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Response to Mahir Gachabayov, et al, 'Methodological Biases May Render a Clinical Study Underpowered'

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To the editorial board of Journal of Trauma

We acknowledge the letter to the editor and the potential conflicts of interests of the authors.

To avoid selection bias, the inclusion or exclusion of patients was carried out by an independent emergency department physician who included patients at the emergency department (please refer to page 42 of the trial protocol (1)). The ASA scores reported in the manuscript correspond to the scores as recorded by anesthesiologists at a later time point after the inclusion of study participants. Indeed, in some patients, the ASA score may have deteriorated after the study inclusion. Furthermore, the severity of comorbidities may have been estimated differently by physicians at study inclusion and anesthesiologists, leading to higher recorded ASA scores by the latter. Of note no patient rated as ASA 5 died within 30 days of the operation.

We acknowledge that many surgical facilities may not be familiar with intra-abdominal placement of mesh and this lack of experience may be detrimental to outcome. However, at the Bern University Hospital, placement of intra-abdominal meshes is performed routinely in both emergency and elective procedures. The implantation of intra-abdominal mesh has not been shown to be associated with specific complications in previous studies published by our department (2-6)~~[1–5]~~. Furthermore, the described complications in patients following mesh placement, such as mesh dissolution, non-integration into the abdominal wall or late onset mesh infection are unlikely to be related to the surgical technique.

Our study was designed and powered for incisional hernia as its primary outcome. However, detection bias as described in the letter to the editor concerns a safety outcome and not the primary outcome parameter. We agree with the authors that the meshes should not affect anastomotic healing and patient deterioration. However, patients #3 and #10 both had severe mesh-associated complications such as torn mesh, necrosis or hematoma of the abdominal wall that are highly likely to become clinically apparent. In addition, case #12, had a type 2 surgical site infection according to CDC criteria (7)~~[6]~~.

Based on the letter to the editor by Gachabayov and Latifi, we recalculated the p-value in question using SPSS and received the same result as reported in our publication. The corresponding SPSS output has been made available to the editorial board.

This study has been designed to assess incisional herniation in an at risk patient cohort. However, the significantly higher rate of complications seen with the implantation of Strattice meshes did not allow the completion of the study and to reach the primary endpoint. Therefore this study is obviously underpowered to identify differences for the primary endpoint. However, the main statement of the publication is the description of safety related events, which were significantly different. Thus, we disagree with the authors of this letter that no robust conclusion can be drawn from this study. Based on the results of this study, the prophylactic use of biologic Strattice meshes cannot be recommended in patients undergoing emergency abdominal surgery because of safety concerns.

Your Sincerely,

Manuel Jakob, MD Guido Beldi,MD

References:

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Authors contributions: Jakob M.O., Beldi G.: Writing of the manuscript.

Supplemental Material: SPSS output HPACS (http://links.lww.com/TA/B826)

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Crosstabs

Notes

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Notes

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Case Processing Summary

	Cases					
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Strattice * Dindo_greater_2_abdominal_wall_complication	13	100.0%	0	0.0%	13	100.0%

Strattice * Dindo_greater_2_abdominal_wall_complication Crosstabulation

			Dindo_greater_2_abdominal_wall_complication		
			0	1	Total
Strattice	0	Count	6	1	7
		% within Strattice	85.7%	14.3%	100.0%
	1	Count	1	5	6
		% within Strattice	16.7%	83.3%	100.0%
Total		Count	7	6	13
		% within Strattice	53.8%	46.2%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	6.198[a]	1	.013	.029	.025
Continuity Correction[b]	3.731	1	.053		
Likelihood Ratio	6.796	1	.009	.029	.025
Fisher's Exact Test				.029	.025
Linear-by-Linear Association	5.721[c]	1	.017	.029	.025
N of Valid Cases	13				

Chi-Square Tests

	Point Probability
Pearson Chi-Square	
Continuity Correction[b]	
Likelihood Ratio	
Fisher's Exact Test	
Linear-by-Linear Association	.024
N of Valid Cases	

a. 4 cells (100.0%) have expected count less than 5. The minimum expected count is 2.77.

b. Computed only for a 2x2 table

c. The standardized statistic is 2.392.