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European Society for Surgery of the Shoulder and Elbow (SECEC) rotator cuff tear registry Delphi consensus

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Background: The purpose of this study was to establish consensus statements via a Delphi process on the factors that should be included in a registry for those patients undergoing rotator cuff tear treatment.
Methods: A consensus process on the treatment of rotator cuff utilizing a modified Delphi technique was conducted. Fifty-seven surgeons completed these consensus statements and 9 surgeons declined. The participants were members of the European Society for Surgery of the Shoulder and Elbow committees representing 23 European countries. Thirteen questions were generated regarding the diagnosis and follow-up of rotator cuff tears were distributed, with 3 rounds of questionnaires and final voting occurring. Consensus was defined as achieving 80%-89% agreement, whereas strong consensus was defined as 90%-99% agreement, and unanimous consensus was defined by 100% agreement with a proposed statement.
Results: Of the 13 total questions and consensus statements on rotator cuff tears, 1 achieved unanimous consensus, 6 achieved strong consensus, 5 achieved consensus, and 1 did not achieve consensus. The statement that reached unanimous consensus was that the factors in the patient history that should be evaluated and recorded in the setting of suspected/known rotator cuff tear are age, gender, comorbidities, smoking, traumatic etiology, prior treatment including physical therapy/injections, pain, sleep disturbance, sports, occupation, workmen's compensation, hand dominance, and functional limitations. The statement that did not achieve consensus was related to the role of ultrasound in the initial diagnosis of patients with rotator cuff tears.
Conclusion: Nearly all questions reached consensus among 57 European Society for Surgery of the Shoulder and Elbow members representing 23 different European countries. We encourage surgeons to use this minimum set of variables to establish rotator cuff registries and multicenter studies. By adapting and using compatible variables, data can more easily be compared and eventually merged across countries.

Rotator cuff tears are a common cause of shoulder pain for patients globally, with more than two-thirds of patients older than the age of 70 years in the general population having rotator cuff tears.[8] As a result, rotator cuff tears result in a large disease burden with a large impact quality of life on the general population.[2,3] There is also a spectrum of rotator cuff pathology, with a variety of treatments available depending on patient symptoms and the extent of degeneration/tear. It is an important research topic for surgeons and nonoperative treating physicians due to the volume of patients treated annually.[8] However, there are discrepancies in study designs with heterogenous outcomes measures and there is a need for consistency as we move towards more big data.[14,18]

Several orthopedic societies have developed both national and international consensus statements on a variety of topics utilizing the Delphi method.[4,5,12,13,22,23,26,29] The Delphi method was

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originally developed by the US army during the cold war.[24] The Delphi method requires multiple rounds of questionnaires to encompass expert opinion on a topic, ultimately leading to defined consensus statements. Therefore, the European Society for Surgery of the Shoulder and Elbow (SECEC-ESSSE) sought to use a Delphi consensus approach to variables of interest in the study of rotator cuff pathology could be of interest for those performing clinical research to European registry use. The purpose of this study was to establish consensus statements via a Delphi process on the factors that should be included in a registry for those patients undergoing rotator cuff tear treatment. Our hypothesis was that there would be consensus in the majority of statements on the factors that should be included in a registry for those undergoing rotator cuff tear treatment.

Methods

Consensus working group

Fifty-seven orthopedic European shoulder surgeons participated in these consensus statements on rotator cuff, with 66 initially being invited and 9 declining. The participants were members of the SECEC-ESSSE standing committees from 23 European countries. This included the Executive Committee, Membership Committee, Education Committee, Research and Development Committee, Ad Hoc Committees, Ethical Committee, Digital Media Committee, Eastern Europe Support Committee, Program Committee, Health Care Delivery Committee, Qualification Committee, Committee for European Shoulder and Elbow Registries, and the Junior Membership Committee. The participants were instructed to answer the questionnaires with what they considered the best answer, regardless of their personal bias concerning the answer. A liaison (ETH) served as the primary point of contact and facilitated communication and the distribution of surveys to ensure consistency across the working groups. Additionally, they formulated each subsequent round of questionnaires based on the prior round's responses. To reduce the potential for bias in the data analysis and/or literature review, the liaison did not submit answers to the questionnaires or partake in the voting process.

Delphi consensus method

A set of questions on rotator cuff tears was generated by the registry committee. The questions were developed based on areas of controversy in the experts' opinions as well as on questions identified through several systematic reviews of the literature. The Delphi method was used to generate consensus statements, with groups completing 3 initial rounds of questionnaires, amendments, and, lastly, a final vote. All the questionnaire responses and voting were anonymous. Questions progressed from an open-ended to a more structured format and were designed to elucidate areas of agreement and disagreement between group members. The final voting process allowed all study participants to assess the consensus statements generated by the other working groups and vote on whether they "agreed" or "disagreed" with them. Thus, all 57 participants voted on all statements. Surveys were distributed in a blinded fashion using REDCap (Vanderbilt University, Nashville, TN, USA), and managed with REDCap electronic capture tools hosted at Duke University.

Final voting

After the final votes for each question occurred, the degree of agreement was expressed using a percentage rounded to the nearest whole number. Consensus was defined as 80%-89%, strong consensus as 90%-99%, and unanimous consensus was indicated by receiving 100% of the votes in favor of a proposed statement.

Results

Overall consensus

Of the 13 total questions and consensus statements on rotator cuff tears, 1 achieved unanimous consensus, 6 achieved strong consensus, 5 achieved consensus, and 1 did not achieve consensus. All 3 rounds are fully delineated in the Supplementary Appendix S1.

Consensus statements

Q1: What factors in the patient history should be evaluated and recorded in the setting of a suspected/known rotator cuff tear?

A1: The factors in the patient history that should be evaluated and recorded in the setting of suspected/known rotator cuff tear are a) Age, b) Gender, c) Comorbidities, d) Smoking, e) Traumatic etiology, f) Prior treatment including physical therapy/injections, h) Pain, i) Sleep disturbance, j) Sports, k) Occupation, l) Workmen's compensation, m) Hand dominance, and n) Functional limitations.

Unanimous Consensus—100% Agreement (67% Strongly Agreed, 33% Agree)

Q2: Which aspect(s) of the physical examination should be performed/documented in the setting of a suspected/known rotator cuff tear?

A2: The aspects of the physical examination that should be performed/documented in the setting of suspected/known rotator cuff tear are a) Inspection, b) Active range of motion, c) Passive range of motion, d) Strength of the different muscles of the rotator cuff, e) Jobe test, f) Lift off test, g) Belly press test, h) Bear hug test, and i) Hornblower test.

Strong Consensus—93% Agreement (62% Strongly Agreed, 31% Agree, 7% Neutral)

Q3: Should radiographs be obtained in all patients with a suspected rotator cuff tear?

A3: A radiograph should be obtained in all patients with a suspected rotator cuff tear.

Consensus—80% Agreement (58% Strongly Agreed, 22% Agree, 13% Neutral, 7% Disagreed)

Q4: How should rotator cuff tears be graded/classified?

A4: Rotator cuff tears should be classified based on a) Size, b) Tendons involved, c) Partial vs full thickness, d) Patte, and e) Goutallier.

Strong Consensus—91% Agreement (56% Strongly Agreed, 34% Agree, 7% Neutral, 2% Disagreed)

Q5: When should advanced imaging studies, that is, magnetic resonance imaging (MRI) or computed tomography (CT), be performed in a patient presenting with a suspected/known rotator cuff tear?

A5: Advanced imaging (MRI or CT) should be performed in a patient presenting with suspected/known rotator cuff tear when planning or considering surgery.

Consensus—89% Agreement (58% Strongly Agreed, 31% Agree, 5% Neutral, 6% Disagreed)

Q6: When performing advanced imaging, should an MRI or CT be performed in a patient with a suspected/known rotator cuff tear?

A6: An MRI should be performed except when planning for an arthroplasty, in which case CT is preferrable.

Consensus—87% Agreement (43% Strongly Agreed, 44% Agree, 4% Neutral, 9% Disagreed)

Q7: When should an ultrasound be performed in a patient presenting with a suspected/known rotator cuff tear?

A7: An ultrasound should be performed routinely as a first-line investigation.

No Consensus—60% Agreement (25% Strongly Agreed, 35% Agree, 16% Neutral, 20% Disagreed, 4% Strongly Disagreed)

Q8: How can treatment success be defined?

A8: Treatment success should be defined as a) Improved pain, b) Improved range of motion, c) Improved strength, d) Improved quality of life, and e) Patient satisfaction with treatment.

Strong Consensus—98% Agreement (69% Strongly Agreed, 29% Agree, 2% Neutral,)

Q9: Which of the following aspect(s) of the physical examination should be performed on patients after the treatment of a rotator cuff tear?

A9: The following aspects of the physical examination should be performed on patients after the treatment of a rotator cuff tear a) Inspection, b) Active range of motion, c) Passive range of motion, d) Strength of the different muscles of the rotator cuff, e) Jobe test, f) Lift off, and g) Belly press test.

Consensus—87% Agreement (49% Strongly Agreed, 39% Agree, 11% Neutral, 2% Disagreed)

Q10: For how long should patients who underwent treatment of a rotator cuff tear be followed up?

A10: Patients who are treated for a rotator cuff tear should be followed up for 6 months to 1 year depending on the treatment they have undergone and their symptoms.

Consensus—84% Agreement (40% Strongly Agreed, 44% Agree, 3% Neutral, 13% Disagreed)

Q11: For how long should patients who underwent treatment of a rotator cuff tear be followed up for research purposes?

A11: Patients who are treated for a rotator cuff tear should be followed up for research purposes at a) 6 weeks, b) 3 months, c) 6 months, d) 1 year, and e) 2 years.

Strong Consensus—93% Agreement (25% Strongly Agreed, 35% Agree, 4% Neutral, 3% Disagreed)

Q12: What components should be included in a patient-reported outcome measure? Is there a preferred clinical outcome score?

A12: The components that should be included in a patient-reported outcome measure are a) Pain, b) Strength, c) Function/limitations, d) Range of motion, e) Return to sport/work, f) Impact on daily activities, and g) Satisfaction. The preferred clinical outcome scores are the Constant score and subjective shoulder value/single assessment numeric evaluation score.

Strong Consensus—93% Agreement (44% Strongly Agreed, 49% Agree, 5% Neutral, 2% Disagreed)

Q13: Should any routine imaging be performed at follow-up? If not, is there any patient population that should undergo follow-up imaging?

A13: Routine imaging should not be performed at follow-up visits, apart from those in research studies.

Strong Consensus—93% Agreement (44% Strongly Agreed, 49% Agree, 4% Neutral, 3% Disagreed)

Discussion

The most important finding from this consensus process was that the majority statements reached unanimous or strong consensus. The statement that reached unanimous consensus was that the factors in the patient history that should be evaluated and recorded in the setting of suspected/known rotator cuff tear are age, gender, comorbidities, smoking, traumatic etiology, prior treatment including physical therapy/injections, pain, sleep disturbance, sports, occupation, workmen's compensation, hand dominance, and functional limitations. The statement that did not achieve consensus was related to the role of ultrasound in the initial diagnosis of patients with rotator cuff tears.

The SECEC-ESSSE provides for scientific cooperation and continuing training of European orthopedic surgeons specialized in surgery of the shoulder and elbow in order to contribute to the development of the physiological, pathological and therapeutic study of those joints. Thus, one of SECEC-ESSSE aims is play a key role in the management of national registries and their international expansion, as well as to develop clinical research. National registries provide valuable data that can be highly beneficial to those interested in the treatment of shoulder pathologies, as registries are competent tools for monitoring new trends in surgical practice.[7,25,27,28] Furthermore, multinational registry data can be pooled to gather larger statistical data and to understand the inclinations of the orthopedic community to an international perspective. However, one of the limitations in utilizing data from multiple registries or in comparing data from different clinical studies is the lack of homogeneity across the different variables.[18]

The history and physical exam are essential in the evaluation and management of rotator cuff tears, as they can determine the most appropriate treatment.[17] A comprehensive understanding of a patient's history, including their symptoms, the mechanism of injury, and any previous shoulder-related issues, provides valuable insights into the underlying cause and progression of the tear. Thus, it is important that this area achieved unanimous consensus. As a result, these factors should also be considered in both inclusion/exclusion criteria for research as well as the variables that should be reported in patient demographics of studies. Furthermore, a thorough physical examination helps identify specific clinical findings, such as weakness, limited range of motion, and tenderness, which aid in confirming the diagnosis and assessing the severity of the tear.[17] These evaluations also help differentiate between partial and full-thickness tears, identify associated injuries, and the severity of the tear. All of these variables can influence whether conservative measures are appropriate or if surgical intervention, such as an arthroscopic repair or a more extensive procedure, is necessary.

A radiograph is typically the first-line imaging modality used to evaluate any patient with shoulder pain, as it can help identify potential fracture, degenerative changes, and structural abnormalities.[16,31] Therefore, it is surprising that it only achieved consensus, but this may be as a result of its limited ability to detect rotator cuff tears, although superior migration of the humeral head can influence treatment. MRI is considered the gold standard for evaluating rotator cuff tears, as it detailed information about the size, location, and extent of the tear, as well as the condition of the surrounding tissues. MRI is particularly useful in assessing the integrity of the rotator cuff tendons, identifying associated injuries, and determining the suitability for surgical repair.[20] CT scans may be used in select cases to further evaluate complex tears, assess bone quality, or in those who may ultimately require a shoulder arthroplasty.[15,21] In contrast, the role of ultrasound in the diagnosis of rotator cuff tears is unclear. While it is a cost-effective and dynamic imaging modality, its accuracy highly depends on the investigator's skill and experience, and may not always provide a definitive diagnosis.[1,19] This may also have some element of regional bias, as ultrasound is performed in some countries by the radiologists, in others by the practitioner/surgeon itself, and thus may change the availability and feasibility of using US as a quick, cost efficient tool.

There are a variety of outcome measures used to determine success or to compare between treatments after conservative and operative management. Thus, it is important to define treatment success, which this Delphi process determined was patient outcome specific with pain, range of motion, strength, quality of

life, and satisfaction. Therefore, it was interesting to note that retears were not considered essential to treatment success, despite being shown to correlate with outcomes, patients with retears often can be symptomatically improved following treatment.[11] Additionally, as a result it was determined that routine imaging should not be performed at follow-up visits, with the exception of those in research studies.[6] Finally, there was strong consensus that the Constant score and SSV/SANE were the preferred clinical outcome scores, with the Constant score taking pain, range of motion, strength, quality of life, and satisfaction into account, but requiring the use of a goniometer, and the SSV/SANE being based on the patient's perception. Both of these outcome measures have relatively few questions and help to mitigate survey fatigue in those filling out outcome scores.[30] However, the Constant score also requires surgeon input and time to complete, with a goniometer required and may be observer dependent.

Limitations

This study has several potential limitations. Firstly, consensus statements are considered to be Level V data as they represent expert-opinion, which makes them susceptible to inherent biases in the selection and allocation of participants.[9,10] However, we sought to include surgeons who have an active interest and level of expertise in this area, as evidenced by their clinical and academic achievements on the topic. Furthermore, the questions and topics addressed may represent a potential source of bias as there was no standardized process for generating them. Instead, they were each selected and agreed upon by the group leaders. During the process, all the included authors had the opportunity to contribute to the manuscript and raise points for discussion. This was done in a blinded fashion in an effort to further reduce potential sources of bias. Furthermore, the use of a Likert scale may be better as it allows for a more nuanced response allowing authors to have varying levels of agreement where statements had multiple subparts to indicate that they do not agree in full with the statement. Finally, there are some limitations with the Delphi process itself as it may represent the lowest common denominator of expert opinion with less ownership of ideas, ultimately representing Level V data.[9]

Conclusion

Nearly all questions reached consensus among 57 SECEC members representing 23 different European countries. We encourage surgeons to use this minimum set of variables to establish rotator cuff registries and multicenter studies. By adapting and using compatible variables, data can more easily be compared and eventually merged across countries.

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Supplementary Data

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