any side effects such as nausea and vomiting.

Both B and R given as 0.25% solutions administered subcutaneously, even in rather small volumes of 10 mL to 20 mL, proved effective and safe in treating pain after hernioplasty.

In single dose studies by different authors[2,5–11] different volumes and concentrations of LA have been used for wound infiltration at the end of hernioplasty. Doses of 40 mL of 0.75% R,[2] 30 mL of 0.5% and 30 mL 0.75% R,[6] 40 mL–50 mL 0.75% R,[9] 30 mL 0.25% B,[10] 40 mL 0.25% R and 40 mL 0.25% B[7] doses have been studied. The LA was injected into various layers of the surgical wound: under the fascia,[3,5] subcutaneously[11] and into the edges of the wound,[2,3,6,8–10] subcutaneously and into the muscle.[12] When added to the LA and used in single doses, NSAIDs[13] and clonidine[10] did not significantly prolong the duration of analgesia.

Our study shows that rather small volumes and low concentrations of LA (10 mL of 0.25% R or B) are effective in providing sufficient analgesia – at rest and with movement. Only three patients from Group R and two from Group B required rescue analgesia. In our study, the surgeon placed the epidural catheter subcutaneously alongside the wound. The reason why subcutaneous analgesia alone (as opposed to infiltration in multiple layers of the wound) is effective in the present study may be due to the surgical approach adopted at our centre, which causes less pain than usual. This surgical approach is not different by the type or size of incision but less tension is created.

A serious concern with the type of pump used is that the entire volume of LA can be delivered if the patient or the nurse fails to close the clamp. To avoid this, the following steps were taken: a) precise oral and written instructions were given to the patient and to the nursing staff; b) the use of a timer was encouraged; c) the patient was instructed to close the clamp and contact the nurse if he/she felt numbness of the tongue or tinnitus; and d) the nurse was instructed to call the anesthesiologist in such a case. In spite of all safety measures, in one patient 60 mL of 0.25% R and

in another 60 mL of 0.25% B were injected into the wound accidentally on the surgical ward. Yet, no toxic effects were observed. Analgesia in both cases was long lasting: the patient in Group B needed no other medication for 24 hr, while the patient from Group R took the rescue medication once. We did not measure blood levels of the LA; however, all plasma levels reported in the literature[8,9,14] after even higher doses of B (repeated administrations of 20 mL of 0.5% B)[14] or R (30 mL, 40 mL, 50 mL of 0.75% R)[8,9] did not show toxic levels of LA.

The recent availability of newer and safer elastomeric pumps can be expected to reduce the risk of overdose. This pump allows delivery of LA only if the patient presses a button, a safety feature that eliminates the risk of accidental delivery of the entire content of the pump. Pressure on the button for 45 sec allows the patient to receive 10 mL of LA (I-Flow Corp, USA). Light-weight delivery pumps with lockout function have also become available (Microject pump, Sorenson Medical, USA). Such devices have improved the safety of patient controlled regional anesthesia (PCRA) techniques outside the hospital. However, controlled trials are necessary to confirm the safety of these pumps.

Other theoretical concerns relate to the risk of delayed wound healing and infection. However, the literature on the subject does not support these concerns: LA drugs even have bacteriostatic and antimicrobial effects.[15] No signs of local inflammation were noted in any patient and wound healing was normal.

The great majority of patients from both groups were very satisfied with this method of pain relief, as over 80% of them would decide in favour of using PCRA again. They expressed their desire to take "their" pumps home with them when they left the hospital. We consider this technique appropriate not only for inpatients but also for outpatients; however, more reliable pumps will be required.

The patients in our study needed very little rescue medication – i.e., opioids. Therefore, good analgesia without sedation, nausea, vomiting and risk for respiratory depression was ensured in both groups.

Our double-blind randomized study showed that incisional analgesia with self-administration of a LA on demand is an effective method of pain relief after IHR. Further studies are necessary to determine the optimal concentration and volume of LA for pain relief after other surgical procedures. The role of opioids, NSAIDs and clonidine as adjuvants to LA drugs also needs to be studied.

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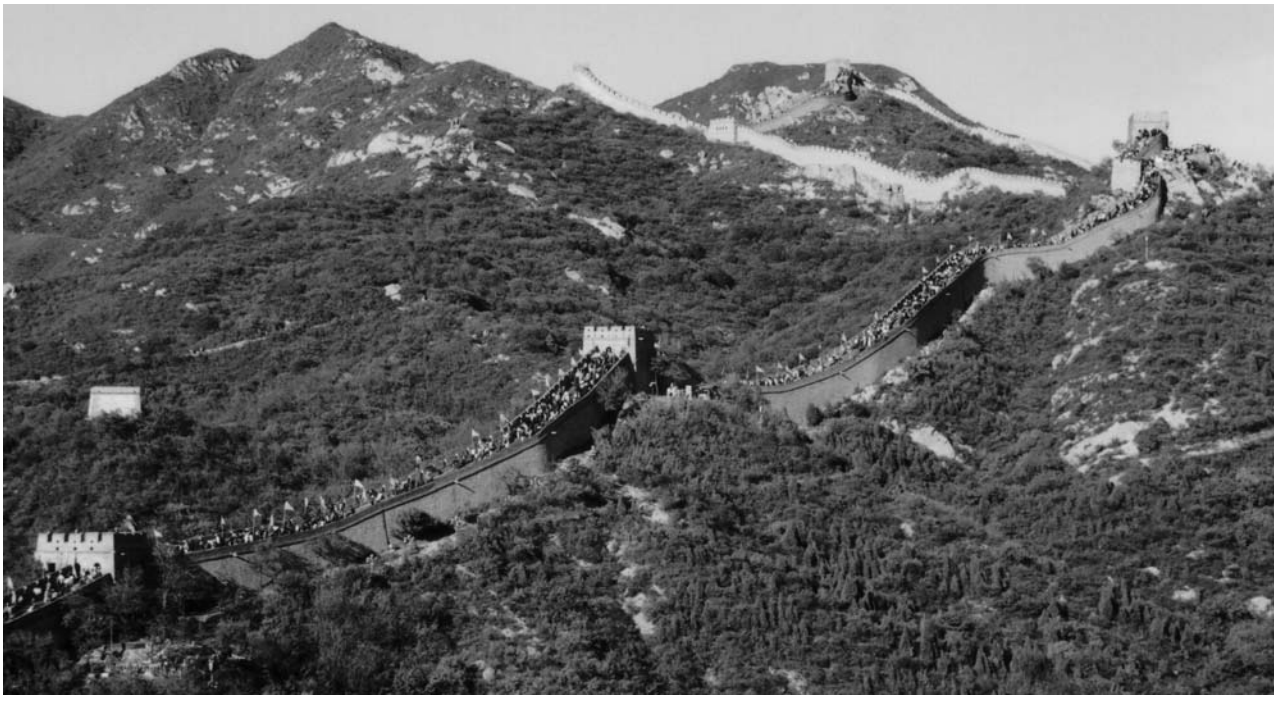

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