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ORIGINAL ARTICLE

Complications associated with arthroscopic rotator cuff tear repair: definition of a core event set by Delphi consensus process

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Background: The literature does not consistently report on complications associated with arthroscopic rotator cuff repair (ARCR). Valid comparison of the occurrence of complications between ARCR interventions requires standardization. This project was implemented to define a core set of negative (untoward) events associated with ARCR along with their terms and definitions, which should be systematically documented and reported in routine care and clinical research.

Materials and methods: A Delphi consensus process was applied. An international panel of experienced shoulder surgeons was nominated through professional societies and personal contacts. On the basis of a systematic review of terms and definitions, an organized list of relevant events associated with ARCR was developed and reviewed by panel members. Between each survey, all comments and suggestions were considered to revise the proposed core set, including local event groups along with definitions, specifications, and timing of occurrence**.** Consensus was defined as at least two-thirds agreement.

Results: Three successive online surveys were implemented involving 84 surgeons. Consensus with over 86% agreement was reached for a core list of local events including 3 intraoperative event groups (device, osteochondral, and soft tissue) and 9 postoperative event groups (device, osteochondral, pain, rotator cuff, surgical-site infection, peripheral neurologic, vascular, superficial soft tissue, and deep soft tissue). Experts agreed on a period for documentation of each event or group of events ranging from 3 to 24 months after ARCR.

Conclusion: A structured core set of local events associated with ARCR has been developed by international consensus. Further evaluation and validation in the context of clinical studies are required.

Level of evidence: Development of Classification System

Keywords: Shoulder; rotator cuff; complications; standardization; Delphi process; core event set

Institutional Review Board/Ethics Committee approval was not required.

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Valid reporting of surgical complications is essential to support quality control,[4,21] as well as to foster adequate decision-making processes. Unfortunately, a lack of consensus on what comprises a surgical complication and which adverse events (AEs) should be documented contributes to inconsistent reporting.[11,21,27] Consensus is therefore required on which clinical parameters and outcome instruments should be used[9] in the evaluation of surgical interventions, including AEs.

This may be particularly true for arthroscopic rotator cuff repair (ARCR) because complication rates vary substantially between studies. Shoulder stiffness and rotator cuff rerupture are commonly reported complications, with rates ranging from 1.5% to 11.1% and from 11.4% to 94%, respectively.[25] Strauss et al[29] reported postoperative complication rates ranging from 2.5% to 11.9%. There are several reasons for this heterogeneity. Some events (eg, shoulder stiffness) may occur naturally after ARCR but may be perceived as a complication if they persist. Yet time limits to differentiate between a naturally occurring event and a complication are rather based on subjective judgment. Moreover, some events (eg, absence of tendon healing) may be regarded as complications depending on the surgeon's or patient's perspective. Finally, without appropriate training and monitoring, the reporting of complications is likely to be incomplete.[7,31] Without an agreed list of events, investigators and clinicians will continue to determine for themselves if an event should be reported as a surgical complication, considered part of the normal treatment and recovery course, or simply ignored because of its apparent irrelevance with the applied procedure.

In addition to trial registration,[22] the standardization of outcome measurement in ARCR should help resolve these problems.[5] A core outcome set (COS) represents an agreed minimum set of parameters to be assessed within the context of clinical studies and registers of health-related interventions.[5,32,6] The number of published reports on COSs increased over recent years[9] but was limited in orthopedics. The Outcome Measures in Rheumatology (OMERACT) consensus initiative agreed on a conceptual framework within which core sets can be developed and stated that "developers must also decide whether specific adverse events need to be monitored as part of the core set."[3] Available COSs, however, do not always clearly define AEs. In general, there is a clear need for structure in documenting complications in orthopedics,[2,11] which should be complemented by the specification of context-specific core event sets (CESs). Preliminary work was implemented regarding distal radius fractures[23] and total knee replacement.[15]

The aims of this project were to highlight the lack of standardized documentation of ARCR complications and to develop an internationally accepted CES. Our hypothesis was that by using Delphi methodology, we could achieve consensus on a clearly structured and defined list of complications associated with ARCR, which may be used for systematic reporting in routine care and clinical research.

Materials and methods

For CES (hereafter referred to as *core set*) development, we applied a methodology process[32] used for COS development that included a literature review, panel consensus process, and field evaluation (Fig. 1).

Systematic review

A systematic review of the literature was implemented to search for terms and definitions related to the occurrence of negative (untoward) events associated with ARCR as described in detail elsewhere.[1] In short, the PubMed, Embase, Cochrane Library, and Scopus databases were searched on November 2013 for English or German reviews, clinical studies, and reports of complications involving human subjects with ARCR published after 2007. Reference lists of selected articles were screened for additional relevant publications. The terminology of complications and their definitions were extracted from 233 original articles resulting in 242 terms used to describe local events with no standardized and consistent reporting. We made a preliminary list by grouping all terms according to similarity of events to support the development of an initial core set proposal and survey (Appendix S1).

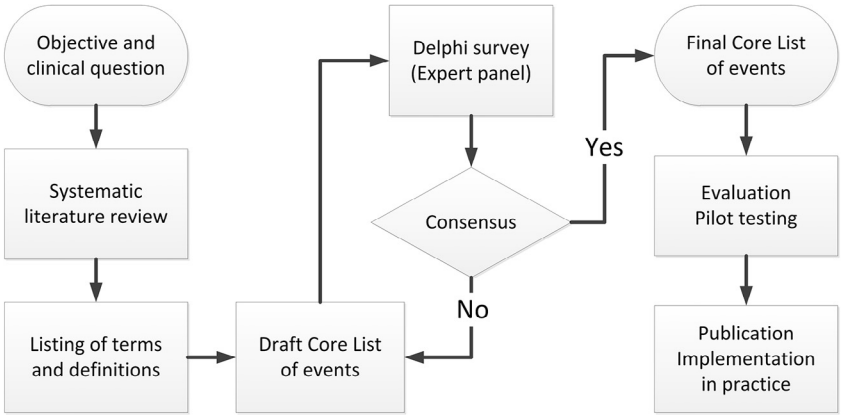

Figure 1 Development process for consensus core event set.