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## ***Dilute Betadine Lavage for Preventing Infection in Arthroplasty: A Clean Look at the Fragility of My Practice***

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I read with interest, perhaps even hope, the results of two recent publications regarding the use of betadine wash for the prevention of infection in primary (1) and revision (2) arthroplasty procedures. I finished disappointed.

Let me be clear, I was not disappointed in the research, I am disappointed in myself not being more reflective on prior work. I'm likely similar to others in that I do not like infections. I incorporated the dilute betadine lavage into my practice from time zero based on the publication several years ago (3), and am aware of many of my colleagues who have done the same. Fortunately, the recent publications (1, 2) suggest that there may not have been harm in my adoption of that practice. The intervention is also cheap. But, what if? What if the new data suggested the possibility of harm? What if I had adopted an expensive intervention without benefit?

In the years since the initial publication regarding dilute betadine lavage, I have also developed more insight into the design, conduct, and interpretation of clinical research. Specific to my current angst, I went back and calculated the Fragility Index in the initial publication (3). The Fragility Index is 1; if only one additional patient in the dilute betadine lavage group had the outcome of infection, the results would have no longer been significant.

But, why do we rely on a p-value of 0.05 to drive us so much? Is a 6 or 7% chance of type-1 error so much worse than 5%? Perhaps we should also consider what it would take for a given study to show statistical significance? In other words, what is the robustness of findings for a "negative" study? In the recent publication (1) the unadjusted number of additional events needed to be significant (NAENTBS) for infection after treatment with povidone-iodine irrigation at 3 months following primary total hip arthroplasty (THA) is 8 and following primary total knee arthroplasty (TKA) is 4 (4), based on simple Fischer's exact test of data provided in Table 3 (1). These are small numbers when considering a rather large study population, which directs the interpretation of results (5). One is led to accept the null

hypothesis, but a post-hoc power analysis for the THA data at 3 months is 2.8%, and for TKA data at 3 months 28.3%. Finally, the number needed to harm (NNH) for TKA is only 448 (6). This could be considered small based on the number of TKAs done yearly in North America. Of note, the authors should be commended for the use of a propensity-score weighted adjustment, which shows substantially more robust statistical measures in terms of supporting no difference with or without povidone-iodine wash.

We are full-throttle in the era of evidence-based medicine. Evidence based medicine is being taught in medical schools, residencies, and fellowships, but is likely variably robust. It is now a common requirement that the level of evidence be submitted to the journal along with the article. But, level of evidence is about the methodology, and not the conclusions. In teaching clinical research design, I not only incorporate the importance of level of evidence to promote sound study design, but I also discuss p-values/confidence intervals, fragility index/NAENTBS, and minimally important clinical differences/NNH to engage thinking into how reliable the results may be and how they may translate into practice. In other words, is the result significant? How robust is that significance? Does it clinically matter?

While I fully bear the responsibility for what I do/do not incorporate into my practice and how thoroughly I analyze an article versus just reading the abstract or taking it as here say from a course or one of my partners, I am left to wonder if we can do better as a profession. I admit that I am no trained statistician. However, I am a consumer of information. Would it be appropriate to require that a submitted article go beyond just reporting on statistical significance, but also have to report on the robustness of that significance and quantifiable clinical relevance, if appropriate? Perhaps this should be part of the primary review process and be stated right below the abstract adjacent to the level of evidence.

Sincerely,

A concerned practitioner

Roman M. Natoli, MD, PhD

## References

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**Conflict of Interest: None Declared**