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Original Research

The effect of transversus abdominis plane block on acute and chronic pain after inguinal hernia repair. A randomized controlled trial

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ABSTRACT

Background: This prospective double-blind randomized study aimed at evaluating the short- and long-term postoperative analgesic efficacy of the ultrasound-guided tranversus abdominis plane (TAP) block in inguinal hernia repair under general anesthesia.

Methods: Sixty patients undergoing inguinal hernia repair were allocated to TAP block with either ropivacaine 0.75% 20 mL or placebo 20 mL. Postoperatively, they had access to a patient-controlled analgesia (PCA) device administering 1 mg doses of morphine as rescue analgesia. Pain was assessed at rest and during movement with the numeric rating scale (NRS) score 3,6 and 24 hs postoperatively. Other variables recorded were intraoperative dose of remifentanil required to maintain systolic arterial pressure within 20% of baseline, mg of morphine used in the Post Anesthesia Care Unit (PACU) and total dose of morphine administered via the PCA device. Six months after surgery, the occurrence of chronic pain was assessed with the NRS score at rest and during movement. Patients were also asked to fill in the DN4 questionnaire to estimate the development of neuropathic pain.

Results: Patients who were administered ropivacaine demonstrated significantly less pain at rest and on movement, as expressed by NRS scores in comparison to patients in the placebo group. The former group also required less remifentanil intraoperatively, less morphine during the PACU stay and had lower morphine consumption through the PCA device. Six months after surgery, pain scores at rest and during movement were comparable between the two groups. At the same time DN4 scores were low and comparable between the two groups.

Conclusion: Ultrasound-guided TAP block provided better pain control than placebo in the acute setting after inguinal hernia repair. However, the incidence of chronic pain was low and not significantly affected by the performance of the block.

1. Introduction

Inguinal hernia repair is one of the most commonly performed surgical procedures worldwide, especially in the day-case setting [1]. The Lichtenstein “tension-free” hernioplasty using mesh prostheses is currently one of the most popular techniques for repair of inguinal hernia [2]. Although the Lichtenstein technique is relatively simple and is considered the standard surgical approach for unilateral or bilateral hernia repair with a low recurrence rate, it can be accompanied by moderate to severe postoperative pain, which can delay return to normal daily activities or lead to the development of chronic pain [3].

Chronic pain after hernia repair has a reported prevalence ranging between 0% and 43% with both nociceptive and neuropathic features [3]. Chronic postoperative pain, especially of neuropathic nature can untowardly affect the patient's functional status and impair overall quality of life [4,5]. Predisposing factors that have been implicated in the development of chronic pain post herniorrhaphy are preoperative pain, nerve injury during surgery and inadequate management of the acute pain related to the surgical procedure [6].

The transversus abdominis plane (TAP) block is an effective regional anesthetic technique to reduce postoperative pain intensity, time to first rescue anesthetic administration and opioid demand after upper and lower abdominal surgery [7–9]. It involves local anesthetic injection in the neurofascial plane between the fascia of the internal oblique and

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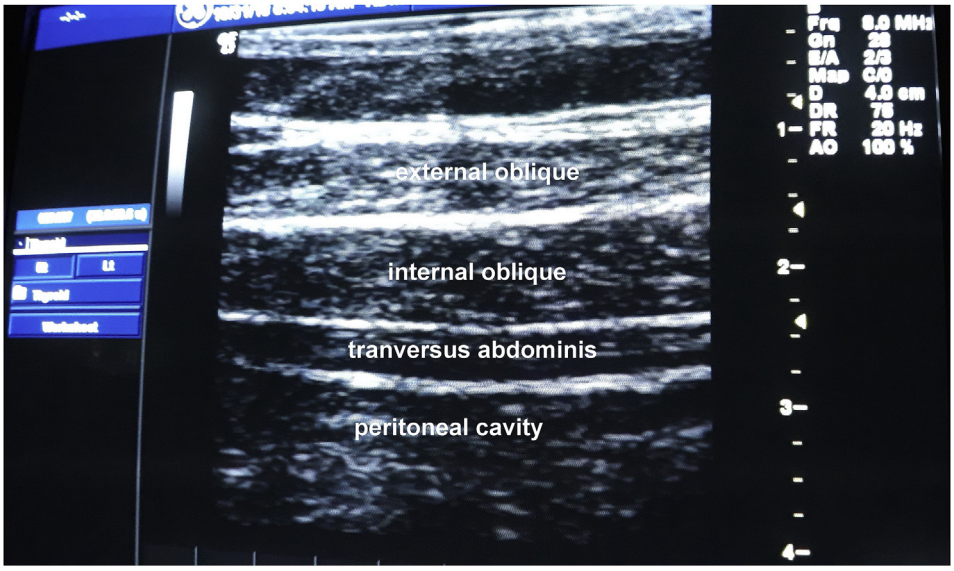

Fig. 1. Sonographic view of the three abdominal muscle layers before local anesthetic injection.

transversus abdominis muscles, aiming at blocking the neural afferents from the anterolateral abdominal wall and specifically the ilioinguinal, iliohypogatsric and lower intercostals nerves (T_7-T_{11}), which traverse between the internal oblique and transversus abdominis muscles [10]. Initially performed as a landmark-guided technique, it has evolved in recent years to an ultrasound-guided technique, being widely utilized due to its technical simplicity as part of a multimodal regime for postoperative analgesia following a variety of surgical procedures, such as abdominoplasty, laparoscopic procedures, cesarean section, total abdominal hysterectomy and even open colorectal surgery, with a satisfactory duration of analgesic action for up to 24 h [7,11–16].

The aim of this prospective, double-blind placebo controlled randomized study was to evaluate the analgesic efficacy of ultrasound-guided TAP block in patients undergoing unilateral elective inguinal hernia repair with the Lichtenstein technique under general anesthesia. We sought to investigate the efficacy of the TAP block as an adjunct to a basic analgesic regimen with paracetamol and parecoxibe on acute postoperative pain parameters as well as on the development of chronic or neuropathic pain.

2. Materials and methods

2.1. Study population and anesthetic management

This was a randomized double-blind placebo-controlled clinical trial conducted between October 2013 and August 2017. The protocol of the study was registered on www.clinicaltrials.org (NCT02030223), took place in compliance with the Helsinki Declaration and its design was in accordance with the Consolidated Standards of Reporting Clinical Trials (CONSORT) [17]. After evaluation of eligible patients during the preoperative visit and after obtaining written informed consent from each participant, 60 American Society of Anesthesiologists (ASA) I-III patients scheduled for elective unilateral inguinal hernia repair using the Lichtenstein technique (open repair of inguinal hernia with a mesh) met inclusion criteria and were enrolled in the study. Patients were randomized according to a computer-generated sequence of random numbers into ultrasound-guided TAP block with either ropivacaine 0.75% 20 mL (study group) or normal saline (placebo group). An anesthetic nurse not involved in the patient's postoperative care prepared identical-appearing syringes of the solution intended for injection containing either ropivacaine or saline. Exclusion criteria were an inability to consent to the study due to language barriers or cognitive dysfunction, bilateral inguinal hernia repair, body mass index over 40 $kg\,m^{-2}$, skin infection at the puncture site, contraindication to paracetamol or non-steroidal anti-inflammatory drug (NSAIDs) administration, known previous hepatic or renal impairment as assessed by the patients' history and routine biochemical markers, coagulation abnormalities, a history of gastroesophageal reflux and preoperative use of opioids or NSAIDs for chronic pain conditions and reoperation of recurrent inguinal hernia after previous mesh repair.

During the preoperative visit, patients were asked to fill in the Hospital Anxiety and Depression Scale (HADS), which has been translated and validated in the Greek language [18]. They were also instructed to the use of the pain numeric rating scale (NRS) graded from 0 (no pain) to 10 (worst pain imaginable) as well as to the use of a patient controlled analgesia (PCA) device for postoperative pain management.

On the operation day, standard monitoring consisting of three-lead electrocardiography, non-invasive blood pressure measuring and pulse oximetry was applied and intravenous access was secured. Followingly, all patients were subjected to a standardized anesthesia regimen. In specific, they were premedicated with midazolam 0.025 $mg\,kg^{-1}$, ranitidine 50 mg and metoclopramide 10 mg. Anesthesia was induced with remifentanil (1 $\mu g\,kg^{-1}$), propofol (2 $mg\,kg^{-1}$) and rocuronium (1 $mg\,kg^{-1}$) and the patient's airway was secured with a supraglottic airway device (Supreme Laryngeal Mask, Malaysia, Teleflex Ireland). Ventilation was performed with 40% oxygen in air mixture with partial pressure of carbon dioxide maintained at 35–45 mmHg during mechanical ventilator support. Anesthesia was maintained with an intravenous infusion of propofol at 120 $\mu g\,kg^{-1}\,min^{-1}$ and remifentanil between 0.1 and 0.5 $\mu g\,kg^{-1}min^{-1}$. The remifentanil infusion was titrated intraoperatively as to maintain systolic arterial pressure within 20% of baseline values.

The TAP block was performed under real –time ultrasound guidance after anesthetic induction. After the skin had been disinfected with a povidone-iodine solution and under sterile conditions of probe handling, a linear array transducer probe, with frequency set at 10 MHz and connected to a portable ultrasound unit (Vivid I Safelock, GE Medical Systems Ultrasound Israel Ltd), was positioned at the lateral part of the abdominal wall at the umbilical level, between the iliac crest and the subcostal margin, with a perpendicular orientation of the probe to a line joining the anterior superior iliac spine and the inferior rib. The probe was carefully manipulated until the three layers of the lateral abdominal wall were visualized from superficial to the depth, that is external oblique, internal oblique and transversus abdominis muscles respectively (Fig. 1). A 21 G short-beveled 90 mm needle (StimuQuick Echo, Arrow International Inc, USA) was advanced from medial to lateral

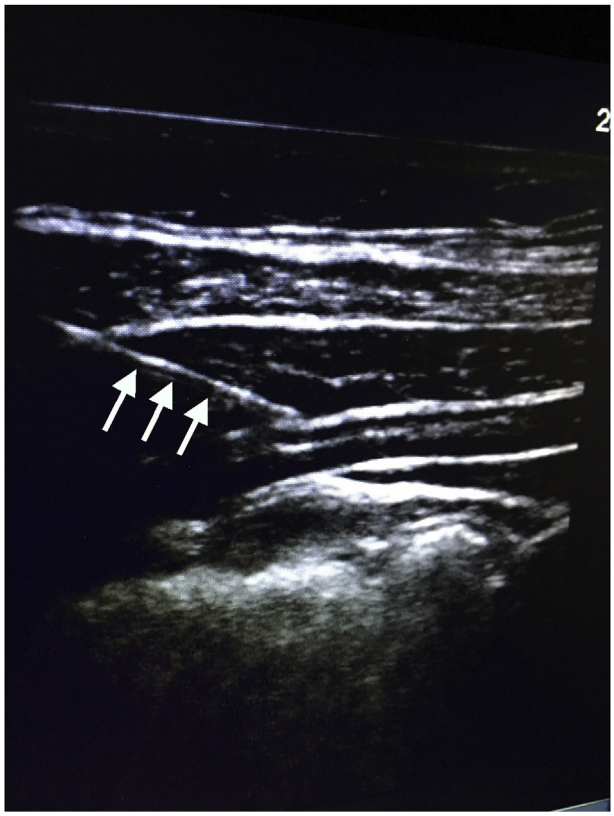

Fig. 2. Sonographic view of the needle (arrows), with its tip between the aponeurosis of the internal oblique and transversus abdominis muscles.

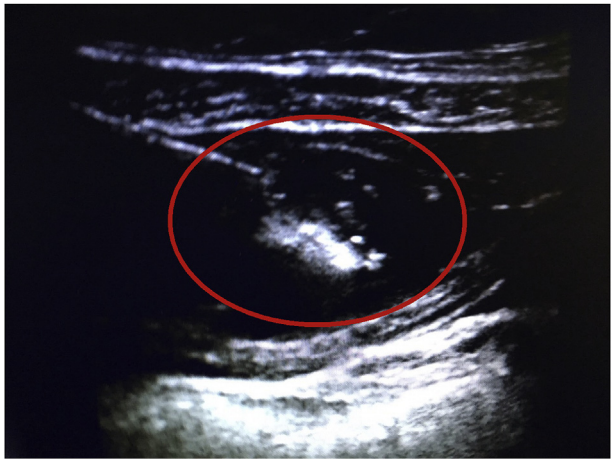

Fig. 3. Sonographic view of local anesthetic injection (red circle) during transversus abdominis plane block performance. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

direction using the in-plane insertion technique, ensuring visualization of the entire needle during advancement as a bright hyperechoic line and aiming at the aponeurosis between the internal oblique and transversus abdominis muscles (Fig. 2). When the tip of the needle was visualized at the targeted fascial plane, 2 mL of 0.9% normal saline was initially injected to verify the correct position of the needle with the hydrolocation technique. Followingly, ropivacaine 0.75% 20 mL or normal saline 20 mL (depending on group allocation) were incrementally injected. During the procedure, intermittent aspiration along with confirmation of the correct placement of the needle by expansion of the local anesthetic deposition as a hypoechoic oval shadow in the targeted plane between the aponeuroses of the internal oblique and transverse abdominis muscles were ensured (Fig. 3). All TAP blocks were performed by the same anesthesiologist, experienced in ultrasound-guided techniques and blind to patient group allocation. The surgical procedure was allowed to start 15 min after completion of the TAP block. All operations were performed by the same two trained surgeons, with the Lichtenstein tension-free meshplasty, so as to minimize confounding.

All patients received paracetamol 1 g and parecoxib 40 mg intravenously 30 min approximately before the end of surgery. Ten minutes before surgery completion, propofol and remifentanil infusions were discontinued, residual neuromuscular blockade was reversed with sugammadex 2 mg kg^{-1} and the patients were allowed to awake just before laryngeal mask removal. The laryngeal mask was removed having ensured that patients were breathing spontaneously and responded to command.

In the Postanesthesia Care Unit (PACU), patients received 2 mg morphine boluses on request, until NRS score was ≤ 3. Postoperative nausea and vomiting (PONV) were treated with ondansetron 4 mg intravenously. Patients were discharged from the PACU as soon as they fulfilled the modified Aldrete criteria, with no PONV and with an NRS score ≤ 4 on coughing. After discharge from the PACU, patients received a combination of paracetamol 1 g at 8 h intervals and parecoxib 40 mg 12-hourly. While in the ward, they also had access to a PCA device administering 1 mg doses of morphine as rescue analgesia, with a 15-min lockout period.

2.2. Study endpoints and postoperative follow-up

Pain was assessed at rest and on coughing with the NRS score three, six and 24 h after surgery by an anesthesiologist unaware of patient allocation to the study or control group. Other variables recorded or measured were intraoperative dose of remifentanil infusion (μg kg^{-1}), mg of morphine requested in the PACU, total dose of morphine administered via the PCA device for a 24-h period and patient satisfaction from postoperative analgesia on a four-point Likert scale with 1 marked as minimal satisfaction and 4 as maximal satisfaction. The incidence of PONV as well as TAP block-related complications were also recorded. All patients were evaluated six months after surgery to assess the occurrence of chronic pain at the site of the operation, with the use of the NRS, at rest and during movement. They were also asked to fill in the DN4 questionnaire for estimation of the development of neuropathic pain. The DN4 questionnaire is a 10-item questionnaire, with 1 marked as yes and 0 marked as no, allowing a maximal score of 10 and with higher scores corresponding to a higher probability of neuropathic pain [19]. It has also been translated and validated in the Greek language [20].

2.3. Statistical analysis

The primary endpoint of the study was the NRS score on coughing 24 h after surgery. Prior to the study, sample size estimation indicated that approximately 27 patients should be included in each group in order to detect a clinically relevant difference in the NRS score between the two groups, with a power of 0.80 and an alpha error of 0.05. The estimation was based on a previous study describing a 24-h Visual Analogue Scale score of 4.61 (SD 1.77) after open inguinal hernia repair and a belief that a 30% reduction in this score with the TAP block would be clinically significant [21]. We aimed for 30 patients per group to allow for drop-outs. Secondary outcomes of the study were pain scores at rest, intraoperative remifentanil consumption, postoperative request for analgesia, incidence of nausea, side-effects related to the TAP block, satisfaction from anesthesia and occurrence of chronic pain.

Variables were tested for normality of distributions with the Kolmogorov-Smirnov test. Comparison of numeric data between the two groups were performed with the unpaired *t*-test or the Wilcoxon

rank sum test for independent samples, depending on whether the variables followed a normal or non-normal distribution. The chi-square test or Fisher's exact test as appropriate was used for comparisons of categorical data. NRS scores at rest and during movement three, six and 24 h postoperatively were analyzed with two factor mixed design analysis of variance with repeated measures for one factor (time). The Student-Neuman-Keuls test was used post-hoc for pairwise comparisons where appropriate. Correlations between preoperative HADS scores and postoperative DN4 scores were performed with the Spearman rank order correlation test. Results are expressed as mean ± SD or as median (25^{th}-75th percentiles), depending on normality of distributions and as frequency for categorical variables. A value of $p < 0.05$ was considered as statistically significant. Data were analyzed with the Sigmaplot for Windows statistical software (Systat Software, Inc., San Jose, CA).

3. Results

One hundred and nine patients were approached for participation on the study between October 2013 and August 2017. Among the 60 enrolled patients, one from the study (ropivacaine) group withdrew his consent for immediate postoperative follow-up, so data on him were not collected. Therefore, 59 patients were analyzed in respect to the immediate postoperative period (29 patients in the study group and 30 patients in the placebo group). One out of the 29 patients in the study group and one out of the 30 patients in the placebo group could not be contacted six months after surgery, therefore parameters regarding chronic pain were complete for 28 patients in the study group and 29 patients in the placebo group. The flow chart of the study is presented in Fig. 4.

Patient demographics, preoperative psychometric tests and duration of surgery were similar in the two patient groups (Table 1). Patients in the ropivacaine group required less remifentanil intraoperatively as compared to those in the placebo group (3.6 ± 1.1 vs. 4.3 ± 1.5 $\mu g\, kg^{-1}$, $p = 0.036$). The ropivacaine group also had a lower requirement for morphine boluses during stay in the PACU (2 [2–4] vs. 4 [4–6] mg, $p = 0.011$) and had lower median morphine consumption via the PCA device for the first 24 h in comparison to the placebo group (3 [2–4.25] vs. 5 [2.75–6.25] mg, $p = 0.017$). Moreover, patients who were administered ropivacaine demonstrated significantly less pain at rest as expressed by NRS scores six and 24 h postoperatively in comparison to patients in the placebo group (p 0.025 and 0.009, respectively), (Fig. 5). Significant differences were also noted for NRS scores on movement at three, six and 24 h postoperatively between the two groups (p 0.010, 0.048 and 0.001, respectively) (Table 2), (Fig. 6).

Patient satisfaction from anesthesia was similar between the two groups, while there were no differences in the incidence of PONV (Table 2). Additionally, the incidence of complications related to the performance of the TAP block was low and comparable between the two groups. In specific, one patient in the ropivacaine group and one patient on the placebo group developed localized bruising at the site of injection that resolved within a couple of days, one patient in the ropivacaine group complained of postoperative hypesthesia at the medial aspect of the thigh that was self-limiting in nature and resolved completely within a week and a patient in the placebo group developed localized edema of the abdominal wall at the site of block performance without signs of infection, which also finally resolved.

Six months after surgery, pain score values at rest and on movement were low and comparable between the two groups. Only two patients in each group had NRS scores on movement higher than 4. Similarly, evidence of neuropathic pain was low, with no differences in the DN4 between the two groups (Table 2). No significant correlations between preoperative HADS scores for anxiety and depression and DN4 scores six months postoperatively were demonstrated. One patient from each group had to be referred to the Pain Clinic due to persistent pain at the surgical incision site that interfered with daily activity.

4. Discussion

According to our results, ultrasound-guided TAP block significantly improved acute postoperative pain parameters in comparison to placebo after inguinal hernia repair. In specific, the ropivacaine group, as compared to the placebo group, required a lower dose of intraoperative remifentanil infusion, had a lower need for analgesics in the PACU and via the PCA device and experienced less pain postoperatively as evidenced by NRS scores both at rest and on movement. On the other hand, the incidence of chronic pain after hernia repair with the Lichtenstein technique was low and not significantly affected by the performance of the block.

The TAP block has gained popularity in recent years after Rafi originally described it in 2001 using traditional anatomical landmarks [22]. It has been shown to provide effective analgesia for surgical procedures where the irritation of the parietal peritoneum is a significant component of postoperative pain and one of its main advantages is the fact that it can be performed even if neuraxial techniques are contraindicated [23]. However, the blind technique does not always lead to a successful block. In fact, McDermott et al. showed that needle tip placement and local anesthetic spread were in the correct plane in only 23.6% of cases when the standard landmark-based approach was used during TAP block performance [24]. In recent years, ultrasound guidance has overcome the high failure rate of the blindly performed TAP block, enabling precise visual assessment of drug injection and allowing the spread of the local anesthetic in the correct plane between the internal oblique and the transversus abdominis muscles fascia layers, close to the targeted nerves. This was further confirmed in a cadaveric study, where successful administration of the injectate was demonstrated by dissection in all 16 hemi-abdominal walls after ultrasound-guided TAP block [25]. In this setting, there have been several studies documenting the efficacy of ultrasound-guided TAP block in the provision of effective analgesia in a series of abdominal procedures.

Our results are in accordance with studies of a similar setup demonstrating the favorable effect of TAP block in the context of various types of abdominal surgery. Specifically, the TAP block with ropivacaine as compared to placebo was shown to reduce postoperative visual analogue pain scores and total morphine requirements in the first 48 h after elective cesarean deliveries, both via the ultrasound-guided technique or the landmark-guided technique [14,26,27]. Furthermore, TAP block, as a component of a multimodal analgesia regimen, provided superior analgesia when compared to placebo after elective total abdominal hysterectomy, with lower pain scores at rest and movement and a lower requirement for analgesic consumption [15,28]. Its advantages have also been studied in the context of laparoscopic cholecystectomy, following open retropubic prostatectomy and in laparoscopic and open colorectal resections [7,12,13,16,29,30]. As in our study, in all the aforementioned studies, the superiority of TAP block versus placebo plus a prolongation in the time for first rescue request for analgesia was demonstrated.

The TAP block is a relatively safe technique with complications such as inadvertent visceral perforation and pelvic hematoma reported very rarely and mainly in connection with the anatomic landmark technique [31,32]. Additionally, the risk of systemic toxicity from the local anesthetic due to its injection into a highly vascular plane should always be under consideration, especially when the TAP block is performed using a blind technique [24,33]. In our series of studied patients, we did not encounter any major complications, a fact that reinforces the satisfactory safety profile of the TAP block, especially when it is performed under ultrasound guidance, as in our group of patients.

Of note, satisfaction from analgesia was similar between the two groups, although the ropivacaine group experienced lower pain postoperatively, as assessed by the NRS scores and required a lower amount of postoperative analgesics. This probably had to do with the fact that both groups had access to a PCA device and thus were able to self-

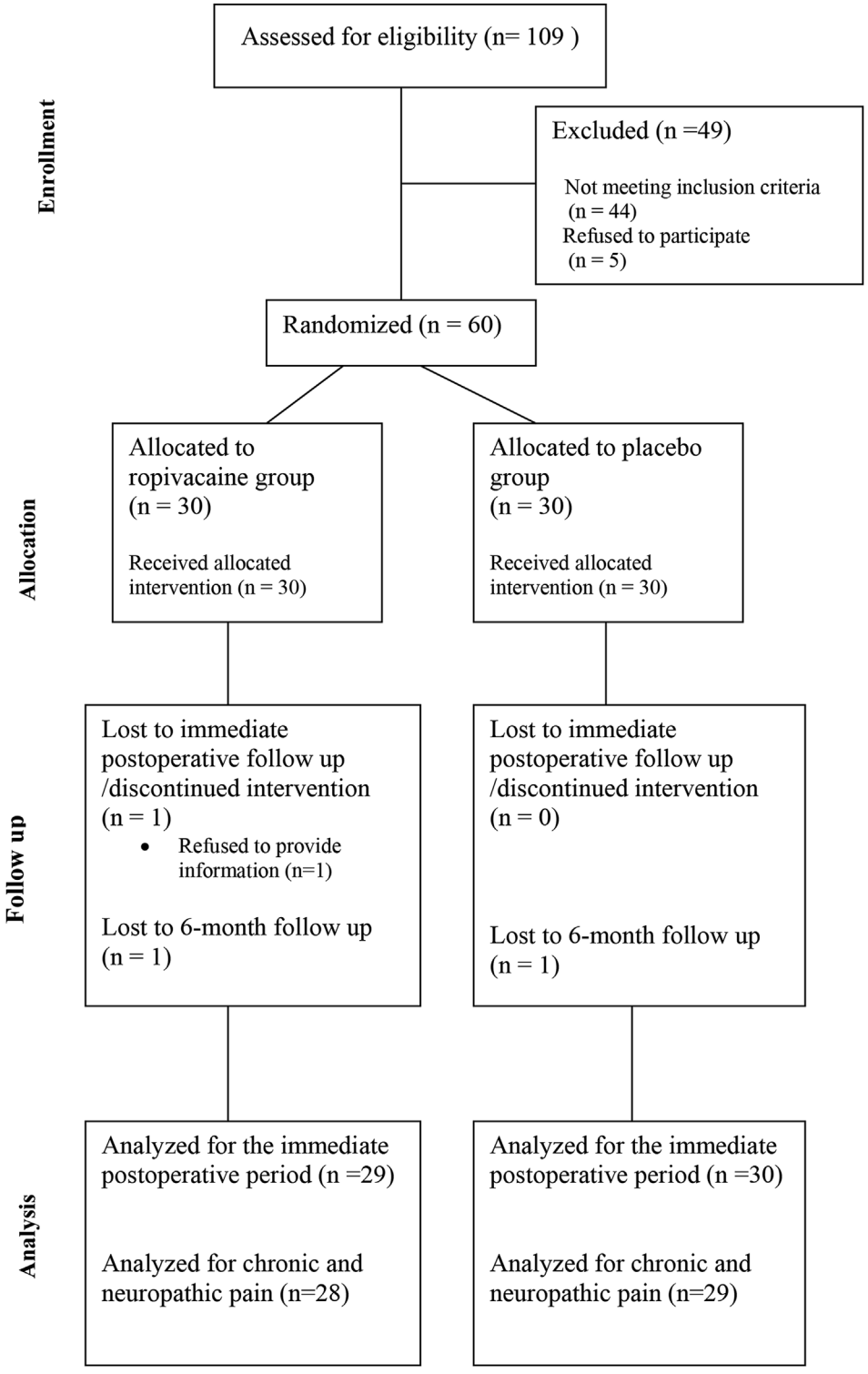

Fig. 4. Flow diagram of the study.

administer pain-relieving medications without having to wait for provision of analgesia on request. The reliance on a PCA device has been shown to establish feelings of self-sufficiency and independence in patients, while the perception of being in control of their provision of analgesics has been independently associated with increased satisfaction from their analgesic management [34,35].

An interesting finding of our study was the fact that the incidence of chronic pain in our set of patients, as this was evaluated six months after surgery was low. Chronic pain after inguinal hernia can be multifactorial in origin, has quite often neuropathic features, while the inadequate management of acute postoperative pain is one of the leading causes implicated in its development [6,36,37]. We used the DN4 questionnaire in the assessment of neuropathic pain in our group of patients, which has been shown to have satisfactory sensitivity and specificity (84.9% and 88.9% respectively) in the detection of the neuropathic component of pain [19]. This questionnaire is a well-validated evaluation tool used in the assessment of probability of neuropathic pain and has also been recently validated in the greek language

Table 1
Demographic characteristics of the ropivacaine and placebo groups.

Variables	ropivacaine group (n = 29)	placebo group (n = 30)	p value between groups
Age (years)	61.9 ± 14.6	59.6 ± 14.4	0.541
Gender (m/f)	24/5	22/8	0.576
Weight (kg)	76.7 ± 12.5	75.7 ± 9.5	0.733
ASA (I/II/III)	15/10/4	18/9/3	0.798
Duration of surgery (min)	72.9 ± 16.1	76.0 ± 17.3	0.485
HADS score (anxiety)	5 [3–8]	5 [4–7]	0.642
HADS score (depression)	6 [4–9]	6 [4–8]	0.450

Data are presented as mean ± SD, absolute number or median [25th-75th percentile].
ASA, American Society of Anesthesiologists; HADS, Hospital Anxiety and Depression Scale.

[20]. The low incidence of neuropathic pain in our study is in contrast with other reports demonstrating a higher prevalence of neuropathic pain after inguinal hernia repair, escalating to as high as 30% incidence of numbness and hypesthesia on the incision location [3,36,38]. In fact, nerve injury could also be a cause of chronic pain, whereas the possibility of nerve injury varies depending on the surgical procedure. Although open procedures are potentially linked with a high possibility of nerve damage in comparison to laparoscopic herniorrhaphies, the meticulous surgical technique used in our institution as well as mastering of the Lichtenstein technique by our surgeons could account for the low incidence of chronic pain, since a careful surgical approach in combination with moderate operative trauma can result in less severe tissue damage. However, this favorable long-term outcome could also be attributed to the fact that this study was not powered to the development of chronic pain, which is an outcome that requires a much higher number of patients, a fact that at present time was difficult to attain based on our current hospital resources. We had asked our patients to fill in the HADS questionnaire preoperatively because we thought that it would be useful to correlate postoperative neuropathic pain, if any, with preoperative personality traits of anxiety and depression, which are known predisposing factors for the development of chronic pain. The fact that no such correlations were demonstrated might also be a reflection of the low incidence of chronic neuropathic pain in our sample. Based on this low incidence of chronic pain post hernia repair demonstrated in our study, it is not surprising that the performance of the TAP block did not affect its development. Interestingly, another study of TAP block, although in an entirely different setting of breast reconstruction did not demonstrate an improvement of chronic pain with the performance of the TAP block, either [39].

Despite the relatively low number of subjects included in our study, our patient group had a remarkably low loss to follow-up at six months postoperatively. Therefore, we were able to obtain information about the chronic and neuropathic component of post-hernia repair pain in the vast majority of our patients. As already mentioned, only one patient per group could not be contacted six months postoperatively. This low loss to follow-up provided us with the opportunity to obtain reliable (albeit limited due to the low number of patients enrolled) information about the chronic and neuropathic component of post-hernia repair pain, a fact which is scarcely achieved in studies aiming at follow-ups extending to several months postoperatively.

Our study has some limitations; firstly, the period of postoperative observation was limited to 24 h postoperatively; secondly, the study was not powered to the evaluation of chronic pain, as already mentioned. However, since the effects of the TAP block on the occurrence or modification of chronic pain is a relatively scarce topic of investigation in literature with limited data available, we thought that it was worth following-up our group of patients for six months in order to record the development of chronic pain or any potential alteration of its components by the performance of the block, although we were aware of the fact that our sample was small for this purpose.

In conclusion, under the present study design, the TAP block with ropivacaine proved to be an effective abdominal field block in the setting of inguinal hernia repair, demonstrating superiority versus placebo in respect to acute postoperative pain parameters, with no major complications occurring. Since chronic pain after this surgical procedure continues to be a concern, further studies including larger numbers of patients in order to achieve the required power are warranted. These studies should be specifically aimed at investigating the impact of performing such a block on chronic pain incidence and features in the setting of post-inguinal hernia repair.

Provenance and peer review

Not commissioned, externally peer-reviewed.

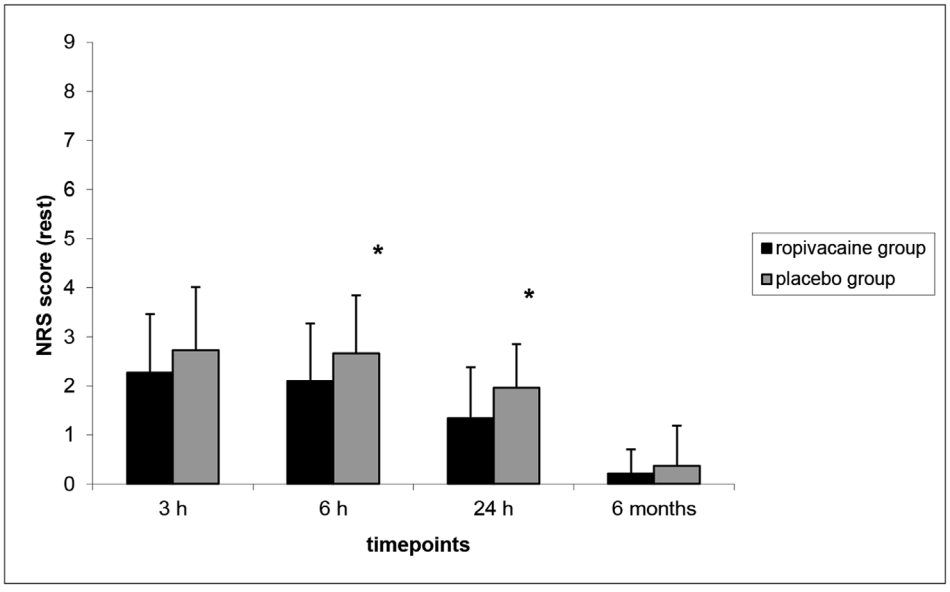

Fig. 5. NRS scores at rest, *p < 0.05 for the comparison between the two groups.

Table 2
Pain parameters and VAS scores of the ropivacaine and placebo groups.

Variables	ropivacaine group (n = 29)	placebo group (n = 30)	p value between groups
Intraoperative remifentanil consumption (μg kg^{-1})	3.6 ± 1.1	4.3 ± 1.5[a]	**0.036**
Morphine consumption (mg) (PACU)	2 [2–4]	4 [4–6][a]	**0.011**
Morphine consumption (mg) (PCA)	3 [2–4.25]	5 [2.75–6.25][a]	**0.017**
postoperative NRS (rest)			
3 h	2 [1.75–3]	3 [2–4]	0.093
6 h	2 [1.75–3]	3 [2–3][a]	**0.025**
24 h	1 [1–2]	2 [2–3][a]	**0.009**
Postoperative NRS (movement)			
3 h	4 [3–5]	5 [4–6][a]	**0.010**
6 h	4 [3–5]	5 [4–6][a]	**0.048**
24 h	3 [2–4]	4 [4–5][a]	**0.001**
Patient satisfaction	4 [3–4]	4 [3–4]	0.364
PONV	5	9	0.398
6-month NRS (rest)	0 [0-0]	0 [0-0]	0.668
6-month NRS (movement)	0 [0–2]	0 [0–2.25]	0.877
Postoperative DN4	0 [0–1]	0 [0–1]	0.935

PACU, PostAnesthesia Care Unit; PCA, Patient Control Analgesia; NRS, Numeric Rating Scale; PONV, Postoperative Nausea and/or Vomiting; DN4, Douleur Neuropathique (Neuropathic Pain) Questionnaire.
[a] Significant difference between groups; data are presented as mean ± SD, absolute numbers or as median [25th-75th percentile].

Conflicts of interest

The authors declare that they have no potential conflicts of interest.

Ethical approval

This study was approved by the Institutional Review Board of the Aretaieion University Hospital, University of Athens School of Medicine, Athens, Greece (approval number: F-26/20-06-2013).

Research registration unique identifying number (UIN)

The protocol of this randomized controlled trial was registered on www.clinicaltrials.org (NCT02030223).

Author contribution

K.T., P.P. and E.A. were responsible for study conception and design. K.T. was responsible for analysis and interpretation of data and wrote the manuscript. A.T. and A.V. contributed to data collection. All authors revised the manuscript for important intellectual content and approved the final version of the manuscript. K.T. and P.P. contributed equally to the manuscript.

Guarantor

Kassiani Theodoraki and Panagiota Papacharalampous are the guarantors for this study.

Data statement

Data for this study are available on request.

Declaration of interests

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://

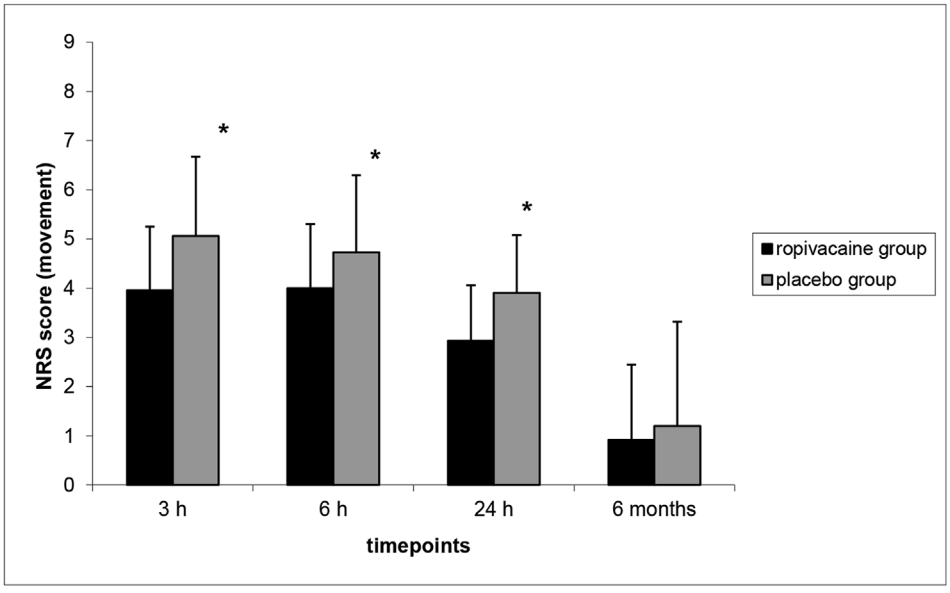

Fig. 6. NRS scores during movement,*p < 0.05 for the comparison between the two groups.

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