

Comparing non-mesh and sutured inguinal hernia repairs in groin surgery: A randomized clinical trial

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ABSTRACT

Purpose: Mesh technique is the standard for inguinal hernia repair because of less recurrence, but it is inferior or equal to sutured technique in case of other post-operative complications such as chronic pain. This clinical trial set out to compare these two techniques.

Materials and Methods: A total number of 322 cases of unilateral inguinal hernia in participants older than 18 years old were divided into 158 cases for mesh (Lichtenstein) and 164 for non-mesh (Bassini-McVay) hernia repair techniques. In order to compare the complications in the two groups, they were followed up from one to five years.

Results: During the study period, 12 and 7 participants were excluded from the mesh and non-mesh suture groups, leaving 146 and 157 participants in each group, respectively. The mean ages were 50.9 and 46.6 years old in mesh and sutured groups, respectively and mean follow up time was 2.9 years. Compared to mesh group, all complications were equal or less in non-mesh group, except for recurrence which had a statistically significant difference. Chronic post-operative pain, foreign body sensation, returning time to daily activities and costs were significantly less in non-meshed group ($P = .0083$).

Conclusion: Non-mesh suture technique still has its place in hernia repair. Mesh can be preserved for special conditions such as weak fascia wall, contralateral unsuccessful surgery, and recurrence, if suture technique is expensive or not easily available.

Keywords: herniorrhaphy, methods, postoperative complications; treatment outcome; hernia; male.

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INTRODUCTION

Inguinal hernia is the most frequent diagnosis in patients referred to general surgery clinics with groin pain.¹ Symptomatic inguinal hernia has 16% prevalence in adult men, and herniorrhaphy is a common surgery in western countries.²⁻⁴ Today, herniorrhaphy using mesh is generally used for inguinal hernia.⁵ Mesh constricts the repair site. Complication rate in non-mesh suture of inguinal hernia has a range of 4.4% to 17% compared to 0.3% to 2.2% for meshed repair.⁶⁻⁷ While mesh decreases the hernia recurrence, it increases the rate of chronic pain from 5.16% to 9.7%⁸⁻¹³ and foreign body sensation in the operation site up to 43.8%¹⁴ and decreases quality of life.

The exact origin of chronic pain because of mesh has not been mentioned in the literature. It may be due to nerve injury or entrapment. As a foreign body, mesh can

lead to severe tissue inflammation and scar formation, reducing abdominal wall compliance.¹⁵ Some studies have found less severe post-operative pain after using light versus heavier meshes like prolyn mesh,⁸ which has not been confirmed by others.¹⁶

In 2002, Scott and colleagues reported less operation time (7-10 minutes) with non-mesh method, but no deference in complication rates such as hematoma, seroma, and wound infection.¹⁷ Another research by Gran showed less recurrence rate in mesh method with no significant difference in complications, but less hospital stay time and less pain.¹⁸ In 2008, van Veen observed no pain and complaint in patients after 10 years follow up in mesh and non-mesh suture methods. Their patients returned soon to their daily activities.¹⁹

Recurrence rate has significant importance in post-

operation complications. It is reported to occur from 2% to 36% in mesh repair compared to 12% to 54% in non-mesh repair.^{20,21} However, detection of recurrence requires long time follow up. Without mesh, tension occurs on suture line leading to tissue ischemia, repair break down, and recurrence.^{22,23} Studies by EU Hernia Trialists Collaboration and also Malik and colleagues have shown that using mesh decreases chronic pain and is preferred to non-mesh suture,^{24,25} however due to the remaining foreign body some surgeons do not accept this method easily.

Concerning the rising rate of hernia repair in groin surgeries, this study was performed to compare the mesh and non-mesh methods in order to determine complications, quality of life, cost effectiveness.

MATERIALS AND METHODS

This randomized clinical trial was performed on 420 patients older than 18 years old with groin pain who had referred to general surgery clinics of Imam Reza Hospital from 2006 to 2011, with the diagnosis of primary inguinal hernia. Any patient who had been pregnant six months before referral to our clinic, had had contralateral hernia repair, had chronic obstructive pulmonary disease, previous right lower quadrant incisions, ascites, genitourinary disorders, body mass index > 35 kg/m² and bilateral inguinal hernia was excluded from the study. Afterwards, they underwent an orthopedic consultation to exclude co-existing bone and joint disorders such as hip osteoarthritis, femoral head osteonecrosis, osteomalacia and osteoporosis, impact fractures, joint infections and synovial inflammations, collagen vascular disease and so on.

All 367 remaining patients with unilateral primary inguinal hernia who were scheduled for herniorrhaphy received complete information about the two operation methods and were asked to sign a consent form. However, only 322 patients signed it and became the participants of this study. From among them, 158 and 164 participants underwent mesh and non-mesh suture techniques, respectively. Three surgeons operated them using the Bassini-McVay method, by nylon-0 suture material (Iran-SUPA) in a standard manner for non-meshed group and 6×11 centimeter prolyn mesh (France-Cousin) for meshed group.

The participants were followed up for one to five years after surgery (mean, 2.9 years). They were visited in a clinic about one week, one month, and one to five years later by another surgeon who did not know the type of operation. Each time, the wound infection, weakness of abdominal walls, swelling of hernia site, and prominent recurrence were evaluated. They underwent ultrasonography for detection of recurrence. Also demographic characteristics, hospital

stay time, type and duration of antibiotic therapy, foreign body sensation and the time of return to daily activities were recorded in previously prepared questionnaire.

Statistical Analysis

Normal distribution of samples was examined by Kolmogorov Smirnov test. Student's *t*-test and Mann-Whitney *U* test were used for continuous variables and χ^2 test for categorical variables. The percentages were compared by means of Fisher's exact test. These statistical tests were two-sided and were considered significant if *P* value was equal or less than 0.05. All statistical analyses were performed using Statistical Package for Social Sciences (SPSS) software version 15.

RESULTS

In this study, 322 patients were randomized into two groups: 158 participants (0.49%) in mesh and 164 participants (51%) in non-mesh repair groups. Lichtenstein surgical technique was used for the mesh group and Bassini-McVay for non-mesh suture group. Twelve (7.6%) participants from the mesh and seven (4.3%) participants from the non-mesh group were excluded from the study during the follow up because of withdrawal of consent, change of address and death.

So, 146 participants (127 men and 19 women) in mesh group and 157 participants (130 men and 27 women) in non-mesh suture group were followed up. Mean age was 50.9 years old for mesh group and 46.6 years old for non-mesh group. The hospital staying time for the two groups was 3.6 and 3.4 days, respectively. Mean follow up time was 35 months (2.9 years) ranging from 12.3 to 60.2 months (1-5 years). Foreign body sensation existed in 49 participants (33.6%) of mesh group and three participants (2%) of non-mesh group.

Infection rate was 3.4% (five participants) in mesh and 2.5% (four participants) in sutured group. 87 participants (59.6%) of mesh group and 121 participants (77.1%) of non-mesh group returned to normal daily activities in seven days after surgery. Hematoma was seen in 2.7% and 3.2% of the participants and testis swelling was detected in 1.4% and 1.3% of the participants of mesh and non-mesh groups, respectively. Post-operative chronic pain was 9.6% (14 participants) in mesh and 1.9% (three participants) in non-mesh groups, respectively. Recurrence was detected in two participants (1.4%) of mesh and 21 participants (13.4%) of non-mesh suture groups.

Statistical analysis showed no significant difference regarding demographic variables, loss of patients to follow up, hospital stay time, testis swelling, hematoma

and wound infection rate in the two groups. However, established significant difference for a less chronic pain, less foreign body sensation and higher rate of return to daily activities was in favor of non-mesh group compared to a less recurrent rate in mesh group ($P = .0063$).

DISCUSSION

Although nowadays herniorrhaphy with mesh technique is a standard method in groin hernia repair, is an easy surgical technique to learn, and has few complications,²⁶ surgical method of suturing without mesh, however, has been used by surgeons for a long time with wide acceptance. The mesh method was accepted with some hardships because of hesitation of many surgeons about implanted artificial material.

Today, long-term studies have confirmed the safety of mesh method of repair. When a polypropylene mesh was used in the Lichtenstein technique, the risk of infections came down. Now polypropylene meshes are implanted without any severe complications such as rejection or cancer induction. Also, the emergence of minimally invasive procedures (either transabdominal, preperitoneal or extraperitoneal approaches) has helped to create confidence in the implanted mesh, so that today the Lichtenstein technique is a valuable alternative for a patient suffering from primary inguinal hernia.

On the other hand, there is another technique known as the Shouldice technique, which is free of any foreign material and is the standard in some hospitals. This randomized prospective clinical trial set out to find out which of these two techniques are more efficient. The Lichtenstein technique requires a simple, less accurate preparation of the inguinal canal (no need to open the fascia transversalis) and is therefore performed faster than the Shouldice procedure. This explains the slightly shorter operation time in the mesh group.

In this investigation, immediate and early complications such as infection, hematoma, testis swelling and hospital stay time were almost equal in the two groups, compared with a British hernia surgery study results. They had reported 2% hematoma, 1.3% infection needing antibacterial drugs and 1% testicular swelling.²⁷ In another study, infection and hematoma were reported to be 3.3% and 1.1% in non-mesh technique using two layer suturing method with non-absorbable thread.²⁸ Infection rate in a study was less than 1% in mesh method.²⁹

The subcutaneous wound infection in the mesh group was treated without any further problems. The wound was reopened, washed out and a small drain placed before it was closed again. In all cases the mesh was not removed

and there was no need to reopen the external aponeurosis. The participants had antibiotics for 7-10 days. The monofilamented polypropylene mesh had an ideal pore size (larger than 75 nm) and was therefore resistant to infections. Bacteria cannot hide in the intermediate space of the mesh because the space size allows the entrance of the bigger neutrophilic granulocytes (10-15 nm). Slight increase of infection in our report may be due to poor patient hygiene conditions which many of them were soldiers.

In a study by Hertz and colleagues, mean hospital stay time was 3.5 days in mesh and 3 days in non-mesh group.³⁰ In other reports it has been one to three days.²⁶ The results of these reports are consistent with our results. In our study it was impossible to discharge the participants sooner, because of far distance of their home towns.

Hernia repair results are usually analyzed due to recurrence rate and chronic post-operative pain. Bisgaard and colleagues found these to be equal in their two groups. However, preference was with mesh technique.³¹ Recurrence rate in several investigations was reported from zero to 1.3%, using Lichtenstein mesh method.²⁹ It is noticeable that recurrence may take place after many years post-operatively with or without mesh, until 10 years, and thus, may be underestimated.³²⁻³³ So, these low recurrence rates may be due to insufficient follow up time, like our study, requiring longer follow up time for more exact results.

CONCLUSION

Considering the post-operative complications of this study compared to the literature, there were almost equal or more desirable results in non-mesh group, especially in case of less chronic pain and foreign body sensation. Of course, there was a higher rate of recurrence in this group which requires more follow up time to be confirmed. Although most authors have preferred to use mesh, the sutured technique still has its own place in groin surgery.

There are different economic, geographic and political variables in some countries for using some devices in surgery. The cost and availability of certain devices like mesh can be a problem. Thus, it can be wise to preserve the method of using mesh for attenuated fascia wall, previous unsuccessful contralateral hernia repair or recurrences.

It is suggested that the sutured technique be used in case of need. It is also reasonable to check the post-operative infection rates in such studies. Long-term post-surgery follow-ups are recommended for the future investigations.

CONFLICT OF INTEREST

None declared.

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