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Comparison of postoperative analgesic effects of two doses of dexamethasone in ultrasound-guided transversus abdominis plane block for inguinal hernia repair: a randomized controlled trial

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Abstract

Background: Ninety patients American Society of Anesthesiologists (ASA) I–II, aged (18–60 years), were enrolled in this randomized controlled trial. All enrolled patients had undergone elective unilateral open inguinal hernia repair under spinal anesthesia; at the end of the surgery, transversus abdominis plane (TAP) block was done by bupivacaine combined with 4 mg dexamethasone in (group I), 8 mg dexamethasone in (group II), or saline in (group III). We aimed to compare the analgesic efficacy of two different doses of dexamethasone (4 mg and 8 mg) added to bupivacaine in a unilateral single-injection (TAP) block. The first outcome measure was the time of the first analgesic request, and the secondary outcome measure was the VAS scale in the first postoperative 24 h.

Results: There was no need for any analgesia in group I and group II in the first postoperative 24 h. The time of the first analgesic request in group III was 720 ± 90 min. VAS scores were significantly lower in group I and group II than in group III, with no significant difference between group I and group II.

Conclusions: There is no difference in the first postoperative 24 h analgesic effect of the two doses of dexamethasone when added to a long-acting local anesthetic mixture in TAP blocks in patients undergoing inguinal hernia repair.

Trial registration: ClinicalTrials.gov, [NCT03863977](https://clinicaltrials.gov/ct2/show/study/NCT03863977)

Keywords: TAP block, Inguinal hernia, Dexamethasone

Background

Inguinal hernia repair (IHR) is one of the most common one-day surgeries (Callesen et al. 2001), it is associated with 60% of the incidence of moderate to severe postoperative pain (Beldi et al. 2008). Several methods used to reduce this pain are pharmacological methods, topical anesthetics, epidural analgesia, ilioinguinal, and iliohypogastric nerve blocks, TAP block, and non-pharmacological

methods (Joshi et al. 2012; Demirci et al. 2014; Toivonen et al. 2001).

Ultrasound-guided transversus abdominis plane block (TAP block) used for postoperative analgesia following abdominal surgeries by blocking sensation to the skin, muscles of the anterior abdominal wall, and parietal peritoneum (Bajwa and Kaur 2013).

Dexamethasone is commonly used as an adjuvant to local anesthetics in TAP block to prolong the duration of the block (Ammar and Mahmoud 2012; Akkaya et al. 2014; Yildiz and Bayir 2015). Dexamethasone doses were varied in the previous studies and ranging from 4 to 8

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mg and no one of them identified the ideal effective dose (Ammar and Mahmoud 2012; Akkaya et al. 2014; Yildiz and Bayir 2015; Wegner et al. 2017; Deshpande et al. 2017; Kartalov et al. 2015), so we planned this study to identify if there is any difference in the postoperative analgesic effect of the two commonly used doses of dexamethasone (4 mg and 8 mg) (Chen et al. 2018), added to bupivacaine in ultrasound-guided TAP block for inguinal hernia repair.

Methods

Enrollment and eligibility

After approval from the local Medical Ethics Committee (IRB 17100670), and clinical trials registration ClinicalTrials.gov (ID NCT03863977), this randomized, double-blind clinically controlled trial was started on the 15th of March 2019 and ended in December 2019, in the department of general surgery. Ninety male patients American Society of Anesthesiologists (ASA) I or II, aged from 18 to 60 and scheduled for elective unilateral open inguinal hernia repair under spinal anesthesia, were included in this study. We got written informed consent from all patients before participation in this study. Excluded from this study any patients with known allergy to amino amide local anesthetics, skin infection, diseases at the site of injection, coagulation disorders, patients with body mass index (BMI) > 35 kg/m² or scrotal hernias.

Randomization and blinding

An independent researcher did the randomization of ninety patients to receive unilateral TAB block by using computer-generated randomized tables. At the end of surgery after closure of the surgical wound, unilateral TAB block (at the side of the surgery) was done. To perform the block, we used the injection of either 4 mg dexamethasone added to 1 mg/kg of 0.5% bupivacaine in (group I), 8 mg dexamethasone added to 1 mg/kg of 0.5% bupivacaine (group II), or 1 mg/kg of 0.5% bupivacaine in the control group (group III); the study drugs were prepared by an independent researcher in syringes with an equal volume (25 ml) of the study solutions (studied drugs diluted with normal saline 0.9%), and he put them in coded envelopes according to the randomization order and the anesthesiologist opened the envelopes just before the injection.

Study protocol

In the preoperative visit, we described to the patients the seclude of spinal anesthesia, TAB block, and the visual analog scale (VAS) for pain description. 12.5 mg. In the operating room, insertion of peripheral IV cannula (18 or 20 gauge) to all patients to revive 20 ml/kg crystalloid fluid followed by spinal anesthesia was done, and spinal anesthesia was administered to patients at sitting

position using intrathecal 12.5 mg of 0.5% bupivacaine at the level of L3-4 by 25-G spinal needle; we checked the block level and surgery started when the level established at T7, and intraoperative patients were monitored with standard monitor (ECG, pulse oximeter, and non-invasive blood pressure). At the end of the surgery, sensory and motor spinal levels were recorded; then, we did ultrasound-guided TAB block using the ultrasound probe (Sonosite Inc., Bothell, WA, USA). A high frequency (5–10 MHz) after sterilization of the skin, the probe was sheathed and placed in the midaxillary line between the lower costal margin and the iliac crest; then, we introduced a needle of 21-G, 100 mm 22 (SonoPlex Stim cannula, Pajunk®GmbH, Geisingen, Germany) medially in the plane of the ultrasound beam and directed towards the transversus abdominis plane; after the tip of the needle was at the correct position between the internal oblique muscle and transversus abdominis muscles, we injected the study drugs according to group assignment, during injection the distribution of the studied drugs observed by hypoechoic enlargement in the screen of the ultrasound. Then, all patients were transferred to PACU; in arrival at the PACU, the successes of the TAP block were examined by pinprick sensory test of the abdominal wall and the Bromage scale was used to examine the motor block (to ensure that the effect of spinal anesthesia was abolished and exclude failed block from the study).

Postoperative patients assessment

Postoperatively, we evaluated motor and sensory regression of spinal anesthesia. Visual analog scale (VAS) and demonstrated by using a ruler numbered from 0 to 10 (0 = no pain, 1–3 = mild pain, 4–6 = moderate pain, and 7–10 = severe pain) (Gao et al. 2017), and it was recorded at rest and during coughing. These were assessed on admission to PACU (baseline), and 2, 4, 6, 12, and 24 h postoperatively. If the VAS scale was more than 3, 1 g IV paracetamol was administered to the patient, and repeated after 8 h if needed. Time and total dose of analgesic consumption was recorded. We recorded also heart rate and mean arterial blood pressure before the block, and 2, 4, 6, 12, and 24 h postoperatively. Incidence of nausea and vomiting and any postoperative adverse effects were recorded.

Statistical analysis

Data entry and data analysis were done using SPSS version 22 (Statistical Package for Social Science). Data normality was tested with the Kolmogorov–Smirnov test. Data were presented as mean (standard deviation), median (range), and number. The Student *t* test was used for normally distributed continuous data and the Wilcoxon signed-rank test in case of nonparametric data.

The chi-squared test or the Fisher exact test was used to analyze frequency variables, and ordinal variables were analyzed using the Mann-Whitney *U* test. A *P* value of < 0.05 was considered statistically significant.

Results

Ninety-six patients were screened for eligibility and 90 patients were involved in the study 30 patients in each group (Fig. 1).

There were no significant changes between the studied groups according to demographic data, anesthesia time, and surgical time (Table 1).

The postoperative VAS score was classified to VAS at rest and VAS at exertion (by asking the patient to cough) (Figs. 2 and 3). Postoperative VAS scores at rest were significantly lower in group I and group II than group III from 1 h postoperatively to 24 h (*P* value between group I and group III at rest was 0.013 at 1 h, 0.001 at 2 h, and 0 at 4h, 8 h, 16 h, and 24 h, while *P* value between group II and group III was 0 from 1 h to 24 h). Also, postoperative VAS scores at exertion were significantly lower in group I and group II than group III from early postoperative to 24 h (*P* value between group I and group III at exertion was

0.005 immediately after injection, 0.001 at 15 min, 0.032 at 30 min, 0.026 at 1 h, 0.011 at 2 h and 4 h, 0.003 at 8 h, and 0 at 16 h and 24 h, while *P* value between group II and group III at exertion was 0 immediately after injection and 15 min, 30 min, 1 h, 2 h, 4h, 16 h, and 24 h while was 0.001 at 8 h).VAS scores were not significantly reduced in group II than group I at rest or at exertion at any time postoperatively.

The time to first analgesic request for IV paracetamol was 720 ± 90 min in group III versus 24 h in group I and group II. No patients request for rescue analgesia in group I and group II in the first postoperative 24 h versus all patients request analgesia in group III; three patients received IV 1 g paracetamol once and 27 patients received IV paracetamol twice during the first postoperative 24 h (Table 2).

The mean blood pressure was decreased significantly in group I and group II than group III at 8 h, 16 h, and at 24 h postoperatively (*P* value between group I and group III was 0.024 at 8 h and 0 at 16 h and 24 h, and *P* value between group II and group III was 0.042 at 8 h and 0 at 16 h and 24 h), with no significant difference between groups I and II (Fig. 4).

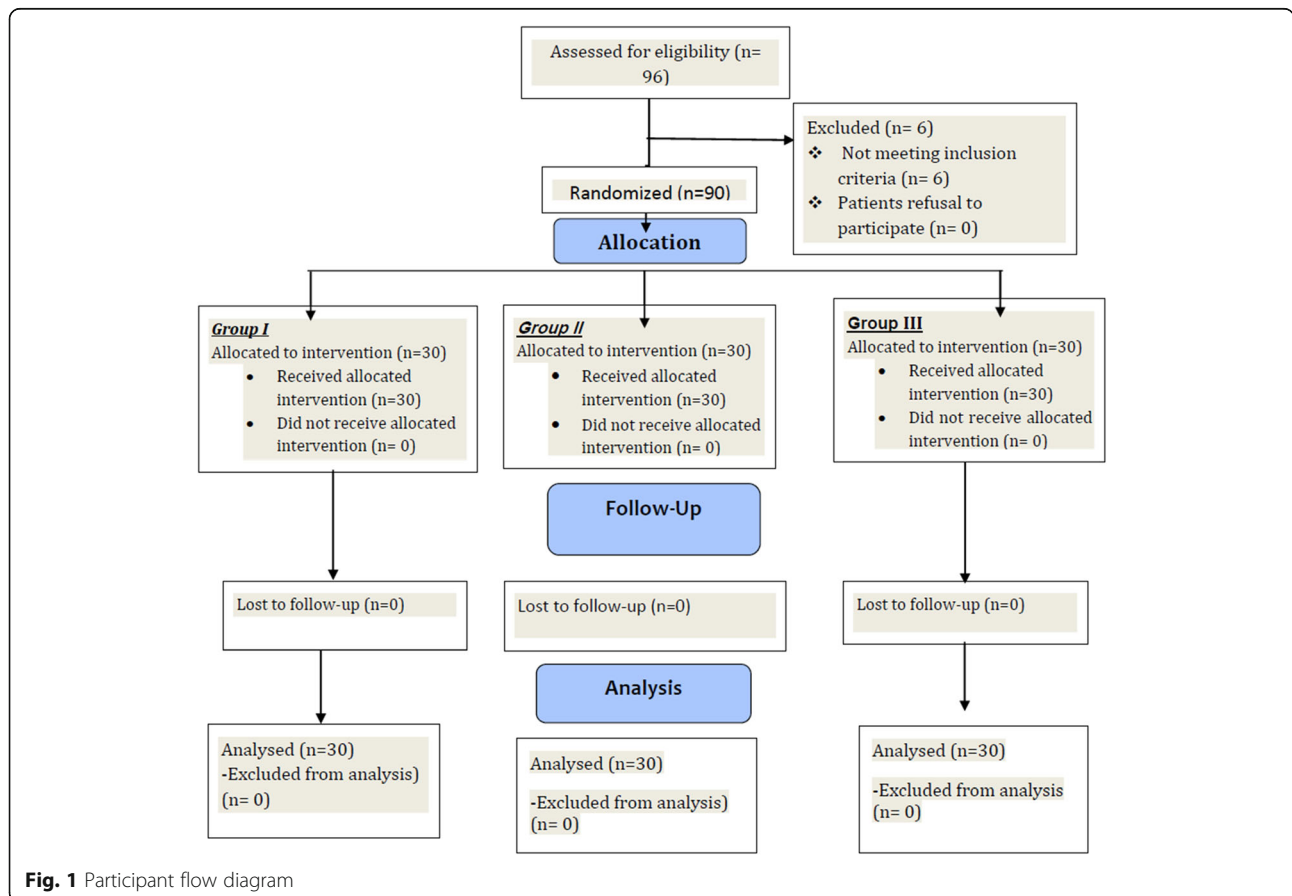


Fig. 1 Participant flow diagram

Table 1 Patients' demographics and operative details

	Group I (n = 30)	Group II (n = 30)	Group III (n = 30)	P value
Age (years)	41.63 ± 12.96	39.53 ± 13.63	43.20 ± 11.54	0.537
Weight(Kg)	71.30 ± 9.90	75.60 ± 12.92	74.93 ± 10.99	0.292
ASA score				
I	24 (80.0%)	26 (86.7%)	25 (83.3%)	0.787
II	6 (20.0%)	4 (13.3%)	5 (16.7%)	
Comorbidity				
Free	24 (80.0%)	26 (86.7%)	25 (83.3%)	0.787
Diabetic	3 (10.0%)	1 (3.3%)	2 (6.7%)	0.585
Hypertensive	2 (6.7%)	2 (6.7%)	1 (3.3%)	0.809
Asthma	0 (0.0%)	1 (3.3%)	2 (6.7%)	0.355
COPD	1 (3.3%)	0 (0.0%)	0 (0.0%)	0.364
Anesthesia duration (h)	4.14 ± 0.65	4.13 ± 0.52	4.35 ± 0.49	0.220
Surgical duration (min)	57.67 ± 21.61	55.33 ± 17.27	60.67 ± 26.93	0.651

Data are presented as mean ± SD and number. SD Standard deviation, ASA American Society of Anesthesiologists. P < 0.05 significant difference between groups

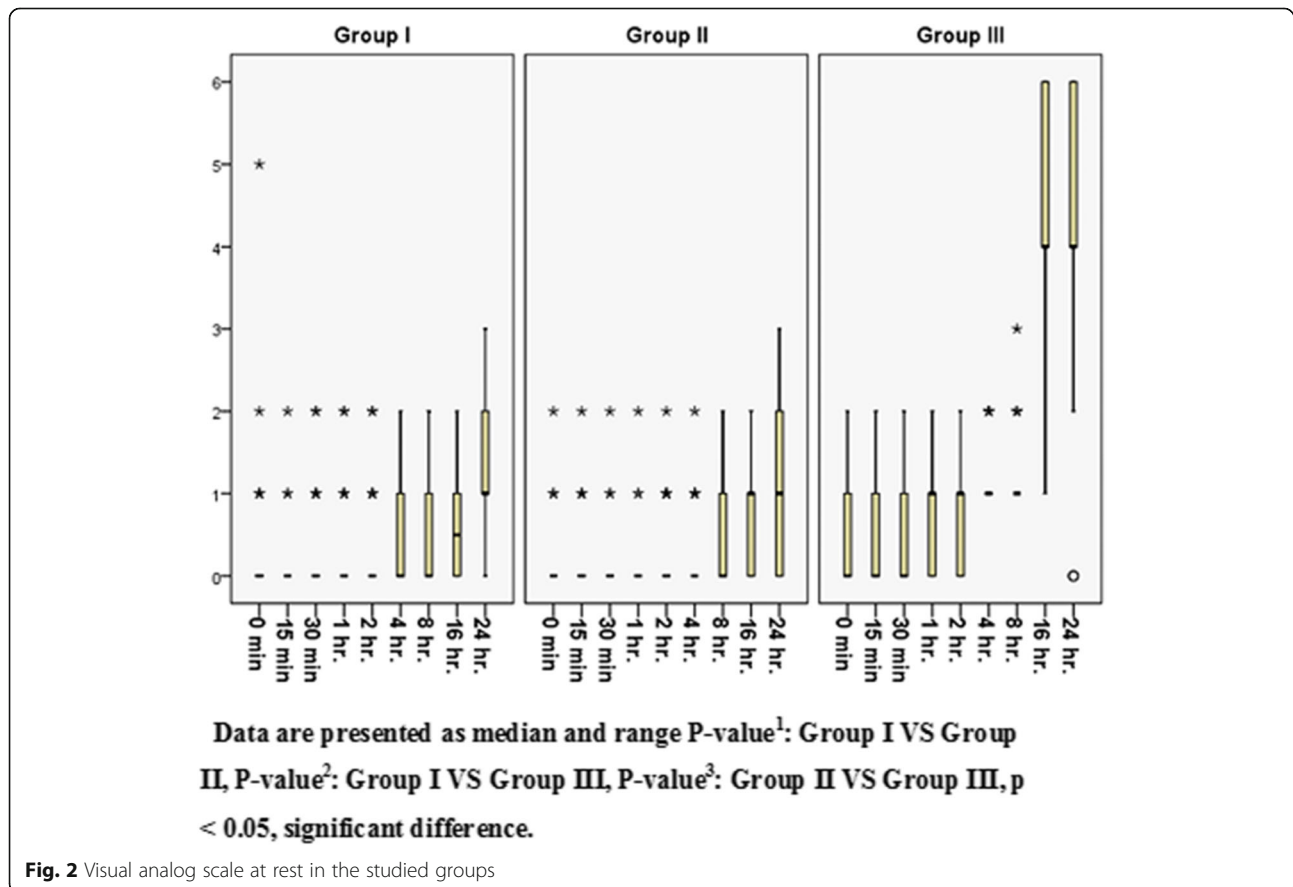
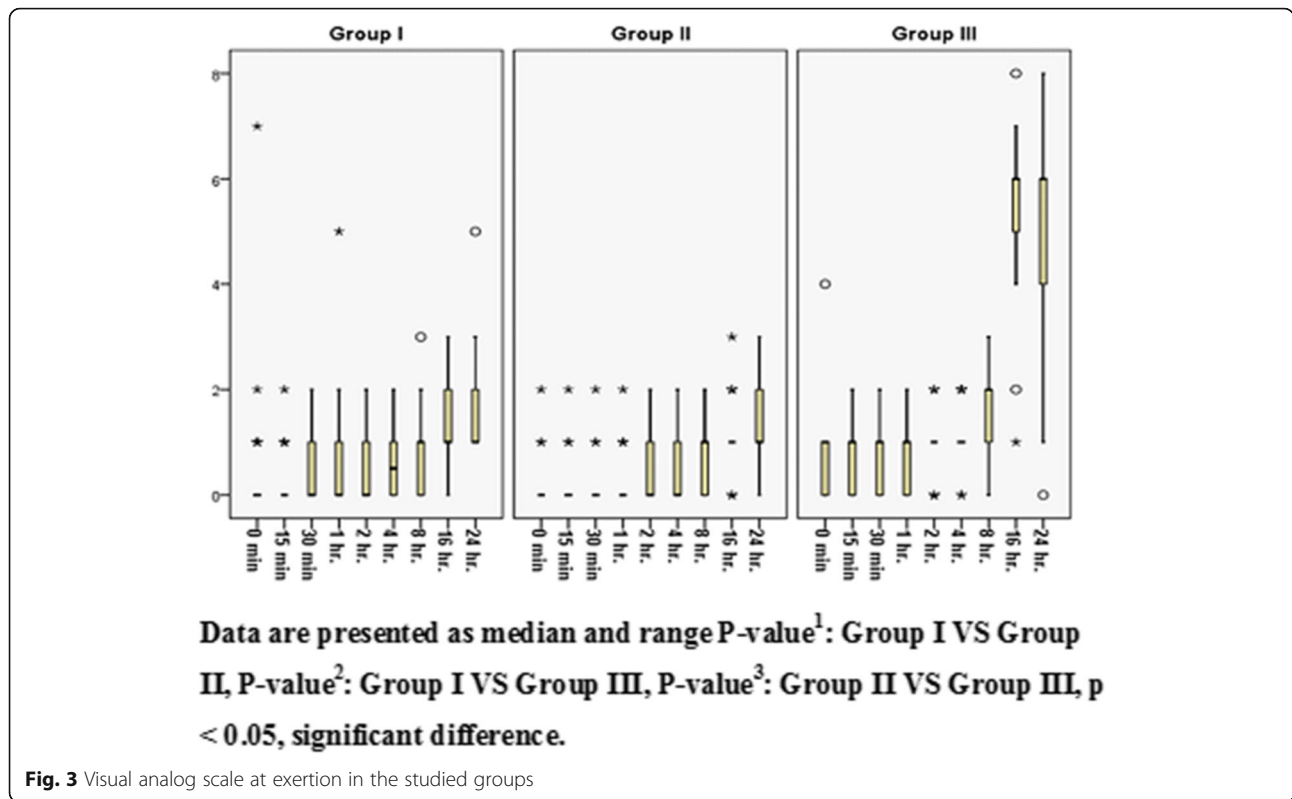


Fig. 2 Visual analog scale at rest in the studied groups



This study reported also that the heart rate was decreased significantly in patients of group I and group II than group III at 16 h and 24 h postoperatively (*P* value between group I and group III was 0.005 and 0.004 at 16 h and 24 h, respectively, and *P* value between group II and group III was 0 at 16 h and 24 h) (Fig. 5).

Hemodynamics effects were significantly lower in dexamethasone groups than the control group and corresponded to the visual analog score but without clinical significant as there were no incidence of bradycardia (heart rate bradycardia < 60 beat/min) or hypotension (mean BP < 20% of the base line). There were no postoperative adverse effects recorded in all patients (not presented).

Discussion

In this study, we studied the postoperative analgesic effect of two doses of dexamethasone (4 mg and 8 mg

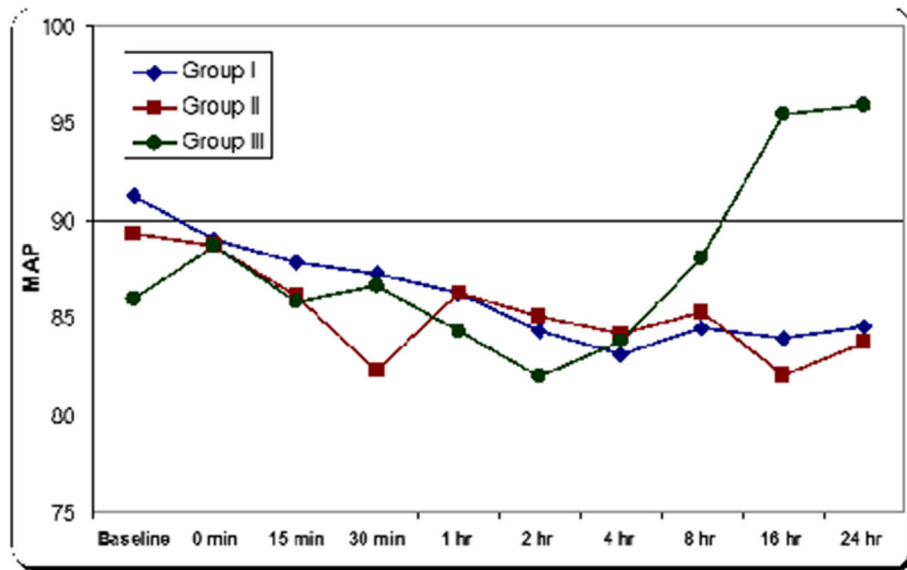
added to bupivacaine in unilateral TAP block for inguinal hernia repair), and we noted that VAS scores, time to rescue analgesia, and total postoperative analgesic consumption were lower in dexamethasone groups than the control group with no difference between the two doses of dexamethasone.

Ultrasound use makes TAP block more easily in performance, very safe, with a high rate of success, and low incidence of complication (Ripollés et al. 2015; Belavy et al. 2009). Multiple previous studies noticed that TAP block reduced postoperative analgesic consumption (Gao et al. 2017; Seervi et al. 2019; Sujatha et al. 2017), but this effect has a limited duration (Moyo et al. 2016). Several adjuvants were used to prolong the duration of local anesthetics and suggested that dexamethasone is the best adjuvant to local anesthetics agents in peripheral nerve block and could be superior to clonidine, fentanyl, neostigmine, and tramadol (Yaghoobi et al. 2013;

Table 2 Paracetamol request and dose

	Group I (n = 30)	Group II (n = 30)	Group III (n = 30)	P value
Number of patients' requests for analgesics				
Once	--	--	3	
Twice	--	--	27	NA
Time to first request for rescue analgesia (min)	--	--	720 ± 90	NA

Data are presented as mean ± SD and number. NA not applicable
All cases of group III requested analgesia at 12 h postoperatively



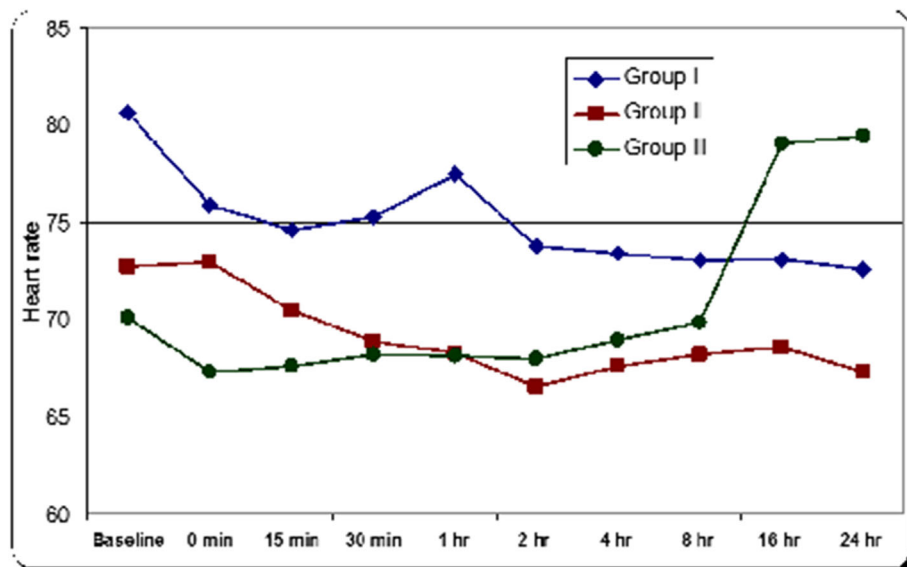
Data are presented as mean ± SD, P-value < 0.05 significant difference.

Fig. 4 Postoperative mean arterial pressure in the studied groups

Shah et al. 2015; Yadav et al. 2008; Trabelsi et al. 2013) and has similar analgesic effect as dexmedetomidine without any adverse hemodynamic effect associated with dexmedetomidine (Lee et al. 2016; Verma and Ranjan 2016).

Efficacy of addition of dexamethasone in the TAP block studied previously (Ammar and Mahmoud 2012;

Akkaya et al. 2014; Yildiz and Bayir 2015). Dexamethasone is a long-acting steroid used to prolong the duration of the effect of local anesthetics in a dose-dependent manner, and it does not have any effect if used alone without local anesthetics (Kartalov et al. 2015). This effect may be due to their anti-inflammatory or immune-suppressive actions (McCormack 1994),



Data are presented as mean ± SD, P-value < 0.05 significant difference.

Fig. 5 Postoperative heart rate of the studied groups

perineural vasoconstriction may decrease the absorption rate of local anesthetics (Wang et al. 2011; Shishido et al. 2002), direct inhibition of ectopic neural discharge (Devor et al. 1985), or through modulation of potassium channels (Pennington et al. 1994).

Similar to our results, Chen et al. (2018) and Zhang et al.'s (2019) in their meta-analysis demonstrated that dexamethasone in the TAP block improve the analgesic effect of local anesthetics in a dose ranging from 4 to 8 mg and recommended the need for further studies to identify the optimal dexamethasone dose.

The duration of analgesia depends on the dose of local anesthetics used in the block (Demirci et al. 2014) and the dose of dexamethasone. Several studies investigate the effect of dexamethasone and demonstrated different results; some results were similar to our results and recorded the duration of analgesia ranges from 20 to 24 h and others recorded duration of analgesia ranges from 12 to 16 h (Ammar and Mahmoud 2012; Kartalov et al. 2015).

Deshpande et al. (2017) reported that time to first analgesic request was 13.2 ± 7.6 h when using ropivacaine 0.5% added to 4 mg dexamethasone in TAP block, Sharma et al. (2018) found time to first analgesic request was 10 h using 8 mg dexamethasone added to ropivacaine 0.5% in TAP block; similar to these studies, our result suggested the equipotent analgesic effect of 4 mg and 8 mg dexamethasone, and time to first analgesic request was prolonged up to 24 h in our study; this prolongation may be due to the use of bupivacaine. Cummings III and coworkers noticed prolonged duration of interscalene blocks when using 0.5% bupivacaine dexamethasone than 0.5% ropivacaine dexamethasone (Singh et al. 2013), as ropivacaine has lower pH than bupivacaine (Wegner et al. 2017).

In our study, there was no incidence of postoperative nausea and vomiting in all groups in contrast to our results. Chen et al.'s (2018) meta-analysis found that dexamethasone in TAP block associated with a 72% decrease in the incidence of (POVN) compared with local anesthetics alone, due to reduction in opioid consumption (Singh et al. 2013; McMorro et al. 2011); we did not use opioid in the rescue analgesia, and this may explain the absence of postoperative nausea and vomiting in our results.

Although the use of perineural dexamethasone is still an off-label route (Choi et al. 2014), there were no observed complications in our study; similar to our results, Ma et al. (2010) suggested that dexamethasone may have a protective effect on bupivacaine-induced neuron injury in vitro by activating the Akt (threonine-serine protein kinase B) signaling pathway.

Limitation

Our observation period was limited to 24 h because patients were discharged from the hospital as a part of our

surgical department protocol, so we could not assess the definite duration of analgesia of the two doses of dexamethasone, and the effect on the mobilization time, so a large study is needed with prolonged observation period. Another limitation was we did not measure the serum level to prove the local effect of dexamethasone.

Conclusion

There is no difference in the first postoperative 24 h analgesic effect of the two doses of dexamethasone when added to a long-acting local anesthetic mixture in TAP blocks in patients undergoing inguinal hernia repair.

Abbreviations

ASA: American Society of Anesthesiologists; TAP block: Transversus abdominis plane block; IHR: Inguinal hernia repair; BMI: Body mass index; VAS: Visual analog scale; IV: Intravenous; PACU: Postanesthesia care unit; POVN: Postoperative nausea and vomiting; Akt: Threonine-serine protein kinase B

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Authors' contributions

AH: This author helped in study design, data analysis, and manuscript writing and editing. EA: This author helped in conduct of study and manuscript writing. AY: This author helped in conduct of study, data collection, and Excel sheet formation. All authors read and approved the final version of the manuscript for publication.

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Availability of data and materials

Confidential patient data can be asked by special request from the corresponding author.

Ethics approval and consent to participate

1. Local Medical Ethics Committee, Faculty of Medicine, Assiut University, Assiut, Egypt (IRB 17100670)
2. ClinicalTrials.gov registration number is NCT03863977
3. Written informed consent was taken from all the study participants.

Consent for publication

Participants accepted publication in a written consent.

Competing interests

The authors declare no competing interests.

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