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Original Article

Short-term outcomes of inguinal hernia Liechtenstein repair by using self-fixing progrip mesh in comparison with sutured prolene mesh: a clinical trial study

Amin Gorjizadeh[1], Yasser Asghari[2], Sekineh Kamali Ahangar[3], Ali Zahedian[2]

[1] General Surgeon, Student Research Committee, Babol University of Medical Science, Babol, Iran
[2] Assistant Professor Department of Surgery, School of Medicine, Babol University of Medical Sciences, Babol, Iran
[3] Expert Clinical Research Development Center, Shahid Beheshti Hospital, Babol University of Medical Sciences, Babol, Iran

Corresponding Author:
Tel: +98 9126331766
Email: bcrdc90@yahoo.com

Abstract

Introduction: Due to the high prevalence of inguinal hernia surgery and its impact on quality of life and workforce, it is necessary to find a method with the least complication and recurrence. Since the use of the progrip mesh clearly reduces the operating time and surgical site manipulation, it seems to be a good treatment option.

Methods: This clinical trial study was performed on 80 patients with inguinal hernia repair candidates admitted to Beheshti and Rohani Hospitals in Babol, Iran. The patients were randomly divided into two groups. In the first group, the repair was done with progrip mesh, and in the second group, the prolene was restored. 4,8 and 12 hours after the operation, a checklist pain score based on VAS and EQ-5D-3L questionnaire was completed before surgery, 6 to 12 hours after surgery, and 24 hours after surgery for each patient. Data was analyzed using Chi-square, T-test, and the Mann-Whitney test. A significance level of (0.05) was considered.

Results: The mean duration of operation in the progrip group was(31.15 ± 9.35)minutes and in the prolene group was(9.53 ±14.46) minutes, which was significantly shorter in the progrip group(p=0.048). Complications of surgery were not reported in any of the patients. The mean of pain intensity 4 hours after surgery in the progrip group was(5.04 ±1.05) and in the prolene group was(5.50 ±1.24), which was significantly lower in the progrip mesh group(p=0.048). The mean pain intensity was 8 hours(5.25 ±0.81versus 5.83±1.37)and was significantly lower in the progrip group(p=0.024). Also within 12 hours after was (3.38±1.23 versus 4.20±1.34) significantly lower in the progrip group(p=0.005).

Conclusion: Based on the results of this study, the use of progrip mesh is associated with shortening the duration of the surgery and also reducing pain in postoperative patients.

Keywords: Inguinal Hernia, Progrip Mesh, Prolene Mesh

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Introduction

Inguinal hernia repair is one of the most common surgical procedures in the general surgery. About 700,000 hernia repair surgery is performed annually, which, in addition to imposing medical expenses, will result in the absence of labor and discomfort following surgery and complications. Therefore more definitive treatment, with less complications and more efficacy has to be selected (1).

During the last two decades, using the Liechtenstein (tension-free) method, the results of the hernia surgery were clearly improved so the use of this method is considered as the first choice in many centers. In this method, a prolene mesh is used to strengthen the transversalis muscle fascia (2,3).

using the Liechtenstein method has many benefits such as reducing costs, the rate of relapse, and reducing postoperation discomfort (4,5). The complications of open techniques include longer postoperative recovery and the incidence of chronic pain and the Chronic pain may cause a patient's disability or reduce his quality of life (6). In a study in Sweden, about one-third of patients experienced chronic pain remaining up to(3-5) years after surgery (7,8).

some reported having chronic pain that disrupts their daily routine (9).

The cause of the groin pain after the surgery remains unknown. But it seems to be relevant to the technique of surgery, such as the degree of damage to the nerves, the mesh, and the fixation method (4,10). The use of heavy-weight prolene mesh has been shown to trigger an inflammatory reaction that, after the development of the scar, causes mesh retention (11).

Therefore, it is recommended to use low-weight mesh (12,13).

Progrip mesh, which does not require additional intervention to fix the mesh was introduced to limit the fixation, and itself leads to a reduction in the operating time and the amount of manipulation of the site Progrip mesh is available for use in incisional and inguinal hernia by open and laparoscopic methods.

In the studies, the amount of pain and infection after the operation with the progrip mesh was less, as well as the patient's satisfaction By the novelty of this method, further studies in different populations can help to improve it.

Therefore, the purpose of this study was to evaluate the patient's satisfaction after inguinal hernia repair with progrip mesh, as well as compare complications such as pain, infection, etc. with prolene mesh and suture.

Material and Methods

In this clinical trial study, 80 patients with inguinal hernia candidates for surgery who were referred to Shahid Beheshti and Ayatollah Rouhani Hospitals in Babol in the years 2016 and 2017 were enrolled. (Consort flow diagram 1).

written informed consent was obtained from all patients after explaining the goals of the research.

Then, patients were randomly divided into two treatment groups. In the first group, the hernia was repaired using progrip mesh, and in the second group using prolene mesh with suture.

4, 8, and 12 hours after the operation, a list of complications including postoperative complications and visual analog scale (VAS) was completed for all patients. EQ-5D-3L questionnaire was completed before surgery, 6-12, and 24 hours after surgery for each patient.

This study was approved by the Ethics Committee of the Babol University of Medical Sciences with the code MUBABOL.REC.1395.197 and has been registered as a clinical trial study with the code IRCT20171213037857N1.

Information was collected in a completely private environment and in all stages it was used only for the purposes of the study and kept its secret nature. The data are then coded and entered into SPSS (Version. 21) statistical software.

The chi-square test was used for qualitative data. To compare the quantitative variables in two groups, T-test was used if the distribution was normal, and the Mann-Whitney test was used if the normality was rejected. A significance level of 0.05 was considered.

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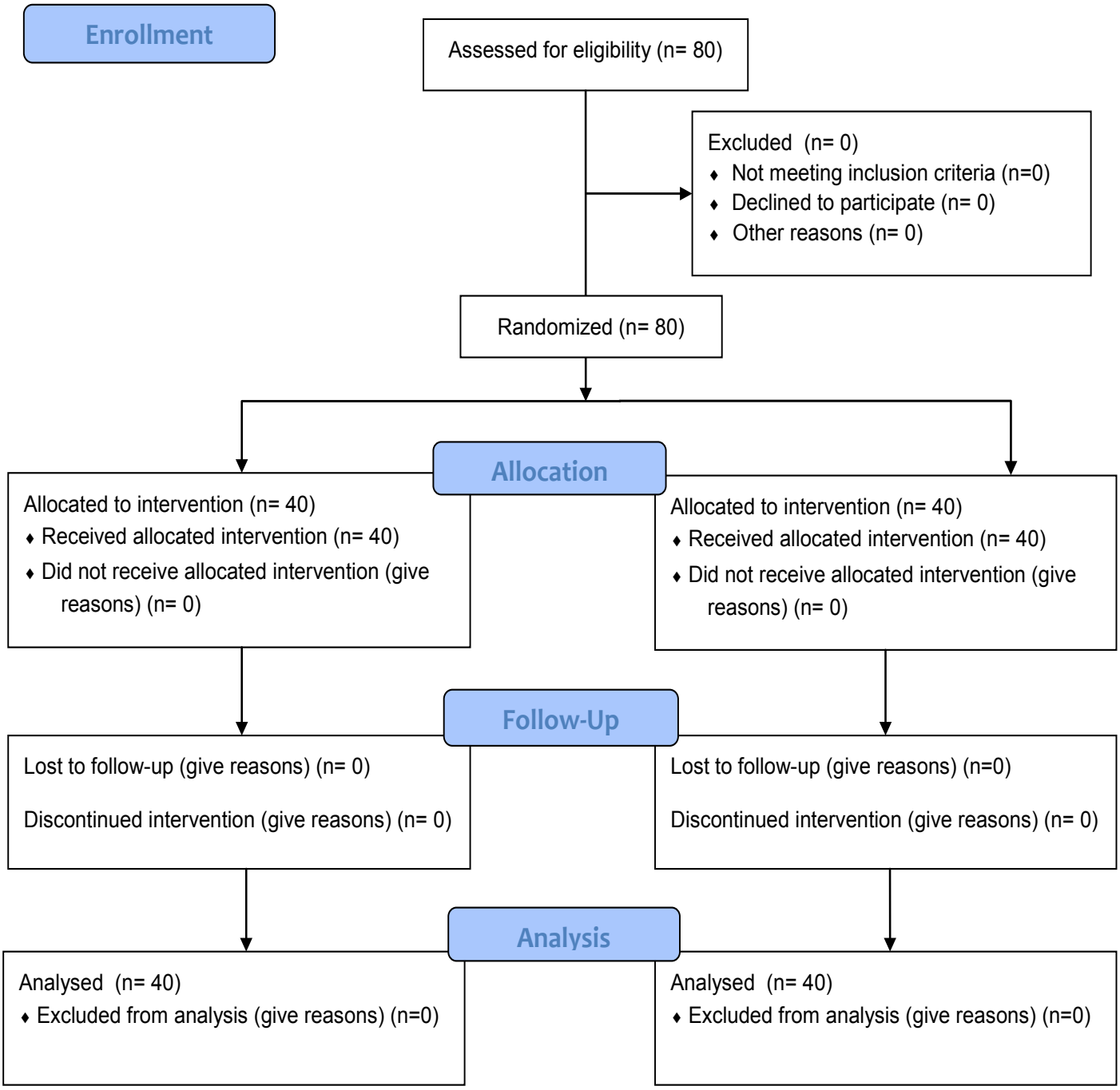

CONSORT 2010 Flow Diagram

Results

The average age of the studied patients was 52.82 ± 18.15 and the age range was 17 to 84 years. The mean age of the patients in the progrip group was 50.87 ± 17.26 and the prolene group was 55.15 ± 19.24 years, which the age difference was not significant (p=0.592). All patients were male. Sixteen (20%) of the patients had cigarette smoking, of which 9 patients (22.5%) were in the progrip group and 7 (17.5%) in the prolene group (p = 0.842). Also, 4 patients (10.0%) had opium use, of which 3 (7.5%) were in the progrip group and one in the prolene group. Five patients (6.3%) had a family history of hernia, of which 3 (7.5%) were in the progrip group and 2 (5.0%) were in the prolene group. The most common underlying disease was hypertension in 22 patients (27.5%) of patients. In terms of the frequency of various underlying diseases, the two treatment groups did not have significant differences. The mean Body Mass Index (BMI) in the patients was (24.23 ± 1.98

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kg/m2). The mean BMI of the progrip group was (24.23 ± 2.14 kg/m2) and (24.24 ± 1.84 kg/m2) in the prolene group, which was not significantly different between the two groups (p = 0.561). Anesthesia was spinal in all patients.The mean duration of operation in the progrip group was (31.15 ± 9.35 minutes) and in the prolene group was (49.53 ± 14.46 minutes), which was significantly shorter in the progrip group (p=0.048). Postoperation complications were not reported in any of the patients. In Table 1, the severity of pain was shown based on VAS criteria (4, 8, and 12 hours) after surgery. The mean of pain intensity four hours after surgery was (5.04 ± 1.05) in the progrip group and (5.50 ± 1.24) in the prolene group, which was significantly lower in the progrip group. The mean pain intensity 8 hours after surgery was significantly lower in the progrip mesh group, so in the progrip group it was (5.25 ± 0.81) and in the proline, the group was (5.83 ± 1.37). Also, the mean pain intensity (12 hours) after surgery was significantly lower in the progrip mesh group (3.38 ± 1.23 in the progrip group and 4.20 ± 1.34 in the proline group). The severity of pain one month after surgery was also investigated. The mean of pain intensity one month after surgery was significantly lower in the progrip mesh group so in the progrip group it was (1.95 ± 1.01) and in the prolene group (2.75 ± 1.49). Before surgery, the two treatment groups did not have a significant difference in any of the five dimensions of the EQ-5D-3L questionnaire, including mobility, personal care, normal activities, pain or discomfort, and anxiety or depression (p>0.05) (Table 2).

Table 1: The mean pain severity based on VAS, 4, 8 and 12 hours after surgery in progrip and prolene groups

	Progrip group	Prolene group	p-value
4 hours postoperation	5.04±1.05	5.50±1.24	0.048
8 hours postoperation	5.25±0.81	5.83±1.37	0.024
12 hours postoperation	3.38±1.23	4.20±1.34	0.005
One month postoperation	1.95±1.01	2.75±1.49	0.006

Table 2: Comparison of five dimensions of EQ-5D-3L questionnaire before surgery in two groups

		Progrip group N (%)	Prolene group N (%)	p-value
mobility	Level 1	35 (87.5)	34 (85)	0.657
	Level 2	5 (12.5)	6 (15)	
	Level 3	0 (0)	0 (0)	
Self care	Level 1	40 (100)	40 (100)	1.000
	Level 2	0 (0)	0 (0)	
	Level 3	0 (0)	0 (0)	
Usual activities	Level 1	24 (60)	27 (67.5)	0.483
	Level 2	16 (40)	13 (32.5)	
	Level 3	0 (0)	0 (0)	
Pain / discomfort	Level 1	21 (52.5)	20 (50)	0.881
	Level 2	19 (47.5)	20 (50)	
	Level 3	0 (0)	0 (0)	
Anxiety / depression	Level 1	31 (77.5)	26 (65)	0.214
	Level 2	7 (17.5)	13 (32.5)	
	Level 3	2 (5)	1 (2.5)	

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6 to 12 hours after surgery, pain/discomfort (p=0.014) and anxiety/depression (p=0.023) criteria were significantly lower in progrip group in Table 3. 24 hours after surgery, the two groups had only a difference in pain/discomfort score (p=0.002), which was significantly lower in the progrip group in Table 4.

Table 3: Comparison of five dimensions of EQ-5D-3L questionnaire 6-12 hours postoperation in two groups

		Progrip group N (%)	Prolene group N (%)	p-value
Mobility	Level 1	11 (27.5)	12 (30)	0.185
	Level 2	29 (72.5)	24 (60)	
	Level 3	0 (0)	4 (10)	
Self care	Level 1	18 (45)	19 (47.5)	0.519
	Level 2	22 (55)	21 (52.5)	
	Level 3	0 (0)	0 (0)	
Usual activities	Level 1	4 (10)	3 (7.5)	0.337
	Level 2	36 (90)	33 (82.5)	
	Level 3	0 (0)	4 (10)	
Pain / Discomfort	Level 1	37 (92.5)	33 (82.5)	0.014
	Level 2	3 (7.5)	7 (17.5)	
	Level 3	0 (0)	0 (0)	
Anxiety / Depression	Level 1	20 (50)	21 (52.5)	0.023
	Level 2	18 (45)	14 (35)	
	Level 3	2 (5)	5 (12.5)	

Table 4: Comparison of five dimensions of EQ-5D-3L questionnaire 24 hours postoperation in two groups

		Progrip group N (%)	Prolene group N (%)	p-value
mobility	Level 1	28 (70)	25 (62.5)	0.491
	Level 2	12 (30)	11 (27.5)	
	Level 3	0 (0)	4 (10)	
Self care	Level 1	29 (72.5)	30 (75)	0.843
	Level 2	11 (27.5)	10 (25)	
	Level 3	0 (0)	0 (0)	
Usual activities	Level 1	24 (60)	20 (50)	0.537
	Level 2	16 (40)	16 (40)	
	Level 3	0 (0)	4 (10)	
Pain / discomfort	Level 1	16 (40)	12 (30)	0.002
	Level 2	24 (60)	23 (57.5)	
	Level 3	0 (0)	5 (12.5)	
Anxiety / depression	Level 1	34 (85)	33 (82.5)	0.442
	Level 2	6 (15)	7 (17.5)	
	Level 3	0 (0)	0 (0)	

Discussion

For more than a century, Open herniorrhaphy is the golden standard of inguinal hernia repair. With the surgical techniques improvement, the Lichtenstein method was simplified in learning, fewer complications and lower recurrence rates were acceptable (16). Although by laparoscopic methods, bilateral hernia repair or recurrent inguinal

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hernia repair using transperitoneal and preperitoneal laparoscopic repair is very beneficial(17). Open surgery continues to play a key role in patients who are not fit for general anesthesia or patients with a history of abdominal surgery. It has been reported that inguinal hernia is associated with chronic pain and illness that affects the patient's quality of life after surgery (18). It has been shown in studies that the use of lightweight mesh has no effect on postoperative pain in these patients (19). Other option that is used to strengthen the inguinal anterior wall these days is absorbing mesh. Some studies reported that these mesh are associated with less pain and discomfort after surgery (20). But these results were not confirmed in some other studies (21).

In this study, progrip mesh with prolene mesh was compared in patients undergoing open inguinal hernioplasty. The duration of surgery in the progrip group was significantly shorter than in the prolene group. The results are consistent with two meta-analysis(22, 23). Fan et al clinical trial also reported similar results to our study (24). Performing surgery faster will improve the allocation of financial resources, and manpower, and reduce the waiting time for patients to undergo surgery (25). No postoperative complications were reported in the patients. Therefore, the two groups of progrip and prolene had no significant difference in complications of surgery. In the study of Zhang et al in China, there was no significant difference in the postoperative complications in the two groups of progrip mesh and prolene mesh, and only the surgical time in the progrip mesh group was shorter (26). Based on the results of our study, postoperative pain in the progrip group was significantly lower than in the prolene group. Also, evaluation of (5 dimensions) of (EQ-5D-3L) questionnaire (mobility, personal care, normal activities, pain or discomfort, and anxiety or depression) in these two groups showed that after the operation, pain or discomfort in the progrip group was significantly lower In the Chastan study, the pain of Inguinal hernia patients who were operated on by the Liechtenstein method and with progrip mesh was measured using VAS. The result of this study showed that the use of progrip mesh could be a good solution for post-operative pain in Inguinal hernia (27). Similar to our study, in the Kapischke study, on the first day after the operation, the progrip mesh group has significantly less pain than the prolene mesh group (28). In a study by Kingsnorth et al., the effect of Surgery with Progrip mesh and Suture Prolene mesh by the Liechtenstein method has been compared in surgical repaired hernia patients. The duration of surgery, immediate pain after surgery, and wound infection in the progrip mesh group was significantly lower (4). In Sander et al., a study in the UK, (270 patients) with progrip mesh and (287 patients) with prolene mesh underwent inguinal hernia surgery. Postoperative pain was lower in the progrip mesh group (29). In a study by Porrero et al. In Spain, 89 patients with bilateral inguinal hernia were randomly assigned to one side of the progrip mesh and on the other side of the prolene mesh using the Liechtenstein method, underwent a surgical repair of the hernia. The pain was immediately lower in the place where the progrip mesh was used (30). unlike our study, in Pierides et al., study, Which compared the Lichtenstein-treated hernia with prolene mesh and suturing with progrip mesh, pain in patients during the first two weeks after surgery was not different (31).

Pain is a common complication after inguinal hernia repair and its maximum intensity is on the first postoperation day, which decreases over time and lasts for up to four weeks in (11% of patients). Pain after inguinal hernia repair occurs in both acute and chronic forms as well as somatic, visceral, and neuropathic pain (23). These pain affect the quality of life of patients. The most common mechanism of pain is somatic pain, which is often due to injuries and inflammation of the muscles and ligaments. Neuropathic pain is caused due to direct damage to the nerve or its trapping. It is usually localized and can be early or late. Most cases of neurological damage occur following traumatic dislocation or stitch mesh fixation (29). Despite the anatomical differences in the inguinal area in various people, nerve involvement occurs in (70 to 90% of patients) during surgery. Moderate to severe postoperative pain in (6 to 8 percent) of patients can affect physical

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activity, social interactions, health care, quality of work, and other things in a person's life (32). Clinical manifestations of nerve trapping are similar to acute neuropathic pain and within the innervation of that particular nerve (29). pubis osteitis due to inflammation of the symphyses of pubis is another cause of postoperative pain in the inguinal hernia that occurs due to involvement of the bone priost during stitching mesh which may lead to chronic debilitating pain and even lead to bone resection or curettage (19).

In hernioplasty using a progrip mesh, due to the lack of suture in the fixation, there is no chance of trapping the nerves in the sutures or pubis osteitis (33).

The main limitation that we face in this study and similar studies is the impossibility of increasing the duration of patient follow-up (for example, 5-year follow-up), and access to a larger sample size to achieve more accurate results is also a concern.

Conclusion

Based on the results of this study, the use of progrip mesh reduces the duration of surgery and also pain in postoperative patients. Also, patients who suffer from pain in the inguinal hernia repair on one side may use this method more confidently to repair the hernia on the other side.

The sample size of this study is one of its limitations. Although, the use of progrip mesh clearly reduces postoperative pain in many studies, but comprehensive studies with high sample sizes require more accurate results and economic and health benefits of this method. Also, in this study, long-term complications, chronic pain, and relapse were not investigated, and only acute pain and short-term complications were evaluated.

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Conflict of interests

None declared.

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