



An analysis of changing statistical significance from .05 to .005 in Foot and Ankle Randomized Controlled Trials



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INTRODUCTION

The use of p-values as a means of reducing Type I error is advantageous, but studies have shown misjudgment of results using p-values can have ramifications.

In 2018, a group of methodologists met together and suggested a move to minimize the misinterpretation of p-values, which was simply reducing the P-value threshold for significance from .05 to .005; P-values between .05 and .005 would be labeled “suggestive”.

In this study, we are looking to evaluate the effect of the protocol suggested by Benjamin et al. on Foot and Ankle-related RCTs in the top 3 Foot and Ankle-related journals. We hypothesize that there will be a large number of outcomes that will change their designation when applying the methodology.

METHODS

- We conducted a Pubmed search looking at studies published from January 1st, 2016 to November 10, 2021,
 - Foot and Ankle International,*
 - Journal of Foot and Ankle Surgery*
 - Foot and Ankle Surgery.*
- Inclusion criteria for the study were RCTs published in the above journals with specifically stated primary endpoints.
- Each RCT’s endpoint was extracted and each p-value was cataloged

RESULTS

Endpoint Characteristics

Table 1: Characteristics	
Characteristics	Number (%)
Journal n=83	
Foot and Ankle International	44 (53.0)
The Journal of Foot and Ankle Surgery	16 (19.3)
Foot and Ankle Surgery	23 (27.7)
Intervention Type n=83	
Anesthesia/Analgesia	10 (12.0)
Drugs	2 (2.4)
Preoperative Management	3 (3.6)
Procedures	18 (21.7)
Surgery	39 (47.0)
Others	11 (13.3)
Funding Source n=83	
Industry	8 (9.6)
Hospital	3 (3.6)
Private	6 (7.2)
University	5 (6.0)
None	57 (68.7)
Not Mentioned	4 (4.8)
Trial Centers n=83	
Single Center	65 (78.3)
Multicenter	18 (21.7)
Type of Endpoints n=83	
Subjective	55 (66.3)
Objective	28 (33.7)
Sample size median	60 individuals

- 222 endpoints,
 - 101 endpoints (45.5%; 101/222) were at or below the .05 threshold
 - 121 endpoints (54.5%; 121/222) were above the .05 threshold.
 - 59 endpoints (26.6%; 59/222) were below .005.
- 58.4% (59/101) of the endpoints that were statistically significant would remain statistically significant
- 41.6% (42/101) of the endpoints would be reclassified to “suggestive” under the proposed protocol change.

CONCLUSION

- Our results suggest that changing the threshold for statistical significance from .05 to .005 in foot and ankle RCTs would heavily alter literature published in the field.
- By implementing this methodology, it is a promising measure to be able to increase RCT quality until a more substantial solution can be found.
- With that being said, caution must be taken when interpreting our results, also requiring further evaluation.

REFERENCES

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