Universität Basel

Research Project

Surgical safety and effectiveness in orthopedics: Swiss-wide multicenter evaluation and prediction of core outcomes in arthroscopic rotator cuff reconstruction

Third-party funded project

Project title Surgical safety and effectiveness in orthopedics: Swiss-wide multicenter evaluation and prediction of core outcomes in arthroscopic rotator cuff reconstruction
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Valid clinical outcome data are essential to assess the safety and effectiveness of surgical interventions, to perform benchmarking activities and to foster a well-founded decision-making process in orthopedics. In the fields of arthroscopic rotator cuff repair (ARCR), the number of ARCR procedures and published studies has grown exponentially in the last decade, yet reporting standards differ dramatically. This is particularly notable concerning adverse events (AE) as in most fields of orthopedic surgery. In addition, published prognostic studies were methodologically poor, based on small datasets and explored only limited numbers of potentially influencing factors.A prospective multicenter clinical study of a large ARCR patient cohort will be implemented on a representative group of 17 Swiss and one German specialized clinics allowing for the evaluation of targeted core safety, clinical and patient-reported outcomes. The primary objective will be the development of prediction models for individual patients. The primary outcomes will be the patient-reported subjective assessment of shoulder function (Oxford Shoulder Score) and the occurrence of shoulder stiffness up to 12 months after primary repair surgery. Multiple prognostic factors will be investigated including patient baseline demographics, psychological, socioeconomic and clinical factors, rotator cuff integrity and concomitant local findings, operative and postoperative management factors. The secondary objectives are to evaluate the content and applicability of a consensus core set of AEs (CES) considering the patient's perspective, validate a severity classification for AEs, and quantify clinically-relevant ARCR outcomes up to 24 months postoperatively. Prognostic models will also be extended to all secondary outcomes.A sample size of 970 ARCR patients will be included; baseline patient demographics, history, shoulder status, magnetic resonance imaging based diagnosis and operative details will be recorded. Patient outcomes will be documented 6, 12 and 24 months after surgery. Clinical examinations at 6 and 12 months will include shoulder range of motion and strength (Constant Score), as well as the documentation of AEs. Tendon repair integrity status will be assessed by ultrasound examination at 12 months. Patient-reported outcome questionnaires at all follow-up time points will determine functional scores (Subjective Shoulder Value, Oxford Shoulder Score), anxiety and depression scores, working status, quality of life (EuroQol EQ-5D-5L), and AEs. All AEs will be documented according to the consensus CES and classified by their degree of severity; patients will rate the perceived severity and disturbance of experienced AEs. We will use the web-based REDCap data capture system for data management. Intensive central monitoring will be performed and investigator meetings will be coordinated during the study. The adapted AE severity classification will be

validated. All data will be tabulated and prediction models will be developed using internationally supported methodology.This project will initiate the development of personalized risk predictions to support the surgical decision process in ARCR. The consensus CES may become an international reference for the reporting of complications in clinical studies and registers. The proposed study will foster the condition towards the development of a Swiss national ARCR register. Such a study and registry is an important step to increasing transparency in orthopedic surgery as requested by the federal strategy in healthcare “Health 2020”. Methodological insights gained from this work will be easily transferable to similar initiatives in orthopedics.

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