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Open Treatment of Abdominal Wall Hernias: Mesh Repair is Superior to Suture Repair and Onlay Mesh is Better than Sublay Mesh – Five-Year Multicentric, Prospective, Randomised Clinical Trial

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Abstract

Background: The aim of study was to compare the results of different surgical modalities/mesh (onlay/sublay position) and suture repair in treatment of abdominal hernias.

Methods: According to the size of hernia gate patients were divided into two groups: small hernias (hernia gate between 5-25 cm^2) and large hernias (gate > 25 cm^2). In these two groups patients were randomized according to the surgical procedure: in group 'A' suture vs. mesh repair and in group 'B' onlay vs. sublay mesh reconstruction.

Results: n = 734. In small hernia group significantly higher recurrences occurred after suture repair than in mesh repair (27.2% vs. 8.3% – p < 0.001). In large hernia group onlay mesh reconstruction showed significantly better results than sublay mesh repair, recurrence rate was much lower in onlay group (12.2% vs. 20.1% – p = 0.038). Wound infection presence was more significant (p=0.029) in onlay group.

Conclusion: Among small hernias mesh repair provides better results than suture repair. In case of large hernia group the onlay mesh repair is significantly superior to the sublay repair, but the infection rate is much higher with only one.

Keywords: Hernia; Mesh repair; Onlay; Sublay; Abdominal wall; Recurrence; Pain

Introduction

More than 2 million laparotomies are performed annually in the United States, with a reported 2% to 11% incidence of incisional hernia [1]. Suture repair techniques have dominated ventral and incisional hernia repair over a century. The most popular of these techniques was the Mayo duplication. In larger hernias, suture repair requires the application of tension to the fascia in order to close the orifice. Therefore, many suture repairs failed mechanically, and recurrence rates were found to be as high a 54%. The advantages of mesh implantation have first been confirmed in an influential trial by Luijendijk et al. [18] who found recurrence rates to be nearly halved in mesh as compared to suture repair.

The choice of a type of open operative repair is controversial; the technique of hernia repair is often based on tradition rather than evidence [1]. According to databases [2] and reviews there is a good evidence that open mesh repair is superior to suture repair in terms of recurrences and an insufficient evidence as to which type of mesh or which mesh position (on- or sublay) should be used.

The main goal of this study was to compare the recurrence rate of suture versus mesh repair and sublay versus onlay position of mesh reconstruction in care of small and large hernias.

Methods

A multicentric, prospective, randomised internet-based clinical trial was performed in 20 Hungarian surgical departments between 2002 and 2009, with permission of ethical committee. During the randomization period (from March of 2002 to March of 2004) 953 patients were involved. During five-year follow-up each patient was controlled regularly and recorded to our online database.

All patients with primary umbilical or incisional abdominal hernia were included into this study. The involving criteria were the following: good patient compliance, signed consent form and normal wound healing conditions. The preoperative exclusion criteria were age under 18 or above 70 years, hernia orifice under 5 cm^2, planned other gastrointestinal surgery, unstable circulation, uncontrollable diabetic or autoimmune diseases, severe renal or hepatic failure, advanced stage of tumours or currently treated malignancies. If the intraoperative findings showed inflamed or muddy content of hernia sac, accidental intraoperative lesion of bowels are resulted exclusion from the study.

To define the standardized surgical protocol a workshop was organized with the participation of all centres. In this platform the used operative techniques and uniform questionnaire were discussed and agreed.

Randomization procedure is shown in Figure 1. After recording body parameters (height, weight, gender, etc) patients were divided into two groups according to the size of abdominal wall defect. In group 'A' the surface of hernia orifice was 5-25 cm^2 (small hernia), and in group 'B' it was above 25 cm^2 (large hernia). The following step was the randomization inside group 'A' (suture versus mesh) and in group 'B' (onlay versus sublay position). The randomization was performed by inaccessible computer software using online connection between the centres and displayed on website of the Hungarian Surgical Society.

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In our database several parameters of patients were recorded in different panels. On preoperative chart location and size of the abdominal wall defect were recorded. From patient's history the previous abdominal surgery, abdominal pressure increasing factors (coughing, pulmonary diseases, chronic constipation), systemic disorders (mild hepatic or renal failure, well-controlled diabetes), or former malignancies (already cured tumours or radio-chemotherapy deep in the past) were registered. Patient's general conditions (ASA Score), hernia location, prophylactic antibiotic or antithrombotic therapy were also recorded.

Operative panel summarized the exact size of the musculo-aponeurotic defect, type of implanted prosthesis and used suture (for closing peritoneal sac, fixing mesh, closing fascia and skin), date and duration of operation, type of anaesthesia, and the identification of surgeon. Usage of different types of prosthesis, types of applied sutures and sutures technique were optional, but exact record to database were needed. Every qualified general surgeon who worked at any of participating departments was allowed to involve patients under observation of the local study coordinator.

In the postoperative period early complications (bleeding, infections, foreign body reaction, ileus, etc) were recorded and individual pain was evaluated using verbal analogue scale on the 1st, 2nd and the 7th postoperative days. Visual analogue scale was applied at early postoperative period and at each follow-up as well. First sign of bowel motion, mobilization, and local status of the wound or usage of any hernia support were also recorded. According to study protocol follow-up investigations were in 1, 6, 12, 24, 36, 60 month-time. The postoperative pain was divided into early postoperative pain (within 30 days) and chronic pain (over a month). Postoperative monitoring was done by a surgeon who had not operated on the patient.

Main steps of operative techniques were also standardized such as preparation of hernia orifice or sac, resection and suture of the peritoneum. There was difference among the randomized groups in method of fascia closure or positioning and fixating of implanted mesh. In case of suture repair musculo-aponeurotic tissue were duplicated using Mayo-type transversal stitches [1].

In sublay mesh repair after suturing the peritoneum, mesh was implanted under the musculo-aponeurotic layer fixed by stitches, and then fascia was closed over the mesh [2-4]. Component separation (CS) technique was also used if it was needed to reach the tension free state. In midline hernia the mesh was placed behind the rectus muscle but over the back sheet of rectus fascia. Below the arcuate line, the mesh was placed into the preperitoneal space. In sublay position the mesh was overlapped on the incision line at least 5cm in all directions.

In case of onlay mesh repair mesh was implanted after suturing the peritoneum and the fascia with overlapping of 5 cm and fixed with interrupted or running suture. Drainage was applied following each mesh repair, but subcutan or skin closure techniques were optional. Special form of onlay reconstruction, Chevrel type [5] was also allowed in midline hernias. His technique consisted of relaxing incisions in the anterior rectus sheath with primary approximation of the linea alba and medial turnover of the anterior rectus sheath (CS technique) followed by mesh placement.

Polypropylene prosthesis was implanted with fixing 5 cm overlapping of the incision line in all mesh groups. Fixation of the implanted mesh was also optional, absorbable-running, absorbable-interrupted, non-absorbable-running and non-absorbable-interrupted sutures could be chosen. Single shot antibiotic prophylaxis was given before the incision.

In this study the previous operations, BMI, location of abdominal wall defect, mean time of operations, fixation of the implanted mesh, technique of fascia closure, post surgical mobilization, discharge time, recurrence rate, early and chronic (over 30 postoperative days) postoperative pain (visual analogue scale) and wound healing complications (presence of haematoma, perigraft fluid or infection) was analysed as well.

Results are expressed as mean values and standard deviation (S.D.). Data were analysed many way of statistical analysis, like chi-square test, K-S test, Mann-Whitney test, Fischer's exact-test. The level of significance was set at $p < 0.05$. The study was registered at clinicaltrials.gov (title: "Open Mesh Versus Suture Repair in Treatment of Abdominal Wall Hernias (HSS-AHS)" – reg.no: NCT01018524).

Results

953 patients (345 men and 608 women) were included into this study and distributed into group 'A' (small hernia) and group 'B' (large hernia) according to the size of abdominal wall defect. After randomization, in 247 cases suture repair (subgroup 'A'/suture) and in 247 patients mesh repair (subgroup 'A'/mesh) were performed. In group 'B' mesh was implanted in 235 cases in sublay (subgroup 'B'/sublay) and in 224 patients in onlay position (subgroup 'B'/onlay).

During five-year follow-up from 953 randomized cases altogether 219 patients (23%) finished the study earlier than planned. 59 (6,2%) patients were excluded because of breaking the protocol of the trial, such as new disease realized which had been in exclusion criteria (9/59), not the randomized procedure performed (10/59) inadequate effect of therapy (2/59) adverse reaction (3/59), at the request of patient (19/59), if patient had passed during the five years (5/59), or other reason (11/59). In 160 cases (16.8%) the database was not completed for different reasons: data could not be reproduced, for instance less than five-year follow-up because patient failed to attend on controls after emission, or lack of operative or postoperative data intake. Our nationwide, internet-based study geographically covered the whole country. In this clinical trial 953 patients were randomized and 734 patients completed study, datasheet was completed 262 men and 472 women. Age 23-70 (mean 59.1 years).

The mean BMI was 29.88 (S.D. 5.61) in complete randomized population. BMI was 30.16 (S.D. 4.24) in recurrent group, but this change was not significantly different ($p = 0.302$). There was no significant difference ($p = 0.253$) found when BMI results of men and women were separated (Men: mean 29.55 – S.D. 4.21, Women: mean 30.54 – S.D. 4.26).

Concerning the previous operation in 189 cases there were no abdominal surgeries in patients histories. Most of them had umbilical hernias and some had Spigelian hernias. In 247 cases gastrointestinal operation appeared in medical history. 126 patients had gynaecological surgery, and 82 cholecystectomies. Rest of patients (90 cases) had vascular, urological procedure, or first recurrence of umbilical reconstruction.

Before reconstruction localization of abdominal wall defect was exactly detected and the incisions were divided into four groups (Table 1). Among small hernias umbilical location (n = 195), and in large group the midline hernias (n = 200) were the most frequent. Suture repair provided the worst results at each location in aspect of recurrence (23-33%). If the procedure was mesh repair in small hernia group there was no recurrence after transverse incision. After midline hernia reconstruction there was a bit higher recurrence rate comparing

to transverse incision in small hernia group. Midline incisional hernias were the most frequent among large hernias, and also showed higher recurrences, mainly in the sublay reconstruction group (Table 1). Comparing the different locations at each group significant differences were only found in umbilical ($p = 0.027$) and transverse-subcostal ($p = 0.033$) groups among small hernias. Differences of other locations were not significant ($p > 0.05$) (Figure 1).

The mean time of operations at in group 'A' was 46 minutes (S.D. 15-150) at suture repair subgroup and 59 minutes (S.D. 15-135) at mesh repair subgroup. This time was 81 minutes (S.D. 25-220) at sublay and 73 minutes (S.D. 30-210) in onlay subgroup in cases of large hernias. There was no significant difference in the mean times between these subgroups. Comparing the mean time in recurrent cases at in large hernia groups the time interval was shorter in onlay than in sublay subgroup which could be explained with easier operative technique.

Most of surgeons used non-absorbable-interrupted stitches for fixing the prosthesis (65% of cases in subgroup 'A'/mesh; 63% of cases in subgroup 'B'/sublay; 55% of cases group 'B'/onlay). Statistical analysis showed significantly higher recurrence in subgroup 'B'/sublay, than in subgroup 'B'/onlay if we used interrupted suture technique ($p < 0.05$). Moreover, in these subgroups the recurrence rate difference was much lower with usage of running suture for fixing the mesh ($p > 0.05$) irrespective of it was absorbable or not. There was not any recurrent case in absorbable running suture (only 11 cases altogether) group (Table 2). Comparing the running and interrupted suture together in group 'B', running suture provided far better results ($p = 0.002$). In case of small hernias the different fixation types did not show significant difference.

Analysis of fascia closure in case of group 'A' the non-absorbable sutures (both running and interrupted) provides lower rate of recurrence comparing to absorbable threads (5% in non-absorbable running and 7% in non-absorbable interrupted vs. 14% in absorbable running and 11% in absorbable interrupted sutures). However, no difference was found between running and interrupted groups. In subgroup 'B'/sublay the fascia closure with running sutures provided nearly two times lower recurrence rate than with interrupted one (14% in non-absorbable running and 10% in absorbable running vs. 23% in non-absorbable interrupted and 24% in absorbable interrupted sutures), but this was not found significant when interrupted and running ($p = 0.068$) and when absorbable and non-absorbable ($p = 0.093$). There was not significant difference noticed in subgroup 'B'/onlay (interrupted/running – $p = 0.855$, absorbable/non-absorbable – $p = 0.389$) (Table 3).

The bowel movements were also recorded in the postoperative periods, but there was no significant difference between groups. The mean time of first post-surgical mobilization was 15.4 hours in group 'A'/suture repair and 16.1 hours in group 'A'/mesh repair subgroups without significant difference. In large hernia group could not found remarkable difference between subgroup 'B'/sublay (18.0 hours) and subgroup 'B'/onlay (18.8 hours) in point of postoperative mobilization.

Comparing discharge time after operation in each subgroup, there was no significant difference between subgroup 'A'/suture repair (mean 6.2 days) and subgroup 'A'/mesh repair (6.5 days). Similar results were found between subgroups 'B'/sublay (7.7 days) and subgroup 'B'/onlay (7.9 days) ($p = 0.938$). In subgroup 'B'/sublay patients were kept longer in the hospital (7.5 days) than subgroup 'B'/onlay patients (6.4 days) ($p = 0.728$). Our patients came back to the everyday activity in average 26

Hernia localisation	Group 'A'/suture (n = 50/184)	Group 'A'/mesh (n = 15/180)	Group 'B'/sublay (n = 38/189)	Group 'B'/onlay (n = 22/181)
Umbilical (n = 244)	23/102 (23%)	6/93 (6%)	6/22 (27%)	3/27 (11%)
Midline (n = 311)	18/54 (33%)	9/57 (16%)	23/104 (22%)	10/96 (10%)
Transversal + subcostal (n = 97)	5/15 (33%)	0/18 (0%)	6/35 (17%)	4/29 (10%)
Other (n = 82)	4/13 (31%)	2/12 (14%)	3/28 (11%)	5/29 (17%)

Table 1: Hernia recurrence according to harnia location.

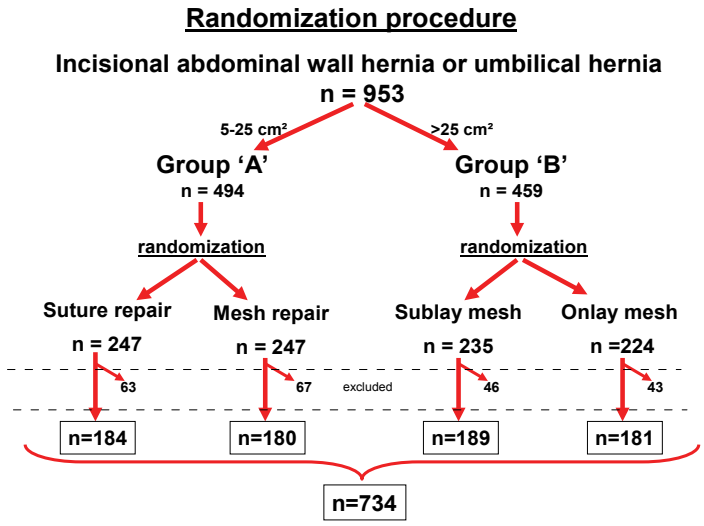

Figure 1: Study design. In group 'A' (small hernias) patients were selected with hernia orifice between 5-25 cm^2, in group 'B' (large hernias) patients were included with hernia orifice above 25 cm^2. In group 'A' suture or mesh repair (in sublay position) was performed according to randomization, in Group 'B' mesh implantation was obligatory, randomly in onlay or in sublay position. Patients were excluded because of protocol break from each group. The conclusions were drawn after 734 cases.

Mesh fixation	Group 'A'/ mesh (n = 180)	Group 'B'/ sublay (n = 189)	Group 'B'/ onlay (n = 181)
Absorbable running suture	0/3 (0%)	0/6 (0%)**	0/2 (0%)
Absorbable interrupted suture	2/24 (8%)	4/21 (19%)*	0/15 (0%)
Non-absorbable running suture	2/35 (6%)	2/43 (5%)**	8/63 (13%)
Non-absorbable interrupted suture	13/118 (11%)	30/119 (25%)*	15/101 (15%)

Table 2: Mesh fixation in all implanted and recurrent cases.

Fascia Closure	A/suture (n = 184)	A/mesh (n = 180)	B/sublay (n = 189)	B/onlay (n = 181)
Absorbable running suture	7/23 (30%)	4/28 (14%)	3/30 (10%)	3/33 (9%)
Absorbable interrupted suture	21/88 (24%)	8/75 (11%)	14/58 (24%)	5/45 (11%)
Non-absorbable running suture	6/13 (46%)	1/21 (5%)	5/35 (14%)	6/41 (15%)
Non-absorbable interrupted suture	16/60 (27%)	4/56 (7%)	15/66 (23%)	9/62 (15%)

Table 3: Fascia closure techniques in recurrent cases per all implanted meshes in each group.

days after suture and 29 days after mesh repair in small hernia group. In large hernia group returning to everyday life took in average 32 days / 35 days at in subgroup 'B'/sublay per in subgroup 'B'/onlay (p = 0.811).

After five-year follow-up 50 (27.2%) recurrences from 184 suture repair, and 15 (8.3%) recurrent hernia from 180 cases in mesh repair population were recorded in small hernia group. The statistical analysis showed absolutely worse results in recurrence rate after suture repair comparing to mesh repair (p < 0.001). In large hernia group (group 'B') our data showed 38 (20.1%) recurrent cases from 189 sublay mesh reconstructions, and 22 definite recurrences (12.2%) from 181 patients in onlay mesh repair subgroup. Data evaluation showed significantly higher hernia recurrence rate after sublay mesh repair than in onlay mesh reconstruction (p = 0.038) (Figure 2). Recurrence free survival after abdominal wall reconstruction is shown by Figure 3. These data demonstrated that the most part of the hernia recurrences presented between 6 and 24 month postoperative time.

The pain characterization was evaluated in the randomized groups and no significant difference was found among these groups, neither if we compared small and large hernia groups (Figure 4).

Among wound healing disorders the perigraft fluid was most frequently observed (12.6% altogether), and was more common in group 'B', there was no difference between its subgroups. Significant difference was only in group 'B' in field of wound infection (p = 0.029) and in case of sterile fat necrosis (p = 0.037) where onlay mesh repair is inferior to sublay one (Table 4).

Discussion

Incisional hernia is the most common complication after abdominal wall surgery. In the last decade the rate of tension-free surgical technique has been highly increased. According to literature the results of different methods of abdominal wall reconstructions represent wide variety. Until the 1990s, suture repair of incisional hernias was the gold standard technique [1]. Unacceptable high recurrence rates associated with primary suture repair have led to an increased application of prosthetic mesh for the repair of incisional hernias. Placement of

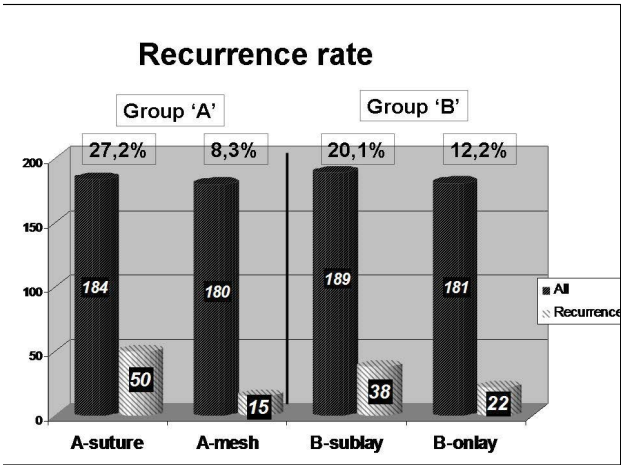

Figure 2: Hernia recurrence rate after five-year-follow-up.

The recurrence rate was significantly higher in subgroup 'A'/suture vs. in subgroup 'A'/mesh (p < 0.001), and in subgroup 'B'/sublay vs. in subgroup 'B'/onlay (p = 0.038).

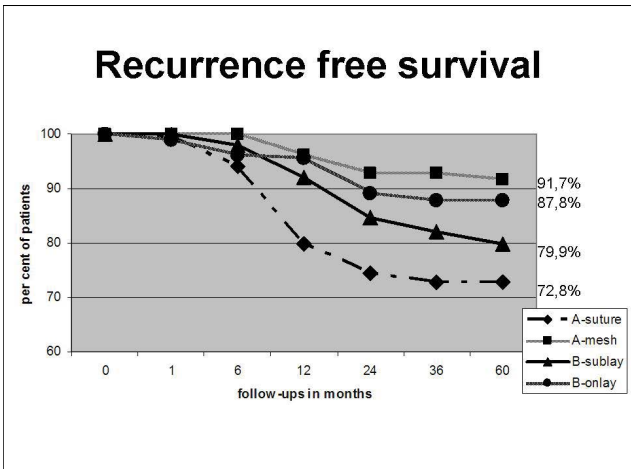

Figure 3: Recurrence free period. Best results are in small hernia with mesh repair. The recurrences occur most often between 6 and 24 months in all groups.

mesh allows for a tension-free restoration of the abdominal wall. The ultimate goal when using mesh is for it to become incorporated into the surrounding tissues. Several methods of securing the mesh to the fascia have been described, with the most common being mesh onlay (prefascial placement) and sublay (retrorectus placement). The onlay technique is popular among surgeons because it avoids direct contact with the bowel and technically is not difficult for surgeons [1,6]. However, it requires wide tissue undermining, which may predispose wound-related complications [1].

Only a few controlled trials have compared the different open mesh techniques. Notwithstanding this, onlay and sublay mesh repair with different implanted materials are the most popular procedures [6-8]. Couple of studies have not found difference in recurrence rate between onlay and sublay reconstruction techniques (Shell et al. [1], Csaky et al. [9], den Hartog et al. [10] in Cochrane database 2008) [1,9,10]. On the other hand, there are also studies which prove lower recurrence rate following sublay mesh repair (Israelsson et al. [7], Schumpelick et al.

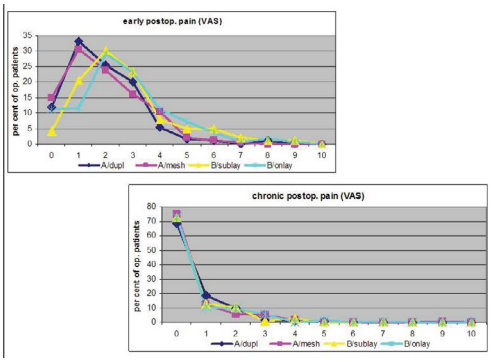

Figure 4: Abdominal and wound pain after abdominal wall hernia reconstruction on visual

Figure 4: Abdominal and wound pain after abdominal wall hernia reconstruction on visual analogue scale. According to the score 0 means no pain at all, while 10 show an intolerable pain. Postoperative pain in this trial was determined on the 1st, 2nd and 7th days, on the time of discharge, and at each follow-up (1, 6, 12, 24, 36, 60 months). Early postoperative pain was characterized up to end of first postoperative months. Pain after 30 postoperative days – in literature – is defined as chronic pain.

[11], Langer et al. [12]). One apparent drawback of the onlay technique is the higher risk of infection [13,14]. Furthermore, some of the non-randomised showed a tendency towards less recurrences after sublay compared to onlay repair [12,13,15,16], but longer hospital stay [17]. The high recurrence rates of primary suture repair were supported comparing to mesh repair in a large, prospective, randomized trial by Luijendijk et al. [18]. According to some prominent hernia study – like Swedish hernia study from 2002 – we also find absolutely better results in abdominal wall reconstructions when mesh repair was compared with direct suture. Chevrel [5] reported their results of 389 patients and found a recurrence rate of 18.4% without the use of mesh compared with 5.5% with the use of polypropylene onlay mesh.

Sublay placement of mesh (Rives and Stoppa) has been used with increasing frequency [2-4] because it has a hypothesis to support its background statically, however it is technically more difficult. Mesh is placed above the hernia sac and on the posterior rectus sheath and beneath the rectus muscle. It is generally recommended to place the mesh with at least 4-5 cm contact between the mesh and fascia, which allows for distribution of pressure over a wider area. This surgical technique also requires wide tissue undermining like onlay does, when forming space for mesh implantation. This certainly predisposes to wound-healing problems as well. Using this type surgeons need to prepare greater internal surface causing higher tissue reaction. That can be the basic reason why several studies with high number of patients can not find significant difference between recurrence of onlay and sublay hernia reconstructions [1,2], or that comprehends the potential why sublay technique can be inferior to onlay reconstruction.

It has also been experimentally demonstrated that polypropylene may shrink up to 30% after implantation [19,20], but the shrinkage has not been published in onlay position. These papers haven't respect for tissue reaction which is caused by surgical preparation and the foreign body reaction resulted from the greater surface. Furthermore, sublay technique seems to be the most difficult among open abdominal wall reconstructions and it has longer learning curve but shows acceptable outcome in expertise hands [21,22]. In our point this fact also can play part in our results. Langer et al. also confirmed that the most important prognostic factor following mesh repair is the surgeon's experience [12]. We also agree with this opinion and the randomized surgical trials need to involve more and more expert surgeons. On the other hand incisional hernias surgery is often performed young surgeons, so those scientific groups, which presented too small numbers of involved surgeons or too small numbers of involved patients or make too strict rules when start a clinical trial can make mistake when draw their conclusions, because it can be amounts of miles from the everyday practice.

In our current study each participating surgical departments had great experiences in hernia surgery. To retain variability every qualified general surgeon of each involved department were allowed to operate patients within the study which is one important pile of an objective randomized trial. Compare to many other studies who do not take attention to the personal incompatibilities, we attended the objectivity so the postoperative monitoring and internet-database recording were done by a surgeon who had not operated on the patients.

Burger et al. presented that transverse, oblique and paramedian incisions caused significantly less incisional hernias than the midline incisions [23]. Grantcharov and Rosenberg in their review recommended transverse incision for abdominal operations because it showed lower incidence of late incisional hernia as well [24]. In contrast, Seiler et al. did not find significant difference in recurrence after 200 randomized cases [25]. Even though, O'Dwyer and Courtney observed that transverse abdominal incisions did not show advantage over midline incisions in reducing incisional hernia rate [26]. In the present study comparing the locations of hernias we found that midline incisional hernia recurrence is most frequently presented in small hernia group and sublay group among large hernias than in other locations and also shows higher recurrences after wall defect reconstructions. As it was already supposed after analysing our partial results year by year (partial results had presented in Hungarian by our workgroup) [27]. According to our experiences onlay mesh reconstruction provides much better result in aspect of recurrence and mesh repair is superior to suture repair irrespectively of hernia location.

The mean surgical time is basically determined by the size of hernia and intraperitoneal adhesion formation and not essentially by the methods of reconstruction [2]. We confirmed these observations when we found numerous difference between two groups (group 'A' and group 'B'), but there was no significant differences between the types of reconstructions inside these groups.

Making difference between types of meshes was not the goal of this study. Only polypropylene meshes were used, we can not compare absorbable or other non-absorbable mesh types. However, suture for mesh fixation and fascia closure by the database we have enough data to compare different suture materials and suture techniques. These data showed that non-absorbable sutures were most frequently used for mesh fixation. These data also established significant higher recurrence rate in subgroup 'B'/sublay, than in subgroup 'B'/onlay after interrupted suture applied, while the recurrence rate was significantly lower at each group after usage of running suture against interrupted one. The most of operations performed by using interrupted suture, the bigger part of these were non-absorbable thread. The recurrence rate in this group showed a wide spectrum also between 11% and 25%. Inside large hernia group higher recurrence rate was recorded in sublay reconstruction group comparing to onlay one (25% vs. 15%). Our data demonstrated differences in non-absorbable running suture groups with representing 5% recurrence rate in sublay and it was 13% in onlay group. According to this study – because a well detectable difference between the fixation methods – our experiences showed that using non-absorbable running suture for mesh fixation less number of recurrence is expected. The reason can be the more balanced force between the stitches at running

Complications	summ	a-repair	a-mesh	b-sublay	b-onlay	
Bleeding/ haematoma	19	5 (2.7%)	2 (1.1%)	8 (4.2%)	4 (2.2%)	2.60%
Perigraft fluid	93	18 (9.8%)	15 (8.3%)	31 (16.4%)	29 (16.0%)	12.60%
Dehiscence	3	0	1 (0.5%)	0	2 (1.1%)	0.40%
Wound infection	16	3 (1.6%)	2 (1.1%)	3 (1.6%)	8 (4.4%)	2.20%
Fat necrosis	32	2 (1.1%)	6 (3.3%)	9 (4.7%)	16 (8.9%)	4.40%
	734	184	180	189	181	

Table 4: Wound healing conplications. The perigraft fluid was the most frequently observed, but significant difference showed only in group 'B' in field of wound infection ($p = 0.029$) and in case of fat necrosis ($p = 0.037$) where onlay mesh repair is significantly inferior to sublay one.

sutures. Unfortunately in our study the conclusion in difference between absorbable and non-absorbable suture for mesh fixing can not be drawn, because the low number of absorbable thread applied cases. Likewise in his review of mesh fixation Amid can not provide any specific recommendation for fixing the prosthesis. He stated meshes are traditionally sutured by non-absorbable sutures to the abdominal wall [28,29]. For sublay repair, however, many experts today recommend to attach the mesh only with a few absorbable stitches to the posterior fascia or to use no fixation at all [30]. Rather than being based on empirical evidence, this change was guided by the general shift towards tension-free repair techniques in hernia repair. So far, the only one randomized trial that has addressed the topic of mesh fixation provided less complications and a shorter hospital stay when tissue adhesives were applied in addition to conventional mesh fixation [31].

Account of different type of the threads for fascia closure there was no significant difference recorded at onlay reconstruction among large hernias. But there was a big difference between them in case of mesh repair in small hernia group or in sublay reconstruction inside group 'B'. While in small hernia group different kinds of non-absorbable threads provide better results comparing to absorbable ones (5% vs. 14% in running and 7% vs. 11% in interrupted groups), in large hernia group any kind of running suture is preferable (both absorbable and non-absorbable) if we compare to interrupted sutures (10% vs. 24% in absorbable groups; 14% vs. 23% in non-absorbable groups). The good results of non-absorbable thread in small hernias were not confirmed is large hernia group. We also cannot confirm that the types of running sutures are superior to interrupted ones in each subgroup. The controversial results in fascia closure make difficult to draw the conclusion and give general recommendation to surgeons. The bigger part of abdominal wall closure trials recommend (long term-) absorbable thread for fascia closure [32,33]. The question of running and interrupted suture is much more controversial [33,34].

Burger et al. [35] in his study characterized the postoperative pain on visual analogue scale after suture versus mesh hernia repair. Suture repair patients rated their abdominal pain during the past month as 1.9 on average, while patients in the mesh repair group rated the pain as 1.0 ($p = 0.04$). Patients in the suture repair group rated their abdominal pain in the last years as 2.2 on average, while patients in the mesh repair group rated the abdominal pain during the past years as 1.0 ($p = 0.009$) [35]. Venclauskas et al. from Lithuania compared postoperative pain after using open suture repair (keel technique - primarily hernia closing under tension with continuous suture) and onlay mesh repair technique. They presented significant lower pain after tension-free reconstruction in 1, 3, 6, and 12 month follow-up time ($p < 0.05$ in each follow-ups) [14]. Randomised trials by Armstrong et al. showed a significant reduction in postoperative pain in patients who received a transverse incision compared to patients who were after a midline incision [36]. While several papers demonstrate data about abdominal pain from different aspects, but we have no enough data from randomized trials comparing postoperative pain after the different surgical techniques of mesh hernia repairs. Because feeling pain is highly subjective and individual, it is very difficult to be characterized, and find and a score system to make it objective. Visual analogue scale, which scores from 0 (no pain at all) and 10 (agony because of pain), is the most reliable among these ones whereas the patients are actively involved into the score system. Using this score system, in our trial no significant differences were found among randomized groups and subgroups, neither if we compare small and large hernia groups.

There was no remarkable difference between the subgroups in point of view of bowel movements, postoperative mobilization and in hospitalization time or return to normal activity. Venclauskas et al. showed higher percentage of patients returning to normal activity in 1, 3, 6, and 12 months after tension free abdominal wall reconstructions comparing to suture repair cases [14]. Our study can not confirm this. Significant difference was observed by comparing recurrent mesh repairs to all mesh reconstruction in small hernia subgroup ($p = 0.044$), it could show that the recovery was too short or the return to daily routine was too early, but more randomized studies are surely needed.

Several authors presented [2,6,10,14] that mesh implantation increases the risk of wound infections and also states difference in location of the mesh. What is more form the other hand the postoperative wound infection is known as one reason of hernia recurrence. Most of the papers demonstrate higher wound infection when the mesh is used in onlay position [2,6,10,14]. While we can not present a relevant difference between mesh and non-mesh repair, but our data show significant lower infection rate when the mesh is under the muscle. Higher infection risk of onlay repair can be confirmed. However fluid production is increased with mesh implantation (foreign body reaction), and the perigraft fluid was the most frequent complication in our trial, and that is the potential base of infection, according to this study this is not confirmed. Other papers present the only way of wound infection reduction is the laparoscopic hernia repair [37], but our trial discusses only open approach.

Summarising the long-term results of our randomized, multicentric, prospective clinical trial we should draw two conclusions. Only keyhole hernias which can be treated by direct sutures, where the abdominal wall tension is negligible. The uniform observation of higher recurrence rates associated with primary suture repair has led to an increased application of prosthetic mesh for the repair of incisional hernias. According to our study these literature data [18,38] confirm that mesh is mandatory needed to reach acceptable low recurrence rate if the defect is larger than a trockar hernia.

From the other hand the results of experiences with different locations of prosthesis implantation are controversial. Most of authors have better results with sublay technique and other notable part of literature can not make distinction between sublay and onlay reconstructions. Against the former evaluated study results in the literature we found that recurrence rate is significantly better with onlay technique. This contradictory facts call for further randomized trials. But according to our experiences in case of incisional hernias the onlay reconstruction is an equivalent option that provides acceptable low rate of recurrence.

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