

Norbert Boos

## Outcome assessment and documentation: a friend or foe?

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N. Boos  
Center for Spinal Surgery,  
University of Zurich, Balgrist,  
Forchstrasse 340, 8008 Zurich, Switzerland  
E-mail: Norbert.boos@balgrist.ch  
Tel.: +41-44-3861270  
Fax: +41-44-3861609

In all European countries, the ever-raising healthcare costs prompt discussions on rationalization and reallocation of resources. Restrictions in the application of various medical treatments have already become reality, for example, in Switzerland, where the implantation of disc arthroplasty and kyphoplasty has been regularized by the government. As a result, a nation-wide quality control for the use of these emerging technologies had to be implemented prior to further reimbursement by health insurers.

The treatment of spinal disorders is becoming more and more technology driven rather than being based on scientific evidence. It appears that the gap between clinical practice and scientific evidence is rapidly opening up. However, the lack of scientific data demonstrating the effectiveness of various forms of spinal treatment [6] may have a substantial and detrimental impact

in the near future when debates on reallocation or restriction of healthcare resources further arise. In some areas, such as spinal fusion, it is already argued that this technique should be a case of restraint [1]. Spinal surgery is predominantly focusing on the improvement of health-related quality of life and in most cases is not a life-saving intervention. By virtue of this, the treatment of the vast majority of spinal disorders is theoretically dispensable.

It appears mandatory that the *European Spine Journal*, as the official publication of the *Spine Society of Europe*, take a leading role in stipulating the generation of convincing scientific evidence of not only the effectiveness but also the cost-effectiveness of various treatment modalities. As a prerequisite, improved knowledge in the field of outcome assessment and documentation is necessary. In recent years, much research efforts were directed to develop and evaluate appropriate instruments to assess outcome. Meanwhile consensus among clinicians and researchers has been reached regarding the use of the classic subjective and objective single rating scale “excellent, good, fair and poor” being insufficient for a valid, reliable and comparable outcome assessment. Nevertheless, many clinicians are confused about what type of outcome assessments is

the most important and which questionnaires are best suited for clinical investigations, quality control or benchmarking. It is the objective of this special issue to provide an up-to-date overview on the current knowledge in the field of outcome assessment of spinal disorders, which may serve as a reference base to researchers and clinicians.

The prerequisite for understanding research articles on the treatment outcome of various spinal procedures is a thorough understanding of the methodological principles, which will determine the level of generated scientific evidence. As an introduction, Hiebert and Nordin highlight in their article the methodological aspects that determine high-quality research. This knowledge allows for a critical review of articles in this field and to decide on the effectiveness of the corresponding treatment.

The subsequent papers focus on the four key elements that constitute the basics of a comprehensive outcome assessment, i.e. pain, back-related compromise of physical functioning, work-related outcome and health-related quality of life. Pain is the most predominate indication for the treatment of spinal disorders and therefore outcome assessment must concentrate on this parameter. Haefeli and Elfering provide an overview on the current status of pain assessment and discuss

tools for a minimum and a more comprehensive assessment. Müller et al. summarize the current literature on the six most widely used, condition-specific, self-administered assessment questionnaires for low-back pain and discuss the strengths and weaknesses of these instruments. In the treatment of back disorders only 15% of the costs are generated by the actual treatment while 85% are related to indirect costs resulting from compromised work capacity, lost work days and early retirement. Elfering therefore highlights the importance of the work-related outcome assessment, reviews work-related outcome measures currently in use and discusses the validity of these measures. Health is an essential part of quality of life and spinal interventions often aim to improve this quality of life. Nemeth describes some commonly used health profile instruments and highlights that preference-based instruments will become more and more important when quality-adjusted life-years are calculated in cost-effectiveness analysis.

Although randomized controlled trials will remain the gold standard for a scientific comparison of two or more competing treatment modalities, this study design is not universally applicable, is very time consuming and requires considerable resources. Some research questions can only be addressed by very large data. In this context, large observational data collections, i.e. registries, will come into the focus of outcome research. Roeder et al. provide conceptual arguments for the need of a European spine registry such as the SSE Spine Tango [7]. Fritzell and co-workers highlight the obstacles of implementing such a registry and report

practical solution as exemplified by the Swedish Spine Registry.

The next series of articles provide an up-to-date overview on the current state of scientific evidence on conservative and operative treatment outcomes, which is based on the work by the Cochrane group. The two articles by van Tulder and co-workers provide an excellent overview and should help to focus future outcome research on areas where scientific evidence is most needed to improve patient care in clinical practice. Failure in surgical treatment substantially adds to the enormous costs of back-related problems. Mannion and Elfering focus, in their review, on the psychosocial predictors of outcome, which may be helpful for clinical decision-making in daily clinical practice and have substantial impact on treatment outcome.

Thus far, outcome research has predominantly focused on the ability of a treatment modality to reduce pain and improve the functional status of the patient with spinal disorders. Today, clinical effectiveness does not suffice in the light of limited health care resources, and economic evaluations will become a genuine part of future outcome assessments. The objective of the article by Van der Roer et al. is to provide an overview of the current views on economic evaluations and to help clinicians to better understand and interpret results from these studies.

The primary goal of this special issue is not to overwhelm the reader with facts and innumerable outcome instruments. The intention is to guide the reader through outcome assessment and help the reader to separate important aspects from less important aspects.

In the final article, Grenough summarizes this special issue and provides practical guidelines on the indication and practical use of the various outcome tools for busy clinical practice.

Very recently, the adverse effects of outcome research have become more apparent. In many hospitals, a patient is overwhelmed with completing questionnaires that he receives from physicians, nursing staff, hospital administration and governmental institutions, which results in incomplete and unreliable data sets owing to the reluctance of the patient to fill in all these questionnaires. Following the development and introduction of outcome tools for the various aspects of treatment, one must now consider what is really needed to improve patient care. It is not helpful if the data collected ends up in a data cemetery. The golden rule of "less is more" also applies to outcome assessment. Our next goal must be to simplify outcome assessment to a minimal acceptable question set which needs to be validated also with regard to cross-cultural aspects. This trend is reflected in recent publications [4, 5] and upcoming studies [2, 3].

My personal perspective and hope is that the European spinal community will manage, in the near future, to reliably and validly assess the outcome of spinal interventions by only a few questions including economic aspects, which will allow us to decide not only on the clinical but also on the economic effectiveness and benefits of various treatment modalities. If we succeed outcome research and documentation will be a friend and not a foe of clinicians and patients.

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