Quantification of pain in laparoscopic transabdominal preperitoneal (TAPP) inguinal hernioplasty identifies marked differences between prosthesis fixation systems

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Background. *Various systems exist for prosthesis fixation in hernia repair. These techniques vary in terms of postoperative complications and pain. This study compares prosthesis fixation techniques employed in laparoscopic transabdominal preperitoneal (TAPP) hernioplasty using a visual analog scale (VAS) to quantify postoperative pain.*

Methods. *Patients (n = 600) underwent TAPP inguinal hernia repair in a randomized prospective study. Prostheses were fixed with Protak (Tyco, Norwalk, Conn), (Group A; n = 150), EndoANCHOR (Ethicon Endo-Surgery, Inc., Cincinnati, Ohio) (Group B; n = 150), EMS (Ethicon Endo-Surgery, Inc.) (Group C; n = 150), or Tissucol (Baxter Healthcare, Milan, Italy) (Group D; n = 150). Patients were interviewed up to 1 month post-intervention. Post-operative pain was evaluated on a 0- to 10-point VAS (0 = no pain, 10 = maximum pain). Morbidity, length of stay, return to work and recurrence were also assessed.*

Results. *Overall, 803 hernias were treated: 397 patients (66.2%) had unilateral hernias and 203 (33.8%) had bilateral hernias. In total, 96 (12%) hernias were recurrences and 707 (88%) were primary. Postoperative pain ranged from VAS1 to VAS2 (mild pain) between 12 hours and 72 hours with Tissucol (Group D), and it was higher in Groups A-C: Maxima ranged from VAS4 (moderate pain) with EMS to VAS7 (severe pain) with Protak at 48-hour follow-up. Significant differences in length of stay occurred, no recurrence or conversion rates were observed among groups, and morbidity was generally lower with Tissucol. Patients in Group D (Tissucol) also returned to work sooner than did Groups A-C (Protak, EndoANCHOR, and EMS).*

Conclusions. *We found differences in postoperative pain among different laparoscopic TAPP prosthesis fixation methods. The use of the biocompatible fibrin sealant Tissucol seems to reduce significantly postoperative pain, complications, and resumption to work times compared with other systems.* *(Surgery 2007;142:40-6.)*

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SURGERY has undergone a radical transformation within the past 10 years, not only because of technological progress but also in response to the requirement that surgical decisions should be supported by findings from robust surgical studies. The results of such studies are particularly important for common procedures such as hernioplasty. Previous techniques, such as the Bassini, McVay, and Shouldice methods have been associated with significant recurrence rates and postoperative morbidity. In the past 15 years, the advent of new techniques and concepts, such as tension-free repair, the use of mesh prostheses, and the laparoscopic approach, has dramatically improved outcomes in terms of postoperative pain, recurrence rate, and time to return to normal activity.

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The widespread use of prosthetic meshes in hernia repair has reduced the rate of recurrence from approximately 10% to approximately 1%, as documented in studies showing a significant reduction in recurrence rates with no increase in complications such as infections, functional impotence, and pain.[1-7] Several factors affect the perception of patients of postoperative pain, including the type of intervention, complications, age, and individual tolerance. In particular, prosthesis fixation methods employed during hernioplasty can result in varying degrees of postoperative pain.[8,9]

Several methods for quantifying perioperative pain are described in the literature. Options include simple verbal categorical measures, numerical scales, and visual analog scales (VASs).[10-12] The use of VAS is a simple, uniformly accepted method for evaluating pain employed in most hospitals, and differences between VAS point scores are a useful comparison tool. Whereas some VAS tools rely on the assignment by patients of a rating of pain along a simple line rating from 0 (none/mild) to 100 (severe), the VAS used in our unit uses pictures of facial expressions, from which patients choose to quantify their pain. Patients seem to be more definite in their choice of image than if asked to give an evaluation based on a numerical scale. Several previous studies have demonstrated that our VAS is a reliable and linear gauge of moderate-to-severe postoperative pain.[13-15]

To identify and quantify differences in postoperative outcome in patients undergoing inguinal hernia repair using a range of prosthesis fixation techniques, we measured subjective perceptions of postoperative pain using an established and tested VAS. We started using laparoscopy (TAPP) for repair of inguinal/femoral hernias in January 1991 and have repaired 1350 hernias to date.

MATERIALS AND METHODS

Patients and protocol. Six hundred patients undergoing TAPP hernia repair were enrolled in a randomized prospective study planned to compare inguinal mesh fixation methods. TAPP procedures were performed by 2 expert surgeons from the Surgical Department of San Gerardo Hospital, Monza, Italy, between September 2001 and September 2004. The type of procedure was randomized, and follow-up visits were conducted by an additional surgeon blinded, as well as the patient, to what sort of fixation was used. These interviews incorporated assessment for pain quantified using a VAS and complications including hematoma, seroma, urinary retention, and recurrences. TAPP was proposed to all patients under the age of 80 years, irrespective of the type of hernia. Exclusion criteria were contraindications to laparoscopic procedures (ie, severe cardiopulmonary disorders and portal hypertension). All patients received one 100-mg dose of Ketoprofene to manage postoperative pain. If patients did not choose TAPP, they were submitted to the Lichtenstein repair under local anesthesia.

Different methods of inguinal fixation were studied: EMS (Ethicon Endo-Surgery, Inc., Cincinnati, Ohio), Protak (Tyco, Norwalk, Conn), EndoANCHOR (Ethicon Endo-Surgery), and Tissucol/Tisseal (Baxter Healthcare, Milan, Italy).

Procedures. Polypropylene prostheses (14 × 13 cm) were fixed with Protak in 150 patients (Group A), with EndoANCHOR in 150 patients (Group B), with EMS in 150 patients (Group C), or with the biocompatible fibrin sealant Tissucol in 150 patients (Group D). The surgical technique employed has been described in detail elsewhere[2] and, except for the different fixation methods used, did not change throughout the 4-year study period because of the previous long experience.

In the case of the use of staples, an Endopath Multifeed Stapler 10-mm shaft, EndoANCHOR, or Protak were used. We used two L-shaped 14-×-13-cm meshes. The technique that we adopted involved positioning 2 tacks medially and 3 laterally to epigastric vessels and 2 tacks on the Cooper ligament. No tacks were positioned on the "triangle of disaster" and "triangle of pain." In a patient undergoing Tissucol fixation, we used 1 mL of Tissucol for unilateral hernias and 2 mL for bilateral hernias. The prosthesis was fixed along its upper margin, from the Cooper ligament to the "triangle of disaster" and to the "triangle of pain," using a 3-mm catheter (Duplotip; Baxter Healthcare), which fits the Tissucol syringe.

Local infiltration at the incision sites was not used, and the abdomen was not irrigated with any form of analgesic solution after closure of peritoneum over the mesh. The study was conducted according to the ethical standards of the Committee on Human Experimentation and the ethical standards of the Helsinki Declaration of 1975. Informed consent forms were signed by each patient before the procedure.

Outcomes. Objective data including patient demographics, hernia characteristics (unilateral, bilateral), history (primary or recurrent hernia), and general therapeutic outcomes (operating time, hospitalization time, time taken to return to work, and rates of conversion, morbidity, mortality, and recurrence) were compiled for each patient. All patients completed individual questionnaires col-

Table I. Patient and hernia characteristics in Protak, EndoANCHOR, EMS, and Tissucol fixation groups undergoing TAPP hernia repair

	Protak (A)	*EndoANCHOR (B)*	*EMS (C)*	*Tissucol (D)*
Number of patients (m/f)	150 (147 m/3 f)	150 (148 m/2 f)	150 (148 m/2 f)	150 (145 m/5 f)
Age (range)	47 (21-70)	45 (20-75)	42 (23-72)	44 (18-77)
Number of hernias	189	198	194	222
Unilateral, n (%)*	111 (59)	102 (52)	106 (55)	98 (44)
Bilateral, n (%)*	39 (21)	48 (24)	44 (23)	62 (28)
Recurrences, n (%)*	21 (11)	16 (8)	21 (11)	38 (17)

f, female; *m*, male.
*Calculated relative to number of hernias per group.

lecting both subjective and objective data with the support of the observer of the patients. After discharge, patients recorded follow-up data themselves and then sent them in to the unit. Data were collected up to 1 month postintervention.

Measurement of pain. As part of the subjective questionnaire-based assessment, pain was rated on the basis of a 10-point VAS according to methods described in previous publications.[13-15] Briefly, patients were asked to indicate an image of a face that most closely expressed their level of post-operative pain. Each image was associated with a score between 0 (no pain) and 10 (most pain). Patients were asked to rate their pain in this way at 6 hours, 12 hours, 24 hours, 48 hours, 72 hours, and 7 days after the intervention. Follow-up evaluations were also performed at 15 days, 1 month after surgery.

Statistical analysis. Statistical comparisons of postoperative complication rates between the different fixation system groups in this report have been performed using a chi-square test. Comparisons among the 4 groups of postoperative pain, operating times, and resumption to work were performed applying the ANOVA test and Tukey test for the post hoc analysis.

All results were considered statistically relevant with a confidential interval 95% and $P < .05$. Statistical analysis has been performed using SPSS 13.0 for MAC OS system (SPSS, Inc ©, Chicago, Ill).

RESULTS

Patient characteristics. The characteristics of the 4 groups are summarized in Table I. Of the 600 patients undergoing laparoscopic hernia repair, 588 were male (98%) and 12 were female (2%). The overall median age was 44.5 years (range, 18-77 years). The total number of hernias treated was 803; 397 patients (66.2%) had unilateral hernias, and 203 patients (33.8%) had bilateral hernias. A total of 96 hernias (12%) were recurrences, and 707 (88%) were primary. The total numbers of hernias in each group were 189 in Group A (Protak), 198 in Group B (EndoANCHOR), 194 in Group C (EMS), and 222 in Group D (Tissucol). Age, gender split, and proportions of different hernia types were numerically similar across the patient groups.

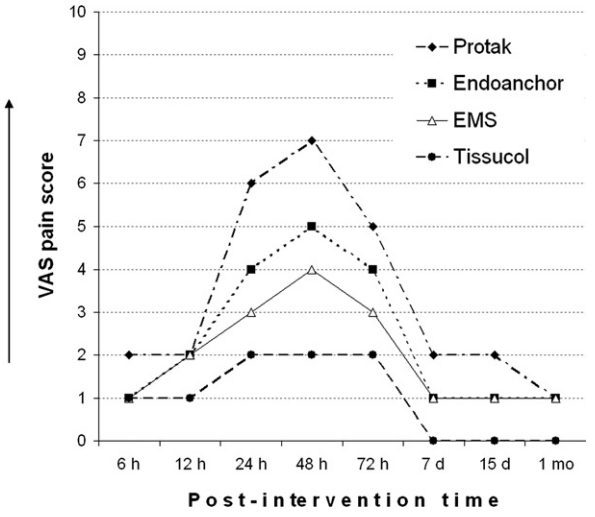

Figure. Patient-reported postoperative pain during follow-up after TAPP hernia repair using different fixation techniques, as recorded on the VAS (data points represent mean scores for each group).

Postoperative pain. Overall, patients rated their pain as greatest between 24 and 72 postoperative hours, and pain was rated as lowest in severity in the Tissucol group (Figure). The mean maximum pain score reported by Tissucol patients was VAS2 (mild pain) during this period. In contrast, mean pain scores ranged between VAS5 and VAS7 (moderate-to-severe pain) with Protak between 24 and 72 postoperative hours. Mean reported pain scores were between VAS4 and VAS5 (moderate pain) with EndoANCHOR, and between VAS3 and VAS4 (mild-to-moderate pain) with EMS. Maximal pain scores occurred at 48 hours after intervention in Groups A-C and at 24 hours with Tissucol.

At 7-day follow-up, mean VAS scores had decreased to VAS0 in the Tissucol group and had

Table II. General surgical outcomes of TAPP hernioplasty

Parameter	*Protak (A) (n = 150)*	*EndoANCHOR (B) (n = 150)*	*EMS (C) (n = 150)*	*Tissucol (D) (n = 150)*
Operating time in minutes				
Unilateral hernia, mean (range)	35 (18-50)	36 (15-50)	38 (20-50)	30 (15-45)*
Bilateral hernia, mean (range)	50 (35-75)	52 (35-80)	55 (37-80)	50 (30-75)†
Hospital stay in days, mean (range)	1.1 (1-3)	1.1 (1-3)	1.2 (1-4)	1 (1-3)*
Resumption of work in days, mean (range)	9 (5-20)	7 (5-12)	9 (5-22)	5 (3-8)*

*P value $< .05$ among Group D and Groups A-C.
†P value $< .05$ among Group D and Groups B and C.

Table III. Overall morbidity and specific complications

Parameter	*Tissucol (D) n = 150*	*Protak (A) n = 150*	*D vs. A* P *value*	*EndoANCHOR (B) n = 150*	*D vs. B* P *value*	*EMS (C) n = 150*	*D vs. C* P *value*
Conversions, n (%)	0	0	*>.05*	0	*>.05*	1 (.5)	*>.05*
Recurrences, n (%)	0	0	*>.05*	0	*>.05*	3 (1.5)	*>.05*
Seroma, n (%)*	5 (2.2)	12 (6.3)	*<.05*	15 (7.5)	*<.05*	13 (6.7)	*<.05*
Neuralgia, n (%)*	0	9 (4.7)	*<.05*	6 (3.0)	*<.05*	6 (3.0)	*<.05*
Hematoma†, n (%)*	0	3 (1.5)	*>.05*	3 (1.5)	*>.05*	4 (2.0)	*<.05*
Persistent pain, n (%)*	0	3 (1.5)	*>.05*	3 (1.5)	*>.05*	2 (1.0)	*>.05*
Urinary retention, n (%)*	0	0	*>.05*	0	*>.05*	2 (1.0)	*>.05*
Total morbidity, n (%)*	5 (2.2)	27 (14.2)	*<.05*	27 (13.6)	*<.05*	28 (14.4)	*<.05*

*Calculated relative to number of hernias per group.
†Including both inguinal and scrotal.

remained there up to 1 month of follow-up. In both the EndoANCHOR and the EMS groups, pain scores remained at VAS1 (some pain) between 7-day and 1-month follow-up assessments. Patients in the Protak group recorded pain at VAS2 (mild pain) at both 7-day and 15-day follow-up, but scores decreased to VAS1 by the 1-month time point. Within each group, bilateral hernias did not show significant differences in VAS score compared with monolateral hernias of the same group. We recorded a VAS score in postoperative time (24-72 hours) of 5.89 for monolateral hernia versus 6.07 for bilateral hernia in the Protak group; 4.47 versus 4.56 in the EndoANCHOR group; 3.46 versus 3.59 in the EMS group; and 1.95 versus 2.03 in the Tissucol group. No significant differences (always $P > .05$) were found, and results with the same characteristic ($P > .05$) were obtained for all of the following VAS endpoints.

Statistical comparisons of postoperative pain among the different fixation system groups have been performed using the ANOVA test and the Tukey test with a confidential interval 95% and $P < .05$ (Table IV).

General surgical outcomes. The mean operating time for performance of TAPP interventions was significantly ($P < .05$) shortest with Tissucol (30 minutes for unilateral hernias and 50 minutes for bilateral hernias). Next lowest in terms of operating time was the Protak group, followed by the EndoANCHOR and the EMS groups (Table II).

In addition, total hospitalization time was lowest with Tissucol ($P < .05$), and overall patients could resume normal working activity sooner: The mean time to resumption of work was 5 days (range, 3-8) with Tissucol compared with a mean time of 7-9 days in Groups A-C ($P < .05$).

Postoperative morbidity. The lowest overall morbidity rate was noted in the Tissucol group (Table III), where there were a total of 5 reports (2.2%), followed by the EndoANCHOR (27 reports [13.6%]), the Protak group (28 reports [14.2%]), and the EMS group (28 reports [14.4%]). Three indirect recurrences were recorded throughout the study, with EMS, because of the inferior lateral part of the prosthesis becoming unstuck. One conversion was also noted in another patient treated using EMS.

No reports of neuralgia, persistent pain, hematomas, or acute urinary retention with Tissucol were made; all morbidity reports in Group D are related to seroma (2.2% rate) (Table III). In Groups A-C, seroma (6.3% to 7.5%), neuralgia, and hematoma were the most frequently reported

Table IV. ANOVA test

	Sum of Squares	*df*	*Mean Square*	*F*	*Sig.*
VAS (24-72 hours)					
Between groups	1603.125	3	534.375	1498.76	4.23E-277
Within groups	212.5	596	.356543624		
Total	1815.625	599			
VAS (days 7-15)					
Between groups	298.005	3	99.335	59601	0
Within groups	.993333333	596	.001666667		
Total	298.9983333	599			
VAS (1 month later)					
Between groups	111.005	3	37.00166667	22201	0
Within groups	.993333333	596	.001666667		
Total	111.9983333	599			
Monolateral hernia (minutes)					
Between groups	5212.5	3	1737.5	479.866	1.7718E-158
Within groups	2158	596	3.620805369		
Total	7370.5	599			
Bilateral hernia (minutes)					
Between groups	2512.5	3	837.5	119.072	2.00696E-60
Within groups	4192	596	7.033557047		
Total	6704.5	599			
Hospital stay (days)					
Between groups	2.62	3	.873333333	26.4038	4.79171E-16
Within groups	19.71333333	596	.033076063		
Total	22.33333333	599			
Resumption of work (days)					
Between groups	1650	3	550	827.778	5.0917E-212
Within groups	396	596	.66442953		
Total	2046	599			

complications, followed by persistent pain and urinary retention (the latter in Group C only). No major complications or mortalities were recorded in any patient group. Statistical comparisons of postoperative morbidity between the different fixation system groups were summarized with the chi-square test, considering significant differences ($P < .05$) between group D and each other group (Table III).

DISCUSSION

This study identifies differences in subjective assessment by patients of postoperative pain and objective surgical follow-up measures between TAPP hernia repair procedures employing different prosthesis fixation techniques. Postoperative pain was shown to decline 2 days after TAPP, and hernia repair recipients, including those who underwent bilateral procedures, were soon able to resume daily activities and go back to work. Tissucol was associated with the lowest levels of postoperative pain up to 3 days after surgery, and patients were pain-free at 7-day follow-up and up to 1-month postintervention. Other fixation techniques (Protak, EndoANCHOR, and EMS) were associated with continued, low-level pain at both 7-day and 1-month follow-up. Within each group, bilateral hernias did not show significant differences in VAS score compared with monolateral hernias of the same group, showing that bilaterality did not significantly increase postoperative pain ($P > .05$) contrary to fixation system.

Overall patient pain perception, reflecting the hernia repair experience as a whole, is of great importance but is difficult to quantify. This parameter is often evaluated nonsystematically using categorical measures on the basis of broad adjectival descriptions (eg, very satisfied, moderately satisfied, or dissatisfied). Such assessments have been used to compare different laparoscopic techniques in previous publications, but past reports have suffered because of the imprecise terminology employed.[16-18] Various authors have used the VAS scale to compare hernia repair techniques.[16-22]

With regard to the surgical interventions reported in this study, we found the use of the fibrin

sealant, Tissucol, during TAPP hernia repair to be atraumatic compared with other fixation techniques, and that it avoids the problems associated with stapling. No neuralgia or persistent pain was observed with the procedure involving Tissucol in 222 hernia interventions. During a previous large-scale, multicenter study reviewing 9955 laparoscopic hernia repair procedures, Sayad et al.[23] reported a 2% incidence of neuralgia and a .4% incidence of chronic pain. Our data showed higher incidences of these complications in the Protak, EndoANCHOR, and EMS groups. In particular, the frequency of neuralgia with persistent inguinal pain after interventions using stapling has been reported to range from .5% to 14%.[12,24,25] In a study by Stark et al.,[26] the rate of nerve entrapment after laparoscopy procedures was 4.2% (19/448), with the genitofemoral nerve being affected with particularly high frequency (2% of cases). The ilioinguinal nerve and lateral cutaneous nerve of the thigh (LCNT) were each affected in 1.1% of cases.[26]

Some units do not use any mesh fixation during hernioplasty, but mesh-free procedures were not included as a comparator in this study as they are not standard practice in our unit. With procedures involving mesh prostheses, fixation of a 14-×-13-cm mesh at any site can help to ensure stability of the prosthesis, with no dislocation and no recurrence. The use of smaller prostheses (11 × 6 cm) fixed by stapling is associated with a recurrence rate of up to 5% during TAPP hernia repair.[25] A bigger prosthesis (15 × 10 cm), even if not fixed, has proved to count a recurrence rate of up to .6%.[27] A recent review of 7661 laparoscopic hernioplasty procedures[28] indicated that inadequate lateral fixation of prostheses during TAPP leads to a recurrence rate that is almost 15% greater than that observed with TEP (36% vs 22%, respectively). This finding is caused by most of the relevant nerves being centered in this area, which precludes stapling and, in turn, heightens the risk of recurrence. The option of fixing a large prosthesis at the site of both the injury and the pain prevents the prosthesis from lifting and becoming dislodged, thus preventing a possible recurrence at an inferior medial or inferior lateral location, as happened in 3 (1.5%) of our hernia repairs involving stapling with EMS.

The use of fibrin sealant in TAPP hernia repair is associated with specific advantages related to its hemostatic properties, which help to reduce the incidence of postoperative seromas and hematomas. In our experience, postoperative seromas occurred in only 2.2% of hernia repairs (in 5/222 patients) with Tissucol, whereas incidences with other fixation methods (Protak, EndoANCHOR, and EMS) ranged from 6.3% to 7.5% ($P < .05$), and the general incidence of these morbidities reported in the literature ranges from 3.8% to 10.5%.[23,25,27-30]

Actually, at a mean follow-up of 26 months, in the Tissucol group, we had no recurrences. Similar results are reported by very few clinical studies available in literature on the use of Tissucol in the TAPP technique.[31-34] In regard to the morbidity, a longer follow-up will be necessary to adequately assess the chronic pain issue.[35]

CONCLUSIONS

We conclude from this study that subjective patient assessments of postoperative pain can provide surgeons with additional information that can be used to determine the best type of method to use and to more accurately predict the postoperative course of the patient. The use of Tissucol as a prosthetic fixation system during TAPP hernia repair seems to be atraumatic, and data suggest that postoperative pain symptoms, complications, and resumption to work may be reduced. Tissucol gives the prosthesis stability and security across its entire surface, which results in a significant reduced incidence of seroma formation, prevention of hematomas at the prosthesis site (Group D vs Group C, $P < .05$), and a decreasing of postoperative neuralgia related to nerve entrapment or fixation to the Cooper ligament.

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