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GUIDELINES

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Concise guidelines of the European Cardiac Arrhythmias Society (ECAS) on "catheter ablation of atrial fibrillation": A prepublication of the methods in preparation of the final guidelines document

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1 | PREAMBLE

While detailed and heavily referenced guidelines and consensus manuscripts are useful documents for the purpose of defining a point in the historical evolution of clinical practice,[1-3] they can often be too dense to be of a real value to front-line clinicians and may not always be read from beginning to end. The purpose of this document is to provide a concise description of the methodology for the upcoming concise AF ablation guidelines document. This will be a comprehensive guide to catheter ablation of AF written by a wide range of recognized experts in the field under the umbrella of the European Cardiac Arrhythmias Society (ECAS). ECAS is an independent society founded in 2004 in Paris with the mission to promote high-quality care in patients with cardiac arrhythmias.

By providing the methodology before publication for reference, we can accomplish two tasks: (1) respond to the need for increased rigor and transparency in guidelines production; (2) reduce the size of the guideline document, and thus make it of greater practical value for the clinician.

2 | WHY A PRE-PUBLICATION DOCUMENT ON GUIDELINES

The potential benefit of guidelines can only be as good as the quality of the guidelines themselves[4,5] and it is recognized that some of these documents fall short of basic standards.[6-8] Therefore, appropriate methodologies and rigorous strategies are important to favor successful adoption of guidelines in daily practice. To this aim, dedicated instruments have been proposed to favor the rigor and transparency with which guideline documents are developed.[8,9] The main purpose of these instruments is to assess the quality of guidelines, provide a methodological strategy for their development, and clarify what information and how this information should be reported in guideline documents.[8,9]

When finalizing our document, we will comply with the methods suggested in the instruments mentioned above. This includes a clear identification of the scope, the role played by all participants, the development methodology, its mode of presentation and possible applicability in daily practice. We believe that by providing a predetermined design and plan of activity, publication of the methods in a separate manuscript will add to the rigor and transparency of the final document. Prepublication of the methods used in preparation of the final guidelines document is also intended for benefit to health care providers, policy makers, hospitals, manufacturers, educators and insurers.[10]

3 | METHODS

Pre-publication of the methods used in the development of the formal guideline document was undertaken following approval of this strategy among all authors. The strategy of providing a pre-publication manuscript is compliant with the suggestions for guidelines production proposed by the World Health Organization and other parties.[11-16]

The driving cause leading ECAS to engage in the present effort was based on the intention to mitigate the mismatch between the paucity of high-quality studies and the abundance of recommendations commonly released by scientific societies. Catheter ablation represents a paradigmatic example in which, in spite of a few high-quality studies, guideline and consensus documents are copious and recommendations are overly articulated.

Therefore, the present guidelines will be developed in a concise scheme preceded by a separate description of the strategies adopted while developing the final document. Simplified guidelines are also intended to reconcile medical practitioners with the art of medicine[17] by alleviating them from the obligation generated by a large body of recommendations, rarely supported by solid evidence.

3.1 | Criteria for recommendations

3.1.1 | General considerations

The present guidelines will adopt a simple method to distinguish between I, II, and III recommendation classes. No sub-classification will be contemplated based on level of evidence. Similarly, use of consensus among experts will be eliminated. In replacement, elaboration of literature data will be made with the purpose to heighten, when possible, the quality of documentation in those fields where high-quality studies are missing. This scheme is designed with the purpose of providing the practitioner with a dedicated custom-built documentation that may facilitate clinical free-judgment in the individual patient.

Alongside, flowcharts will be developed to facilitate a clinically oriented approach. Flowcharts will indicate the stages along the conventional work-flow where the use of catheter ablation is recommended or not recommended based on the methodology adopted in the guideline document.

3.1.2 | Criteria of classification

The guideline recommendations will be focused on the following two main themes:

1. Favorability of practicing catheter ablation or not: whether and in what circumstances the benefit of catheter ablation outweighs its risk
2. The comparison of ablation strategies and means: whether and in what circumstances the benefit of competitive ablation strategies or techniques, including deployment, grouping, sequence of ablation lesions as well as technical means, devices and energy sources outweighs their risk.

The three recommendation classes in the final document will be defined as follows:

3.2 | Class I

Class I will indicate a recommendation in favor of the practice of catheter ablation or of any specific ablation strategy or technique where evidence of greater benefit versus risk is provided by high-quality randomized multicenter controlled trials adopting pre-determined working hypotheses and supported by sufficient sample sizes. High-quality controlled trials will be those defined by a low Risk of Bias for all crucial domains[18]; a high precision of effect expressed by a narrow 95% Confidence Interval[19]; absence of other contradicting similar high-quality evidence[19]; and, compliance with the principle of directness, expressing the comparability between the population investigated in the reference trial and the population to which the recommendation is directed. Failure to comply with at least one of the above mentioned quality criteria will result in down-grading of the ablation practice, strategy or technique to a recommendation Class II level.

3.3 | Class II

Class II will indicate recommendations in favor of the practice of catheter ablation or of any specific ablation strategy or technique, where evidence of greater benefit versus risk is not provided by high-quality randomized multicenter controlled trials, as specified in the paragraph on Class I recommendations. To qualify for this class, evidence in favor of ablation practice, strategy or technique will need to be provided by: (1) randomized multicenter or single center trials that are not adopting pre-determined working hypotheses and/or are not supported by sufficient sample sizes; (2) meta-analyses from randomized clinical trials in which the investigated outcomes represent pre-determined endpoints of the selected studies.

3.4 | Class III

Class III will indicate recommendations against the practice of catheter ablation or of any specific ablation strategy or technique, as derived from high-quality multicenter randomized clinical trials adopting predetermined working hypotheses and sufficient sample sizes.

Notably, downgrading to a Class II level of those recommendations from randomized clinical trials that failed to comply with at least one of the quality criteria reported above will serve two purposes. Firstly, readers will recognize in the class I level only those recommendations that are corroborated by the currently recognized highest level of quality. Secondly, researchers will be provided with the opportunity to accurately recognize the weaknesses pertaining to conditions listed in Class II recommendations and overcome current limitations by properly designed future clinical trials.

3.5 | Reasons for elimination of levels of evidence and consensus among experts

While the motivations behind the introduction of "levels of evidence" within each recommendation class are recognized, there are several reasons why we elected to delete them from the general scheme of our manuscript. Firstly, arbitrariness is already adopted to qualify recommendation classes. In this context, subcategorization based on levels of evidence adds further arbitrariness and, by so doing, subtracts accuracy from the final document. Secondly, assignment of different levels of evidence applies to conditions that, by definition, lack the methodologic rigor required to be promoted to the level of recommendation. Finally, the heterogeneity of methods used in the various individual sources of information leads to disparities within the same level of evidence group.

A further contributive element in the direction of reducing the degree of arbitrariness introduced in guideline documents will be represented by removal of the "expert consensus" modality from the methods commonly used for compiling recommendations. Removal of this methodology will also help to reduce the degree of inter-expert variability in adjudication and perpetuation of the *status quo ante*.

While removing redundant arbitrary interference, the authors of this document intend to widen the field of the operator's decision and mitigate the prevarication resulting from an excessively populated and over-articulated recommendation scheme.

3.6 | Custom-made elaboration of literature data for fulfillment of class II recommendation scheme

Fulfillment of a class II recommendation scheme represents a most challenging segment in guidelines document development. This is mainly due to the fact that this segment is the one least supported by scientific evidence. To compensate for this limitation, most scientific societies tend to adopt articulated schemes that: (1) sub-categorize class II recommendations into those for which evidence is in favor (A) and those for which evidence is against (B); and, in some circumstances, (2) provide de-escalating levels of evidence (usually, a., b, an c) in any sub-category.

In keeping with the scope of a simplified presentation scheme, sub-categorization and levels of evidence for class II recommendations will be removed from our guideline document. In their place, evidence in favor of catheter ablation or similarity of efficacy and/or safety of competitive ablation strategies or techniques will be derived from: (1) randomized clinical trials with no predetermined hypotheses and/or insufficient sample size; (2) targeted meta-analyses elaborated by the authors of this document with the purpose of generating higher quality information than it is present in the literature. To this aim, targeted meta-analyses will be carried out by extracting relevant information from equivalent studies with individually insufficient data on clinically or technically relevant aspects of atrial fibrillation ablation.

The meta-analysis section of the present guidelines will be accomplished by a designated team within the group of authors. To this aim, data available in the literature of the last 10 years that are possibly in favor of catheter ablation or compare efficacy and/or safety among competitive ablation strategies or techniques will be extracted and elaborated according to the conventional methods used in meta-analyses studies. When applicable, the results of these meta-analyses will be used to enhance the quality of the scientific source to guide the authors in the selection of Class II recommendations. The questions to be addressed by these systematic reviews will be:

1. What is the impact of catheter ablation of AF on clinical outcomes?
2. What is the best technology/energy source to perform PV isolation?
3. What is the best lesion set or combination of lesions set for treating persistent AF?
4. What is the best anticoagulation management before and after catheter ablation of AF?

More details on the PICO for each question and systematic review methodology will be provided on the protocols published on PROSPERO.[20,21]

The present guideline protocol on the website—PRACTICE guidelines REGISTRATION PLATFORM www.guildeline-registry.org.

4 | MANUSCRIPT ORGANIZATION

After an introductory note, three brief paragraphs will be dedicated to the electrophysiological rationale of catheter ablation of AF, the description of AF types, and the ablation techniques and technologies available for clinical use in 2024. Recommendation tables and figures will follow. They will be developed based on the methods described in the paragraph "Criteria for recommendations."

A subsequent paragraph will provide a descriptive table with outcome data from most relevant studies for readers' consultation. Data report will be categorized based on sub-groups of clinical interest, such as, for example, efficacy on and off antiarrhythmic drug use or based on type of AF, energy form and ablation design. A next paragraph will be dedicated to the peri and postprocedural anticoagulation therapy, whereas a following paragraph will be addressing procedure-related complications. A paragraph will then be dedicated to ablation designs other than pulmonary vein isolation for which evidence in favor of benefit is missing or elusive. They include linear lesion deployment as well as complex fractionated atrial electrogram and ganglionated plexi ablation. One paragraph will then be dedicated to substantiate the rationale for a concise guideline document and outline its main differences as compared with previous documents in the target field. Two final paragraphs will be dedicated to a summary of the document, and to gaps in current knowledge and pending items in catheter ablation of AF.

Supplementary material will provide, where necessary, detailed information relative to the items concisely presented in the main document. Detailed information on the searches and results will be provided with the systematic reviews. Information on the voting process and discussions between guideline panel members will be reported in this section, alongside with the comments and issues raised by the document reviewers. In addition, a table will be presented incorporating all relevant ongoing clinical trials in the field of catheter ablation of AF. This table is intended for providing an accurate perspective on which clinical and technical aspects are currently being investigated in this field. Answers from the questions raised in ongoing trials will contribute to improve our knowledge in the next future and will likely provide high-quality information to be implemented in a next guideline document from this and other groups.

Finally, an internal review of the final document will be performed by a group of experts (Review Committee) designated by ECAS. Aim of this group will be to verify that the final guideline document corresponds to the current recommended standards of scientific society document production.

We plan to update guidelines relative to catheter ablation of AF in 5 year time or before, if a significant body of evidence will be gathered as to make the currently planned guideline document obsolete. We will update the systematic reviews, and add/remove questions raised by professionals at that specific time. Similar to the scheme adopted here, a prepublication manuscript will be produced ahead of the main guideline document to describe the plan and the methods used in preparation of the next guideline document.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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REFERENCES

1. Joglar JA, Chung MK, Armbruster AL, et al. 2023 ACC/AHA/ACCP/HRS guideline for the diagnosis and management of atrial fibrillation: a report of the American college of Cardiology/American heart association joint committee on clinical practice guidelines. *Circulation*. 2024;149:e1-e159. doi:10.1161/CIR.0000000000001193
2. Hindricks G, Potpara T, Dagres N, et al. ESC guidelines for the diagnosis and management of atrial fibrillation developed in

collaboration with the european association for cardio- thoracic surgery (EACTS): the task force for the diagnosis and management of atrial fibrillation of the european society of cardiology (ESC). developed with the special contribution of the european heart rhythm association (EHRA) of the ESC. *Eur Heart J 2020*. 2020;42(5): 373-498. doi:10.1093/eurheartj/ehaa612
3. Calkins H, Hindricks G, Cappato R, et al. HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. *Heart Rhythm*. 2017;14(10):e275-e444. doi:10.1016/j.hrthm.2017.05.012
4. AGREE Collaboration. Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: the AGREE project. *Qual Safe Health Care*. 2003;12(1):18-23. doi:10.1136/qhc.12.1.18
5. Woolf SH, Grol R, Hutchinson A, Eccles M, Grimshaw J. Clinical guidelines: potential benefits, limitations, and harms of clinical guidelines. *BMJ*. 1999;318(7182):527-530. doi:10.1136/bmj.318.7182.527
6. Shaneyfelt TM, Mayo-Smith MF, Rothwangl J. Are guidelines following guidelines? The methodological quality of clinical practice guidelines in the peer-reviewed medical literature. *JAMA*. 1999; 281(20):1900-1905. doi:10.1001/jama.281.20.1900
7. Grilli R, Magrini N, Penna A, Mura G, Liberati A. Practice guidelines developed by specialty societies: the need for a critical appraisal. *The Lancet*. 2000;355:103-106. doi:10.1016/S0140-6736(99)02171-6
8. Burgers JS, Fervers B, Haugh M, et al. International assessment of the quality of clinical practice guidelines in oncology using the appraisal of guidelines and research and evaluation instrument. *J Clin Oncol*. 2004;22:2000-2007. doi:10.1200/JCO.2004.06.157
9. Brouwers MC, Kho ME, Browman GP, et al. AGREE II: advancing guideline development, reporting and evaluation in healthcare. *Can Med Assoc J*. 2010;182:E839-E842. doi:10.1503/cmaj.090449
10. Cappato R. Implementation of guidelines on atrial fibrillation management in the global arena: so many actors on stage! *Eur J Intern Med*. 2021;86:22-24. doi:10.1016/j.ejim.2021.03.013
11. World Health Organization. WHO handbook for guideline development. *World Health Organization 2014. Chapter 4: Preparing the planning proposal*. 2nd ed. WHO; 2014:39-44.
12. Grol R. Success and failures in the implementation of evidence-based guidelines for clinical practice. *Med Care*. 2001;39(8 suppl 2): 1146-1154. doi:10.1097/00005650-200108002-00003
13. Davis DA, Taylor-Vaisey A. Translating guidelines into practice. A systematic review of theoretic concepts, practical experience and research evidence in the adoption of clinical practice guidelines. *CMAJ*. 1997;157(4):408-416.
14. Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *The Lancet*. 1993;342:1317-1322. doi:10.1016/0140-6736(93)92244-n
15. Chen Y, Guyatt GH, Munn Z, et al. Clinical practice guidelines registry: toward reducing duplication, improving collaboration, and increasing transparency. *Ann Intern Med*. 2021;174(5):705-707.
16. Yang N, Zhao W, Qi W, et al. Publishing clinical practice GuidelinEs (PAGE): recommendations from editors and reviewers. *J Evid Based Med*. 2022;15(2):136-141.
17. Kirchhoff P, Benussi S, Kotecha D, et al. ESC guidelines for the management of atrial fibrillation developed in collaboration with EACTS. *Eur Heart J*. 2016;7:2893-2962. doi:10.1093/eurheartj/ehw210
18. Higgins JPT, Altman DG, Gotzsche PC, et al. The cochrane collaboration's tool for assessing risk of bias in randomised trials. *BMJ*. 2011;343:d5928. doi:10.1136/bmj.d5928
19. Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ*. 2008;336(7650):924-926. doi:10.1136/bmj.39489.470347.AD
20. Providencia R, Ali H, Creta A, et al. Catheter ablation for atrial fibrillation and impact on clinical outcomes. *PROSPERO*. 2023. https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42023483166
21. Jacobs AK, Kushner FG, Ettinger SM, et al. ACCF/AHA clinical practice guideline methodology summit report. *J Am Coll Cardiol* 2013;61:213-265.

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