Real-life results of balloon kyphoplasty for vertebral compression fractures from the SWISSspine registry

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BACKGROUND CONTEXT
The Swiss Federal Office of Public Health mandated a nationwide health technology assessment-registry for balloon kyphoplasty (BKP) for decision making on reimbursement of these interventions. The early results of the registry led to a permanent coverage of BKP by basic health insurance. The documentation was continued for further evidence generation.

PURPOSE
This analysis reports on the 1 year results of patients after BKP treatment.

STUDY DESIGN
Prospective multicenter observational case series.

PATIENT SAMPLE
The data on 625 cases with 819 treated vertebrae were documented from March 2005 to May 2012.

OUTCOME MEASURES
Surgeon-administered outcome instruments were primary intervention form for BKP and the follow-up form; patient self-reported measures were EuroQol-5D questionnaire, North American Spine Society outcome instrument /Core Outcome Measures Index (including visual analog scale), and a comorbidity questionnaire. Outcome measures were back pain, medication, quality of life (QoL), cement extrusions, and new fractures within the first postoperative year.

METHODS
Data were recorded preoperatively and at 3 to 6-month and 1-year follow-ups. Wilcoxon signed-rank test was used for comparison of pre- with postoperative measurements. Multivariate logistic regression was used to identify factors with a significant influence on the outcome.

RESULTS
Seventy percent of patients were women with mean age of 71 years (range, 18-91 years); mean age of men was 65 years (range, 15-93 years). Significant and clinically relevant reduction of back pain, improvement of QoL, and reduction of pain killer consumption was seen within the first postoperative year. Preoperative back pain decreased from 69.3 to 29.0 at 3 to 6-month and remained unchanged at 1-year follow-ups. Consequently, QoL improved from 0.23 to 0.71 and 0.75 at the same follow-up intervals. The overall vertebra-based cement extrusion rates with and without extrusions into intervertebral discs were 22.1% and 15.3%, respectively. Symptomatic cement extrusions with radiculopathy were five (0.8%). A new vertebral fracture within a year from the BKP surgery was observed in 18.4% of the patients.

CONCLUSIONS
The results of the largest observational study for BKP so far are consistent with published randomized trials and systematic reviews. In this routine health care setting, BKP is safe and effective in reducing pain, improving QoL, and lowering pain_killer consumption and has an acceptable rate of cement extrusions. Postoperative outcome results show clear and significant clinical improvement at early follow-up that remain stable during the first postoperative year.

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