Improving Surgical Care of the Spinal Disorders: The Osteoporotic Spine

Neil R. Malhotra*

Assistant Professor of Neurosurgery at the Pennsylvania Hospital, USA

Introduction

Surgical treatment of the osteoporotic spine is a treatment of last resort, when all less invasive options have failed. Medical therapy and core strength building act to reduce spinal injury, however, injuries will continue to occur. Surgical care for injuries to the osteoporotic spine is complex and relies on limited literature. Surgical spinal intervention in general has never been more advanced. However, the objective evidence for intervention has never been more assailed. To definitively answer critical questions about spinal interventions, a system that records data for every clinical encounter, in perpetuity, is needed. The data on each patient encounter needs to be organized to permit easy search and analysis thus permitting, for the first time, continuous quality improvement and hypothesis driven research.

The Patient Protection and Affordable Care Act, passed March 2010, focused national attention upon areas of healthcare with high costs. Expensive technology and advanced treatments, such as in spinal disorders, continue to outpace high quality research needed to guide practice in neurological surgery. Prospective, non-randomized registries provide a solution to the current limitations of clinical data collection and offer several advantages compared to a randomized controlled trial for study of many diseases. We believe that a successful registry system will revolutionize American medicine.

Between 1997 and 2006, the number of US patients that sought treatment for spine problems increased from 14.8 million to 21.9 million [1]. From 1995 to 2000, Medicare claims showed a 40% increase in spine surgery rates, a 70% increase in fusion surgery rates, and a 100% increase in the use of implants [2]. Efforts to systemically study degenerative spine conditions have been compromised by a lack of clinical equipoise, the heterogeneity of the disease, and limited follow-up. Enrollment in randomized trials is often difficult for patients and physicians to accept, as both usually have preferences and beliefs regarding the various treatment options [3]. There may only be specific spinal diagnoses where true clinical equipoise exists, allowing ethical randomization to various treatment options [4].

Prospective, non-randomized registries provide a solution to the current limitations of clinical spine data collection and offer several advantages compared to a randomized controlled trial for study of spine diseases. High-quality prospective data, including validated outcome measures, may be collected on a long-term basis. A registry will more accurately reflect true practice conditions, as there are no strict inclusion/exclusion criteria, and therefore increase the generalizability of the results. Patients that cross-over between treatments may represent an independent study population, rather than a limitation of intention-to-treat analysis. Even with significant patient heterogeneity, the clinical effectiveness of a spinal intervention may be assessed with appropriate sample size and follow-up using a registry. A registry offers the opportunity to perform multiple comparisons of treatment options, without being constrained by a lack of clinical equipoise.

For a registry to yield valuable data, it must have several characteristics. It must collect patient Demographic information (i.e. BMI, smoking status, age), clinical and operative information (i.e. OR time, blood loss, procedure), validated outcome measures prospectively (i.e. EQ-5D, Short-Form 36 (SF-36), ODI), and financial information about the cost of care for each patient (i.e. total hospital charges, Current Procedural Terminology (CPT)/Diagnosis Related Group (DRG) codes). In addition, 80% of the patients enrolled in a registry study must be present at follow-up for the evidence to be considered Class I [5]. The registry data must be input and stored in an appropriately protected database, but in a form to allow later query. Finally, a registry should have little impact on the flow of daily clinical practice and should not add significant burden to patients or care providers.

National efforts by organized neurosurgery and orthopedic surgery are underway to develop centralized outcomes databases and standardized outcome instruments. The timing of such projects is urgent, as national payers have started comprehensive literature reviews of spinal surgical interventions to determine whether withdrawal of coverage is warranted. However, individual institutions, particularly those with a high volume of spine patients, currently lack infrastructure and resources to collect clinical data and contribute to centralized outcomes databases. Several commercial clinical data collection systems exist, but the cost of the software platform and ongoing maintenance fees are prohibitive for many centers. As of today there is no reimbursement for the collection or analysis of this data. For a center to accomplish data collection and analysis in a meaningful way it must do so in a manner that is low cost and has minimal impact on patient care workflow.

We have built an automated, web-based registry system, within the confines our electronic medical record system, to capture patient level data, including outcomes measures, on every single patient we evaluate. We have leveraged existing technology to reduce cost and effort. We have built, from the ground up, the Neurosurgery Quality Improvement Initiative (NQII pronounced Nikki) to be a sustainable approach to capture patient level data in order to answer complex medical questions. The NQII has been designed and built to be a prospective nonrandomized registry that surpasses prior efforts by effectively improving quality of care, supporting future research endeavors, reducing cost, being user friendly, and supporting scalability to any type of clinical practice. Further, NQII is extraordinary in that it both supports personalized medicine and seeks population-based cures simultaneously in one user-friendly package.

The NQII project represents one of the first efforts to establish a low cost model for electronic data collection that is scalable and

*Corresponding author: Neil R. Malhotra, Assistant Professor of Neurosurgery at the Pennsylvania Hospital, USA, E-mail: neil.malhotra@uphs.upenn.edu

reproducible for other centers. The proposed registry will allow the delivery of clinical care to proceed uninterrupted, while automatically amassing relevant outcomes data. We have built the NQII, from concept to implementation, to leverage our existing commercial electronic medical record to create a sustainable low cost system for individualized care. We have optimized impact on workflow by connecting datasets to eliminate data entry burden. NQII supports well informed decisions about the most effective treatment paradigms for various disease states. It enables health care providers to perform multiple comparisons of treatment options, without being constrained by a lack of clinical equipoise.

There are still many hurdles to overcome both specific to our efforts and generalized to all registries. Because we are developing web-based versions of outcome instruments that have been traditionally presented to patients in a paper format, the validity of our surveys has not been rigorously tested. A selection bias may exist for a web-based registry, as an elderly patient may not have access, or enough computer training, to complete the questionnaires. Finally, because the patients within a registry are not randomized, baseline confounders may exist between two populations selected for a comparative effectiveness study.

NQII is the first low cost effort to begin answering the critical questions about the care we provide based on every outpatient clinical encounter. The data on each patient encounter is organized to permit easy search and analysis thus permitting, for the first time, continuous quality improvement and hypothesis driven research. Through NQII, high-quality prospective data, including validated outcome measures, is collected on a long-term basis and more accurately reflects true practice conditions. NQII is a pioneering, low cost, safe, effective, approach to fulfill this critical societal need and creates an opportunity to improve care in the subset population of spinal osteoporosis. To our knowledge the NQII project is the first of its kind to comprehensively accomplish this monumental task.

References

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