Clinical Trial On Pleural Cavity Opening During Median Sternotomy

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2025-04-13

Clinicsl Trials are the backbone of the modern medicine. They are the only way to test securly a hypothesis and to put out an evidence based medicine. In this paper we will discuss the first and second stage of a clinical trial on how to make sternotomy without opening plerual cavities.

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1 Introduction

The median sternotomy is a common surgical approach used in cardiac surgery. It provides access to the heart and great vessels, allowing for various procedures such as coronary artery bypass grafting (CABG), valve repair or replacement, and aortic surgery(Angelini and Newby 1989). However, one of the potential complications of median sternotomy is the opening of the pleural cavities, which can lead to postoperative complications such as pneumothorax, hemothorax, and respiratory distress.

2 Material & Methods

Patients were randomly assigned to two groups: the experimental group, which underwent median sternotomy with lungs down 10 second and two thorax compression, and the control group without this maneuver. The primary outcome was the incidence of pleural cavity opening given two operators, hospital mortality. Secondary outcomes included length of hospital stay and postoperative pain from drenages. The data was collected from a single center and included demographic information, surgical details, and postoperative outcomes. The data was analyzed using statistical software to compare the outcomes between the two groups.

2.1 Statistical Inference

All data was collected prospectively by multiple operators in a shared single file with version control. The all manuscript was written using Quarto Manuscript writing system with R programming incorporated. The article is published using the github pages on authors personal page. All the code and relevant data is available on github page.

3 Results

The first stage of the clinical trial was designed to assess the feasibility and safety of the experimental approach. The results showed that the experimental group had a lower incidence of pleural cavity opening compared to the control group Figure 1. The length of hospital stay was also shorter in the experimental group, indicating a potential benefit of the new approach. ## Conclusion

4 Figures

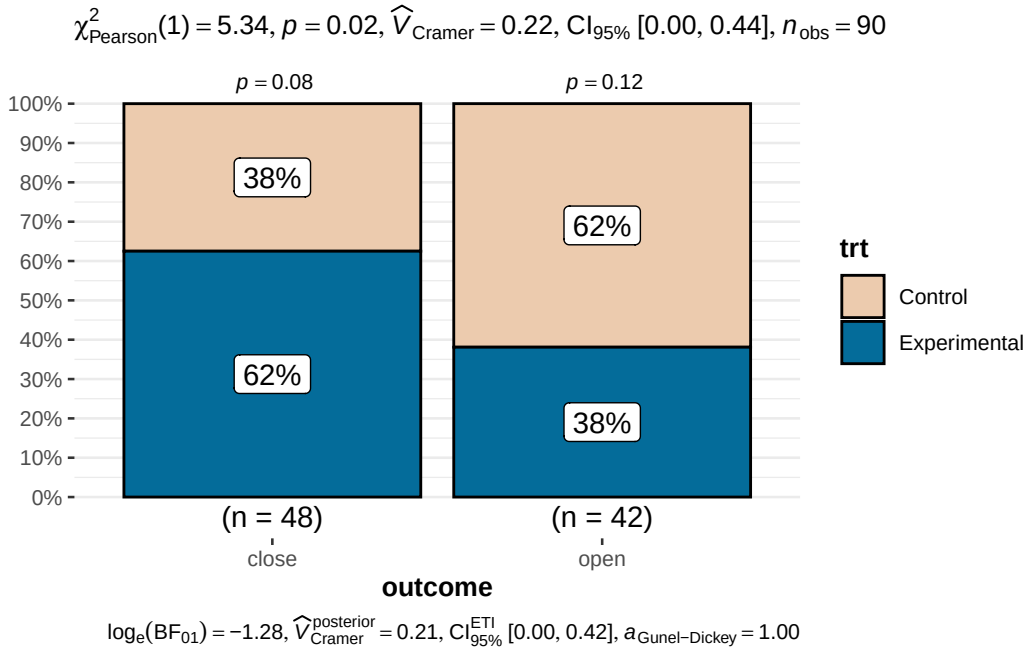

Figure 1: Pleural cavity opening

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Table 1: Demographics of the first stage

Characteristic	**Overall** N = 90[1]	**Experimental** N = 46[1]	**Control** N = 44[1]	**p-value**[2]
Pleural cavity opening				0.021
close	48 (53%)	30 (65%)	18 (41%)	
open	42 (47%)	16 (35%)	26 (59%)	
Body Mass Index	31 (6)	31 (6)	31 (7)	0.8
Diabetis	36 (40%)	20 (43%)	16 (36%)	0.5
sex				0.033
female	33 (37%)	12 (26%)	21 (48%)	
male	57 (63%)	34 (74%)	23 (52%)	

[1]n (%); Mean (SD)
[2]Pearson's Chi-squared test; Wilcoxon rank sum test

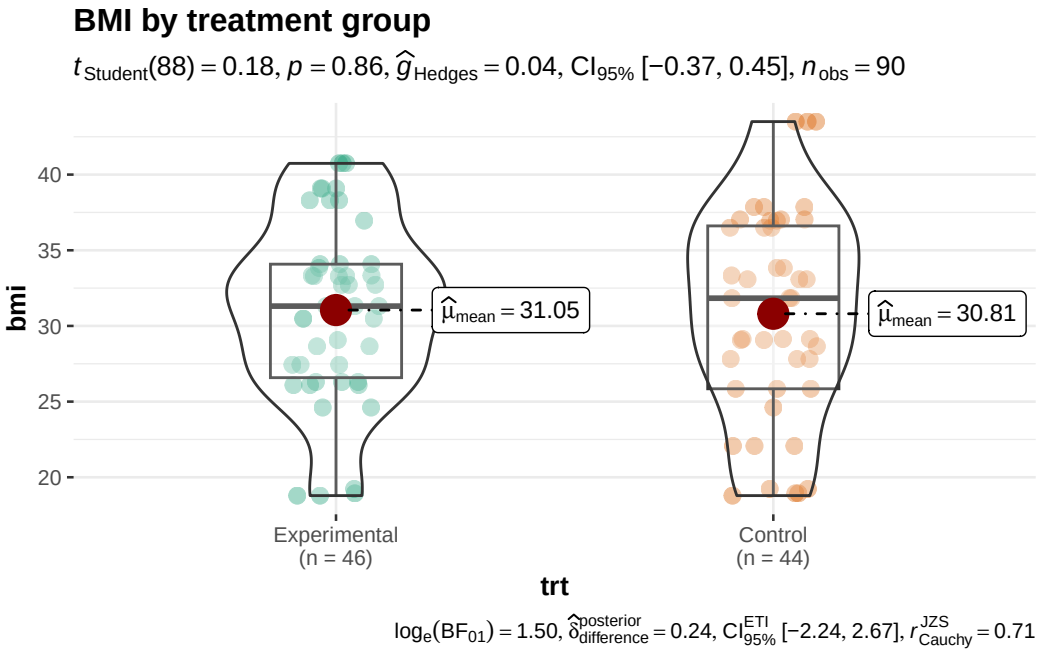

Figure 2

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5 Tables

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6 Acknowledgements

References

Angelini, G. D., and A. C. Newby. 1989. "The future of saphenous vein as a coronary artery bypass conduit." *European Heart Journal* 10 (3): 273–80. https://doi.org/10.1093/oxfordjournals.eurheartj.a059476.