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Original Research

Adherence to Complication Reporting for Randomized Controlled Trials Contained in Clinical Practice Guidelines for the Management of Carpal Tunnel Syndrome

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Purpose: Randomized controlled trials (RCTs) are frequently used in creating recommendations contained within clinical practice guidelines (CPGs). However, investigations outside of hand surgery have reported that RCTs within CPGs infrequently report complications and harms-related data. Our purpose was to assess adherence to complication reporting and harms-related outcomes contained in the Consolidated Standards for Reporting (CONSORT) Extension of Harms and Standards for Reporting of Diagnostic Accuracy Studies (STARD) reporting checklists for RCTs within the American Academy of Orthopaedic Surgery (AAOS) CPGs for carpal tunnel syndrome (CTS).

Methods: We identified all RCTs within the AAOS CTS CPGs. All therapeutic RCTs and diagnostic studies were included. We used the CONSORT Harms Checklist criteria to assess adherence to the reporting of adverse events for therapeutic RCTs and the STARD criteria to assess the diagnostic accuracy of the articles. We defined adequate compliance as adherence to $\geq$50% of the checklist items.

Results: We identified 82 therapeutic RCTs and 90 diagnostic accuracy articles within the AAOS CTS CPG. For therapeutic RCTs, we found that the average compliance with the published checklists was 19%. For diagnostic studies, the average compliance with checklists was found to be 55%. Eleven therapeutic RCTs (13%) and 60 diagnostic studies (67%) were determined to have adequate compliance for the CONSORT and STARD checklists, respectively.

Conclusions: Randomized controlled trials in the AAOS CPGs for CTS have low compliance with the CONSORT Extension for Harms Checklist. Although the overall adherence to the items published in the STARD statement for diagnostic accuracy evaluation remains higher, future efforts should be made to improve the adherence rates to both checklists.

Clinical relevance: Improved standardization of complication reporting may aid in comparing outcomes across multiple clinical investigations of upper-extremity procedures.

The Agency for Health Care Policy and Research was created in 1989, with responsibilities to enhance the quality, appropriateness, and effectiveness of health care services.[1] In collaboration with the Institute of Medicine, the Agency for Health Care Policy and Research released a report in 1990, aimed at applying these responsibilities to clinical practice guidelines (CPGs).[1] In 2011, the Institute of Medicine (now the National Academy of Medicine) provided an updated report on the CPGs and defined them as statements that include recommendations intended to optimize patient care and are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.[2] Clinical practice guidelines are common in all fields of medicine, with >2,600 CPGs indexed in 2014.[2] Within the orthopaedic specialty, the American Academy of Orthopaedic Surgeons (AAOS) is the primary organization responsible for providing the

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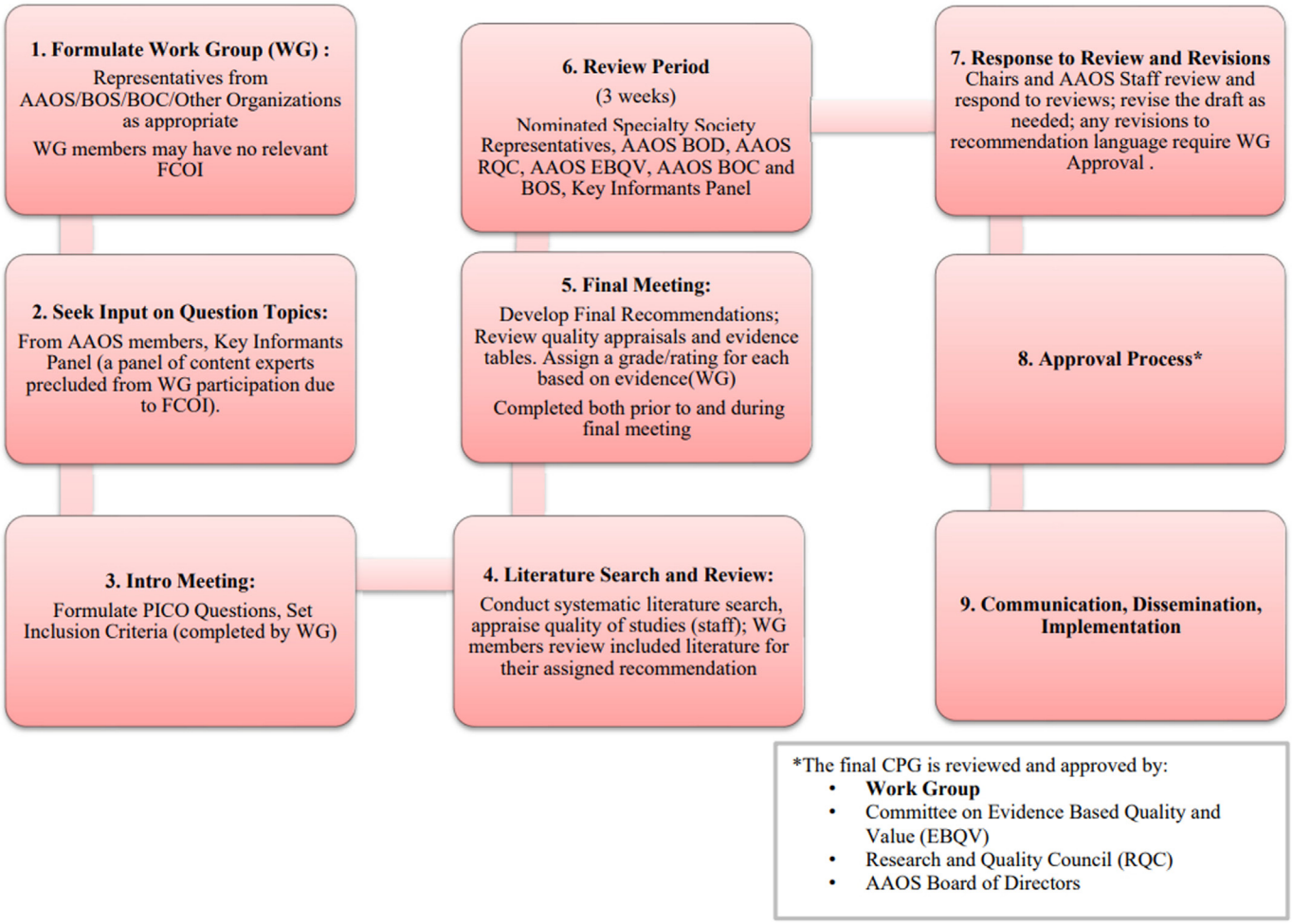

Figure. Clinical practice guideline process flowchart.

CPGs. In 2013, the AAOS released a statement detailing substantial changes to the processes and language of their CPGs, designed to improve both clarity and clinical relevance.[3] These updates included the addition of rating the strength of the recommendation and the basis for the determination (increased harm, lack of efficacy, etc) within it.[3] In 2022, the AAOS outlined the methodology behind the process for maintaining the CPGs, including the process for literature review and article selection from the AAOS clinical quality value staff (Fig.).[4]

Recommendations provided within AAOS CPGs are based, in-part, on the findings from randomized controlled trials (RCTs). The inclusion of RCTs in formulation of CPGs allows for evaluation of the benefits and risks of an intervention using the best available clinical evidence. Historically, the occurrence of adverse events (AEs) during the course of a study was often unreported, creating a challenge for the assessment and recommendation of a treatment in CPGs.[5,6] In an effort to standardize the reporting of RCTs, the Consolidated Standards for Reporting (CONSORT) checklist was developed and has been extensively used by practitioners and researchers since its creation.[7] An additional 10-item checklist was introduced (CONSORT Extension of Harms) focusing on the reporting of complications and related outcomes.[8] A similar guideline was also developed for reporting in diagnostic accuracy studies known as the Standards for Reporting of Diagnostic Accuracy Studies (STARD) statement.[9,10] Standardization of AE reporting would enhance evidence-based practice by providing a more balanced assessment of interventions for creating CPGs. However, several years have passed since the introduction of these guidelines, and adherence to reporting of harms remains low.[11,12]

A recent investigation found that RCTs cited as supporting evidence for the AAOS CPGs for management of hip and knee osteoarthritis poorly reported harms-related data.[11] In a survey of 770 members of the American Society for Surgery of the Hand (ASSH) regarding the AAOS CPGs for carpal tunnel syndrome (CTS), it was found that only 38% of the respondents believed that the current CPGs were appropriate and >42% did not know what the guidelines contained.[13] A prior 2009 AAOS CPG recommended the use of electrodiagnostic studies in patients where surgery was being considered. However, in the updated 2016, AAOS CPG no longer recommended the use of these studies for carpal tunnel release (CTR) patients, in cases without diagnostic uncertainty.[14] Instead, the diagnosis may be supported through history and physical examination in cases without diagnostic uncertainty.[14,15] With respect to the current AAOS CPGs for management of CTS (that are endorsed by the ASSH), it remains unclear how the included trials comply with standardized checklists for reporting of harms and harm-related outcomes.

The purpose of this investigation was to assess the adherence to complication reporting and harms-related outcomes in RCTs cited in the current AAOS CPGs for the management of CTS. We hypothesized that harms and complication-related data would be

Table 1
Study Characteristics for the Therapeutic RCTs Assessed in This Study

Variable	Value
Total number of included articles assessed, n	82
Mean sample size (SD)	133.9 (396.6)
AAOS quality, n (%)	
Low	3 (3.7%)
Moderate	24 (29.3%)
High	55 (67.1%)
Level of evidence, n (%)	
1	54 (65.9%)
2	28 (34.1%)
Funding source, n (%)	
No statement	52 (63.4%)
No funding received	10 (12.2%)
Private	8 (9.8%)
Public	12 (14.6%)
Study design, n (%)	
Multicenter	9 (11%)
Single center	71 (86.6%)
Pilot study	2 (2.4%)
Blinding, n (%)	
Unblinded	31 (37.8%)
Single	30 (36.6%)
Double	21 (25.6%)

Table 2
Study Characteristics for the Diagnostic Accuracy Studies in This Investigation

Variable	Value
Total number of included articles assessed, n	90
Mean sample size (SD)	516.2 (896.3)
AAOS quality, n (%)	
Low	15 (16.7%)
Moderate	59 (65.6%)
High	16 (17.8%)
Level of evidence, n (%)	
1	27 (30%)
2	63 (70%)
Funding source, n (%)	
No Statement	37 (41.1%)
No funding received	38 (42.2%)
Private	11 (12.2%)
Public	4 (4.4%)
Study design, n (%)	
Single center	88 (97.8%)
Multicenter	2 (2.2%)
Blinding, n (%)	
Unblinded	63 (70%)
Single	27 (30%)
Identification, n (%)	
Identification as a study of diagnostic accuracy using at least one measure of accuracy	66 (73.3%)

infrequently reported in the studies cited as supporting evidence for the AAOS CTS CPGs.

Materials And Methods

Approval from the institutional review board was not sought as this study did not involve human subjects and included publicly available data. Cited articles from the 2016, AAOS CPG on CTS were manually reviewed by five authors to identify all therapeutic RCTs and diagnostic accuracy studies. The CONSORT Harms Checklist criteria was used to assess adherence of the reporting of adverse events in therapeutic articles.[8] The checklist includes 18 binary questions, with higher scores indicating better reporting of AEs. The STARD criteria were used to assess the diagnostic accuracy of the diagnostic articles.[9] The scale included 34 binary questions, with higher scores indicating better reporting of key elements for diagnostic accuracy studies. Although there is not a defined acceptable score for checklists, we defined adequate compliance as articles being compliant with $\geq$50% of the criteria, similar to that in the study by Anderson et al.[11] The AAOS quality score—a categorical scoring system in the CPGs with scores consisting of low, moderate, or high quality—was recorded from the published CPGs. The level of evidence was recorded using all articles that reported a level of evidence published as part of their text. For articles that did not report a level of evidence, a standardized rubric was used.[16] Study characteristics such as multicenter or single-center investigations, whether and how blinding was used, or the presence of conflict of interest statements were obtained and recorded after a critical review of the manuscripts.

Statistical Analysis

Descriptive statistical analysis was performed to assess the average compliance rates for the included articles in this study. Cumulative scores were obtained and expressed as percentages for each article and for each item in the checklists to denote compliance rates. The mean scores and standard deviations were calculated for both of the checklists used in the study.

Results

Of the 264 articles published in the AAOS CTS CPGs, 90 therapeutic RCTs and 95 diagnostic investigations were identified. Of these studies, 82 (91%) therapeutic RCTs and 90 (95%) diagnostic studies were able to be accessed for full-text review.

The results showed variability in the AAOS quality rating of the included therapeutic RCTs, in which 55 of the 82 (67%) articles showed high quality ratings. Single-center investigations accounted for 71 of the 82 (87%) studies, and 52 of the 82 (63%) showed no statements regarding funding sources. Most articles (54 of the 82, 66%) were determined to have level I evidence. The mean sample size for the therapeutic RCTs was 134. A detailed breakdown of the characteristics of these RCTs can be found in Table 1.

A majority (59 of the 88, 66%) of the diagnostic accuracy studies were found to have moderate AAOS quality ratings, and 63 of the 90 studies were found to have level II evidence. Table 2 shows the bibliographic information of the diagnostic accuracy studies.

The mean score of therapeutic RCTs scored on the CONSORT Harms checklist was 4.02 ($\pm$4.03). Only 11 articles (13%) achieved adequate compliance. Overall, 41 articles (50%) showed a balanced discussion section with regard to efficacy and AEs. Table 3 shows the breakdown of the articles' compliance with the CONSORT Harms Checklist.

The mean score of diagnostic accuracy studies on the STARD checklist was 18.7 ($\pm$3.7). Of the included articles, 73% used at least one measure of accuracy (such as sensitivity or specificity). Overall, 60 of the 90 articles (66%) achieved adequate compliance. Table 4 shows the breakdown of the articles' compliance with the STARD checklist.

Discussion

The results of this investigation indicate that compliance with harms reporting by therapeutic RCTs cited in the AAOS CPGs for CTS is low. We observed that only 11% of the cited trials showed adequate compliance with harms reporting. This rate is lower than previous studies analyzing harms reporting from studies included in other AAOS CPGs. Anderson et al,[11] in a review of hip and knee

Table 3
Compliance with CONSORT Harms Checklist for Therapeutic RCTs

CONSORT Harms Checklist Component, n (%)	Value
Articles with adequate compliance with the CONSORT harms checklist (/82)	11 (13.4%)
Average compliance with CONSORT harms checklist (/18)	4.02 (22.4%)
AEs mentioned in title/abstract	30 (36.6%)
AEs mentioned in introduction	31 (37.8%)
Adverse event definitions	
Includes comprehensive list of AEs reported or definition of AEs	30 (36.6%)
Distinguishes between expected and unexpected AEs	9 (11%)
Mentions use of a validated instrument to measure AE severity	17 (20.7%)
Collection of Harms data	
Includes harm-associated mode of data collection	27 (32.9%)
Includes harm-associated timing of data collection	27 (32.9%)
Includes attribution methods or intensity of ascertainment	14 (17.1%)
Includes harm-associated monitoring and stopping rules, if pertinent	5 (6.1%)
Analysis	
Includes plans for presenting and analyzing information on harm	15 (18.3%)
Withdrawals	
Includes, for each arm, the participant withdrawals that are because of harm and their experiences with the allocated treatment	8 (9.8%)
Includes information on timing of withdrawals	10 (12.2%)
Denominator	
Provides denominators for AEs	28 (34.1%)
Provides definitions used for analysis set in methods section (eg, intention to treat)	8 (9.8%)
AE data	
Includes the absolute risk per arm and per adverse event type or presents appropriate metrics for recurrent events, continuous variables, and scale variables, whenever pertinent	7 (8.5%)
Includes information on grade or seriousness of AEs	11 (13.4%)
Subgroup	
Describes any subgroup analyses or exploratory analyses for harm	12 (14.6%)
Balanced discussion	
Discussion balanced with regard to efficacy and adverse events	41 (50%)

osteoarthritis CPGs, reported that 47% of the RCTs showed adequate harms reporting and that overall compliance was poor. In a review of CPGs on rotator cuff injuries, Anderson et al[17] reported that 32% of the cited RCTs adequately reported AEs.[17] Batioja et al,[18] in a review of AAOS CPGs related to pediatric orthopedics reported that the cited RCTs showed an average compliance rate of 69.8%. A recent publication by Thompson et al[19] also indicated that 55% of RCTs related to distal radius fractures adequately reported >50% of all required items in the CONSORT Harms Checklist and cited an average compliance rate of 50.9%. Moreover, a Cochrane review reported suboptimal compliance with the CONSORT completeness checklist in the broader context of RCTs published in medical journals.[20]

Our results also showed low rates of compliance compared with previous reports examining adherence to the CONSORT Harms checklist. Although previous reports around this topic showed low compliance overall, studies examining compliance with the CONSORT Harms checklist related to other upper-extremity RCTs showed even lower rates.[17] With suboptimal reporting of complications, the cumulative data may overstate the benefit of specific treatment options. In addition, a lack of standardization with respect to complication reporting can make comparisons across multiple clinical series more difficult for clinicians. This may have a larger effect on the assessment of emerging or novel techniques for CTR, such as ultrasound guided procedures, thread carpal tunnel release, and CTR performed by nonsurgeons.

Our results indicate moderate compliance with the STARD checklist for reporting diagnostic accuracy. The average compliance score was 18.7 of the 34 (55%) and 60 of the 90 (66.7%) articles showed adequate compliance. Rama et al[21] reported that 37 diagnostic studies in three major hand surgery journals reported a mean adherence score of 15 and that only 38% of the articles showed adequate reporting, which was defined as scoring >two-thirds of the items. Although published literature in upper-extremity surgery related to adherence to the STARD checklist is limited, previous reports in the area of radiology have shown compliance rates between 47% and 69%.[22–25] Similarly, a previous report showed compliance rates with the STARD checklist of diagnostic pathology articles to be 45%.[26] Overall, published literature seems to support that diagnostic articles have moderate-to-adequate compliance with the STARD checklist, which is encouraging as better compliance and adherence to established guidelines will improve evidentiary standards and increase the overall quality of scientific and clinical research.

Low compliance with established guidelines, particularly those related to the reporting of AEs, can cloud clinical risk assessment. Unpublished AEs might have exaggerated downstream effects as missing data will also skew the accuracy of future systematic reviews and meta-analyses. There are also concerns related to publication bias or selective omission of outcomes data as suggested by a study by Golder et al,[27] in which the authors have noted that these are serious threats to the accuracy and validity of aggregate studies such as systematic reviews and meta-analyses.[27] The authors also reported examples of published review papers that arrive at a different conclusion after unpublished or omitted data has been incorporated into the analysis.[27] Hodkinson et al[28] noted that readers should be able to balance AEs and benefits; however, low compliance with the CONSORT Harms checklist jeopardizes the objectivity of these results and makes a balanced interpretation more difficult. Although we found that the specific item from the CONSORT Harms checklist that assesses whether articles have a balanced discussion or not showed the best overall compliance, only 50% of the articles in our investigation showed a balanced discussion with regard to benefits and AEs. Although there might be logistical challenges such as limited review power for journals, following the rules set out by the CONSORT statement remains the most effective method for improving publication rates of AEs.[27,28] The responsibility of improving objectivity, transparency, and reliability in the field of medical research

Table 4
Average Compliance With STARD checklist for Diagnostic RCTs

STARD checklist Component	Maximum Potential Score	Average Score
Background and objectives	1	0.9
Methods	4	1
Results	2	0.7
Discussion	2	1.1
Registration	1	0.1
Scientific background	1	0.8
Objectives and hypothesis	1	0.9
Design	1	0.9
Participants	4	2.5
Test methods	7	2.3
Analysis	5	1.4
Participants	5	1.4
Test results	3	1.4
Limitations	1	0.8
Implications	1	0.9
Registration number	1	0.1
Access	1	0.4
Funding sources	1	0.6
Average STARD checklist compliance	34	18.7

falls both on the authors and reviewers. Authors should evaluate the reporting of AEs such as how they occurred, timing of AEs, duration of AEs, and serious complications that may lead to trial discontinuation. Although, many journals have mandated reporting of similar guidelines, journals should comprehensively incorporate these established checklists with clear instructions for their reviewers.[11,17,28]

Several limitations must be considered when interpreting these results. First, the CONSORT statement was initially published in 1996, updated in 2001, and then showed future modifications and extensions, most notably in 2004, when the Harms extension was published.[8] Our investigation showed 10 articles that were published either in or before 1996, which could have a limited effect on the accuracy of our results. Second, the analysis of compliance with these two guidelines was not performed in a blinded and duplicated methodology and this might negatively affect the reliability of our results. Finally, we have only investigated the compliance rates of articles published in the AAOS CPG for CTS, which limits generalizability to other clinical topics.

Most articles cited in the AAOS CPGs for CTS do not adequately report complication-related outcomes. A majority of studies on physical examination maneuvers adequately reported essential information for diagnostic accuracy. Improved standardization with respect to complication reporting may aid in comparing outcomes across multiple clinical investigations of upper-extremity procedures. Future efforts should be focused toward improving the reporting of harm outcomes, especially those included in guideline-level recommendations.

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