

## Mesh plug versus Bassini operation: a randomized prospective study

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**Summary:** The advantages of Rutkow's mesh-plug hernioplasty over the Bassini operation have never been proved in a prospective randomized study. Since 1995 through 1998, in such a study, 70 patients were allocated to the Rutkow mesh plug repair group and 70 treated with the Bassini procedure. Both groups were well-balanced with regard to age, sex, ASA score and type and size of hernia ( $p > 0.05$ ). The duration of the mesh plug procedure was shorter than for the Bassini operation (mean  $42.8 \text{ min} \pm 8.5$  (30-65) vs mean  $59.2 \text{ min} \pm 17.5$  (30-120)). Postoperative pain according to the Visual Analog Scale (VAS) in the plug group ranged from 0-6, mean 2.6 vs 2-9, mean 5.2, in the Bassini group ( $p < 0.05$ ). Postoperative complication rates did not differ statistically: 7 (9.5%) vs 13 (16.7%) respectively, wound infection: 2 (2.7%) vs 5 (6.4%) ( $p > 0.05$ ). Length of hospital stay was statistically shorter in mesh repair (mean  $4.3 \pm 1.8$  days (1-13) vs mean  $6.2 \pm 5.2$  days (1-30) ( $p < 0.05$ ). Return to everyday activities was faster after the mesh plug procedure than after the Bassini operation due to a shorter and less painful postoperative course. Long-term follow up revealed mild intermittent groin discomfort in over 20% of patients in both groups ( $p > 0.05$ ). The recurrence rate after the mesh plug procedure was lower than after the Bassini operation - 7 (9.4%) vs 16 (20.5%) ( $p < 0.05$ ). There was greater patient satisfaction after mesh hernioplasty ( $p < 0.05$ ). Physical examination revealed 4 (51.1%) and 3 (18.8%) recurrences respectively in patients unaware of having this complication ( $p > 0.05$ ). This kind of follow-up examination is obligatory to assess the true recurrence rate. Results after the mesh plug procedure were better than after the Bassini operation. Postoperative complication rates and long-term discomfort did not differ statistically in the two groups.

**Key words:** Groin hernia surgery – Randomized prospective study – Rutkow mesh plug repair – Bassini operation

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According to Rutkow, the mesh plug procedure seems to be an excellent method of groin hernia repair. It yields a low rate of recurrences, operative morbidity, and short- and long-term complications. It is a universal technique for all types of hernia and permits prompt resumption of virtually unrestricted physical activity [Rutkow 1998].

Before 1994 the Bassini procedure was the method of choice for groin hernia repair in our Department. Up to now there has been no prospective randomized study comparing these two methods, therefore we decided to conduct this work.

### Material and methods

Between 1994 and 1995, 100 mesh plug hernioplasties were done as a feasibility study and to optimize the technique. From 1995 to 1998, 140 patients referred to our Department for inguinal hernia repair were submitted to the randomized and prospective study. The protocol and consent forms were approved by the Medical University of Gdansk Ethics Committee. The exclusion criteria for patient selection were: age lower than 14, pregnancy, presence of local or diffuse infection (ie, skin, lung, sepsis,), and refusal of random group allocation. Randomization was performed with a blind envelope system, the seal being broken in the anesthetic room before surgery. The plug group consisted of 70 patients treated with mesh plug hernioplasties and the same number of patients were allocated to a group treated by Bassini repair group. The operation was performed by an experienced surgeon or under his supervision by residents. Hernia type was evaluated according to Gilbert's classification as modified by Rutkow [Rutkow 1993].

Patients were offered spinal or local anesthesia with a 1:1 mixture of 1% lidocaine and 0.5% bupivacaine. Midazolam 1 mg and Fentanyl 50 mikrog were used as needed. If preferred, general anesthesia with a 0.5% Bupivacaine injection along the wound at the end of the procedure was carried out. Neither antibiotic nor antithrombotic prophylaxis was used in either groups. Bilateral hernias

was operated on at the same time with the same method.

Mesh plug repair was performed as described by Rutkow using a cone-shaped mesh rolled up during the operation from a flat piece of polypropylene mesh (Ethicon) or Surgipro Mesh® (Auto Suture) [Rutkow 1993]. The Bassini procedure was performed with nonabsorbable, monofilament, interrupted sutures (2-0) [Wantz 1989]. The skin was closed in the same way in both groups with nonabsorbable continuous 4-0 sutures. No drains were left in the wound. The time of operation from first incision to last suture was recorded. The level of the pain was assessed on the VAS 6-8 hours after surgery during the evening ward round, when, depending on patient discomfort. Midazole 500 mg or Pethidine 1 mg/kg i.m. was administered.

Postoperatively, patients were allowed to perform any physical activities that they were capable of in spite of pain. Only patients after spinal anesthesia had to stay in bed 24 hours after surgery. Skin sutures were removed on the fourth day after surgery. Patients were discharged home as their comfort allowed. Total inpatient stay was also recorded.

The first follow-up examination was performed 4 weeks after operation, the

second 1-4 years after surgery. Patients were asked to come to the Clinic for physical examination and telephone information was accepted only for those who refused to attend.

### Statistical analysis

Values with normal distribution are expressed as mean  $\pm$  standard deviation (SD), values with other distributions (eg, time) are expressed as median and range. Continuous non-paired variables were tested with the Mann-Whitney independent rank sum test or the t-test, depending on distribution. Pearson's chi-squared test as corrected by Yates was used to compare categorical variables. The statistics were calculated using Statistica 5.77 software (StatSoft Inc., USA). For all comparisons, a p level lower than 0.05 was considered significant.

### Results

#### Comparison between groups

Both groups were well-balanced with regard to age, sex, ASA score and type and size of hernia ( $p > 0.05$ ). Table 1 compares the clinical features of the two groups. In the mesh plug group spinal

Table 1. Comparison of the clinical features of the two groups. Baseline data

	PLUG		BASS		p
Age	Mean 57,9 $\pm$ 14,8 (17-88)		Mean 54,9 $\pm$ 19,6 (14-88)		p > 0,05
Sex	61 male,	9 female	52 male,	18 female	p > 0,05
ASA					
Score I	39		39		
Score II	28		28		p > 0,05
Score III	3		3		
Type of hernia					
1	2	2,7%	1	1,3%	
2	27	36,5%	22	28,2%	
3	29	39,2%	27	34,6%	
4	8	10,8%	17	21,8%	
5	1	1,4%	0	0	
6	3	4,0%	3	3,8%	
7	4	5,4%	8	10,3%	
Total	74		78		p > 0,05
Incarcerated hernia	6	8,1%	16	20,6%	p > 0,05
Recurrent hernia	9	12,2%	7	9,0%	p > 0,05

anesthesia was mainly carried out: 37 (52.9%) patients; in the Bassini group general anesthesia was used in 26 (37.1%) patients ( $p < 0.05$ ) (Table 2).

*Comparison of outcomes*

Duration of the mesh plug procedure was statistically shorter than the Bassini operation: mean 42.8 min  $\pm$  8.5 (30-65) vs. 59.2 min  $\pm$  17.5 (30-120) ( $p < 0.05$ ).

Postoperative pain according to the VAS was significantly lower in the mesh plug group: mean 2.6  $\pm$  1.5 vs mean 5.2  $\pm$  2.0 in the Bassini group ( $p < 0.05$ ). Due to differences in types of anesthesia in both groups, the level of pain according to the type of anesthesia was additionally assessed in the mesh group but revealed no significant differences ( $p > 0.05$ ) (Table 3). Fewer patients needed narcotic drugs after mesh hernioplasty than after the Bassini operation: 26 (37.1%) versus 47 (67.1%) respectively ( $p < 0.05$ ). Although the number of postoperative complication was lower in the PLUG group: 7 (9.5%) than in the Bassini group: 13 (16.7%), the difference did not differ statistically ( $p > 0.05$ ). Wound infection occurred in 2 (2.7%) and 5 (6.4%) patients respectively in the two groups ( $p > 0.05$ ) (Table 4). Three (4.2%) patients suffered from pneumonia after the Bassini and none after the mesh plug operation. Length of hospital stay was statistically longer in the Bassini group: mean 6.2 days  $\pm$  5.2 (1-30) than in the plug group: mean 4.3  $\pm$  1.8 (1-13) ( $p < 0.05$ ). At the first follow-up examination 61 (87%) patients after mesh plug repair described pain as none or mild. It disappeared within 2 weeks in 52 (74%) cases and 48 (70%) patients resumed daily activities in the same time. Moderate pain was recorded in 35 (50%) patients from the Bassini group and lasted nearly one month in 29 (44%) cases. Fourteen (21%) patients needed over 1 month to return to normal daily activities ( $p < 0.05$ ). Table 5 shows results at first follow-up examination: level of postoperative pain, duration of postoperative discomfort, time of return to normal home activity.

**Table 2.** Comparing groups. Type of anesthesia.  $p < 0.05$

Type of anesthesia	PLUG		BASS	
general	14	20%	26	37,1%
spinal	37	52,9%	20	28,6%
local	19	27,1%	24	34,3%

**Table 3.** Level of postoperative pain (VAS) in PLUG group according to type of anesthesia  $p > 0.05$

Type of anesthesia	N	Mean	Median	Min	Max	SD
General	14	2.9	3.0	0.0	6.0	1.5
Spinal	37	2.6	2.0	0.0	6.0	1.6
Local	19	2.3	2.0	0.0	5.0	1.6

**Table 4.** Comparing groups. Postoperative complications.  $p > 0.05$

Type of complication	PLUG		BASS		total	
Seroma	2	2,7%	1	1,3%	3	1,9%
Wound infection	2	2,7%	5	6,4%	7	4,6%
Hematoma	2	2,7%	5	6,4%	7	4,6%
Testis edema	1	1,4%	2	2,6%	3	1,9%
TOTAL	7	9,5%	13	16,7%	20	13,2%

**Table 5.** Results of first follow up examination. 1 month after surgery

	PLUG		BASS		p
level of postoperative pain <sup>a</sup>					
0-	25	35,7%	12	18,5%	
1-	36	51,4%	15	23,1%	
2-	9	12,9%	35	53,8%	
3-	0	0	3	4,6%	$p < 0.05$
Time of postoperative discomfort					
till 2 weeks	52	74,3%	30	46,2%	
till 1 month	13	18,6%	29	44,6%	
longer	5	7,1	6	9,2%	$p < 0.05$
Time of return to normal home activity					
2 weeks	48	69,6%	28	43,1%	
1 month	15	21,7%	23	35,4%	
longer	6	8,7%	14	21,5%	$p < 0.05$

- a
- 1. without pain
- 2. mild-pain does not limit normal life activity
- 3. moderate-pain limits some activity
- 4. severe-permanent pain which limits normal, home activity

**Long-term results**

At the second follow-up rate 96.4% of patients overall, 70 (100%) patients from the mesh group and 65 (92.8%) from the Bassini group, were examined. Physical examinations were carried out in 47 (63%) cases in the PLUG group and 43 (58%) of the Bassini group ( $p > 0.05$ ). Information from patients who did

attend was taken by telephone. Seven (9.4%) recurrences after mesh plug and 16 (20.5%) after the Bassini operation were observed ( $p < 0.05$ ). Physical examination revealed 4 (51.1%) and 3 (18.8%) recurrences respectively in patients unaware of having this complication ( $p > 0.05$ ) (Table 6). Three (42.8%) recurrences in the mesh group and 5 (31.2%) after Bassini herniorrha-

**Table 6.** Comparing groups-Recurrences

Recurrences	PLUG	BASS	P
Based only on phone information	3 (4,1%)	13 (16,8%)	p < 0,05
Additionally found by physical examination	4	3	p > 0,05
TOTAL RATE	7 (9,4%)	16 (20,5%)	p < 0,05
Found within the first year after surgery	3 (42,8%)	5 (31,2%)	p > 0,05
Age of patients with recurrences	Median 55 SD = 13,7 (28-70)	Median 54,1 SD = 19,2 (14-74)	p > 0,05

**Table 7.** Comparing groups-Influence of types of hernia and early complication on recurrence rate. p > 0,05

	PLUG recurrences	BASS recurrences	P
Indirect hernia	6 (10,3%)	9 (18%)	p > 0,05
Direct hernia	2 (22,2%)	6 (35,3%)	
Scrotal hernia	2 (13,3%)	4 (17,3%)	
Wound infection	2 (100%)	3 (60%)	
Other complication	2 (40%)	2 (25%)	
Recurrent hernia	1 (11,1%)	3 (42,3%)	
Incarcerated hernia	0	3 (18,7%)	
Bilateral hernia	1 (25%)	3 (37,5%)	

% percentage of recurrence among particular type of hernia or complication

**Table 8.** Long term results-1-4 years after surgery

	PLUG		BASS		TOTAL	P
Pain						p > 0,05
0	55	74,3%	49	67,1%	104	
1	17	23,0%	19	26,0%	36	
2	2	2,7%	5	6,8%	7	
Patient satisfaction (result)						p < 0,05
1-bad	1	1,4%	13	20,0%	14	
2-fair	9	12,9%	5	7,7%	14	
3-good	5	7,1%	15	23,1%	20	
4-very	55	78,6%	32	49,2%	87	

0. without pain

1. mild-pain does not limit normal life activity

2. moderate-pain limits some activity

phy appeared within the first year after operation (p > 0.05). The mean age of patients with recurrence was similar in both groups: 55 ± 13.7 (28-70) and 54.1 ± 19.2 (14-74) respectively (p > 0.05). Statistical evaluation of the influence of types of hernia and early complication on the recurrence rate did not reveal significant differences in the two groups (Table 7). Long-term follow-up revealed mild intermittent groin pain in over 20% of patients and moderate pain in a small percentage in both groups (p > 0.05). More patients after mesh plug hernioplasty were very satisfied: 55 (78%), compared to 32 (49%)

(p < 0.05) after the Bassini procedure (Table 8).

### Discussion

The Bassini operation has been the method of choice for inguinal hernia repair for over 100 years. Many modifications were described but the Shouldice operation is now considered the most effective [Paul 1994, Kux 1994, Simons 1996,]. Tension of connected tissue in the suture line is thought to be the main reason for postoperative discomfort and recurrences. Synthetic mesh has been widely adopted in tension-free methods

of groin hernia repair from the beginning of the 1990s [Morris-Stiff 1998]. The excellent results published by Rutkow encouraged us to employ the mesh plug method in our Department in 1994 [Rutkow 1993]. After experience with our first 100 operated patients, we began a randomized prospective study comparing the new mesh plug hernioplasty with the previously used Bassini operation [Pirski 1995]. Up till now there has been no such study, so we compared our results with those of other mesh vs non-mesh trials.

There is no doubt that Rutkow's mesh plug procedure is easier and faster than the Bassini operation. Insertion of the plug into the hernial orifice is easier and safer than sophisticated suturing of the posterior wall of the inguinal canal. It takes less time, especially for young apprentice surgeons [Paul 1994, Zieren 1998, Rutkow 1998, Kingsnorth 2000].

The discrepancy between the two groups in our study relative to the use of spinal or general anesthesia resulted from varying patient demand. We now make more effort to explain to patients the superiority of spinal or local over general anesthesia.

Postoperative pain depends on many factors: analgesic administration, age of patients and their activity in the postoperative period, and surgical technique: tension in suture line and size of wound [Callesen 1998]. We measured pain on the VAS 6-8 hours after surgery, when the effect of analgesic drugs had decreased almost completely. Pain after the mesh plug procedure was definitely lower in the VAS and fewer patients needed narcotic drugs. Results of most other trials also reveal that pain after mesh hernioplasty is lower than after non-mesh repair [EU Hernia Trialists Collaboration 2000, Zieren 1998], but in some series there were no statistical differences [Barth 1997]. It is known that young, walking and coughing patients feel more pain, regardless of the type of procedure [Callesen 1998]. These factors did not influence our study because patients were well-balanced regarding age, and pain was assessed before walking.

The superficial wound infection rate does not depend on the method of hernia repair from an anterior approach [Mann 1998]. It is very closely connected with the standards of aseptic routine in the hospital. Antibiotic prophylaxis has been used in some trials but without evidence of its advantage [Millican 1996]. Incarcerated hernia is a risk factor of wound infection. Polish epidemiologic data reflect that there was an 11% infection rate after incarcerated hernia repair and 3% after elective herniorrhaphy [Korfel 1980]. In our study, after the Bassini operation 3 of 5 (60%) wound infections occurred in patient with incarcerated hernia. In one case (1.4%) there was a chronic deep infection and mesh removal was necessary. Although the preperitoneal space is the best site for mesh implantation, aspiration of seromas was required in only 2 cases in the mesh plug group (2.7%). Seromas occur more often after laparoscopic procedures and when polyester instead of polypropylene mesh is used [Morris-Stiff 1998]. The hematoma rate varies between 3 and 16% and is closely connected with insufficient bleeding control during the operation [Paul 1994, Zieren 1998]. Rutkow uses electrocautery throughout the procedure and leaves the distal part of the sac open in cases of scrotal hernia [Rutkow 1998]. In our series we did the same. Testicular edema seems to be commoner after traditional herniorrhaphy and this complication can be reduced from 6% to 2% by avoiding suturing the muscles [Kux 1994]. Gilbert found no testicular edema after his 400 sutureless plug procedures [Gilbert 1992]. In our study this complication rate did not differ statistically in the two groups. Length of hospital stay depended on patient recovery and was shorter after the mesh plug procedure. Patients are now often operated in "a one day surgery" system and even local complications are treated in the outpatient clinic. At one time patients used stay in Polish hospitals much longer. This factor of hospital stay is not often used in comparative studies, only in 5 out of 16 [EU Hernia Trialists Collaboration 2000].

The time of return to normal daily activity is very important for patients and from the socioeconomic point of view. Our study revealed an advantage of the mesh plug over the Bassini technique. Postoperative discomfort disappeared within 2 weeks in 74% of patients after the Rutkow operation and 70% resumed their home activity. In most trials return to usual activities is quicker after mesh than non-mesh operative repair [EU Hernia Trialists Collaboration 2000], but in some studies there is no difference, especially in the Shouldice vs mesh repair [Barth 1995]. We did not compare time away from work in our study because it depends largely on socioeconomic factors (motivation, type of insurance), or on the doctor's advice, which varies widely [Millican 1996].

The recurrence rate in the literature ranges from 0.1% to 30%. This wide variation is not solely due to the different effectiveness of surgical methods, but depends on many factors: definition of recurrence, type of study (retrospective or prospective, randomized or not), type of patient population, type of hernia, type of surgical technique, experience of surgeon, type of suture material and mesh, method of follow-up examination and evaluation of results [Lichtenstein 1976, Simons 1996, Rutkow 1998]. An experienced hernia surgeon who operates electively on primary, small, indirect hernias using mesh or nonabsorbable sutures, and who counts only patients who return suffering from recurrence, has the lowest recurrence rate. The most reliable evaluation comes from randomized, prospective multicenter trials with meta-analysis of individual patient data. In our series the recurrence rate seems to be very high, but all patients with every kind of hernia were included and were operated by over 20 different surgeons (mostly residents) with a follow-up rate of 96%. Over 50% of recurrences after mesh plug repair were small and found in patients unaware of this complication. This reflects the importance of this part of the follow-up examination. In most cases the causes of recurrences are well-

known: plug not adequately fixed, flat mesh too small, recurrences in the femoral canal. After Bassini operation they were localized, as described elsewhere [Lichtenstein 1976]. The high recurrence rate shows the need to improve the operating technique. In most series, as in our own, recurrence rate after mesh repair is lower than after a non-mesh operation: 1.4% versus 4.4%, but these are usually early results [EU Hernia Trialists Collaboration 2000]. Longer follow-up examinations reveal a higher recurrence rate after the Bassini than the Shouldice operation: 8-12% vs 2-6% and a very low rate after plug repair: 0.4-1% [Paul 1994, Kux 1999, Zieren 1998, Rutkow 1998, Campanelli 1999].

Chronic pain is considered to be caused by nerve entrapment in the scar. Some think that the probability of such a lesion is higher after mesh repair but our study and similar ones reveal no difference in the two groups [Bendavid 1998, EU Hernia Trialists Collaboration 2000]. Neurapraxia and hyperesthesia have been reported in 15-20% of patients following open repair, whereas chronic pain is seen in 5% [Bendavid 1998]. Our results for long-term pain are almost the same. More patients after mesh plug procedure were very satisfied. In our opinion this is due to their faster recovery after operation and the smaller number of local complications. The mesh plug procedure offers patients a faster return to physical activity. We perform tension-free repairs only, and as a one-day procedure.

## Conclusions

Our study revealed the advantages of the mesh plug procedure over the Bassini operation: shorter operating time, less postoperative pain, faster return to daily activity, lower recurrence rate and greater patient satisfaction. Postoperative complication rates and long-term discomfort did not differ statistically in the two groups. Physical examination is essential to assess the true recurrence rate.

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