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Research Article

A prospective comparative study of Lichtenstein's mesh hernioplasty performed under local and spinal anesthesia

Pradeep Saxena*, Saurabh Saxena

Department of Surgery, Gandhi Medical College, Bhopal, MP, India

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***Correspondence:**
Dr. Pradeep Saxena,
E-mail: pradeep@bhopalsurgery.com

ABSTRACT

Background: The present study was designed to compare Lichtenstein's hernioplasty performed under local anesthesia and spinal anesthesia in terms of intra operative and short term post-operative events.
Methods: In this study total 244 adult patients (236 male & 8 female) of primary uncomplicated unilateral inguinal hernia operated for open tension free mesh hernioplasty were included. 114 patients were operated under local anesthesia and 130 under spinal anesthesia. The two groups were compared for intra operative & short term (30 days) post-operative events, hospital stay and return to activity.
Results: The two groups were similar in terms of intra operative events like nausea, vomiting, hypotension & arrhythmias. Local wound complications like edema, ecchymosis, infection and seroma formation were comparable in both groups and clinically insignificant. However there was advantage for the local anesthesia group in terms of less post-operative pain, less anesthesia related complications, less urinary retention, faster discharge from hospital, faster return to activity and lesser cost of treatment.
Conclusions: The study comparing local anesthesia with spinal anesthesia showed advantage for the local anesthesia group in terms of less post-operative pain, less anesthesia related complications, less urinary retention, faster discharge from hospital, faster return to activity and lesser cost of treatment. Thus open inguinal hernioplasty performed under local anesthesia is well suited for our smaller community-based, regional, and teaching hospitals.

Keywords: Tension-free hernioplasty, Open tension-free mesh technique, Mesh hernioplasty, Hernia mesh surgery, Open hernia repair, Inguinal hernia surgery, Lichtenstein hernioplasty, Hernioplasty under local anesthesia, Day care inguinal hernia repair, Ambulatory hernia surgery

INTRODUCTION

Inguinal hernias occur in about 15% of adult population, and mesh hernioplasty is the most common surgical procedure performed by general surgeons. Approximately 800,000 are performed each year in the United States; 100,000 in France; and 80,000 in the United Kingdom. It is estimated that an average man has life time risk of 24% for development of hernia (Abramson, 1978). The risk increase with age and risk for development of hernia is more than 50% in a patient who are older than 75 years. Since hernia is associated with complications like groin pain, incarceration, bowel obstruction and strangulation elective repair of inguinal hernia is recommended treatment.

There is morphologic and biochemical evidence that adult male inguinal hernias are associated with altered collagen type I-to-type III ratio. These changes lead to weakening of the fibro connective tissue of the groin and development of inguinal hernias. Thus the need for prosthetic reinforcement of weakened abdominal wall tissue was recognized. Open inguinal mesh hernioplasty can be performed under local, regional or general anesthesia.

The open tension-free mesh hernioplasty, performed under local anesthesia, is a simple technique to be learned (learning curve = 5 cases), and trained surgical residents are able to perform it without compromising the patient's care and long-term outcome.[1,2] The procedure is time tested, safe, economical, as well as quick and easy to perform.[3] In addition, it carries fewer complications and has become the gold standard in open tension-free hernioplasties.[4,5] In a comparative study of open mesh techniques for inguinal hernia repair, Lichtenstein's operation was similar to mesh plug or Prolene Hernia System (PHS) repair in terms of time to return to work, complications, chronic pain, and hernia recurrence in the short term to midterm.[6]

Lichtenstein's hernioplasty performed under local anesthesia has short post anesthesia recovery period, lesser complications and shorter hospital stay. In western world most of the hernioplasty are done as day care procedure. The procedure is well suited for smaller community-based, regional, and teaching hospitals, and it offers good immediate and long-term results. Moreover, the excellent results achieved with the open tension free mesh hernioplasty appear to be unrelated to the surgeons' experience. The technique has been evaluated in large series and has become popular among surgeons all around the world. Open tension free Lichtenstein hernioplasty is suitable for all adult patients of inguinal hernia irrespective of age, weight, general health, and the presence of concomitant medical problems. For large scrotal (irreducible) inguinal hernias, after major lower abdominal surgery, and when no general anesthesia is possible, the Lichtenstein repair is preferred over laparoscopic hernioplasty. Despite these advantages local anesthesia is not much popular outside the specialty centers.

Since introduction of tension free mesh hernioplasty recurrence (less than 1%) was not a problem in hernia surgery. Focus then shifted to other factors like patient acceptance, short term postoperative events and complications, early ambulation, duration of hospital stay, early return to work and cost of the treatment. Apart from the surgical technique thus type of anesthesia has an impact on these modern parameters. The present study was designed to compare Lichtenstein's hernioplasty performed under local anesthesia and spinal anesthesia in terms of intra operative and short term post-operative events.

METHODS

This prospective observational study on comparison of inguinal hernioplasty performed under local and spinal anesthesia was carried out in department of surgery Gandhi Medical College, Bhopal from June, 2009 to Dec, 2012. In this study total 244 adult patients (236 males and 8 females) of primary uncomplicated unilateral inguinal hernia operated for open tension free mesh hernioplasty under local or spinal anesthesia were included.

The operations were performed by the consultants, senior residents or third year residents of surgery department. The study was approved by the ethical committee of our hospital and informed consents were taken from the patients. The patients were distributed in 2 groups.

Group A (Local Anesthesia group)

In this group 114 patients were operated under local anesthesia. Our choice for unilateral repair was 0.5-1% lidocaine with 1/200000 adrenaline average of 35 to 50 ml was sufficient for unilateral hernia.

Group B (Spinal Anesthesia Group)

130 patients of this group were preoperatively examined by physician and after getting fitness for surgery, as per institutional protocol, spinal block was given at L1 – L2 level by lidocaine.

Local anesthesia was preferred for ASA III /lV patients, whereas spinal anesthesia was chosen for anxious patients and obese.

Inclusion criteria

- Primary repair of uncomplicated unilateral inguinal and femoral hernia in adult patients.
- Recurrent hernias - Recurrence after primary posterior technique (such as laparoscopic TEP, TAPP, or open posterior technique).

Exclusion criteria

It includes complications such as incarceration, obstruction or strangulation and a history of allergy to local anesthesia or prosthesis. Bilateral hernias and recurrent hernia after primary anterior technique were also excluded and dealt with using laparoscopic TEP, TAPP, or the open posterior technique.

Antibiotic prophylaxis

We used IV cefuroxime 1 gm, 1 hour before surgery in all our patients. Oral cefuroxime 500 mg BD was also prescribed to the patients for 5-7 days postoperatively.

Equipment

Anesthetic equipment included a cardiac monitor and a pulse oximeter for high-risk patients with co morbidities.

Technique of Local Anesthesia

We used for local anesthesia 0.5-1% lidocaine with epinephrine, 0.25-0.5% bupivacaine, or a combination of these 2 agents in a 50:50 mixture. About 30-45 ml of a 50:50 mixture of 1% lidocaine and 0.5% bupivacaine, with 1/200,000 epinephrine, is usually sufficient for a unilateral hernia repair.

Lidocaine provides rapid onset and bupivacaine results in a longer duration of local anesthesia. Epinephrine further prolongs the duration of anesthesia but should be avoided in hypertensive patients and patients with ischemic heart disease. Local infiltration is performed in sequential steps as the operation progresses.[17]

As the incision begins at the pubic tubercle and extends 5–6 cm laterally up to the midinguinal point, about 10 ml is infiltrated into the subcutaneous adipose tissue underneath the site of incision, beginning from the lateral end of incision site. The needle is withdrawn until its tip reaches the intradermic level. About 3-5 ml is then infiltrated intradermally along the line of the incision. Another 10 ml is injected deep into the subcutaneous adipose tissue along the line of incision.

After incising the skin and subcutaneous tissue, another 10 ml is injected underneath the aponeurosis of the external oblique muscle. This creates plains for dissection underneath the external oblique and anesthetizes all 3 nerves of this region, i.e., the ilioinguinal and iliohypogastric nerves and the genital branch of the genitofemoral nerve.

A few ml of local anesthetic solution is then infiltrated around the pubic tubercle and the neck of the hernia sac. At the end of surgery, about 10 ml of solution is splashed in the inguinal canal and the subcutaneous tissue for good postoperative analgesia.

Sedative drugs and anxiolytic agents may be given by the surgeon as a supplement to local anesthesia in some patients to reduce apprehension. In very large, incarcerated inguinal hernias, apprehensive patients or patients not willing to undergo the surgery under local anesthesia, the procedure was performed under spinal anesthesia.

Surgical Technique

Lichtenstein's open mesh hernioplasty was performed in all patients. Light-weight, macro porous proline mesh was available from hospital supply and was used in all patients.

Postoperative Care

Group A patients operated under local anesthesia were asked to rest for few hours and discharged on the same day or the day after surgery. Group B patients operated under spinal anesthesia were hospitalized for few days.

There is some pain in the postoperative period, and suitable analgesics were prescribed. The dressing was removed on the fifth postoperative day, and stitches were removed on seventh postoperative day. Patients were advised to resume light work after a week and heavier jobs after 6 weeks.

Intra Operative Observation

Intra operative nausea and vomiting, hypotension & arrhythmias, conversions to general anesthesia and operative time were recorded parameters.

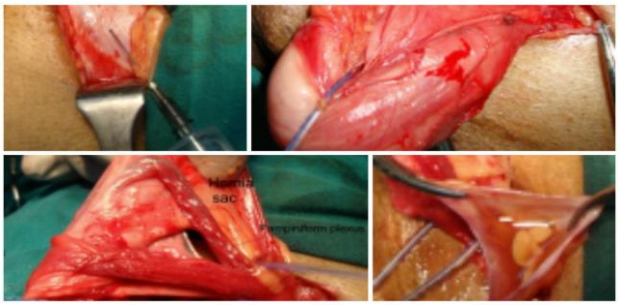

Figure 1: Hernia sac dissected and divided in mid inguinal region.

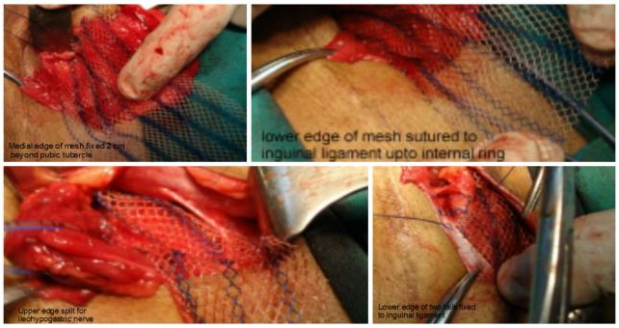

Figure 2: Fixation of mesh.

Post-operative Observation

Patient data were recorded at following points:

- During in hospital stay
- At a time of suture removal (usually on 7th day)
- Follow up at 30th post-operative day.

Following parameters were recorded in post-operative period

- Post-operative nausea vomiting
- Post-operative pain and need for analgesia
- Early post-operative complications (like urinary retention, seroma/hematoma, headache and wound infection
- Duration of mobilization
- Duration of hospital stay
- Time to return to activity.

Need for analgesia was assessed by standard numerical rating scale. The relevant data was collected by surgery residents and recorded in a database using Microsoft Office Excel. The statistical evaluation was performed with a Student's t test for paired values and Chi-squared

test with Yates correction between the groups. P <0.05 was regarded as significant for both tests.

RESULTS

Patient's age, sex and type of hernia were as per Table 1. Two patients of recurrent hernia following primary posterior technique were included. One had recurrence following laparoscopic TEP and other had recurrence following stoppa's procedure.

Table 1: Distribution of cases.

Demography and type of hernia	No. of patients	Age	Sex M/F	Type of hernia					
				Direct	Indirect	Pantaloon	Femoral	Sliding	Recurrent
Local anesthesia group	114	56.24 (15-81 years)	112/2	37	71	-	-	4	2
Spinal anesthesia group	130	44.12 (16-74 years)	124/6	34	84	2	2	8	-

Eight female patients, six with inguinal hernia and two with femoral hernia were included.

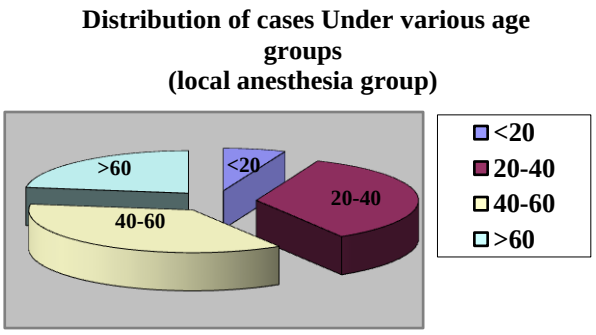

Figure 3: Distribution of local anesthesia group on basis of age.

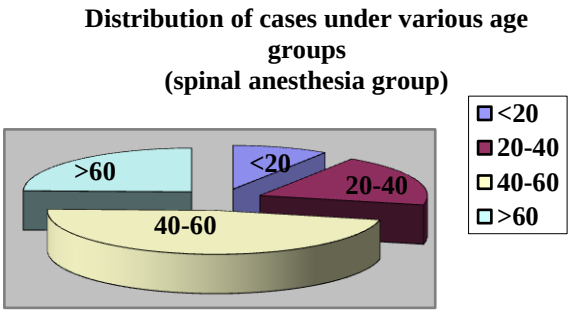

Figure 4: Distribution of spinal anesthesia group on basis of age.

Co-morbid condition

Many patients with co morbidity and considered high risk for spinal anesthesia were operated under local anesthesia. Concomitant medical problems observed were as per table-2. In patients with hypertension with ischemic heart disease 0.5% plain lignocaine (without adrenaline) was used for local anesthesia. The patients were given nitroglycerine drip and kept under blood pressure and ECG monitoring.

Table 2: Co-morbidities.

Co morbidity	Group A (Local Anesthesia)	Group B (Spinal Anesthesia)
Hypertension	6	5
Ischemic heart disease	4	-
Benign prostatic hypertrophy	4	3
Chronic Obstructive Pulmonary disease	8	-
Diabetes	4	2
Chronic renal failure	1	-
Chronic liver disease with ascites	1	-
Hypothyroidism	1	-
Total	**29**	**10**

Intra operative observations

Intra operative nausea, vomiting, hypotension & arrhythmias were similar in both groups. None of the patient in either group required conversion to general anesthesia. Operative time (incision to final stitch) was slightly more in local anesthesia group (mean 54 minutes) as compared to spinal anesthesia group (42 minutes), presumably because the surgeon had to infiltrate local anesthetic and wait for the effect to occur. However time required for giving spinal anesthesia was not included in operating time. only six patients out of 114 operated under local anesthesia required intra operative analgesic supplementation due to pain. All operations in local anesthesia group were done in fully awake patients and no sedative or anxiolytic drugs were used.

Table 2: Intra operative observations.

Intra operative observations	Local anesthesia group (n = 114)	Spinal anesthesia group (n = 130)
Nausea/Vomiting	8 (7.01%)	6 (4.6%)
Hypotension/ Arrhythmias	0	3
Conversion to G.A	0	0
Operative time (mean)	54 minutes (Min- 28 min, Max- 96 min)	42 minutes (Min- 26 min, Max- 55min)

Post-operative complications

Incidence of procedure related complications were almost similar in the two study groups. Local wound complications like edema, ecchymosis, infection and seroma formation were comparable in both groups and clinically insignificant. Post-operative fever was more in spinal anesthesia group (11) probably due to use of more IV fluids.

None of the patient under local anesthesia group had hematoma, but 3 patients in spinal anesthesia group developed hematoma. One of the patient required opening the wound for this complication. None of the patient had recurrence of hernia in follow up period of one month.

Complication like urinary retention, post spinal headache, post-operative nausea and vomiting occurred exclusively in spinal anesthesia group. 11 patients in spinal anesthesia group had post spinal headaches. Urinary retention was seen in 9 patients of spinal anesthesia group. This difference was found statistically significant ($P<0.05$).

The incidence of urinary retention did not have any relation with age of the patient. Spinal anesthesia frequently causes urinary retention, which required catheterization and resulted in delayed postoperative recovery and prolonged hospitalization. Post-operative nausea and vomiting was seen in 6 patients of spinal anesthesia group.

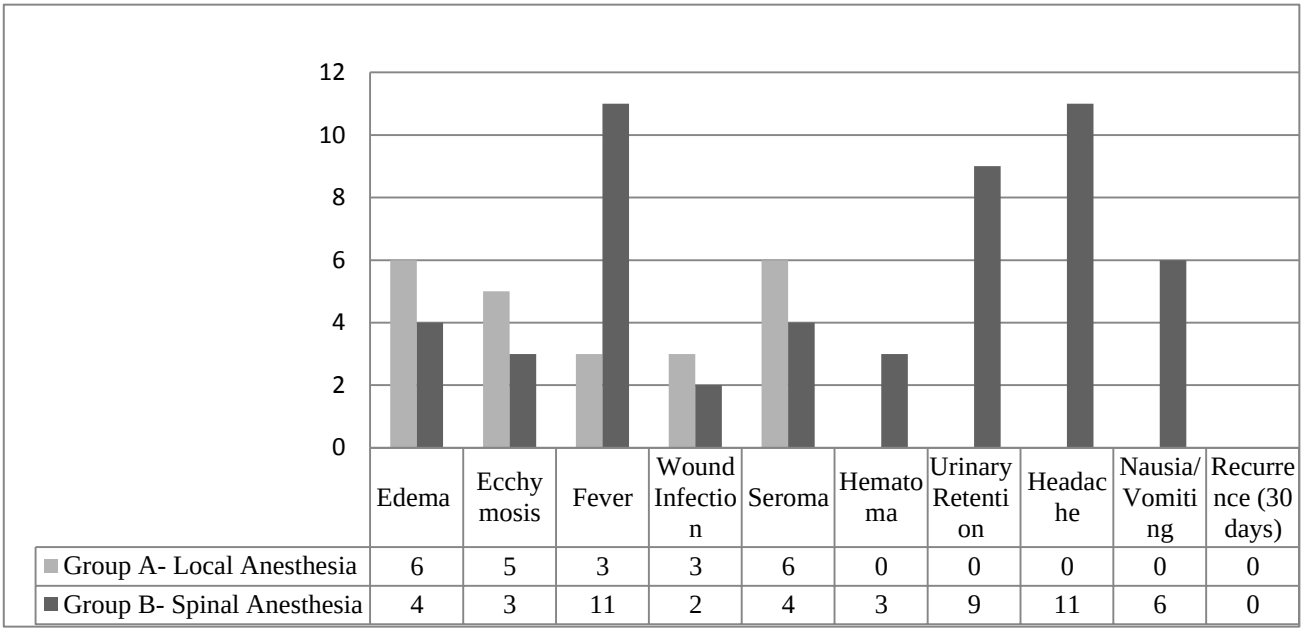

Figure 5: Bar digram showing post-operative complications in group A & B.

Postoperative pain: Median pain score on first post-operative day was less in patient of local anesthesia group. Pain and analgesic requirement was significantly lower in local anesthesia group ($p < 0.02$).

Duration of Mobilization

All of the patients in the local anesthesia group except three were mobilized immediately after surgery.

Most of the patients in this group could get up and walk out from the operation theatre. However one patient having hypothyroidism, one with history of CAD and one patient with chronic liver disease was not mobilized immediately. But they too started mobilization within 12 hours of surgery. None of the patient under spinal anesthesia group started mobilization within 6 hours. Some of the patients started mobilization even after 12 hours of surgery as given in Table 4.

Table 4: Duration for mobilization.

Study Group	0-3 hours	3-6 hours	6-12 hours	12-24 hours
Local anesthesia group	90	21	3	
Spinal anesthesia group	0	0	110	40

Duration of Hospital Stay

In local anesthesia group duration of hospital stay range from 8 hours to 90 hours. Mean duration of hospital stay was 18.42 hours. In spinal anesthesia group none of the case was taken as day care surgery. The duration of hospital stay range from 27 to 98 hours and mean duration of hospital stay in this group was 56 hours as shown in Figure 6 this difference in mean hospital stay was found significant (p <0.01).

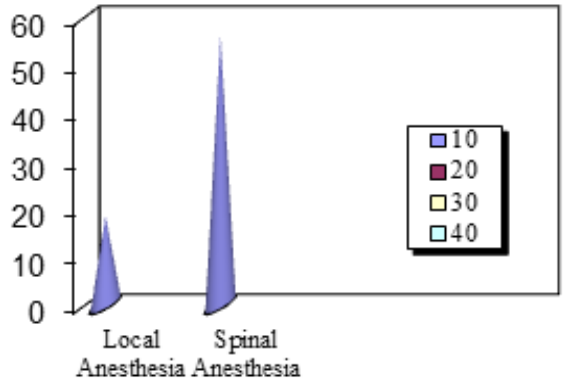

Figure 6: Mean duration of hospital stay in hours.

Return to activity

Most of the patient of local anesthesia group returned to their activities within 6 to 18 days (mean 9 days) after surgery. Some patients took longer time due to pain or infection. Patients of spinal anesthesia group took longer time for return to their normal activity.These patients returned to activities after 8 to 20 days (mean 11.85 days) as shown in Figure 7.

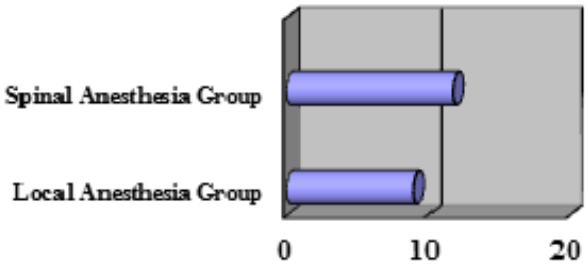

Figure 7: Return of activity in days.

DISCUSSION

Antibiotic prophylaxis

In clinical settings with low rates (<5%) of wound infection, there is no indication for the routine use of antibiotic prophylaxis in low-risk patients. In the presence of risk factors for wound infection (recurrent hernia, advanced age, immunosuppressive conditions, expected prolonged operating times) the use of antibiotic prophylaxis should be considered. Such prophylaxis should also be used at centers where high rates of wound infection are observed in elective settings.[13,14] We used IV Cefuroxime 1 gm given one hour before surgery for all of our patients for antibiotic prophylaxis.

Postoperative Complications

Early post-operative complications like seroma, hematoma, edema etc. were not affected by type of anesthesia used (P >0.05). The incidences of local complications in our study were similar to various reported series. The overall risk of complications after inguinal hernia surgery reportedly varies from 15-28% in systematic reviews. Early complications include seroma formation and hematoma (8-22% of cases), urinary retention, and wound infection (1-7% of cases). Most seroma disappear spontaneously within a period of 6–8 weeks. Should a seroma persist, it can be aspirated. Late complications include sensory loss, hyperesthesia, chronic inguinal pain, mesh-related problems, hydrocele, testicular pain, testicular swelling, atrophy, and recurrence of hernia.

Vascular injury and hematoma formation

Vascular injury is a less common, but potentially disastrous, complication. This can be avoided by respecting the proximity of the femoral vessels, particularly when suturing the mesh to the inguinal ligament. Hematoma formation can result from injury of the inferior epigastric vessels or pampiniform plexus veins or from failure to ligate the superficial subcutaneous veins. A small hematoma can be treated conservatively. For larger hematomas, which are asymptomatic, evacuation under anesthesia should be considered. Meticulous dissection with adequate hemostasis will reduce the incidence of seroma and hematoma formation. The use of adrenaline in local anesthesia group provides better hemostasis and lesser incidence of hematoma formation. The surgeon should always be aware of the vas deferens and should protect it from injury. The incidence of vas deferens injury is about 0.3%. Bladder injuries are very rare in open hernia

surgery but more frequent with laparoscopic hernioplasty (01% - 4.2%).

Urinary retention

In a meta-analysis of 72 studies, the incidence of urinary retention after hernioplasty was 0.37% (33 in 8991 patients) with local anesthesia, 2.42% with regional anesthesia (150 in 6,191 patients), and 3% with general anesthesia (344 in 11,471 patients).[3] Such retention is said to be due to the inhibitory effect of regional and general anesthesia on bladder function. The volume of IV fluids administered post operatively is also a significant risk factor for urinary retention. In our study urinary retention was seen in 9 patients of spinal anesthesia group as compared to none in local anesthesia group. This difference was found statistically significant ($P< 0.02$). This complication was seen even in younger patient of 15 year and 18 year of age, who did not had preexisting bladder outlet obstruction. We can say that urinary retention is an anesthesia related complication and association of spinal anesthesia with urinary retention in our study was statistically significant. Since our study was designed to compare open mesh hernioplasty under local and spinal anesthesia in terms of intra operative and short term postoperative events (30 days), long term complications like recurrence, chronic pain after mesh hernioplasty and ischemic orchitis etc were not assessed.

Anesthesia for inguinal hernia repair

Inguinal hernia repair should preferably be performed using a simple and safe anesthetic technique that is acceptable for the patient as well as the surgeon. Type of anesthesia chosen has been often correlated to postoperative side effects and prolonged hospital stay after inguinal hernia surgery. The anesthesia chosen should carry a low morbidity risk and also be cost-effective. The choice of anesthesia in inguinal hernia surgery depends upon personal preference of surgeon. General anesthesia is used for laparoscopic repair. Open repair can be done in general, regional or local anesthesia. The best available evidence suggested that majority of open hernia surgery are performed under general anesthesia in western countries while local anesthesia is popular in specialty clinics. (Hair) In a study conducted by Royal College of surgeon Edinburg percentage of open hernia surgery performed under local anesthesia varied from 18% in Sweden 6% in France, 16% of Denmark to 100% in specialization hernia clinics.

Local Anesthesia

It has as an advantage of ease of induction, awakening and short post anesthesia recovery period. It can be given to the patients having co-morbidities in which general or regional anesthesia cannot be used. Local anesthesia can be administered as direct infiltration into the tissue or local nerve block using ilioinguinal and iliohypogastic nerve. The local nerve block technique avoids tissue edema caused by infiltration of solution, but it is difficult to achieve. As per various studies both techniques have similar outcome. The major drawback of local anesthesia is to convince the anxious patients. Also it cannot be used in complicated hernias. Various single and multi-centric trials show that local anesthesia is superior to spinal or general anesthesia in early post-operative period. It is associated with less post-operative pain, nausea, shorter in hospital stay and few unplanned overnight admission. A recent study shows that local anesthesia can be applied safely and effectively in adolescent patient (Olsha et al). Although local anesthesia is very safe and effective method it is not free from complications. Some possible disadvantages of local anesthesia are:

- In effective block leads to intra operative pain and sometimes conversion to general anesthesia.
- Cardiac arrhythmias secondary to inadvertent intravenous injection
- Transient femoral nerve block leading to immobilization
- Local anesthetic cannot be applied to anxious patient and children. It is proven affective among adolescents (Olsha O).

Intravenous injection can be avoided by applying aspirate before inject rule. In present study we used lignocaine & adrenaline with or without bupivacaine. We never came across such complications. It indicates that these are very rare miss happenings.

Few patients had complaints of intra operative pain for which IV inj. Tramadol was given. These patients had large indirect sac and cause of pain may be peritoneal irritation due to dissection. Infiltration of local anesthetic around the neck of sac not only helps in minimizing the pain but also creates plains for dissection. Local anesthesia sprayed in the wound prior to closure produces prolonged analgesic effect via inhibition of building of nociceptive molecules. In our study median pain score on first post-operative day was less in patient of local anesthesia group. This fact is also reported by Nordin P, Subramaniyam P and other authors.

Local anesthesia does not having any amnesia or muscle weakness and allows early mobilization of patients. Due to analgesic effect of local anesthetic patient did not have any problem during mobilization. Other authors like Gonullu, Mehave, Paprik also reported less post-operative pain and early recovery after local anesthesia.

Regional Anesthesia (Spinal and Epidural)

Allows the surgeon greater freedom in operating field but carry their own risk such as urinary retention, prolonged anesthetic effect, hypotension and spinal headache. It is also associated with longer in hospital recovery time. Although general or regional anesthesia is very safe now a days but it also requires specialized anesthesia equipment and staff and increases over all cost of

treatment (Gonullu). Spinal anesthesia cannot be safely given to many patients with ASA grade III or more.

General Anesthesia and laparoscopic hernia repair

Laparoscopic hernia surgery is feasible in expert hands, but the learning curve for laparoscopic hernia repair is long (200-250 cases), the severity of complications is greater, detailed analyses of cost effectiveness are lacking, and long-term recurrence rates are not known.[9] Laparoscopic Hernioplasty claims to have less post-operative pain, early ambulation and early return to activity by various authors (Chung RS and Rowland DY, Grant A.M.). Despite these advantages Laparoscopic repair has its own disadvantages, such as need for general anesthesia, visceral and vascular injuries, post-operative adhesion formation etc. Facilities and expertise of this repair is not available everywhere. Counting these facts European hernia society guidelines & National Institute for Clinical Excellence (NICE) London recommended open anterior mesh hernioplasty for unilateral uncomplicated inguinal hernia. So the role of laparoscopic inguinal hernia repair in treatment of an uncomplicated, unilateral hernia is still unresolved. However transabdominal preperitoneal (TAPP) or totally extraperitoneal (TEP) laparoscopic inguinal hernioplasty may offer specific benefits in some situations, such as recurrent hernia after conventional anterior open hernioplasty, bilateral hernias, and patients undergoing laparoscopy for other clean operative procedures.

Postoperative hospital stay, return to activity & cost of treatment

The post-operative hospital stay was significantly lower in local anesthesia group. Average hospital stay in local anesthesia group was 18 hours compared to 56 hours in spinal anesthesia group ($P < 0.01$). Less post anesthesia recovery period, early mobilization and less pain following surgery are the likely factors behind less hospital stay period. None of the patients in spinal anesthesia group could be managed as day care surgery in our study. Patients in whom hernioplasty was done under local anesthesia resumed their work earlier than the spinal anesthesia group thus minimizing the loss of working days. Less post operative pain and early discharge from hospital are the contributing factors for early return to activity.

We have a larger patient burden on our tertiary care hospitals where a number of patients are put on waiting list for various elective operations. Open hernia surgery under local anesthesia does not need specialized anesthesia staff, is associated with less analgesic and IV fluid use. The waiting time as well as overall cost of treatment on patient and health care system can be reduced by performing more and more inguinal hernioplasties under local anesthesia.

Inguinal hernioplasty performed under local anesthesia has been proven cost effective by various other authors like Nordin P, Subramaniam P and Gonullu in their studies. In a review thirteen of the fourteen randomized studies comparing local anesthesia with spinal anesthesia showed advantage for the local anesthesia group in terms of less post-operative pain, less anesthesia related complications, less urinary retention, faster discharge from hospital, faster return to activity and lesser cost of treatment.

CONCLUSION

Lichtenstein's hernioplasty under local anesthesia can be performed very safely with good patient satisfaction, early postoperative recovery and mobilization, less postoperative pain, shorter hospital stay and early return to activity. Thus the cost of hernioplasty under local anesthesia is lower than that of spinal anesthesia. In present study local anesthesia does not show any anesthesia related complications. Surgical procedure related complications are similar in both local and spinal anesthesia groups. Thus open inguinal hernioplasty performed under local anesthesia is well suited for our smaller community-based, regional, and teaching hospitals.

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Ethical approval: The study was approved by the institutional ethics committee

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