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Original Research Article

Self-gripping lightweight polyester mesh in open inguinal hernia repair in the Philippines: a long term followup study

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ABSTRACT

Background: Feasibility of using the self-gripping mesh in open repair of inguinal hernia in the Philippines in terms of recurrence rate, postoperative pain, operating factors and postoperative surgical complications.
Methods: Prospective observational study using of a self–gripping polyester mesh (TEM1208GR Parietex ProGrip™). Operative time and mesh deployment time were recorded. Assessment at 6, 12 and 24 hours after surgery for postoperative complications and pain score. Recurrence assessed one-week post op then phone interview one and two years after surgery.
Results: There were 95 participants with 99 hernias from September 2011 to March 2014. Eighty-nine participants (93.7%) were male with average age of 43 years SD ±18 (15-81). Of the 91 patients with unilateral hernia, 50 (54.9%) were right-sided. Mean deployment time was 145.33 seconds SD±38.55 (30-240). Mean operating time was 77.59 minutes SD 73.64±(22-480). Mean pain score of the patients at 6, 12 and 24 hours postoperatively are 3 SD±2.69 (0-10), 2.91 SD±2.35 (0-9) and 2.25 SD±2.06 (0-10). Intraoperative bleeding occurred two cases (2%), seroma in one patient (1%). Five cases of inguinal numbness one year after surgery; and four of them resolved spontaneously within the second year after surgery. No recurrence in 2 years-followup.
Conclusions: The use of a self-gripping mesh is feasible and safe in the Philippine setting with no recurrence after a 2 year-followup.

Keywords: Inguinal hernia, Open hernia repair, Polypropylene mesh, Self-fixating mesh

INTRODUCTION

The repair of inguinal hernia is a very common surgical procedure worldwide.[1] The advent of mesh based repairs has flourished due to a significant decrease in recurrence rates and chronic postoperative inguinal pain as compared to that of tissue based repairs.[2] The most common of these repairs that was popularized in 1984 was the Lichtenstein hernia repair, which used a heavyweight mesh that was secured to the floor of the inguinal region using a nonabsorbable monofilament suture.[3] Nowadays, new mesh materials of the lightweight macroporous meshes show less foreign body reaction which translates to a reduced foreign body reaction by the patient.[4] Novel ideas in mesh fixation has also emerged, one of which is the idea of self-fixation wherein one side of the mesh has resorbable polylactic acid microhooks which provide atraumatic fixation of the mesh to the underlying tissues.[5] The selfgripping polyester mesh (TEM1208GR or GL Parietex ProGrip™) was utilized in open inguinal hernia repair. It had the advantages of having a low- density material, being macroporous, and the option to do away

with the use of sutures to secure the mesh. Our objective is to assess the feasibility of using the self-gripping mesh on Filipino patients, with recurrence after 2 years as the primary endpoint.

METHODS

Ethics approval was requested from the De La Salle Health Sciences Institutional Ethics Committee. Inclusion criteria were participants who are 18-80 years-old, with primary reducible hernia, hernial sac not greater than 4 cm in diameter with informed consent. Exclusions were those who had non-reducible hernias, be it incarcerated or strangulated; bleeding disorders; patients below 18 (lower age limit) and above 80 (upper age limit) years old and hernia defects of. greater than 4 cm.

Informed consent was obtained with the participant being given a signed copy in both vernaculars (English and Tagalog). The purpose, procedure, followup, possible risks and complications, benefits from the study, and costs of the procedure were detailed.

Preoperative preparations included the following: nothing per orem 6 hours prior to operation, intravenous fluid infusion, preoperative antibiotics given an hour prior to surgery. Preoperative antibiotics were administered on the surgeon's discretion. Other medications such as Midazolam 15mg/tablet, Omeprazole 40 mg/tablet and intravenous Metoclopromide 10mg (5mg/ml) were given one and a half hours prior to the procedure. All operations used a 12 × 8 cm (TEM1208GR or GL Parietex ProGrip™).

The operative site was prepared by shaving the abdominal wall as well as the pubic hair, after which, asepsis and antisepsis techniques were employed. Standard preoperative safety checks (surgical timeout) commenced.

Majority of the patients underwent spinal anesthesia, which was done with 20 mg of Bupivacaine, 0.5% heavy. As the skin and subcutaneous tissues were cut, the external oblique aponeurosis was opened and the ilioinguinal and iliohypogastric nerves were identified and preserved.

The hernial defect was identified; and the hernia characteristics were documented (type, classification, size). The self–gripping polyester mesh (TEM1208GR or GL Parietex ProGrip™) was then deployed over the defect while being timed by a research assistant. No sutures were used to secure the mesh.

After proper hemostasis, suturing of the external oblique aponeurosis in a continuous fashion using Maxon™ (Covidien, USA) 20 and skin closure with V-Loc™ (Covidien, USA) 4-0 was used. Diet was resumed after operation; and the patient is discharged upon the surgeon's discretion.

Data was collected on the possible intraoperative problems such as profuse bleeding, difficulty in identification of the hernial sac and nerve injury. The duration of the operation and time mesh deployment were recorded. Immediately after surgery, the participants were repeatedly reassessed 6, 12 and 24 hours after surgery for the pain score using the visual analog scale.

Occurrence of other postoperative complications like hematoma formation, bleeding and seroma accumulation was recorded. Participants were seen at the clinic one week after surgery and were reassessed for the primary and secondary endpoints one and two years after surgery through a phone interview. Primary endpoint was recurrence rate at two years. Secondary endpoints were postoperative pain, surgical and wound healing complications, and operating time factors.

Data stated above was collected prospectively and saved in the SPSS statistical software 17.0.

RESULTS

There were, a total of 95 participants with 99 hernias from September 2011 to March 2014. Ninety (93.7 %) of the participants were male while the average age of all of the participants was 43 years SD +18 (15¬81). The hernia characteristics were demonstrated in Table 1.

Participants all underwent mesh repair for the inguinal hernia using the pre-cut self-gripping polyester mesh (TEM1208GR or GL Parietex ProGrip™). Of the 91 (95.8%) participants with unilateral hernial defects, 51 (56%) were right-sided and 41 (45.1 %) were left sided. Four (4) patients had bilateral inguinal hernia. The average size of the hernial sac was 2 cm SD ±0.716 (1-4).

Majority of the participants were operated under regional anesthesia whereas two patients underwent mesh repair under general anesthesia and one patient under local anesthesia. The four patients who had bilateral inguinal hernias underwent surgery under spinal anesthesia. The use of general anesthesia and local anesthesia was up to the discretion of the surgeon.

Among the four participants with bilateral hernia, all had indirect inguinal hernia except one who had indirect hernia on the left and direct inguinal hernia on the right. The characteristics of the patients who had bilateral hernia repair are illustrated in Table 2.

The only intra operative complication that occurred during the procedure was excessive venous bleeding (>100 cc) in two patients (2%) during mobilization of the cord which was controlled with suture ligation of the bleeder. These two patients did not manifest with hematoma formation or seroma accumulation immediately postoperatively or even during the first followup.

Table 1: Characteristics of hernia and intraoperative findings.

	n=(99)	Frequency %
Hernia location		
Right	54	54.6
Left	45	45.5
Hernia type		
Indirect	87	87.9
Direct	8	8.0
Mixed	4	4.0
Mean hernia size (cms)	2	SD ±0.716 (1-4)
EHS classification		
LP1	7	6.9
LP2	56	55.4
LP3	26	25.7
LP4	1	1
LP3, MP3	1	1
MP2	4	4
MP3	3	3
MP4	1	1
Mean incision length(cms)	6	SD + 0.85 (5-9)
Anesthesia		
Spinal	92	92.93
Local	1	1.01
General	2	2.02
Intra-operative complications (excessive venous bleeding)	2	2

Immediate postoperative complications included seroma in one patient (1%), congestion around the area of the incision site in two patients (2%) and foreign body sensation in one patient (1%).

The patient who manifested with seroma postoperatively did not have overt bleeding intraoperatively. These were managed conservatively.

The symptoms of congestion and foreign body sensation resolved one week after surgery. However, the seroma of one patient persisted until the first follow-up which was one week postoperatively. On the first follow up, there were three (3%) reported cases of subjective feeling of decrease in size of the testicles on the ipsilateral side of the hernioplasty.

There were also two cases of seroma (2%), and one of which was the same patient who had seroma immediately after surgery. Both participants were asked to come back after two weeks with complete resolution of the seroma.

At one year after surgery, there were five reported cases of numbness along the distribution of the ilioinguinal nerve wherein all of them, except for one, resolved on the second year after surgery. Upon completion of the 2-year followup period, all 99 hernia defects had no recurrence.

The deployment time was determined by counting in seconds the time the surgeon got hold of the mesh until it was completely deployed on the inguinal floor.

In this study, the average deployment time using the self-gripping polyester mesh (TEM1208GR or GL Parietex ProGrip™) was 145.33 seconds SD ±38.55 (30-240). The average operating time for unilateral inguinal hernia, using the self-gripping polyester mesh (TEM1208GR or GL Parietex ProGrip™) was 77.59 minutes SD 73.64± (22480). The pain score, which was evaluated using the visual analog scale (VAS), was assessed in each patient with a unilateral inguinal hernia, on the 6th, 12th and 24th hour postoperative.

Table 2: Hernia characteristics of bilateral defects.

	Hernia Type	Age	Sex	Operative time (mins)	Deployment time (sec)	Pain score after 6 hours	pain score after 12 hours	Pain score after 24 hours
Pt 1	Indirect	51	Male	93	118/157	0	5	0
Pt 2	Indirect	62	Female	145	150/130	2	1	2
Pt 3	Indirect	81	Male	185	185/140	4	4	4
Pt 4	Indirect/Direct	47	Male	110	270/120	0	6	4

The mean pain score of the patients at 6, 12 and 24 hours postoperatively were 3 SD ±2.69 (0-10), 2.91 SD±2.35 (0-9) and 2.25 SD ±2.06 (0-10), respectively.

The average pain score one week after surgery was 0.43 SD ±0.73 (0-3). At one and two years after surgery, the pain scores were negligible.

DISCUSSION

Inguinal hernia accounts for 75% of all abdominal hernias, with a lifetime risk of 27% among males and 3% among females. Its repair is one of the most commonly performed surgeries in the world.[4] The management of open inguinal repair has evolved in the past centuries, beginning with

various techniques of primary tissue repair. However, the era of tissue-based repairs continued only until the 20th century with the advent of prosthetic mesh use in the repair of inguinal hernia, thus called the tension free repair.

In 1989, the Lichtenstein hernia repair was introduced. This technique entailed the use of a polypropylene mesh, which is secured to the floor of the inguinal region using non¬ absorbable monofilament suture. This subsequently provided strength to the floor while minimizing the risk of recurrence. However, this method was associated with significant postoperative discomfort, which was estimated to be as high as 50%, although around 11-40% suffered from chronic pain, depending on the terminology of pain after surgery, still pain was still a significant factor.[6] Although it is acknowledged that comparisons between studies are difficult because the definition of pain and time points of pain assessment vary.[7]

With regard to the mesh composition, the high density, microporous or "heavyweight" polypropylene mesh stimulates intense inflammatory reaction, which may be responsible for mesh shrinking. Consequently, low-density macroporous polypropylene mesh with self-gripping properties was introduced. This innovation addressed the concern to minimize the postoperative pain from mesh suture fixation and incorporate the new recommendation to utilize a low density macroporous mesh.[8]

Subsequently, this prospective study was conducted to assess the feasibility of using a self-gripping lightweight polyester mesh to repair inguinal hernia in the Philippines in terms of recurrence rate, postoperative pain, postoperative surgical complications, wound healing complications and operating factors (mesh deployment time, total operating time). In present study, we performed open inguinal hernia repair on eligible participants using the pre-cut self-gripping polyester mesh (TEM1208GR or GL Parietex ProGrip™) and monitored them for perioperative complication, intraoperative factors, and pain score, with recurrence rate as our primary endpoint.

Long term results show decreased recurrence in repairs using long term absorbable sutures that retain long term tensile strength as compared to fixation with cyanoacrylate and short-term absorbable sutures.[9] Recent data on a 24-month follow-up show that there is no significant difference between sutured repair and self-fixating repair.[10] Present study shows a 2 year follow up with no recurrence.

The pre-cut self-gripping polyester mesh (TEM1208GR or GL Parietex ProGrip™) is made of knitted monofilament macroporous polyester with polylactic acid (PLA) monofilament with bio resorbable pins on one side, fixating it to the inguinal floor; thus, routine use of sutures to secure it to the inguinal floor is no longer necessary. This subsequently offered less contraction and shrinking of the mesh which ensures that the entire area intended to be covered is still covered properly. Moreover, the presence of a mesh reinforcing the inguinal floor offered tension free repair of the inguinal hernia. The absence of sutures to secure the mesh contributed to less postoperative pain since the likelihood of entrapping the nerves are minimized. However, it cannot be over emphasized that proper identification and preservation of the ilioinguinal and iliohypogastric nerves throughout the surgery is of utmost importance to decrease the incidence of postoperative pain. Thus, in this study, the average pain score of the participants from the 6th, 12th and 24th hour post-surgery was only 3/10. One week, one year and two years after surgery, the pain score was negligible.

The durations of deployment time and operative time were markedly varied because the surgery was performed by different surgeons who were not all accustomed to the self-gripping mesh. However, the mesh is easy to handle; and learning how to properly deploy it is straightforward. Intraoperative complications included venous bleeding, which were immediately controlled with ligation of bleeders, and did not contribute to the occurrence of hematoma formation after surgery. However postoperative complications like seroma still occurred but resolved spontaneously. The occurrence of numbness observed within one year may be due to neuropraxia and resolved within the second year after surgery. The data gathered from this study will be of better help in managing open inguinal hernia repair if it will be further compared to patients who underwent the conventional Lichtenstein technique.

CONCLUSION

The use of a self-gripping mesh is feasible and safe in the Philippine setting due to the minimal intraoperative and postoperative complications noted with its use. All 99 hernia defects had no recurrence of inguinal hernia after a two-year followup.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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