Hernia (2006) 10: 223–228
DOI 10.1007/s10029-006-0067-5

ORIGINAL ARTICLE

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Is there a need for a mesh plug in inguinal hernia repair? Randomized, prospective study of the use of Hertra 1 mesh compared to PerFix Plug

Received: 6 June 2005 / Accepted: 14 December 2005 / Published online: 1 April 2006

Abstract Although the mesh plug procedure is an effective operation, sutureless implantation of a single onlay mesh, if successful, would avoid the risks of plug-related complications. One hundred patients with primary inguinal hernias were randomized to undergo PerFix Plug or Hertra 1 implantation. Mean duration of the operation was similar, 38 versus 35 min for plug and onlay mesh implantation, respectively (nonsignificant, NS). The level of postoperative pain and early complication rate was similarly low in both groups (NS). Recurrence rate was the same—2 patients in each group (4%)—all following large hernia repair. The level of long-term discomfort was low after each type of operation (NS). Implantation of the onlay mesh—Hertra 1 as compared to the use of PerFix Plug is simple, safe, and equally effective in small and medium inguinal hernia repair, suggesting that a plug device is not necessary for successful hernia surgery.

Keywords Mesh plug · Inguinal hernia · Randomized study · Sutureless repair · Trabucco · Tension-free

Introduction

The efficacy of all hernioplasties using polypropylene mesh is very similar [1, 2]. It appears, however, that the results of the various techniques performed by general surgeons are still not as good as those obtained by specialists [1, 2, 3]. One option for improvement is to simplify the procedure as much as possible and thus decreasing the possibility for human error and shortening the learning curve.

Placement of the PerFix Plug (Bard, NJ, USA) device, which consists of a mesh plug and onlay preshaped mesh, is considered a relatively simple procedure [4, 5]. It can, however, lead to complications such as injury to the bowel, vessels or urinary bladder as well as postoperative inguinal discomfort. These are all related to the presence or migration of the mesh plug after surgery [4, 6–12]. It is, therefore, natural to ask if the plug is necessary in the repair, and if the implantation of a preshaped onlay mesh without plug or suture fixation could be equally effective to simplify the technique and avoid further risk complications.

It has been previously demonstrated in many studies with a lengthy follow-up that use of a single preshaped onlay mesh placed without sutures according to the Trabucco technique is effective in small indirect, and small- and medium-sized direct inguinal hernia repair [13, 14]. In this study, we extended the indications for this technique to all primary inguinal hernia repairs. We compared the use of Hertra 1 (Herniamesh, Turin, Italy) sutureless implantation to the use of PerFix Plug (Bard, Sunmed, Łódź, Poland) and evaluated the efficacy and complication rate.

Materials and methods

One hundred patients were referred to the Department of Surgery at the Medical University of Gdansk for elective primary inguinal hernia operation and were prospectively randomized to one of the two techniques to be studied. The protocol and consent forms were previously approved by the Medical University of Gdańsk Ethics Committee. The exclusion criteria for patient selection were: age lower than 16, pregnancy, presence of local or diffuse infection (i.e. skin, lung, sepsis), a recurrent, bilateral or incarcerated type of

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hernia, or refusal to enter the study. Patients were randomized using a blind envelope system; the seal of the envelope was broken in the anesthetic room before surgery. Group I (HERTRA) consisted of 50 patients treated with Hertra 1 implantation; Group II (PLUG) also consisted of 50 patients treated with the PerFix Plug. Each operation was performed either by an experienced surgeon or by a resident under his/her supervision. Hernia type and size was classified according to the Gilbert classification with Rutkow modification [16]. Patients were offered local anesthesia with 1:1 mixture of 1% Lidocaine and 0.5% Bupivacaine. Additionally Midazolam 1 mg and Fentanyl 50 μg were used as needed. Some patients preferred spinal or general anesthesia. No antibiotic or antithrombotic prophylaxis was used in either group.

Operative procedures

PerFix Plug repair was performed as described by Rutkow using nonabsorbable 2-0 suture to secure the plug and to reapproximate the external oblique aponeurosis [5]. Hertra 1 was implanted according to Trabucco's description for small and medium size hernias [14]. After dissection, the hernia sac was invaginated into the peritoneal cavity and the edges of the defect were approximated with a running superficial absorbable 2-0 suture placed without tension to flatten the posterior wall of the inguinal canal. A preshaped onlay mesh—Hertra 1 was then placed without suture fixation on the posterior wall allowing the spermatic cord to pass through an aperture in the mesh (Fig. 1). Hertra tails were secured with one interrupted suture in a similar fashion as the onlay mesh in the PerFix Plug device. The external oblique aponeurosis was reapproximated below the spermatic cord with the same nonabsorbable suture. Skin and Scarpa's fascia were each brought together with absorbable 4-0 continuous sutures. The wounds were not drained. The duration of operation was recorded for each procedure. Control of postoperative pain was maintained with ketoprofol (KETONAL—Lek Polska, Pruszkow, Poland) 50 mg IM given as frequently as needed. Postoperatively physical activity was not restricted except for the patients who underwent spinal anesthesia and remained in bed rest for 24 h. The level of pain was assessed by visual analog scale (VAS) on the morning after surgery. Patients were allowed to return to manual work 2 weeks after surgery and to harder physical work 2 weeks later. The follow-up examinations were at 4 weeks after operation (first visit), and again 6 months postoperatively. Patients who refused to return to the clinic were interviewed by telephone.

Statistical analysis

Values with normal distribution are expressed as mean ± standard deviation (SD); values with other distributions are expressed as median and range. Continuous nonpaired variables were tested with the Mann–Whitney independent rank sum test or the *t* test, depending on the distribution. The Pearson's chi-square test as corrected by Yates was used to compare categorical variables. The results were calculated using Statistica 5.77 software (StatSoft Inc., USA). For all comparisons, a *P* value less than 0.05 was considered significant.

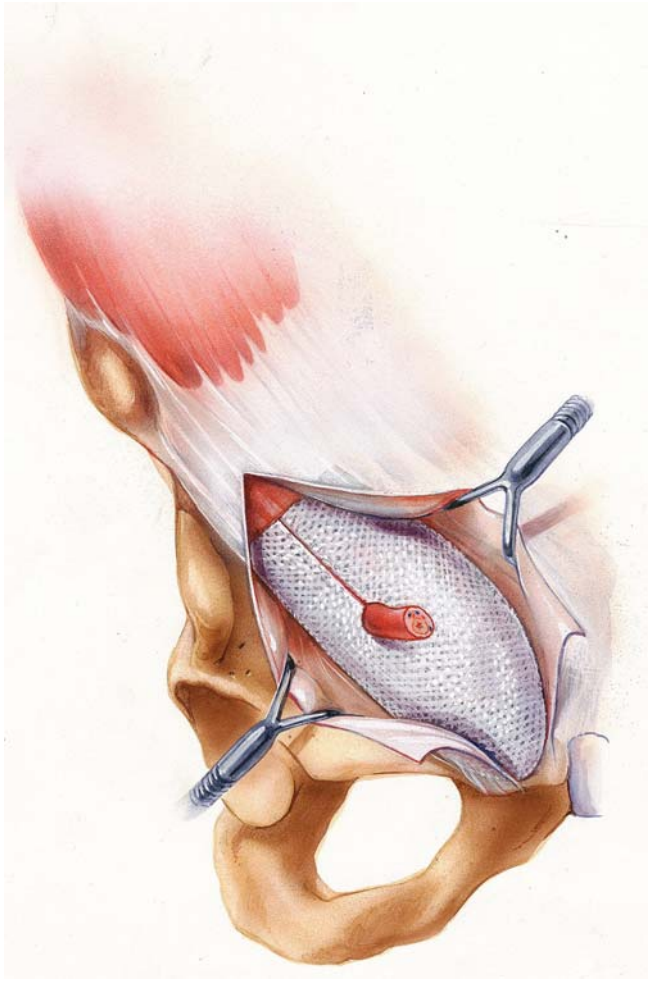

Fig. 1 Preshaped onlay mesh- Hertra 1 is placed without suture fixation on the posterior wall of the inguinal canal. Next, external oblique aponeurosis is approximated over the mesh and below the spermatic cord with running nonabsorbable suture (reprinted after permission of Ermanno E. Trabucco, M.D.)

Results

Comparison between groups

Both groups were similar with regard to age, sex, ASA score, and type and size of hernia (NS). Table 1 compares the clinical features of the two groups. Most patients underwent the procedure under local anesthesia—43 (86%) in group HERTRA and 42 (84%) in

Table 1 Patients and hernia characteristics

		HERTRA	PLUG
Age (mean ± SD)		55.4 ± 17.9	54.2 ± 17.2
Range		(17–89)	(19–85)
Sex		48 M, 2 W	48 M, 2 W
ASA	I	28 (56%)	25 (50%)
	II	8 (16%)	12 (24%)
	III	14 (28%)	13 (26%)
Hernia size	Hernia type*		
Small (defect < 1 cm)	1	1 (2%)	5 (10%)
	5	8 (16%)	6 (12%)
Medium (defect < 4 cm)	2	13 (26%)	14 (28%)
Large (defect > 4 cm)	3	17 (34%)	16 32%
	4	10 (20%)	8 (16%)
	6	1 (2%)	1 (2%)
		$P > 0.05$	

*Gilbert–Rutkow classification (15)

group PLUG; (NS). Spinal and general anesthesia was carried out in 4 (8%) and 3 (6%) patients during Hertra 1 implantation and in 7 (14%) and 1 (2%) cases when plug was applied, respectively ($P > 0.05$).

Comparison of outcomes

Duration of Hertra 1 implantation did not differ statistically from PerFix Plug procedure—mean 35 min (range 25–80) versus 38 min (range 30–75), respectively (NS). The amount of local anesthesia solution used during the operation was 39 ± 6 and 35 ± 6 ml respectively (NS). Level of postoperative pain according to VAS was also similar in both groups: 4 (1–9) in group HERTRA versus 5 (2–9) in PLUG (NS). Patients needed NSAID equally in the first week after surgery in both groups: 3 days (2–10) and 4 days (2–11) ($P > 0.05$), and they resumed their normal home activity: 4 days (range 3–11) versus 5 days (range 3–12), respectively ($P > 0.05$). Although the number of postoperative complications was higher in the PLUG group—8 (16%) versus 2 (4%) in Hertra group ($P < 0.05$), the difference between specific types of complication did not differ statistically ($P > 0.05$; Table 2). Scrotal or wound hematoma occurred in 1 (2%) case after Hertra 1 and in 2 (4%) cases after PerFix Plug implantation. Scrotal or wound edema was found in 1 (2%) patient from the Hertra group and 3 (6%) patients in the Plug group. One patient with wound infection after plug repair recovered after wound debridement and antibiotic therapy without excision of the mesh. One case of deep vein thrombosis and urinary retention followed a plug repair.

Table 2 Early postoperative complications

Complication	HERTRA	PLUG	*P* value
Total	2 (4%)	8 (16%)	$P = 0.048$
Scrotal edema	1 (2%)	3 (6%)	NS
Wound or scrotal hematoma	1 (2%)	2 (4%)	NS
Deep vein thrombosis (side of surgery)	0	1 (2%)	NS
Wound infection	0	1 (2%)	NS
Urinary retention	0	1 (2%)	NS

See Table 3 for long-term results. Since the follow-up at 6 months was poor, we changed the protocol and all patients were called for examination on the same date, approximately 21 months (12–33) after surgery. Physical examinations were performed in 29 (58%) patients in group HERTRA and in 28 (56%) patients in group PLUG (NS). Telephone follow-up was performed in patients who did not comply. Two patients were lost to follow-up in each group; the follow-up rate was 96%.

Two cases (4%) of recurrence were found in each group on physical examination. In the HERTRA group recurrences appeared after large direct hernia repair at 3 weeks and after large indirect hernia repair after 4 months. Recurrences were found next to the pubic tubercle and were repaired by insertion of the PerFix Plug. In the PLUG group one recurrence appeared 1 year after large direct hernia repair, also in the pubic tubercle region and was treated with another plug; another recurrence was found on the second postoperative day during exploration of the large wound hematoma in a patient with a coagulopathy. The plug was removed and Hertra 1 was implanted instead.

Six percent of the patients had moderate groin pain, which restricted patients' physical activity. Most of the patients in both groups were very satisfied or satisfied after the procedure. The result of operation was assessed as very good by 29 (58%) versus 22 (44%) patients after Hertra 1 and Plug implantation, respectively; good by 16 (32%) versus 20 (40%), fair by 2 (4%) versus 4 (8%), and bad by 1 (2%) versus 2 (4%) patients in groups, respectively ($P > 0.05$).

Discussion

PerFix Plug repair has become very popular because it is simple and easy to learn [5]. It is the optimal procedure for femoral and recurrent hernia repair, where the plug

Table 3 Long-term follow-up results ($P > 0.05$)

	HERTRA	PLUG
Follow up (months)	21 (12–33)	21 (12–33)
Physical examination	29 (58%)	28 (56%)
Telephone call	19 (38%)	20 (42%)
Total follow-up rate	48 (96%)	48 (96%)
Recurrence	2 (4%)	2 (4%)
Hernia type and size	III, IV (large)	III, IV (large)
	$P > 0.05$	
Long-term pain		
No pain	33 (66%)	29 (58%)
Pain—does not limit physical activity	12 (24%)	16 (32%)
Pain—limits some activity	3 (6%)	3 (6%)
Pain—limits normal life activity	0	0
	$P > 0.05$	

naturally fills the earlier existing cylindrical space. For our study, we chose a group of patients with primary inguinal hernia repairs, whose risk for plug-related complications was increased due to the flat shape of the fascial defect and to the lack of three-dimensional space [5, 7–13]. Although specialists who use the plug do not generally see complications, they appear in the patients operated on in general surgery units. Technical failures, such as inappropriate plug fixation or insufficient plug mass reduction, could be one of the reasons for complications. [4, 6–12]. Rutkow describes excision of the inner plug petals in 90% of cases while suggesting the need for individualization based on personal surgical experience [5]. Millican recommends suturing the inner petals of the plug to flatten out the umbrella in the preperitonael space to decrease the risk of complications [4, 16]. Trabucco, for similar reasons abandoned the tridimensional plug and replaced it with flat preshaped meshes T4 or T5 (Herniamesh, Turin, Italy) placed in the preperitoneal space in addition to the onlay mesh. He later found that preperitoneal meshes are not necessary in small indirect and medium size direct hernia repairs [13]. Based on these data, we hypothesized that avoidance of plug implantation and a sutureless inguinal hernia repair using Hertra 1 placed according to the Trabucco description may be both efficient and safe for all primary inguinal hernioplasties.

Duration of Hertra 1 operation did not differ from PerFix Plug repair. Mesh placement is quick and simple in both procedures compared to dissection of the hernia sac, which usually consumes more time and is technically more challenging. Therefore, dissection of the hernia sac as a common part of both procedures most strongly influences the total procedure time in both study groups. Nevertheless, the Hertra 1 operation is technically simpler, avoiding the plug insertion and fixation. It is easy to learn and teach, even to surgeons in training as long as they are familiar with the anatomy of the inguinal canal. Both procedures can be easily performed under local anesthesia, which was similar in both groups.

Postoperative pain depends on many factors: consumption of analgesics, tachyphylaxis, patient age, postoperative activity, and surgical technique [17, 18, 19, 20]. The perioperative routine was the same in both groups. In most studies, as in ours, the level of postoperative pain was similar after different tension-free techniques [17, 18]. Although the total early complication rate was higher after PerFix Plug repair, the number of specific complications was similar. One patient from the Plug group developed urinary retention and deep vein thrombosis; however, inguinal sonography revealed no plug migration or vein compression. Spinal anesthesia and 24 h bed immobilization afterwards could have contributed to urinary retention and vein thrombosis in this patient. Wound infection rate in our study was 2%, low, considering the procedure was performed without antibiotic prophylaxis. Superficial wound infection does not depend on the method of hernia repair from the anterior approach [19]. It is strongly related to standards of aseptic routine in the hospital. Both Hertra 1 and PerFix Plug are made of macroporous monofilament polypropylene, which is relatively resistant to bacterial invasion. Wound hematoma is the result of insufficient hemostasis during the procedure, and may be related to scissor dissection rather than electrocautery, as suggested by Rutkow [5]. Edema of the testes is more common after traditional suture herniorrhaphy and may be caused by the extensive dissection and muscle approximation [21]. During mesh hernioplasties, these technical stresses are avoided, as it is excessive manipulation of the spermatic cord. In our study, this was a rare complication and none of them resulted in testicular atrophy in long-term follow-up. Patients were discharged from the hospital the morning after surgery since the Polish health insurance system requires at least 24 h hospitalization in order to allow reimbursement. Most of our patients resumed their normal home activity within a few days after either procedure. We did not compare time away from work in our study because this depends largely on socioeconomic factors (motivation, type of insurance), or on the local doctor's advice, which differs widely [22, 23, 24].

Reported recurrence rate ranges from 0.1 to 10% [2, 4, 5, 24]. This wide variation is not only solely due to different surgical methods, but also due to factors such as the definition of recurrence, type of study, patient population, type of hernia, surgeon experience, type of suturing material and mesh, method of follow-up examination, and evaluation of results [20]. The most reliable evaluation of recurrences is found in randomized, prospective multicenter trials with meta-analysis of individual patient data [1]. In our series, the recurrence rate appears to be high at 4%. This may be explained by the following: about half of all operated hernias were large, operations were performed by 12 different surgeons (mostly residents) and the follow-up rate was high at 96%. Our study tested the effectiveness of each procedure as performed by general surgeons, mainly residents rather than hernia specialists. All recurrences in both groups occurred after large direct or indirect hernia repair in the space next to the pubic tubercle. Mesh, which covers and repairs large defects of the posterior wall of the inguinal canal is subjected to greater intra-abdominal pressure and must be very well fixed to the surrounding tissue. A large hernia may be better treated with the Lichteinstein repair or with a large mesh sheet placed in the preperitoneal space according to Stoppa, Wantz (Rignault), or laparoscopically. In this study, we were most interested in the simplest and least invasive method; for large hernias, the Hertra 1 implantation appears insufficient unless an additional larger, preshaped, flat, rigid mesh—T5 with a hole for the spermatic cord is implanted in the preperitoneal space [13]. Our results suggest that PerFix Plug may also be ineffective in such cases—even "plug specialists" found a recurrence rate of 2% after repair of large direct or

pantaloon primary defects [5]. Some surgeons have tried placing two or more plugs next to each other, suturing them together in the defect and covering them with sutureless onlay mesh, but this technique, in our opinion, seems unstable, complicated, and ineffective. Moreover, this mass of prosthetic material is more difficult to infiltrate with connective tissue than a single piece of macroporous, flat mesh, such as the Hertra 1. Even ''plug specialists'' prefer the Lichteinstein onlay mesh repair instead of PerFix Plug for type III hernias due to the unacceptable high recurrence rate after plug insertion [4].

In this study, we found that both Hertra 1 and PerFix plug implantation were very effective in small and medium size hernia repairs, when the defect was smaller than 4 cm. We found no recurrence in these cases with nearly 2-year mean follow-up. Previous reports by Trabucco and others have shown that Hertra 1 implantation is effective in small and medium size direct defects and small indirect hernias [13, 14, 25, 26]. We found this technique was also effective in medium indirect hernia repairs. It is still necessary, however, to evaluate this type of operation in a larger group of selected patients before the procedure is universally recommended for this type of defect. Trabucco has suggested placement of an additional round-shaped mesh T4 with a hole for the spermatic cord without suture fixation in the preperitoneal space in this type II hernia [13].

With regard to pain there was little difference between the two procedures. We defined chronic pain as discomfort in the inguinal region that lasts longer than 3 months after surgery. In our study, 6% of the patients from both groups complained of chronic pain, which limited their physical activity and 20% of patients reported only mild discomfort, which did not influence their normal activities. Similar results were found by many others, where both mesh and nonmesh techniques were used, supporting the idea that pain is not only related to chronic reaction to mesh [2]. In some patients, it can be a result of scar tissue formation and/or nerve entrapment in the region of surgery, while in others pain may be due to myalgia, neuralgia or even joint or bone disease, especially in patients, who had similar symptoms prior to surgery [2, 5]. In the Trabucco repair, Hertra 1 is separated from the spermatic cord by the external oblique aponeurosis, which is approximated below the cord [13]. Thus, nerves and vessels of the cord are separated from the prosthesis and the surrounding inflammation process, decreasing the risk of chronic damage to these structures during scar formation.

Most of the patients in both study groups subjectively assessed results of their procedures as very good and good, which correlates well with their uncomplicated postoperative courses.

Implantation of the Hertra 1 mesh constitutes the simplest form of inguinal hernia repair and offers the advantage of using a minimal amount of prosthetic material and sutures. Hertra 1—onlay mesh is similar to only one part of the PerFix Plug set and correlates with the upper mesh of the Prolen Hernia System device (PHS; Ethicon, Irvine CA). Volume of prosthetic material used should be limited, especially in young, thin, active patients because of the higher risk of discomfort due to the more robust acute and chronic inflammatory reaction in a smaller anatomical space. Preperitoneal dissection and plug or PHS device placement unnecessarily increases the risk of complication [17]. Compared to the Lichtenstein technique, Hertra 1 implantation without suture anchoring avoids the tension on the mesh-suture-tissue line which may cause pain and tissue rupture. Additionally, it is very likely that separation of the mesh from the spermatic cord by the oblique aponeurosis in the Hertra 1 implantation can decrease the risk of damage to the vas deferens described lately after other tension-free techniques [27].

Hertra 1 is commercially available as a ''ready to place mesh''. Adjusted in shape to the posterior wall of the inguinal canal, it is made of macroporous, monofilament polypropylene with high rigidity and flat shape memory. These features allow Hertra 1 to lie flat without suture fixation and remain without tension between two fascial layers compressed by intraabdominal pressure and tissue. Mesh that is too malleable and soft may not be appropriate for this type of repair, since it may curl and wrinkle, thus leading to complications when placed without suture. The external oblique aponeurosis envelops the mesh in interfascial planes and prevents migration. Therefore, the approximation of the aponeurosis should be performed carefully, since it is responsible for wound integration in the early postoperative period. Next, scar formation seals the two fascial layers and maintains a protective role. Assessment of the ability to successfully close the aponeurosis is required before deciding to use the Hertra 1 implantation.

Compared to many other complex standard repairs, the Hertra 1 may also be cost-effective since it requires limited dissection and suturing, thus shortening operation time and accelerating recovery [25]. Although small differences in operative time do not influence the cost of the procedure in Polish and European hospitals as much as in the USA, in the long run, Hertra 1 implantation may be cost-effective by limiting the risk of complications [2, 24].

Conclusions

In this prospective randomized study, we have shown that the implantation of a preshaped onlay mesh Hertra 1 without suture fixation is a simple and effective operation for the repair of primary small or medium size, inguinal hernias. The simplicity and effectiveness of this operation favors its use for repair of the most common types of inguinal hernias by general surgeons.

Acknowledgment We would like to express our appreciation to Professor Mark A. Hardy, M.D., Ermanno E. Trabucco, M.D. and Eric Liu, M.D. for their review of the manuscript and suggestions.

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