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Infective Native Aortic Aneurysms : A Delphi Consensus Document on Terminology, Definition, Classification, Diagnosis, and Reporting Standards

the Academic Research Consortium of Infective Native Aortic Aneurysm (ARC of INAA)

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Editor's Choice – Infective Native Aortic Aneurysms: A Delphi Consensus Document on Terminology, Definition, Classification, Diagnosis, and Reporting Standards

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WHAT THIS PAPER ADDS

This Delphi study has established the first consensus document on infective native aortic aneurysm with regard to the terminology, definition, classification, diagnostic criteria and algorithm, as well as reporting standards. The results of this study create essential conditions for future scientific research on this disease.

Objective: There is no consensus regarding the terminology, definition, classification, diagnostic criteria, and algorithm, or reporting standards for the disease of infective native aortic aneurysm (INAA), previously known as mycotic aneurysm. The aim of this study was to establish this by performing a consensus study.

Methods: The Delphi methodology was used. Thirty-seven international experts were invited via mail to participate. Four two week Delphi rounds were performed, using an online questionnaire, initially with 22 statements and nine reporting items. The panellists rated the statements on a five point Likert scale. Comments on statements were analysed, statements revised, and results presented in iterative rounds. Consensus was defined as $\geq 75\%$ of the panel selecting “strongly agree” or “agree” on the Likert scale, and consensus on the final assessment was defined as Cronbach's alpha coefficient $> .80$.

Results: All 38 panellists completed all four rounds, resulting in 100% participation and agreement that this study was necessary, and the term INAA was agreed to be optimal. Three more statements were added based on the results and comments of the panel, resulting in a final 25 statements and nine reporting items. All 25 statements reached an agreement of $\geq 87\%$, and all nine reporting items reached an agreement of 100%. The Cronbach's alpha increased for each consecutive round (round 1 = .84, round 2 = .87, round 3 = .90, and round 4 = .92). Thus, consensus was reached for all statements and reporting items.

Conclusion: This Delphi study established the first consensus document on INAA regarding terminology, definition, classification, diagnostic criteria, and algorithm, as well as reporting standards. The results of this study create essential conditions for scientific research on this disease. The presented consensus will need future amendments in accordance with newly acquired knowledge.

Keywords: Classification, Criteria, Definition, Diagnosis, Infective native aortic aneurysm, Mycotic aneurysm

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INTRODUCTION

In 1885, Sir William Osler presented a case of a man with infective endocarditis and its association with four concomitant aortic aneurysms morphologically resembling fungus.¹

The term “mycotic” was thus introduced to describe these aneurysms. Later, when it was understood that most of these aortic aneurysms were caused by bacterial infection, it became evident that the term “mycotic”, implicating a fungal genesis, was a misnomer.²

The term mycotic has since been criticised, and a plethora of other poorly defined terms have been in use over the years.³ The disease itself is rare, making it difficult to study and statistical analyses challenging; meanwhile, its management is very demanding and the condition carries a high mortality rate, a nadir of vascular surgery.^{4,5} To this day, there is no consensus regarding the terminology, definition, classification, or diagnostic criteria for this pathology.^{6,7}

[†] A list of the authors in the collaborative study group is included in [Appendix A](#).

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Two recently published systematic literature reviews have demonstrated that this lack of standardisation results in divergent reporting and great difficulties in comparing studies.^{4,8} This problem severely hampers development in the scientific knowledge of this disease. Due to the variety in terminology and disparate definitions, and sometimes non-existent diagnostic workups in publications, consensus on these issues, as well as reporting standards, is warranted to facilitate study comparability.^{4,8–12}

A new, clearly defined term was introduced for this disease in 2020: “infective native aortic aneurysm” (INAA).⁶ The word infective was chosen in analogy with infective endocarditis, and the word native explicitly to exclude other infectious diseases of the aorta, such as aortic vascular graft and endograft infections (VGEI), and secondary aortic fistulas.¹³ Along with the new term, propositions for definition, classification, diagnostic criteria, and reporting standards have been made.

The aim of this study was to form an academic research consortium (ARC) for the disease entity INAA, in order to establish Delphi consensus on the terminology, definition, classification, diagnostic criteria, and algorithm, as well as reporting standards. This could create the essential conditions for scientific advancement in all aspects of the disease.

MATERIALS AND METHODS

The study was performed using an online survey tool (www.surveymonkey.com) from January 2022 to April 2022. A modified Delphi^{14–17} approach was used to reach consensus based on the components of the editorial “Infective Native Aortic Aneurysms: Call for Consensus on Definition, Terminology, Diagnostic Criteria, and Reporting Standards” published in 2020 in the *European Journal of Vascular and Endovascular Surgery*.⁶

The Delphi panellists could comment and rate each statement using a five point Likert scale (1 = strongly agree, 2 = agree, 3 = neutral, 4 = disagree, or 5 = strongly disagree). Consensus was *a priori* defined if $\geq 75\%$ of the panellists agreed (1 – 2) or disagreed (4 – 5) on the Likert scale. This was applied to proposed statements regarding terminology, definition, classification, diagnostic criteria, and diagnostic algorithm. The Likert scale was not used for reporting items. Instead, panellists could vote “yes” or “no”; they also had the opportunity to comment on the items. Consensus was *a priori* defined for the reporting items if $\geq 75\%$ of the panellists chose the same answer. The facilitators of the study were K.S. and T.R.W., who were allowed to vote but not comment on the statements.

Survey development

The principal investigators were K.S. and T.R.W. Ethical approval was not necessary as the study did not deal with patient data or biological material.

The aforementioned editorial was a distillate from four systematic literature reviews published between 2018 and 2021 covering the subjects of the terminology, definition, classification, diagnostic criteria, treatment management, procurement of microbiological specimens, and the role of

18F-fluorodeoxyglucose (FDG) positron emission tomography (PET) computed tomography (CT) in INAA.^{3,4,18,19} For this study, the content of the editorial was supplemented by additional information on the importance and methods of microbiological specimen collection, interpretation of microbiological findings, and the role of CT and 18F-FDG PET-CT.

Data from all the reviews, and the additionally included studies, were summarised by K.S. and subsequently controlled and approved by T.R.W. See [Figure 1](#) for the literature review process and development of the survey.

Developing the academic research consortium and Delphi panel recruitment

The ARC of INAA, which consisted of international experts in the field who agreed to participate in the panel, formed the Delphi panel.

An expert was defined as an active researcher on INAA, who had extensive practical knowledge of its management, or who was part of a writing group of international guidelines related to the disease. Experts were invited by an email which included the study protocol outlining the aim of the study, the aforementioned editorial, and information on the formation of the ARC of INAA.⁶

Purposive sampling was used to ensure wide international representation. Although there is no consensus on the size of a Delphi panel, there is a general recommendation to have 15 to 30 participants.^{14–17} Therefore, 39 experts (including the principal investigators) from 17 countries were invited to participate.

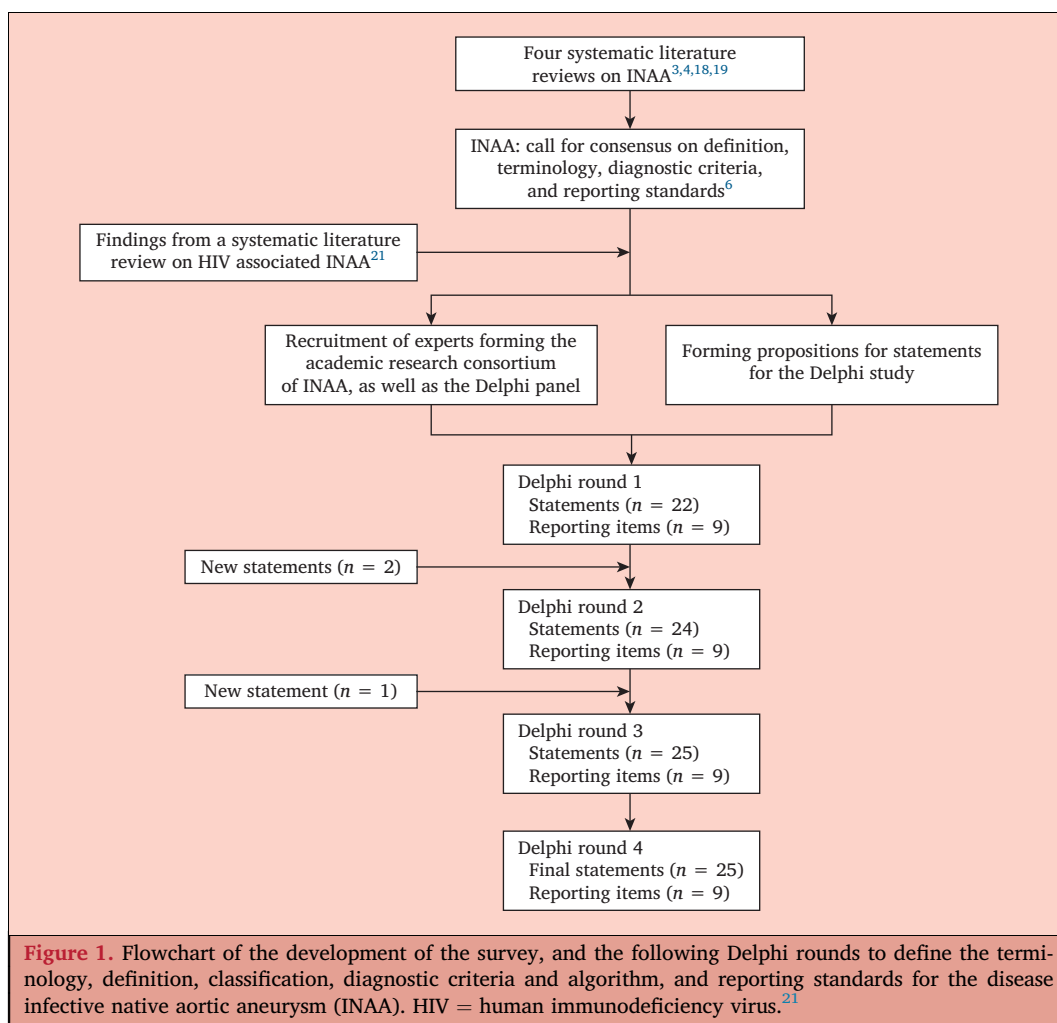
Membership of the Delphi panel was kept confidential throughout the study.^{14–16}

Experts who accepted the invitation to the ARC and the study, and fulfilled all the Delphi rounds, constituted the study panellists and were offered co-authorship. Experts who did not actively participate in the Delphi process were excluded from further rounds. Their contribution until the time of exclusion was included in the analysis and they are acknowledged for this in the paper.

Executing the Delphi study

Round 1. Panellists voted on all statements and reporting items in an online questionnaire. Panellists also had the opportunity to comment anonymously on each statement.

Rounds 2 – 4. The voting results, comments on statements, and reporting items were then analysed by the principal investigators. This information was then provided to the panellists by an anonymised summary of the results before starting the following round. The statements voted on could be revised during the course of the study, as a response to the results of the previous round. Each panellist’s vote or comment was given equal weight. Panellists were encouraged to re-vote and comment on all statements in the online questionnaire. New statements and reporting items, or revisions of the statements and items proposed by the panellists, were marked in the subsequent round for clarity, transparency, and uniformity.



All rounds were stopped once all panellists had replied, or after a maximum of three weeks. The Delphi process was planned for four rounds.

Statistics

Cronbach's alpha coefficient was used to determine the internal consistency of the assessment tool after each round. Cronbach's alpha value demonstrates how closely related a set of test items are as a group, and varies between 0 and 1, with 1 corresponding to 100% consistency. Consensus on round 4 (final round) was defined as Cronbach's alpha > .80. Categorical variables were expressed as proportions (%). SPSS 25.0 (IBM, Armonk, NY, USA) was used for the statistical analysis.

RESULTS

Of 39 identified and invited experts, 38 agreed to participate, and thus formed the panellists of the Delphi study. The expert who declined to participate did so because of doubts of competence in the subject of the study. All panellists were physicians, specialised in vascular surgery ($n = 32$; 84%), radiology ($n = 3$; 8%), cardiothoracic surgery

($n = 1$; 3%), cardiovascular surgery ($n = 1$; 3%), and plastic and reconstructive surgery ($n = 1$; 3%).

Panellists were from Europe ($n = 27$, 71%), Asia ($n = 7$, 18%), and North America ($n = 4$, 10%).

Figure 1 demonstrates the development of the survey, invitation of panellists, and consecutive rounds with the addition of statements.

Survey results

All 38 panellists fulfilled all four rounds within the given timeframe, resulting in 100% participation.

Delphi round 1 consisted of 22 statements on the rationale for conducting the study, followed by establishing statements on the terminology, definition, classification, diagnostic criteria, and diagnostic algorithm of INAA, as well as nine reporting items. Round 1 resulted in consensus (at least 75% agreed or strongly agreed) for all but one statement, the latter of which concerned the procurement of microbiological specimens for culture other than the aorta and blood.

Delphi round 2 was amended according to the comments of the panellists by adding two statements on the

Table 1. The final consensus statements, the results from Delphi round 4, for the terminology, definition, classification, diagnostic criteria, and algorithm, and reporting standards for the disease infective native aortic aneurysm (INAA)

No.	Statements	Consensus in round 4
1	There is a lack of consensus in the literature regarding terminology, definition, classification, diagnostic criteria, and reporting standards of aortic aneurysms arising due to infection, more commonly known as mycotic or infected aortic aneurysms.	100%
2	International consensus amongst experts on terminology, definition, classification, diagnostic criteria, and reporting standards for aortic aneurysms due to infection would improve and facilitate standardised research in this field.	100%
3	The term mycotic aortic aneurysm is a historical misnomer and is imprecise whilst implicating a fungal genesis.	92%
4	A more appropriate term would be infective native aortic aneurysm (INAA) analogous to infective endocarditis. This to explicitly replace mycotic by infective, and native to exclude aneurysms arising in an aorta, which has previously undergone surgery.	87%
5	The definition of INAA is an aortic aneurysm, which is caused by microbial infection of the aortic wall. The infection causes degradation of the vessel wall, resulting in formation of a localised aneurysm.	95%
6	The microbial infection is predominantly bacterial, but may also be fungal, or possibly viral in patients with advanced HIV infection.	95%
7	An aorta with extensive atherosclerosis, or a pre-existing aneurysm, is more susceptible to such infection.	95%
8	The common definition of degenerative aortic aneurysm based on diameter is not applicable to INAA because the morphology is predominantly saccular, multilobular, amorphous but could also be fusiform.	95%
9	Other infective states involving the aorta, such as aortic vascular graft or endograft infections and secondary aorto-enteric or -bronchial fistulas, are not part of this disease entity.	100%
10	Classification of various INAA should preferably be done according to the following modification of the previously published subgroups based on pathophysiology: ⁵ A) Blood borne bacteria inoculated in the aortic wall during bacteremia. B) Infection of pre-existing aneurysm due to blood borne bacteria. C) Due to septic emboli lodging in the aortic wall from infective endocarditis. D) Direct spread of infection from adjacent infected tissue. E) Aneurysms developing in patients with advanced HIV infection. F) Unknown.	95%
11	Patients with INAA are typically symptomatic. The two most common symptoms are pain and fever. Other infection related symptoms might be present such as fatigue or malaise, or local symptoms depending on the anatomical location of the aneurysm. Patients may have a concomitant infection and may express specific symptoms from that.	100%
12	Patients suffering from INAA typically show elevated inflammatory markers such as C reactive protein and leukocytes.	100%
13	Cultures refer to any culture harvested during the period of illness. Even though a positive culture result is not a requisite for making the diagnosis of INAA, procurement of microbiological specimens is absolutely fundamental and should be of highest priority.	100%
14	Cultures should ideally be harvested before initiation of any antimicrobial therapy.	100%
15	Microorganism identification should be performed in a similar approach to that of infective endocarditis; to use at least three blood cultures (both aerobic and anaerobic) from different venepuncture sites, and to repeat blood cultures every 24 to 48 hours until bloodstream infection has cleared in order to certify effectiveness of treatment, and to use PCR when agar cultures are negative.	95%
16	Microorganism identification from the aneurysm wall should be obtained when possible.	95%
17	Positive cultures from the aneurysm, aneurysm adjacent tissue or blood will be considered more likely to identify the causative agents than other positive results from other locations.	97%
18	Procurement of specimens for culture from urine and the respiratory tract or other symptomatic organs should also be performed in order to capture possible causative organisms.	100%
19	The recommended first line imaging modality for making the diagnosis of INAA is contrast enhanced computed tomography.	100%
20	Findings on computed tomography typical for INAA are: rapid expansion of aneurysm, saccular aneurysm, multilobular aneurysm or eccentric aneurysm, peri-aortic soft tissue mass, gas, or fluid, and an atherosclerotic aorta. There might also be multiple aneurysms along the aorta.	92%

Table 1-continued		
No.	Statements	Consensus in round 4
21	The pre-operative diagnostic work up should consist of a combination of the following three clinical criteria: 1) Clinical presentation: either pain, fever $\geq 38^{\circ}\text{C}$, sepsis and or concomitant infection. 2) Laboratory results: either elevated inflammatory markers like C reactive protein and leucocytes, and or positive cultures.* 3) Imaging: either rapid expansion of aneurysm, saccular aneurysm, multilobular aneurysms or eccentric aneurysms, peri-aortic gas, soft tissue mass, or fluid, and multiple aortic aneurysms with the aforementioned characteristics.	100%
22	The diagnostic algorithm for INAA is: <i>Clinical criteria</i> Definite diagnosis: 3/3 clinical criteria and no differential diagnosis being more likely. Probable diagnosis: 2/3 clinical criteria and no differential diagnosis being more likely. Not probable diagnosis: 1/3 clinical criteria OR <i>Pathological criteria:</i> Intra-operative finding of pus or abscess in the aneurysm wall, or positive microbiological culture or histology from guided aspiration from aneurysms with a clinical suspicion of INAA (definite or probable INAA).	92%
23	If available and the patient's status permits, 18F-FDG PET-CT may be helpful in making the diagnosis of INAA.	87%
24	The role of 18F-FDG PET-CT in making the diagnosis of INAA is not clear. In the case of two of three clinical criteria (classified as probable INAA) there is a potential role and value of performing a 18F-FDG PET-CT. Specific SUV_{max} cutoff values to make the diagnosis of INAA are lacking.	95%
25	Infection related complication is a composite of post-operative infectious complications consisting of either persistent or recurrent sepsis, development of vascular graft or endograft infection, recurrent infective aortic aneurysm, or development of aorto-enteric or -bronchial fistula.	95%

PCR = polymerase chain reaction; 18F-FDG PET-CT = 18F-fluorodeoxyglucose positron emission tomography computed tomography; SUV = standard unit value.

* Cultures refer to any culture harvested during the period of illness. Even though a positive culture result is not a requisite for making the diagnosis of INAA, procurement of microbiological specimens is absolutely fundamental and should be of highest priority.

procurement of microbiological specimens (#15 and #18), and how the results should be interpreted, and revision of the statement in round 1 that did not reach consensus. Round 2 resulted in consensus on all 24 statements and nine reporting items.

Delphi round 3 included one more statement than the previous round, based on the panellists' comments on the use and role of 18F-FDG PET-CT in diagnosing INAA. Round 3 resulted in consensus on all 25 statements and nine reporting items.

The final Delphi round consisted of 25 statements and nine reporting items, and consensus was reached for all. For details see [Figure 1](#).

Cronbach's alpha increased with each consecutive round: round 1 = .84, round 2 = .87, round 3 = .90, and round 4 = .92.

The final established statements and the final reporting standards, with respective levels of agreement, are listed in [Tables 1 and 2](#), respectively.

DISCUSSION

This is the first consensus document on INAA. By standardising the terminology, definition, classification, diagnostic criteria, diagnostic algorithm, and reporting

standards of INAA this study creates essential conditions for scientific advancements in the disease. The possibility for interstudy comparability and meta-analyses should now increase, which is very important as gathering and evaluating large numbers of patients is very demanding due to the rarity of the disease. In the only two existing systematic literature reviews on the treatment of INAA, there were issues on inherent uncertainties regarding which studies were eligible and which were not, which highly influenced the results and conclusions of the respective studies.^{4,8,12} The present study could potentially be seminal in this regard.

The study is the result of the 100% participation of all experts (no dropouts over all four rounds), generating a high level of agreement throughout the entire study. The Cronbach alpha values indicate the high internal consistency of the survey, which increased with each round. The iterative manner, the anonymity of the panellists, the ability to comment and read others' comments, and to reconsider every vote in each round allowed honest and well reflected answers. The additional sense of a consensus document is to equalise the impact of the views of dominant panel members, and hence allow for an even group dynamic where all participants play an equal role.²⁰

Table 2. The final reporting standards, the result of the nine reporting items with the respective level of consensus from round 4, for the terminology, definition, classification, diagnostic criteria and algorithm, and reporting standards for the disease infective native aortic aneurysm (INAA)

Reporting items to be included in research on INAA to enhance comparability between studies, and make meta-analyses possible are:	Consensus in round 4
Use of the above (see Table 1) accounted terminology, definition, classification, and diagnostic criteria.	100%
Exclusion criteria: e.g., aortic vascular graft and endograft infections, secondary aorto-enteric or -bronchial fistulas, inflammatory aneurysms, penetrating aortic ulcers, etc.	100%
Patient characteristics: medical history, e.g., cardiopulmonary disease, smoking, immunosuppressive state or medication; data on presentation: symptoms, concurrent or recent infection.	100%
Laboratory results: levels of inflammatory markers such as C reactive protein and leucocytes, microbiological cultures, results of polymerase chain reaction.	100%
Imaging findings: aneurysm morphology such as fusiform, saccular, eccentric, multilobular; rapid expansion, peri-aortic gas, soft tissue mass, or fluid; imaging modality (computed tomography, magnetic resonance imaging, positron emission tomography). Rupture.	100%
Aneurysm anatomy: level of aorta engaged.	100%
Details on surgical treatment: open repair; location of aortic clamp; in situ reconstruction or extra-anatomic bypass and graft material; endovascular aortic repair; type of stent graft, hybrid procedure. Include non-operated patients.	100%
Details of antimicrobial treatment: pre-operative and post-operative duration and drugs.	100%
Outcome and follow up: duration, symptoms, laboratory results, imaging modality and results, survival with confidence interval, bacteriology in case of infection related complications, need for re-operations.	100%

There was 100% agreement that this study was necessary. There was 95% agreement on the definition, 92% agreement that “mycotic” is an imprecise historical misnomer, and there was 87% agreement that a more appropriate term would be “infective native aortic aneurysm”. This emphasises the value and importance of introducing a new term for this disease, which is both more correct and not historically associated with previous incorrect definitions or misconceptions of the disease that do not align with this document. Arguably, the ideal term would be “infective aortic aneurysm”, which is simpler and easier on the tongue, but as many publications still mix INAA with aortic VGEL or aortic fistulas, the word “native” is pertinent in explicitly distinguishing these disease entities from one another. The definition of INAA, statements 5 to 9, also emphasises the exclusion of aortic VGELs and aortic fistulas. However, it must also be acknowledged that both aortic VGELs and aortic fistulation may, respectively, develop as a complication of the treatment of INAA or as a consequence of the disease.

The classification of INAA resulted in 95% agreement between panellists. This could be important for future epidemiological work.

In total, 10 (40%) statements resulted in 100% agreement, including the essential pre-operative diagnostic workup, which should consist of a combination of clinical evaluation, laboratory results, and imaging findings. Of note, a positive culture is not a requisite for the diagnosis of INAA, and that the recommended first line imaging modality is contrast enhanced CT. Without a pathognomonic symptom, laboratory test, or radiological sign, the definite diagnosis will sometimes remain challenging; however, consensus on this is indispensable.

With 87% agreement, it was decided that 18F-FDG PET-CT might be helpful in making the diagnosis of INAA.

Further, with 95% agreement it was acknowledged that the role of 18F-FDG PET-CT in making the diagnosis of INAA is not clear, but in the case of two of three clinical criteria (classified as probable INAA) there is a potential role of and value in performing a 18F-FDG PET-CT. This implicit statement is the result of a lack of studies in the field, which will, hopefully, be resolved in the near future.¹⁶

All nine reporting items resulted in 100% agreement. However, in reporting item nine, on reporting survival outcomes (including confidence interval), it must be added that hazard ratios should also preferably be reported, to enhance the possibility of performing meta-analyses, even though median survival rates may also be used in time to event analyses. Also, in reporting item nine, on reporting infection related complications, it would be desirable to report the separate outcomes individually, as sepsis, aortic VGEL, recurrent infective aortic aneurysm, and aortic fistula, do not have an intercomparable impact on patient survival.

To achieve consensus the Delphi methodology has become accepted; however, there is no gold standard for which level of agreement consensus is needed.²⁰ In this study, a 75% level of agreement was used, which was the median threshold for defining consensus in a recent systematic literature review on the subject.¹⁶ The panel size is generally recommended to consist of at least 12 experts on the field of interest, and panel sizes of more than 30 have been shown to add little to the results and are difficult to maintain following low response rates. To invite non-experts is not recommended. This study contained 38 panellists, because the invitation acceptance rate was very high. Selecting the appropriate panellists is probably one of the most important steps in the methodology, as it directly relates to the quality of the study results. A significant criticism of this study is that no infectious disease specialists participated. This was due to

the inability to find specialists who fulfilled the expert criteria. This will have to be resolved for an eventual consensus study on the management and treatment of INAA. There was broad representation from Europe, North America, and Asia. However, a possible limitation was not to have experts from other continents. Inter-specialty and inter-origin differences were not analysed.

Another limitation of the study was to omit defining “recurrent infective aortic aneurysm”; patients who are treated for an INAA and post-operatively develop a new infective aortic aneurysm. Even though this is a rare complication, it does occur, and might pose specific challenges. Also unaddressed was whether the diagnostic algorithm developed in this study could also be applied to peripheral infective native aneurysms. While awaiting consensus, using this algorithm seems appropriate. A statement on aetiology, including ruling out infective endocarditis, and the presence of psoas abscess, would have been desirable, and is recommended for reporting on this disease.

Conclusion

This Delphi study managed to establish the first consensus document on the disease of INAA regarding its terminology, definition, classification, diagnostic criteria, and algorithm, as well as reporting standards. The results create essential conditions for scientific research of this disease. The presented consensus will need future amendments in accordance with newly acquired knowledge.

CONFLICT OF INTEREST STATEMENT AND FUNDING

None.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejvs.2022.11.024>.

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