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


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