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International Expert Consensus on the Management of Acute Aortic Type B Intramural Haematoma and Penetrating Ulcer

Francesco Squizzato, Mario D'Oria, Michele Antonello, Santi Trimarchi, Kevin Mani, Andrew Holden, Tilo Kölbel, Stephan Haulon, Eric Verhoeven, Dittmar Böckler, Tim Resch, Ali Azizzadeh, Joseph Lombardi, Michele Piazza, IDEAAS-IMH/PAU Investigators

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RUNNING TITLES

Odd pages: Consensus on the Management of Acute Aortic Type B Intramural Haematoma and Penetrating Ulcer

Even pages: Francesco Squizzato *et al.*

International Expert Consensus on the Management of Acute Aortic Type B Intramural Haematoma and Penetrating Ulcer

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WHAT THIS PAPER ADDS

The aim of this study was to achieve an international expert consensus on the management of acute aortic intramural haematoma (IMH) and penetrating aortic ulcer (PAU), addressing areas of inconsistencies or knowledge gaps in existing guidelines. The expert panel agreed on the indication for thoracic endovascular aortic repair (TEVAR) for complicated IMH/PAU, defined by rupture or refractory pain/hypertension. Uncomplicated IMH/PAU should be managed conservatively and followed with serial computed tomography imaging during the acute phase. High risk uncomplicated IMHs are identified by imaging criteria of progression during the acute phase and may be considered for TEVAR. In performing TEVAR, a proximal sealing length > 20 mm in a site free from haematoma should be achieved, eventually extending in zone 2, with a 0 – 10% oversize.

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Objective: The aim of this study was to achieve an international expert consensus on managing acute type B penetrating aortic ulcers (PAUs) and intramural haematomas (IMHs).

Methods: A modified Delphi consensus process was employed to develop recommendations for the management of acute type B PAU and IMH. Surveys were sent to international experts practicing in high volume aortic centres worldwide. Statements were voted on using a four point Likert scale in a three round Delphi process. Statements achieving grade A (full agreement 75%) or B (overall agreement 80%, full disagreement < 5%) were included as expert recommendations. Consistency of responses was measured using Cohen's κ and the intraclass correlation coefficient.

Results: Eighty three experts were included in the final analysis: 25 statements achieved a consensus, 18 (72%) receiving a grade B strength and 7 (28%) a grade A strength. Most statements (97%) had a high consistency classified as grade I or II. The expert panel agreed on the indication for thoracic endovascular aortic repair (TEVAR) for complicated IMH/PAU, defined by rupture or refractory pain/hypertension. Uncomplicated IMH/PAU should be managed conservatively and followed up with serial computed tomography imaging during the acute phase. High risk uncomplicated IMHs are identified by increased haematoma thickness, new onset or increased size of ulcer like projections, or transition to aortic dissection; high risk uncomplicated PAUs are defined by new associated haematoma, PAU width/depth increase, or total aortic diameter increase. Uncomplicated high risk IMH/PAUs may be considered for TEVAR. In performing TEVAR, a proximal sealing length > 20 mm in a site free from haematoma should be achieved, eventually extending in zone 2, with a 0 – 10% oversize. Patency of the left subclavian artery should be maintained.

Conclusion: An agreement among international experts was achieved on assessment, management, and follow up of acute type B IMHs and PAUs, addressing areas of inconsistencies or knowledge gaps in existing guidelines.

Keywords: Acute aortic syndrome, Consensus, Endovascular aneurysm repair, Guidelines, Intramural haematoma, Penetrating aortic ulcer

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INTRODUCTION

Acute aortic syndrome refers to a spectrum of thoracic aorta pathologies, including traditional aortic dissection, penetrating aortic ulcer (PAU), and intramural haematoma (IMH). PAU and IMH have substantially different aetiologies, but they share the presence of media layer disruption, a similar clinical presentation, and potential acute evolution to dissection and or rupture.[1] The natural history and clinical management of aortic dissection are well defined; however, the definitions, clinical management protocols, and treatment details for IMH and PAU still lack standardisation.[2–4]

It is generically accepted that acute complicated aortic syndromes should be addressed with thoracic endovascular aortic repair (TEVAR); however, currently available guidelines[2,5,6] do not agree on the definition of complicated *vs.* uncomplicated presentations and do not provide clear recommendations regarding assessment, management, and follow up. Furthermore, a variety of clinical and morphological risk factors have been described for IMH and PAU, in an attempt to identify aortic syndromes at higher risk for complications that may benefit from early intervention.[7–14] However , there is a lack of consensus on the definition and treatment protocols for high risk IMHs and PAUs. In this scenario, the management of acute aortic syndrome may be subject to great variability, depending on the centre and operator. Nevertheless, a standardisation in definition, indication, operative planning, and technique is necessary to improve the clinical outcomes and set the basis for further clinical investigation. This study aimed to achieve an international expert consensus through a Delphi process, investigating practices in high volume aortic centres, in order to create recommendations for managing acute type B PAU and IMH and identify areas needing further research.

MATERIALS AND METHODS

Study design

A modified Delphi consensus process was used to obtain expert consensus on the management of acute aortic syndrome presenting with aortic type B IMH or PAU. All surveys were submitted online and recorded through REDCap. Invited experts were unaware of the identity of other members of the international panel, and answers were de-identified. Participation in the second round of the study was limited to individuals who completed the first round, and only those who responded in the second round could access the third round.

Core team and selection of panel of international experts

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The core team was composed of the study's principal investigators (M.P., F.S., and M.D.), with the addition of three external facilitators selected for their expertise in the consensus topic. Panel members were recruited from vascular and cardiovascular surgeons practicing in Europe, North America, Latin America, Asia, and Oceania. Selection criteria included prior publications in high impact cardiovascular journals, presentations at international conferences on acute aortic syndrome, and editorial roles in peer reviewed journals relevant to the study. Eligibility for the expert panel required physicians to have consolidated clinical experience in dealing with IMH and PAU and to be affiliated with a department providing a 24/7 service with a mean overall TEVAR volume of > 15 cases per year.

Delphi methodology

A modified Delphi method was employed to establish expert consensus. To develop the set of statements for expert evaluation, a first round was distributed, incorporating multiple choice questions and open ended suggestions to assess current practices in diagnosis, indications, and management of IMH and PAU. To ensure full standardisation, questions were provided with appropriate radiology images and or definitions as reference.

IMH was defined as an intramural haemorrhage without evidence of an intimal tear.[1,15] Haematoma thickness was defined as the intima to adventitia distance.[8,10] Ulcer like projections (ULPs) were defined as small focal areas of contrast enhancement within the haematoma, with a visible communication with the aortic lumen. These are sometimes also referred to as focal intimal disruption and may evolve in size or number on repeated imaging. Intramural blood pools were defined as a focal area of contrast enhancement within the haematoma, without evident communication with the aortic lumen; these are usually connected with aortic side branches such as intercostal, bronchial, or lumbar arteries (Fig. 1).[1] PAU was defined as an ulceration of an atherosclerotic aortic plaque penetrating the internal elastic lamina.[1,15] PAU (Fig. 2) depth and width were defined as previously reported.[2,16] Presence of peri-aortic haematoma in combination with a PAU was considered as an imaging feature of PAUs, with the latter being the primary pathology, and this was defined as PAU associated haematoma in order to clearly distinguish it from IMH.

Responses were analysed by the core team, which formulated statements covering the pre-, intra-, and post-operative management of acute aortic syndrome. A four point Likert scale was used to measure agreement levels: "fully agree" (3), "agree" (2), "disagree" (1), and "completely disagree" (0). The neutral option ("no opinion") was deliberately excluded, assuming that all panellists possessed the necessary expertise to provide an informed opinion. None of the statements offered only open questions, and all statements were evaluated through a Likert scale for at

least two rounds. Any open ended questions included in the first round were converted into closed questions for assessment using a Likert scale in the following rounds.[17]

The subsequent Delphi process consisted of two iterative rounds. In the second round, experts evaluated the statements formulations, providing a measure of agreement. Statements were revised based on expert feedback, and in round 3 a final validation and confirmation of consensus strength were performed. Throughout the process, statements were refined and adjusted based on expert comments to maximise consensus while preserving the clarity and clinical relevance of the recommendations. For the assessment of timing of early imaging follow up, the following options were assessed in the first round, based on the literature and common clinical practice,[2,6] as evaluated by the core team: (1) two, seven, and 14 days; (2) 14 and 30 days; (3) seven and 14 days; (4) 30 days; (5) two and 14 days; and (6) other (with the possibility to specify). The first option was the most selected answer (68% of respondents for high risk PAU/IMH and 39% for low risk). For this reason, this was the option that was tested for consensus in the following rounds.

Statistical analysis

The strength of consensus was classified based on the experts' responses into four categories (Table 1). For each statement, the corrected mean score (range 0 – 3), along with its 95% confidence interval (CI), was evaluated. The Wilcoxon test was used to assess the change from the previous round, and the significance of correlation with the previous rating was also calculated. These items were used to confirm the strength of consensus considering the lower bound of the 95% CI (> 2.00 to confirm strong consensus). A p value of .025 was regarded as statistically significant, considering that a degree of multiplicity was expected.

The consistency of scoring between rounds with the proportion of agreement was estimated using p values from Cohen's κ and from the intraclass correlation coefficient (ICC) set for consistency using a two way model between second *vs.* third rounds. Consistency was defined as grade I (very high) if both had p values ≤ .001 and as grade II (high) if one analysis had a p value ≤ .001 and the other was ≤ .010. The proportion of ratings exceeding the critical difference was estimated to monitor the test–retest reliability according to Bland and Altman and was considered as a modifier of consistency: a proportion of outliers > 10% indicated significant heterogeneity across experts. Fleiss's κ was complemented with the estimate of category wise κ in the case of statement double resubmission. Statements with consistency grade III or IV according to the repeated Cohen's κ analysis, but otherwise highly consistent

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according to Fleiss's κ, were eventually classified as grade III. All statistical analyses were conducted using R software (R Foundation for Statistical Computing, Vienna, Austria).

Criteria for selection or modification of statements

The decision to refuse or modify and resubmit a statement was based on pre-defined composite statistical criteria. The criteria for submission or resubmission after the first round were as follows: items with a proportion of full disagreement ≥ 10% and or a mean score < 2.0 were not resubmitted; all other statements were resubmitted after eventual textual adaptations and or merging of statements, as appropriate. The pre-defined criteria for submission or resubmission after the second round were (1) statements with a proportion of overall agreement < 80% and a proportion of full disagreement > 5% (grades C and D) were removed from the consensus and (2) statements with at least five of the following criteria were accepted in their current form unless suggestions from the core team recommended resubmission: a proportion of "fully agree" > 75% or a proportion of overall agreement > 80%; a proportion of full disagreement < 5%; a non-significant mean score change from first to second round (Wilcoxon test); a significant score correlation between the first and second rounds; a significant measure of agreement (Cohen's κ); and a significant ICC set for consistency. At the final round, only statements with grades of strength A and B were considered of sufficient quality to be included in the final set of recommendations.

RESULTS

Participants and consensus

Eighty-nine experts were invited to the initial survey and 83 participants (93%) completed all rounds. All of the respondents met the pre-specified inclusion criteria and were included in the analysis.

The median participant age was 50 years (interquartile range 44,56) and 74 participants (89%) were men. Countries of experts practice were in Europe in 58 (70%), North America in 17 (20%), South America in two (2%), Asia in three (4%), and Oceania in three (4%). Supplementary Table S1 shows the statements that were rejected during the first round owing to high disagreement (full disagreement ≥ 10% and or a mean score < 2.0). Supplementary Table S2 summarises the proportion of consensus obtained by each statement after the third round. At the end of the process, 25 statements achieved a consensus; 18 (72%) received a grade B strength and 7 (28%) received a grade A consensus strength. Most statements (97%) were classified as grade I or II; Supplementary Table S3 shows the estimates of consistency across rounds and their classification based on Cohen's κ and ICC. The complete text of the

statements evaluated in the final round, along with the respective final strength and consistency, is detailed in Table 2.

Imaging and baseline assessment

The experts suggested the use of electrocardiography gated thin slice computed tomography angiography (CTA), with arterial and venous phases, for the diagnosis and follow up of PAUs and IMHs (statements 1 and 2, grade B). Patients presenting with acute type B IMH/PAU may be considered for genetic testing for connective tissue disease only in selected cases, such as family history, young age < 50 years, or presence of high risk factors (statement 3, grade A).

At presentation, complicated PAUs are identified by the presence of imaging signs of rupture, or refractory pain, or refractory hypertension (grade B). The presence of pleural effusion, PAU depth and width, and total aortic diameter were rejected as criteria to define complicated or high risk PAUs. Uncomplicated PAUs should be considered at high risk for complications only in the presence of any of the following signs on two consecutive CTAs: associated new haematoma; PAU width/depth increase; and total aortic diameter increase (statement 11, grade A), regardless of the presence of associated symptoms. Regarding IMH, suggested criteria for complications were the presence of rupture, refractory pain, or refractory hypertension (statement 6, grade B). The presence of ULPs, by itself, was rejected as a sign of complicated IMH. The presence of high risk factors is evaluated on consecutive CTAs as an increase in haematoma thickness, onset of new ULPs or ULP size increase, or transition to aortic dissection (statement 12, grade A).

Clinical management

According to the answers of respondents, acute complicated PAU/IMH should be treated in the acute setting (statement 8, grade A), while uncomplicated PAU/IMH should be managed with a conservative approach and followed with CTA performed at two, seven, and 14 days after onset. TEVAR may be considered in selected cases with acute uncomplicated PAU/IMH with high risk features (statement 14, grade B); however, a consensus regarding the optimal timing for intervention in uncomplicated cases was not achieved. In this regard, the relative majority (39%) of experts suggested to perform TEVAR after > 14 days from the onset. TEVAR is not indicated in patients with uncomplicated acute type B PAU/IMH without high risk features (statement 16, grade A).

Operative management

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In TEVAR planning, a 0 – 10% endograft oversizing should be applied to the proximal (statement 19, grade A) and distal (statement 20, grade B) sealing zones. A thoracic endograft without proximal bare stents should be preferred (statement 22, grade B). In IMHs, which are characterised by variable extension of haematoma along the thoraco-abdominal aorta, a proximal sealing length > 20 mm in a site free from haematoma should be achieved (statement 23, grade B), while the distal landing should be above the coeliac trunk, eventually in a site with some degree of haematoma (statement 24, grade B). As many ULPs as possible should be covered by TEVAR. In planning TEVAR for PAU, a proximal sealing length > 20 mm in a site free from PAU associated haematoma should be achieved. When performing TEVAR for acute PAU/IMH, intravascular ultrasound may be used intra-operatively to assess landing zones, *in situ* sizing, or check for eventual graft induced dissection at the proximal or distal landing site. If the left subclavian artery (LSA) ostium is involved by the disease in patients undergoing urgent or elective TEVAR, LSA patency should be preserved via extra anatomic bypass, branched endograft, or *in situ* fenestration (statement 17, grade A). If the LSA ostium is involved by the disease in patients undergoing emergent TEVAR, LSA patency should be preserved via extra-anatomic bypass, branched endograft, or *in situ* fenestration (statement 18, grade B). Use of the chimney graft technique did not reach consensus as a viable option for maintaining LSA patency. The overall flowchart derived from the consensus is shown in Figure 3.

Follow up

After TEVAR for acute PAU/IMH, the first follow up imaging should be performed after three to seven days, unless otherwise indicated by the clinical picture (statement 29, grade B).

DISCUSSION

Currently available guidelines on the management of IMHs and PAUs[2,3,5,6] are characterised by a low level of evidence and lack of consistency on important clinical aspects, such as definitions of complications, characterisation of high risk features, indications for TEVAR, and technical aspects of the surgical treatment. In this study, international experts from high volume aortic centres achieved a consensus on several of these unsolved topics, providing valid insights that may be used as a reference for everyday clinical practice.

In the assessment of IMH and PAU, the first important clinical step is to discriminate between complicated and uncomplicated cases. Rupture and persistent symptoms are generally accepted as complications, but the significance of other anatomic features, such as pleural effusion, size parameters, and ULPs, is still unclear (Tables 3 and 4). Part

of the inconsistency across guidelines may derive from the retrospective, single centre design of most studies as well as the use of different definitions, confounding the concepts of PAU, ULP, focal intimal disruption, PAU associated haematoma, and IMH.[16] Also, as IMH and PAU are relatively rare diseases, recommendations for IMH and PAU are traditionally derived from experience with aortic dissection, rather than specific evidence on IMH/PAU. For these reasons, the Delphi survey was provided with appropriate definitions and radiological images, avoiding potential misunderstandings and improving consistency. In this consensus, experts considered only the presence of rupture or persistent symptoms as signs of complication, similar to the Society for Vascular Surgery/Society of Thoracic Surgeons reporting standards on aortic dissection;[3] the presence of malperfusion was not considered as a possible scenario in this case, as it occurs only in cases of evolution of IMH/PAU to aortic dissection. Different from most guidelines, such as the American College of Cardiology/American Heart Association,[4] European Association for Cardio Thoracic Surgery/Society of Thoracic Surgeons,[6] and European Society for Vascular Surgery (ESVS)[2] guidelines, other morphological features were not considered sufficient to characterise a complicated PAU or IMH. It is important to note that the different definition of complications is important from a clinical standpoint, as it directly influences the indication for TEVAR. According to the experts' practice, the presence of morphological factors alone, such as pleural effusion, ULPs, PAU diameter > 20 mm, or PAU depth > 10 mm, is not sufficient to consider an acute endovascular treatment.

Another result of this consensus is that the characterisation of uncomplicated IMH/PAU at high risk for complications is not determined on baseline features, but rather on negative morphological evolution evaluated through strict follow up imaging, with a CTA repeated after two, seven, and 14 days. The presence of ULPs alone was not considered sufficient to classify IMHs as complicated. Instead, high risk uncomplicated IMHs were defined by an increase of haematoma thickness, onset of new ULPs, increase in ULP size, or transition to aortic dissection on consecutive CTAs. This is in line with the observation that ULPs are frequent and detected in up to 50% of cases,[18] and are not necessarily related to worsened outcomes. On the other hand, the increase in size and or numbers of ULPs should be considered as an indication for TEVAR to prevent further complications, regardless of the presence of associated symptoms. Similarly, also for PAUs, the definition of high risk features derives from the imaging evolution during the early period follow up, and not from the anatomic characteristics at presentation. This is in contrast to, in particular, the ESVS guidelines,[2] which list among complications a PAU diameter > 20 mm and depth > 10 mm. These morphological criteria were rejected as a definition of complication during the first round,

highlighting an existing gap between available guidelines and current practice in most aortic centres. For both IMH and PAU, reclassifying uncomplicated PAU/IMH as high risk based on CTA changes, rather than baseline characteristics, may result in a less aggressive approach at many centres, where TEVAR is currently performed solely due to certain risk factors (such as haematoma thickness, total IMH aortic diameter, pleural effusion), although the limited supporting evidence.

The necessity to prospectively evaluate IMH/PAU in a short time window, suggested by the respondents, may lead to a high number of CTAs, especially in those without high risk factors. While it is recognised that there may be some underlying bias, this is in accordance with another important result of the survey, which is the concept that high risk features are not determined by baseline characteristics, but rather are based on the signs of evolution on control CTAs. Nevertheless, the imaging protocol may be individualised in favour of a less strict protocol, based also on the course of symptoms, age, general clinical conditions, and renal function. Also, further studies are still necessary to determine the best short and long term follow up protocols, and improvement of cost effectiveness.

This is the first study aiming to set a standard for technical choices in treating IMH/PAU by TEVAR. An important aspect is that the proximal sealing zone should not be compromised, settling for a less complex and invasive intervention. A sealing length of at least 2 cm free from haematoma (both in IMH and PAU) should be selected, eventually extending into zone 2. This practice likely derives from larger experience in aortic dissections, where a proximal landing in a site with some degree of residual haematoma is a known risk factor for proximal complications, including type Ia endoleaks and retrograde dissection.[19–21] In case coverage of the LSA is required, LSA revascularisation should be performed in the urgent or elective setting, choosing between the use of surgical debranching, a dedicated branched device, or *in situ* fenestration. The chimney graft technique was rejected as a possible solution to maintain LSA patency, since today there are other available options that do not carry the risk of proximal gutter endoleak.[22] Similarly to acute aortic dissection, experts suggested the use of an endograft without a proximal bare stent and a minimal oversize (0 – 10%). Intra-operative intravascular ultrasound may be considered to assess the quality of landing zones, *in situ* sizing, and check for eventual graft induced dissection. IMH often extends to the thoraco-abdominal aorta, and there may be discussions about the appropriate site for the distal landing. There was a consensus that distal landing just above the level of the coeliac trunk is acceptable, in a site of some degree of haematoma, with a 0 – 10% oversizing, and covering as many ULPs as possible.

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There was a lack of consensus on the timing of endovascular treatment. While it is well established that complicated patients should undergo urgent/emergent TEVAR, the situation is more nuanced in uncomplicated, high risk IMH/PAU. Also, clinical guidelines do not mention the suggested timing of intervention in this clinical setting and, although there was no overall agreement, most experts wait until the end of the acute phase. Regardless of the timing of TEVAR, a post-operative CTA should be obtained within three to seven days to assess for technical success and potential complications, such as dissection at the level of the proximal or distal landing site.

The results of this study should be interpreted considering its limitations. Delphi studies reflect the opinions and practice patterns of selected experts and cannot be considered as a substitute for traditional scientific literature. A selection bias of experts may derive from initial selection by the core team and an incomplete initial response rate. Different opinions and lack of agreement do not necessarily reflect an incorrect practice, but may be the result of different available options, institutional setting, local regulations, and geographic habits, in topics where there is a low level of evidence. Although the Delphi methodology has been increasingly used in medical sciences and vascular surgery guidelines,[17,23] its use is more efficient in the assessment of qualitative data, and it may not be ideal for the assessment of discrete variables.

It is important to underline that the statements were prompted and refined starting from the currently available guidelines. For some topics that are not adequately covered by guidelines, the proposed statements represent the only available clinical evidence on the standard of care. For topics where there is inconsistency between guidelines, which is a hallmark of the low level of evidence, the current statements suggest alternative recommendations to be considered in clinical practice or future guidelines, and these need to be confirmed by further research.

Conclusion

A consensus among international experts was achieved in dealing with acute type B IMHs and PAUs, addressing areas of inconsistencies or knowledge gaps in existing guidelines. Key findings include a cleaner definition of complications, the weakened significance of certain well known morphological criteria as sole indications for TEVAR, and the importance of strict imaging follow up in the early period to assess for high risk features, which are primarily defined on anatomic criteria of aortic evolution, rather than baseline morphological characteristics. Furthermore, specific recommendations are provided regarding the planning and technical aspects of TEVAR.

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Overall, the suggested statements offer valuable insights for current clinical practice and may be considered for updated guidelines. Additional research is warranted to further investigate the topics of recommendations.

CONFLICTS OF INTEREST

Francesco Squizzato has signed a consulting agreement with Medtronic and Gore; all of his consulting fees are paid to the Department of Cardiac, Thoracic Vascular Sciences and Public Health, University of Padua. Santi Trimarchi is a consultant and speaker for Gore, Medtronic, and Terumo Aortic. Kevin Mani has a research grant from and is consulting for Cook Medical Inc. Andrew Holden is an Advisory Board Member for Medtronic, Gore, Philips, and Boston Scientific, and clinical investigator for Abbott, Artivion, Bard-BD, Biotronik, Boston Scientific, Cagent, Cook, Cordis, Efemoral, Endospan, FluidX, Gore, Inari, Medtronic, Merit, Nectero, Penumbra, Philips, Reflow Medical, Shape Memory, Shockwave, Terumo, and Vesteck. Tilo Kölbel is a consultant for Cook, Terumo Aortic, Arterica, Philips, Artivion, and Getinge; he receives royalties from and has intellectual property with Cook and Terumo Aortic; he also receives speaking fees and research, travel, and educational grants from Cook, Terumo Aortic, Philips, Artivion, and Getinge. Stephan Haulon holds a consulting agreement and has intellectual properties with Cook and GE Healthcare. Eric Verhoeven is a consultant and speaker, has intellectual properties in, and receives research grants from Cook; he is also a consultant and speaker for Gore. Dittmar Bökler holds a consulting agreement with Gore, Cook, Artivion, and Brainlab. Tim Resch is a consultant for Cook, Terumo, Philips, Artivion, and Gore; he has intellectual property with Cook; and he receives speaking fees and research, travel, and educational grants from Cook, Terumo Aortic, Philips, Artivion, Lombard, and Shape Memory Medical. Michele Piazza holds a consulting agreement with Artivion, Medtronic, Gore, and Cook; all his consulting fees are paid to the Department of Cardiac, Thoracic, Vascular Sciences and Public Health, University of Padua. All other authors do not have any conflicts of interest.

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None

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FIGURE LEGENDS

Figure 1. (A) Multiplanar reconstruction of an intramural haematoma (IMH) at presentation. The red arrow indicates the presence of an intramural blood pool at the level of the distal thoracic aorta. (B) Multiplanar reconstruction of the same case after two days. White arrows indicate the onset of multiple intramural blood pools and the red arrow indicate the ulcer like projection, with associated increased thickness of the haematoma. (C) Intra-operative surgical specimen of an IMH.

Figure 2. (A) Computed tomography angiography axial view of a penetrating aortic ulcer (PAU), showing the total aortic diameter (white dashed arrow), PAU width (yellow dotted arrow), and PAU depth (red solid arrow). (B) Intra-operative surgical specimen of a PAU.

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Figure 3. (A) Flowchart of the management of acute type B intramural haematoma (IMH) resulting from the expert consensus. (B) Flowchart of the management of acute type B penetrating aortic ulcer (PAU) resulting from the expert consensus. CTA = computed tomography angiography; LSA = left subclavian artery; TEVAR = thoracic endovascular repair; ULP = ulcer like projection.

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TABLES

Table 1. Strength and consistency grading definitions used in the development of the Delphi consensus for the recommendation of antithrombotic therapy in fenestrated and branched aortic endovascular procedures.

Grade	Description	Definition
Strength grading		
A	Very strong	Full agreement ≥75%
B	Strong	Full agreement <75% Overall agreement ≥80% Full disagreement <5%
C	Fair	Full agreement <75% Overall agreement <80% Full disagreement ≥5%
D	Poor	Full disagreement ≥10%
Consistency grading		
I	Very high	Cohen's κ and ICC, *p* value < .001 in both analyses
II	High	Cohen's κ and ICC, *p* value < .001 in one and < .010 in the other analysis
III	Fair	Repeated Cohen's κ *p* value > .050, Fleiss's κ *p* value < .001
IV	Poor	Repeated Cohen's κ *p* value > .050, Fleiss's κ *p* value > .010

ICC = intraclass correlation coefficient.

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437 **Table 2**. **Complete text of the statements evaluated in the final round, along with the respective final strength**
438 **and consistency.**
439

Statement	Text	Strength*	Consistency*
1	For the diagnosis of acute PAU and IMH, EKG-gated thin slice CTA with arterial and venous phases should be the imaging method of choice	B	I
2	For the follow-up of acute PAU and IMH, EKG-gated thin slice CTA with arterial and venous phases should be the imaging method of choice	B	I
3	Patients presenting with acute type B IMH/PAU may be considered for genetic testing for connective tissue disease only in selected cases (family history, young age <50 years, presence of high risk factors)	A	I
4	A complicated PAU is identified by the presence of: rupture OR refractory pain OR refractory hypertension	B	II
5	The presence of pleural effusion, by itself, is a sign of complicated IMH/PAU	D	III
6	A complicated IMH is identified by the presence of: rupture OR refractory pain OR refractory hypertension	B	II
7	The presence of ulcer-like projections (ULPs), by itself, is a sign of complicated IMH	D	I
8	Acute complicated PAU/IMH should be treated in the acute setting	A	II
9	Acute uncomplicated PAU/IMH may be considered for treatment in the acute setting, only in selected cases with high risk features	C	I
10	Follow-up of CTA should be performed at 2 days, 7 days, and 14 days after the onset of acute uncomplicated PAU/IMH with high-risk features	B	I
11	Acute uncomplicated PAU should be considered at high risk for complications in presence of any of the following signs on two consecutive CTAs: associated new hematoma, PAU width/depth increase, total aortic diameter increase	A	I
12	Acute uncomplicated IMH should be considered at high risk for complications in presence of any of the following signs on two consecutive CTAs: increase of hematoma thickness, new onset or increased size of ulcer like projections (ULPs), transition to aortic dissection	A	I
13	Follow-up of CTA should be performed at 2 days, 7 days, and 14 days after the onset of acute uncomplicated PAU/IMH without high-risk features	B	I
14	TEVAR may be considered in selected cases with acute uncomplicated PAU/IMH with high-risk features	B	I
15	In selected acute uncomplicated PAU/IMH with high-risk features, TEVAR should be performed after 15–28 days from the onset	C	I
16	TEVAR is not indicated in patients with uncomplicated acute type B PAU/IMH without high risk features	A	I
17	If the LSA ostium is involved by the disease in patients receiving urgent or elective TEVAR, LSA patency should be preserved via extra-anatomic bypass, branched endograft, or in situ fenestration	A	I

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18	If the LSA ostium is involved by the disease in patients receiving emergent TEVAR, LSA patency should be preserved via extra-anatomic bypass, or branched endograft, or *in situ* fenestration	B	I
19	Proximal oversizing of TEVAR should be 0–10%	A	I
20	Distal oversizing of TEVAR should be 0–10%	B	I
21	In TEVAR planning, the aortic diameter should be preferentially measured from inner to inner	D	I
22	In TEVAR for IMH/PAU, a thoracic endograft without proximal bare metal stent should be preferentially used	B	I
23	In planning TEVAR for IMH, a proximal sealing length >20 mm in a site free from hematoma should be achieved	B	I
24	In planning TEVAR for IMH, distal landing above the celiac trunk, eventually in a site with some degree of hematoma, may be achieved	B	II
25	In planning TEVAR for IMH, as much ULPs as possible should be covered	B	I
26	In planning TEVAR for PAU, a proximal sealing length >20 mm in a site free from PAU-associated hematoma should be achieved	B	I
27	To prevent spinal cord ischemia, LSA revascularization (either concomitant or delayed based on individual scenarios) and hemodynamic optimization should be employed	A	II
28	When performing TEVAR for acute PAU/IMH, IVUS may be used intraoperatively (i.e. to assess landing zones, *in situ* sizing, check for eventual graft-induced dissection)	B	I
29	After TEVAR for acute PAU/IMH, the first follow-up imaging should be performed after 3–7 days, unless otherwise indicated by the clinical picture	B	I
30	A randomized trial should be carried out to address unresolved issues in the management of acute type B PAU/IMH	C	III

PAU = penetrating aortic ulcer; IMH = intramural haematoma; EKG = electrocardiography; CTA = computed tomography angiography; ULP = ulcer like projection; TEVAR = thoracic endovascular aortic repair; LSA = left subclavian artery; IVUS = intravascular ultrasound.

* See Table 1 for definitions for strength and consistency.

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445 **Table 3. Review of definitions and indications provided by the major available guidelines on the management of**
446 **intramural haematoma (IMH), compared with the present expert consensus.**
447

Characteristic	ACC/AHA 2022	EACTS/STS 2024	SVS 2020	ESVS 2017	Current consensus
Complicated IMH	• Malperfusion • Persistent, refractory, or recurrent pain • Peri-aortic haematoma • Rupture	• Malperfusion • Persistent pain • Persistent hypertension • Pleural effusion containing blood • Rupture	• Rupture • Malperfusion	• Recurrent pain • Expansion of the haematoma • Peri-aortic haematoma • Intimal disruption (ULP)	• Rupture • Refractory pain • Refractory hypertension
High risk IMH	• Progression to aortic dissection • Aortic diameter >47 mm • Increasing aortic diameter • Increasing haematoma thickness • Haematoma thickness >13 mm • Increasing pleural effusion • ULP developed in the acute phase	• Age >70 y • Aortic diameter >45 mm • Growth rate >5 mm/y • Haematoma thickness >10 mm • Pleural effusion • Presence of ULPs	• Persistent pain • Haemodynamic instability • Maximum aortic diameter>45 mm • Haematoma thickness >10 mm • ULPs • Pleural effusion • Haemomediastinum • Peri-aortic haemorrhage	• Not specified	• Increase of haematoma thickness • New onset or increased size of ULPs • Transition to aortic dissection
Indication for TEVAR	• Complicated IMH (1, b) • Reasonable in high risk uncomplicated IMH (2b, C)	• Complicated IMH (1, b) • Should be considered in high risk uncomplicated IMH (2a, C)	• Patients with persistent symptoms or complications or evidence of disease progression (1, b) • Suggested in high risk IMHs (2, b)	• Should be considered for complicated IMHs (2a, C)	• Complicated IMH • May be considered in acute uncomplicated IMHs, only in the presence of high risk features

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449 ACC = American College of Cardiology; AHA = American Heart Association; EACTS = European Association for
450 Cardio Thoracic Surgery; STS = Society of Thoracic Surgeons; SVS = Society for Vascular Surgery; ESVS =
451 European Society for Vascular Surgery; IMH = intramural haematoma; ULP = ulcer like projection; TEVAR =
452 thoracic endovascular aortic repair.

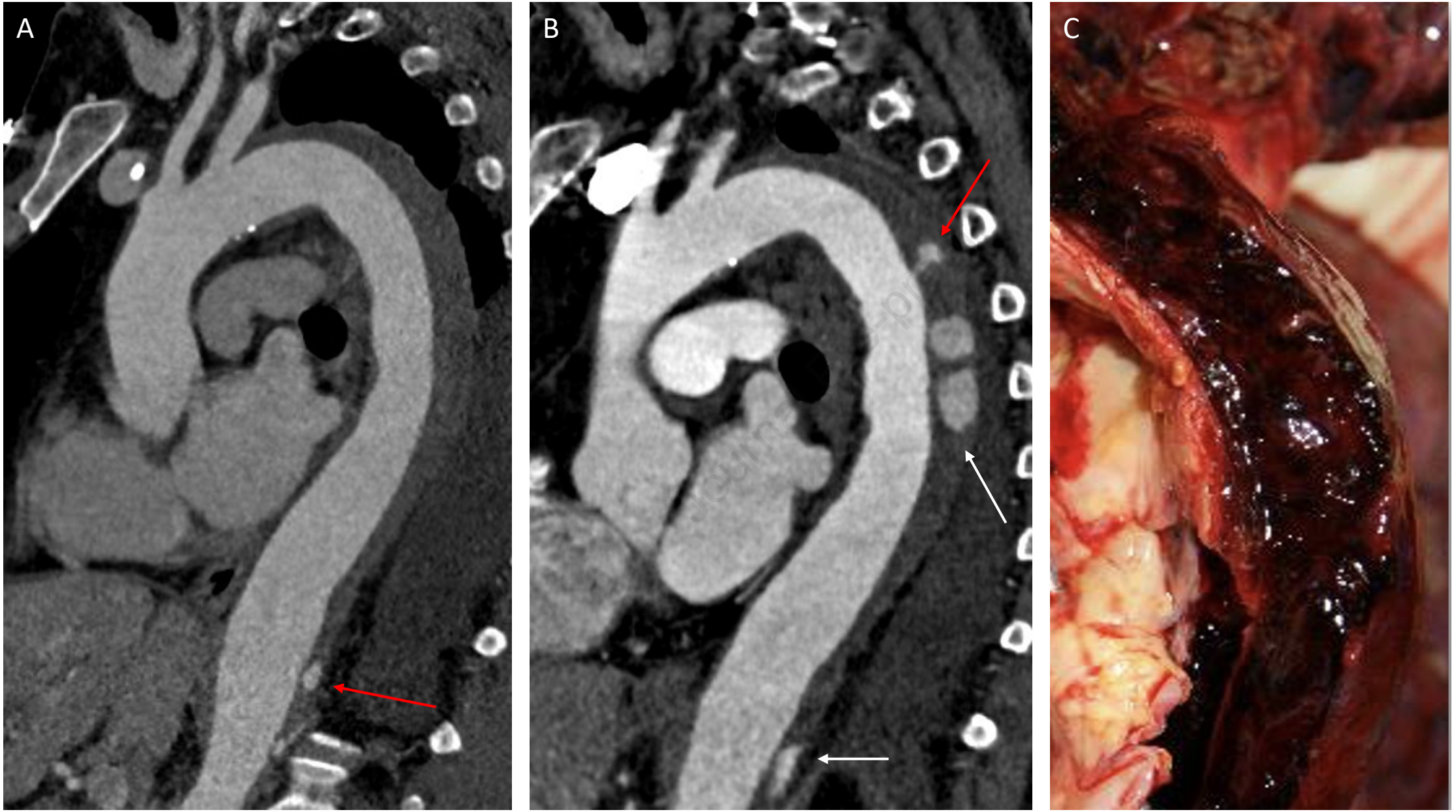
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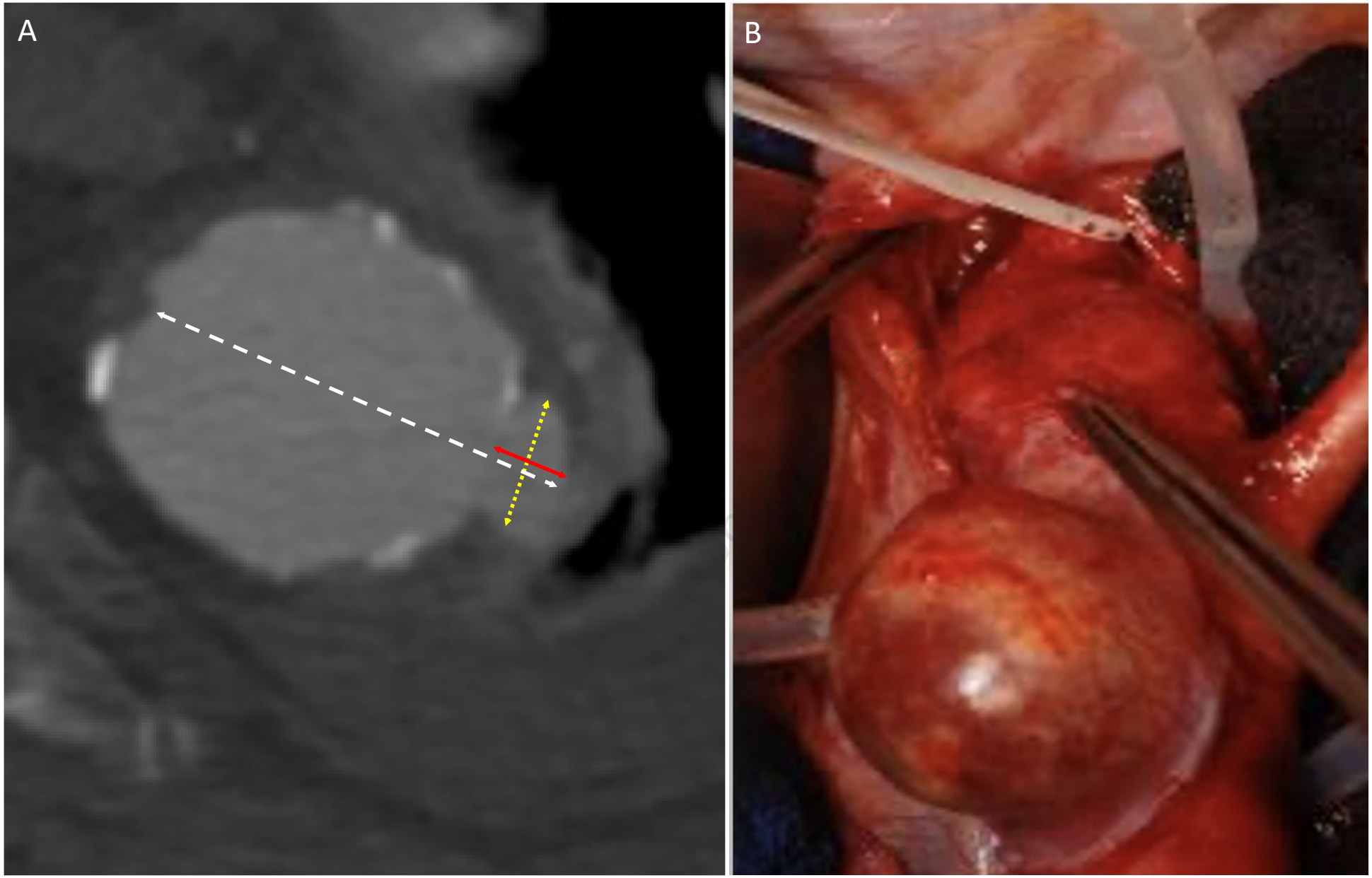
Table 4. Review of definitions and indications provided by the major available guidelines on the management of penetrating aortic ulcer (PAU), compared with the present expert consensus.

Characteristic	ACC/AHA 2022	EACTS/STS 2024	SVS 2020	ESVS 2017	Current consensus
Complicated PAU	• Rupture • Persistent pain	• Rupture	• Persistent symptoms	• Recurrent pain • Diameter >20 mm • Depth >10 mm • Progression of total aortic diameter	• Rupture • Refractory pain • Refractory hypertension
High risk PAU	• Diameter >13–20 mm • Depth >10 mm • Significant growth of diameter or depth • Associated saccular aneurysm • Increasing pleural effusion	• Persistent pain • Pleural effusion • Presence of IMH • Depth >10 mm • Diameter >20 mm	• Symptoms • Associated IMH • Increased pleural effusion	• Not specified	• Associated new haematoma • PAU width/depth increase • Total aortic diameter increase
Indication for TEVAR	• Complicated PAU (1, B) • Reasonable in PAU with associated IMH (2a, C) • May be considered in high risk uncomplicated PAU (2b, C)	• Should be considered in high risk PAU (2a, b)	• Patients with persistent symptoms or complications or evidence of disease progression (1, b) • Suggested in high risk PAUs (2, b)	• Should be considered for complicated PAUs (2a, C)	• Complicated PAU • May be considered in acute uncomplicated PAUs, only in the presence of high risk features

ACC = American College of Cardiology; AHA = American Heart Association; EACTS = European Association for Cardio Thoracic Surgery; STS = Society of Thoracic Surgeons; SVS = Society for Vascular Surgery; ESVS = European Society for Vascular Surgery; PAU = penetrating aortic ulcer; IMH = intramural haematoma; TEVAR = thoracic endovascular repair.

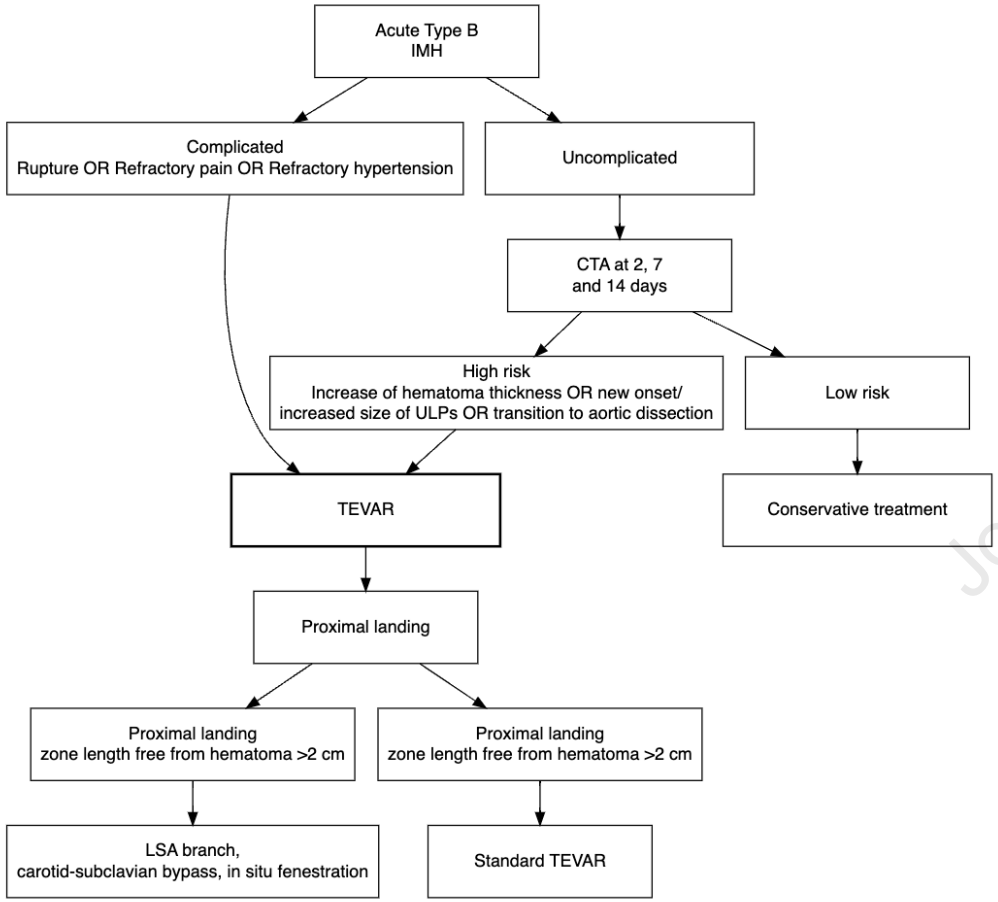
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A
B
C

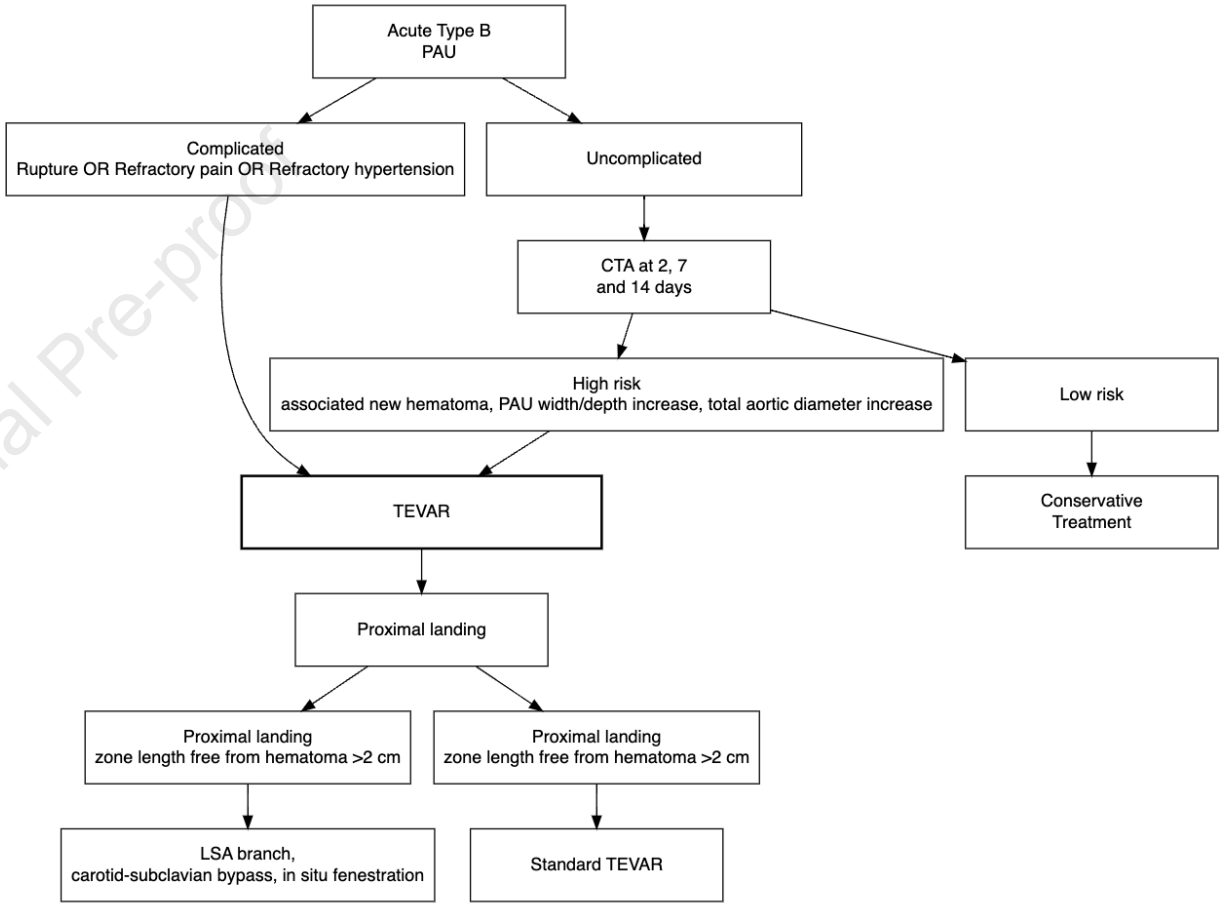

A
B

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A



B



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