Neurosurgical Forum
LETTERS TO THE EDITOR

Xiao procedure: problems with ethics, methodology, and results from the double-blind trial of Tuite et al.

TO THE EDITOR: I am writing regarding the recent article by Tuite et al.¹¹ (Tuite GF, Polsky EG, Homsy Y, et al: Lack of efficacy of an intradural somatic-to-autonomic nerve anastomosis [Xiao procedure] for bladder control in children with myelomeningocele and lipomyelomeningocele: results of a prospective, randomized, double-blind study. *J Neurosurg Pediatr* 18:150–163, August 2016) and the accompanying editorials^{1,3} (Kestle JRW: Editorial. The learning curve in surgical randomized controlled trials. *J Neurosurg Pediatr* 18:145, August 2016; Jea A: Editorial. The positives of a negative study. *J Neurosurg Pediatr* 18:146–147, August 2016).

There are major factual, scientific, and ethical problems in this article, and in the accompanying editorials. I will begin by clarifying the facts of my involvement in “the first in history” double-blind clinical trial for a major surgery in disabled children.

First, regarding my involvement in the trial, Dr. Tuite’s team traveled to China in 2009 and personally examined more than a dozen children with myelomeningocele (MM) and lipomyelomeningocele (LMM) who were cured by the Xiao procedure 2 to 3 years ago. These children voided voluntarily and emptied their bladders almost completely without incontinence. Dr. Tuite and colleagues then invited me to All Children’s Hospital to help them to begin the Xiao procedure 2 days before my keynote speech at the First World Congress on Spina Bifida Research and Care, March 15–18, 2009, in Orlando, Florida. They scheduled 2 cases in 2 operating rooms (ORs) at the same time. I observed and helped in identifying the correct nerve roots; then they stopped the operations and I was informed for the first time that they were conducting a randomized, double-blind trial. I immediately expressed my strong objection, based on 2 reasons. The first reason I objected was that the Xiao procedure had been proven to be very effective by many centers involving thousands of cases and many formal publications,^{4–6,12} including in the US (Beaumont Hospital, New York University Medical Center, and Louisiana State University; Patwardhan R, Mata J: Case report on Xiao procedure for a 6 year old SCI girl to gain bladder control, presented at the International

Symposium on Neural Regeneration, Detroit, Michigan, 2009^{2,7,9}). I believe it is unnecessary and unethical to perform a double-blind trial using major surgery in children, especially these disabled children. My second objection was that it is impossible scientifically and technically to perform a double-blind trial for a very complicated major surgery in children with spina bifida whose history, anatomy, neural defects, bladder situation, and voiding management may be quite different from each other. The major technical dilemma was that children who had undergone the Xiao procedure had to stop clean intermittent catheterization (CIC) and anticholinergic medications 3 months postoperatively to allow regenerated axons working with the bladder and urethra to coordinate voiding, while children who did not undergo the Xiao procedure were to continue using CIC and anticholinergics as the guidelines indicated to protect the upper urinary system. How could you manage this dilemma in a double-blind trial for 3 years?

Despite my strong objections, Dr. Tuite’s team decided to proceed with the double-blind trial. I immediately and permanently withdrew my involvement in the trial on the very first day. Thus, unlike the description in the article, I did not personally assist with the first 7 cases, but only 2 cases on the first day. With sorrow, I had to tell the investigators that I found the donor ventral root (T-12) was cut incorrectly and closely from the cord in 1 of the 2 cases; the root had to be reattached to the cord by microanastomosis, and then its distal end was anastomosed to the S-3 root as in the Xiao procedure. If this kind of accident occurs, the patient should be excluded from any type of trial, because the root re-attached to the cord may not work at all and could jeopardize the rest of the Xiao procedure. Yet, I found the child was still listed as Case 5 (detethering [DT] + Xiao procedure [X]) in the article.

Second, the trial and the article showed major defects and errors in terms of methodology and statistics. A randomized, double-blind study requires the strictest methodology and the most objective quantity and quality control. Whereas in the randomized, double-blind trial by Tuite et al., in addition to using another result (variable surgery) as a control, and a very small sample size that cannot meet the statistical power requirements, each subject’s preoperative lower urinary tract condition, abnormal anatomy, neural defects, and prior surgical history were different from those of the other patients. In addition, each of the 4 neurosurgeons who performed the procedure had

different levels and experience in surgical skills. But the most significant defect of the trial was that postoperative care was different among the enrolled children regarding anticholinergics and CIC. The authors tried to cover up the defect by twice stating in the article that “CIC and the use of BAMs [bladder-active medications] were terminated 2 weeks prior to preoperative evaluations, and most patients were able to refrain from both of these modalities for the entire 3-year follow-up.” This statement completely invalidated the scientific and methodological grounds of this so-called double-blind study: postoperative care must be strictly the same in all patients, i.e., either all should use CIC and the same dosage of BAMs, or all should not use CIC and BAMs. How many patients was “most”: 11, 15, 18? The authors did not report these critical and most important data. But nevertheless, it was fundamentally wrong to paralyze the bladders of some patients using BAMs while not paralyzing those of other patients during postoperative follow-ups in a double-blind trial, and then collect and analyze their data together.

Third, I do not believe it was true that “CIC and the use of BAMs were terminated 2 weeks prior to preoperative evaluations, and most patients were able to refrain from both of these modalities for the entire 3-year follow-up.” Given my experience during the first US pilot study of the Xiao procedure at Beaumont Hospital, I know how hard and difficult it was to try to convince the team of Peters et al.⁸ and the local primary care doctors to stop anticholinergics and CIC for children with spina bifida who underwent the Xiao procedure. These investigators refused to follow my methods for 2 years before agreeing reluctantly, and then got the expected good results in 1 month. I would also like to cite a passage from a paper published by researchers in Denmark regarding use of anticholinergics in the Xiao procedure, to show how urologists deal with anticholinergics seriously in the US and Europe:¹⁰ “Although these criteria were first published after the current study began, most of them were met in our series except the upper limit of bladder capacity and the cessation of anticholinergic medication. In regard to the latter we deemed that the medication was essential for patient well-being throughout the 18-month study period.”

This seemed to be a similar situation with the patients in the trial of Tuite et al.: they were scattered over different states under the care of their local primary care doctors who would not dare to not use anticholinergics and CIC for 3 years. So I would suggest the authors and/or the editor of the *Journal of Neurosurgery: Pediatrics* collect data from these children's local doctors and provide the real facts regarding the postoperative usage of CIC and anticholinergics over the 3 years of the study. In fact, I did ask Dr. Tuite about this information last year during the only email contact I had with him since my withdrawal, but he did not provide details in his response.

Fourth, the article is not the end of this trial. I am confident I can reverse the results to some degree. My suggestions are as follows.

Because the study is no longer double-blind, please let the 10 children who underwent the Xiao procedure wear a diaper, stop anticholinergics, and let them try to void by pushing, leaking, or any other means for 2 months, and

then see what happens. Giving the neurosurgeons a 50% learning curve deduction, there should still be at least 3 or 4 children who will be able to void voluntarily without incontinence and CIC. All kids with spina bifida do not need to scratch to pee after undergoing the Xiao procedure. For the 3000 kids who had the Xiao procedure performed, none needed bladder augmentation.

In China, my hospital has an open policy regarding Xiao procedure patients, which is: “If the patient cannot void voluntarily within 1 year (for a child) or 18 months (for an adult) post Xiao procedure, Prof. Xiao will redo the procedure himself for you for free, no matter who did the original Xiao procedure or where it was performed.” Now, I would like to extend this policy internationally. I will redo the Xiao procedure for free for all children in the trial of Tuite et al. who did not attain success, including those who served as controls. I am confident that 80% of the kids will regain bladder and bowel control and voluntarily void within a year, or at least as well as in the trial results of Peters et al.⁸ The results could be better than 80%, but I have to be cautious in my predictions because these patients underwent intradural neurosurgery on the same location at least 2 times.

I also have to respond in this letter to part of Dr. Andrew Jea's editorial, which was aimed at my hospital and the Xiao procedure directly. I built a hospital 5 years ago with 300 beds, and 30 beds have been dedicated to helping patients with spinal cord injury and spina bifida undergo the Xiao procedure in connection with 3 major charity organizations for disabled children in China. All patients who undergo the Xiao procedure only pay \$8000 US or less for all costs, and many poor people do not pay anything. My hospital and I have not “capitalized on medical tourism, where despairing foreigners, including Americans, would pay out of pocket to have this procedure performed” as stated in the editorial by Jea.¹

Lastly, I appreciate Dr. John R. W. Kestle's comments. They are objective and helpful comments from an experienced surgeon. I welcome Dr. Kestle, and any other interested neurosurgeons, to team up with urologists and visit China, to scrub in with me for the Xiao procedure for 10 cases, and to follow up as many of these kids cured of spina bifida as you wish. Before the Xiao procedure, all patients with spina bifida were unable to experience any meaningful improvement in their bladder function or their urinary system; it would only get worse and worse until the patient died. The Xiao procedure is now as effective, safe, reliable, and simple as a hernia repair for restoring bladder function and voluntary voiding for the great majority of kids with spina bifida, as long as the crossover anastomosis is satisfactory. Most fortunately, there are already a dozen successful cases of the Xiao procedure in the “polarizing” soil of the US, which preserves hope for millions of desperate kids with spina bifida and their parents.

Chuan-Guo Xiao, MD

C.G. Xiao Hospital, Shenzhen, China

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Disclosures

The author reports no conflict of interest.

Response

Drs. Kestle and Jea declined to respond to this letter.

Response

Thank you for the opportunity to respond to Prof. Xiao's comments. Many of the criticisms contained in his letter were, in fact, previously addressed by us in the 9 paragraphs of our paper that we dedicated to discussing the limitations of our study. While we certainly acknowledge that our study has limitations, other criticisms made by Prof. Xiao are misleading or have no basis in fact.

His criticism of our use of 4 neurosurgeons with “different levels and experience” is misleading. All 4 surgeons involved in the study are fellowship-trained, board-certified pediatric neurosurgeons who practiced full-time during the study. Additionally, 3 of the 4 neurosurgeons who participated in the study had at least 15 years of surgical experience at the inception of this study. In each case, 2

experienced neurosurgeons performed the procedure, and all the neurosurgeons were initially instructed in the surgical technique by Prof. Xiao himself. This certainly appears to be sufficient training for a procedure that does not require any additional technical abilities above and beyond those a typical pediatric neurosurgeon routinely employs.

Prof. Xiao states that we checked “more than a dozen children with myelomeningocele (MM) and lipomyelomeningocele (LMM) who were cured by the Xiao procedure” when we went to China before initiating our trial. Prof. Xiao did graciously host us in China, allowing us to observe his team performing surgery on patients over a 2-day period. However, we never saw a single patient who had undergone the surgery weeks, months, or years before, and we never witnessed even a single patient “scratch and pee.” Some of the operations we observed during our visit with Prof. Xiao were performed on patients who would not be expected to have neurogenic bladder dysfunction (e.g., fatty filum). Overall, our experience in China strengthened our resolve to perform a carefully planned and controlled study.

While it is true that during his visit to our facility at the outset of our study Prof. Xiao became quite upset with us when he learned we were performing a double-blinded randomized controlled trial (RCT), he was actually present in the operating room for 2 entire days of surgery at our hospital. He generously shared his time with our entire team; at least 5 operations were performed under his direct proctorship and we spent hours with him discussing operative nuances, preoperative and postoperative management strategies, and potential pitfalls. Similarly, his recollection of the operation for Case 5 is not completely accurate. While L-1 was originally selected as the donor root, the surgeons inadvertently injured the dorsal root at that level, requiring a primary anastomosis. What Prof. Xiao apparently does not recall is the fact that we then moved up a level, using T-12 as the donor ventral root.

Much of Prof. Xiao's criticism relates to the use of BAMs and CIC after the procedure. Xiao et al. contend that such measures should be eliminated after the Xiao procedure, to facilitate bladder reinnervation.⁹ Prof. Xiao feels strongly about this issue, using it as his primary explanation for the lack of effectiveness of the Xiao procedure in previous trials by other investigators.⁷ Fortunately, we heard of many of the potential pitfalls in postoperative management directly from Prof. Xiao when we were originally designing our research, which allowed us to manage our patients as Prof. Xiao recommends.

Prof. Xiao states that he believes it is “impossible scientifically and technically to perform a double-blind trial” because he considers it wrong to withhold BAMs and CIC from patients who only underwent detethering. He refers to this as a “significant defect” in our scientific method, and he states that “I do not believe it was true” that CIC and BAMs were terminated, even in our patients who underwent the Xiao procedure, because he assumes that patients who lived great distances from our center were enrolled in the study.

We vigorously disagree with Prof. Xiao's assertions concerning the use of BAMs and CIC. First, as we clearly

state in the supplementary material for our article, patients were only enrolled if they lived, and received medical care, in our immediate catchment area. We turned down dozens of potential enrollees from other states and countries who contacted us because we considered it essential that our group of investigators be able to manage and closely monitor patients during their entire 3-year follow-up (see first page of Supplementary Appendix of the article). During the study, 2 patients did move out of our area. However, these patients continued their regular contact with us, and they returned to our hospital for their scheduled follow-up evaluations, with the exception of 1 patient who could not return to Florida for her 2-year follow-up. Because our group was so committed to meticulous follow-up, the principal investigator (G.T.) and the study coordinator (L.T.) traveled to New York City to supervise the patient's 2-year urodynamic study, her voiding tests, and the completion of her questionnaires. This patient did return to Florida for her 3-year follow-up. Primary care physicians did not manage BAMs, CIC, or have any say in how any of these patients managed their bladders.

Prof. Xiao's assertion that we were not truthful about our results is also completely unfounded. Xiao's criticism of our statement in the *Journal of Neurosurgery: Pediatrics* article about the "majority of patients in both groups" being able to stay off CIC and BAMs is reasonable because the statement is imprecise. This was intentional, as described in the final paragraph of the introduction to the paper, because detailed and voluminous urological results were reported in a separate paper published in the *Journal of Urology* shortly after the *Journal of Neurosurgery: Pediatrics* article.⁵ If Prof. Xiao had read our June 8, 2016, *Journal of Urology* publication before he submitted his July 20, 2016, letter to the *Journal of Neurosurgery: Pediatrics*, the fundamental premise for his criticisms would have been answered. In this *Journal of Urology* article, Supplementary Table 1 clearly outlines the safety criteria we used to ensure that patients could stay off BAMs and CIC.⁵ Supplementary Table 3 shows that no patients in either group (DT+X vs DT only) were on BAMs at post-operative years 1 and 2. By 3 years, 2 patients in the Xiao procedure group (DT+X) and 1 in the control group (DT only) returned to BAMs. Similarly, 2 patients in the Xiao procedure group were using CIC at the 1- and 2-year time points, with a third using CIC at 3 years. A similar proportion of patients in the control group also returned to CIC.⁵ Our research nurse (L.T.) devoted a tremendous amount of time corresponding with the patients and study urologists about the patients' BAMs and CIC use, ensuring safety and compliance with the protocol. Most patients in both groups remained off both measures for the vast majority of the study.

Even though we went to extraordinary lengths to keep patients off all BAMs and CIC for the entire 3-year study period, we are not surprised Prof. Xiao points to the minimal BAM and CIC use in our patients as a way to attempt to invalidate our findings, as he has done with other investigators who have tried to replicate his results.⁷ Furthermore, we find his unsubstantiated accusations inappropriate, especially to our patients and their families, who were so invested in the merits of our study that they commit-

ted themselves to being wet for 3 years, even though they knew there was a possibility that they were in the control group (DT only).

Prof. Xiao also considers our study "unethical" because we did, in fact, ask all patients in our study to commit to stopping BAMs and CIC, even though they might not be randomized to receive the Xiao procedure. Our study group and our Institutional Review Board all considered this scenario carefully when we designed the protocol. We believed then, and we still believe now, that it was ethical and safe to stop all BAMs and CIC in our study because all patients and their families gave consent after an exhaustive informed consent process was completed and because all activities in the study were closely monitored by a data safety and monitoring board.

We find Prof. Xiao's claim that our RCT was "unethical" to be unfounded. He states his belief that the Xiao procedure has been previously "proven to be very effective" and that RCTs should not be performed with "children, especially these disabled children." In fact, we chose to vigorously study this procedure because the spectacular results reported by Xiao et al. have never been reproduced by investigators outside China, raising questions about the applicability of his procedure for widespread use.^{1-4,6} It is true that Prof. Xiao claims amazingly good results in thousands of patients, yet he has reported clinical outcome data in only a small fraction of those patients.⁷⁻¹¹ Even his publications in peer-reviewed journals offer limited clinical outcome data, and none provide the detailed individual patient data expected of a publication related to a novel technique.⁷⁻¹¹ Even though Prof. Xiao considers the US "polarizing soil," 2 very well-designed studies of the Xiao procedure in patients with spinal cord injury, by Rasmussen et al. in Denmark³ and by Sievert et al. in Germany,⁴ failed to produce any meaningful improvement for their patients.

Even in the US, Prof. Xiao's close collaboration with Peters et al. failed to reproduce the spectacular results that Xiao et al. have reported in his patients in China.^{1,2} Prof. Xiao's repeated citation of positive results from New York University (NYU) and Louisiana State University (LSU), neither of which appear in PubMed, also requires closer scrutiny. The *Journal of Urology* publication he repeatedly cites is not a peer-reviewed article; instead, it is an abstract presented at a national meeting, based on 2 adults with spinal cord injury operated on at NYU, the results of which have never appeared in a peer-reviewed article to our knowledge. Similarly, his citation for his success at LSU is not related to a peer-reviewed publication, but instead is a proceeding of a meeting in Detroit sponsored by Ken Peters in 2009. This solitary patient in Louisiana did improve in the short term but it was unclear if the improvement was related to the nerve anastomosis or from recovery after her gunshot wound to the cauda equina. She has been lost to follow-up (personal communication, John Mata, MD).

We and our patients considered an RCT more ethical than simply performing the procedure on patients and reporting our results because we wanted to be sure that the effects we were observing after surgery were not simply related to the placebo effect, the effect of spinal cord detethering, or some other mechanism.

In summary, despite Prof. Xiao's sudden, disappointing, and unexpected withdrawal of support from us at the outset of our study when he learned that we were performing an RCT, we are indebted to him for his gracious support during our visit to China and his generous instruction at our hospital in 2009. Despite his skepticism, we were able to complete a double-blind RCT, due largely to the dedication of our patients and the diligence of our entire study team. Like Prof. Xiao, we were disappointed that we did not witness the type of benefit that he and his colleagues have described.^{8–11} We and our patients remain hopeful that future basic science research related to bladder reinnervation will be fruitful and will ultimately yield clinical treatments that are beneficial to patients with neurogenic bladder dysfunction.

Gerald F. Tuite, MD^{1,3}

Ethan G. Polsky, MD⁴

Yves Homsy, MD⁴

Margaret A. Reilly, PT⁵

Carolyn M. Carey, MD, MBA^{1,3}

S. Parrish Winesett, MD³

Luis F. Rodriguez, MD^{1,3}

Bruce B. Storrs, MD^{1,3}

Sarah J. Gaskill, MD³

Lisa L. Tetreault, RN, BSN, CCRP^{1,6}

Denise G. Martinez, MPH⁶

Ernest K. Amankwah, PhD⁶

¹Neuroscience Institute, Johns Hopkins All Children's Hospital, St. Petersburg, FL

²Johns Hopkins Medicine, Baltimore, MD

³University of South Florida, Tampa, FL

⁴Children's Urology Group, Tampa, FL

⁵Johns Hopkins All Children's Hospital, Saint Petersburg, FL

⁶Clinical and Translational Research Organization, Johns Hopkins All Children's Hospital, St. Petersburg, FL

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Ascenda catheter versus silicone catheter in intrathecal baclofen therapy

TO THE EDITOR: We read with great interest the article by Motta and Antonello⁴ (Motta F, Antonello CE: Comparison between an Ascenda and a silicone catheter in intrathecal baclofen therapy in pediatric patients: analysis of complications. *J Neurosurg Pediatr* 18:493–498, October 2016). In the March 2014 issue of the journal, the same authors, who are considered key opinion leaders on intrathecal baclofen therapy in cerebral palsy, published a study on complications after this therapy in a historical cohort of 430 patients.³

Although we fully agree with the statement that complications with the new Ascenda catheter seem to be remarkably lower, we want to make a comment. In the current study the authors compared the complication risk per patient in the Ascenda group with the complication rate in their historical cohort. In the *Discussion* they wrote that most adverse events occur in the first 12 months after implantation, a statement with which we also fully agree.

Through this communication we want to make a comment on the fact that both patient populations do not have the same average follow-up (Table 2 in their article), which makes statistical comparisons difficult. The group with a longer follow-up is more likely to suffer complications if the number of years a catheter has been in place is not taken into account. It would therefore be more relevant

to compare the risk in the historical cohort in their first 2 years after implantation, with the risk in the Ascenda group in their first 2 years after implantation, for example.

Another way of calculating the complication rate could be formulated as risk per catheter-year, meaning the number of complications that occur per number of years the catheter has been in place. In our opinion, it would be very interesting if the authors could add this information to make their results more comparable to other studies.^{1,2}

Nathalie Draulans, MD

Tom Theys, MD, PhD

Bart Nuttin, MD, PhD

Charlotte Kiekens, MD

University Hospitals Leuven, Pellenberg, Belgium

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Disclosures

Dr. Draulans and Dr. Kiekens are members of the Ability Network, an international panel of clinical experts interested in spinal cord injury and supported by Medtronic. Prof. Nuttin and Prof. Theys hold the Medtronic Neuromodulation Learning Chair for Research. Prof. Nuttin and Prof. Theys receive support from Medtronic for a research effort that they oversee. Prof. Nuttin is a patent holder with Medtronic.

All authors have received resources for travel and education from Medtronic. For preparation of this letter, there was no kind of support nor scientific interference by Medtronic.

Response

No response was received from the authors of the original article.

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The Preventable Shunt Revision Rate and the measurement of quality in pediatric hydrocephalus

TO THE EDITOR: Venable and associates have made a novel and serious contribution to the unsettled quest for

a useful quality metric in the treatment of hydrocephalus (Venable GT, Rossi NB, Jones GM, et al: The Preventable Shunt Revision Rate: a potential quality metric for pediatric shunt surgery. *J Neurosurg Pediatr* 18:7–15, July 2016).⁷ They have developed a definition of “preventable” shunt failure and, working from a large, prospectively maintained operative database, they have documented its prevalence—about one-third of all failures within 90 days—and predictive clinical factors. Their definition of preventable shunt failure is reasonable from a technical surgical standpoint: infection, misplacement of the ventricular or distal catheters, and failure to secure shunt components or to secure the shunt in its tissue bed. They argue that this metric meets the requirements of measurable, modifiable, and making sense. I submit that these “3 Ms” are not enough. In this era of accountable medicine, quality metrics must be credible to the public, and they must be patient centered.

A “preventable” episode of shunt failure is an event that can only be identified by confession of the responsible surgeon or by expert review of complete medical records. In the absence of a confession, it cannot be identified by coders or other auditors. The concept might have meaning in an old-fashioned departmental “morbidity and mortality” conference, but it cannot carry much weight with patients or payers. It is surgeon centered.

Patients do not experience preventable episodes of shunt failure differently from other unplanned admissions to hospital for surgery, and surgeons can fail their patients with hydrocephalus by other omissions and commissions besides what Venable and associates judge to be preventable. A surgeon who explores many shunts because of migraine headaches ought to receive a different score on a patient-centered metric from a surgeon who does not. A surgeon who treats hydrocephalus due to a tectal glioma with a shunt and with multiple subsequent shunt revisions ought to receive a different score from a surgeon who performs endoscopic third ventriculostomy (ETV) for that condition. A list of preventable errors puts blinders on the quality improvement process.

The 30-day reoperation rate is an objective metric that is easy to measure and to understand, and recent work has shown that aggregate rates measured in various geographical locales at various times over the past 20 years fall in a very narrow range.^{1,3–5} The scope of this metric is limited to certain technical aspects of surgery for hydrocephalus, however, and no work has been undertaken to assess variation among surgeons or practices.

The performance of a mutual fund is measured by its return over time on the dollars that it has under management—the greater the better. Neurosurgical practices likewise are charged with managing populations of patients with hydrocephalus over time, and a practice’s performance ought to be measured by how many operations it must perform to keep that population healthy—the fewer the better. A count of operations against a denominator of patients under care is a metric that is patient centered and objectively determinable from billing records. This concept has been discussed under the moniker Surgical Activity Rate (SAR).^{2,6} I have looked at this metric in our institutional practice, and it is quite stable over time. A

comparative study has yet to be performed, so the magnitude of variation among practices is unknown.

Venable and associates deserve the appreciation of the pediatric neurosurgical community for keeping attention focused on the challenge of quality measurement in pediatric hydrocephalus, but we have not arrived.

Joseph Piatt, MD

Nemours Neuroscience Center, A I duPont Hospital for Children,
Wilmington, DE

Sidney Kimmel Medical College, Thomas Jefferson University,
Philadelphia, PA

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Disclosures

The author reports no conflict of interest.

Response

We greatly appreciate the thoughtful and expected comments by Dr. Piatt. While we share his interest in identifying and applying quality metrics to the treatment of pediatric hydrocephalus, our underlying philosophies are significantly divergent.

Dr. Piatt and his group have proposed 2 metrics—the 30-day reoperation rate and the SAR—which essentially equate all revision shunt surgeries as an undesirable outcome, providing the rather unsettling analogy of a mutual fund performance for the latter. Their proposed metrics cast a wide net; within their haul, they will capture many revisions that are technically done correctly and for the right reasons, as dictated by the patient's pathology, as well as revisions that could have been potentially prevented. Dr. Piatt provides 2 examples of surgeons who should be “scored” differently, but what he is really advocating is penalizing providers for having a different approach to children with hydrocephalus, which is a slippery slope indeed. While most of us would likely attempt an ETV in a

child with a tectal glioma, it is not wrong to place a shunt. Maybe the child's third ventricular anatomy does not allow for an ETV, or the child is too young, or the surgeon is simply not comfortable performing the procedure. Some surgeons have a lower threshold to explore shunts than others. How and why someone decides to perform shunt surgery is either right or wrong, or it falls within a “gray zone,” the latter being very difficult to critically evaluate from a quality standpoint. Dr. Piatt's models also rely on nonneurosurgical support—coders and auditors—to calculate his metrics.

As detailed in our paper, our proposed metric, the Preventable Shunt Revision Rate (PSRR), has its strengths and weaknesses. It is absolutely dependent on “confession of the responsible surgeon,” but that is what makes it much more specific than the 30-day reoperation rate or the SAR. It gives pediatric neurosurgeons the main voice in the process of assessing quality. There is no doubt that surgeons can, as stated by Dr. Piatt, “fail their patients... by other omissions and commissions” besides what is defined as the PSRR, but we believe that: 1) the number of patients within this “other” category is small and 2) this number most likely relates to questionable surgical judgment, which, as stated previously, is a difficult aspect of shunt surgery to capture within a quality metric.

Pediatric hydrocephalus, as all of us are painfully aware, is variable in its severity, with some children having relatively few problems and others having many operations or complications. Surgeons should never be penalized for doing the right thing, even if it means taking a child back to the operating room repeatedly to revise a shunt. It is those surgeries that could have been done better that should be the focus of our quality efforts. The PSRR does satisfy what we feel should be the core components of any quality metric in medicine—the 3 Ms, with “making sense” being applicable to physicians, families, and patients.

Quality, in the simplest sense, means doing the right thing for the right patient at the right time. Where does the road go from here? Maybe what we, Dr. Piatt, and others have been pursuing amounts to nothing more than intellectual exercises. Most hospitals, we suspect, will track outcomes, such as shunt infection and readmission rates. We will continue to add our voices to the debate.

Garrett T. Venable, MD¹

Paul Klimo Jr., MD, MPH^{1,2}

¹University of Tennessee Health Science Center, Memphis, TN

²Semmes-Murphey Clinic, Memphis, TN

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Stereoelectroencephalography for insular-opercular/perisylvian epilepsy

TO THE EDITOR: I read with great interest the study

by Weil et al.⁶ (Weil AG, Fallah A, Lewis EC, et al: Medically resistant pediatric insular-opercular/perisylvian epilepsy. Part 1: invasive monitoring using the parasagittal transinsular apex depth electrode. *J Neurosurg Pediatr* 18:511–522, November 2016), reporting a technical note for the invasive study of insular-opercular/perisylvian epilepsy.

The authors describe a series of 11 pediatric patients who underwent implantation of subdural grids or strips on the convexity of the perisylvian region, plus a depth electrode advanced freehand into the insular cortex through its apex.

The authors discuss the pros and cons of this newly described technique, comparing it with other methods adopted for the invasive study of this challenging brain region. One point that I would like to argue is the comparison between subdural grids and stereoelectroencephalography (stereo-EEG) electrodes for sampling the region of interest. In fact, Weil and colleagues state, "...the coverage and spatial resolution is greater with open techniques utilizing large grids than with stereo-EEG. The open techniques are thus favored when the suspected focus is thought to be both unilateral and either extending beyond the insula or involving the opercula/perisylvian structures and convexity, which is often the case in children." I disagree with this opinion because subdural grids enable recordings only from the crowns of the perisylvian gyri. Distribution of the leads is limited to the convexity; thus the spatial resolution with subdural grids is only apparently higher. The most common pathological substrate of drug-resistant epilepsies originating from this region is focal cortical dysplasia (FCD), as reported also by the second paper from the same group.⁷ Since most small FCDs are located at the bottom of sulci,¹ direct recording from the sensu stricto opercular cortex (the cortex buried under the convexity) is mandatory. The distribution of subdural grid leads is strongly unbalanced: there are a large number of convexity contacts (probably redundant), and none of them is located where subtle FCDs are more likely seated. The additional parasagittal apex depth electrode covers the midposterior insular cortex, but it does not provide any information from the true opercular cortex.

Moreover, I would like to provide some additional information about stereo-EEG safety. The authors reported a 1%–2% severe morbidity of permanent deficit, mentioning a 10-year-old paper from our group.⁵ In autumn 2008, we started to adopt a new stereotactic technique for the implementation of Talairach methodology, based on multimodal image-guided robotic assistance. Trajectories are planned using 3D cone-beam CT digital subtraction angiography coregistered with 3D MRI. In 2013, we reported the first 81 procedures performed with this technique without any major intracranial bleeding (and only 2 minor, subclinical, postoperative intracranial clots).³ In 2014, we reported 110 additional similar procedures, without any further complications.⁴ Finally, we recently updated our clinical series with 46 additional stereo-EEG procedures, again without any further complications. In total, we have performed

237 stereo-EEG procedures with the updated Talairach methodology, implanting 3252 electrodes that caused no major intracranial bleeding.² Of note, more than 20% of our stereo-EEG implantations covers mainly the insular-opercular/perisylvian region.

In conclusion, while Weil and colleagues must be complimented for their excellent results, it must be highlighted that the stereo-EEG method, now gaining popularity even outside the European borders, should be considered as the best option to explore the insular and insular-opercular/perisylvian region because of its safety profile and extremely low invasiveness compared with subdural grid implantation.

Francesco Cardinale, MD

"Claudio Munari" Center for Epilepsy Surgery,
Niguarda Hospital, Milan, Italy

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Disclosures

The author is a consultant (paid expert testimony) to Renishaw Mayfield, the manufacturer of Neuromate robotic system. Moreover, he served once as a consultant (advisory board) to Medtronic, the manufacturer of the O-Arm, Stealth navigation systems, and Visualase.

Response

No response was received from the authors of the original article.

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