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Editor's Choice – European Society for Vascular Surgery Clinical Practice Guideline Development Scheme: An Overview of Evidence Quality Assessment Methods, Evidence to Decision Frameworks, and Reporting Standards in Guideline Development

George A. Antoniou [a,b,*], Frederico Bastos Gonçalves [c,d], Martin Björck [e], Nabil Chakfé [f,g], Raphaël Coscas [h,i], Nuno V. Dias [j], Florian Dick [k], Stavros K. Kakkos [l], Barend M.E. Mees [m], Timothy Resch [n], Santi Trimarchi [o,p], Riikka Tulamo [q], Chris P. Twine [r,s], Frank Vermassen [t], Anders Wanhainen [e,u], Philippe Kolh [v,w,x]

[a] Department of Vascular and Endovascular Surgery, Manchester University NHS Foundation Trust, Manchester, UK
[b] Division of Cardiovascular Sciences, School of Medical Sciences, Manchester Academic Health Science Centre, The University of Manchester, Manchester, UK
[c] Centro Hospitalar Universitário de Lisboa Central, Lisbon, Portugal
[d] NOVA Medical School, Universidade NOVA de Lisboa, Portugal
[e] Department of Surgical Sciences, Section of Vascular Surgery, Uppsala University, Sweden
[f] Groupe Européen de Recherche sur les Prothèses Appliquées à la Chirurgie Vasculaire, Strasbourg, France
[g] Department of Vascular Surgery and Kidney Transplantation, University Hospital of Strasbourg, France
[h] Department of Vascular Surgery, Ambroise Paré University Hospital, Assistance Publique - Hôpitaux de Paris (AP-HP), Boulogne-Billancourt, France
[i] Faculté de Médecine Paris-Ile de France-Ouest, UFR des sciences de la santé Simone Veil, Université Versailles Saint-Quentin en Yvelines, Montigny-le-Bretonneux, France
[j] Vascular Centre, Skåne University Hospital, Malmö, Sweden
[k] Department of Vascular Surgery, Kantonsspital St. Gallen, University of Bern, Bern, Switzerland
[l] Department of Vascular Surgery, University of Patras Medical School, Patras, Greece
[m] Department of Vascular Surgery, Maastricht University Medical Centre and CARIM School for Cardiovascular Diseases, Maastricht University, Maastricht, The Netherlands
[n] Department of Vascular Surgery, Copenhagen University Hospital- Rigshospitalet, Faculty of Health and Medical Sciences, University of Copenhagen, Copenhagen, Denmark
[o] Vascular Surgery, Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico, Milan, Italy
[p] Department of Clinical Sciences and Community Health, Università degli Studi di Milano, Milan, Italy
[q] Department of Vascular Surgery, Helsinki University Hospital, University of Helsinki, Helsinki, Finland
[r] Department of Vascular Surgery, North Bristol NHS Trust, Bristol, UK
[s] Centre for Surgical Research, University of Bristol, Bristol, UK
[t] Department of Thoracic and Vascular Surgery, Ghent University Hospital, Ghent, Belgium
[u] Department of Surgery and Peri-operative Sciences, Umeå University, Umeå, Sweden
[v] Department of Biomedical and Preclinical Sciences, University of Liège, Belgium
[w] GIGA Cardiovascular Sciences, University of Liège, Belgium
[x] Department of Information System Management, University Hospital of Liège, Belgium

WHAT THIS PAPER ADDS

This paper describes the different processes, and their respective challenges, in developing clinical practice guidelines, in a structured and novel way. An overview and analysis of critical components in health guideline development is provided, including certainty of evidence assessment methods, evidence to decision frameworks, and guideline reporting. Although the principles described in this guide are focused on accumulated experience of the European Society for Vascular Surgery, this structured methodological document may be of benefit for health guideline development of other societies and organisations.

Objective: A structured and transparent approach is instrumental in translating research evidence to health recommendations and evidence informed clinical decisions. The aim was to conduct an overview and analysis of principles and methodologies for health guideline development.

Methods: A literature review on methodologies, strategies, and fundamental steps in the process of guideline development was performed. The clinical practice guideline development process and methodology adopted by the European Society for Vascular Surgery are also presented.

Results: Sophisticated methodologies for health guideline development are being applied increasingly by national and international organisations. Their overarching principle is a systematic, structured, transparent, and iterative

☆ The authors are members of the ESVS Guideline Steering Committee.

* Corresponding author. Room G37, Vascular Offices, J Block, The Royal Oldham Hospital, Rochdale Road, Oldham OL1 2JH, UK.
E-mail address: Georgios.Antoniou@manchester.ac.uk (George A. Antoniou).

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process that is aimed at making well informed healthcare choices. Critical steps in guideline development include the assessment of the certainty of the body of evidence; evidence to decision frameworks; and guideline reporting. The goal of strength of evidence assessments is to provide well reasoned judgements about the guideline developers' confidence in study findings, and several evidence hierarchy schemes and evidence rating systems have been described for this purpose. Evidence to decision frameworks help guideline developers and users conceptualise and interpret the construct of the quality of the body of evidence. The most widely used evidence to decision frameworks are those developed by the GRADE Working Group and the WHO-INTEGRATE, and are structured into three distinct components: background; assessment; and conclusions. Health guideline reporting tools are employed to ensure methodological rigour and transparency in guideline development. Such reporting instruments include the AGREE II and RIGHT, with the former being used for guideline development and appraisal, as well as reporting.

Conclusion: This guide will help guideline developers/expert panels enhance their methodology, and patients/clinicians/policymakers interpret guideline recommendations and put them in context. This document may be a useful methodological summary for health guideline development by other societies and organisations.

Keywords: AGREE, Certainty of evidence, Clinical practice guidelines, Evidence to decision framework, GRADE, Quality of evidence
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INTRODUCTION

Clinical practice guidelines are evidence informed statements that include recommendations intended to optimise patient care. Sophisticated methodologies and implementation strategies for health guideline development are being adopted increasingly by national and international organisations. Overarching principles underpin the importance of a systematic, structured, transparent, and iterative process that is aimed at making well informed healthcare choices. Principal components of the process are assessment of the quality of the body of evidence; evidence to decision frameworks; and guideline reporting. This article describes methodologies and strategies of guideline development, and outlines practices adopted by the European Society for Vascular Surgery (ESVS) and its Guideline Steering Committee. The ESVS Guideline Steering Committee is actively looking at improving the quality of the clinical practice guidelines, and this work is an essential step in that process.

QUALITY OF EVIDENCE ASSESSMENT

The goal of strength of evidence assessments is to provide well reasoned judgments about the guideline developers' confidence in study findings. A growing number of organisations adopt systematic approaches to making judgements about the strength of evidence, and several frameworks have been described outlining the criteria to be considered for this purpose.

It is important to make a distinction between evidence hierarchy schemes and strength of evidence systems, also called evidence rating systems. Evidence hierarchies traditionally stratify the level of evidence based on study design, and some use additional quality indicators, such as setting and sample size, whereas evidence rating systems typically involve an examination of different characteristics of the body of evidence. Both approaches aim to give clinicians, patients, and policymakers a comprehensive evaluation of the evidence.

Evidence hierarchy schemes

Evidence hierarchy systems are ranking schemes that consider strengths of evidence for therapeutic effects and harms, and some expand to a wider range of clinical questions, including prevalence, accuracy of diagnostic tests, prognosis, and screening. Commonly used systems in clinical practice guidelines are summarised in Table 1.[1–4] Most of them have been designed by health organisations for the purpose of their guideline development. Such frameworks classify the level of evidence based on study design, with systematic reviews of randomised controlled trials (RCTs) assigned the highest level of evidence, and mechanism based reasoning or expert opinion reports, the lowest. An example is the system developed by the European Society of Cardiology, which defines three levels of evidence for data derived from multiple RCTs (level A), a single RCT or large non-randomised studies (level B), and expert consensus or small studies (level C).[2] Some systems describe the class of recommendation that reflects the magnitude of benefit over risk and corresponds to the strength of the recommendation. Of note, the level of evidence does not necessarily affect the class (strength) of a recommendation, especially in the case of weak evidence.

Strength of evidence/evidence rating systems

Evidence rating systems that have been described for use in the context of clinical practice guideline development are summarised in Table 2.[5–11] Some are bespoke frameworks and not widely adopted. The most widely used system for rating the quality of the body of evidence on the effectiveness of health interventions is the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology. It has been endorsed by over 100

Table 1. Evidence hierarchy schemes used in clinical practice guideline development

Name	Study designs	Levels of evidence	Class (strength) of recommendation
Oxford Centre for Evidence Based Medicine (OCEBM) Levels of Evidence*	Systematic reviews of randomised trials Randomised trial or observational study with dramatic effect Non-randomised controlled cohort/follow up study Case series, case control studies, or historically controlled studies Mechanism based reasoning	Level 1 Level 2 Level 3 Level 4 Level 5	Not reported
European Society of Cardiology (ESC) levels of evidence	Multiple randomised clinical trials or meta-analyses Single randomised clinical trial or large non-randomised studies Consensus of opinion and/or small studies, retrospective studies, registries	Level A Level B Level C	Class I Class IIa Class IIb Class III
American Diabetes Association (ADA) Evidence Grading System	Clear evidence from well conducted, generalisable RCTs that are adequately powered; compelling non-experimental evidence; supportive evidence from well conducted RCTs that are adequately powered Supportive evidence from well conducted cohort studies; supportive evidence from a well conducted case control study Supportive evidence from poorly controlled or uncontrolled studies; conflicting evidence with the weight of evidence supporting the recommendation Expert consensus or clinical experience	Level A Level B Level C Level D	Not reported
American College of Cardiology/American Heart Association (ACC/AHA) Clinical Practice Guideline Recommendation Classification System	High quality evidence from >1 RCT; meta-analyses of high quality RCTs; one or more RCTs corroborated by high quality registry studies Moderate quality evidence from ≥ 1 RCTs; meta-analyses of moderate quality RCTs Moderate quality evidence from ≥ 1 well designed, well executed non-randomised studies, observational studies, or registry studies; meta-analyses of such studies Randomised or non-randomised observational or registry studies with limitations of design or execution; meta-analyses of such studies; physiological or mechanistic studies in human subjects Consensus of expert opinion based on clinical experience	Level A Level B: randomised Level B: non-randomised Level C: limited data Level C: expert opinion	Class I (strong) Class IIa (moderate) Class IIb (weak) Class IIIa: no benefit (weak) Class IIIb: harm (strong)

RCT = randomised controlled trial.
* The reported study designs are for treatment benefits; other study designs are reported for different clinical questions (e.g., diagnosis or prognosis).

organisations worldwide, including the World Health Organisation (WHO), Cochrane, and the Society for Vascular Surgery. Interestingly, national guideline development organisations, including the National Institute for Health and Care Excellence (NICE) in the UK, the Scottish Intercollegiate Guidelines Network (SIGN), and the National Health and Medical Research Council (NHMRC) in Australia, have recently moved from other models to the GRADE approach. GRADE defines the certainty of the body of evidence on intervention effectiveness as "the extent of confidence that an estimate of the effect is correct".[5]

Evidence rating systems are based on a discrete set of domains, many of which are reported across the systems, although there are significant variations in specifications. The most frequently used domains include study design and quality, consistency, precision, directness, publication bias, magnitude of effect, dose—response, plausible residuals, and generalisability.[12] Most systems report specific criteria on how to rate each domain and determine whether to downgrade the evidence in a particular domain; for instance, for inconsistency, the following criteria have been set by GRADE: wide variance of point estimates across studies; minimal or no overlap of confidence intervals; and tests of heterogeneity.[13] The GRADEpro Guideline Development Tool (GDT) is software used to summarise and present information for healthcare decision making and make judgements and recommendations in a systematic way informed by research evidence.[14]

Pros and cons of evidence hierarchy and evidence rating systems

Evidence hierarchy schemes are simple, easy to use heuristics that can be used by guideline developers not trained in the complex methodology of evidence appraisal. They are also easy to comprehend by clinicians seeking clinical practice guidance. However, such systems have been criticised for being simplistic, not incorporating facets of evidence other than the study design, which are critical in clinical decision making.

Evidence rating systems offer a rigorous, transparent, and structured process for developing and presenting summaries of evidence. Notably, surgical guidelines that have been developed applying the GRADE methodology have been found to be of higher quality than those using other methods for the assessment of the quality of evidence.[15] However, evidence rating systems may be complex, require methodological expertise and training, and quantitative synthesis is commonly employed. Furthermore, they may be challenging to use in clinical questions other than benefits or harms of therapeutic interventions, such as questions about diagnostic tests, public health, or health systems, although many are evolving systems being adapted

Table 2. Evidence rating systems used in clinical practice guideline development

Name	Domains of evidence	Evidence ratings	Class (strength) of recommendation
Grading of recommendations assessment, development, and evaluation (GRADE)	Study design Inconsistency of results Indirectness of evidence Imprecision Publication bias Magnitude of effect Dose response gradient Plausible residual confounding	High Moderate Low Very low	Strong Weak
U.S. Preventive Services Task Force (USPSTF)	Study design Study quality Generalisability Quantity Consistency Other (e.g., dose response effects)	High Moderate Low	Not reported
Strength of Recommendation Taxonomy (SORT)*	Study quality Consistency	Level 1: good quality patient oriented evidence Level 2: limited quality patient oriented evidence Level 3: other evidence	A: recommendation based on consistent and good quality patient oriented evidence B: recommendation based on inconsistent or limited quality patient oriented evidence C: recommendation based on consensus, usual practice, opinion, disease oriented evidence, and case series for studies for diagnosis, treatment, prevention, or screening
Let Evidence Guide Every New Decision (LEGEND)	Study quality Study quantity Consistency	High Moderate Low Grade not assignable	Not reported
FORM: an Australian method for formulating and grading recommendations in evidence based clinical guidelines†	Evidence base Consistency Clinical impact Generalisability Applicability	A: excellent B: good C: satisfactory D: poor	A: body of evidence can be trusted to guide practice B: body of evidence can be trusted to guide practice in most situations C: body of evidence provides some support for recommendation(s), but care should be taken in its application D: body of evidence is weak and recommendation must be applied with caution
The Guide to Community Preventive Services	Study execution Study design suitability Number of studies Consistent Effect size Expert opinion	Strong Sufficient Insufficient empirical information supplemented by expert opinion Insufficient	Not reported

* Level of evidence refers to individual studies.
† Each of the domains can be rated from A to D.

and extended to cover different areas and types of evidence, such as CERQUAL for qualitative evidence[16] and GRADE for diagnostic studies.[13] Furthermore, such systems eliminate neither the need for judgements nor legitimate disagreements about the interpretation of evidence.

EVIDENCE TO DECISION FRAMEWORKS

Commonly, there may be ambiguity around how best to conceptualise and interpret the construct of the quality of the body of evidence on the effectiveness of an intervention. Evidence to decision frameworks address this problem; they are formats that help health guideline developers use evidence in a structured and transparent way to inform healthcare decisions in the context of clinical recommendations. Such frameworks consist of three distinct components: background, assessment, and conclusions.

- The background includes details of the question addressed by the framework, which is typically formulated in a specific PICO (patients, intervention, comparison, outcomes) format, and information on settings, perspectives, and subgroups.
- The assessment includes substantive criteria that should be considered for making a recommendation and judgements that panel members must make in relation to each criterion. Such criteria include, but are not limited to, benefits and harms of an intervention, certainty of evidence, resource requirements, and health equity.
- Conclusions include the direction of a recommendation (for or against an intervention) and the strength of the recommendation. Furthermore, justifications for recommendations, implementation considerations including strategies to address concerns about acceptability and feasibility of the intervention, monitoring and evaluation if the intervention is implemented, and research priorities should be provided in a structured, concise, and actionable manner.

Table 3. Criteria used in evidence to decision frameworks developed by the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group and World Health Organisation (WHO)

GRADE	WHO-INTEGRATE
Consideration	
Patient perspective	Individual level
Population perspective	Population level
	System level
Criteria	
Problem priority	*Quality of evidence*
Desirable effects	Balance of health benefits and harms
Undesirable effects	Human rights and sociocultural acceptability
Certainty of evidence	Health equity, equality, and non-discrimination
Outcome importance	Societal implications
Balance between desirable and undesirable effects	Financial and economic considerations
Resource requirements/cost effectiveness	Feasibility and health system considerations
Health equity	
Acceptability	
Feasibility	

Conclusions can be reached in different ways, including using informal or formal consensus processes or voting.

The most widely used evidence to decision framework for clinical practice recommendations is that developed by the GRADE Working Group.[17] They follow the general structure described above (background, assessment, conclusions), and specific criteria have been set that should be considered from the population and individual patient perspective (Table 3).[17] The interactive evidence to decision framework, which was developed by the GRADE Working Group in the European Union funded DECIDE project, is a tool that can be used by health guideline developers to facilitate use of the evidence to decision frameworks. The tool is free to use and is programmed on a technical platform provided by Epistemonikos.[18] It enables health guideline panels to generate summaries of recommendations for different audiences, and standard templates for clinicians, patients, the public, and policymakers are available.

More recently, the WHO has developed an evidence to decision framework called WHO-INTEGRATE.[19] The framework is devised as a tool to facilitate structured reflection and discussion in guideline development and is conceived for individual level, population level, and system level interventions at the global and national levels. WHO-INTEGRATE comprises six substantive criteria and the metacriterion of quality of evidence (Table 3).[19] It has been built on established terms and concepts of the GRADE evidence to decision framework and has expanded on such criteria as health equity, equality, and non-discrimination and societal implications. Context specific and problem specific considerations are made by guideline panels to decide which criteria and subcriteria are most relevant.

GUIDELINE DEVELOPMENT, REPORTING, AND ASSESSMENT

In recent years, strategies have been employed to ensure methodological rigour and transparency in guideline development as part of a quality mandate aimed at improving health care. Methodological and reporting standards have been published to guide the process and help enhance the quality of clinical practice guidelines. Two practice guideline reporting tools have been developed to address this purpose: the Appraisal of Guidelines for REsearch and Evaluation (AGREE) II[20] and the Reporting Items for practice Guidelines in HealThcare (RIGHT).[21]

The AGREE II instrument has been developed by a group of international guideline developers and researchers to provide quality criteria in the entire process of guideline development. It has been designed to provide a methodological framework for guideline development; inform the reporting of clinical practice guidelines; and assess the quality of guidelines. It comprises 23 key items, which are organised into six thematic areas (Table 4):[20]

1. Scope and purpose.
2. Stakeholder involvement.
3. Rigour of development.
4. Clarity of presentation.
5. Applicability.
6. Editorial independence.

Table 4. The Appraisal of Guidelines for REsearch and Evaluation (AGREE) Reporting Checklist

Domain	Item
Domain 1: Scope and purpose	1. Objectives
	2. Questions
	3. Population
Domain 2: Stakeholder involvement	4. Group membership
	5. Target population, preferences, and views
	6. Target users
Domain 3: Rigour of development	7. Search methods
	8. Evidence selection criteria
	9. Strengths and limitations of the evidence
	10. Formulations of recommendations
	11. Considerations of benefits and harms
	12. Link between recommendations and evidence
	13. External review
	14. Updating procedure
Domain 4: Clarity of presentation	15. Specific and unambiguous recommendations
	16. Management options
	17. Identifiable key recommendations
Domain 5: Applicability	18. Facilitators and barriers to application
	19. Implementation advice/tools
	20. Resource implications
	21. Monitoring/auditing criteria
Domain 6: Editorial independence	22. Funding body
	23. Competing interests

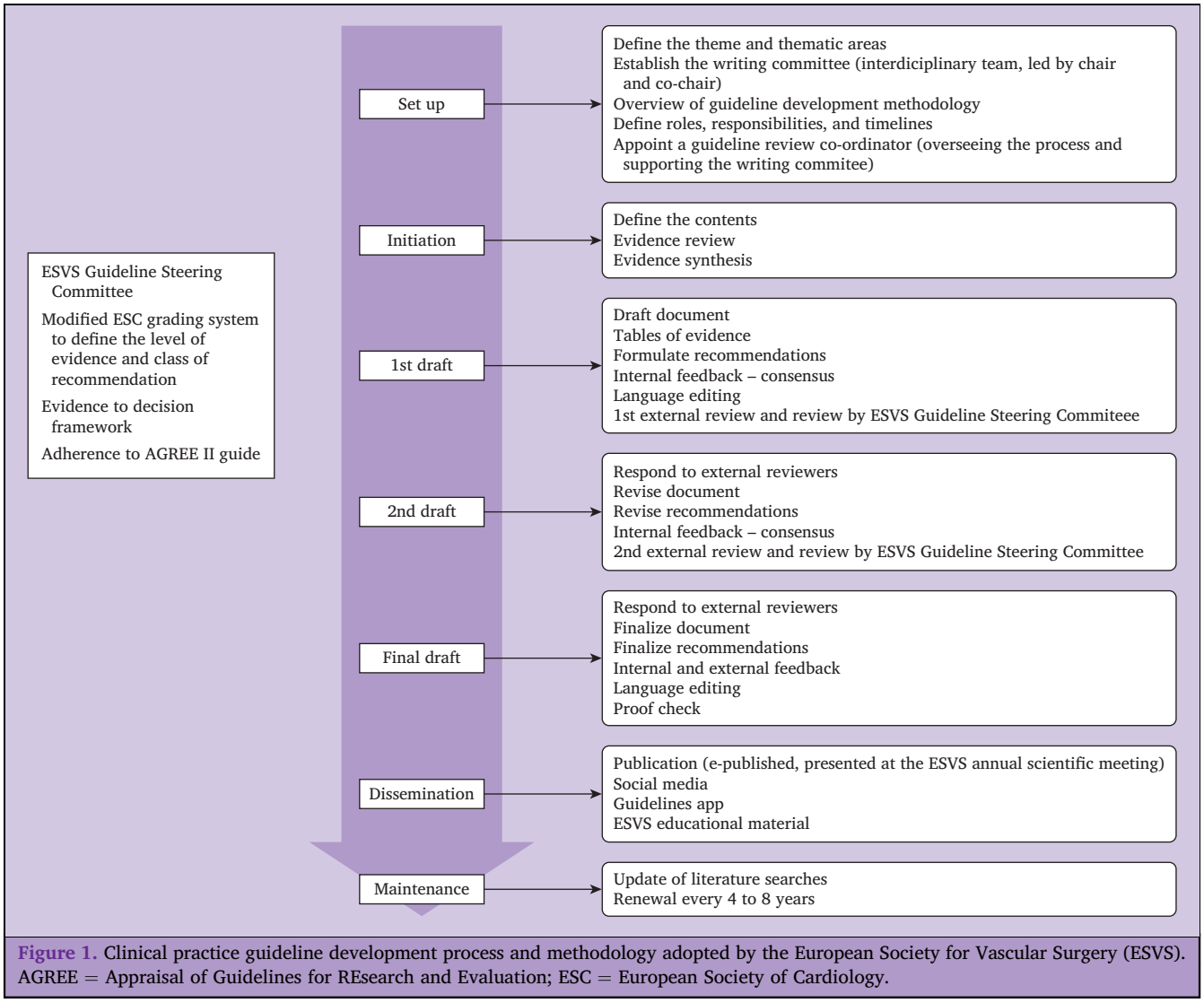

Figure 1. Clinical practice guideline development process and methodology adopted by the European Society for Vascular Surgery (ESVS). AGREE = Appraisal of Guidelines for REsearch and Evaluation; ESC = European Society of Cardiology.

The instrument is intended to be used by guideline developers, healthcare providers, policymakers, researchers, and educators. The AGREE reporting checklist, which aligns with the structure and content of AGREE II, can be used prospectively during the development process and drafting of the guideline document or retrospectively, after the guideline is completed, as a quality assurance measure, ensuring all necessary information is provided. AGREE II is a generic tool that applies to any health area and expands to every aspect of health care, including public health and promotion, prevention, screening, diagnosis, and treatment. The research ecosystem of surgical interventions has specific characteristics that need to be considered in guideline development, such as expertise, experience, and infrastructure. To this end, work is underway by the Guideline Assessment Project (GAP) Consortium to develop an expanded AGREE instrument with specific applicability in surgical interventions.[22]

AGREE Recommendation EXcellence (AGREE REX) is a complement to AGREE II that is designed to inform the development, reporting, and evaluation of recommendations in clinical practice guidelines. It consists of nine items organised in three domains: clinical applicability; values and preferences; and implementability. It is aimed at helping in the implementation of clinical practice guidelines and is a useful tool in differentiating and identifying recommendations that are clinically credible and relevant to healthcare providers, policymakers, and other health stakeholders.[23]

The RIGHT working group is an international multidisciplinary team that was established in 2013 and included policymakers, methodologists, epidemiologists, clinicians, editors, and consumer representatives from 12 countries across Asia, Africa, Europe, Oceania, and North America.[24] Its goal was to improve the reporting of practice guidelines by providing guidance and standards for such reporting in health care. The RIGHT checklist comprises 22 items that are organised in seven sections: basic information; background; evidence; recommendations; review and quality assurance; funding, declaration, and management of interest; and other information. They should be reported in a high quality practice guideline.[24]

Table 5. Modified European Society of Cardiology evidence hierarchy scheme adopted by the European Society for Vascular Surgery to determine the level of evidence and class of recommendation

Level of evidence	Hierarchy scheme	Class of recommendation	Definition	Suggested wording
A	Data derived from multiple RCTs* or meta-analyses of RCTs	Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, and effective	Is recommended
B	Data derived from a single RCT, large non-randomised studies, or meta-analyses of non-randomised studies	Class II	Conflicting evidence and/or divergence of opinion about the usefulness/efficacy about the given treatment or procedure	
		Class IIa	Weight of evidence/opinion is in favour of usefulness/efficacy	Should be considered
		Class IIb	Usefulness/efficacy is less well established by evidence/opinion	May be considered
C	Consensus of the experts and/or small studies, retrospective studies, registries, or meta-analyses of small studies	Class III	Evidence or general agreement that a given treatment or procedure is not useful/effective and in some cases may be harmful	Is not recommended, should not be done

The level of evidence and the class of recommendation are two independent factors, and the level of evidence does not necessarily affect the class (strength) of a recommendation.
RCT = randomised controlled trial.
* Pre-defined and large subgroup analyses of RCTs may be classified as level A, while other subgroup analyses of RCTs are level B.

THE EUROPEAN SOCIETY FOR VASCULAR SURGERY GUIDELINE DEVELOPMENT PROCESS

The ESVS has created a guideline development programme that is overseen by a steering committee, with a considerable output over the past seven years (14 guideline documents).[25–38] Interestingly, both factors (i.e., guideline committee and high guideline output) have been shown to be associated with high surgical guideline quality and higher odds of the surgical guideline being recommended for use applying the AGREE II instrument (odds ratio [OR] 4.15, 95% confidence interval [CI] 1.47 — 11.77; and OR 3.79, 95% CI 1.01 — 12.66, respectively).[15] The ESVS guideline development cycle is presented in a schematic diagram (Fig. 1). The speed of renewal of the guidelines is individualised, depending on the scientific activity in the relevant field.

A modified evidence hierarchy scheme developed by the European Society of Cardiology has been adopted by the ESVS to determine the level of evidence and class of recommendation (Table 5).[2] Modifications were recently decided by the ESVS Guideline Steering Committee following calls for clarification from writing committees and reviewers. Such modifications mainly include a distinction between meta-analyses of randomised clinical trials (level A), meta-analyses of non-randomised studies (level B), and meta-analyses of small studies (level C).

Tables of Evidence have a pre-specified format and are used by guideline developers to present the body of evidence for each recommendation. Such tables present the class of recommendation and level of evidence, and data of key supporting studies applying the PICO structure. They facilitate the interpretation of the evidence, provide rationale underlying the assignment of a grade of recommendation, and ensure consistency across the guideline document and transparency of the recommendation development process. Tables of Evidence are provided as a supplementary material alongside the main guideline document.

Furthermore, ESVS guideline developers follow the structured and rigorous development methodology described in AGREE II and use the AGREE Reporting Checklist to guide reporting of clinical practice guidelines. The AGREE II is also used to conduct internal assessments ensuring sound guidelines.

The aim of the ESVS guidelines is to be clinically relevant and practically useful. Much effort is put into precise wording of recommendations, so that their meaning is clear and corresponds to the class given. In the event of weak, or even lack of, evidence on a clinical question that is nevertheless considered clinically important, it is possible to issue a recommendation based solely on the expert opinion of the writing committee. Unanimity is always sought, and when it is not possible to achieve, consensus is reached by voting, with the voting results reported in the guideline document.

Conclusion

An overview and analysis of level of evidence assessments, evidence to decision frameworks, and guideline reporting, which are critical components of healthcare guideline development, have been provided. A structured and transparent approach is instrumental in translating research evidence to health recommendations and evidence informed clinical decisions. This guide will help guideline developers/expert panels enhance their methodology and patients, clinicians, and policymakers interpret guideline recommendations and put them in context.

CONFLICT OF INTEREST STATEMENT AND FUNDING

None.

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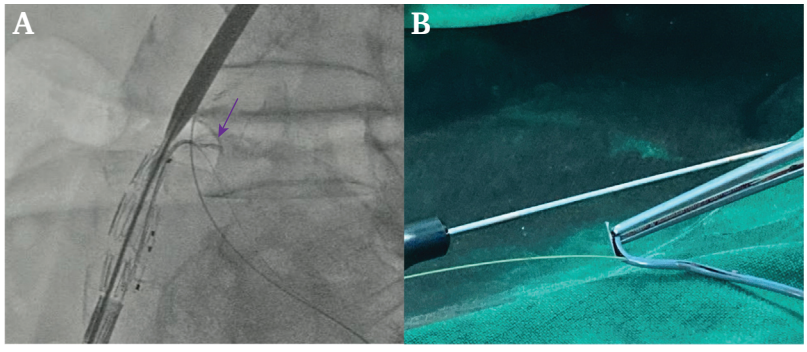
COUP D'OEIL

Broken Iliac Branch Device Indwelling Catheter Tip

Woo-Sung Yun *
Division of Vascular and Endovascular Surgery, Department of Surgery, Kyungpook National University Hospital, Kyungpook National University School of Medicine, Daegu, Republic of Korea



A 79 year old man presented with bilateral common iliac artery aneurysms. The left hypogastric artery was embolised and a Zenith iliac branch device (Cook Medical, Bloomington, IN, USA) was introduced through the right groin. After snaring the through and through wire, the broken tip (arrow) of the indwelling catheter was detected. It was floating but still attached (A). Attempts to snare and remove it to avoid embolism were unsuccessful. However, contrary to expectations, the catheter was safely withdrawn without tip embolism. After removal of the indwelling catheter, further inspection showed no transverse but a longitudinal laceration, which is less likely to embolise (B).

* Corresponding author. Division of Vascular and Endovascular Surgery, Department of Surgery, Kyungpook National University Hospital, Kyungpook National University School of Medicine, 130 Dongdeok-ro, Jung-gu, Daegu 41944, Republic of Korea
E-mail address: wsyun@me.com (Woo-Sung Yun).

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