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Risk-benefit assessment of onlay and retrorectus mesh augmentation for incisional hernia prophylaxis: A secondary analysis from network meta-analysis

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Abstract

Background: Mesh augmentation has proved efficacious for the prevention of incisional hernia (IH). A recent network meta-analysis (NMA) identified onlay and retrorectus mesh (OM and RM) as the most effective therapeutic options, but the risk of surgical site infection (SSI) and other complications require additional consideration.

Methods: The NMA generated pooled risk differences (RD) for the benefits of reducing IH and the risk of SSI and composite seroma/hematoma (CSH) for use in Monte-Carlo data simulations with 1000 replications. Mean incremental risk-benefit ratios (IRBR), i.e., the ratio of incremental risk (or RD) and incremental benefit, and 95% confidence intervals (95% CI) were estimated with a probability of risk-benefits (PRB) across risk-benefit acceptability thresholds from the acceptability curves generated.

Results: The RDs of IH were 0.237 and 0.201 lower in OM and RM than primary suture closure, compared to 0.027 and -0.001 for SSI. IRBRs (95% CI) for SSI risk were -0.118 (-0.124, -0.112) and 0.006 (-0.002, 0.013) for OM and RM, respectively. PRBs were much higher in RM than OM, especially at low acceptability thresholds of 0.05 and 0.1. IRBRs (95% CI) for CSH were -0.388 (-0.395, -0.381) and -0.105 (-0.111, -0.100) for OM and RM, respectively. RM yielded a PRB of 0.87 at an acceptability threshold of 0.2, in contrast to OM, which did not.

Conclusion: Overall, RM offered improved benefit in IH prophylaxis over the risk of complications relative to OM and appeared to be the preferred treatment option for this indication.

Keywords: Incisional hernia, Onlay mesh, Retrorectus mesh, Prophylaxis, Risk-benefit analysis

1. Introduction

Incisional hernia (IH) occurs in over 30% of high-risk patients following abdominal surgery [1] and may lead to surgical complications such as intestinal obstruction and internal organ strangulation. Prevention of IH would lead to healthcare savings; even an estimated 5% reduction in IH would lead to savings of approximately 4 million euros annually in France [2].

Evidence from randomized clinical trials (RCTs) [3-13] has confirmed the efficacy of mesh in hernia prevention under various conditions. In addition, meta-analyses [14-19] have identified a 70-86% reduction in risk of IH following mesh placement during fascia closure. Our recent network meta-analysis (NMA) [20] compared mesh augmentation techniques for IH prophylaxis for onlay (OM), retrorectus (RM), preperitoneal (PM), intraperitoneal mesh (IM), and primary suture closure (PSC). Our findings suggested that only OM and RM significantly reduced IH incidence compared to PSC, but OM may lead to increased risk of seroma and surgical site infection (SSI) compared to other treatment modalities. As such, the mesh technique of choice should consider the potential benefits of IH prevention together with the risk of complications.

The balance between potential therapeutic benefit and complication risk is analogous to an economic evaluation comparing the interventional benefits of clinical effectiveness to incremental cost. Instead of using incremental costs, an analogous comparison of complication risk and the associated clinical benefits could be considered [21]. This study applied a risk-benefit assessment (RBA) framework to evaluate the associated risk and incremental benefit of OM and RM compared with PSC, for the prevention of IH and the risk of SSI.

2. Methods

This current analysis is a part of NMA published in the *International Journal of Surgery Volume 83 November 2020* [20]. The previous NMA was conducted in line with the PRISMA [22] and AMSTAR [23] guideline and registered with PROSPERO (CRD42019145939). Some details of this NMA, including study selection diagram, were provided in [Supplement](#).

We used previously pooled NMA data representing incremental or risk differences (RD) for IH, SSI, and composite seroma/hematoma (CSH) between PSC and any of the OM, RM, PM and IM interventions. The NMA identified only OM and RM to significantly reduce IH incidence and, as such, both interventions were selected for RBA. RDs of IH between OM/RM and PSC were considered as Δ benefit, whereas RDs of SSI and CSH between OM/RM and PSC were considered as Δ risk, see [Table 1](#). Monte-Carlo simulations for Δ benefits and Δ risks were performed with 1000 replications. Incremental risk-benefit ratios (IRBRs) were calculated for each simulated data comparison according to the following equation:

$$\text{IRBR} = \Delta\text{risk}/\Delta\text{benefit}$$

Mean IRBRs and 95% confidence intervals (95% CI) represented the change in risk associated with each additional event of IH prevented. As such, a higher IRBR (closer to zero) is considered more beneficial compared to the associated risk, given that Δ benefit is expressed as a negative value. A risk-benefit plane curve represents Δ benefit and Δ risk on the x-axis and y-axis, respectively. Mesh interventions would be considered superior to PSC if all coordinates fell in the lower left quadrant; in contrast, PSC would be more efficacious if all coordinates were located in the upper right quadrant. Risk-benefit acceptability thresholds (i.e., 0.05, 0.10, 0.20, and 0.30) were pre-defined to represent the maximum level of acceptable incremental risk as a form of reference on the risk-benefit plane curve. The probability of a risk-benefit (PRB) intervention, i.e., the probability of an IRBR lower than the acceptability threshold, was estimated for each threshold

level. A risk-benefit acceptability curve plotted PRBs against the risk-benefit acceptability thresholds [21]. All analyses were performed using STATA version 16.

3. Results

The RDs of IH (95% CI) for OM and RM vs PSC were -0.237 (-0.324, -0.151) and -0.201 (-0.289, -0.114) respectively, indicating a significantly lower risk of IH associated with both OM and RM compared to PSC. However, the associated incremental SSI risk for OM was slightly higher [RD = 0.027 (-0.012, 0.066)], and a little lower for RM [-0.001 (-0.046, 0.044)], although neither were significant. The risk of CSH was also higher for both OM and RM [0.090 (0.052, 0.128) and 0.020 (-0.012, 0.051), respectively], although only OM was significant.

When the risk of SSI was considered, the IRBRs (95% CI) were lower for OM -0.118 (-0.124, -0.112) and slightly higher for RM 0.006 (-0.002, 0.013) relative to PSC. Risk-benefit plane curves were constructed, see [Fig. 1](#), suggesting that in order to reduce IH, RM was associated with a lower rate of SSI than OM. As a result, PRB was higher in RM than OM at every acceptability threshold. For example, PRBs of RM were 0.70 and 0.82 at the threshold of 0.05 and 0.1, respectively, whereas PRBs of OM were only 0.24 and 0.44 at equivalent threshold levels.

Considering CSH as a risk, the IRBRs (95% CI) were -0.388 (-0.395, -0.381) and -0.105 (-0.111, -0.100) for OM and RM compared to PSC, respectively. The risk-benefit plane curves (see [Fig. 2](#)) indicate PRBs of RM were 0.50 and 0.87 at the 0.1 and 0.2 thresholds, while the PRBs of OM were very small, based on these thresholds.

4. Discussion

We conducted an RBA on the findings from our previous NMA that compared and ranked the effect and safety of various mesh-augmented fascia closure techniques on hernia prophylaxis in midline laparotomy [20]. Our results suggest RM might be the optimal mesh technique considering the benefits of lowering IH and the risk of SSI and CSH compared with OM.

Our data used for analyses were based on data of NMA, which included different RCTs, where they had common comparisons, to increase the power of the test in the detection of differences [24]. Considering a direct comparison between OM and RM, to date, only one RCT [10] is available with a sample size of 188 and 185; although OM and RM were not significantly different in benefit of lowering IH and risks of SSI and seroma, equivalence could not be confirmed. Therefore, increasing the sample size of OM and RM to 385 and 359 using data of NMA with Monte-Carlo 1000-simulation should improve the power of the test between OM and RM.

When considering SSI, the risk to benefit ratio was considered relatively favorable, especially for RM, with preventive benefits at thresholds of 0.05, 0.1, 0.2, and 0.3. SSI risks were initially estimated to be 1% to 5%, 3% to 11%, 10% to 17%, and >27% in clean, clean/contaminated, contaminated, and dirty surgical wounds [25]. A more recent study [26] reported reduced SSI risks of 2.3%, 4.8%, 6.1%, and 7.3% for these same categories, respectively. The majority of studies included in the previous NMA involved clean and clean/contaminated groups, representing an appropriate SSI acceptability threshold of 0.05. Given the threshold of 0.05, the PRB was as high as 0.70 for RM and 0.24 for OM. As a result, RM offered greater benefit to risk compared to OM, which may be due to the application of RM in the well-vascularized rectus plane that may be more infection resistant.

The term surgical site occurrence (SSO) was recently used to incorporate all adverse surgical wound events into a single composite endpoint [27]. Use of a single composite outcome could facilitate RBA by comparing benefits represented by a composite risk. However, all outcomes rarely represent similar levels of clinical importance, and combining such outcomes may be misleading and open to interpretation [28]. As such, we considered SSI separately given the severity of this adverse event, and combined seroma and hematoma, which are considered less severe and self-limited complications, as a single endpoint (CSH). A seroma is a common complication following abdominal wall reconstruction that is detectable by ultrasound [29]. RM is an appealing procedure if the acceptability threshold exceeds 0.2, in contrast to OM. However, given the management options associated with CSH, a higher threshold level may be considered more acceptable.

Long-term mesh-related complications (e.g., mesh migration, enterocutaneous fistula, and chronic infection) are also very important, although they are quite rare. However, we could not assess them in the current analysis because most original RCTs included in the previous NMA [20] followed patients up in a relatively short time (2-3 years) which may not be long enough to detect them. As a foreign body, mesh could induce fibrosis and migrate into visceral organs, especially if bare mesh was exposed to those organs. As a result, enterocutaneous fistula and chronic infection could develop. These long-term complications were mainly reported in case reports [30, 31]; thus, data from clinical trials with longer follow-up are further required.

Our results suggest that RM is a preferred technique for IH prophylaxis. However, RM would make hernia repair in the retromuscular plane problematic if IH did occur subsequently. Complications might be more difficult to manage when compared with after OM. In addition, RM

needs more experience than OM to perform. We should balance RM's benefits with all of these concerns.

This study had several strengths. RBA allows benefits to be simultaneously juxtaposed in the context of risks providing an opportunity to clearly differentiate between procedures in an objective manner. PRB, derived from comparisons of IRBR against acceptability thresholds, is informative for decision-making. Nevertheless, the present study also had several limitations. Firstly, this study was based on a previous NMA, which included a relatively small number of original articles, limiting the precision of the treatment effect estimates. Secondly, some rare but severe complications, such as enterocutaneous fistula, were not considered due to a lack of available data in the original studies. Nevertheless, the rarity of such events, while acknowledged, are less likely to significantly attenuate the potential risk-benefit estimates. Finally, using the higher number of combined seroma and hematoma events as a single CSH endpoint may underestimate the CSH rates and over-estimate IRBRs. Consideration of risks and benefits in various clinical settings against pre-defined thresholds should be considered fully to inform appropriate communication and decisions with patients.

5. Conclusions

RM might have a better risk-benefit profile than OM with regard to SSI risk, especially at low acceptability thresholds. In addition, RM appeared more beneficial for CSH at higher thresholds, in contrast to OM. As such, RM likely offers the best risk-benefit profile of the various mesh-augmented fascia closure techniques on hernia prophylaxis in midline laparotomy.

Ethical approval: Not applicable

Data statement: All data are available from previously published articles.

Disclosure information

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Appendix A. Supplementary materials

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Table 1. Pooled risk differences and 95% confidence intervals with standard error of the risk difference

Outcomes	Comparisons	RD (95% CI)	SE
IH	OM vs PSC	-0.237 (-0.324, -0.151)	0.044
	RM vs PSC	-0.201 (-0.289, -0.114)	0.044
SSI	OM vs PSC	0.027 (-0.012, 0.066)	0.020
	RM vs PSC	-0.001 (-0.046, 0.044)	0.023
CSH	OM vs PSC	0.090 (0.052, 0.128)	0.019
	RM vs PSC	0.020 (-0.012, 0.051)	0.016

CSH composite seroma/hematoma, IH incisional hernia, OM onlay mesh, PSC primary suture closure, RD risk difference, RM retrorectus mesh, SE standard error of risk difference, SSI surgical site infection

Fig. 1: Risk-benefit analysis of onlay and retrorectus mesh, considering surgical site infection (SSI) as a risk a) scatter plot of simulated Δ benefits and Δ risks on the risk-benefit plane along with reference acceptability thresholds of 0.05, 0.1, 0.2, and 0.3. The left lower quadrant of the plane represents the area that mesh procedures dominate primary suture closure b) risk-benefit acceptability curve (OM onlay mesh, RM retrorectus mesh)

Fig. 2: Risk-benefit analysis of onlay and retrorectus mesh, considering composite seroma/hematoma (CSH) as a risk a) scatter plot of simulated Δ benefits and Δ risks on the risk-benefit plane along with reference acceptability thresholds of 0.05, 0.1, 0.2, and 0.3. The left lower quadrant of the plane represents the area that mesh procedures dominate primary suture closure b) risk-benefit acceptability curve (OM onlay mesh, RM retrorectus mesh)