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ORIGINAL ARTICLE

The effect of inguinal canal and intraincisional infiltration of tramadol versus bupivacaine 0.25% on postoperative pain relief in patients undergoing inguinal hernioplasty under general anesthesia

Amr Samir Wahdan, Ahmed Abd Elaziz Seleem

Department of Anesthesiology, Faculty of Medicine, Cairo University, Cairo (Egypt)

Correspondence: Dr Amr Samir Wahdan, Department of Anesthesiology, Faculty of Medicine, Cairo University, Cairo (Egypt); Phone: 00201001422499; E-mail: amr_amw010@hotmail.com

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ABSTRACT

Background and Aims: the aim of the study was to evaluate inguinal canal block together with intra-incisional injection of tramadol against bupivacaine 0.25% in cases undergoing inguinal hernioplasty under general anesthesia (GA).

Methodology: In this randomized controlled trial, 120 male patients were chosen for this study with ASA I or II criteria, between 18 and 60 years of age. They were divided into three groups: either control (Group A), 0.25% bupivacaine (Group B), or tramadol (Group C). After induction of GA, the inguinal canal block and intraincisional infiltration were performed under ultrasound guidance, maintaining the heart rate (HR) and mean arterial blood pressure (MABP) within 20% of their values before induction by the use of Fentanyl bolus intraoperatively. The pain assessment was done postoperatively by visual analogue score (VAS), the time for the first analgesic requirement and the total amount of meperidine consumption was measured. The data analysis was carried out with unpaired Student's t-test and Chi-square test using software SPSS 22.0 version.

Results: The fentanyl requirements intra-operatively, the postoperative VAS and total dose of postoperatively meperidine consumption were statistically higher in control group compared to both other groups. But the total amount of meperidine consumption postoperatively was statistically lower in tramadol group compared with other groups.

Conclusion: An improved intra-operative and postoperative pain was provided by locally infiltrated tramadol, together with reducing the need of post-operative pain control agents with consequent beneficial reduction of narcotic side effects.

Key words: Bupivacaine; Inguinal hernia; Postoperative pain; Tramadol

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INTRODUCTION

Inguinal hernia repair is considered a procedure that requires analgesia to achieve the best intra-operative conditions and satisfactory postoperative pain relief. Regional analgesia for inguinal hernia repair in adults has been highly considered over the previous years.[1] A significant reduction of anesthetic and analgesic requirement is achieved by blockade of inguinal canal and intra-incisional injection in patient undergoing inguinal herniorrhaphy. The blocks are performed using blind techniques and more recently under ultra-sound guidance.[2] It's been proven that inadequate analgesia may delay discharge

or prolong hospital stay. Small doses of analgesics were used with a consequent sacrifice of their efficacy, due to concerns of agents' side-effects.[3] Preemptive use of analgesics including local anesthetics is recommended to block central sensitization without first pass drug metabolism by the liver.[4] Opioids may produce analgesia through peripheral mechanisms. Endogenous opioid-like substances are produced by the immune cells at the inflammation site, whose effect is mainly on the opioid receptors at the primary sensory neuron.[5] Tramadol has a central acting affect therefore it's used for controlling moderate to severe pain. It has been proven an effect as potent as morphine. Direct infiltration into the wound can also be used as it reduces the various side effects of the drug.[6] On another note, bupivacaine with its longer duration of action was also preferred. Its prolonged analgesic effect could be due to the concept "preemptive analgesia," but it could involve mechanisms other than the modulation of central nervous system hyperexcitability.[7] The goal of the present study was to assess the effect of inguinal canal block and intra-incisional injection of tramadol versus bupivacaine 0.25 % on pain relief post inguinal hernioplasty under general anesthesia.

METHODOLOGY

Once the approval of the local ethical committee was obtained, thorough and detailed explanation to the patients and signing consents, 120 male patients were chosen for this parallel prospective double blinded controlled trial. The inclusion criteria were; male patient ASA I or II and aging between 18 and 60 years of age scheduled for elective inguinal herinoplasty with the use of general anesthesia, after refuse regional anesthesia between January 2016 till January 2017. The exclusion criteria included; Patient refusal, history of allergy to the drug used, coagulopathy, body mass index above 35 kg/m^2, infection at the site of the block, patient with low lung compliance, a history of analgesic intake within the last 24 hours or impaired liver function. Clinical assessment and investigations were performed to all patients to exclude any of the above mentioned contraindications. On arrival to operating theatre, all patients were connected to the following monitors; noninvasive blood pressure, pulse oximetry, electrocardiography and a venous access was inserted. Anesthesia induction was done using IV propofol (2 mg/kg and fentanyl bolus doses (0.5 μg/kg. After confirmation of loss of consciousness, an intravenous injection of (0.5 mg/kg of atracurium was given and after confirming that the muscle relaxation is sufficient, laryngeal mask was inserted and the patient was mechanically ventilated (keeping peak airway pressure < 25 mmHg. Anesthesia was maintained by isoflurane (MAC 1) and 100% O_2 air combination with a total fresh gas flow (FGF) of (3L/min. The $EtCO_2$ was kept within the range of 30 to 40 mmHg. Fentanyl bolus doses (0.5μg/kg were adjusted to keep the heart rate (HR) and (MABP) within 20% of the pre-induction values. Atracurium maintain was started 20 min after induction (0.1 mg/kg). While the patient in supine position, under complete aseptic conditions, inguinal canal block and intra-incisional infiltration were performed. An 80 mm or 100 mm atraumatic 22-G blunt needle was used. The palpation of the anterior superior iliac spine (ASIS) was done, and a point was marked 5 cm superior and 5 cm posterior to the ASIS. After appropriate preparation of the US probe, the probe is placed above the ASIS and then moved superior and then posteriorly so that the probe lies at an oblique transverse position just above the iliac crest. The probe is adjusted so that cross-sectional view of the ilioinguinal nerve and iliohypogastric nerve is obtained. After identifying the nerves, it is positioned at the centre of the US screen - the gain and depth are adjusted. The three layers of muscles are identified; the external, the internal oblique, and the transversus abdominis muscles. Ilioinguinal nerve and iliohypogastric nerve are identified as two hypoechoic shadows lying within the split of the internal oblique fascia. After skin sterilization the needle is advanced in-plane from lateral to medial direction, keeping tip of the needle under vision at all times. The needle passes through the skin and subcutaneous tissues and then the external, the internal oblique muscles. The needle is then advanced to pierce the internal oblique fascia just lateral to the nerves. After confirming that the position of the tip of the needle is in the correct plane, the study drug was deposited under the internal oblique fascia so as to surround the two nerves. Patients were randomly divided into three equal groups of 40 patients. Each using a computer-generated number for randomization. The medications were loaded in the syringes by a pharmacist who was blinded to the study and was checked and marked by anesthetist on the spot who was not blinded to the patients, and then the syringes were endorsed to another anesthetist who was blinded to the patient. The later was the one who gave the medications to the patients and follow them up. All the staff members inside the theater were blinded to the prepared study drugs and only it was disclosed in case of facing emergency situation. The inguinal canal block and intra-incisional infiltration were performed using 20 ml solution of normal saline 0.9%. in Group A (control group), while inguinal canal block and intra-incisional infiltrated were performed using 20 ml solution of bupivacaine 0.25 % concentration (0.7 mg/kg) in

Group B: (bupivacaine group), moreover, inguinal canal block and intraincisional infiltration were performed using tramadol 1 mg / kg diluted in sterile normal saline to give 20 ml solutions in Group C (tramadol group). The HR and MABP, were recorded preoperative and every five minutes intraoperative till the end of surgery, the total intra-operative fentanyl requirement to maintain the intra-operative HR and MABP within 20% of the value before the induction and calculated amount of blood loss intra-operatively by counting the surgical gauze used and in suction. At the end of the procedure, neostigmine 0.04 mg/kg and 0.01 mg/kg atropine were used to reverse the neuromuscular blockage. The laryngeal mask was removed then the patients were transferred to the recovery room. The pain assessment was done using VAS (0 = no pain to 10 = worst pain). The studied groups were registered and compared postoperatively at 2, 6, 12, and 24 h. Also, the MABP and HR were traced at the same time interval for pain assessment as well as incidence of complications in the form of toxicity from bupivacaine 0.25 % or tramadol was also monitored including nausea and vomiting, which were traced at the same time postoperatively using a categorical scoring system (none = 0, present = 1). Metoclopramide 0.15 mg/kg was given to patients who complained of nausea or vomiting. The time between the ends of the procedure to first analgesic need was compared in all groups. And the total meperidine doses used in 24 hours postoperatively was calculated and compared. A standard postoperative analgesia regimen was prescribed as paracetamol 1 gm/6h IV and meperidine 25 mg if visual analogue score was ≥ 3 or when patient suffering from pain between the assessment intervals.

Statistical analysis: Statistical analysis was done using SPSS version 22.0 (SPSS Inc., Chicago, IL). Data were reported as mean, standard deviation (SD), range (median) or number (%). Comparison between the groups was done by using the unpaired Student's t-test and Chi-square test. P-values < 0.05) was considered statistically significant. Sample size calculation: Power analysis was done using one-way analysis of variance on postoperative pain assessment by the VAS after 2 hours postoperatively because it was the main outcome variable in the present study. Previous studies showed that the mean of postoperative pain assessment by VAS after 2 h was 2.5 with SD 0.6 in the tramadol group, and in the control group with a mean of 2.7 with SD one , and in the bupivacaine group with a mean of 2.9 ± SD 1.[8] At a power of 0.8 and *a*-error of 0.05, a minimum sample size of 112 patients was calculated for the three groups. A total of 40 patients were included in each group to compensate for possible dropouts

RESULTS

135 patients were assessed for eligibility, 15 were excluded because of patients' refusal**.** (Figure 1). No differences were noticed statistically regarding demographic data between the three groups, e.g. the patient age, body mass index and the surgical time (Table 1).

The mean intraoperative fentanyl requirement was statistically lower in both the bupivacaine and

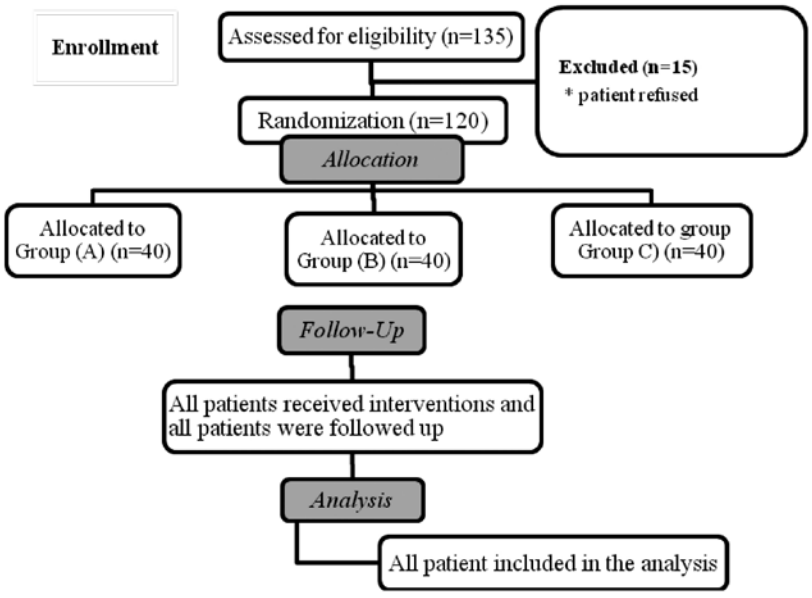

Figure 1: Flow diaagram

Table 1: Demographic data of the patients and operative data. Data presented as mean ± SD

Variable	Group A	Group B	Group C	p-value
Age (y)	44± 7.8	43 ± 7.1	43.1 ± 8.1	0.98
BMI (Kg/m^2)	32.2 ± 1.1	31.3 ± 8.2	31.3 ± 45.5	0.95
Surgical time (min)	64.3 ±10.2	65 ± 13	64.2 ± 13	0.98
Intraoperative fentanyl requirement (µg)	120 ± 29	60.1 ± 20*	57 ± 18*	0.000
Intraoperative blood loss (ml)	105 ± 30	128 ± 27†	99 ± 26	0.01

* Statistically significant lower compared to control group, ($p < 0.05$)
† Statistically significant higher compared to control and tramadol groups, ($p < 0.05$)

Table 2: Postoperative mean arterial blood pressure (mmHg) and postoperative heart rate (bpm). Data presented as mean ± SD

Time interval	Group A	Group B	Group C	p-value
Postoperative Mean Arterial Blood Pressure (mmHg)				
2 h	118 ± 1	98 ± 4*	96 ± 3*	0.000
6 h	105 ± 7	102 ± 6	96 ± 3*†	0.000
12 h	106 ± 8	102 ± 9	101 ± 8	0.6
24 h	105 ± 8	101 ± 8	101 ± 7	0.4
Postoperative heart rate (bpm)				
2 h	97 ± 11	88 ± 4*	87 ± 5*	0.001
6 h	96 ± 11	92 ± 5*	87 ± 5*†	0.007
12 h	88 ± 7	87 ± 4	87 ± 3	0.9
24 h	87 ± 8	88 ± 4	88 ± 2	0.8

* Statistically significant lower compared to control group ($p < 0.05$)
† Statistically significant lower compared to bupivacaine group ($p < 0.05$)

Table 3: Postoperative visual analogue scale score VAS. [Data presented as median (range)]

Time	Group A	Group B	Group C	p- value
2 h	5 (2 - 6)	2 (1 – 5)*	2 (2 – 5)*	0.000
6 h	4 (2 – 6)	4 (1 – 5)	2 (1 – 4)*†	0.000
12 h	1 (0 – 2)	1 (0 – 2)	1 (0 – 2)	0.5
24 h	1 (0 – 2)	1 (0 – 2)	1 (0 – 2)	0.3

* Statistically significant lower compared to control group ($p < 0.05$)
† Statistically significant lower compared to bupivacaine group ($p < 0.05$)

Table 4: Time for the first postoperative analgesic requirement (min) and total dose of postoperative meperidine consumption (mg). Data presented as mean ± SD

	Group A	Group B	Group C	p-value
Time for 1st. analgesic requirement (min)	30 ± 10	115 ± 25*	149 ± 30*†	0.000
Total dose of postoperative meperidine (mg)	99.5 ± 19	60 ± 17**	26 ± 7**♣	0.000

* Statistically significant higher compared to control group ($p < 0.05$)
† Statistically significant higher compared to bupivacaine group ($p < 0.05$)
** Statistically significant lower compared to control group ($p < 0.05$)
♣Statistically significant lower compared to bupivacaine group ($p < 0.05$)

Table 5: Postoperative nausea & vomiting. Data presented as number of patients

Time	Group A	Group B	Group C	p-value
2 h	10 / 40	6 / 40	20 / 40*	0.04
6 h	12 / 40	4 / 40†	16 / 40	0.000
12 h	4 / 40	2 / 40	2 / 40	0.7
24 h	0 / 40	2 / 40	1 / 40	0.6

* Statistically significant higher compared to control and bupivacaine groups, ($p < 0.05$)
† Statistically significant lower compared to control and tramadol groups ($p < 0.05$)

tramadol groups compared to the control group, where as there were no statistical differences between tramadol and bupivacaine groups). The intra-operative blood loss showed statistically significantly higher value in the bupivacaine group, when compared to the control and tramadol groups; however, there were no statistically significant differences between tramadol and bupivacaine groups. (Table 1) The postoperative MABP and mean postoperative HR were statistically lower two hour post-operatively in both the bupivacaine and tramadol groups compared with the control group, whereas it was statistically lower after six hours postoperatively in tramadol group compared with the control and bupivacaine groups. However there was no statistical differences among the three studied groups after 12 hours postoperatively (Table 2). The postoperative VAS was statistically lower two hour postoperatively in both the bupivacaine and tramadol groups compared to the control group. It was statistically lower after six hours postoperatively in tramadol group compared to the control and bupivacaine groups; however, there were no differences among the three studied groups after 12 hours postoperatively (Table 3). The time for the first postoperative analgesic requirement was lower statistically in the control group compared to the bupivacaine and tramadol groups, however, it was lower statistically ($p < 0.05$) in bupivacaine group compared to tramadol group. The total dose of postoperative meperidine consumption was lower statistically in both the groups compared to the control group, However it was statistically lower in tramadol group compared with bupivacaine group ($p < 0.05$) (Table 4). The postoperative nausea and vomiting were higher statistically ($p < 0.05$) two hours postoperatively in tramadol group compared to both the control group and bupivacaine group, however, it was lower statistically ($p < 0.05$) after six hours postoperatively in the bupivacaine group compared to the control and tramadol groups (Table 5). There were no other recorded complications in any group, either intra- or postoperatively.

DISCUSSION

This double-blind, randomized, prospective study has shown that the inguinal canal and intra-incisional infiltration, performed preemptively using tramadol 1 mg/kg provided better intra and postoperative pain control for hernia surgery. With wound infiltration by tramadol, the amount of intra-operative requirement of fentanyl was reduced, the time to first pethidine use was prolonged, and the total 24 hour analgesic consumption was decreased. Side effects like nausea and vomiting were detected during the study. In the tramadol group, the incidence of nausea & vomiting was more than in the bupivacaine and control group throughout the 2 hours of assessment, but after 6 hours postoperative; the results of postoperative nausea/vomiting indicated that patients in the bupivacaine groups had less nausea and vomiting than in the control and tramadol group.

Tramadol's action on central monoaminergic system was proven to be the cause of its analgesic effect.[6] Furthermore, despite the main differences in their action, it was suggested that both local anesthetics and opioids decrease sensitization peripherally and centrally via direct central nervous system effect. The tramadol causes its analgesic and anti-nociceptive effects by affecting the supraspinal and spinal sites. Moreover, many studies showed that it can also have local anesthetic action.[9-11] The results of the present study go in line with the findings of Madhuri S. Kurdi et al, who deduced that tramadol has local anesthetic effect postoperatively in case of minor surgical operations and can be given as an adjunct to other local anesthetics.[12] Also the results by Malik AI et al. proved that infiltrating tramadol locally provides postoperative analgesia with decreasing the postoperative analgesic requirement when compared to bupivacaine.[13] Also the results of the present study go in line with the findings of Jawad et al., whose study showed that the combination of xylocaine and tramadol extend the pain free period postoperatively to double the period achieved using each drug alone.[14] Also the results of the present study go in line with the findings of other studies.[6,15,16] The present study showed that, tramadol had an equianalgesic effect to that of bupivacaine. Hopkins D et al. showed that tramadol causes more postoperative nausea and vomiting than morphine, as was our observation.[17] Considering the limitations to our study we think that the minimal safe intraincisional dose of tramadol and its effect of inguinal canal block and intraincisional injection need further investigation.

CONCLUSION

Our study concludes that an improved intra-operative and postoperative pain relief is provided by locally infiltrated tramadol in inguinal canal as well as incision line for hernia surgery under general anesthesia as compared to bupivacaine 0.25%, thus decreasing the need of postoperative analgesic agents and consequently reducing the side effects associated with narcotics.

Conflict of interest: None declared by the authors

Authors' Contribution:
ASW: collection of data and manuscript writing
AAES: patient consultation, collection data

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