EDITORIAL

Early unplanned reoperation: we need more data**John R. W. Kestle, MD**

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THIS paper analyzes very early complications after pediatric neurosurgical procedures. The authors review events that occur within 48 hours of surgery and suggest that they are likely to be the direct consequence of adverse events that occurred intraoperatively.¹ Furthermore, they propose that these events are more likely to be modifiable because they occurred in a relatively controlled environment (i.e., the operating room).

The authors used an institutional database of almost 8000 procedures performed during a 7-year period. They identified index procedures and categorized them using Accreditation Council for Graduate Medical Education case categories. They present procedure-specific rates of early reoperations (within 48 hours) and analyze the risk factors for early reoperation.

Overall, 221 index procedures were followed by an early reoperation (2.78%). Sixty-two of these were judged to be planned reoperations, leaving 159 index procedures resulting in unplanned early reoperations. These unplanned early reoperations, most of which (117/159) were shunt related, are the focus of the analysis.

To identify risk factors for early reoperation, the authors performed univariate and multivariate analyses, from which they concluded that both admission through the emergency department and surgery between 3 PM and 7 AM significantly increase the risk of early reoperation. This is interesting but not surprising. It makes sense clinically that patients who present to the emergency department and/or those who require surgery urgently (and therefore after hours instead of on the elective list) are likely to be sicker and at higher risk of complications. Unfortunately, I don't think this analysis tells us much more than that. It tells us when and how the high-risk patients get into the system, but it doesn't tell us much about them. Despite the large numbers of children in this data set, the data elements used in the analysis aren't granular enough to identify any modifiable risk factors.

A multivariate regression analysis is a useful technique to assess the impact of various parameters on the outcome of interest—but a multivariate regression can only inform us about the factors that are incorporated in the statistical model. In this case, the variables included are age, payment method (self-pay or public assistance), race (Caucasian yes/no), language spoken (English yes/no), admission from the emergency department, intensive care unit stay after surgery, procedure starting after 3 PM, posting status (emergency surgery or other), intubation status after surgery, and surgeon identity. Aside from age, the analysis doesn't account for important patient or surgery risk factors. For example, in hydrocephalus, these might include cause of hydrocephalus, shunt history, time from last shunt operation or infection, ventricle size, complexity of shunt equipment, and type of surgery. The risk of repeat surgery surely varies from one type of procedure to another, and this was available in the data set but wasn't included in the regression analysis. This limits the usefulness of the analysis. Most clinicians recognize that a child who was premature; has 2 shunts, slit ventricles, multiple previous revisions, and a shunt infection in the last 6 months; has a gastrostomy and tracheostomy tube; and requires a shunt revision is likely to be at a higher risk for problems, regardless of when the child presents or whether the child comes through clinic or the emergency department. This analysis does not have the data to address these patient-related factors.

In addition, the analysis doesn't have any data on intraoperative techniques or decisions. The authors postulate that early unplanned reoperation is "likely to be the direct consequence of adverse events that occurred intraoperatively." That may be true, but the analysis doesn't address this issue. None of the factors in the analysis inform us about what was done in the operating room and whether it was associated with the reoperations. Again using hydrocephalus procedures as an example, we would like to

know things such as the following: What measures were used to prevent infection? Was navigation used? Was new or different shunt equipment used? And how was the skin closed? None of this information was included.

Although it is helpful to have our clinical suspicions confirmed by a large data set such as the one offered in the authors' paper, we need more. We need to understand the clinical factors that lead to early reoperations, especially the ones that we can modify. This paper identifies the patients who need to be studied in more detail. Unfortunately, the data set isn't granular enough to tell us what to do to help them. This will require further work.

<https://thejns.org/doi/abs/10.3171/2016.12.PEDS16618>

References

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Disclosures

The author reports no conflict of interest.

Response

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I very much appreciate Dr. Kestle's comments and agree that granular, quantifiable data are needed in order to make evidence-based clinical practice recommendations. However, it is useful to take a pause and consider the nature of the data that are being used in today's database-driven clinical research. Doing so will help us understand the limitations of such research and clarify future directions.

If all information relevant to clinical care is arranged in a spectrum, the left side of the spectrum would contain those quantifiable, verifiable, and digitally stored data that are easy to share and analyze. On the other end of the spectrum, there would be qualitative data that are hard to define and measure, such as surgeon fatigue, patient compliance to complex medical instructions, and severity of hydrocephalus. Often, surrogate markers are used, albeit imperfectly, such as zip code and income levels to

approximate health care access. Over time, the process of "datafication" moves information toward the left side of the spectrum in order to extract meanings and insights.

Current administrative and clinical databases are populated with data fields that are relatively easy to obtain, and the regression methods used in their analysis have the major pitfall of "you could only see what you are looking for." In terms of organizing and obtaining quantifiable data a priori, none has done better than the Hydrocephalus Clinical Research Network. In a recent paper from Dr. Kestle and colleagues¹ documenting clinical events after initial CSF shunt placement, 21 clinical, radiographic, and shunt design variables were prospectively recorded for 1036 patients. The size of the cohort and the number of variables were carefully matched to enable robust statistical analysis. Even with this carefully crafted data set, the lack of granularity is apparent after some considerations. For example, the location of the proximal catheter was listed as intraventricular, subdural, or within a cyst, when one might have wished to see the intraventricular location subcategorized into frontal, parietal, and posterior fossa locations. Including ever more details in the analysis requires larger and larger study cohorts, but with enough patience and financial support, one may suppose that this logistical barrier can be eventually overcome.

My feeling is that the true breakthrough, if there is one, will have to come from better quantification of the "soft" factors and the inclusion of factors that were previously unmeasurable. To assess how sick the patient is before the surgery, instead of using case priority (elective vs emergent) or ASA (American Society of Anesthesiologists) classifications as categorical variables, continuous, real-time digital inputs from vital signs analyzed by machine learning will yield a much more meaningful, but yet messy-looking, data. Eventually, some clever ways will be devised to measure surgeon skill levels and their mental and physical fatigue before their impact on clinical outcome can be understood. These efforts will be born from cooperation among physicians, engineers, and data scientists, and the construction of the database will be fundamentally different from that at present.

References

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