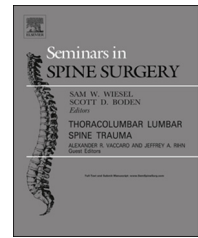


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Value analysis of minimally invasive spine surgery

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ABSTRACT

The purpose of this article is to acquaint readers with the current methodology and evidence on outcome assessment and economic value for minimally invasive spinal surgical procedures. This article will review the standardized outcome measures, calculations of direct and indirect costs, quality-adjusted life years, and economic comparisons of spinal surgical procedures. The available literature suggests that minimally invasive spine surgery is cost effective; however, further research is needed to better assess the longer-term outcomes and cost-utility benefits of minimally invasive spinal interventions in comparison to open surgical approaches.

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1. Introduction

In recent years, there has been an increasing interest in less invasive surgical approaches for various spinal pathologies. In order to assess the benefits of minimally invasive spinal surgeries compared to open surgeries, a variety of clinical measures have been utilized. Simple process measures such as operative time, blood loss, length of hospital stay and postoperative complications are the most commonly reported outcome measures. Although these measures provide some evidence of patient outcome, they generally fail to provide insight into the clinical effectiveness or value of the procedure. In recent years, there has been a shift within healthcare towards value-based assessments of medical interventions.¹ In the value-based model, each healthcare intervention can be assessed by the following simple formula.

$$\text{Value} = \text{Quality}/\text{Cost}$$

For value-based calculations, the direct and indirect costs of a particular medical intervention must be determined. Direct costs include the monetary charges for the medical procedure and all associated costs including hospitalization, drugs, radiology services, and future medical treatments for the same condition. The indirect costs include the time lost from

work or normal productivity due to disability associated with the medical condition. The quality of a medical procedure can be thought of as a measure of how effectively an intervention improved the life of the affected individual. A variety of outcome instruments have been devised to assess the clinical outcome following spinal procedures. Some outcome instruments are disease-specific while others measure general wellbeing and can be used across the spectrum of healthcare conditions and interventions.

The concept of a quality-adjusted life year (QALY) involves assessing the therapeutic effects of an intervention over a specific timeframe. Both the effectiveness and durability of the medical intervention are measured with the QALY. The greater the effectiveness and durability of a procedure, the greater the benefits of the procedure as measured in QALYs. To accurately analyze the durability of an intervention, long-term follow-up studies are the most useful. Unfortunately, long-term follow-up studies are scarce in the field of spinal surgery. Short-term studies can still be used to calculate the effect of a procedure in QALYs, however the measured benefits of the procedure will be limited by the length of follow-up. As longer-term follow-up data becomes available, the QALY calculations can be updated and will improve in the case of durable medical procedures.

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One definition of QALYs is the amount of time spent in a particular health state weighted by a health-related quality of life given to that health state. Mathematically, QALYs can be expressed by the formula:

$$\text{QALY} = 1 * Q$$

where Q is a value given to a health-related state and generally varies between 0 and 1. The highest Q value of 1.0 represents a state of perfect health. As the quality of life (QoL) decreases so does Q . Death is assigned a Q value of 0. Some have suggested that there can be QoL states worse than death, which are assigned a negative value.²

Although QALY can be used to assess an individual's quality of life, it is more often used to assess the effect on QoL following a particular intervention.² Although controversial, current policies in some developed countries have suggested that for an intervention to be considered cost effective (and therefore funded) the cost per QALY gained should not exceed \$50,000–\$100,000.¹

Having determined the effects of an intervention in terms of QALY, it is then possible to compare the cost–utility of two treatment approaches for a given disease. This is done with the incremental cost-effectiveness ratio, ICER, represented by the equation:

$$\text{ICER} = (C1 - C2) / (Q1 - Q2)$$

where $C1$ and $C2$ are the costs of the two different treatments and $Q1$ and $Q2$ are the QALY values obtained following the two different treatments. Interventions that produce a better outcome or are less costly to administer will be favored by these types of analyses. With surgical procedures, a reduction in the rate of postoperative complications can be a major driver in the cost-effectiveness of the procedure as complications can affect both cost and outcome of the procedures.

In order to produce a cost–utility analysis, utility scores are required, which can be calculated from a variety of outcome surveys. Common outcomes surveys used in cost–utility analyses include the EQ-5D, the SF-36, or the SF-6D, which incorporates a subset of items from SF-36 to describe general health.

It is possible to convert from certain disease-specific measurements such as the Oswestry Disability Index (ODI) to utility scores. In one study, the authors found a good correlation between ODI scores and SF-6D scores (Pearson = 0.83 and Spearman = 0.82). To convert an ODI score to a SF-6D score, the following formula was offered: $\text{SF-6D} = 0.78275 - 0.00518 (\text{ODI})$.³

Although the field of spinal surgery offers a limited number of studies that provide the necessary data to produce a formal cost–utility analysis, there has been an increasing emphasis on outcome data and economic benefit in recent years. The remainder of this article will review the spinal literature for studies that provide insights into the outcome and economic impact of MIS spinal procedures in comparison to traditional open spinal procedures.

2. Tubular decompression

Tubular decompression is a MIS procedure that involves using a tubular retractor system to access the spine and viewing technologies such as an endoscope or microscope to

assist the surgeon in performing a decompression of the neural structures. The procedure utilizes a short paramedian incision and serial dilation through the paraspinous soft tissues to reduce injury to the multifidus muscle.⁴ Multiple studies have suggested that tubular decompression surgery reduces the amount of operative blood loss and lowers the rate of surgical site infections in comparison to traditional open procedures.^{4–6}

In one study, tubular decompression was compared to open decompression using clinical outcome instruments including the short form 12 (SF-12), Oswestry Disability Index (ODI), and a modified visual analog scale (VAS). In addition, surgical variables such as blood loss and operative time were determined for the procedures. The mean blood loss was significantly less in the tubular retractor group, averaging 34.5 cc per level compared to 122.5 cc per level in the open surgical group. Operative time was also significantly less in the tubular retractor group averaging 52 min per level compared to 63 min per level in the open group. Clinical outcome measures demonstrated significant improvements in both the tubular retractor and open cohorts but did not demonstrate a significant difference between the groups at a mean follow-up time point of nearly 2 years.⁴

Palmar also reported improved VAS, ODI, and SF-36 scores 1 year postoperatively using a tubular retractor system while keeping the complication rates similar to other traditional microdiscectomy procedures. In addition to improved clinical outcomes, decompression using the tubular retractor was found to be cost effective. Decompressions using the tubular retractor system had a mean hospital charge of \$10,877 compared to decompressions with a traditional approach which had an average hospital cost of \$13,272. The mean savings of \$2395 (18%) was attributed to the decreased length of stay associated with the minimally invasive approach.⁶

One recent study evaluated the cost–utility of multilevel tubular decompression compared to open hemilaminectomy surgery. Tubular decompressions were shown to provide equivalent improvements in QALY while producing similar costs compared to open hemilaminectomies. Two years postoperatively, tubular and open decompressions were both associated with an improved QALY of 0.72. Total costs over those two postoperative years averaged \$23,109 for tubular decompressions. The itemized breakdown showed a mean direct cost of \$13,976 and a mean indirect cost of \$9447. Open decompressions had a total average 2-year cost of \$25,420 with a mean direct cost of \$14,290 and mean indirect cost of \$11,130. The difference in total costs and QALYs were not found to be significant at the 2-year time point.⁷

3. MIS transforaminal lumbar interbody fusion

Transforaminal lumbar interbody fusion (TLIF) has been used for a variety of spinal pathologies since the 1980s.^{8,9} Traditionally, the open approach involves extensive soft tissue stripping and retraction of the paraspinous muscle to provide access to the posterior vertebral column. In contrast, the MIS TLIF approach utilizes a tubular retractor system positioned from a paramedian approach to perform the decompression and interbody fusion. The theoretical advantages of this

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