

EFFECTIVENESS OF 0.5% BUPIVACAINE INSTILLATION INTO EXTRA PERITONEAL SPACE FOR POST OPERATIVE PAIN CONTROL IN LAPAROSCOPIC TOTALLY EXTRAPERITONEAL (TEP) HERNIOPLASTY

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Abstract

Background: Laparoscopic TEP hernia repair has emerged as a gold standard repair for inguinal hernia in today's era. Daily studies have been carried to make it more effective so has minimal discomfort to the patient. Here we conducted study of instillation of 0.5% bupivacaine versus normal saline in preperitoneal space during laparoscopic totally extraperitoneal (TEP) repair for inguinal hernia with an aim to see its effectiveness on post-operative pain relief. **Materials and Methods:** 80 patients underwent laparoscopic TEP hernioplasty under standard setup at tertiary care center with 40 cases each divided to bupivacaine and normal saline group. Post-operative pain relief was evaluated and results obtained. **Results:** Post-operative pain relief was highly significant for bupivacaine in comparison to normal saline group for a period of 24 hours post-operative with no added complications in laparoscopic TEP hernioplasty. **Conclusions:** Bupivacaine instillation in extra peritoneal space is effective in reducing postoperative pain and thus helpful for early ambulation and discharge and thus can be practiced to reduce use of post operative analgesics, early discharge and enhanced patient comfort and satisfaction.

INTRODUCTION

Inguinal hernia is the most prevalent surgical disease in clinical practice. Laparoscopic inguinal hernia repair has been shown to be superior to open approaches. Recent modifications in laparoscopic technique may improve the totally extraperitoneal repair (TEP) results. Laparoscopic hernioplasty is well recognised to have less postoperative pain, hospital stay, and faster recovery when compared to open inguinal hernia repair. Early postoperative pain has been a major concern in postoperative care. In laparoscopic total extraperitoneal hernioplasty, postoperative pain can be accounted by the port sites, as well as the dissection of preperitoneal space in post-operative period. Infiltrative analgesia is suggested to be more effective in the postoperative pain control of open hernioplasty. The total extraperitoneal approach is the method of choice in the laparoscopic repair of the inguinal hernia. It is technically a difficult procedure and creation of extra peritoneal space with the help of balloon is

helpful in the learning curve.^[1] The totally extraperitoneal procedure (TEP) combines the advantages of tension-free mesh reinforcement of the groin with those of laparoscopic surgery, reduces postoperative pain and shortens recovery time while avoiding the need for a transabdominal approach. The establishment of this technique by Dulucq in Europe may be considered a logical further development of total extra peritoneal hernia repair (TEP).^[2] The purpose of this study was to evaluate the effectiveness of instillation of local anaesthetic agent into preperitoneal space for postoperative pain control. This randomised study aims to investigate the effectiveness of 0.5 % Bupivacaine instillation in the preperitoneal space after mesh placement for postoperative pain relief.

MATERIALS AND METHODS

This was a prospective comparative randomised control study. This study consisted of 80 patients of

inguinal hernia treated with laparoscopic TEP repair in our hospital from June 2019 to November 2020.

Aims and objectives

➤ **Primary aim of study**

- To evaluate the effectiveness of pre peritoneal instillation of 0.5% Bupivacaine in postoperative pain control in laparoscopic total extra peritoneal (TEP) hernioplasty.

➤ **Secondary aims of study**

- To evaluate the effect of study related complications like urinary retention, urinary hesitancy, seroma, rescue analgesia requirement and surgical site infection.

➤ **Inclusion Criteria**

- 1) Age 18 to 75 year with reducible unilateral and/ or bilateral inguinal hernia
- 2) Patient fit for general anaesthesia according to American association of anaesthesia grade 1 and 2

➤ **Exclusion Criteria**

- 1) History of allergy to local anaesthesia
- 2) Unable to come for follow up
- 3) Any deviation from study protocol
- 4) History of lower abdominal surgery
- 5) Diabetes mellitus

Methodology

All patients were seen and evaluated in outpatient clinics and wards prior to surgical intervention. An in-depth history and physical examination was performed paying significant attention to any previous groin surgeries or prostatic intervention. Detailed clinical evaluation was carried out followed by routine investigations and an ultrasound evaluation. All patients fit for surgery, giving consent for surgery and study protocol were included in study. A written informed consent was taken and patients were allocated alternately in both groups for study. History data collected on printed proforma here with.

Patients were taken for laparoscopic TEP hernioplasty with standard operative procedure done by experienced group of surgeons in all 80 patients. Per urethral catheter was done prior to surgery, and prophylactic antibiotic was given at a time of induction. No any analgesic given at time of induction. Post operatively foley's catheter was removed on table before extubation and pain assessment done at 4hour 8hour 16 hour and after 24 hour. We recorded full procedure in operative during all steps for uniformity of study. We used a standard laparoscopic unit and standard set of instruments and setup for laparoscopic TEP.

Statistical analysis was done by independent t test, chi square test.

Operative Technique

All TEP repairs were performed with the patient in the supine position. All patients were operated under general anaesthesia and no any analgesic given perioperatively except anaesthetic agent if required.

After painting and draping a standard laparoscopic TEP repair was carried out. Creation of Preperitoneal space.^[11] was done either by direct dissection or balloon dissection. The anterior rectus fascia was opened through a 1 cm infra umbilical transverse incision placed slightly toward the side of hernia, which helps to prevent inadvertent opening of the peritoneum. A hegar dilator of appropriate size was inserted on the medial aspect of the exposed rectus-abdominis and slide over the posterior rectus sheath. In this plane, a preperitoneal tunnel between the rectus abdominis and the peritoneum was created in the midline by side-to-side movement of the hegar dilator and performing gentle blunt dissection to the level of the symphysis pubis.

10 mm hassons trocar was inserted through which a 0(zero) degree 10mm operating laparoscope was inserted for visualization of the development of the correct plane while insufflation of the preperitoneal space with carbon dioxide gas was done, with the rectus abdominis seen anteriorly and the peritoneum posteriorly. Fixation of 10mm port to sheath was done to prevent leak. After space creation 30-degree operating laparoscope was used. Maximal inflation pressure was kept 10 to 12 mmHg to prevent disruption of the peritoneum or development of extensive subcutaneous emphysema. Blunt gentle dissection with the laparoscope was employed to develop the space sufficiently to allow placement of additional trocars. An alternative approach to dissection of the preperitoneal space was to employ a preperitoneal balloon system.^[15] which was used to develop the preperitoneal space by atraumatically separating the peritoneum from the abdominal wall. The laparoscopic visualization was carried throughout the distension process.

After the peritoneum was dissected away from the rectus abdominis, a midline 5 mm trocar was inserted under direct vision three finger breadths below the infra-umbilical port. A second 5 mm trocar was then inserted another three fingerbreadths below the first 5 mm trocar. Care was taken to prevent peritoneal rent, If the peritoneum was penetrated, it was either repaired with a suture or we placed a Veress needle in the upper abdominal peritoneal cavity. Wide dissection of the preperitoneal space was then undertaken with blunt graspers in a two-handed technique by bluntly dividing the avascular areolar tissue between the peritoneum and the abdominal wall, the pubis, Cooper's ligament, and the inferior epigastric vessels are located first and used to orient the dissection. Hernial sac was carefully dissected and separated. Vas and vessels dissected and identified. After completion of dissection from visualization of psaos laterally to vas turning medially and peritoneal reflection inferiorly and upto pubic symphysis medially mesh of 12 x 15 cm polypropylene, was used to cover the dissected space between the peritoneal sac and abdominal wall.

The space was sprayed by 0.5 % Bupivacaine or normal saline by infant feeding tube passed through lower midline port under vision as per study protocol. In one group, 10 ml 0.5 % bupivacaine after mesh placement (20 ml in case of bilateral) was instilled. In second group, 10 ml 0.9 % normal saline was instilled after mesh placement. Extra peritoneal space was then deflated. Patients were alternately enrolled in both groups. Infra umbilical rectus sheath was closed by port vicryl and skin sutured by nylon 2.0 R.C.

The primary outcome measure was postoperative pain measured at 8, 16, 24 hours after surgery using a visual analogue score. In both group injectable diclofenac 50 mg Intra muscular stat was given as rescue analgesia only when VAS score was more than 4. No other oral or injectable analgesia was used within first 24 hour.

All patients were given Tab.Amoxicillin and clavulanic acid 625 mg TDS orally for 5 days. Local examination on 1st postoperative day was done for hematoma, bleeding and patients were discharged if no complication. Patients were followed up on 5th post-operative day and 10th post-operative day. Sutures were removed on second follow up day. Following points were noted on follow up: Pain by visual analogue, Infection, Early recurrence of hernia, Wound discharge, Hematoma, Seroma formation.

Pain assessment. [3-7,10]

- Pain evaluated by asking direct question to assess severity of pain at particular instance at 4 hour 8 hour 16 hour and 24 hour.

| Score | Pain level |
|-------|--|
| 0 | No pain |
| 1-3 | Mild Pain (nagging, annoying, interfering with activities of daily life) |
| 4-6 | Moderate Pain (interferes significantly with activities of daily life) |
| 7-10 | Severe pain (disabling, unable to perform activities.) |

Patient was encouraged for early ambulation and started orally by gradual feeds after 6 hours.

Recurrence was defined as reappearance of clinical hernia during follow up period of 10 days from surgery.

Infection was defined as redness/ edema /tenderness with or without pus discharge through surgical site and was treated with standard guidelines.

Urinary retention was defined as patient unable to pass urine spontaneously requiring catheter reinsertion.

Seroma or hematoma was defined as clinical or radiological collection of fluid around mesh on follow up

RESULTS

The study consisted of 80 patients, with 40 patients in bupivacaine group and remain 40 patients in normal saline group. All cases underwent detailed preoperative assessment, their preoperative finding intra operative finding and postoperative findings were tabulated and the following observations were made.

Table 1: Age distribution of patients studied;

| Age in year | Bupivacaine group (N= 40) | Normal saline group (N= 40) |
|-------------|---------------------------|-----------------------------|
| 18- 20 | 1 | 1 |
| 21-30 | 6 | 3 |
| 31-40 | 7 | 7 |
| 41-50 | 7 | 6 |
| 51-60 | 10 | 12 |
| 61-70 | 6 | 10 |
| 71-75 | 3 | 1 |
| Total | 40 | 40 |

The mean age of bupivacaine group was 46.13 year and mean age of patients in normal saline group is 48.08 years.

Table 2: Types of inguinal hernia

| Types of hernia | Bupivacaine group | Normal saline group |
|-----------------|-------------------|---------------------|
| Direct | 19 | 27 |
| Indirect | 21 | 13 |
| Total | 40 | 40 |

Table 3: Side of inguinal hernia

| Side of hernia | Bupivacaine group | Normal saline group |
|-----------------------|-------------------|---------------------|
| B/L inguinal hernia | 10 | 9 |
| Right inguinal hernia | 16 | 20 |
| Left inguinal hernia | 14 | 11 |

Postoperative pain

- In this study, postoperative pain was assessed by visual analogue score. score 1 to 10 as described in methodology. For comparison we had taken 8 hour as value for post-operative pain evaluation.

Table 4: Analgesic Requirement at 8 HOUR Post-Operative

| | Rescue analgesia required | Rescue analgesia not required |
|---------------------|---------------------------|-------------------------------|
| Bupivacaine Group | 14 | 26 |
| Normal saline group | 30 | 10 |

Chi square test at 95% confidence interval, p value is 0.0007 which statistically significant.

Table 5 Analgesic Requirement at 16 HOUR Post-Operative

| | Rescue analgesia required | Rescue analgesia not required |
|---------------------|---------------------------|-------------------------------|
| Bupivacaine group | 10 | 30 |
| Normal saline group | 25 | 15 |

In above table, chi square test at 95% confidence interval p value is 0.0016 which is statistically significant.

Table 6 Analgesic Requirement at 24 HOUR Post-Operative

| | Rescue analgesia required | Rescue analgesia not required |
|---------------------|---------------------------|-------------------------------|
| Bupivacaine Group | 4 | 36 |
| Normal saline group | 12 | 28 |

In above table chi square test at 95% confidence interval, p value is 0.005 which is statistically significant.

So, in this study 0.5 % bupivacaine instillation intraoperatively in preperitoneal space during laparoscopic TEP hernioplasty was statistically significantly effective in postoperative pain relief for upto 24 hours.

None of our patients had hematoma, seroma, infection, recurrence and urinary retention in post-operative period and on follow up.

DISCUSSION

This study is undertaken in effort to identify better of two method of extra peritoneal instillation of 0.5 % bupivacaine and normal saline for postoperative pain. This is comparative study consisting of 80 patients, 40 patients in bupivacaine group and 40 patients in normal saline group undergone laparoscopic TEP hernioplasty.

Some degree of postoperative pain is common and expected following surgery. however, persistent pain become a problem. In this study we have excluded chronic pain disorder. meanwhile the incidence following laparoscopic repair is 6 % in sajid *et al.* study noted that the aetiology of chronic pain is unclear but it is thought to includes inguinal irritation by mesh, inflammatory reaction to mesh and foreign material and abdominal wall compliance reduction.

Comparison of postoperative pain assessed by visual analogue score (score 1 to 10).^[3-7,10]

Pain in Bupivacaine group

14 patients (35%) with score at 1 to 3

21 patients (52.5%) with score at 4 to 6

5 patients (12.5%) with score at 7 to 10

Pain in Normal saline group

9 patients (22.5 %) with score at 1to 3

19 patients (47.5%) with score at 4to 6

12 patients (30 %) with score at 7 to 10

The difference between two group is statistically significant.

One study was conducted at department of surgery the queen Elizabeth hospital, east kent hospital university nhs foundation trust united kindomat from 16 November 2015 to 15 September 2017. During this study period, a total 105 patients were randomised. A total 55 patients were analysed in

analysed arm and 50 patients were analysed in control arm. Mean pain score at VAS at 6 h after laparoscopic ventral hernia repair in the intervention arm was 5.05 ± 1.2 , whereas in the control arm, it was 5.54 ± 1.1 and the difference was statistically significant ($P = 0.03$ -independent sample *t*-test). Mean pain score at VAS at 24 h after laparoscopic ventral hernia repair in the intervention arm was 3.16 ± 1.2 , whereas in the control arm, it was 3.58 ± 1.4 and the difference was not statistically significant ($P = 0.11$ -independent sample *t*-test).

The limited space developed in totally extraperitoneal laparoscopic inguinal hernia repair (TEP) provides the ideal setting for direct instillation of local anaesthetic. This study evaluates the efficacy of extraperitoneal bupivacaine analgesia in patients undergoing day care TEP. Fifty-six consecutive patients were randomized to intraoperative extraperitoneal instillation of bupivacaine (n = 29) or normal saline. Control (n = 27). Patients were blindly assessed on discharge from hospital, at 24 hours, 1 week, and 1 month postoperatively. Bupivacaine patients 100% were completely satisfied with the procedure compared with 81% of controls ($P = 0.0002$).

Most of the literature relates to chronic pain after hernia repair and its management. Local anaesthetic infiltration of ports and sutures sites is shown to be effective for laparoscopic procedures and open operations.^[16]

Another trial named Hernioplasty And Postoperative pain after Impregnating MESH with Topical anaesthetic (HAPPIEST) trial.^[18] In Hernioplasty And Postoperative pain after Impregnating MESH with Topical anaesthetic (HAPPIEST) trial, instillation of local anaesthetic at port and suture site was at the discretion of the operating surgeon.^[18] They conducted intention to treat analysis.

Quantitative variables are reported as mean \pm standard deviation. Qualitative variables are reported as numbers and percentages. Distribution of co-variables among two arms is tested using the Chi-square test or independent sample t-test for qualitative and quantitative variables, respectively. Independent sample t-test is applied to test the impact of the use of bupivacaine solution as opposed to normal saline solution on post-operative pain as measured by VAS. The Chi-square test is used to test the impact of intervention on the length of hospital stay.

Bupivacaine is long-acting local anaesthetic drug. Although minimum toxic dose of bupivacaine for intra-peritoneal use is not defined, the analgesic effect of its intra-peritoneal use, especially after laparoscopic cholecystectomy, has been assessed in several interventional studies. Intra-peritoneal use of up to 50 ml of 0.25%.^[8,12,13] or up to 20 ml of 0.5% solution has not shown any drug related adverse reaction.^[19]

Post-operative pain was assessed by trained staff. Pain was graded on visual analogue scale (VAS).^[10] VAS is validated scoring system according to which intensity of pain is scored on a scale of 0–10, 0 being no pain and 10 being worst pain. Scale is as shown in annexes II. Scale was presented to the participants at 6 and 24 h post-procedure.

They were required to mark appropriate score on that scale according to the severity of their pain. After the operation, the first assessment of pain was made 6 h postoperatively. The second assessment was made at 24 h from the end of the operation. This assessment was made face-to-face if the patient was admitted in the hospital or on the telephone if patient got discharged. Postoperatively, two doses of intravenous paracetamol were given at interval of 6 h starting 3 h after the end of the operation. Intravenous tramadol was given on as per required basis on request of patient in dose of 50 mg with gap of at least 8 h. Number of times additional tramadol required was recorded. Considering the design of the study, effect if any on post-operative pain would not have confounded the results due to random allocation and blinding. During the study period, a total of 114 patients were randomised. Nine patients were excluded after randomisation. A total of 55 patients were analysed in the intervention arm and 50 patients were analysed in the control arm.

Mean pain score at VAS at 6 h after laparoscopic ventral hernia repair in the intervention arm was 5.05 ± 1.2 , whereas in the control arm, it was 5.54 ± 1.1 and the difference was statistically significant ($P = 0.03$ -independent sample *t*-test). Mean pain score at VAS at 24 h after laparoscopic ventral hernia repair in the intervention arm was 3.16 ± 1.2 , whereas in the control arm, it was 3.58 ± 1.4 and the difference was not statistically significant ($P = 0.11$ -independent sample *t*-test). Length of hospital stay was not statistically significant among two groups. Overall 9 (16.4%) patients went home the same day in intervention arm, whereas in control arm, 5 (10%)

patients went home the same day ($P = 0.338$ – Chi-square test). No drug-related adverse events occurred in the trial participants.

The conclusion of this study was Soakage of mesh in 0.5% bupivacaine solution before application in laparoscopic ventral hernia repair significantly reduces early post-operative pain.

The cumulative prevalence of inguinal hernia in males aged 25 to 34 years is 5%, rising to 10.5% in 35 to 44 years, and 18.5% in for age of 55 to 64 years and 31% for age 66 to 74 years and finally 45.5% for males of age 75 more. Inguinal hernia occurs eight times as often in men as in women.

In our study the mean age in bupivacaine group 46.16 year and normal saline group 48.08. and all cases were males.

Infections when compared to injecting via continuous infusion catheters or transcutaneous injections at surgical sites were very low with instillation as in our study. In their discussion, the difference could be due to higher numbers of large defects and complete hernia in TAPP group. In our study no any patient had local site infection in TEP hernioplasty in both group of patients.

Majority of patients can perform normal activities at after 24 hours after TEP hernioplasty in this study, data regarding time to return to activity are rather subjective. type of employment or profession, to which patient is returning will influence how long he needs to be. We discharged all patients on next day

In HAPPIEST trial, length of hospital stay was taken in number of days from the day of operation. It was divided into two categories as day case surgery and one or more days stay in the hospital. away from work.^[17,18]

CONCLUSION

- The effect of instillation of 0.5 % Bupivacaine in extraperitoneal space in compare to instillation of normal saline is effective in reducing postoperative pain in TEP hernioplasty.
- There were no secondary complication likes seroma formation, urinary hesitancy or urinary retention.
- We conclude by this study that bupivacaine instillation in extra peritoneal space is effective in reducing postoperative pain and early ambulation and thus can be practiced to reduce use of post operative analgesics, early discharge and enhanced patient comfort and satisfaction.

Limitations

- Our study had a small sample size.
- We performed at a single centre and few surgeons, so multicentre study should be conducted and for better result.
- Aim of study limited duration of follow up, so complications likes recurrence and other complications were not recorded.

- Our hospital is a government institute, so cost could not be evaluated.

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