



Letter to the Editor

The accelerated Ponseti method – Is it safe? Maybe



Doctors Ahmad and Aker are to be commended on recording their experience with an accelerated Ponseti method: a case series in which they employed a dramatic reduced cast change interval [1]. As highlighted elsewhere [2], this is potentially of great utility: a major advantage in resource poor environments or where prohibitive time and distance are involved in travel.

Much evidence in surgery is of low level, based on case series which have substantial limitations [3]. In particular, there is an understandable temptation to describe a procedure as 'safe', if no (or few) adverse events are observed. Asserting that a procedure is safe on the basis of inadequate data is a form of Type III error [4] in which the conclusions are not justifiable. It may seem semantic, but there is a difference between the following two sentences:

"In our small case series, there were no adverse events."
(sentence 1)

"The procedure is safe." (sentence 2)

To bridge the gap between sentence 1 and 2 needs a sufficient number of procedures, and few enough adverse events to ensure a 95% probability that the procedure is 'safe' (whatever major complication rate is defined as 'safe'). For case series with zero numerators, Hanley and Lipman-Hand [5] emphasised that the zero numerator (i) 'does not necessarily mean "no risk"', and (ii) 'does not preclude inferences about the size of a risk'; they elaborated the useful 'rule of three' for case series in which zero adverse events occurred: the upper 95% confidence interval of an observed $\{0/n\}$ rate is approximately $\{3/n\}$. Consider the margin of risk for which 'safe' might be defined: 5% risk entails observing no

adverse events in 60 procedures (as $\{3/60\}=5\%$); 1% risk entails observing no adverse events in 300 procedures (as $\{3/300\}=1\%$). Unfortunately, this 'rule of three' is underappreciated by surgeons. Similar formulae have been developed for low (but non-zero) numerators [6].

This study's over-reaching conclusion is a specific example of a widespread general error in thinking. In an analysis of 5 years worth of papers in *Journal of Paediatric Orthopaedics* wherein a procedure was described as 'safe', 75% of datasets were not sufficient to achieve this claim [7].

References

- [1] Ahmad AA, Aker L. Accelerated Ponseti method: first experiences in a more convenient technique for patients with severe idiopathic club feet. *Foot Ankle Surg* 2019;19:S1268–7731 30028–30021.
- [2] Giesberts RB, van der Steen MC, Maathius PGM, Besselaar AT, Hekman EEG, Verkerke GJ. Influence of cast change interval in the Ponseti method: a systematic review. *PLoS One* 2018;13(6):e0199540.
- [3] Wright JG, Kocher MS, Sanders JO. Evidence-based pediatric orthopaedics: an introduction, part 1. *J Pediatr Orthop* 2012;32:S83–90.
- [4] Condon R. Type III error. *Arch Surg* 1986;121:877–8.
- [5] Hanley JA, Lippman-Hand A. If nothing goes wrong, is everything all right? *JAMA* 1983;249:1743–5.
- [6] Newman TB. If almost nothing goes wrong, is almost everything all right. *JAMA* 1995;274(1013).
- [7] Augustithis GA, Ensor HM, Huntley JS. Evidence-based pediatric orthopaedics: how safe is "safe"? *J Pediatr Orthop* 2017;37:e440–5.

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