ORIGINAL ARTICLE

Port Site Infiltration and Extraperitoneal Instillation of Ropivacaine in Totally Extraperitoneal Hernia Repair: A Randomized Controlled Trial

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Abstract

Aim: To evaluate the role of intraoperative local anesthetic use in the reduction of postoperative pain after totally extraperitoneal (TEP) hernia repair.

Settings and design: Teaching hospital in Delhi, RCT.

Materials and methods: 18–60-year-old men with unilateral inguinal hernia were randomized to either ropivacaine group (30) or placebo group (30) using a randomization sequence generated online. Port sites and preperitoneal space received either 0.75% ropivacaine or 0.9% saline (placebo). The primary outcome was numerical response scale (NRS) pain score at 6 hours after surgery. The secondary outcomes include NRS at 2 hours, 24 hours, and total analgesic requirement during the first postoperative week. The same surgeon using the same type of mesh performed all procedures using three midline ports and without mesh fixation. The patient, surgery team, and observer were blinded.

Statistical analysis used: Shapiro–Wilk test of normality, median test for independent samples.

Results: All patients underwent allocated procedure. There were no conversions. The baseline parameters were comparable in the two groups. The Shapiro–Wilk test of normality revealed that the data were not distributed normally. The median NRS at 6 hours was 3 (IQR 1, 3) in the ropivacaine group compared with 3 (IQR 1, 4) in the placebo group ($p = 0.981$, Independent samples median test). Similar comparable pain scores were obtained at 2 and 24 hours. No significant difference was noted in analgesic requirement in the first 24 hours, till postoperative day 7, time to ambulation or micturition between groups.

Conclusions: Infiltration of port sites and preperitoneal space with ropivacaine does not reduce postoperative pain or analgesic requirement in TEP.

Clinical significance: The use of local anesthetic agents intraoperatively has no added benefit in reducing postoperative pain in TEP hernia repair.

Keywords: Abdominal pain, Hernia, Hernioplasty, Inguinal hernia, Inguinal hernia repair, Laparoscopic, Laparoscopic hernia repair, Laparoscopic inguinal hernia repair, Postoperative pain, Randomized controlled trial.

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Introduction

Totally extraperitoneal (TEP) repair has been recommended as one of the two preferred treatment options in adult patients with unilateral inguinal hernia.[1] The technique has been refined over the last decade and the results have been found to be good in the hands of experienced surgeons. As most surgeons performing laparoscopic inguinal hernia repair are now using a mesh size of 15 × 10 cm or more, the recurrence rates have become very low.[1] Surgeons' efforts are now directed toward reducing early and late postoperative pain as this has a great impact on the patient's satisfaction. Local anesthetics are believed to reduce the postoperative pain when used intraoperatively in the surgical wound sites. The limited space developed in TEP laparoscopic inguinal hernia repair (provides an ideal setting for direct instillation of local anesthetic agent. When local anesthetic is injected intraoperatively at wound sites, it can serve to minimize the postoperative pain. A few studies have previously evaluated this question and some have found a remarkable decrease in the postoperative pain score.[2–5] Conversely, other studies have found no decrease in pain after infiltration of port sites or instillation of local anesthetic solution in the preperitoneal space.[6–9] Ropivacaine is a newer local anesthetic with a longer duration of action with a favorable side effect profile compared with older local anesthetic agents.[10,11] We performed this randomized controlled trial to evaluate whether intraoperative use of local anesthetic (ropivacaine) in extraperitoneal space and in port sites in TEP mesh hernioplasty reduces postoperative pain.

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Materials and Methods

The aim of this study was to compare the infiltration of port sites and instillation of extraperitoneal space with ropivacaine vs placebo for postoperative pain relief after TEP inguinal hernia repair. The primary objective was to compare the postoperative pain scores using numerical response scale (NRS) scoring at 6 hours (h) postoperatively. Secondary objectives were to compare the postoperative pain scores at 2 h and 24 h postoperatively using NRS and to determine the total analgesic requirement in postoperative period till postoperative day 7.

This randomized clinical trial was conducted from November 2014 to March 2016 in the Department of Surgery at a teaching hospital in Delhi, India. Clearance from Institutional Ethics Committee was obtained prior to recruitment of patients into the study protocol. The protocol was submitted to the University of Delhi and the research was conducted as a part of a postgraduate thesis.

Male patients between the ages of 18–60 years falling under ASA grades I and II with a diagnosis of unilateral inguinal hernia falling in Nyhus classification types 1, 2, and 3a undergoing TEP repair were included in the study. Patients with a complicated hernia including irreducible, obstructed, or strangulated hernias, patients with previous lower abdominal surgery, patients with coagulopathy, patients who have received analgesic in the last 24 hours, and patients not giving informed consent for randomization were excluded from the trial.

Sample size was calculated assuming effect size of 0.8, power of the study as 90% and type 1 error of 0.5. Calculated sample size was 28 in each group (using G-Power software version 3.1.9). The anesthesiologist co-investigator randomized 30 patients in each group using a web generated randomization sequence (www.randomization.com). The randomization sequence was sealed in serially numbered opaque envelopes and kept in the custody of the anesthesiologist co-investigator. The anesthesiologist in the operating room called up our anesthesiologist co-investigator to allocate the group of the patient provided either the drug or placebo to the surgeons as determined by the randomization sequence. The patient, surgery team, and observer were kept blinded.

The same surgeon performed all the procedures. Totally extraperitoneal repair was performed with reusable trocars and instruments. The same type of mesh was used in all patients. General anesthesia was administered to all patients following standard anesthesia protocol and morphine 0.1–0.15 mg/kg was used intravenously for intraoperative analgesia, as routinely practiced. No further analgesics were used intraoperatively.

Each port site was infiltrated with 1 mL of 0.75% ropivacaine or placebo (0.9% saline) before the skin was incised for inserting ports. Horizontal infra-umbilical skin incision was made. A camera port was inserted over posterior rectus sheath. A telescope was inserted and preperitoneal space was developed using telescopic dissection. The other two ports were inserted under visual guidance. Direct and small indirect hernia sacs were reduced completely while large indirect sacs were ligated close to the deep ring and transected. Parietalization of peritoneum and cord structures was done. Extraperitoneal space was instilled with 14 mL of 0.75% ropivacaine or placebo under laparoscopic vision after adequate space creation for mesh placement. The mesh was not fixed with either sutures or tacks. Port sites were again infiltrated with 1 mL of 0.75% ropivacaine or placebo at the time of closure of skin incisions.

The patients were monitored during surgery and postoperatively as per hospital protocol. Patients were followed up at 2, 6, and 24 h after surgery for postoperative pain using NRS scoring. Paracetamol 1 gm was administered intravenously as and when required; the first 24 hours of postoperative analgesia were used at a minimum interval of 6 hours. when the NRS score was more than 3/10. Diclofenac 50 mg intravenous or oral was used as a rescue analgesia if the patient's pain was not controlled using 1 gm paracetamol.

Tablet diclofenac 50 mg was prescribed for pain relief in the postoperative period after discharge from the hospital, till 7th postoperative day. The postoperative analgesic requirement was calculated after 7 days. Time to ambulation, first act of micturition, and postoperative complications, such as hematoma, seroma, and wound infection were recorded.

Data were analyzed using SPSS statistical software (version 23.0). Independent samples median test was used to compare the numerical data without normal distribution. The Chi-square test (χ^2) test or Fischer exact test was used for categorical data. A p-value of < 0.05 was considered significant.

Results

A total of 221 patients with inguinal hernia who presented during the period November 2014 to March 2016, were assessed for eligibility for inclusion in the study. Out of them, 60 patients met the inclusion criteria and were selected for enrollment in the study. Patients were randomized into the ropivacaine group and placebo group, each consisting of 30 patients.

All the patients underwent the allocated procedure and patient's data were collected in the case record form. None of the procedures was converted to open surgery.

The CONSORT diagram of the study is shown in Figure 1.

The two groups were similar in their baseline characteristics as given in Table 1.

Pain scores were lower for ropivacaine group as compared with placebo group, but the difference was not statistically significant. Table 2 compares the postoperative pain scores between the two groups.

No significant difference was noted in the mean analgesic requirement in the first 24 h (0.57 vs 0.83 tablets) as well as till postoperative day 7 (11.3 vs 10.8 tablets). The duration of surgery, as well as the time spent by the patient in the operating room was found comparable in the two study groups.

Preperitoneal space creation was satisfactory in all the cases. The instillation of fluid in the extraperitoneal space did not cause difficulty in dissection. No significant differences were noticed in the intraoperative or postoperative complications between the two groups.

Discussion

Our study was a double-blinded randomized controlled trial with 0.75% ropivacaine used in the test group and 0.9% saline used in the control group of patients with uncomplicated unilateral inguinal hernia undergoing TEP repair. Pain score at 6 h was considered as the primary objective as there could have been a confounding effect of general anesthesia on pain scores at 2 hours.

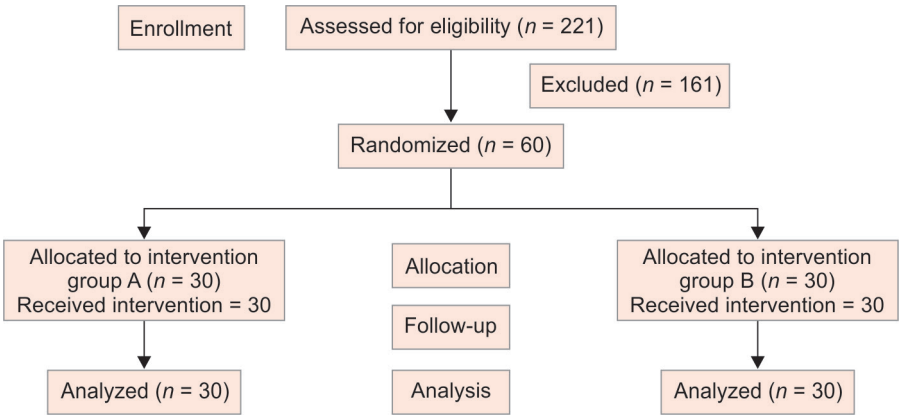

Fig. 1: CONSORT diagram of the study

Table 1: Baseline characteristics in the two groups

Study groups	*Ropivacaine group*	*Placebo group*
Age (In years) Mean ± Standard deviation (SD)	41.7 ± 13.2	35.3 ± 11.2
BMI (In kg/m^2) Mean ± Standard deviation (SD)	22.5 ± 2.6	22.7 ± 2.3

Table 2: Comparison of postoperative results between the two groups

	Ropivacaine group Median (IQR)	*Placebo group Median (IQR)*	*p-value (Independent samples median test)*
Pain at 2 hours (VAS)	1 (0,3)	2 (0,3)	0.187
Pain at 6 hours (VAS)	3 (1,3)	3 (1,4)	0.981
Pain at 24 hours (VAS)	3 (2,4)	3 (2,4)	0.160
Time to ambulation (hours)	4 (4,6)	4 (3,6)	0.411
Time to micturition	4 (4,6)	4 (4,6)	0.595

Pain scores at 2, 6, and 24 h were lower in ropivacaine group as compared with the control group but the difference was not statistically significant. Various other studies in the literature have compared postoperative pain scores following intraoperative use of bupivacaine in laparoscopic hernia repair.

Kumar et al. reported significantly lower VAS scores for pain in bupivacaine group as compared with the control group (1.69 ± 1.04 vs 3.47 ± 1.04, respectively, at 24 h postoperatively, $p < 0.0001$; 1.36 ± 0.81 vs 2.29 ± 1.44, respectively, at 48 h postoperatively, $p = 0.0063$).[3] They administered intravenous diclofenac to all 53 studied patients before anesthesia reversal. This might have a confounding effect on pain scores in the early postoperative period. Mesh fixation was not done in their study group as well as ours. This may be responsible for lower pain scores in both groups as compared with other studies. O'Riordain et al. found patients treated with bupivacaine had lower median [range] visual analogue pain scores on discharge; [1.5 (0–5.9) vs 3.7 (0.2–6.9), $p = 0.03$], and were more frequently pain-free (54% vs 31%, $p = 0.078$).[2] Bar-Dayan et al. also found the average pain levels as significantly reduced in bupivacaine group compared with the control group at 1 hour (4.0 vs 5.0, respectively; $p = 0.0038$), 2 hours (4.0 vs 5.9, respectively; $p = 0.0015$), and 4 hours (4.3 vs 5.8, respectively; $p = 0.0038$) after surgery.[5] However, the drawback in his study was that no clear randomization method was mentioned, multiple surgeons and observers were involved, and no standard anesthesia protocol and analgesic use during surgery was defined in his study of 44 patients. Pain scores reported in their study were considerably higher than those reported in our study. This may be attributed to the use of tacks for mesh fixation. Hon et al. also concluded preemptive use of bupivacaine in surgical bed in TEP hernioplasty to be beneficial in their randomized trial with three arms of 30 patients each.[4] They randomized patients in to three groups: (a) preemptive bupivacaine group (PBU) which received port site infiltration of bupivacaine before skin incision and instillation of bupivacaine in preperitoneal space before mesh placement, (b) standard bupivacaine group (SBU) which received bupivacaine in preperitoneal space after mesh placement, and (c) control group which received port site infiltration and preperitoneal instillation with saline. In his study, the PBU group had lower pain scores as compared with the SBU group at 2 hours (1.1 ± 1.5 vs 2.3 ± 1.7, $p = 0.005$) and 24 hours (0.7 vs 1.5, $p = 0.004$) while no significant difference in pain score was noted at 6 h (1.1 ± 1.3 vs 1.6 ± 1.4, $p = 0.153$). The PBU group was superior to control group in pain relief at all times with pain scores at 2 h (1.1 ± 1.5 vs 3.4 ± 1.7, $p = 0.000$), 6 h (1.1 ± 1.3 vs 1.8 ±1.7, $p < 0.001$), and at 24 h (0.7 ± 0.0 vs 1.4 ± 1.6, $p = 0.001$), respectively while the SBU group showed better pain relief only at 6 h postoperatively as compared with the control group [pain score at 2 h (2.3 ± 1.7 vs 3.4 ± 1.7, $p = 0.022$), at 6 h (1.6 ± 1.4 vs 1.8 ± 1.7, $p = 0.006$) and at 24 h (1.5 ± 1.3 vs 1.4 ± 1.6, $p = 0.404$) respectively]. Although they did not fix the mesh, they ligated all indirect hernia sacs and invaginated transversalis fascia in direct hernias. These techniques might potentially have increased pain. In our study, we have reduced all direct and small indirect inguinal hernias completely and ligated large indirect sacs.

On the contrary, Abbas et al. reported no significant difference in the postoperative pain scores at 4 h and 24 h; between bupivacaine group and the control group of 20 patients each (p-value = 0.615 and 0.100, respectively).[8] Deans et al. studied 100 patients and also found no significant difference between bupivacaine 0.25%, bupivacaine 0.25% with adrenaline 0.25%, bupivacaine 0.5% and control group for median pain scores at 24 h as [4 (2–8) vs 3 (2–8)

vs 4 (1–8), vs 4 (1–8), $p = 0.71$] respectively.[6] They used adrenaline with a view that adrenaline might increase the availability of local anesthetic in preperitoneal space by limiting its systemic absorption as it does in open surgery; but did not find it useful. The drawback in their study was that port site infiltration was not done and as they have performed TAPP repair, the diaphragmatic and visceral components of pain due to pneumoperitoneum and diffusion of carbon dioxide into bowel during TAPP surgery may contribute to the visceral component of pain. These may be responsible for significantly higher pain scores than those observed in our study. Further, the drug may escape from the preperitoneal space through gaps in peritoneal suture-line. Suvikapakornkul et al. found the mean pain scores in bupivacaine and placebo group as 3.5 vs 5.2 ($p = 0.059$), 2.9 vs 4.5 ($p = 0.117$), 2.1 vs 3.2 ($p = 0.101$), 1.5 vs 2.7 ($p = 0.145$), and 1.6 vs 2.0 ($p = 0.672$) after the 1st, 2nd, 6th, 12th, and 24th hour, respectively.[8] Although the pain scores in their study were lower in bupivacaine group, the difference was not statistically significant and they concluded that there is no strong evidence to confirm that bupivacaine instillation into preperitoneal space after laparoscopic hernioplasty can reduce postoperative pain. The drawback in the study was that they did not infiltrate the port sites and used tacks for mesh fixation. These factors might be responsible for higher pain scores observed in their study as compared with our study.

A meta-analysis by Tong et al. also concluded that extraperitoneal bupivacaine treatment during laparoscopic TEP inguinal hernioplasty was not more efficacious for the reduction of postoperative pain than the placebo.[9] Results in our study for postoperative pain relief were consistent with the results of some studies[6–9] while others[2–5] differ.

We also compared the postoperative analgesic requirement between the test and the control group. There was no significant difference in analgesic consumption in the 1st 24 hours as well as till the postoperative day 7 between the two groups.

Deans et al.,[6] Suvikapakornkul et al.[7] Abbas et al.[8] also reported comparable use of analgesics postoperatively in local anesthetic and placebo group, whereas Bar-Dayan et al.[5] O'Riordain et al.,[2] and Kumar et al.[3] have reported reduced analgesic use in the treatment group.

No significant difference was noted regarding space creation, fall of inferior epigastric vessels or bleeding from inferior epigastric vessels in the two groups.

There was no incidence of injury to vas deferens and visceral injury. No significant difference was noted regarding time to ambulation and micturition in the two groups.

There was no incidence of hematoma formation and early recurrence. The incidence of postoperative seroma formation was 10% in ropivacaine group and 16.6% in the control group but the difference was not statistically significant. The incidence of seroma formation varies from 14 to 30% in various studies.[4,7] In our study, all seromas resolved spontaneously in 2–4 weeks.

One patient in placebo group developed surgical site infection which was managed on oral antibiotics and serial dressings. The incidence of postoperative complications in our study was comparable to what is reported in the literature.

In our study, we tried our best to strengthen our research protocol. Patients were randomized using computer generated sequence, double-blinding was done, no patient received preoperative and intraoperative analgesic, standard anesthesia protocol was followed, single surgeon for all surgeries and single observer who were blinded about the groups, similar type of mesh was used in all patients, and no mesh fixation was done. Various other studies cited before has also used a sample size ranging from 40 to 60. The sample size in our study comparable to other similar studies.

Researchers have used varying amount of bupivacaine (10–60 mL) for postoperative analgesia.[4–8] We have used a total of 20 mL of 0.75% ropivacaine for postoperative analgesia. The amount of drug required to be effective in preperitoneal space might be high and further studies may be done in this regard.

Conclusion

Postoperative pain following laparoscopic TEP mesh hernioplasty may still be a concern but the pain itself is mild that any reduction in pain score after local anesthetic use in preperitoneal space and port sites is not significant. Also, there was no difference in analgesic consumption in postoperative period in the local anesthetic group as compared with the placebo.

We concluded that port site infiltration and extraperitoneal instillation of ropivacaine in TEP mesh hernioplasty is not beneficial.

Ethical and Humane Considerations

Ethical clearance: It was obtained from institutional ethical committee, UCMS and GTB Hospital.

Trial Registered with CTRI—CTRI Reg No. CTRI/2016/07/007088.

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