Comparison of Different Types of Mesh Used in Open Ambulatory Inguinal Hernioplasty

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Abstract

Introduction: The use of a tension free technique is consensual on inguinal hernia surgery. This option provides less postoperative pain and is associated with a lower recurrence rate. However, the type of mesh used is not so consensual, regarding not only the recurrence rate but also the patient comfort and the duration and easiness of the surgery itself.

Aim: This study aims to compare three types of meshes used in open inguinal hernia surgery: the self-gripping mesh, the conventional suture-fixed mesh and the bilayered mesh. We performed operations between December 2015 and November 2016 with a mean follow-up time was 29.38 months. Our endpoints were the occurrence of acute pain (according to Visual Analogue Scale), haematoma, seroma or infection and the duration of surgery. We also evaluated the occurrence of chronic pain (defined as pain longer than 6 months) and the recurrence of hernia (evaluated by physical exam on the follow up consults and/or ultrasound in cases of doubt).

Methods: Three groups were assigned to receive the self-adherent mesh, a sutured mesh, or a bilayered mesh. The surgical and anesthetic techniques were identical for the 3 groups and all surgeries were performed by the same surgical team. We included adult male patients with unilateral inguinal hernia suited for ambulatory surgery. Patients were evaluated at 6 moments: phone contact 24h after surgery and post-operative appointments at 10-15 days, 1 month and 1, 2 and 3 years after surgery.

Results: Excluding drop-outs and operative complications we had 67 men included on final analysis (group 1= 20, group 2=22 and group 3=26). We had no cases of chronic pain and 1 case of early recurrence in group 3. Mean VAS at 24h was slightly higher with sutured mesh (group 1=2.75, group 2=2.96, group 3=2.3) but there was no significant difference between the three groups (p value=0.634). Mean VAS at 10/15 days was lower on group 3 (group 1=1, group 2=0.96, group 3=0.4) but there was no significant difference between the three groups (p value=0.241). We registered 5 cases of seroma (group 1=2; group 2=1; group 3=2), 14 cases of hematoma (group 1=5; group 2=2; group 3=7) and no cases of wound infection/mesh rejection. The duration of surgery was lower on group 1 (mean of 43.8 min vs 51.36 min for group 2 and 51.96 min for group 3) and this difference was statistically significant (p value 0.003) and also globally decreased as the study progressed.

Conclusion: In our study, the choice of the mesh for open inguinal hernia repair didn´t affect patient outcome regarding post-operative pain (acute or chronic), nor occurrence of seroma, hematoma or infection. The only endpoint with a significant difference among the 3 groups was the duration of surgery, which was lower for the self-gripping mesh. We concluded that the use of a correct technique is the gold-standard for a successful surgery despite the mesh used.

Keywords: Ambulatory surgery; inguinal hernioplasty; mesh.

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Introduction

The use of a tension free technique is consensual in inguinal hernia surgery [1]. This option provides less postoperative pain and is associated to a lower recurrence rate. However, the type of mesh used is not so consensual, regarding, not only recurrence rate, but also patient comfort and the duration and easiness of surgery itself [2].

Post-operative pain is probably the most important predictor factor to recovery, with a strong impact on patient quality of life [1]. The causes for such pain are unclear but mesh material, foreign body reaction, difficulty on dissection, nerve damage or entrapment and mesh fixation are suggested reasons [1]. In that way, it would be expected that self-gripping meshes would accomplish a better outcome. However, the use of a mesh that causes less pain/discomfort may have a higher risk of recurrence, with higher costs for both patient and for the National Health System. We also have to consider that a surgery for a recurrent hernia has higher risks and morbidity than a primary hernioplasty [2].

Considering this, our study aims to compare the results in terms of acute/chronic pain, recurrence, duration of surgery and recovery and occurrence of hematoma, seroma or infection of three types of meshes used in open inguinal hernia surgery: a self-gripping mesh, a conventional suture-fixed mesh and a bilayered mesh.

Methods

We performed a controlled, prospective, randomised, double blind study, involving 90 patients, divided into 3 groups, comparing long-term results focusing on acute and chronic pain, recurrence rate, operation duration, recovery duration and the occurrence of seroma, hematoma, wound infection and rejection.

The first group was assigned to receive the self-adherent mesh Progrip® (Medtronic, Dublin, Ireland) which is a semi-resorbable with macroporous knit made of monofilament polypropylene lightweight mesh (density of 38g/m2 after absorption) [3].
The second group was assigned to receive a standard sutured polypropylene mesh. The third group received the PHS® (Polypropylene Hernia System) bilayered lightweight mesh (Ethicon - Johnson& Johnson, Warsaw, USA), that incorporates the concept of simultaneous anterior and posterior repair [4]

This study included adult male patients with unilateral inguinal hernia suited for ambulatory surgery at our surgical centre. All patients were clinically evaluated at a pre-operative consult and informed consent was obtained.

All surgeries were performed by the same surgical team (a second/third year resident and a senior surgeon) in a 12 month period.

Our endpoints were the occurrence of acute pain (according to the Analogic Visual Scale), hematoma, seroma or infection and the duration of surgery. We also evaluated duration of surgery (time from operating room to recovery room), duration of recovery (time to accomplish discharge criteria from ambulatory surgery recovery room), the occurrence of chronic pain as defined by the International Association for the Study of Pain (pain that persists beyond normal tissue healing time, usually longer than 3 months) [5] and the recurrence of hernia (evaluated by physical exam on the follow up consults and/or ultrasound in cases of doubt).

All patients were evaluated at fixed schedules:

- Hourly during the first four hours after surgery: quantitative representation of patient pain using the Visual Analog Scale (VAS), pain location and analgesic medication used.
- 10 to 15 days after surgery: first follow up appointment, registering primary endpoints.
- 1 month after surgery: second follow up appointment, confirming primary endpoints.
- 1 year after surgery: third follow up appointment, registering secondary endpoints.
- 2-3 years after surgery: forth follow up surveillance appointment.

Exclusion criteria were: Urgent surgery; Female sex; Prior incarceration needing manual reduction, American Society of Anesthesiologists (ASA) physical status classification> 3; Non-controlled Diabetes Mellitus (defined as HbA1C < 6.5% or fasting capillary blood glucose>110 mg/dL or postprandial blood glucose> 180 mg/dL, following the International Federation of Diabetes guidelines [6]; Body Mass Index <25 or > 40; Any medical allergy that interferes with protocol; Any anaesthetic or surgical complication that interferes with protocol

The surgical and anaesthetic techniques were exactly the same for the 3 groups and are described in Appendix 1 and 2 at the end of the article.

This study was approved by local Ethics Committee.

Data processing:

All patients are identified by a numeric code and we performed a computer generated randomization technique and a computer generated list to allocation concealment.

All data were processed using SPSS 22.0 (IBM SPSS Statistics Inc, Chicago, IL) and the analysis of data was performed on April 2019.

The baseline group difference was checked for random distribution by the independent T test and X2 test for normally distribution categorical variables. A $p<0.05$ difference was considered statistically significant. For continuous data the mean difference with a 95% confidence interval (CI) was calculated; for dichotomies data, the effect measures Odds Ratio (OR) and Risk Ratio (RR) with a 95% CI were calculated to evaluate the statistical difference between outcomes.

Results

Baseline Characteristics

From the 90 patients initially enrolled we had 23 excluded for the following reasons:

- 11 patients that dropped out early
- 1 patient needing tracheal intubation for severe bronchospasm
- 1 patient with an allergic reaction (cutaneous rash) during induction
- 8 patients with nerve damage during surgery
- 1 patient missing the surgery date
- 1 patient needing reintervention for early recurrence.

Excluding dropouts and operative complications, 67 men were included on final analysis (group 1= 20, group 2=22 and group 3=26). Mean follow up time was 29.38 months.

When we analysed the profile of our patients, the mean age was 55 years old (min 52; max 78) and 52.2% of all patients were non-qualified workers, according to Table 1 and as expected. However, we must emphasise that our centre is a public hospital, so we might have a selection bias since the most differentiated patients may choose to drop out our long waiting list and be operated on a private care facility. Therefore, we cannot conclude that there is an association between non-qualified workers and the occurrence of hernia.

Table 1 Patients' Professional Group.

Professional Group[1]	Frequency	Percentage (%)
Scientific and intellectual activity	3	4.5
Intermediate level techni-cians	2	3.0
Administrative personnel	1	1.5
Personal service and pro-tection workers	2	3.0
Farmers and rural workers	3	4.5
Industry workers	14	20.9
Non-qualified workers	35	52.2
Non-available	7	10.4
Total	**67**	**100%**

[1] According to CPP - Classificação Portuguesa das Profissões 2010 (Portuguese Professional Classification 2010) by INE Statistics Portugal [5]

The mean Body Mass Index was 25.32 (mín 19.72; max 32.41) and the main co-morbilities are registered on Table 2, based on what we may conclude that our patient profile is similar to the Portuguese general population.

Table 2 Patients Co-morbidities (NYHA=New York Heart Association; COPD = Chronic Obstructive Pulmonary Disease; BPH= Benign Prostatic Hyperplasia).

Co-morbidities	Frequency	Percentage
Type II Diabetes	3	4.4
High Blood Pressure	30	44.1
Heart Failure NYHA I	1	1.5
COPD	1	1.5
Smoking	21	30.9

Duration of surgery and recovery

The mean operating time was significantly shorter on group 1, as showed on Table 3 (p value 0.013 Confidence Interval 95%) and also globally decreased as the study progressed (Figure 1).

The mean time from skin closure and entering the recovery room was 15 minutes (minimum 4 minutes, maximum 40 minutes). The mean time of phase 1 recovery was 1h37 minutes (min 20, max 3h). The mean time of phase 2 recovery was 1h20 minutes (min 30, max 2h40).

Table 3 Duration of surgery.

Group	Mean (minutes)	Median	Standard deviation (minutes)	Confidence interval for a 95% average		Minimum (minutes)	Maximum (minutes)
				Lower limit	Upper limit		
1	43.9	44	8.66	39.8	47.9	32	69
2	51.4	51.5	10.22	46.8	55.9	24	70
3	52	44.5	36.74	37.1	66.8	31	226

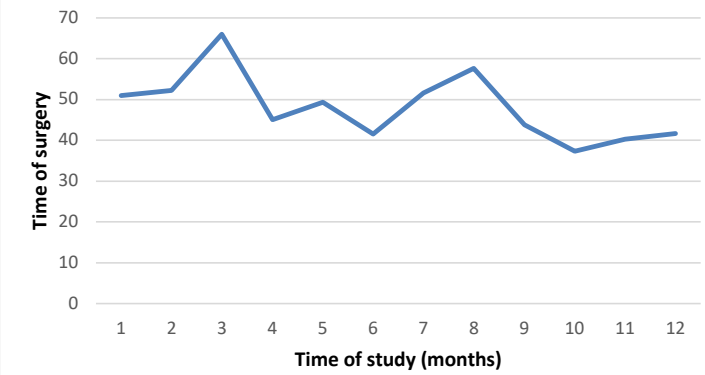

Figure 1 Duration of surgery during the study.

Acute pain

Most of the patients did not feel any pain during the recovery phase (1-4h after surgery), as showed on Figure 2. The majority of patients referred only a slight discomfort on the inguinal area. One patient needed rescue analgesics (tramadol) due to inguinal pain. We also had one case of partial motor blockage resolved spontaneously after a few waiting hours.

Mean VAS at 24h was slightly higher with sutured mesh as showed on Table 4, but there was no significant difference between the three groups (p value=0.634).

Mean VAS at 10/15 days was lower on group 3 (group 1=1, group 2=0.96, group 3=0.4) as showed on Table 5 but there was no significant difference between the three groups (p value=0.241). We also registered that most of the patients took all the analgesics prescribe at home but they did it as a preventive measure, not because they had pain.

Chronic Pain

During the long time follow-up we had no cases of chronic pain.

Recurrence Rate

We had one case of early recurrence (group 3), noticed at the first month appointment. The patient had a inguinal indirect hernia and received the PHS mesh. On the first appointment we noticed a crural hernia that was he had not at pre-operative examination. Ultrasound confirmed the crural hernia, correct positioning of the mesh and no inguinal hernia so probably this recurrence was due to wrong surgical technique rather than mesh failure.

Other outcomes

We registered 5 cases of seroma (group 1=2; group 2=1; group 3=2) and 14 cases of superficial hematoma (group 1=5; group 2=2; group 3=7). None of them needed other intervention than surveillance and analgesia.

We had no cases of wound infection/mesh rejection.

Conclusion

In our study, the choice of the mesh for open inguinal hernia repair didn't affect patient outcome regarding post-operative pain (acute or chronic) and occurrence of seroma, hematoma or infection.

Chronic pain poses a major health issue since there are few effective therapeutic options and it implies a social and economic burden. Pain is a subjective feeling and the fear of pain enhances this feeling, so it is very important to get the most effective early postoperative pain control in order to give confidence to the patient that the procedure went well. In that way, we believe that an ilioinguinal/iliohypogastric nerve block associated to an appropriate multimodal analgesic protocol is the best option to achieve this goal, since most of our patients had minimal or no pain after the procedure.

The risk for chronic pain depends not only on the type of mesh and its fixation technique (lightweight meshes are associated with less

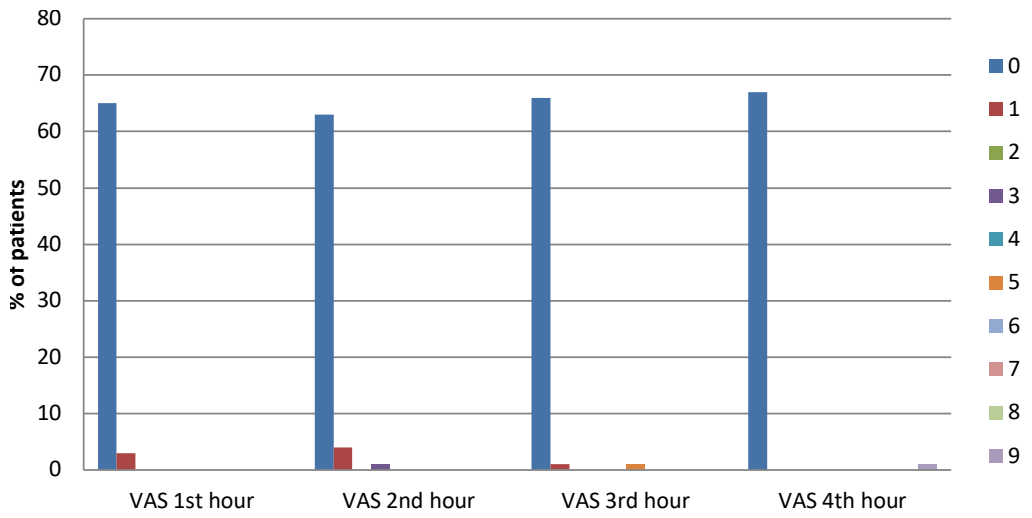

Figure 2 VAS 1st-4th hour (VAS = Visual Analogic Scale).

Table 4 VAS at 24h (VAS = Visual Analogue Scale).

Group	Mean VAS	Median VAS	Standard deviation	Confidence interval for a 95% average		Minimum VAS	Maximum VAS
				Lower limit	Upper limit		
1	2.75	2.0	2.53	1.57	3.94	0	8
2	2.99	2.0	2.68	1.77	4.13	0	7
3	2.31	2.0	2.02	1.49	3.12	0	7

Table 5 VAS at 10/15 days (VAS = Visual Analogue Scale).

Group	Mean VAS	Median VAS	Standard deviation	Confidence interval for a 95% average		Minimum VAS	Maximum VAS
				Lower limit	Upper limit		
1	1.00	0	1.747	0.182	1.818	0	6
2	0.96	0	1.496	0.292	1.618	0	5
3	0.42	0	1.102	0.022	0.868	0	5

chronic pain and foreign body feeling) but also with the dissection in a neuralgic plane, thus the importance of nerve preservation. Other studies that had a higher incidence on chronic pain leave to the surgeon the choice to preserve or not the iliohypogastric and ilioinguinal nerves. In our study we excluded all the patients who had nerve damage or non-visualization in order to exclude that bias. Nerve injury during fixation of the mesh is an important determinant for pain so their mobilization and security during positioning of the mesh is important, despite whatever the mesh is chosen.

Recurrence is also an important endpoint since it implies pain and psychological discomfort for the patient, costs for the health and social system. We also have to consider that a reintervention (even by laparoscopy) poses more risks than a primary intervention. These premises enlighten the importance of a correct surgical technique that ensures that the space adjacent to the pubic tubercule and the new deep inguinal ring (the two main places of recurrence) are properly covered.

The only endpoint with a significant difference among the 3 groups was the duration of surgery, which was lower for the self-gripping mesh. The main advantage of the self-gripping mesh is thus the reduction of the operative time but we cannot say that it has a significant economical impact, because cost-effectiveness studies still need to be developed. In our study, time savings were not enough to schedule an additional patient to the OR period, so the higher price of self-gripping meshes may not justify its usage.

We also found that the resident´s skills increased with the number of surgeries performed, leading us to emphasize that surgeons should be familiar with all kind of meshes and residents should learn several techniques in order to achieve proficiency in hernia surgery.

We recognize that this study has some limitations as it is underpowered because enrolled less than 100 patients and we couldn´t complete the 3 years follow up as recommended by European Hernia Society to determine long term outcome for pain and recurrence rate. We also didn't perform an analysis of preoperative pain, so baseline comparation was not achieved.

Yet, we believe that our results show that independent of the mesh type, it is of paramount importance that surgeons develop skills that spare nerve injury during hernioplasty and anesthesiologists have multimodal analgesic protocols that include loco-regional techniques.

References

1. Li J, Ji Z, Li Y. The comparision of self-gripping mesh and sutured mesh in open inguinal hernia repair. ***Annals of Surgery*** 2014;**259(6)**:1080-5.
2. The Hernia Surge Group.International guidelines for groin hernia management Hernia. ***Hernia*** 2018;**22(1)**:1–165.
3. http://medtronicsolutions.medtronic.eu/ProGrip
4. Gilbert AI, Young J, Graham MF, Divilio LT, Patel B. Combined anterior and posterior inguinal hernia repair: Intermediate recurrence rates with three groups of surgeons. ***Hernia*** 2004;**8(3)**:203–7.
5. Schug SA, Lavand'homme P, Barke A et al. The IASP Taskforce for the Classification of Chronic Pain, for ICD-11. ***Pain*** 2019;**160(1)**:45–52.
6. International Diabetes Federation. Recommendations For Managing Type 2 Diabetes In Primary Care. 2017. www.idf.org/managing-type2-diabetes
7. Molegraaf M, Kaufmann R, Lange J. Comparison of self-gripping mesh and sutured mesh in open inguinal hernia repair: A meta-analysis of long-term results. ***Surgery*** 2018;**163(2)**:351-360.
8. Smeds S, Nienhuijs S, Kullman E, et al. Identification and management of the ilio-inguinal and ilio-hypogastric nerves in open inguinal hernia repair: benefits of self-gripping mesh. ***Hernia*** 2016;**20(1)**:33-41.
9. Zwaans WAR, Verhagen T, Wouters L, et al. Groin Pain Characteristics and Recurrence Rates. Three-year Results of a Randomized Controlled Trial Comparing Self-gripping Progrip Mesh and Sutured Polypropylene Mesh for Open Inguinal Hernia Repair. ***Annals of Surgery*** 2018;**267(6)**:1028-33.

Appendix 1: Anaesthetic technique:

- **Pre-op:**
- IV infusion 1000 ml of a 5% glucose polyelectrolyte solution
- Standard ASA monitorization and Bispectral Index (BIS) ´
- Pre-medication with 1 – 1.5 mg of midazolam iv
- Ilioinguinal nerve block with 20 ml of a local anaesthetic mixture (10 ml of ropivacaine 0.75% + 10 ml of lidocaine 2%)

- **Peri-op:**
- Induction with fentanyl (2 mcg/kg) and propofol (2mg/Kg)
- Airway Management: laryngeal mask according to weight and size of the patient;
- Pressure controlled Ventilation (max 20cmH20);
- Maintenance with Air/O2/Sevoflurane titrated to BIS between 40 and 70
- Fentanyl iv bolus (0.5mcg/Kg) if Blood Pressure or Heart Rate 20% above the mean baseline measured at pré-op
- Nausea and vomiting prophylaxis: dexamethasone iv(0,15mg/Kg up to 8mg) and droperidol iv (0,625mg/Kg up to 1,25mg)
- Analgesia: Acetaminophen 1000mg iv and Ketorolac 30 mg iv

- **Post-op:**
- Rescue antiemetic if nausea or vomiting: ondansetron 2 mg iv
- Rescue analgesia: fentanyl 25 mcg iv if severe pain or tramadol 1 mg/ Kg if moderate pain
- Take-home analgesia: acetaminophen 1 g PO 8/8h and ibuprofen 400 mg PO 8/8h

Appendix 2: Surgical Technique:

Pre-op:

- Low transverse inguinal incision (about 5 cm) 2 minutes after ilioinguinal blockage with a 24 blade.
- Open and dissection until exposure of the external oblique muscle, which is then sectioned following the orientation of their fibres, exposing the spermatic cord
- Isolating the spermatic cord until the pubic tubercle and mobilization of the proximal 3 cm.
- Visualisation and preservation of ilioinguinal and iliohypogastric nerves
- Exploration of deep inguinal ring with minimal dissection of the cremaster muscle
- Identification of hernia type:
  - If indirect hernia: liberation of hernia sac and ligation with 2-0 vycril
  - If direct hernia: sac imbrication with 2-0 vycril
- Reinforcement of fascia transversalis with 2-0 vycril
- Choose the size of the random mesh accordingly
  - Group 1: Progrip mesh
  - Group 2: Sutured mesh with 2-0 vycril anchored at the pubic tubercle without entering the periosteum, fixation of the superior margin with separated stitches and the inferior margin with continue suture; suture of the two margins in order to create the new deep inguinal ring
  - Group 3: Bilayered mesh, whose inferior part is placed after exposure of Bogros space and the superior part is sutured with 2-0 vycril, reinforcing the floor of the inguinal canal and creating a circular opening forming the new deep inguinal ring and fixating the mesh to the pubic tubercle without hitting the periosteum
- Closure of external oblique muscle aponeurosis with 0 vycril (continuous suture)
- Closure of the subcutaneous cellular tissue with 3-0 monocryl suture
- Closure of skin with 3-0 monocryl intradermic suture.

NOTE: All patients received prophylactic antibiotherapy with 2g of cefazolin 30 min previous to surgery. All patients with allergy to cefazolin were excluded from the study.