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Local Versus Spinal Anesthesia in Lichtenstein Mesh Technique for Inguinal Hernia Repair in Ambulatory Patients: A Randomized Controlled Trial

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Objective: This study aimed to determine whether Lichtenstein mesh Technique under local anesthesia results in better patient outcomes when compared with repair under spinal anesthesia.

Methods: Patients > 18 years old, with primary, unilateral inguinal hernia handled between January 2008 to July 2010, and who fulfilled the specific inclusion criteria were enrolled. They were randomly assigned to either local anesthesia (LA), or, the spinal anesthesia (SA) groups. Outcome variables monitored included: total operative time, postoperative pain from days 1-7, complications, number of analgesic doses, and, time interval from surgery to resumption of routine occupational and sexual activities.

Results: There were 101 patients (98 males and 3 female) LA group included 54 patients (52.5%) while the SA group, 48 patients (47.5%). Patients in LA group are younger in age but this is of no statistical significance (P=0.07). Significant differences between the two groups included: presence of urinary retention and more postoperative analgesia required within the first 24 hours among SA patients. Overall, LA group had less postoperative pain, fewer complications, and faster recovery with early resumption of occupational and sexual activities.

Conclusion: This study offers significant evidence to prove that local anesthesia is a safe, cost-effective and practical alternative to spinal anesthesia for fast-track ambulatory inguinal hernia repair.

Key words: inguinal hernia, lichtenstein mesh repair, local anesthesia, spinal anesthesia

Inguinal hernia repair is one of the most common surgical operations performed by general surgeons all over the country today.[1] Statistics show a steady growth in the number of such cases yearly. Older techniques remain in use, but newer and improved ones, each with distinctive benefits and drawbacks have evolved. Lichtenstein mesh technique is the most widely-used, and, in fact, now serves as the gold standard, upon which all other techniques are compared.

Traditionally, inguinal hernia repair surgery was performed mostly under spinal anesthesia, and on occasion, under general anesthesia. In recent years however, the use of local infiltrative anesthesia, specifically among adult patients, has proven to be an effective alternative, with a wide margin of safety, minor postoperative side effects, few complications and over-all short recovery period.

Several studies indicate that local infiltration anesthesia for inguinal hernioplasty blocks surgical stress effectively, provides extended postoperative analgesia is simple to execute and safe for high-risk patients.[2] In addition, patients are able to mobilize early without post-anesthesia side effects.[3] Local anesthetics are a popular adjunct in inguinal hernia repair that provides adequate peri-operative analgesia without side effects and improved patient's quality of life.[4,2]

Lichtenstein mesh repair for inguinal hernia under local anesthesia has been shown to be an effective day-case technique, particularly in the elderly and medically unfit patients. This procedure has been associated with low morbidity and low recurrence rate.[5,3] It reduces postoperative pain and facilitates patients' mobilization and discharge along with decreasing postoperative complications.[6,4]

Rationale

Presently, there is no current consensus about the surgical anesthetic procedure of choice for ambulatory repair of inguinal hernia, the choice of anesthetic technique for inguinal hernia repair remains arbitrary. There has been an increasing interest in the use of local anesthesia for inguinal hernia repair rendering inguinal hernia repair a day-case surgery.[6, 3] Numerous randomized controlled studies, albeit with small samples sizes, have compared spinal with local anesthesia. Benefits for local anesthesia were shown and inguinal hernia repair under local anesthesia have been recommended as the method of choice.[7] Despite the reported advantages of the local anesthetic technique, most of the hernia repairs except in specialized center, continue to use general or spinal anesthetic technique.[4]

With the continued increase in ambulatory surgery, postoperative pain management and early return to normal daily life activities have assumed[5] an increasingly important role in providing a smooth transition from hospital admission to outpatient unit procedure. Catering primarily to the poorer sectors of the city population, our hospital, a tertiary government institution, would stand to benefit from safe fast-track, low expense, ambulatory surgery programs to meet the growing needs of its clientele. The data offered by this study may be adapted towards the fulfillment of this objective, aims to analyze the outcomes of local versus spinal anesthesia using Lichtenstein mesh repair in all adult ambulatory inguinal hernia patients admitted in our institution which will serve as the bases for the recommendation of using this technique to define the current preference in day-case surgeries.

General Objective

To determine whether Lichtenstein mesh technique under local anesthesia results in better patient outcomes when compared with repair under spinal anesthesia.

Specific Objectives

1. To describe the clinico-demographic characteristics of patients who underwent elective inguinal repair to include:
   a. Age
   b. Gender
   c. Occupational stress
   d. Smoking status
   e. Alcohol drinking status
   f. Type of hernia
   g. Laterality of hernia
2. To determine the postoperative complications of patients who underwent elective Lichtenstein tension free inguinal hernia repair
3. To determine the proportion of patients with varying intensity of pain at 6 hours, 12 hours, 24 hours, 3 days and 7 days, postoperatively
4. To determine the frequency of use of oral opioid pain reliever (Tramadol) within the first 24 hours postoperatively
5. To determine the mean duration (days) from day of surgery to first day of resumption of work
6. To determine the mean duration (days) from day of surgery to first day of resumption of sexual activity
7. To determine the proportion of patients who converted from local to regional anesthesia.
8. To compare the operative time of the two procedures.
9. To compare the outcomes between the two patient groups to include:
   a. Post-operative complications
   b. Proportion of patients with varying intensity of pain at 6 hours, 12 hours, 24 hours, 3 days and 7 days post op
   c. Frequency of use of pain relievers within the first 24 hours post op
   d. Time to resumption of work
   e. Time to resumption of sexual activity

Methods

Study Design: Randomized controlled non-blinded study.

Study Setting: Government tertiary hospital with 60 surgical bed capacity and accredited training program in general surgery

Study Population

Inclusion Criteria: Patients ≥ 18 years of age admitted from January 2008 – July 2010 for management of primary unilateral inguinal hernia.

Exclusion Criteria: Patients with the following conditions were excluded:

1. Femoral hernia
2. Bilateral inguinal hernia
3. Recurrent inguinal hernia
4. Contraindicated to the use of local and regional anesthetics such as:
   a. History to hypersensitivity to anesthetic agents
   b. Patient requiring general anesthesia
   c. Chronic use of analgesics
5. Patients > 40 years of age not medically cleared for elective surgery
6. Patient presenting for an emergency inguinal hernia repair such as incarcerated hernias and strangulated hernias
7. Patients unable to give informed consent

Sampling Procedure: This was a non-probability convenience sampling procedure whereby all eligible patients admitted from January 2008 – July 2010 and who fulfilled the inclusion/exclusion criteria were consecutively entered into the study.

Sample Size Calculations: Based on previous studies reporting a 16% difference in the proportion of patients with urinary retention and a 13% difference in the proportion of patients with surgical complications,[6] this study would have required at least 172 subjects per type of anesthesia group to have a power of at least 80% in rejecting the null hypothesis that the urinary retention rates and surgical complication rates for the local anesthesia and spinal anesthesia subjects are equal with a Type I error probability of 0.05. In another study comparing local anesthesia against spinal anesthesia for inguinal hernia repair, 24.1% and 83.3% of patients in the local anesthesia group and the spinal anesthesia group, respectively, required rescue pain medications within 24 hours post-operatively.[7,8] Inputting these values for sample size calculations, this study would have required only at least 29 subjects per group to have 80% power in rejecting the null hypothesis of no difference in the proportion of patients requiring rescue pain medications within 24 hours with a Type I error probability of 0.05. The number of patients admitted in our institution from January 2008 – July 2010 and who qualified for participation into the study determined the final sample size.

Maneuvers

All potential participants were thoroughly apprised as to the nature, mechanics, possible complications, and degree of required commitment for this study. Forms written in English and in Cebuano were discussed with patients by the primary resident-researcher, prior to acquiring their respective signatures in the informed consent forms.

All other forms to be accomplished by both the researcher and the patients were, likewise, discussed in detail.

Patients admitted within the same week were assigned to one of the two treatment groups. Another set of patients admitted in the succeeding week was assigned to the alternate treatment group. Alternate allocation into the treatment groups by week was done until the specified end of the study period.

Upon enrolment, patients were duly informed about their particular group assignments.

Surgical management was done on a day-care, ambulatory set-up.[9] However, for the specific purpose of this study, patients were admitted to the hospital for 24 hours, just to facilitate postoperative monitoring. We decided on this, considering that a number of our patients cannot afford additional fare expenses for the follow-up consultations, lack of telephone resources, or

cannot just be counted on to come back for follow-up due to varied personal reasons.

The surgical procedure was performed by the primary-resident-researcher, any of the General Surgery consultant staff, or any of the experienced surgical residents under direct supervision of a General Surgery consultant and/or the resident researcher. Proper orientation and instruction regarding this study were discussed for all other surgeons thereby creating a research hernia protocol.

Management protocol was patterned after the Evidence-Based Clinical Practice Guidelines of Primary Unilateral Inguinal Hernia as recommended by the Philippine Society of General Surgeons, using the Lichtenstein Tension-Free Hernioplasty[1] under either local, or spinal anesthesia.

Four code nurses working on varied duty shifts at the Emergency Room were trained to monitor and record the postoperative pain. Pain scoring was based on the Wong-Baker Faces Pain Rating Scale.[10] As soon as patient is wheeled from the Operating Room, the staff nurse on-duty informed the monitor-nurse at the ER. Subsequently, the pain monitoring form was given by the researcher to the monitor code-nurse. All completed monitoring forms were submitted to the resident-researcher after the 24-hour period. No disclosure of the patient's surgical operation to the monitoring code nurses. Both code and ward nurses were encouraged to cooperate on the accurate and on-time monitoring based on the study protocols.

Preoperative regimen was uniform to all participants. Pre-emptive analgesia was instituted at 12 hours and 2 hours preoperatively with oral doses of a COX2 inhibitor (Celecoxib 200mg).[11,12] Patients were placed on "NPO except meds" orders post-midnight prior to surgery. D_5LRS was then started at 30 gtts/min. A single IV dose of H_2-blocker (Ranitidine 50mg) was also given 2 hours prior.

Patients were attached to the cardiac monitor and pulse oximeter all throughout the procedure. Oxygen was given at 3-4L/min through a nasal prong.[8] For the LA group, monitoring was done by an assigned OR nurse. The Anesthesia Consultant was responsible for monitoring those who underwent the procedure under spinal anesthesia. In all cases, an Anesthesia Consultant remained on standby for any cases needing conversion to general anesthesia.

Postoperatively, patients were given Tramadol 50mg 1 capsule every 6 hours prn for frank pain and Celecoxib 200mg 1 capsule bid.[10,11,12] Intravenous fluid was then terminated once consumed.

Close monitoring was done primarily by the staff nurses and surgical clerk on-duty. In the event of any possible complications, the resident-researcher or any senior resident on-duty was called in to evaluate and manage accordingly. Postoperative pain was measured at 6-hour, 12-hour and 24-hour and subsequent analgesia was recorded by the Emergency Room code nurse-monitors, as previously arranged.[3,4]

The resident-researcher made the final evaluation prior to discharge after 24 hours, and repeated all instructions for follow-up. Deferment of discharge was ordered for those with active postoperative site bleeding, hematoma formation, local wound factors like inordinate edema or moisture over the wound, and systemic problems, e.g., HPN, requiring immediate medical attention.

Aside from the usual discharge instructions; patients were also taught how to fill out the pain-diary form, which included the record of postoperative pain at specific time frames, any postoperative complications, and the timing of resumption of routine occupational and sexual activities. Patients were required to bring their completed pain-diary forms every follow-up at 3rd, 7th, and 14th day postoperatively.

All research registry forms were accomplished, reviewed, and completed by the resident-researcher.

Technique of Anesthesia:[13,14,15]

a. Patients were sedated via intravenous administration of a mixture of Midazolam 5mg in 10cc of NSS in increments of 1cc/min until full sedation is achieved.

b. Local infiltrative anesthesia using a mixture of equal amounts (20cc) of 2% Lidocaine and 0.5% Isobaric Bupivacaine + Epinephrine (1:200,000) was then given using the procedure described below.

c. Immediately prior to skin incision, intravenous Nalbuphine hydrochloride 5 mg is administered

Infiltrative Local Anesthesia Technique:[13,4]

a. Subdermal Infiltration: Initially, 5cc of the anesthetic mixture is infiltrated along the drawn incision line, forming a superficial wheal.

b. Intradermal Injection: Without completely withdrawing the needle, it is inserted deeper into the intradermal area and slowly infiltrating 5cc of the same mixture.

c. Deep Subcutaneous Injection: With due care to avoid intravascular infusion, infiltration of about 10cc into the deep subcutaneous fat layer is done thru vertical insertion of the needle along the same incision line.

d. Subaponeurotic/Subfascial Infiltration: Underneath the external oblique aponeurosis, using the window created in the subcutaneous fat layer at the lateral aspects of the incision, 5cc is infiltrated.

e. Pubic tubercle and hernia sac injection: An additional 5cc is infiltrated at the level of the pubic tubercle, around the neck, and inside the hernia sac.

f. Splashing: Prior to closure of the external oblique aponeurosis, the remaining 10cc of the anesthetic mixture is splashed over the inguinal canal.

Spinal Anesthesia Technique:[4]

a. Sedation with 5 mg. of Midazolam + 10cc NSS was not given to patients under the SA group.

b. Nalbuphine hydrochloride 5mg given IV, immediately prior to skin incision.

c. Subarachnoid infiltration with 4cc of heavy .5% bupivacaine was administered thru the L3-L4 intervertebral midline approach.

Lichtenstein Mesh Technique:[13,14,15]

a. A surgical incision extending 5cm-6cm was made on the skin, about 1cm above and parallel to the inguinal ligament, extending from the pubic tubercle to about 1cm beyond the lateral ring.

b. Deepening the incision into the subcutaneous adipose layer, the superficial epigastric and superficial external pudendal veins are identified and ligated. Smaller bleeders are controlled by electrocautery.

c. The external oblique aponeurosis is exposed, identified and split to open the inguinal canal, thereby, exposing the spermatic cord and the cremasteric tissues. Using a Penrose drain, these structures are isolated and elevated *in toto*.

d. Then, the cremasteric fascia is split open, revealing the hernia sac.

e. In the indirect inguinal type, the hernia sac is dissected free down to the neck, marked by the collar of extraperitoneal fat. Then, using 2-0 silk, the neck is ligated, and the distal portion of the sac is excised.

f. In the direst inguinal type, the hernia sac is tucked in or imbricated using silk 2-0 continuous, running sutures.

g. A uniform Propylene mesh measuring 6cmx10cm was used in all patients under this study. This mesh was tailored to a standard shape resembling a footprint tracing, with a lower, sharper angle to fit into the space between the inguinal ligament and the rectus sheath, and a wider, upper angle to fit over the spread of the rectus sheath. With the spermatic cord retracted upward, the upper border was sutured with monofilament nylon to the rectus sheath insertion in the pubic bone. Imbrications of 1-2cm on the pubic bone were done.

h. Using the same continuous running suture with monofilament nylon, the lower border was sutured

to the inguinal ligament, lateral to the internal ring. The long arm of the drooped –down triangle was sewn to the Cooper's ligament; the body of the mesh, to the inguinal ligament. Thus, the spermatic cord was positioned in between the tails of the mesh that were both fixed to the inguinal ligament.

i. Excess patch on the lateral side was then trimmed, leaving about 3cm -5cm of mesh beyond the internal ring.

j. This was then, tucked under the external oblique aponeurosis, and then closed over the cord using the same 2-0 monofilament nylon suture.

k. Hemostasis using electrocautery was done with due care to preserve the ilio-inguinal, ilio-hypogastric and genital nerves.

l. The spermatic cord is carefully checked for position.

m. Then, the incision is closed in layers, using silk 2-O for external oblique aponeurosis and chromic catgut 4-O for the dermis.

n. Staples were used for skin closure.

o. Wound was then covered with sterile gauze and plastered.

p. Skin staples were removed after the 7th postoperative day.

Measurement of Outcomes

The early postoperative pain scores using visual analog scale (VAS) of Wong-Baker Faces Pain Rating, early and late postoperative complications, operation durations and doses of oral opioid analgesic consumed within 24-hours for frank pain, postoperative days where resumption of normal daily activity and sexual activity were evaluated. Evaluation of pain was done at 6 hours, 12 hours, 24 hours, 3 days and 7 days, postoperatively. Patients were clinically evaluated at 3, 7 and 14 days postoperatively. The Wong-Baker Faces Pain Rating measured the severity of perceived pain along a scale of from 0 – 10. For this study, 0 defined no pain, 1-2 defined mild pain, 4-6 defined moderate pain and 8-10 defined severe pain.[10]

Data Analysis

Data were entered with Microsoft Excel Spreadsheet and analyzed with SPSS version 16.0. Due to non-normal distribution, age of patient is summarized as median with corresponding Interquartile Range (IQR). Operative time, duration from day of surgery to first day of resumption of work and first day of resumption of sexual activity are summarized as means $\pm$ SD. All qualitative variables are summarized as proportions. Significant differences in the age of the patients and operative time between patients who underwent local anesthesia and patients who underwent regional anesthesia were determined with Mann-Whitney U test. Significant differences in the mean operative time, duration from day of surgery to first day of resumption of work and first day of resumption of sexual activity were determined with unpaired Student's T test. Significant differences in qualitative variables between the two patient groups were determined using chi-square test. All tests were two-tailed. A P value ≤ 0.05 was considered statistically significant.

Results

One hundred six (106) patients were eligible candidates for inclusion in the study but 5 patients were excluded due to refusal to participate. A total of 101 patients underwent elective Lichtenstein tension free hernia repair due to unilateral inguinal hernia from January 2008 - June 2010. The median age was 36 years (IQR: 25 – 52). The youngest patient was 18 years of age; the oldest was 81 years of age. There were 98 males (97.0%) and 3 females (3.0%). More of the patients (42.6%) were current smokers. Non-smokers and patients who had quit smoking comprised 27.7% and 29.7% of the total study population, respectively. Majority of the patients (60.4%) were non-alcoholic drinkers. Current alcohol

drinkers comprised 19.8% of the study population and the remaining 19.8% were previous alcoholic drinkers. Half of the patients (50.5%) reported strenuous regular work activities. Majority of the patients (77.2%) had indirect type of inguinal hernia. Right-sided inguinal hernia was predominant, involving 73.3% of patients.

Fifty three (53) patients (52.5%) allocated to the local anesthesia group which included 2 of the 3 female patients included in the entire study population. Inguinal hernia repair under spinal anesthesia was performed in 48 patients (47.5%) including the remaining female patient in the study. Table 1 compares the patient demographic and clinical characteristics between patients assigned to receive local anesthesia and patients assigned to receive spinal anesthesia. There were no significant differences in the baseline characteristics of patients between the two treatment groups. Though the patients assigned to local anesthesia were relatively younger than the patients assigned to spinal anesthesia, the difference did not attain statistical significance (P=0.07).

The mean duration of operative time for all patients was 1.43 ± 0.55 hrs. Only 22 patients (21.8%) developed postoperative complications. Table 2 lists the frequency of occurrence of various postoperative complications. The most common complication was urinary retention of up to 6 hours (36.4%) followed by seroma formation (27.3%). There were 3 patients (13.6%) with > 1 type of complication hence percent column total is > 100%.

Table 3 shows the distribution of patients as to intensity of pain at 6 hours, 12 hours, 24 hours, 3 days and 7 days post-operative monitoring. None of the patients reported severe pain at 24 hours, 3 days and 7 days post op. Most of the patients (82.7%) were pain-free at 7 days postoperative.

Table 2. Frequency of occurrence of postoperative complications (n=22)

Postoperative Complications	Frequency	Percent
Urinary Retention	8	36.4
Seroma Formation	6	27.3
Surgical Site Infection	5	22.7
Hematoma	3	13.6
Hydrocoele Formation	2	9.1
Orthostatic Hypotension	1	4.5

Table 1. Comparison of baseline clinico-demographic characteristics between the local anesthesia group of patients and the spinal anesthesia group of patients.

Characteristic	Local Anesthesia (n=53)	Spinal Anesthesia (n=48)	P Value
Age (yrs.)	32 (IQR = 24-49)	43.5 (IQR = 29.5-57.75)	0.07
Current Smokers (%)	41.5	43.8	0.56
Current Alcoholic Drinkers (%)	22.6	16.7	0.68
Strenuous Work Activity (%)	53.8	47.9	0.38
Type of Hernia (%)			0.39
Indirect	79.2	75.0	
Direct	20.8	25.0	
Laterality of Hernia (%)			0.28
Right-sided	69.8	77.1	
Left-sided	30.2	22.9	

'Patients in LA group are younger in age but this is of no statistical significance (P=0.07)

Table 3. Distribution of patients by pain intensity at various time points monitored after surgery.

Pain Intensity	6 Hours	12 Hours	24 Hours	3 Days	7 Days
No pain[I]	6.9	14.9	31.7	57.1	82.7
Mild Pain	30.7	41.6	47.5	37.8	16.3
Moderate Pain	57.4	42.6	20.8	5.1	1.0
Severe Pain [II]	5.0	1.0	-	-	

[I] Most of the patients were pain-free at 7 days post-op.

[II] None of the patients reported severe pain at 24 hours, 3 days and 7 days postoperatively.

Figure 1 shows the frequency distribution of the patients by total number of as needed oral opioId doses received for pain relief within the first 24 hours postoperatively. Only a small proportion of patients (19.8%) did not receive any pain reliever within the first 24 hours immediately following the surgery. More of the patients (42.6%) received > 2 doses of oral opioid analgesics within the first 24 hours.

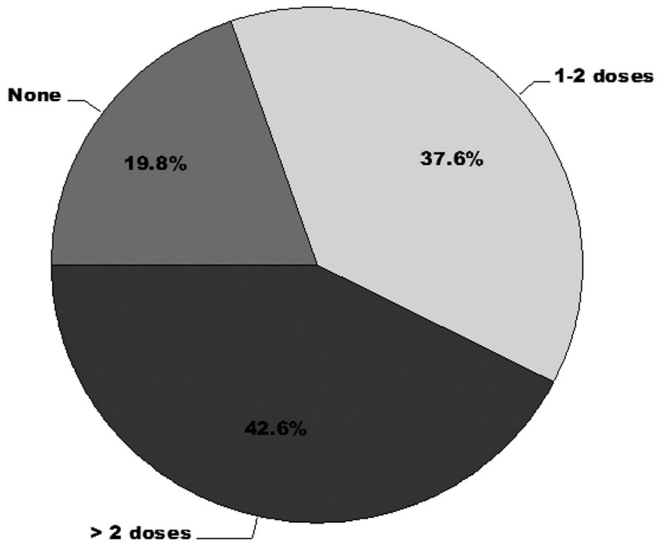

Figure 1. Distribution of patients by total number of doses of pain relievers (Tramadol) taken within the first 24 hours postoperative.

Overall, the mean duration of time from day of surgery to first day of resumption of work was 5.3 ± 2 days. There were only 67 patients (66.3%) who provided an answer to the question regarding number of days post op when resumption of sexual activity was carried out. The mean duration of time from day of surgery to first day of resumption of sexual activity was 8 ± 3.3 days.

Table 4 shows the comparison of proportion of patients with varying pain intensity at different monitoring time points. There were significant differences in the proportion of patients with varying intensity of pain between the two treatment groups during all monitoring times ($P < 0.001$). More patients in the local anesthesia group had earlier relief of pain compared with the patients in the spinal anesthesia group. There were already 7 patients (13.2%) in the local anesthesia group who reported no pain 6 hours after surgery while none of the patients in the spinal anesthesia group were pain-free at that same time period. Furthermore, none of the patients in the local anesthesia group reported severe pain at 6 hours after surgery, whereas 10.4% of the spinal anesthesia group reported severe pain at that same time. Almost all patients (98.0%) in the local anesthesia group did not experience pain at 7 days post-op, while only 32 patients (66.0%) reported no pain during that same time period.

Table 5 shows a comparison of the intra- and postoperative events between the group of patients who had inguinal hernia repair under local anesthesia and the group of patients who had inguinal hernia repair under spinal anesthesia. There was no significant difference in operative time between the two groups of patients. Postoperative complications were more commonly noted among patients who underwent spinal anesthesia. Significant differences between the two groups were noted for incidence of urinary retention ($P = 0.02$), need for > 2 as needed administered oral opioid pain relievers within the first 24 hours ($P< 0.001$). Hydrocoele formation in 2 patients was confirmed by ultrasonography. Both patients were re-admitted and scheduled for hydrocoelectomy after failure of the conservative management. Only 1 patient from the local anesthesia group required conversion to inhalational anesthesia. There were also significant differences between the two groups in terms of number of days from

Table 4. Comparison of proportion of patients with varying pain intensity at different monitoring time points postoperative between the local anesthesia group of patients and the spinal anesthesia group of patients.

Characteristic	Local Anesthesia (n=53)	Spinal Anesthesia (n=48)	P Value
6 Hours Postoperative Pain (%)[&]			< 0.001
None	13.2	-	
Mild	41.5	18.8	
Moderate	45.3	70.8	
Severe	-	10.4	
12 Hours Postoperative Pain (%)[&]			< 0.001
None	28.3	-	
Mild	58.5	22.9	
Moderate	13.2	75.0	
Severe	-	2.1	
24 Hours Postoperative Pain (%)[&]			< 0.001
None	54.7	6.3	
Mild	55.3	50.0	
Moderate	-	43.8	
Severe	-	-	
3 Days Postoperative Pain (%)[&]			< 0.001
None	90.2	21.3	
Mild	9.8	68.1	
Moderate	-	10.6	
Severe	-	-	
7 Days Postoperative Pain (%)[&]			< 0.001
None	98.0	66.0	
Mild	2.0	31.9	
Moderate	-	2.1	
Severe	-	-	

[&] Significant differences in the proportion of patients with varying intensity of pain between the two treatment groups during all monitoring times

day of surgery to first day of resumption of regular work (P< 0.001) and number of days from day of surgery to first day of resumption of sexual activity (P< 0.001).

Discussion

In the light of the global economic climate, surgical trends have gravitated towards fast-track, cost- effective, day-care, ambulatory procedures, especially in the government institutions, where the poorer sectors of society seek medical care. Lichtenstein mesh technique of inguinal hernia repair has gained wide acceptance among surgeons in recent years due to its low-complication and low-recurrence rates, which translate into safety, cost-effectiveness and over-all practicality. In fact, it is now the gold standard in hernia repair, with which newer techniques are compared to.

With the emerging trend of a day-case surgery for inguinal hernia repair performed by general surgeons, efficiency of a repair method is determined according to the low postoperative recurrence rate, the cost-efficient character and the low level of the postoperative pain.[5] Lichtenstein tension free inguinal hernia repair has been the most widely performed groin hernia repair

Table 5. Comparison of intra-operative and post-operative events between the local anesthesia group of patients and the spinal anesthesia group of patients.

Characteristic	Local Anesthesia (n=53)	Spinal Anesthesia (n=48)	P Value
Operative Time (Hours)	1.4 ± 0.57	1.5 ± 0.54	0.72
Postoperative Complications (%)	15.1	29.2	0.07
More than 1 Complication (%)++	0.0	21.4	0.24
Urinary Retention (%)**	1.9	14.6	0.02
Seroma Formation (%)	1.9	2.1	0.73
Surgical Site Infection (%)	3.9	6.4	0.47
Hematoma (%)	2.0	4.3	0.47
Hydrocoele Formation (%)	2.0	2.1	0.73
More than 2 Tramadol Doses 24-hour Postoperatively **	9.4	79.2	< 0.001
Number of Days from Day of Surgery to Work Resumption**	4.08 + 1.11	6.53 + 2.0	< 0.001
Number of Days from Day of Surgery to Resumption of Sexual Activity**	6.18 + 2.4	10.2 + 2.9	< 0.001

**Significant differences between the two treatment groups

++3 patients (13.6%) with > 1 type of complication hence percent column total is > 100%.

with a recurrence rate below 1%.[15] Due to inhibition of tension-related pain this has been used as the golden standard for hernia repair to which newer techniques are compared.[3] It has considerable implications if used as a day-case surgery because it offers early ambulation, early return to normal daily activity and occupational work as well as the sexual activity of the patient.[15]

PK Amid, et al. reported that tension-free mesh repair in conjunction with local anesthesia and mild sedation had a great impact on hospital stay, postoperative discomfort, recovery period, recurrence rate and cost-effectiveness of the surgery.[14] A randomized controlled trial carried out by RN van Veen, et al. showed that local anesthesia was superior than spinal anesthesia and provided benefits to the patients in terms of highly satisfactory intraoperative analgesia, faster recovery, less postoperative pain, faster mobilization, early return to unrestricted activity and higher rate of patient satisfaction. It was therefore concluded that Lichtenstein tension free inguinal hernia repair under local anesthesia translates to early improvement in the patients' quality of life.[4,8]

In the Philippines, inguinal hernia repair is one of the most common surgical procedures perform by general surgeons and the number is expected to rise in the future.[1] The Philippine College of Surgeons Evidence Based Practice Guideline that Lichtenstein tension free inguinal hernia repair is the repair of choice to patient with primary inguinal hernia. Presently, there is no optimum consensus concerning the type of anesthesia to use.

In this present study conducted in a tertiary government training center hospital, with the increasing number of ambulatory inguinal hernia patients, Lichtenstein Mesh Repair under local anesthesia and mild sedation had a comparable result to the internationally published literatures.

Of the 101 patients, 53 patients (52.5%) allocated to LA group and 48 patients (47.5%) of the SA group. Of the 51 patients of the LA group, there were 2 female patients (3.8%) and of the 47 patients of the SA group, only 1 patient (2.1%) was female. Based on Modified Traditional System for Groin Hernia, 70 (69.3%) of all patients were Type I (indirect inguinal hernia) and 26

patients (25.7%) were Type II (direct inguinal hernia).[16] These clinico-demographic characteristics of the patients are comparable with the 3 internationally randomized controlled trials between local and spinal anesthesia.

Postoperative pain, the most troublesome complication in open inguinal hernia repair, was considered the primary outcome of this study. Early postoperative pain is reduced when operation is performed under local infiltration anesthesia with the use of long-acting local anesthetic (Bupivacaine) that lasts 4-6 hours.[17] There were several studies comparing postoperative pain between general, spinal and local anesthesia for inguinal hernia repair. There was a significant difference between LA and GA or SA group.[18] Operative times were significantly longer with LA than in GA or SA. Ninety percent of patients expressed satisfaction with LA.[17] Another randomized controlled study comparing the 3 types of anesthesia used in inguinal hernia repair demonstrated no significant difference between LA, SA, and GA groups.[8] There were 2 other randomized studies on local vs. spinal anesthesia. Initial analysis failed to show any difference in the VAS scores between the two treatment groups.[3] Repeat analysis showed significantly more pain reported after surgery under spinal anesthesia vs. local anesthesia.[4] In our study, only 5 patients (9.8%) in LA group had a VAS score of $\leq$ 2 which corresponded to a mild pain 3 days after surgery. On the 7th day post-op, almost all patients (98%) in the LA group had VAS scores of 0 which corresponded to no pain. This indicates better outcomes with local anesthesia in terms of earlier relief of postoperative pain.

A retrospective study of 93 cases under local anesthesia using Lichtenstein tension free inguinal hernia, the average operative time was 45 minutes.[19] There was no significant difference in the operative time between the LA and the SA groups, this is in accordance with published literature. In our study showed that there was no significant difference in the operative time between local and spinal anesthesia. In a recently published literature in Finland, a ten-year audit of Lichtenstein hernioplasty under local anesthesia showed no significant difference in operation time in inguinal hernia repair procedures performed by surgical residents in training vs. those of the surgical specialists.[20]

Many prospective comparative trials of different anesthetic techniques have documented a consistent pattern of less postoperative pain after LA compared to GA and SA.[21] The mean duration of analgesia (from the end of surgery to first request for analgesic) was shown to vary among the three groups in one randomized trial. It was significantly longer for the LA group than GA group or SA group. Akcaboy, et al. on his published literature that the number of patients needing tramadol and mean tramadol usage were less in peripheral nerve block compare to spinal anesthesia group of patients.[6] In our study, patients who underwent inguinal repair under LA had significantly earlier onset of postoperative analgesia which was supported by the decreased need for rescue oral opioid analgesics within the first 24 hours postoperatively. This may be explained partly by the fact that wound infiltration of local anesthetics (Bupivacaine isobaric plus Lidocaine) after hernia repair has been shown to provide higher quality and long duration of anesthesia because they have different action time and duration of anesthetic effect thus promoted less postoperative pain.[17] This result was also consistent with the finding of Young in which patients operated under local anesthesia had lesser need for postoperative analgesia compared with those had their surgery performed under general and spinal anesthesia.[18] A combination of oral opioid analgesic (Tramadol 50mg) and COX 2 inhibitor (Celecoxib 200mg) resulted in satisfactory analgesia and without adverse effects in our study.[10,17]

In a systematic review described by the European Hernia Society Guideline in the Treatment of Inguinal Hernia in Adult Patients, the overall risk of complications after inguinal hernia operations varied from 15% -28%.[9] Due to more rigorous follow-up of patients in other hernioplasty trials, the incidence of complications rates have even been reported to be higher, ranging from 17%-50%.[9] In hernia surgery, meticulous handling of tissue may play a significant role in the occurrence of postoperative complications irrespective of the method of repair used.[9] Our study with a sample size of only 48 patients in the spinal anesthesia group and 53 patients in the local anesthesia group only had a power of 38.2% in rejecting the null hypothesis of no difference in the incidence of surgical complications between the two groups.

The risk of hematoma formation in open hernioplasty ranges between 5.6% and 16%. A systematic review of 13 trials reported hematoma incidence of 5.5% after open mesh versus 6.5% after open non-mesh repair.[9] In our study, we had 3 patients (3.1%) (1 patient from LA group and 2 patients belong to SA group) who developed postoperative hematoma formation. Due to very few numbers of patients with hematoma in the total population, significant association between type of anesthesia and incidence of hematoma could not be ascertained in our study. Our study with a sample size of only 48 patients in the spinal anesthesia group and 53 patients in the local anesthesia group only had 10.3% power to reject the null hypothesis of no difference in the incidence of surgical complications between the two groups.

The incidence of seroma formation has been reported to be between 0.5% - 12.2%.[9] In the same systematic review of 13 trials cited previously, seroma formation was reported to have an incidence of 2.4% after open mesh repair.[9] In our study, seroma formation was uncommon and there was no significant difference in the incidence of seroma formation between patients with local anesthesia and patients with spinal anesthesia. Resolution of seroma formation was noted after 2-weeks of conservative management for all affected patients regardless of type of anesthesia. Our study with a sample size of only 48 patients in the spinal anesthesia group and 53 patients in the local anesthesia group only had 5.1% power to reject the null hypothesis of no difference in the incidence of seroma formation between the two groups.

Wound infection after inguinal hernia operations with or without mesh is between 0 - 14.4%.[9] In a randomized controlled trial the incidence of open mesh repair is 2.4%.[9] Superficial incisional surgical site infections developed in 5 patients. Though relatively more of these patients were under spinal anesthesia, no statistical significance could be shown for the trend. These could be again due to smallness of sample and non-common occurrence of the complication in the entire study population. No patient in either treatment group developed deep incisional surgical site infection. The trend towards more surgical site infection involving patients with spinal anesthesia may be explained by less meticulous handling of tissue. Patients were managed with wound dressing and oral antibiotics.

Postoperative side effects and prolonged hospital stay after groin hernia surgery often related to the effects of anesthesia.[9] Orthostatic hypotension was defined as a drop in systolic blood pressure of at least 20 mm Hg or a drop in diastolic blood pressure of at least 10 mm Hg within three minutes of assumption of upright position associated with lightheadedness, dizziness, headache and cold clammy skin.[22] This complication was noted in only 1 patient who belonged to the SA group. This could be due to intravascular volume depletion as an anesthetic side effect.

Among the early postoperative complications which were significantly different between the two treatment groups was urinary retention. Only 1 patient developed this complication in the local anesthesia group in contrast to the 7 patients in the spinal anesthesia group. Thermal therapy was provided to all patients but the SA group patients required catheterization due to failure of conservative management.

The resumption of work relies on different factors and is not dependent only on the anesthetic technique.[24] The main cause of prolonged recovery is pain. In addition, existing co-morbidities and individual personal traits may affect the time of recovery, totally unrelated to the procedure or type of anesthesia. An early resumption of daily activities and work has been advocated in all published recommendations but has not generally been adopted.

In the study of SE E-Awaly and AAM Elkholy, inguinal hernia impaired testicular perfusion caused sexual dysfunction. They concluded in the study that there was a considerable improvement of the generic quality of life after hernioplasty.[25]

Among the patients who deemed the question on sexual activity to be applicable, early resumption of sexual activity was notably more common among patients with local anesthesia than among patients with spinal anesthesia. This is expected considering that more patients in the local anesthesia group experienced earlier pain relief hence allowing them to perform sexually without fear of incurring pain.

Some patients may prove unsuitable for local anesthesia, notably very young patient, anxious patient,

morbid obesity and patients suspected of incarceration or strangulation.[6] In our study, only 1 patient from LA group required conversion to general (inhalational) anesthesia. This could have been prevented by better physical examination and preoperative recognition of reducible giant inguinoscrotal hernia. Pre-operative recognition of this condition could have contraindicated open mesh repair using local anesthesia due to difficulty in delineating the sac thereby resulting in pain and discomfort due to the constant manipulation of the hernia sac.[26]

In centers with special interest using local infiltration anesthesia in inguinal hernia repair, the recurrence rate is low. Contrary to some reports based on multivariant analysis that potentially increased risk of recurrence when the operation is performed with local infiltration anesthesia.[17] Analysis reflects these recurrences due local anesthetic technique per se and other factors such as quality of surgical repair or level of expertise.

One limitation detected in this study is the short observation time. Recurrence rate is another determinant to the preference for a particular type of anesthesia. It would have been ideal to monitor for recurrence and compare this between the two treatment groups for a long observation period.

Conclusion

This study provide evidence that local anesthesia has favorable outcome results in Lichtenstein mesh repair in our institution to ambulatory patient with primary inguinal hernia. It has a lower risk of anesthetic related complications and provides more benefits for the patients in terms of less postoperative pain, faster recovery as evidenced by early resumption to normal work activity and sexual activity. Local anesthesia can therefore be used as alternative to spinal and general anesthesia for ambulatory inguinal hernia repair especially in institutions that promote more day-care surgeries for better cost-containment.

The authors concluded that Lichtenstein mesh repair using local anesthesia as the procedure used in all ambulatory patients with primary inguinal hernia had combine advantages such as: simplicity, reliability, effectiveness, safety, comfortable post-operative course with easily controlled pain, rapid return to unrestricted activities, good patients' satisfaction and the most important, that it can be performed by all surgical residents.

Recommendation

Due to short-term follow up, continuation of the study is needed to determine the recurrence rate and long-term patient's satisfaction of the technique. A follow-up study with the appropriate sample would be relevant in determining the true difference in the incidence of surgical complications, hematoma and seroma formation between patients undergoing local anesthesia and patients undergoing spinal anesthesia. Based on outcomes which include time to pain relief, need for rescue pain medications, incidence of urinary retention, time to work resumption and resumption of sexual activity, this study supports the many published studies that recommend local anesthesia over spinal anesthesia for uncomplicated inguinal hernia repair.

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