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Performance and Safety Evaluation of Polypropylene Mesh Used in Inguinal Hernia Repairs

İnguinal Herni Onarımlarında Kullanılan Polipropilen Meshin Performansı ve Güvenlik Değerlendirmesi

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ABSTRACT

Aim: This study aimed to compare the data of patients who underwent open tension-free hernia repair using polypropylene mesh with the data obtained from the literature, and to evaluate the efficacy and safety of this mesh in the early postoperative period. The results of this study will provide additional data to the literature in terms of comparing different mesh materials.
Material and Methods: In this cross-sectional, and observational study, the early postoperative-period data of 96 patients who had undergone standard Lichtenstein tension-free hernia repair using polypropylene mesh in a tertiary-level hospital, using polypropylene mesh were evaluated and compared with the data obtained from the literature.
Results: The mean age of patients was 58.59±13.82 (range, 20-83) years. The median length of hospital stay was 1 (range, 1-4) day. The median of visual analogue scale (VAS) scores was 2 (range, 0-4) for the day of surgery, 0 (range, 0-4) for postoperative day-1, and 0 (range, 0-2) for postoperative day-2. A total of 6 complications developed in 5 of the patients, 3 (3.13%) were hematoma, 2 (2.08%) were wound site infections, and 1 (1.04%) was seroma. In one patient, both hematoma and wound infection were determined. No mortality was encountered.
Conclusion: Polypropylene mesh could be used effectively and safely in groin hernia operations. Although some complications with the use of synthetic mesh materials have been reported since the introduction of these materials into clinical use, none of these have yet been considered as conditions that will adversely affect the use of polypropylene mesh.
Keywords: Hernia; inguinal; mesh; polypropylene; herniorrhaphy; postoperative complications.

ÖZ

Amaç: Bu çalışmanın amacı polipropilen mesh kullanılarak açık gerilimsiz fıtık onarımı yapılan hastaların verilerini literatürden elde edilen verilerle karşılaştırmak ve bu meshin ameliyat sonrası erken dönemdeki etkinliğini ve güvenilirliğini değerlendirmektir. Bu çalışmanın sonuçları, farklı mesh malzemelerinin karşılaştırılması açısından literatüre ek veri sağlayacaktır.
Gereç ve Yöntemler: Bu kesitsel ve gözlemsel çalışmada, üçüncü basamak bir hastanede polipropilen mesh kullanılarak standart Lichtenstein yöntemiyle gerilimsiz fıtık onarımı uygulanmış olan 96 hastanın ameliyat sonrası erken dönem verileri değerlendirildi ve literatürden elde edilen verilerle karşılaştırıldı.
Bulgular: Hastaların ortalama yaşı 58,59±13,82 (aralık, 20-83) yıl idi. Hastanede kalış süresinin ortancası 1 (aralık, 1-4) gün idi. Görsel ağrı skalası (visual analogue scale, VAS) skorlarının ortancası ameliyat günü için 2 (aralık, 0-4) olarak belirlenirken, ameliyat sonrası 1. gün için 0 (aralık, 0-4) ve ameliyat sonrası 2. gün için ise 0 (aralık, 0-2) olarak belirlendi. Hastaların 5'inde, 3'ü (%3,13) hematom, 2'si (%2,08) yara yeri enfeksiyonu ve 1'i (%1,04) seroma olmak üzere toplam 6 komplikasyon gelişti. Bir hastada hem hematom hem de yara yeri enfeksiyonu bir arada belirlendi. Herhangi bir mortalite ile karşılaşılmadı.
Sonuç: Polipropilen mesh, kasık fıtığı ameliyatlarında etkin ve güvenli bir şekilde kullanılabilir. Sentetik mesh malzemelerinin klinik kullanıma girmesinden bu yana bazı komplikasyonlar rapor edilmiş olsa da bunların hiçbiri henüz polipropilen mesh kullanımını olumsuz etkileyecek durumlar olarak değerlendirilmemiştir.
Anahtar kelimeler: Fıtık; inguinal; mesh; polipropilen; fıtık onarımı; ameliyat sonrası komplikasyonlar.

INTRODUCTION

Hernia is defined as the protrusion or prolapsus of an organ through the wall of the cavity where it is ordinarily contained. They can be seen in a variety of shapes and sizes, with the abdominal wall being the area most prone to hernia development. Inguinal hernia is the most common hernia at the rate of 70-75%, followed by femoral (6-17%) and umbilical (3-8.5%) hernias. One of the most frequently performed surgical procedures worldwide is hernia repair. More than 20 million hernia repair surgeries are thought to be performed annually around the globe (1). Since the introduction of the Bassini procedure in 1887, more than 70 forms of pure tissue repair have been recorded in the surgical literature. The tissue approximation techniques of hernia repair have all but been abandoned due to high recurrence rates of up to 34%. Lichtenstein established the idea of tension-free repair for hernias (2). Currently, more than 80% of hernia surgeries in the United States use hernia mesh products. However, there are many different kinds of mesh, and there is much disagreement on the best use of surgical techniques and their success (1).

Currently, most surgeons concur that using a prosthetic mesh is the ideal method for soft tissue reinforcement and the treatment of hernias during open and laparoscopic surgeries (1). Despite tension-free mesh repair of ventral and groin hernias being widely accepted due to lower hernia recurrence rates than primary soft-tissue repair, the use of mesh for other surgical procedures is still a matter of debate because of the rare but serious complications that necessitate mesh removal and surgical repair (3). Infection, discomfort, pain, intestinal complications, seroma, local reaction, erosion/migration, adhesions, and mesh shrinkage are among the unfavorable outcomes associated with mesh use (4).

The aim of this study was to compare the data of patients who underwent open tension-free hernia repair using polypropylene mesh in a tertiary-level hospital with the data obtained from the literature and to evaluate the efficacy and safety of this mesh in the early postoperative period. With the development of technology, new materials and techniques are constantly being introduced and these innovations should be evaluated by comparing them with other applications. The results of this study will provide additional data to the literature in terms of making such comparisons.

MATERIAL AND METHODS

This retrospective, cross-sectional, and observational research included patients aged 18-99 years who met the study inclusion criteria, regardless of gender, who had undergone standard Lichtenstein tension-free inguinal hernia repair between August 2022 and December 2022, using polypropylene mesh, in the General Surgery Department of Health Sciences University Ankara Training and Research Hospital. The study was approved by the Ethics Committee of Ankara Training and Research Hospital (21.09.2022, 1086). The polypropylene mesh, used in this study was Polypropylene Mesh, which is a Class IIb medical device, certified since 2007, and manufactured by Altaylar Medikal, Ankara, Türkiye.

The evaluated parameters regarding the patient and the surgery during the preoperative, operative process and postoperative hospital stay were age, gender, body mass index (BMI), smoking status, additional diseases (diabetes mellitus, hypertension, chronic obstructive pulmonary disease, coronary artery disease, etc.), hernia type (direct, indirect, direct+indirect hernia, etc.), hernia side (right, left), anticoagulant use (such as aspirin, coumadin, Plavix, etc.), American Society of Anesthesiologists (ASA) score, anesthesia method (general, sedation, spinal), postoperative hospital stay, pain assessment during hospitalization according to the visual analogue scale (VAS) pain score, postoperative fever, morbidity, and mortality.

In accordance with standardized principles, all patients who were operated on in the General Surgery Clinic because of an inguinal hernia were invited to the outpatient clinic on the 10th day postoperatively for examination and removal of sutures. In addition to this routine practice, during discharge, the patients were informed that in the case of unexpected signs and symptoms such as severe pain, nausea-vomiting, redness-discharge at the wound site, gas-stool inability, or swelling at the incision site, they should immediately go to the General Surgery Department without waiting for the expiration of the 10-day period. According to the routine practice of the clinic, when patients come to the clinic on the 10th day or are admitted to the hospital due to a developing problem, they are questioned about current complaints, and physical examinations are performed. In patients with wound infection, the wound is drained and a sample is taken for culture-antibiogram, or when a complication such as a hematoma, hydrocele, or early recurrence is considered, ultrasonography is performed.

In the current study, the records were examined of the patients' routine admissions during the 10-day postoperative period and the patient admissions at the General Surgery Clinic in the one-month postoperative period, and complications including seroma, hematoma, wound infection, urinary tract infection, hydrocele, early recurrence, early mesh reaction, spermatic cord injury, testicular atrophy, orchitis, foreign body sensation, pain, or any other complications were determined. No problem was encountered in accessing information in this retrospective study, as all the parameters evaluated during the study were routine and mandatory data recorded in the hospital registry system by the physician evaluating the patient.

The patients with bilateral inguinal hernia, femoral hernia, incarcerated hernia, recurrent hernia, severe cardiopulmonary disease, chronic liver or kidney dysfunction, malignant tumor, serious diseases causing increased intra-abdominal pressure, and patients with incomplete data in the registry system were not included in the study.

Statistical Analysis

The IBM SPSS v.25 program was used for statistical analysis. For quantitative data, mean, standard deviation, median, minimum, and maximum values were used. Frequency tables were used for qualitative data.

RESULTS

The evaluation was made for a total of 96 patients with a mean age of 58.59±13.82 (range, 20-83) years, comprising 87 (90.6%) males with a mean age of 58.92±14.08 (range, 20-83) years, and 9 (9.4%) females with a mean age of 55.44±11.07 (range, 44-79) years.

The demographic and clinical characteristics of patients according to the parameters evaluated in the present study were given in Table 1. Most of the patients (n=53, 55.2%) had an ASA II score, and most (n=60, 62.5%) patients had a BMI of >25 kg/m^2. The median length of hospital stay was 1 (range, 1-4) day, and 79.2% (n=76) of the patients were discharged on postoperative day 1. The VAS scores were evaluated, on the night of the surgery day (VAS-0), postoperative day 1 (VAS-1), and day 2 (VAS-2) for patients who were not discharged. The median of the VAS scores were 2 (range, 0-4) for VAS-0, 0 (range, 0-4) for VAS-1, and 0 (range, 0-2) for VAS-2.

The most preferred anesthesia method was spinal anesthesia (n=81, 84.4%). Postoperative fever was observed in a total of 9 (9.4%) patients, but these patients did not have resistant fever and no additional treatment was required (Table 2).

A total of 6 complications developed in 5 patients, of which, 3 (3.13%) were hematoma, 2 (2.08%) were wound site infections, and 1 (1.04%) was seroma. In one patient, both hematoma and wound infection were determined. One of these patients with a 12-cm diameter hematoma was re-operated without mesh extraction. In the other patients, seroma, the other two hematomas, and the wound infections were drained by removing 2 or 3 sutures when these complications were diagnosed. The demographic and medical parameters of the patients with complications were given in Table 3. No mortality was encountered.

DISCUSSION

The goal of any hernia repair must be to fix the defect permanently with minimal risk. Avoiding recurrence, managing pain, and reducing infection rates are crucial concerns. The most notable improvement in inguinal hernia repair occurred in the 1980s, when Lichtenstein first used mesh to cover the inguinal canal floor, thereby enabling a realistic tension-free repair. Recurrence rates of <2% confirmed the effectiveness of the Lichtenstein Open Method as a mesh reinforcing technique. The Lichtenstein operation, which is technically simple and may be performed with a local anesthetic, has evolved into the standard repair method, and the mesh technique is by far the most used worldwide. With all mesh operations, the recovery time is shorter and less painful. The success of prosthetic repairs has led to much discussion regarding the ideal mesh properties and how the mesh can be fixed. An ideal mesh should be light, flexible, robust, resistant to contraction and infection, immunologically inert, and economical to produce (5,6).

The two types of materials that are employed to manufacture mesh are synthetic and biological. While all biological meshes are bio-degradable, synthetic meshes can either be degradable or permanent. Currently, the majority of meshes are made of carbon polymers such as expanded polytetrafluoroethylene, polyethylene terephthalate polyester, or polypropylene are used to make permanent mesh, which is strong and reasonably priced. There are already more than 100 different products, some

Table 1. Demographic and clinical characteristics of the patients

	Male (n=87)	Female (n=9)	Total (n=96)
Age (years), mean±SD (min-max)	58.92±14.08 (20-83)	55.44±11.07 (44-79)	58.59±13.82 (20-83)
BMI (kg/m^2), mean±SD (min-max)	26.35±3.60 (16.51-38.06)	27.72±7.15 (17.72-42.97)	26.47±4.03 (16.51-42.97)
BMI, n (%)			
<17 kg/m^2	1 (1.2)	0 (0.0)	1 (1.0)
17-25 kg/m^2	31 (35.6)	4 (44.4)	35 (36.5)
>25 kg/m^2	55 (63.2)	5 (55.6)	60 (62.5)
ASA Score, n (%)			
I	10 (11.5)	2 (22.2)	12 (12.5)
II	47 (54.0)	6 (66.7)	53 (55.2)
III	30 (34.5)	1 (11.1)	31 (33.3)
VAS-0, median (min-max)	2 (0-4)	0 (0-2)	2 (0-4)
VAS-1, median (min-max)	0 (0-4)	0 (0-2)	0 (0-4)
VAS-2, median (min-max)	0 (0-2)	0 (0-2)	0 (0-2)
Hospital stay (day), median (min-max)	1 (1-4)	1 (1-2)	1 (1-4)

SD: standard deviation, BMI: body mass index; ASA: American Society of Anesthesiologists, VAS: visual analogue scale

Table 2. Clinical characteristics of the patients

Smoking, n (%)	39 (40.6)
Comorbidities, n (%)	
Hypertension	30 (31.3)
Diabetes mellitus	16 (16.7)
COPD	9 (9.4)
CAD	24 (25.0)
Hernia Type, n (%)	
Direct	35 (36.5)
Indirect	57 (59.4)
Direct + Indirect	3 (3.1)
Other	1 (1.0)
Hernia Side, n (%)	
Right	57 (59.4)
Left	39 (40.6)
Anesthesia Method, n (%)	
General	5 (5.2)
Spinal	81 (84.4)
Sedation + spinal	7 (7.3)
General + spinal	3 (3.1)
Postoperative Fever, n (%)	9 (9.4)
Complications, n (%)	
Seroma	1 (1.0)
Hematoma	3 (3.1)
Wound site infection	2 (2.1)

COPD: chronic obstructive pulmonary disease, CAD: coronary artery disease

Table 3. Demographic and clinical parameters of the patients with complications

Patient No	I	II	III	IV	V
Complication	Hematoma+ Wound Infection	Seroma	Wound Infection	Hematoma	Hematoma
Gender	Male	Female	Male	Male	Female
Age (years)	44	56	72	83	79
ASA Score	II	II	II	II	II
BMI (kg/m^2)	24.38	42.97	24.58	23.94	23.66
VAS Score	VAS-0: 4 VAS-1: 1 VAS-2: 1	VAS-0: 0 VAS-1: 0	VAS-0: 0 VAS-1: 0	VAS-0: 2 VAS-1: 0	VAS-0: 2 VAS-1: 0
Smoking Habit	Smoker	Non-smoker	Non-smoker	Non-smoker	Non-smoker
Comorbidity	None	HT+CAD	BPH	HT+BPH	None
Anticoagulant Usage	No	No	No	No	No
Anesthesia	Spinal	Spinal	Spinal	Spinal	Spinal
Day of Discharge	Postop 3	Postop 1	Postop 1	Postop 3	Postop 1

ASA: American Society of Anesthesiologists, BMI: body mass index, VAS: visual analogue scale, HT: hypertension, CAD: coronary artery disease, BPH: benign prostate hyperplasia

of which differ significantly and others just slightly. Mesh absorbability, weight, thickness, strength, and porosity are the main factors to be taken into account when selecting mesh material. The most popular synthetic prosthetic materials used in hernia repair are polypropylene and polyester, both of which have proven to be excellent for hernia surgery (5-7).

It is challenging to identify the exact influence of the material on the rates of complications because there are so many potential causes of issues following surgery. Even with the best low-risk mesh or without any mesh at all, any severe complication may be caused by poor surgery or a patient with compromised wound healing. Therefore, any other potential non-mesh-related risks must be excluded from any consideration of the specific material-associated risks. Any straightforward association between material and complications in clinical trials should generally be considered with caution because many of these confounding factors may not be known or may not have been appropriately recorded (8).

Bleeding, seroma, infection, urinary retention, damage to adjacent structures, and ileus are the most common complications of groin hernia repair. Hernia recurrence, chronic pubic and inguinal pain, and injury to the testis or spermatic cord are all specific complications of herniorrhaphy. The most often used indicator of postoperative success after inguinal hernia surgery is the incidence of recurrence. Complication rates, hospital stay, quality of life, and operative duration are additional important outcome indicators to consider when comparing the various procedures currently available. The Lichtenstein tension-free repair significantly reduces hernia recurrence. Mesh repair is associated with fewer recurrences, a faster return to normal activities, and shorter hospital stays when compared to open surgical tissue-based repairs. The Lichtenstein approach continues to be the most often performed procedure worldwide among alternative tension-free repairs (6).

There are many studies in the literature that have used different groups of meshes in hernia repair. In this part of the article, the data obtained from the current study will be compared with the data obtained from the literature in order to evaluate the efficacy and safety of polypropylene mesh in the early postoperative period.

Clancy et al. (9) reviewed current research studies on the auto-immune and systemic consequences of polypropylene mesh usage in hernia repair. They identified 23 studies and these studies supported the appropriate usage of mesh in hernia surgery and other procedures.

The outcomes of a retrospective study that evaluated the performance, biocompatibility, and short- and long-term results of meshes used in open inguinal hernia surgery were recently published. The objectives of that study and the current study were very similar, except that the current study only evaluated early post-operative outcomes and not long-term outcomes as the patients only had the operations between August and December 2022. The study conducted by Tanasescu et al. (10) included 255 patients over a 7-year period, who underwent the modified Lichtenstein procedure using a monofilament polypropylene mesh (Premiline Mesh™). At the day-2 visit, there were four cases (1.5%) of postoperative large hematoma that necessitated surgical re-intervention but did not require removal of the mesh. At the 7-day visit, seromas in 16 (6.3%) patients and hematomas in 9 (3.5%) patients were observed as a total of 25 patients (10). In the current study, there were 3 (3.13%) hematomas, and only 1 (1.04%) seroma. One of these patients with hematoma was re-operated without mesh extraction. In the other patients, the seroma and the other two hematomas were drained by removing 2 or 3 sutures. In conclusion, although the rates of hematoma were similar in both studies, the seroma ratio in the current study was significantly low. There was no postoperative wound infection in the previous study whereas two (2.08%) surgical site infections were encountered in the current study.

Some other early postoperative complications, which were not reviewed by Tanasescu et al. (10), were examined in the current study, including early recurrence, early mesh reaction, spermatic cord injury, testicular atrophy, orchitis, foreign body sensation, hydrocele, and urinary tract

infection, were also discussed, and none of these complications was encountered. Early mesh reaction, early recurrence, and foreign body sensation in particular are considered as complications directly associated with the performance and physical properties of meshes, which are directly related to the main aim of the current study. The fact that these complications were not encountered can be accepted as positive data in terms of the performance and safety of the mesh used in the current study.

There are many clinical studies about the usage of polypropylene mesh on different parts of the body. Cavalli et al. (11) retrospectively reviewed 22 patients who underwent open repair of a lateral abdominal wall complex hernia. No major complications developed and it was concluded that any lateral complex hernia, regardless of the size and location, might be repaired with polypropylene mesh in the extra-peritoneal plane.

A recent study showed that using synthetic mesh produced a safe and long-lasting repair and using polypropylene mesh in the infected setting produced results that were similar to clean repairs (12). Although polypropylene mesh was not employed in an infected environment in the current study, the study by Birolini et al. (12) provides highly important information on the safe usage of mesh even in contaminated settings.

Pande and Naidu (13) conducted a systematic observational prospective study to evaluate the incidence of mesh infections, determine the type of related organism, and analyze the results of patients with hernioplasty in order to assess the complications of polypropylene mesh usage. Of the 181 cases, 59 cases of mesh contamination and 9 (4.97%) cases of mesh infection were observed. Groin hernias were the most common type of case that became infected. Mesh extraction was not required in any of these cases (13). In the current study, two (2.1%) patients experienced wound infection, neither of which required mesh removal. This rate was seen to be low in comparison with the rate in the above-mentioned study by Pande and Maidu (13).

Polypropylene meshes have also been used effectively and safely for many different indications, including anterior chest wall reconstruction, abdominal-based free flap breast reconstruction, pelvic organ prolapsus, stress urinary incontinence, laparoscopic sacrocolpopexy, laparoscopic sacrohysteropexy, cystocele, and orbital floor fractures (14-23).

Emral et al. (24) compared the short- and long-term outcomes of the traditional polypropylene mesh and self-adhesive mesh in Lichtenstein repair in a prospective, randomized, controlled study. The findings revealed that except for operation time, the self-adhesive mesh did not provide any statistically significant advantages over the traditional polypropylene mesh in the Lichtenstein repair. As part of that study, 39 patients from the polypropylene group underwent 42 (3 bilateral operations) inguinal hernia procedures and all of these patients were discharged on the first postoperative day. The majority of the patients in the current study were discharged on postoperative day 1, but the length of hospital stay was longer (median, 1; range, 1-4 days) than in the previous study. In the polypropylene group, the mean first-day VAS score was 3.6±1.2 whereas the median VAS score was 2 (range, 0-4) in the current study. Wound infection developed in 3 (3.5%) patients; in two (4.8%) of the polypropylene group and one (2.3%) of the self-adhesive mesh group. In the polypropylene group, only one (2.4%) patient experienced seroma development. Hematoma developed in 4 (4.7%) patients overall; two (4.8%) in the polypropylene group and two (4.5%) in the self-adhesive mesh group. The ratios of hematoma (3.15%), seroma (1.05%), wound infection (2.08%), and median VAS score on postoperative day-1 were all lower in the current study compared with the results of the polypropylene group in the study by Emral et al. (24).

In the study conducted by Sun et al. (25), the incidence of foreign body sensation, incision inflammation, postoperative VAS pain score, orchitis, and hydrocele were assessed as secondary outcome measures. The following were the main clinical outcomes of polypropylene mesh in that study: there was no orchitis, incision inflammation in 2 (3.0%) cases, foreign body sensation in 4 (6.1% on day-1), hydrocele in 1 (1.6%), and a mean VAS pain score of 2.41±0.86 on day-1. When compared with that study, all complication rates and the median VAS score were lower, and there was also no development of orchitis in the current study.

CONCLUSION

Clinical studies are needed to evaluate risk-benefit ratios. According to the early (1-month postoperative period) results of the current study, the authors concluded that polypropylene mesh could be used effectively and safely in groin hernia operations. In addition to its use in hernia repair, which is the main indication for the use of polypropylene mesh, studies were reviewed that have examined different indications, side-effects, and undesirable effects of the product, and for comparisons with other mesh groups. Although some complications with the use of synthetic mesh materials have been reported since the introduction of these materials into clinical use, none of these have yet been considered as conditions that will adversely affect the use of polypropylene mesh. These meshes are still widely used for surgical repair of anatomic defects worldwide even in contaminated environments or in emergent operations.

Ethics Committee Approval: The study was approved by the Clinical Research Ethics Committee of Ankara Training and Research Hospital (21.09.2022, 1086).

Conflict of Interest: None declared by the authors.

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