Letters to the Editor

NEUROSURGICAL FORUM

Readmission and reoperation after shunt surgery

TO THE EDITOR: We read with great interest 2 recent articles^{2,3} on 30-day readmission and reoperation rates after CSF shunt surgery by Dr. Piatt, whose insightful and important work is much appreciated (Piatt JH Jr: Thirty-day outcomes of cerebrospinal fluid shunt surgery: data from the National Surgical Quality Improvement Program-Pediatrics. *J Neurosurg Pediatr* 14:179–183, August 2014) (Piatt JH Jr, Freibott CE: Quality measurement in the shunt treatment of hydrocephalus: analysis and risk adjustment of the Revision Quotient. *J Neurosurg Pediatr* 14:48–54, July 2014). In one of these complementary works, Dr. Piatt delineated risk factors that may be associated with shunt blockage and shunt infection using the National Surgical Quality Improvement Program-Pediatrics (NSQIP-P) database, and in the other he showed that while there are substantial variations among hospitals, the differences tended to persist over time (measured in 3-year intervals). He concluded, and we agree, that this phenomenon is predominantly related to patterns of patient flow through the health care system and may not directly reflect the quality of care.

We would like to add another reason why 30-day readmission or reoperation after shunt surgery is perhaps not the ideal quality measure for individual surgeons or institutions. Dr. Piatt pointed out in his discussion that the shunt failure rate documented in the NSQIP-P is remarkably similar to that in a recent report from the United Kingdom and Ireland¹ and other past prospective trials. Undoubtedly this is so because of powerful averaging. However, this averaging effect is lost at the institutional level where 3 or fewer neurosurgeons may perform the bulk of the cases. This means that a single surgeon's practice pattern, i.e., his/her inclination toward readmission for observation or surgical exploration of a questionably functioning shunt, can significantly skew the rates at the institutional level. We would also like to add that individual variations should not always be viewed negatively and should have been expected when it comes to complex medical conditions.

What are the solutions? If one were to continue to use 30-day readmission or reoperation as a measurement, Dr. Piatt's studies provide a benchmark with other descriptive statistical properties. Perhaps significant statistical outliers can serve as an initial point of inquiry and not as a

proof of poor quality of care. Another possibility is to look for other measures such as CSF culture–positive shunt infection where adjudications of the appropriateness of care are less ambiguous.

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DISCLOSURE

The authors report no conflict of interest.

References

1. Al-Tamimi YZ, Sinha P, Chumas PD, Crimmins D, Drake J, Kestle J, et al: Ventriculoperitoneal shunt 30-day failure rate: a retrospective international cohort study. *Neurosurgery* 74:29–34, 2014
2. Piatt JH Jr: Thirty-day outcomes of cerebrospinal fluid shunt surgery: data from the National Surgical Quality Improvement Program-Pediatrics. *J Neurosurg Pediatr* 14:179–183, 2014
3. Piatt JH Jr, Freibott CE: Quality measurement in the shunt treatment of hydrocephalus: analysis and risk adjustment of the Revision Quotient. *J Neurosurg Pediatr* 14:48–54, 2014

Response

I appreciate the interest that Mr. Sarda and Drs. Moore and Chern express in the problem of measuring quality in CSF shunt surgery.

The 30-day reoperation rate has a number of attractive features as a quality measure; 30 days is a short time compared to the follow-up required for analysis of infection rates or shunt survival. Reoperation is a hard end point compared to shunt infection and shunt failure, which require complex research definitions and adjudication. And at least with respect to shunt surgery, mean reoperation rates in the 13%–16% range seem to be constant in time and space. As Sarda, Moore, and Chern note, we have a firm grasp of the mean rate, but we do not know the variance.

If there is no substantial variation in 30-day reoperation rates among institutions or among surgeons, then this metric will not be useful. If indeed there is substantial variation, the challenge will be to determine what portion can be attributed to clinical factors and what is attributable to surgical skill and practice patterns. Despite the granularity of detail in the NSQIP-P dataset, my attempt

to construct a clinical model for risk adjustment failed. Clinical factors seemed to be only weakly associated with 30-day outcomes.

Further refinement of the 30-day reoperation rate as a quality metric will require analysis of data coded by surgeon or institution. The American College of Surgeons possesses these data for the NSQIP-P but has not released them. The Hydrocephalus Clinical Research Network has relevant data for its participating centers. Suitable data exist in the Pediatric Health Information System and in Medicaid datasets.

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Off-label rhBMP-2 use in pediatric spine deformity surgery

TO THE EDITOR: We read with interest the article by Lam et al.⁷ (Lam SK, Sayama C, Harris DA, et al: Nationwide practice patterns in the use of recombinant human bone morphogenetic protein-2 in pediatric spine surgery as a function of patient-, hospital-, and procedure-related factors. *J Neurosurg Pediatr* 14:476–485, November 2014).

We congratulate them on their study but feel that the use of bone morphogenetic protein (BMP) during pediatric spine surgery needs further clarification. The authors found a significant increase in the use of BMP in children during spinal fusion surgery and determined that BMP use in pediatric spine procedures comprised more than 10% of pediatric spine fusions.⁷ This finding was consistent with previous studies,^{4,5} including the 9.2% rate reported by Dodwell et al. in their 2012 letter to the *Journal of the American Medical Association*.⁴ While these large database studies are welcome, and contribute to our knowledge, especially in the context of the scarcity of literature available on the use of BMP in pediatric spine fusion, they risk legitimizing the use of BMP in skeletally immature patients. Although pseudarthroses may occur in adults, nonunions in children are rarely encountered. In a prospective, randomized study of 91 patients with adolescent idiopathic scoliosis, Betz et al. found that posterior spinal fusion (PSF) without the use of supplemental autogenous bone graft was as successful as PSF with allograft and/or local bone.¹

Administrative database studies provide a limited cross-sectional perspective without, unfortunately, any information on the type and dosage of BMP used, nor do they provide any clinical follow-up data. We analyzed our own institution's experience of off-label BMP in pediatric

deformity spinal fusion surgery over the last 8 years and found that recombinant human BMP-2 (rhBMP-2) was used in only 17 (1.6%) of the total of 1082 children who underwent spine deformity surgery, a rate that reflects more accurately, we believe, the judicious use of off-label BMP by US pediatric spine surgeons. Spondylolysis, neuromuscular scoliosis, and syndromic scoliosis were the principal diagnoses (94%) in our 17 children, with an average dose of 10.0 mg (range 4.9–25.4 mg) of rhBMP-2 being used in all cases. In her study, Dodwell et al. found that 66.2% of BMP usage occurred in the Midwest and Southern regions of the United States, and we feel that these institutions are adversely inflating the rate of BMP usage in pediatric spine surgery.⁴

Recently, two Yale University Open Data Access (YODA) reviews have been published that highlight the outcomes and adverse events of rhBMP-2 use in adult spine cases.^{2,6} Carragee and coauthors have previously concluded that the risk of adverse events with rhBMP-2 was 10 to 50 times the original estimates reported in industry-sponsored, peer-reviewed publications.³ Unfortunately, the equivalent data regarding the safety and efficacy of BMP in pediatrics are not available. Complications developed in 3 (17.6%) of our 17 children, including wound infection, postoperative radiculitis, and heterotopic bone ossification, highlighting the safety concerns of BMP use in pediatric spine deformity surgery.

In summary, BMP was not used in $\geq 98\%$ of pediatric spine fusions in our institution over an 8-year period, and further studies are needed to clarify the indications, use, outcomes, and complications before we can justify the routine use of BMP in pediatric deformity surgery.

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DISCLOSURE

The authors report no conflicts of interest.

References

1. Betz RR, Petrizzo AM, Kerner PJ, Falatyn SP, Clements DH, Huss GK: Allograft versus no graft with a posterior multisegmented hook system for the treatment of idiopathic scoliosis. *Spine (Phila Pa 1976)* 31:121–127, 2006
2. Bono CM, Wetzel FT: Black, white, or gray: how different (or similar) are YODA and the The Spine Journal reviews of BMP-2? *Spine J* 13:1001–1005, 2013
3. Carragee EJ, Hurwitz EL, Weiner BK: A critical review of recombinant human bone morphogenetic protein-2 trials in spinal surgery: emerging safety concerns and lessons learned. *Spine J* 11:471–491, 2011
4. Dodwell E, Snyder B, Wright J: Off-label use of bone morphogenetic proteins in pediatric spinal arthrodesis. *JAMA* 308:1429–1432, 2012
5. Jain A, Kebaish KM, Sponseller PD: Factors associated with use of bone morphogenetic protein during pediatric spinal fusion surgery: an analysis of 4817 patients. *J Bone Joint Surg Am* 95:1265–1270, 2013
6. Krumholz HM, Ross JS, Gross CP, Emanuel EJ, Hodshon B, Ritchie JD, et al: A historic moment for open science: the Yale University Open Data Access project and Medtronic. *Ann Intern Med* 158:910–911, 2013

7. Lam SK, Sayama C, Harris DA, Briceño V, Luerssen TG, Jea A: Nationwide practice patterns in the use of recombinant human bone morphogenetic protein-2 in pediatric spine surgery as a function of patient-, hospital-, and procedure-related factors. **J Neurosurg Pediatr** 14:476–485, 2014

Response

We thank Drs. Kiely and Cunningham for their interest in our study analyzing nationwide practice patterns and use of rhBMP-2 in pediatric spine surgery through a large national administrative database, the Kids' Inpatient Database (KID). The goal of our study was simply to provide a descriptive analysis of the use of BMP in Year 2009 and was not aimed at "[legitimizing] the use of BMP in skeletally immature patients." The strengths and limitations of the database study are openly recognized.

Moreover, our analysis was not limited to pediatric spinal deformity. We examined a spectrum of pediatric spinal procedures, including occipitocervical and atlantoaxial fusions. These latter procedures present a greater challenge to achieving fusion. In a comparison of fusion rates following occipitocervical and atlantoaxial instrumented fusion using administrative data sets, Hankinson et al. (Hankinson TC, Anderson RCE, Brockmeyer DL, et al: Comparison of fusion rates following occipitocervical and atlantoaxial instrumented arthrodesis using administrative datasets. Presented at the Annual Meeting of the American Society of Pediatric Neurosurgeons, Kauai, Hawaii, 2013) reported higher rates of fusion failure (i.e., occipitocervical failure rate: mean 19.0%, range 6.25%–25.9%; atlantoaxial failure rate: mean 11.1%, range 0.0–14.3%) than previously reported in the literature. Similarly, in a study by Mazur et al.,² of the 127 pediatric procedures included, 20 (15.7%) resulted in pseudarthrosis and required revision surgery.

It is clear that Drs. Kiely and Cunningham are thoughtful spine surgeons. They used BMP in 17 (1.6%) of 1082 patients with pediatric spinal deformity over an 8-year span. We would encourage them to share their large clinical experience in pediatric spinal deformity surgery, including a comparison of the BMP versus non-BMP cohorts in terms of fusion rates, complication rates, length of surgery, and estimated blood loss.

Finally, initial studies of beneficial and harmful effects

of BMP utilizing the YODA project were contradictory. For instance, one study concluded that rhBMP-2 has no proven clinical advantage over bone graft and may be associated with significant harm.¹ Another study showed that, at 24 months after surgery, rhBMP-2 increases fusion rates without evidence of increased long-term harm.³ It is difficult to draw any further conclusions based on post hoc analysis.

Nonetheless, we completely agree with Drs. Kiely and Cunningham that further clinical studies are required to characterize the indications, method of use, clinical and radiographic outcomes, and complications in pediatric spine surgery. BMP in children needs to be considered judiciously. At our institution, if BMP use is recommended, we counsel the patient and parents thoroughly about the acute (including wound healing problems and seroma formation) and long-term (including possible reported increased risk of future cancer and birth defects) risks of BMP; a separate and additional consent process is completed to document the patient's and parents' understanding of the risks and benefits of BMP use.

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References

1. Fu R, Selph S, McDonagh M, Peterson K, Tiwari A, Chou R, et al: Effectiveness and harms of recombinant human bone morphogenetic protein-2 in spine fusion: a systematic review and meta-analysis. **Ann Intern Med** 158:890–902, 2013
2. Mazur MD, Sivakumar W, Riva-Cambrin J, Jones J, Brockmeyer DL: Avoiding early complications and reoperation during occipitocervical fusion in pediatric patients. **J Neurosurg Pediatr** 14:465–475, 2014
3. Simmonds MC, Brown JV, Heirs MK, Higgins JP, Mannion RJ, Rodgers MA, et al: Safety and effectiveness of recombinant human bone morphogenetic protein-2 for spinal fusion: a meta-analysis of individual-participant data. **Ann Intern Med** 158:877–889, 2013

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