

Hernia Prevention Utilizing Mesh and/or Small Bites: A 2x2 Factorial Randomized Controlled Trial

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Background

- Ventral incisional hernias (VIH) are the most common surgical complication following abdominal surgery.
- Randomized controlled trials (RCTs) have shown efficacy of prophylactic synthetic mesh and small bites in European populations.
 - There has been limited adoption of these practices due to concerns with placement of synthetic mesh in contaminated cases and small bites in an overweight/obese population.

Bite Size?

Mesh?

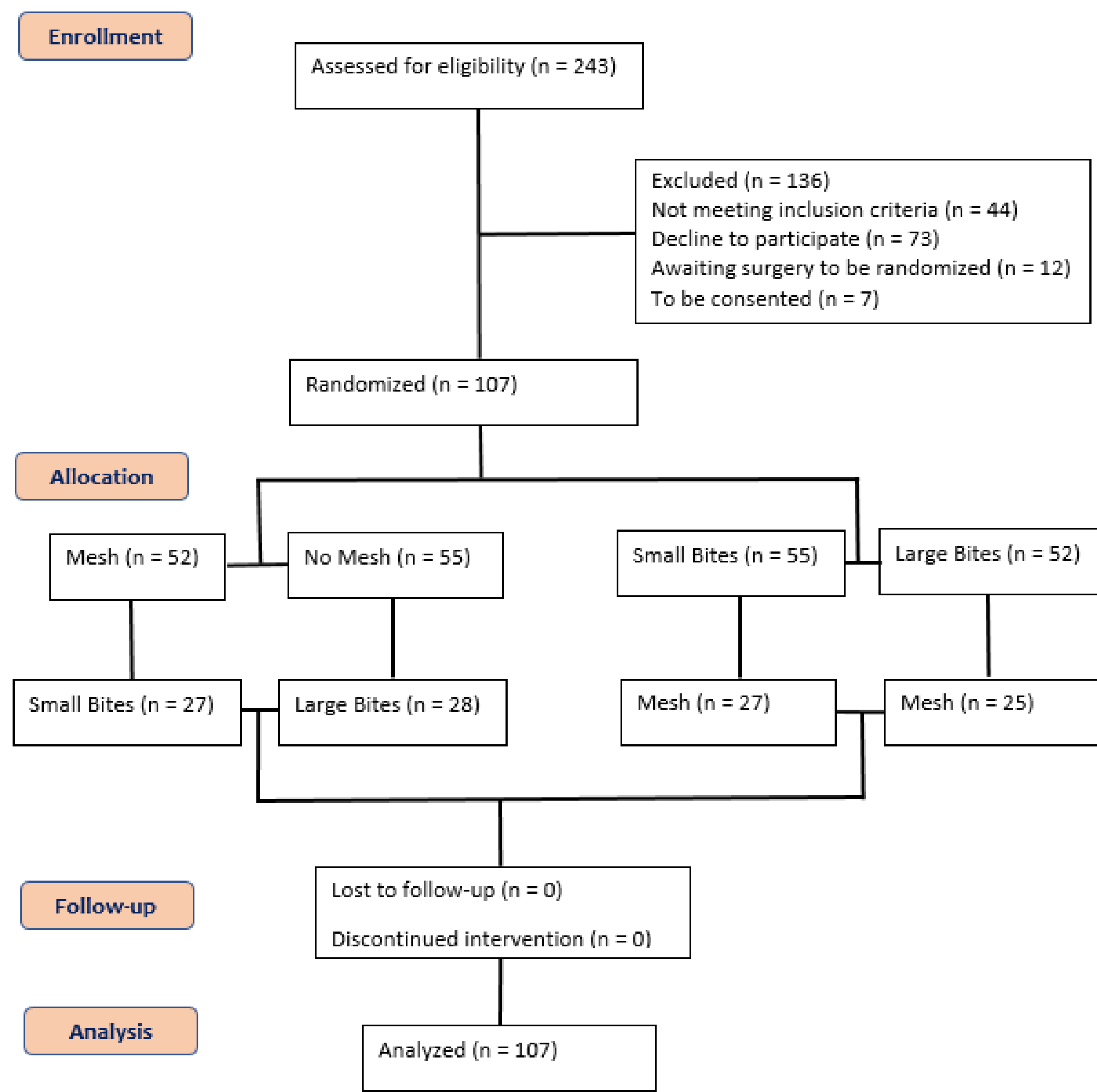
Objective

We sought to assess the effectiveness of two interventions to prevent post-operative wound-related major complications (e.g., surgical site infection-SSI, VIH, and reoperation): prophylactic mesh (biologic mesh) and small bites.

Methods

- Patients at increased risk for major complications (overweight/obese, current smoker) undergoing abdominal surgery with a midline incision of at least 5 cm in length were randomized (2x2 factorial trial) to receive either sublay biologic mesh or no mesh AND either small bites (0.5x0.5 cm) or large bites (1x1 cm) fascial closure.
- The primary composite outcome measure was major complications at 1-year post-operative.
- CONSORT guidelines were followed.
- Assuming alpha=0.05, beta=0.20, Δ=20%, it was estimated that 105 patients were needed.
- Primary outcome was assessed using Fisher's exact test.

Results



2x2 Factorial Outcome of Major Complications for Mesh/No Mesh and Small/Large Bites

	Small Bites	Large Bites	
Mesh	5/27 (19%)	6/25 (24%)	11/52 (21%)
No Mesh	5/28 (18%)	4/27 (15%)	9/55 (16%)
	10/55 (18%)	10/52 (19%)	

Major Complications = surgical site infection, ventral incisional hernia, and/or reoperation

Clinical Outcomes

	Mesh N=52	No Mesh N=55	P-Value	Small Bites N=55	Large Bites N=52	P-Value
Ventral Hernia	6 (12%)	6 (11%)	1.00	6 (11%)	6 (12%)	1.00
SSI	3 (6.0%)	1 (2.0%)	0.35	3 (5.0%)	1 (2.0%)	0.62
SSO	7 (13%)	5 (9.0%)	0.55	5 (9.0%)	7 (13%)	0.55
Bowel obstruction	1 (2.0%)	0	0.49	0	1 (2.0%)	0.49
Reoperation	4 (8.0%)	3 (5.0%)	0.71	3 (5.0%)	4 (8.0%)	0.71
Composite	11 (21%)	9 (16%)	0.62	10 (18%)	10 (19%)	1.00

Discussion

- In this study we found no clear evidence of benefit with small bites or biologic mesh in preventing major complications following surgeries utilizing a midline incision.
- Biologic mesh has been widely utilized by surgeons in the US for contaminated VIH repair. However, recently, multiple RCTs have demonstrated that biologic mesh is inferior compared to synthetic mesh, even in complex or contaminated VIH repair. In addition, studies have been accumulating demonstrating the limitations of biologic mesh for hernia prevention with midline incisions^{1,2,3}.
- A recent systematic review and meta-analysis demonstrated that there has been publication bias with the role of prophylactic mesh of midline incisions⁴. This study would fit into the funnel plot of that systematic review. The main concern has been that there is reluctance to publish both smaller trials as well as negative trials.

Conclusion

- In this trial there was no clear evidence that biologic mesh or small bites were effective in preventing deep or organ space SSI, ventral incisional hernias, or reoperations among high risk patients (overweight/obese, contamination).
- While additional RCTs are needed, we feel there is little or no role to biologic mesh in surgery involving the abdominal wall and future studies should focus on small bites and synthetic mesh.

References

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