EDITORIAL

The learning curve in surgical randomized controlled trials

John R. W. Kestle, MD

Department of Neurosurgery, University of Utah, Salt Lake City, Utah

TUITE et al. are to be congratulated for conducting an important study on an innovative procedure for tethered cord. The authors' randomized, double-blind trial compared standard spinal cord detethering (DT) with DT in addition to the Xiao procedure (DT+X).² They found no improvement in urinary continence or voluntary voiding with or without cutaneous stimulation in the 3-year follow-up. There were no wound infections in the DT group, but half of the DT+X patients had a wound infection. These results are very different from those reported by Xiao et al., in which more than half of the patients reported bladder control after DT+X.

This report has many strengths. The study was randomized. The sample size was small but calculated appropriately, and the study had the power to detect a smaller difference between DT and DT+X than was already reported in the literature. The outcome was well defined and assessed by blinded observers. The follow-up was of sufficient duration. The patients were all accounted for in the results. The study had an independent data safety management board (DSMB) that reviewed outcomes every 6 months in the first 3 years of the study, and then yearly thereafter.

One of the most difficult issues in randomized trials of surgical procedures is the standardization of the surgical technique and the participating surgeons' experience with it. If a new surgical procedure is subjected to randomization before surgeons know how to perform it, the study is at risk of producing a false-negative result.¹ Tuite et al. made great efforts to minimize this risk. They travelled to China to learn the procedure from Dr. Xiao. They had Dr. Xiao in the operating room at their center during the first 7 procedures in the trial. Under Dr. Xiao's guidance, they used "the same protocols for electromyography (EMG) stimulation, donor and recipient root selection, nerve sectioning, and anastomosis" and "followed his recommended postoperative management instructions." They asked for his opinion during specific steps of the procedure and

"relied on Dr. Xiao's intraoperative instructions." It appears to me that they could not have done much more to ensure that they were performing the procedure according to Dr. Xiao's method.

However, the authors imply in the *Discussion* that a number of possible differences in their surgical technique might account for the negative result. I think they are being conservative. They went to great lengths to replicate Dr. Xiao's technique, and despite those efforts they were not able to reproduce the same results. I would therefore raise another concern: if a surgical procedure is so difficult that it cannot be replicated despite a training visit to the surgeon's center and having the surgeon present in the operating room to guide the learners, then the procedure is probably of limited generalizability.

I congratulate the authors for taking on the task of investigating the Xiao procedure and for doing a very good job. I agree wholeheartedly with their conclusion; they have definitely raised doubts about the clinical applicability of the procedure.

<http://thejns.org/doi/abs/10.3171/2015.11.PEDS15623>

References

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Disclosures

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