Patient-Reported Outcomes in Elective Cranial Neurosurgery

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■ BACKGROUND: **The role of patient-reported outcomes (PROs) in elective cranial neurosurgery has been poorly studied, and their significance in reflecting complication rates is unclear.**

■ METHODS: **A prospective, consecutive, and unselected cohort of 418 adult patients underwent elective intracranial operations between 7 December, 2011 and 31 December, 2012 in Helsinki University Hospital, Finland. The questionnaire-based PROs included subjective postoperative assessments of overall health, cognitive function, and subjective change in functional status. Outcome measures included in-hospital major morbidity (including mortality) and in-hospital overall morbidity. We compared the usefulness of PROs with postoperative modified Rankin Scale (mRS) score.**

■ RESULTS: **In univariable analyses, all recorded PROs and 30-day mRS scores ≥3 were associated with in-hospital major and overall morbidity. After multivariable analyses, postoperative deterioration of subjective functional status remained associated with in-hospital major morbidity ($P = 0.001$, odds ratio [OR] 4.9, confidence interval [CI] 1.9–12.0, sensitivity 71%, and specificity 70%) and overall in-hospital morbidity ($P < 0.001$, OR 5.7, CI 3.1–10.7, sensitivity 59%, and specificity 84%). Postoperatively impaired functional status was more sensitive but less specific in detecting in-hospital major and overall morbidity than the widely used mRS cut-off value of 2. A simple composite score combining the 3 recorded PROs was highly sensitive and specific in detecting in-hospital major (sensitivity 87%, specificity 98%) and overall (sensitivity 72%, specificity 99%) morbidity.**

■ CONCLUSIONS: **In elective craniotomy patients, PROs seem promising patient-centered tools for outcomes reporting. Furthermore, neurosurgery-specific patient-reported outcome measures (PROMs) can perhaps be implemented to clinical use to improve patient safety and outcome comparisons in elective cranial neurosurgery.**

INTRODUCTION

Increasing interest in the quality of care has led to a surge of patient-centered outcomes reporting. In addition to clinical assessments and results from modern diagnostics, high-quality health care requires feedback on the effectiveness of treatment and the incidence of adverse events derived from not only physicians but also patients. The patient perspective enables a more holistic and comprehensive assessment of the benefits of treatment.[1]

Patient-reported outcomes (PROs) are defined by the U.S. Food and Drug Administration as "… a report that comes directly from the patient about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else".[2] PROs have the potential to provide feedback and research data for controlling and improving

Key words
- Elective craniotomy
- In-hospital morbidity
- Modified Rankin Scale
- Patient-reported outcome
- Surgical outcome

Abbreviations and Acronyms
AMI: Acute myocardial infarction
CI: 95% confidence interval
Dec: December
DVT: Deep venous thrombosis
EUROHIS-QOL: European Health Interview Survey—Quality of Life
mRS: Modified Rankin Scale
OR: Odds ratio
PE: Pulmonary embolism
PRO: Patient-reported outcome
PROM: Patient-reported outcome measure
TYM: Test Your Memory
US: United States of America
WHODAS-12: 12-item World Health Organization Disability Assessment Schedule

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patient safety, but implementing this to practice can be complicated.[3] Patient-reported outcome measures (PROMs), in turn, are either generic or disease-specific, already validated instruments used for reporting PROs.[4] Clinicians and hospitals use PROMs to guide decision making and improve patient safety, and public reporting of PROMs enables patients to compare treatment facilities and even guide their treatment choices.

In the past few decades, PROMs have been increasingly incorporated into clinical outcomes research and the feasibility of collecting such data has been established.[5] Clear evidence of the benefits of PROMs has been demonstrated, for example, in the diagnosis of depression.[4] One of the most comprehensive collections of PROMs data in surgical patients to date is from a mandatory audit of all providers of hip and knee replacement, groin hernia repair, and varicose vein surgery since 2009 in England.[6] PROMs are routinely used in spine surgery.[7] Individual studies have used patient-reported morbidity as an outcome measure in specific surgical subgroups such as endonasal skull base surgery and epilepsy surgery.[8,9] Two recent studies by Schiavolin et al. confirmed the factor structure and validity of 2 PROMs, the 12-item World Health Organization Disability Assessment Schedule (WHODAS-12) and European Health Interview Survey—Quality of Life (EUROHIS-QOL) 8-item index, in a cohort of 180 unselected neurosurgical patients.[10,11] However, neurosurgery-specific PROMs are lacking.

In this prospective observational study of a consecutive and unselected cohort of 418 adult elective craniotomy patients, we aimed to study the associations of PROs and short-term surgical outcome. We hypothesized that PROs may be applicable for recording surgical outcome of patients scheduled for elective craniotomies. Furthermore, we compared the usefulness of postoperative PROs and a simple composite score, created for the purposes of this study, as outcome assessment tools with the modified Rankin Scale (mRS), which is currently the most widely used outcome measurement tool in cranial neurosurgery.

MATERIALS AND METHODS

Ethical Statement

The study was reviewed and approved by the Ethics Committee of the Hospital District of Helsinki and Uusimaa. We obtained informed consent from each study patient before enrollment. Preoperative consultations, anesthesiological and surgical treatment, and postoperative care adhered to the standard clinical practice of the Department of Neurosurgery.

Study Population

The study enrollment protocol has been described previously.[12] In brief, adult patients who underwent elective craniotomies in Helsinki University Hospital during the study period (from 7 December, 2011 to 31 December, 2012) were eligible to participate in the study. There were 551 such patients, of whom 85 were excluded because an informed consent was not obtained before surgery due to logistical problems. Forty-seven patients refused to participate, and 1 patient withdrew the consent before completing the study. The final study cohort consisted of 418 (75.9%) out of the 551 eligible patients. The study cohort of 418 patients was divided into 4 groups by surgical indications: 138 (33.0%) patients with vascular lesions, 134 (32.1%) patients with benign tumors, 121 (28.9%) patients with malign tumors, and 25 (6.0%) patients with other indications. The mean and median ages were 56.4 and 58.0 years, respectively, and 124 (29.7%) of the patients were $\geq$65 years old. A majority (62.2%) of the patients were female. The mean and median body mass indices (BMI) were 26.5 kg/m^2 and 25.7 kg/m^2, respectively.

Patient-Reported Outcomes

Postoperatively, the patients reported whether their subjective functional status had changed (better, worse, or unchanged) at hospital discharge. At discharge, they also completed a cognitive status self-assessment Test Your Memory (TYM) questionnaire, which provided a measurement of postoperative cognitive function. The cognitive function was dichotomized as normal (score $\geq$45 in TYM test) or diminished (score $<$45 in TYM test) in the statistical analyses. In a structured telephone interview at 30 days after surgery, 1 of the study anesthesiologists asked the patients to report their overall health status on a 5-tier scale as excellent, good, average, poor, or very poor. For statistical purposes, the subjective overall health score was dichotomized as good (average to excellent) or poor (poor or very poor).

Modified Rankin Scale Score

At 30-day follow-up telephone interview, a study anesthesiologist assessed the mRS score through a validated telephone questionnaire.[13] For statistical analyses, mRS score was dichotomized at $\geq$3, which is a common cut-off score for indicating a dependent functional status.

Primary Outcomes

Primary outcomes comprised in-hospital major morbidity and overall morbidity. Major morbidity included $\geq$1 of the following: new or worsened hemiparesis, silent stroke, pneumonia or sepsis, acute myocardial infarction (AMI), deep venous thrombosis (DVT), pulmonary embolism (PE), re-craniotomy/endovascular intervention, or in-hospital mortality. In addition to major morbidity, overall morbidity included wound infection/meningitis, minor infections such as urinary tract infections, subjective visual disturbances, new or worsened facial nerve palsy, dysphasia/dysarthria, dysphagia, and minor cranial reoperations in the operating room (ventriculostomy, wound revision). New or worsened hemiparesis was recorded at hospital discharge and other morbidities at any time during the in-hospital period. Reoperations were recorded up to 30 postoperative days. Hospital databases and the Population Register Center of Finland provided in-hospital mortality rates.

Statistical Analyses

The Pearson chi-square test or Fisher exact test served for studying correlations for categorical variables, and the Mann-Whitney U test was used to study continuous or ordinal variables in relation to dichotomized outcome in univariable analyses. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated for significant factors using 2 $\times$ 2 tables. In all tests, significance was at a P value $<$0.05. We also calculated sensitivities and specificities for postoperative PROs and compared the values with mRS-based results. We used a multivariable logistic regression model of