What's New in Spine Surgery

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One of the more dramatic trends in spine surgery is increased and systematic attention to outcomes. Patient-reported outcome (PRO) questionnaires are becoming the standard measure for treatment effectiveness following spine surgery, as opposed to surgeon-reported results.

The new trend assumes that the patient's perceptions are the true measure of success [1]. To this end, a number of PRO questionnaires have been developed. The Oswestry Disability Index, Short Form 36 (SF-36), Core Outcome Measures Index, and Neck Disability Index are common, subjective indices currently used [2]. The Oswestry Disability Index is a functional index that asks patients to rate outcomes including pain, functional limitations (walking, lifting, sitting, and standing), social life, sexual behavior, sleep, and personal care. This is an ascending scale with 100 as the maximum disability [3]. The SF-36 is a questionnaire which asks the patients to rate 36 items concerning their quality of life – physical functioning and limitations, pain, general health, social health, emotional health, mental health, and vitality. This scale is a descending scale with 100 as maximal health, where the physical and mental component are often reported separately [4]. The Core Outcome Measures Index is a multidimensional index addressing pain (lower extremity, buttock, and lower back pain intensity), function, symptom-specific well-being, quality of life, and social and occupational disability [5]. The Neck Disability Index is a 10-item assessment of physical disability due to neck pain, asking patients to evaluate pain intensity, personal care, lifting, work, headache, concentration, sleep, driving, reading, and recreation [6]. These indices are

categorized as direct or indirect PRO questionnaires. The direct PRO questionnaires are forms completed by the patients about their quality of life – the SF-36 is an example. The indirect PRO questionnaires are multidimensional indices that utilize a wide variety of criteria that are combined to produce a finalized score – the Core Outcome Measures Index, for example.

The PRO questionnaires provide us with a better understanding of the impact spine surgery has on patients' lives, but these are still subjective measures. Thus, there remains a need for objective measures utilized concurrently with PRO questionnaires, anchoring the subjective data to objective data. Currently, some of those outcome measures are time to return to work, the presence or absence of complications, and the number and types of medications prescribed. Almost needless to say, these are not entirely objective either and depend on factors related to the type of work the patient does, economic and legal incentives, and other medical conditions affecting the patient.

The advances in spine surgery outcome research are particularly relevant in the larger context – the efficacy of spine surgery. Addressing this issue, the concept of minimal clinically important difference has been developed, an approximate minimal standard difference on a subjective report that correlates with a clinically significant change for a patient in response to a treatment [7]. The minimal clinically important difference is not a direct index and needs to be defined according to an 'anchor'.

The ideal anchor is objective, graded (not 'yes'/'no'), and not derived from the same data set as that used for calculating the minimal clinically important difference. Some type of a comprehensive and validated test of function, health status and pain perception, measured by an objective third party, would have been an ideal anchor. No such test exists, so we have to settle for less. Clinical endpoints like return to work or achievement of a functional milestone can be used but are not graded; their achievement depends on many health and social factors. Graded anchors include Health Transition Item, Visual Analog Scale of pain, and a new independent anchor currently under investigation by our group, i.e. blinded surgeon rating (SR). Health Transition Item is found in the SF-36 and examines how patients feel at the time of the interview compared to 1 year ago. It may be useful as an anchor because it is not used in the mental component summary and physical component summary calculations of the SF-36. The SR anchor, currently under investigation by our group, uses a 7-point Likert-type scale where the attending surgeon evaluates patient improvement. Our preliminary results show that the SR can be a valid anchor, showing a strong correlation between SR and PRO questionnaires.

In order to estimate the value of spine surgery to society, the concept of quality-adjusted life year (QALY) quantifies health as a function of length and quality of life as a single metric [8]. Using this measure, one assumes that 1 year of life lived in perfect health is equivalent to 1

QALY, whereas a year lived in less than perfect health is worth less than 1 QALY. These values can be derived to determine the change in utility value induced by the treatment over the duration of the treatment effect, representing the number of QALY gained (or lost) by the intervention. These data are then incorporated into a cost analysis model providing an economically based evaluation of QALYs gained for the cost of a given treatment. QALY introduces many assumptions about patients and the value of life with various degrees of pain or disability. QALY compares an outcome to what the patient would have been otherwise without intervention – really difficult to know!

Multicenter prospective outcome databases are now appearing. One such project, the National Neurosurgery Quality and Outcomes Database, is a national database of common neurosurgical procedures, allowing practice groups and hospitals to analyze and report their quality outcomes. Another, the Neurosurgery Patient Outcomes in Treating Spinal Disorders gathers information from surgeons with 1-year outcome data on surgical treatment of lumbar spinal disorders [9].

We have briefly shown the promise and the limitations of the new patient-oriented outcome research in spine surgery, and hope that the science of outcome research will be able to keep up with the demands of payers and policymakers. We must avoid using flawed measures to determine the fate of patient care.

References

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