Comparison of Results of Surgical Treatments of Primary Inguinal Hernia with Flat Polypropylene Mesh and Three-Dimensional Prolene (Phs) Mesh – One Year Follow Up

Nikica Šutalo¹, Anton Maričić², Davor Kozomara¹, Ante Kvesić¹, Hrvoje Štalekar³, Zoran Trninić¹ and Zdravko Kuzman⁴

- ¹ Department of General Surgery, University Hospital Mostar, Mostar, Bosnia and Herzegovina
- ² Department of Urology, University Hospital Center Rijeka, Rijeka, Croatia
- ³ Department of Surgery, University Hospital Center Rijeka, Rijeka, Croatia
- ⁴ Department of Pediatrics, University Hospital Mostar, Mostar, Bosnia and Herzegovina

ABSTRACT

The aim of this study was to compare the results of the surgery of inguinal hernias using flat polypropylene mesh and three-dimensional prolene (PHS) mesh. The study included two groups of 40 male patients, aged 18–50 years, with the diagnosis of inguinal hernia. One group was operated with a flat polypropylene mesh, while the second group was operated with three-dimensional prolene (PHS) mesh. The study has shown that the operation with three-dimensional prolene mesh lasted 15 minutes longer and that the patients had stronger inflammatory response. Statistically, there was no significant difference in post-operative pain intensity, post-operative use of analgesics, length of hospitalization, return to daily activities, early and late post-operative complications. No recurrence was registered in any of the groups. The analysis of results indicates that there is no difference in treatment of inguinal hernia with flat polypropylene and three-dimensional prolene (PHS) mesh.

Key words: inguinal hernia, tension-free hernioplasty, flat polypropylene mesh, three-dimensional prolene, PHS mesh

Introduction

Inguinal hernia is the most common surgery in the domain of general surgeons, and it may be considered as a substantial health and social problem. Out of the total number of surgical procedures on the abdomen, around 15% are the operations of inguinal hernia¹. Surgical treatment of inguinal hernia, hernioplasty or herniorrhaphy has been changing from »tension« repair to modern »tension-free« repair.

Common to all »tension« repairs with the open approach is the use of the only available muscular and fascial anatomical structures of the inguinal region to close the hernia opening. Basic disadvantages of this technique are strong post-operative pain and high recurrence rate, up to 10% according to various reports^{2,3}.

Tension-free repair of inguinal hernia uses various prostheses or implants materials, to fill or cover the hernia opening, and thus prevents herniation. Modern treatment using this method starts with development of prosthetics biocompatible mesh made from polypropylene monofilament, which is placed on the back wall of the inguinal canal, and fixed on the surrounding structures^{4,5}. The main advantages of these methods are less post-operative pain, faster recovery, and a significantly smaller recurrence rate, up to 2%. The deficiencies are the possibility of infection and rejection of the mesh⁶. Step forward in tension-free repair of the inguinal hernia is a three-dimensional prolene mesh, known as Prolene hernia system (PHS). It unites three meshes in one. The

Received for publication March 18, 2009

lower layer implanted in the myopectinal area, the upper layer which is implanted on the floor of the inguinal canal and connector or a cylinder, which connects them through the hernia opening^{7,8}. The proposed method of treatment today is considered to be a method of choice and recommended as a gold standard in treatment of inguinal hernia⁹.

Materials and Methods

The study included 80 patients diagnosed with primary inguinal hernia, aged 18–50 years, classified as ASA I according to anesthesiologists' primary check-up, who underwent surgery in the period from July 2006 to January 2007 in the elective program of the Clinic for General Surgery, University Hospital Mostar. The diagnoses were made by clinical examination. Patients with recurrence or incarcerated inguinal hernia were not included in the study. All patients were operated on under the same conditions and under endotracheal anesthesia. Post-operatively, all of them were treated with antibiotics (Garamycin 80 mg, Metronidasol-Effloran 500 mg iv. in bolus dose), and analgesics as *per* scheme (Diclofenac-natrium,Voltaren-75 mg amp and then Diclofenac-natrium 50 mg tbl. *per* person if needed *per* os).

Patients were randomized into two groups of 40. One group was operated using flat polypropylene mesh and another using three-dimensional prolene (PHS) mesh; manufacturer is Ethicon inc-USA. Analyzed variables included demographic characteristics, position and types of inguinal hernia, duration of surgery in minutes, invasion of the operating methods measured in values of C-reactive protein (CRP), strength of postoperative pain measured by visual analogue pain scale, consumption of analgesics during hospitalization, duration of hospitalization, time required to return to everyday activities, early and late post-operative complications and recurrence. Monitored parameters were measured during hospitalization and at the check-up examinations which were done 7, 15 and 30 days, three, six months and one year after operation.

Statistical analysis

All data were entered in the computer data base, and they were processed by using the statistical program package Statistica 6.0 StatSoft.Inc,Tulsa, SAD. For the comparison of the values for individual groups of patients we used: Student-T test, Mann Witney U test, and X test. The results on the level p<0.05 were considered statistically significant.

Results

In the period July 2006 – January 2007, 80 patients with primary inguinal hernia underwent surgical treatment. They were randomized into two groups of 40. One group was operated by using flat polypropylene mesh, and the other group was operated by using three-dimensional prolene (PHS) mesh. According to the demographic characteristics in both groups, most of the operated patients were aged between 21 and 40. In the group with flat polypropylene mesh there were 30 (75%) patients of this age, and in the group with three-dimensional prolene (PHS) mesh there were 28 patients (70%).

There was no statistically significant difference in groups of patients, the side and the type of hernias (Table 1). Table 2 shows the duration of the surgical treatment in relation to the type of implanted mesh. The average duration of the surgical treatment with flat polypropylene mesh was 15.5 minutes shorter in comparison with the treatment with three-dimensional prolene (PHS) mesh, which points out to a statistically significant difference. Table 3 shows the values of C-reactive protein (CRP) in different time stages of the surgical treatment. The values of CRP were statistically significantly lower in the

		Mesh		
		Flat (n=40)	PHS (n=40)	
Age (year)				
Groups n (%)	≤20	0	1	
	21-30	14 (35)	15 (37.5)	
	31-40	16 (40)	13 (32.5)	
	41-50	10 (25)	11 (27.5)	
	$\overline{\mathrm{X}}\pm\mathrm{SD}$	$34.9{\pm}7.7$	33.8 ± 8.0	t=0.664; p=0.509*
The side of hernia n (%)	Right	22 (55)	20 (50)	$\chi^2 = 0.2; p = 0.654^{\dagger}$
	Left	18 (45)	20 (50)	
The type of hernia n (%)	Indirect	23 (57.5)	24 (60)	$\chi^2 = 7.2; p = 0.027^{\dagger}$
	Direct	14 (35)	11 (27,5)	
	Combination	3 (7.5)	5 (12.5)	

 TABLE 1

 DISTRIBUTION ACCORDING TO PATIENT'S AGE, SIDE AND TYPES OF HERNIA

* t-test; † χ^2 -test

TABLE 2DURATION OF OPERATION					
Mesh					
		Flat (n=40)	PHS (n=40)		
(min)	$\overline{X} \pm SD$	45.4 ± 8.1	60.9±6.8	t=9.3; p<0.001*	
*t-test					

group operated with flat polypropylene mesh after 48 hours (18.6), while in the group operated with three-dimensional prolene (PHS) mesh they were 34.8. (p=0.001).

The intensity of postoperative pain measured by visual analog pain scale, post-operative use of analgesics, postoperative hospitalization, as well as time needed for rehabilitation for everyday activities did not show any decisive statistical difference between two groups. Table 4 shows the early postoperative complications, registered during hospitalization. It is evident that in the group treated with flat polypropylene mesh 37 (92.5%) patients had no complications; only two wound seromas, and one wound infection were registered, in total 7.5%.

In the group treated with three-dimensional prolene (PHS) mesh one scrotum hematoma, two wound seromas and two wound infections were registered, in total 12.5%, while 35 (87.5%) patients had no complications. Table 5 shows late postoperative complications. This table shows that there is no statistically significant difference between two groups concerning the loss of sensation, pain and discomfort in inguinal region at rest and at physical activity which were monitored 1, 3, 6 and 12 months after the surgery. The incidence of recurrence was not registered in the period of one year after the surgical treatment in either of the groups.

Discussion

The surgical treatment of inguinal hernia with non--tension technique is safe, simple and convenient method of treatment for both surgeon and patient. The duration of the surgical treatment, little postoperative pain, quick recovery and return to every day activities as well as small percentage of recurrence are the main characteris-

 TABLE 4

 INCIDENCE OF EARLY POSTOPERATION COMPLICATIONS

 DURING HOSPITALIZATION

		Mesh		
		Flat (n=40)	PHS $(n=40)$	
Complica- tion n(%)	Wound infection	1 (2.5)	2 (5.0)	
	Seroma	2(5.0)	2 (5.0)	
	Hematoma	0	1(2.5)	
	Without complications	37 (92.5)	35 (87.5)	

tics of non-tension surgical treatment method of groin hernia, and therefore it has the advantage over other methods¹⁰⁻¹².

Certain qualities of the meshes as the type of biomaterial, the weight of the mesh, the width of the pores, weaving construction in three surfaces and so on can significantly influence the postoperative pain intensity, the intensity of post-inflammatory reaction, the speed of recovery and the return to every day activities as well as the overall success of the surgical treatment^{13,14}.

In the prospective research carried out on our clinic two implants used in the treatment of inguinal hernia were analyzed in order to recommend one as the optimal choice. They differentiate in the construction, weight, width of pores and weaving. Regarding the age of the patients included in study it is evident that there was not any statistically significant difference between groups. In both groups most of the operated patients were aged between 21 and 40.

The average duration of the operation with flat polypropylene mesh was 15.5 minutes shorter compared to the operation with three-dimensional prolene (PHS) mesh, and here is a statistically significant difference. Such difference in surgical treatments' duration was understandable due to the necessity to place the underlying patch subfascially in the myopectinal area, as well as to place correctly the connector of three-dimensional prolene mesh in hernia opening.

The research has shown that three-dimensional prolene (PHS) mesh provokes more intense inflammatory reaction than flat polypropylene mesh, and the statisti-

TABLE 3

THE PRESENTATIONS OF C- REACTIVE PROTEIN IN BLOOD OF PATIENTS WITH REGARD TO THE TIME OF TESTING AND THE TYPE OF MESH

	Mesh					
Variable	The time of testing	Flat (n=40)	PHS (n=40)			
CRP (mg/L)	Before operation	0.45 (0-5.7)	0.4 (0.1–2)	Z=0.64; p=0.525‡		
	The end of operation	1 (0.2–5.9)	0.65 (0.2-2.3)	Z=1.75; p=0.081‡		
	4 hours after operation	1.6 (0.2-10.8)	0.9 (0.4–4.8)	Z=1.93; p=0.053‡		
	24 hours after operation	11 (1.8-47.5)	$14.8 \ (4.6-66.5)$	Z=1.48; p=0.138‡		
	48 hours after operation	18.6 (8-56.7)	$34.8 \ (8.5-107.4)$	Z=03.8; p<0.001‡		

‡ Mann-Whitney test

			Mark			DUG	Mal	
COMPLICATIONS -	FIAT Mesn			PHS Mesh				
COMI LICATIONS	$1 \mathrm{M}$	3 M	6 M	$12 \mathrm{M}$	$1 \mathrm{M}$	3 M	6 M	$12 \mathrm{M}$
Sensory loss	11	7	1	0	12	8	2	1
The pain and numbness at rest	6	4	0	0	7	4	0	0
The pain and numbness during physical activity	7	3	0	0	9	6	1	0
Recurrence	-	-	-	-	-	-	-	-

 $\begin{array}{c} \textbf{TABLE 5} \\ \textbf{INCIDENCE OF LATE POSTOPERATION COMPLICATIONS <1 YEAR} \end{array}$

M - month

cally significant difference between the groups appears 48 hours after the treatment. Surgical treatment of inguinal hernia with three-dimensional prolene (PHS) mesh is more invasive, and the mesh has larger surface and weight than flat polypropylene mesh and after the operation the reaction of the organism to the implanted material is more intense than with flat polypropylene mesh.

Regardless of the invasiveness of the surgical technique, there is not any statistically significant difference between the groups in the intensity of the postoperative pain as well as in the amount of the postoperative analgesics. Also, there is no statistically significant difference in the duration of hospitalization and time of the return to every day social activites. The most important criterion for the evaluation of the method is the incidence of postoperative complications, including the sensation loss, pain and discomfort in inguinal region at rest and at physical activity, as well as the recurrence^{15,16}.

REFERENCES

1. RUTKOW IM, Surg Clin North Am, 78 (1998) 941. — 2. READ RC, McLEOD MS, Arch Surg, 16 (1981) 440. — 3. BENDAVID R, World J Surg, 13 (1989) 522. — 4. USHER FC, Surg Gynecol Obstet, 117 (1963) 139. — 5. LICHTENSTEIN IL, SHULMANN AG, AMID PK, MONTLLOR M, Am J Surg, 157 (1989) 188. — 6. AMID PK, SCHULMANN AG, LICH-TENSTEIN IL, Int Surg, 79 (1994) 76. — 7. FLAMENT JB, DELATTRE JF, AVISSE C, BURDE A, CONCE JP, Hernia, 2 (1998) 50. — 8. GIL-BERT AJ, GRAHAM MF, VOIGHT WJ, Hernia, 3 (1999) 161. — 9. FOR-TE A, D'URSO A, PALUMBO P, LO'STATO G, GALLINARO E, BEZZI

N. Šutalo

Kneza Višeslava 20b, 88000 Mostar, Bosnia and Herzegovina e-mail: nikica.sutalo@tel.net.ba

Our material shows no statistically significant difference. The registered early postoperative complications are in the domain of general surgical complications and cannot be related to the type of the implanted mesh. Monitored late postoperative complications can be connected to the invasiveness of the method and the type of the used mesh. It was observed that the incidence of the monitored late complications is considerably lower after three months. The treatment of inguinal hernia by using the three-dimensional prolene (PHS) mesh is more expensive and increases the cost of the surgical treatment considerably, as well as requires from surgeon certain skills and experience during the implantation.

Based on the research we can conclude that both methods of the treatment of inguinal hernia with the used meshes are mutually comparable, safe, and reliable, and that with the application of certain surgical principles they guarantee safe and successful treatment of inguinal hernia with a little possibility of recurrence.

M, Hernia, 7 (2003) 35. — 10. AMID PK, LICHTENSTEIN IL, Hernia, 2 (1998) 89. — 11. McGILLICUDY F, Arch Surg, 133 (1998) 974. — 12. PA-VLIDIS TE, TMAZIDIS KS, LAZARIDIS CN, PAPAZIOGAS BT, MAR-KIS JG, Minerva Chir, 57 (2002) 12. — 13. AMID PK, Hernia, 1 (1997) 15. — 14. JUNGE K, KLINGE U, ROSCH R, KLOSTERHALFEN B, SCHUMPELICK V, World J Surg, 26 (2002) 1471. — 15. HEISE CP, STA-RLING JR, J Am Coll Surg, 187 (1998) 514. — 16. KALAN M, CHOW-DHRY S, Hernia, 10 (2004) 101.

USPOREDBA REZULTATA OPERACIJSKOG LIJEČENJA PRIMARNIH INGVINALNIH HERNIJA S RAVNOM POLIPROPILENSKOM I TRODIMENZIONALNOM PROLENSKOM (PHS) MREŽICOM-JEDNA GODINA PRAĆENJA

SAŽETAK

Cilj studije bio je usporediti rezultate operacijskog liječenja ingvinalne hernije uporabom ravne polipropilenske mrežice i trodimenzionalne prolenske (PHS) mrežice. Studija uključuje dvije grupe po 40 pacijenata muškog spola, starosne dobi 18–50 godina, sa dijagnozom ingvinalne hernije. Jedna grupa je operirana ravnom polipropilenskom, a druga grupa trodimenzionalnom prolenskom (PHS) mrežicom. Studija je pokazala za 15 minuta duže trajanje operacije i jači upalni odgovor kod pacijenata operiranih sa trodimenzionalnom prolenskom (PHS) mrežicom.Nema statistički značajne razlike u intenzitetu postoperacijske boli, postoperacijskoj upotrebi analgetika, duljini hospitalizacije, povratku svakodnevnim društvenim aktivnostima, te ranim i kasnim postoperacijskim komplikacijama. U obje grupe operiranih pacijenata nije registriran recidiv. Analizom dobivenih rezultata ne nalazi se razlike u liječenju ingvinalne hernije ravnom polipropilenskom i trodimenzionalnom prolenskom(PHS) mrežicom.