

# Risk assessment of surgical site infection after elective lumbar spinal surgery and long-term success of complication management

PhD thesis outlines

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## **1. Introduction**

Degenerative diseases of lumbar spine require increased attention because of their importance about public health. Low back pain is the leading cause of activity limitation and work absence throughout much of the world. Conservative treatment of symptoms is recommended in case of tolerable pain and the lack of neurological, as well as vegetative deficiency. However, surgical treatment can be recommended after conservative treatment with unsatisfactory results. Nevertheless, lumbar spinal surgeries may also have complications like all invasive interventions. One of the most serious complications is surgical site infection (SSI).

SSI after lumbar spinal surgery belongs to spinal infections as well as all of those inflammatory processes which affect any segment of the spine and its surrounding soft tissues. Propagation of SSI can cause further serious conditions.

A number of patient- and procedure specific risk factors have been identified, such as age, diabetes, atrial fibrillation, previous spinal surgery; higher American Society of Anesthesiologists classification, perioperative transfusion, extended procedure, postsurgical incontinence (bowel, bladder, or both), and duration of hospital stay.

However, most of these studies focused on specific spine surgery patient groups, such as adults with spinal deformities, and they applied only simplified study designs and analyses. Furthermore, only a few studies reported on the occurrence of SSIs in the general population of spine surgery patients, including those undergoing routine elective procedures.

Even less publications can be found in literature about the future of patients with SSI or the impact of SSI on global treatment outcome (GTO).

It is now generally acknowledged that the outcome of treatment for spinal disorders should not be based on radiological results or defined by the health care professional delivering the treatment.

COMI is a short, concise, self-administered multidimensional questionnaire intended to assess the influence of low back pain (LBP) on several domains of everyday life. Patient-reported outcome measures (PROMs) have become increasingly popular in clinical practice and are also commonly used as the primary outcome measures in scientific/clinical studies. The use of validated versions of PROMs in different languages

allows the results from different investigational sites in international, multicenter clinical trials to be summarized and compared. The aims of the present study were to carry out a cross-cultural adaptation of the COMI for use with Hungarian-speaking patients and to investigate the clinimetric properties of the Hungarian version in patients with LBP.

## **2. Objectives**

1. Translation and cross cultural adaptation of COMI Back
2. Clinical validation of COMI Back
3. Determine the prevalence of SSI after routine lumbar spinal surgeries (e.g. decompression or fusion) performed in a maximum of two segments
4. Analyze the preoperatively determinable risk factors for SSI with univariate regression analyzes in patients who require elective routine surgery related to lumbar disc degeneration and to build a multivariable model for the individual risk prediction.
5. Analyze the global treatment outcome at two years after lumbar spinal surgery in terms of SSI using PROMs and the subjective judgment of patients.

### **3. Methods**

#### ***3.1. Methodology of the validation processes***

##### **3.1.1. Methods of translation and cross-cultural adaptation:**

- Translation of the original version of COMI Back into Hungarian
- Synthesis: comparison of native translation, clarification of the differences
- Back translation: V1 Hungarian version translation into original English version
- Consensus
- Pretesting

##### **3.1.2. Statistical methodology of clinical validation processes:**

- Floor and ceiling effects were determined for each COMI domain and the COMI total score.
- Construct validity was examined by determining the difference in COMI score between the surgical and non-surgical patients as well as the differences in COMI in the presence of nerve root deficit (motor weakness and/or sensory disturbance) (t-tests).

- Associations between pain, ODI, WHOQoL, and COMI scores were analyzed using Spearman rank correlation coefficients.
- Differences in the mean COMI scores for the test–retest measurements were analyzed using paired t- tests.
- The change in group mean scores from pre-surgery to 6 months post-surgery was compared using paired t-tests. The receiver operating characteristics (ROC) method was used to evaluate the sensitivity and specificity of the given change score relative to the global treatment outcome.

### **3.2. Risk factors for surgical site infection in elective routine degenerative lumbar surgeries**

Data were collected prospectively from consecutive adults (above the age of 18 years old) who underwent elective surgery for lumbar disc degeneration at one or two levels at a tertiary spine center. Surgical procedures included microdiscectomy, decompression, and instrumented fusion (transforaminal lumbar interbody fusion or posterior fusion).

All procedures were done using the standard median-sagittal posterior approach. Diagnosis and follow-up of an SSI were based on clinical findings, laboratory tests and radiologic imaging studies, and microbiologic tests. In case of a superficial or deep abscess or of a deteriorating sepsis, surgical debridement was performed. Antibiotics were administered systemically depending on the patient's condition, laboratory findings, and the results of microbiologic cultures.

#### ***3.2.1. Predictive factors and probabilistic model for SSI***

The predictive effect of all patient- and procedure-specific variables on the occurrence of SSI was analyzed in logistic regression models. After the univariate analysis of the variables,

those with a p-value less than .1 were entered into a final multivariable predictive model. The discrimination ability of the model was measured by its sensitivity and specificity using receiver operating characteristic (ROC) curve analysis. ROC curves were used to determine the cutoff points of the continuous predictive variables.

### **3.2.2. Validation of prediction model**

The validity of the multivariable predictive model was tested on the data from an independent validation cohort. Alpha was set at 0.05. to determine the probability of a Type II error for the predictive power analysis of the final model, a sample size calculation based on the ROC curve of the test cohort was performed.

### **3.3. Global treatment outcome (GTO) after SSI**

#### **3.3.1. Study population**

GTO analyzes were performed on subjects of test and validation cohorts who were completed the minimum 2 years follow up.

#### **3.3.2. Analyzes of GTO**

Study participants completed Visual Analogue Scale, ODI and COMI Back during the follow up period. Patients could evaluate the successful of the treatment (“Overall, how much did the operation in our hospital help your back problem?”) on a five-point Likert scale. Based on their results good (“Helped a lot” or “Helped”) and poor (“Helped only a little”, “Didn’t help” or “Made things worse than before surgery”) clinical outcome subgroups were developed. Rate of changes between preoperative and postoperative status of mean scores (VAS, ODI, COMI) was compared with t-tests. One-way ANOVA tests were used to analyze the difference of changes in mean scores in terms of SSI and self-reported clinical outcome.

## **4. Results**

### ***4.1. Validation of COMI Back***

During the adaptation of the original English version, the translation of the term ‘back’ and ‘worst pain’ were complex issues. Instead of back pain we used the translation of ‘‘low back or back pain’ (deréktáji or hátfájás). Furthermore, we decided to use the ‘legszörnyűbb’ term to mark the most terrible (worst) expression for describing pain in Hungarian.

Clinimetric properties of COMI Back were tested on two cohorts. The final test–retest cohort consisted of 145 patients. No subject scored the lowest possible COMI score (0) while 1 patient reached the maximum score (10) during the analyzes of floor and ceiling effects. Each COMI item and the COMI total score demonstrated the expected level of correlation ( $\rho > 0,4$ ) with the corresponding reference questionnaires (pain, ODI, WHOQoL physical). No significant difference was found during the test-retest analysis between the scores on the two test occasions for the COMI or its individual domains. The ICC for the COMI total score was 0.92 (95 % CIICC 0.90–0.94). SEM for the COMI total score was 0.59 and thus the MDC95 % was calculated to be 1.63 points.

The responsiveness analysis was performed on a surgical cohort of 159 patients. Surgical patients showed a significant improvement in the mean scores for COMI and ODI 6 months after the intervention. The effect size was calculated to be 1.16 for the COMI and 0.97 for the ODI. The distribution of the self-reported global treatment outcome was as follows: 53.2 % helped a lot; 31.6 % helped; 9.5 % only a little; 5.1 % didn't help; 0.6 % made things worse. The area under the ROC curve was 0.84 for COMI and 0.82 for ODI showing good discriminatory ability of each PROM. The cutoff change score for good outcome was 2.0 for COMI (79 % sensitivity and 78 % specificity) and 8.6 for ODI (77 % sensitivity and 88 % specificity).

#### ***4.2. Risk factors for SSI***

In univariate logistic regression models, five variables were significantly associated with the occurrence of SSI; body mass index (BMI) (B=0.11, p=.004), chronic liver disease (B=3.41, p=.001), arrhythmia (B=1.36, p=.01), insulin-dependent diabetes mellitus (B=1.60, p=.04), and age (B=0.03, p=.05). Two other variables (ischemic heart disease and systemic immune disease) showed a trend to significance (B=1.15, p=.08 and B=1.98, p=.08, respectively). Cutoff points of age and BMI were determined. Significantly increased risk of an SSI was associated with the age older than 54 years and BMI higher than 28 kg/m<sup>2</sup>. These two variables were entered into further multivariable analysis as dichotomous variables. Results of the final multivariate regression model are listed in **Table 1**. From ROC analysis, the c-index value (area under the ROC curve) was 0.71 for the test and 0.72 for the validation cohorts.

**Table 1. :** Final multivariate logistic regression model

<b>Variables</b>	<b>OR (95% CI)</b>	<b>B (SE)</b>	<b>Wald (df)</b>	<b>P</b>
<b>Age</b> (0: ≤54y. 1:> 54y)	1.64 (0.68-4.0)	0.50 (0.45)	1.20 (1)	0.27
<b>Arrhythmia</b> (0: no. 1:yes)	3.12 (1.01 – 9.6)	1.13 (0.58-3.9)	3.91 (1)	0.05
<b>BMI</b> (0 ≤28 kg/m <sup>2</sup> . 1> 28 kg/m <sup>2</sup> )	1.98 (0.85-4.6)	0.68 (0.43)	2.51 (1)	0.11
<b>Ischemic heart disease</b> (0: no. 1: yes)	2.19 (0.57-8.43)	0.78 (0.69)	1.30 (1)	0.25
<b>Systemic immune disease</b> (0: no. 1: yes)	7.93 (0.79-80.0)	2.07 (1.18)	3.08 (1)	0.08
<b>Insulin depend diabetes mellitus</b> (0: no. 1: yes)	2.99 (0.53-16.58)	1.1 (0.88)	1.55 (1)	0.21
<b>Chronic liver disease</b> (0: no. 1: yes)	14.2 (1.72-118.0)	2.66 (1.08)	6.06 (1)	0.01
B, beta coefficients; CI, confidence interval; df, degrees of freedom; OR, odds ratio; SE, standard error. <b>Model: Chi-square=21.8; df=7; p=.003.</b>				

### **4.3. *Impact of SSI on GTO***

Significant improvement was measured in the results of ODI, COMI Back and VAS during the follow up period compared to baseline in terms of total cohort and the subgroups of patients with and without SSI.

No significant changes was measured in the rate of the development between subgroups of patients with and without SSI (dODI=25.6; p=0.370; dCOMI=4.0; p=0.383; dVAS=3.7; p=0.793). Most of the patients reported good outcome after two years of index spinal surgery (N=794, N%=87.3%). Patients without SSI reported similarly good results (N=768, N%=87.8%). Patients with SSI (N=9, N%=25.7%) reported significant poor outcome (Chi-square tests= 5.66; df=1; p=0.017) than patients without SSI (N=107, N%=12.2%).

## 5. Conclusions

In conclusion, the cross-culturally adapted Hungarian version of the COMI showed good clinimetric properties i.e. it was shown to be a reliable, valid, and responsive instrument. The Hungarian COMI can be recommended for use in evaluating Hungarian patients with low back pain in everyday clinical practice as well as in single- and multicenter scientific studies and allows international comparison of data. The prevalence of SSI in our total study cohort corresponds with the previously published risk for SSI in other spinal cohorts. Powerful regression model (Chi-square=21.8; df=7; p=.003.) was made up by predictors which proved to be significant or trend to significant in univariate analyzes. This model was valid for predicting any SSIs as well as just deep ones. The multivariable model was proven to be able to give a valid estimation on the occurrence of SSI, but its application in everyday clinical routine can be a bit complicated in the present form. A possible option to use our research results in everyday practice is the simple summation of the number of risk factors from the final multivariable model for a given patient. With this approach, an 8-point categorical scale from 0 to 7 corresponds to the increasing risk of SSI. Applying this method for our total study cohort, a strongly significant

association between the summary score and the risk for SSI was revealed. Percentage of SSI in the patient groups with 0, 1, 2, 3, and 4 risk factors are listed above in **Table 2**.

***Table 2. Individual risk of SSI after elective one- or two level decompression or fusion lumbar spinal surgeries***

<b>No. of Risk Factors</b>	<b>Risk of SSI</b>
0	1.6%
1	2.8%
2	5.9%
3	12.1%
4	20.0%
Chi-square=24.0; df=4; p<0.0001	

Individual risk prediction based on a multivariable probabilistic model may well be a successful way to improve the safety of spine surgery. A patient with one or more risk factors should undergo a detailed examination and preoperative preparation process. A more strict intra- and postoperative infection control can be applied in cases with higher estimated risk of SSI.

There was no significant difference in long term treatment outcome based on the results of PROMs between patients with and without SSI. However, GTO estimated by patients with SSI was significant less favorable, than patients without SSI. Based on these results, expectations of patients about treatment outcome and also potential complications should be discussed in more detail with patients before the operation in order to improve the subjective judgement of GTO. Close patient management, even psychological intervention is recommended in the event of a complication.

## 6. Bibliography of the candidate's publications

### Original publications related to the PhD thesis:

**Klemencsics I**, Lazary A, Valasek T, Szoverfi Z, Bozsodi A, Eltes P, Fekete TF, Varga PP. (2016) Cross-cultural adaptation and validation of the Hungarian version of the Core Outcome Measures Index for the back (COMI Back). *Eur Spine J.* 25:257-64.

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