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ORIGINAL ARTICLE
VASCULAR SECTION

Insight from an Italian Delphi Consensus on EVAR feasibility outside the instruction for use: the SAFE EVAR Study

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ABSTRACT

BACKGROUND: The SAfety and FEasibility of standard EVAR outside the instruction for use (SAFE-EVAR) Study was designed to define the attitude of Italian vascular surgeons towards the use of standard endovascular repair (EVAR) for infrarenal abdominal aortic aneurysm (AAA) outside the instruction for use (IFU) through a Delphi consensus endorsed by the Italian Society of Vascular and Endovascular Surgery (Società Italiana di Chirurgia Vascolare ed Endovascolare – SICVE).

METHODS: A questionnaire consisting of 26 statements was developed, validated by an 18-member Advisory Board, and then sent to 600 Italian vascular surgeons. The Delphi process was structured in three subsequent rounds which took place between April and June 2023. In the first two rounds, respondents could indicate one of the following five degrees of agreement: 1) strongly agree; 2) partially agree; 3) neither agree nor disagree; 4) partially disagree; 5) strongly disagree; while in the third round only three different choices were proposed: 1) agree; 2) neither agree nor disagree; 3) disagree. We considered the consensus reached when ≥70% of respondents agreed on one of the options. After the conclusion of each round, a report describing the percentage distribution of the answers was sent to all the participants.

RESULTS: Two-hundred-forty-four (40.6%) Italian Vascular Surgeons agreed to participate the first round of the Delphi Consensus; the second and the third rounds of the Delphi collected 230 responders (94.3% of the first-round responders). Four statements (15.4%) reached a consensus in the first rounds. Among the 22 remaining statements, one more consensus (3.8%) was achieved in the second round. Finally, seven more statements (26.9%) reached a consensus in the simplified last round. Globally, a consensus was reached for almost half of the proposed statements (46.1%).

CONCLUSIONS: The relatively low consensus rate obtained in this Delphi seems to confirm the discrepancy between Guideline recommendations and daily clinical practice. The data collected could represent the source for a possible guidelines' revision and the proposal of specific Good Practice Points in all those aspects with only little evidence available.

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KEY WORDS: Abdominal aortic aneurysm; Endovascular aneurysm repair; Informed consent; Shared decision making; Consensus; Delphi technique.

Endovascular aneurysm repair (EVAR) has become more than an established alternative to open repair (OR) for the treatment of infrarenal abdominal aortic aneurysm (AAA), as this approach accounts for more than 75% of AAA elective repairs annually performed.[1] Although, compared to OR, EVAR is certainly associated with lower 30-day mortality and morbidity, and faster discharge,[2] some concerns remain about its durability, and need for reinterventions.[1-3]

Based on preclinical engineering assessments and clinical study results, particular anatomical characteristics, specifically aortic neck diameter, length, angle, and shape, are recommended to guide patient selection for EVAR.[4] Indeed, unfavorable anatomy, documented in 40–60% of treated AAAs, seems to be directly related to a negative procedural outcome.[5-7]

Nevertheless, in "real-world" clinical practice up to 44% of EVAR cases are performed using stent grafts outside their instruction for use (IFU) due to the presence of a "hostile" aortic neck anatomy, with acceptable short- and mid-term outcomes.[8-10]

Nevertheless, because EVAR durability is related to the maintenance of a seal between the stent graft and the aortic neck, some authors suggested that challenging neck could affect long-term outcomes, increasing the risk of type Ia endoleak, reintervention, and aneurysm-related mortality rates[11-15] a result of these long-term results, current guidelines suggest limiting or even refraining from adopting EVAR in patients with challenging aortic necks.[16-19]

This 'inconsistency' between current guidelines and clinical practice raises not only technical and clinical uncertainties — especially in terms of long-term outcomes — but also ethical issues. Indeed, even when standard EVAR is technically feasible, or when patients are not eligible for OS, the ethical implications of performing an elective procedure outside the IFU cannot be ignored.

In these circumstances, it is therefore particularly important — in choosing and recommending the most appropriate procedure — to consider the patient's best interest. To this end, it is essential to include him/her in the decision-making process, considering his/her perspectives, values and preferences, beyond the theoretical advantages of each proposed procedure and the guidelines' indications.[20-22]

Although this type of assessment should always be considered an essential part of good clinical practice, in the case of such patients it takes on an even more important role, precisely because of the uncertainty produced by the gap between clinical practice and guidelines.

However, current evidence shows that shared decision-making is still in its infancy in clinical practice and especially in surgery,[23] even though it has been found to confer several benefits beyond maximizing patients' autonomy. Patients' direct involvement through the proper management of the informed consent process, in fact, improves patient compliance, patient outcomes, and can help to reduce costs that can be associated with both undesirable treatment and subsequent litigation.[24]

Based on these assumptions, we tried to assess whether a consensus exists among Italian vascular surgeons regarding the use of EVAR outside IFUs. Secondly, we investigated their attitudes and beliefs in relation to some ethical aspects, particularly those involving the management of the informed consent process in these circumstances.

Since consensus group methodologies, such as the Delphi method, are widely used to synthesize expert opinions in a systematic way when evidence is lacking, or questions are not manageable with experimental and epidemiological methods,[25] a panel of expert SICVE (Italian Society for Vascular and Endovascular Surgery) members was asked to express their level of agreement with technical, ethical and medico-legal statements on EVAR procedures performed outside the IFU.

Materials and methods

The SAfety and FEasibility of standard EVAR outside the instruction for use (SAFE-EVAR) Study aimed to define the attitude of Italian vascular surgeons towards the use of EVAR outside the instruction for use (IFU) through a Delphi consensus endorsed by the Italian Society of Vascular and Endovascular Surgery (Società Italiana di Chirurgia Vascolare ed Endovascolare – SICVE).

Questionnaire and Survey Procedure

A questionnaire consisting of 26 statements was developed and then validated by an 18-member Advisory Board. Furthermore, participants were asked to indicate their age range (<30, 31-40, 41-50, 51-60, >60 years old), experience in EVAR procedures (<100, 101-200, 201-300, >300 overall procedures performed), the type of hospital in which their activity was mainly performed (university hospital; public hospital; private hospital endorsed by the Italian National Health System; private hospital).

The questionnaire was sent *via* Google Forms to 600 Italian vascular surgeons who are members of SICVE. The Delphi process was structured in three subsequent rounds which took place between April and June 2023. In the first round, participants were sent the questionnaire contain-

ing all 26 statements and, for each statement, respondents could indicate one of the following five degrees of agreement: 1) strongly agree; 2) partially agree; 3) neither agree nor disagree; 4) partially disagree; 5) strongly disagree. We considered a consensus reached when ≥70% of the interviewed agreed on one of the five answer options. After the conclusion of the first round, a report describing the percentage distribution of the answers was sent to the participants. In the second round, collaborators were sent the questionnaire containing only the statements for which no consensus was reached in the first round. Again, after its conclusion, respondents were sent a report describing the results. Finally, in the third round, the participants were sent the questionnaire containing only the statements for which consensus had not been reached in the first two rounds and, to converge consensus, the response options were limited to three: 1) agree; 2) neither agree nor disagree; 3) disagree. Again, the consensus threshold was set at ≥ 70% for each response option. A summary of the results of the three rounds was finally sent to respondents.

Statistical analysis

Descriptive statistics have been reported. Categorical data was reported as counts and percentages. Survey responses collected by Google Forms were converted and analyzed using Microsoft Excel spreadsheets (Microsoft Corporation, Redmond, WA, USA).

Results

Two-hundred-forty-four (40.6%) Italian Vascular Surgeons agreed to join the Delphi Consensus; the main characteristics of the participants to the first round are shown in Table I. The second and the third rounds of the Delphi collected 230 replies, 94.3% of the first-round responders.

Twenty-six statements (S) were proposed as reported in methods; S from 1 to 17 were preeminently technical, focusing on Vascular Surgeons' personal consideration on safety and feasibility of out-IFU EVAR performed in different clinical and anatomical setting, while S from 18 to 26 were focused on informed consent process and others ethical considerations (Supplementary Digital Material 1: Supplementary Table I).

Four statements (15.4%) reached a consensus in the first round (S8 The proximal aortic neck is an important criterion for evaluating the feasibility of an EVAR procedure outside the IFU; S21 Given the inconsistency between what is stated in the guidelines and the results of clinical practice, performing an EVAR procedure outside the IFU requires the physician to give the patient all available information regarding the procedure and its risks/benefits; S23 An EVAR procedure outside the IFU can only be considered after the physician has presented the patient with the best treatment option; S25 An EVAR procedure outside the IFU can only be considered after the physician has presented the patient with all available intervention (and non-intervention) options). Among the 22 remaining statements, one (3.8%) more consensus was reached in the second round (S24 An EVAR procedure outside the IFU can only be considered after the physician has presented the patient with the intervention options that he or she considers to be the safest and most effective). Finally, seven more statements (26.9%) reached a consensus in the simplified last Delphi consensus round: S2 Performing an EVAR outside the IFU affects mid/long-term outcome; S3 Performing an EVAR outside the IFU results in a worse outcome in terms of AAA Related Reintervention; S12 An EVAR procedure can be performed in the presence of a proximal aortic neck <15 mm in length; S14 An EVAR procedure can be performed in the presence of a proximal aortic neck <5 mm in length; S18 Proposing to a patient an EVAR procedure outside the IFU makes the informed consent process more complex (*e.g.* the need to spend more time informing the patient and/or providing him/her with more details regarding risks and benefits); S20 Given the inconsistency between what is stated in the guidelines and the results of clinical practice, performing an EVAR procedure outside the IFU requires the physician to give the patient the information about the procedure relevant to the

TABLE I.—*Demographic characteristics of respondents to the first round.*

Demographics	N. (%)
Overall number of respondents	244
Gender, male	190 (77.9%)
Age	
<30 years	21 (8.6%)
31-40 years	83 (34.0%)
41-50 years	68 (27.9%)
51-60 years	43 (17.6%)
>60 years	29 (11.9%)
Experience in EVAR procedures	
<100	62 (25.4%)
101-200	54 (22.1%)
201-300	36 (14.8%)
>300	92 (37.7%)
Type of hospital	
Academic	117 (48.0%)
Public	109 (44.2%)
Private accredited by the Italian National Health System	18 (7.4%)
Private hospital	0 (0.0%)

patient in order to decide; S26 Even if the physician thinks that performing an EVAR outside the IFU is the most appropriate procedure for a particular patient, he or she must directly and actively involve the patient in the clinical decision-making process). Overall, a consensus was reached for 12 of the proposed statements (46.1%): S 2,3,8,12,14,18,20,21,23,24,25,26 (Supplementary Table I).

Discussion

Despite current guidelines suggest limiting or even refraining adopting EVAR out of IFU,[16-19] in "real world" practice such kind of procedures are routinely performed with acceptable results.[26, 27] Consequently, the aim of this Delphi consensus was to evaluate how Italian vascular surgeons technically and ethically face this inconsistency between "real world practice" and "best practice", and to collect an expert opinion to be used for guidelines' revision whenever needed.

According to Delphi results, Italian vascular surgeons agree that performing a standard EVAR procedure outside IFU may affect the mid/long term outcomes (S2, 71% agreement at round III), especially in term of AAA related reinterventions occurrence (S3, 74% agreement at round III). However, no consensus was reached regarding early outcomes, nor for AAA-related mortality (S1 and S4). Even more interestingly, half of the respondents for each round disagree with refraining from performing EVAR outside of IFU in the elective setting (S5), especially in those patients deemed unsuitable for open repair (S6) and in the elderly (S7). In other words, despite Italian guidelines strongly recommend that endoprosthesis choice should comply with the IFU,[19] Italian vascular surgeons consider favorably to routinely perform out IFU EVAR procedures (at least in selected patients).

From an anatomical point of view, the role of proximal aortic neck characteristics (length, diameter, and angulation), aortic bifurcation, distal landing zone, and access vessels were evaluated.

Not surprisingly, aortic neck was immediately recognized as an important element in addressing EVAR feasibility outside IFU (S8, 79% agreement at round I), while aortic bifurcation (S9, 58% agreement at round III), iliac landing zone (S10, 63% agreement at round III), and adequate access vessels (S11, 61% agreement at round III) were non recognized as important criteria for EVAR feasibility.

More in details, Italian vascular surgeon agreed that a standard EVAR procedure could safely be performed in case of a proximal aortic neck shorter than 15 mm (S12, 92% agreement at round III). No consensus was reached for length <10 mm (S13, 55% agreement at round III). Finally, a consensus was gained about refrain to perform standard EVAR in case of proximal neck <5 mm (S14, 70% at round III). Speculatively, these results could be interpreted as a clear indication to perform EVAR in patients with a proximal neck between 14 and 10 mm in length, a relative contraindication in case of length between 9 and 5 mm, and a clear contraindication to perform standard EVAR in necks shorter than 5mm. Collected opinions could be considered in a future guidelines revision to perform specific technical recommendation, at least as good practice point (GPP, according to guideline methodology).[28, 29]

Besides proximal neck length, according to previous reported statements, no consensus was reached regarding severely angulated neck (S15), wide diameter (S16), and narrowed aortic bifurcation (S17). Theoretically, Delphi responders considered all those parameters by itself not a technical limit for standard EVAR, suggesting it could be safely and effectively performed and consequently proposed to the patients.

As for the ethical issues raised by performing an EVAR procedure outside the IFU (S18-S26), a clarification must first be made. In contrast to the first set of statements (S1-S17), these statements were not intended to establish a consensus among experts, but to collect data related to the knowledge and attitudes of Italian vascular surgeons in relation to specific ethical aspects, namely the involvement of the patient in the decision-making process and the management of the informed consent.

According to our findings, Italian vascular surgeons agree that proposing to a patient an EVAR procedure outside the IFU makes the informed consent process more complex (S18, 70% agreement at round III). However, the percentage of surgeons who answered "neither agree nor disagree" to this statement remains quite high (21% at round III). This result could be interpreted as an indication of a certain amount of uncertainty among respondents regarding how to manage the informed consent process, especially in particularly complex cases such as those investigated.

In terms of the information to be provided to the patient if an EVAR procedure is proposed outside the IFU (S19-S21), no agreement was reached among the respondents about the first proposed option, according to which the physician should only provide the patient with information that he or she believes the subject can understand (S19). In contrast, respondents agreed on both the second

and third options, according to which the physician should provide information about the procedure relevant to the patient to decide (S20, 82% agreement in round III), but also all available information about the procedure and its risks/benefits (S21, 79% agreement in round I).

No agreement was therefore reached regarding the adoption (or non-adoption) of an approach traditionally perceived as paternalistic (S19), according to which it would be the physician's responsibility to decide what information should be given to the patient based on his/her assessment of the subject's ability to understand.

Conversely, respondents immediately agreed on the more comprehensive but, at the same time, less personalized option (S21), as it does not consider how the overabundance of information may confuse the patient and hinder, rather than help, him/her in the decision. Moreover, the idea that all the information about a procedure must be disclosed may reflect the physicians' overly cautious approach, which in some ways recalls forms of defensive medicine.

It is noteworthy that agreement was more difficult to achieve (III round) on the statement that truly values the doctor-patient relationship (S20), which is the one that considers it essential for the physician to consider in managing the informed consent process needs, values, and expectations relevant to the patient.

This difficulty also emerges from the answers given to the next statement, on the perceived importance of prior assessment of patient-relevant clinical and nonclinical preferences and outcomes (S22). No agreement was reached among respondents. In this case, the role played by those who remained uncertain (22% in Round III) may have been even more crucial, as the responses may reflect a lack of consideration of the relevance of patient preferences, but also the physicians' difficulty in evaluating these aspects.

Respondents agreed that the patient should be presented with both what the physician considers to be the best treatment option (S23, 70% agreement in Round I), the options that the physician considers to be the safest and most effective (S24, 70% agreement in Round II), and finally, all available intervention (and non-intervention) options (S25, 79% agreement in Round I). As these three statements were not presented alternatively, these results might suggest that the respondents perceive as important the presentation of all available options (including the non-intervention option) to the patient, but that they consider as equally important that the patient knows which options are the safest and most effective in the specific case, as well as the physician's opinion of the treatment option he or she considers preferable.

Finally, accordingly to last statement, Italian vascular surgeons believe that direct patient involvement in clinical decision making should be considered a requirement in all circumstances, regardless of whether the physician believes-from a technical and clinical perspective-that performing an EVAR outside of the IFU is the most appropriate procedure (S26, 75% agreement at Round III). However, even in this case, it is important to note that agreement on the matter was reached only by administering the statements in a simplified form, reinforcing the idea that there is still some uncertainty on the issue.

To summarize, we argue that the answers provided reflect a certain disposition among physicians to recognize the importance of direct patient involvement in the clinical decision-making process, but not a full awareness of the relevance of assessing preferences and even non-clinical aspects relevant to the patient.

Conclusions

The relatively low consensus rate obtained in this Delphi seems to confirm the discrepancy between Guideline recommendations and daily clinical practice. The data collected could represent the source for a possible guidelines' revision and the proposal of specific Good Practice Points in all those aspects with only little evidence available.

Likewise, although the data collected on the ethical aspects of performing EVAR procedures outside the IFU show, in general, a good predisposition of Italian vascular surgeons to involve patients in the clinical decision-making process, it is undeniable that areas of uncertainty and lack of knowledge about these issues remain. A more thorough training of physicians in relation to these aspects should therefore also be ensured, specifically regarding the proper management of the patient's informed consent process. In fact, proper information of the patient and his or her direct involvement in the decision-making process, besides being unavoidable ethical and legal requirements, are functional in defining the best strategy to be adopted for each specific individual, as his or her preferences, values and real needs are valued.

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Conflicts of interest
The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Authors' contributions
All authors read and approved the final version of the manuscript.

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