**Onlay mesh repair versus sublay mesh repair in open ventral incisional hernia repair: Meta-analysis of randomized controlled trials**

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**Abstract:**

**Background:** Treatment of incisional hernia remains a major issue of abdominal wall surgery. Open onlay mesh repair and open sublay mesh repair were the most frequently used procedures. This meta-analysis aimed to compare onlay mesh repair with sublay mesh repair both indicated for open ventral incisional hernias repair regarding wound infections, hematoma, seroma, operative time, and recurrence.

**Methods:** Literature searches of electronic databases and manual searches up to January 31, 2019, were performed. Review Manager Version 5.3 was used for pooled estimates. We included only randomized controlled trials (RCTs) in this meta-analysis. Random-effects meta-analysis model was used, and meta-regression was applied when appropriate.

**Results:**

Of22 relevant articles, six RCTs met eligibility criteria involved 909 patients (465 onlay mesh repair versus 444 sublay mesh repairs). Sublay mesh repair improves results in terms of wound infection (OR = 2.33, 95%CI: 1.09 to 4.94, p=0.03), and seroma (OR = 3.71, 95%CI: 2.26 to 6.09, p<0.00001) with a longer operative time (MD = -24.68, 95%CI [-35.78 to -13.59], *I2*=61%; p<0.0001).As concerns recurrence, the forest plot did not show a statistical difference (OR = 1.75, 95%CI: 0.55 to 5.55, *I2*=54%; p=0.34), however heterogeneity is high (I2 =54%) and the meta-regression showed a statistical significant difference in favour of sublay mesh repair**.** There was no significant difference between these two techniques regarding hematoma (OR = 2.53, 95%CI: 0.90 to 7.11, p=0.08).

**Conclusions:**

This meta-analysis of RCTs showed that sublay repair was superior to onlay mesh repair for open ventral incisional hernia repair. Sublay mesh repair should probably be the first choice in repair and onlay mash repair can be reserved only for more difficult situations where sublay is not possible.

**Keywords:** Incisional hernia; Onlay; Sublay; Recurrence; Surgical site infection; Wound complications

**INTRODUCTION**

An incisional hernia may occur during a follow up of two years after a midline incision, with a rate ranging between 10-20% (1,2). It is essentially due to a surgical error during the closure of the abdominal wall. This incidence is higher in patients with risk factors such as obesity and steroid-dependent patients (3). Incisional hernia can affect the quality of life with the risk of life-threatening in case of strangulation. Mesh repair ensures a decrease of incisional hernia recurrence (4,5). The two most frequently used procedures are the onlay mesh repair and sublay mesh repair (6). These procedures have advantages such as reducing the recurrence rate significantly and disadvantages such as chronic pain (6,7).

Some surgeons favoured the onlay mesh repair avoiding an advanced abdominal wall dissection while other surgeons insisted that the sublay mesh repair remain the best mesh placement even for incisional hernia. However, onlay repair is flawed by a slightly increased wound complication rate (8). Incisional hernia recurrence and postoperative wound complications depend on the abdominal wall mesh site that is still a debated question among surgeons (9–11). Onlay repair is known to be easier and faster and sublay repair is expected by many to reduce recurrence.

This meta-analysis aimed to compare open onlay mesh repair with open sublay mesh repair performed for ventral incisional hernias regarding wound infections, hematoma, seroma, operative time, and recurrence.

**METHODS**

 **Electronics searches:**

An extensive electronic search of the relevant literature, with no language restrictions, was performed on January 15, 2020, using the following databases: “Cochrane Library’s Controlled Trials Registry and database of systematic review”, “United States National Library of Medicine”, “National Institutes of Health PubMed/MEDLINE”, “Excerpta Medica Database”, “Embase”, “Scopus”, and “Google Scholar”. Keywords used for the final search in all databases were “onlay”, “sublay”, “retromuscular”, “preperitoneal”, “open”, “surgery”, “incisional hernia”, “abdominal wall”, “repair”, “retrorectus”, “prefascial”, “retrofascial”, “Rives-Stoppa”, and “mesh placement”.

**Criteria of eligibility**

**Included studies:** All randomized controlled trials (RCTs) reporting a comparison between Onlay mesh repair and Sublay mesh repair to treat ventral incisional hernia, published in a peer-reviewed journal, were considered for analysis**.** Data from non-randomized trials, non-comparative studies, editorials, letters to editors, review articles, and case series (fewer than ten cases) were excluded from the analysis.

**Participants:** Adults (aged over 18 years) of either sex operated on for ventral incisional hernia and undergoing open onlay or sublay mesh repair were included**.**

**Interventions:** We studied two groups of surgical procedures:

1. Sublay mesh repair according to Rives-Stoppa (12) and Schumpelick (13) for treatment of incisional hernia. The mesh was placed in the retro-rectus muscles (prefascial space or in the preperitoneal and retrofascial space).

2. Onlay mesh repair according to Cheverel description (14). The mesh was placed in the anterior rectus fascial after dissection of the fascia from the subcutaneous plane.

This meta-analysis was in accordance with the 2010 Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) guidelines (15).

**Outcomes measures**

Main outcome measure: recurrence

 Secondary Outcome measures were wound infection, seroma, hematoma, and operative time.

**Data collection and analysis**

**Study Selection:** Two authors (MAC and MWD) independently reviewed all abstracts. All studies, accompanied by the full text that met the inclusion criteria were retained. Disagreements were resolved by discussion after consulting a third member of the review team (IB).

**Assessment of studies quality:** All studies that met the selection criteria were appraised independently by two authors (MAC and MAD) using the CONSORT statement for randomized controlled trials (RCTs) (16).

**Data Extraction:** Each author extracted the data independently from each study. Disparities were settled after discussion with the senior authors (MWD, CD).

**Assessment of heterogeneity:** We used the Cochrane Chi² test (Q-test) to assess heterogeneity and the I² statistic to estimate the degree of heterogeneity (17). I² between 0% and 50% was considered as a low level, between 51% and 100% as a high level of heterogeneity (18). Funnel plots identified studies responsible of heterogeneity.

**Evaluation of effect size:** We used the RevMan 5.3.5 statistical package from the Cochrane collaboration for meta-analysis (19). We selected the mean difference (MD) as an effective measure for continuous data. For dichotomous variables, odds ratios (OR) with 95% confidence intervals (95% CI) were calculated. Random effects model was used. The threshold of significance was fixed to 0.05. WhenI2 was between 51% and 100%, we tested for the interaction between relevant factors and effect size estimates. We performed a meta-regression using the natural log (OR) as the dependent variable and the explored factor as the independent variable (17) as determined by Comprehensive Meta-Analysis Software. The meta-regression concerned the interaction between treatment effects and the main outcome measure “recurrence”. The covariate used was the global rate of recurrence.

**RESULTS**

 **Literature search results**

We retrieved potentially relevant articles **(Figure 1)**. Of these, seven studies published between 2010 and 2018 met eligibility criteria (8,20–25). Sixteen studies were excluded with reasons: one study (26) was a prospective non-randomized trial, two studies (27,28) were descriptive studies, one study was a meta-analysis of onlay versus sublay mesh repair in incisional ventral hernias (29), twelve studies concerned onlay and sublay mesh repair but concern abdominal ventral hernia or included abdominal ventral hernia and abdominal ventral incisional hernia without subgroup analysis (30–41). The seven identified studies were published as full papers and involved a total of 954 patients (487 onlay mesh repair versus 466 sublay mesh repairs). The quality assessment of the included studies was summarized in **Table 1**.

 **Studies and patients’ characteristics**

Details of the included studies were reported in **Table 1.** Studies included were fully matched for year of publication, country, mean age, hernia size, mesh type, number of patients undergoing a sublay mesh repair or onlay mesh repair, prophylactic antibiotic use, and follow up duration. Five studies were published in English (8,20–23) and one study in Hungarian (24).

**Wound infection**

It was reported in six studies (8,20–23,25) **(figure 2.A)**. These studies included 515 patients. Wound infection was reported in 27 out of 263 patients in onlay repair group versus 11 out of 252 patients in sublay repair group. There was a statistically significant low rate of wound infection in sublay repair group (OR = 2.33, 95%CI: 1.09 to 4.94, p=0.03).

**Seroma**

It was reported in five studies (8,21–23,25) **(figure 2.B)**. These studies included 451 patients. Seroma was reported in 84 out of 231 patients in onlay repair group versus 29 out of 220 patients in sublay repair group. There was a lower seroma rate in sublay repair groups with a statistically significant difference between the groups (OR = 3.71, 95%CI: 2.26 to 6.09, p<0.00001).

**Hematoma**

This outcome was reported in four studies including 426 patients (20–23) **(figure 2.C)**. Seroma was reported in 14 out of 217 patients in onlay repair group versus 6 out of 209 patients in sublay repair group. There was no difference between the two groups (OR = 2.53, 95%CI: 0.90 to 7.11, p=0.08).

**Operative time**

Operative time was reported, in minutes, in three studies including 362 patients (21–23) **(figure 2.D)**. It was reported in 185 patients in the onlay repair group and 177 patients in sublay repair group. Operative time was longer in sublay repair group. This difference was statistically significant between the groups (MD = -24.68, 95%CI [-35.78 to -13.59], p<0.0001). There was a substantial heterogeneity level between the studies (*I2*=61%).

**Recurrence**

It was reported in seven studies including 852 patients (8,20–25) **(figure 3.A)**. Recurrence was reported in 37 out of 431 patients in onlay repair group versus 42 out of 421 patients in sublay repair group. There was no statistically difference in term of recurrence rate between the two groups (OR = 1.75, 95%CI: 0.55 to 5.55, p=0.34). However, there was high heterogeneity between the studies (*I2*=54%). The random-effects meta-regression **(Figure 3.B)** was in favour of Sublay repair (p=0.007).

**DISCUSSION**

This meta-analysis of RCTs showed that sublay mesh repair improves results in terms of wound infections and seroma with a longer operative time. As concerns recurrence rate, meta-regression was in favour of Sublay repair (p=0.007). There was no significant difference between these two techniques regarding hematoma. Sublay mesh repair should probably be the first choice in repair and onlay mash repair can be reserved only for more difficult situations where sublay is not possible. This is the first meta-analysis of seven RCTs comparing onlay mesh repair and sublay mesh repair for incisional hernia repair.

Mesh placement has an impact on tissue incorporation, tissue reaction, and tensile strength of the abdominal wall (11,42–44). In the case of incisional hernia, mesh bedding dissection is challenging especially in cases of previous wound infection, hostile abdomen, multiply retromuscular repair and adhesions. However, a wide dissection with a large mesh overlap was favourable with regard to tissue incorporation. This imperative could be associated with increased postoperative wound complications and recurrence.

Wound complications present a problem following mesh repair of incisional hernia. They increase secondary recurrence (45). Many reports indicated sublay mesh repair for incisional hernias (44,46,47). The placement of the mesh on the posterior rectus fascia compared with onlay position would benefit from a more vascularized area (46). On the other side, it is widely recognized that dissection of the onlay mesh placement subcutaneous supra fascial space promotes wound infection and seroma (47).

As concern**s** the wound infection, the results in this meta-analysis were in favour of the sublay mesh repair. This outcome seems to be not related directly to the hernioplasty or mesh, but it is due to poor skin antisepstic. Then, an adequate clean of the skin before the procedure is mandatory. Some authors (29,48) explained the higher rate of mesh infection, in the group of onlay repair, by the more superficial position of onlay repair making it more accessible for bacterial colonization. On another hand, in case of sublay mesh repair, mesh positioning on the retro rectus prefascial space ensure a better body’s immune system infections fights (11,49). Mesh infection ranged from 5 to 10% of mesh repairs (50,51). The management of this complication is complex due to several factors predicting its occurrence: medical history, causal germ, type of the prosthesis and its location in the abdominal wall. Operative time was also incriminated in the increase in wound complications (52). In this meta-analysis, the operative time was longer in sublay mesh repair. In sublay repair, the hernia sac is introduced the hernia in the abdominal cavity. The wall defect is closed and the mesh prevents a new displacement. For this reason the treatment is more prolonged and hard. In onlay repair, the hernias defect is not closed and the mesh recovers the hernia. For this reason onlay repair is in fact faster, but it is only justified when the surgeon is not able to do a sublay repair or does not have an experienced surgeon to help. Seroma is related to a tight contact of any subcutaneous foreign body (mesh) much more than in deeper abdominal wall. Seroma was more frequent with onlay technique than the sublay one (53,54). A meta-analysis of Timmermans et al (29) did not find a statistical difference between onlay and sublay techniques concerning seroma while in our study, sublay mesh repair was associated with lesser seroma rate than onlay mesh repair. This complication could be reduced by wearing abdominal binders and the use of low-thrombin fibrin sealant (55,56). Postoperative complications rate (seroma, hematoma, and wound infection) were higher after onlay mesh repair (49,57).

As concerns recurrence, many factors could affect this outcome: wound complications, operative time, the tensile strength of the abdominal wall, and mesh shrinkage (43,45,58). Studies results were controversial (23,24,29,53,59,60). They reported a less frequency rate of recurrence after sublay technique (53,61) or a similar recurrence rate between the two surgical procedures (23,60). Weber et al (54) reported that recurrence is less frequent after onlay method compared to sublay mesh repair. Surgical care of patients with recurrent hernias may be best provided in referral centers with interest and expertise in the management of complex abdominal hernias (62). Additional variables are missed such as mesh overlap, mesh fixation, and surgeon’s learning curve. In addition, this high heterogeneity was explained in some degree by to the small number of patients with different follow-up.

All included studies had similar endpoints of comparable study populations and similar interventions. In this meta-analysis result, we must keep specific attention to the major outcome: Incisional hernia recurrence. This outcome was associated with a moderate level of heterogeneity. In the forest plot of this analysis, five studies (8,20–23) reported a lower incisional hernia recurrence rate after sublay mesh repair. The study of Weber et al (24) was a source of heterogeneity. RCT of Wéber et al could be a subject of a critical level of heterogeneity and bias. Regarding the substantial heterogeneity concerning outcomes of recurrence in our meta-analysis, we used meta-regression analysiswhich is an extension of subgroup analyses **(Figure 3.B)**. This controversy regarding the recurrence evaluation make difficult to allow for solid conclusions and others multi-center RCTs with longer follow-up were recommended.

This meta-analysis of RCT has several limitations. We have not assessed the hospital stay, postoperative pain scores, time of return to activities, chronic pain, and long-term discomfort. The definition of these criteria was not clearly defined. In addition, we have no data as to the types of ventral incisional hernias and surgical wound classification entered in the reference articles as recurrent, infected, reoperated, previous mesh etc… Moreover, the study of Wéber et al (24), including half of the included participants: 459 out of 909 patients, was the only study to found a lower recurrence rate after onlay mesh repair. It was a source of asymmetry and heterogeneity. When it was removed, the heterogeneity was reduced to 0 and the results became statistically significant in favour of sublay repair. Furthermore, the trial of Weber et al (24) was judged by Timmermans et al (29) to be of mediocre quality and might be subject to location bias. Additionally, this study did differ somewhat compared with other studies. It included only larger hernias, which explain the heterogeneity.

In conclusion, based on the available literature, sublay technique is superior to the onlay technique in term of wound complications and recurrence rate for open ventral incisional hernia repair. Sublay mesh repair should probably be the first choice in open incisional hernia repair and onlay mesh repair can be reserved only for more difficult situations where sublay is not possible.

**AUTHOR DISCLOSURES**

The authors declare that they have no conflict of interest.

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**Figures list:**

**Figure 1:** Flow diagram of included studies

**Figure 2.A:** Meta-analysis of studies on **wound infections**

**Figure 2.B:** Meta-analysis of studies on **seroma**

**Figure 2.C:** Meta-analysis of studies on **hematoma**

**Figure 2.D:** Meta-analysis of studies on **operative time**

**Figure 3.A:** Meta-analysis of studies on **recurrence**

**Figure 3.B:** Meta-regression of studies on **recurrence**

**Table 1:** Details of the included studies

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **References** | **Year** | **Country** | **Mean age (years)** | **Nb of onlay repair** | **Nb of Sublay repair** | **Hernia size** | **Mesh type** | **Prophylactic antibiotics** | **Follow up (months)** | **Quality assessment** |
| Gondal et al (20) | 2012 | Pakistan | 44.9 | 32 | 32 | NF | NF | NF | 6 | 10/25 |
| Demetrashvili et al (21) | 2017 | Georgia | 60.4 | 78 | 77 | Onlay: 62.7 cm2Sublay: 100.4 cm2 | Polypropylene | Yes (Cefuroxime 1.5g) | 26 | 21/25 |
| Sevinc et al (22) | 2018 | Turkey | 55.4 | 50 | 50 | 73.4 cm2 | Polypropylene | No | 37 | 19/25 |
| Venclauskas et al (23) | 2010 | Lithuania | 55 | 57 | 50 | Onlay: 114.5 cm2Sublay: 110 cm2 | Polypropylene | Yes (Oxacillin 1g) | 12 | 15/25 |
| Natarajan et al (8) | 2017 | India | 56.3 | 13 | 11 | ≥ 4 cm | Polypropylene | NF | 6 | 16/25 |
| Weber et al (24) | 2010 | Hungary | NF | 235 | 224 | > 25 cm2 | Polypropylene | Yes (cephazolin) | 60 | 14/25 |
| Ahmed et al (25) | 2019 | Pakistan | 39.13 | 23 | 22 | ≥ 3 cm | NF | Yes | 6 | 14/25 |