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Special Article

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Management of anaesthesia for transfemoral transcatheter aortic valve implantation: an Italian interdisciplinary consensus statement

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Abstract

Background: Transfemoral transcatheter aortic valve implantation (TAVI) is a minimally invasive treatment for patients with severe aortic stenosis who are at elevated surgical risk. Despite widespread use, optimal periprocedural anaesthetic management remains highly variable, and evidence-based guidance is lacking.

Methods: An interdisciplinary panel of Italian experts in anaesthesiology, cardiology, and cardiac surgery conducted a systematic review of the literature and used the RAND/UCLA Appropriateness Method to evaluate 1032 clinical scenarios across a range of risk profiles and comorbid conditions. Ratings were conducted over three rounds, including a moderated in-person meeting to refine and discuss appropriateness scores.

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Results: A minimally invasive approach, local anaesthesia alone, and conscious sedation were judged appropriate across most clinical scenarios. Invasive monitoring, such as placement of an additional arterial catheter or a central venous catheter, was recommended only in selected high-risk patients. Several approaches or interventions were consistently rated inappropriate across all evaluated scenarios, including nurse-administered anaesthesia, pulmonary artery catheterisation, and cardiac output monitoring using pulse wave analysis. Other approaches, such as general anaesthesia and deep sedation, were considered inappropriate in most cases but retained uncertainty in select clinical contexts. Several recommendations were rated as necessary to define a minimum standard of care.

Conclusions: This Italian consensus statement provides practical, expert-driven recommendations to standardise anaesthetic care for transfemoral TAVI. While many recommendations reached strong consensus, areas of uncertainty remain, underscoring the need for further clinical research. Patient-centred, individualised decision-making remains essential, guided by institutional experience and procedural complexity.

Keywords: anaesthesia; cardiac surgery; cardiology; expert consensus; RAND/UCLA Appropriateness Method; transcatheter aortic valve implantation

Editor's key points

- This interdisciplinary Italian expert consensus statement provides recommendations for anaesthetic management in transfemoral transcatheter aortic valve implantation (TAVI) identifying both areas of agreement and topics requiring further research.
- Consensus supports local anaesthesia or conscious sedation as the preferred anaesthetic strategies for transfemoral TAVI, with invasive monitoring reserved for select high-risk patients.
- Nurse-administered anaesthesia, pulmonary artery catheterisation, and pulse wave analysis for cardiac output monitoring were deemed inappropriate across all clinical scenarios.

Transfemoral transcatheter aortic valve implantation (TAVI) is a widely adopted, minimally invasive technique for the treatment of aortic stenosis.[1] Advancements in technology and operator experience have led to a progressive streamlining of the procedure.[2] This evolution paved the way for a minimalist TAVI approach routinely used in several clinical centres with safety and efficacy comparable to conventional surgical strategies.[3–5]

Despite clinical success, considerable uncertainty persists regarding key aspects of TAVI anaesthetic management[6] such as the active involvement of anaesthesiologists, the adequacy of monitoring systems, and the selection of the most appropriate anaesthesia and pain management technique. Local and general anaesthesia administered by the procedural team represent the two extremes, with countless nuances in between. Similarly, pain management options vary from no intervention to regional anaesthesia.

A survey conducted among high-volume centres for TAVI in Italy, highlighted the substantial heterogeneity in management of patients who undergo this procedure. For example, fast-track protocols for TAVI patients were used in only 68% of centres. Urinary catheters were used in half of the hospitals, including 47% of those with fast-track protocols. The transfemoral approach is consistently the first choice, with conscious sedation being the preferred anaesthetic strategy (82%), while general anaesthesia is rarely required.[7] A subanalysis of a French Aortic National Registry reported a progressive increase in the use of local anaesthesia compared with general anaesthesia.[8] This variability highlights the necessity for a structured methodology to evaluate and standardise practices.

The RAND/UCLA Appropriateness Method is a tool for systematically evaluating medical procedures by combining the best available evidence with the collective judgement of expert panels. The RAND/UCLA method uses a structured approach, allowing experts to rate appropriateness across various clinical scenarios.[9] This method is particularly valuable where direct evidence may be limited, and clinical decision-making requires context-specific insights. An interdisciplinary, national task force was established by the Italian Association of Cardiothoracic Anaesthesiology and Intensive Care (ITACTAIC), the Italian Society of Interventional Cardiology (GISE), the Italian Society of Cardiac Surgery (SICCH), and the Italian Society of Anaesthesia, Analgesia, Resuscitation and Intensive Care (SIAARTI) consisting of Italian experts from various fields. This consensus-based guidance of the ITACTAIC task force, developed using the RAND/UCLA Appropriateness Method, aimed to identify optimal strategies and enhance decision-making frameworks for anaesthetic management during transfemoral TAVI procedures.

Methods

Study design

This study utilised the RAND/UCLA Appropriateness Method to systematically evaluate the appropriateness of anaesthesiologic strategies in transfemoral TAVI. The RAND/UCLA Appropriateness Method combines evidence synthesis and expert opinion to develop consensus-based guidelines. The RAND/UCLA Appropriateness Method is an evidence-based, modified Delphi technique in which an expert panel rates a series of statements for appropriateness across at least two rounds of voting. A moderated group discussion occurs between voting rounds in which no attempt is made to force consensus.

Panel formation

A multidisciplinary panel of Italian experts was convened including anaesthesiologists, cardiologists, cardiac surgeons,

and intensivists with extensive experience in TAVI. The expert panel was composed of eight members formally nominated by their respective national scientific societies (ITACTAIC, GISE, SICCH, SIAARTI). Selection criteria included recognised leadership within the nominee's field and diversity in institutional background. The panel consisted of eight members from diverse institutional settings. Six were cardiac anaesthetists and cardiac intensivists nominated by ITACTAIC and SIAARTI, one cardiologist nominated by the GISE, and one cardiac surgeon nominated by the SICCH. Members were selected based on expertise and contributions to clinical practice or research in the field. Conflicts of interest were transparently disclosed.

Literature review

A systematic search of PubMed, Cochrane Library, and EMBASE databases was conducted from inception to January 4, 2025 by two reviewers (MB, PB) to identify studies relevant to anaesthetic management in percutaneous valvular procedures. Inclusion criteria focused on randomised controlled trials, propensity score-matched studies, and case-matched observational studies addressing anaesthesia management and agents, monitoring systems, and pain management strategies in patients undergoing transfemoral TAVI. Data extraction was independently performed by two reviewers (TA, MD) collecting information on study design, methodology, sample size, interventions, and outcomes. Evidence was synthesised into an evidence report by two reviewers (TM, FM) including tables summarising study characteristics, key outcomes, and identified knowledge gaps. This report was distributed to panel members to guide their ratings and inform the consensus-building process. The panellists received the complete systematic review (including all supporting references used to inform the consensus process) which is available in Supplementary Material 1 and Supplementary Material 2. These articles, comprising 72 randomised trials or propensity score-matched analyses, represent the totality of published studies relevant to anaesthetic management in TAVI up to the date of the consensus (Supplementary Fig. 1).

Statement generation

Systematic literature review and expert opinion were used to generate the initial statement list. The selection of topics was guided by expert input and an extensive literature review. All interventions supported by at least one published clinical comparative study (randomised, propensity matched, or case matched) were assessed. We also assessed interventions which were not addressed in a comparative study but could be associated with significant risk or complications—or showed geographical variation. Interventions were grouped into six sections: monitoring; anaesthetic techniques; intraprocedural treatments; antithrombotic management; intraprocedural strategies; and periprocedural strategies.

The clinical scenarios (detailed in Supplementary Material 3) were initially identified by clinicians with extensive expertise in TAVI, nominated by the ITACTAIC in collaboration with members of the research team experienced in the RAND/UCLA Appropriateness Method. These scenarios were reviewed and refined based on panellists' feedback before the first round of voting. During the in-person consensus meeting, scenarios with interpretative ambiguity were revised by unanimous agreement.

Patients were stratified into two categories based on perioperative risk (high-risk and low- to moderate-risk groups). High-risk categories were those with a Society of Thoracic Surgeons Predicted Risk of Mortality $\geq$8% or European System for Cardiac Operative Risk Evaluation $\geq$15%.[9,10] Left ventricular ejection fraction (LVEF >30% or <30%) was used to identify two further groups of risk.

All 37 items (e.g. general anaesthesia, additional arterial catheter) were assessed across a range of nine clinical scenarios: haemodynamic instability, untreated coronary artery disease (CAD) requiring revascularisation, right ventricular (RV) dysfunction, severe chronic obstructive pulmonary disease (COPD), renal failure stage $\geq$3, liver cirrhosis, cognitive impairment or dementia affecting patient cooperation, disorders limiting prolonged immobilisation, and local anaesthesia allergy (defined as a documented hypersensitivity confirmed by an allergist) (Supplementary Material 3).

Consensus process

The first round was conducted via e-mail. The panellists received the literature review, list of clinical scenarios (indications), definitions of terms, and instructions for rating. For each indication, the panel members rated the benefit-to-harm ratio of the procedure on a scale of 1–9, where 1 means that the expected harms greatly outweigh the expected benefits, and 9 means that the expected benefits greatly outweigh the expected harms. A middle rating of 5 may indicate either that the expected benefits and potential harms of the procedure are approximately balanced, or that the rater could not determine the appropriateness of the intervention for the specific patient scenario described.[11] In accordance with the RAND/UCLA Appropriateness Method guidelines, intermediate median values (e.g. 3.5 and 6.5) were rounded up and assigned to the higher appropriateness category.

During the second round, panellists participated in an in-person meeting and were invited to discuss their ratings considering aggregated group results and individual responses. This round allowed for structured discussion and refinement of ratings, using updated forms that included the frequency of responses and each panellist's prior ratings. This second in-person round involved 11 participants: eight voting panellists with recognised expertise in the field, and three non-voting moderators who facilitated the RAND/UCLA Appropriateness Method process and ensured methodological rigour. Indications were then classified into three levels of appropriateness based on the panellists' median ratings and level of agreement and were classified as appropriate, uncertain or inappropriate.

In a third round conducted via e-mail, panellists evaluated the necessity of the indications that had been classified as appropriate in the second round (Fig. 1). This final round determined whether indications were 'appropriate and necessary', 'appropriate but not necessary', 'uncertain' or 'inappropriate'.

Statistical analysis

The median appropriateness rating for each statement and rating distribution, as expressed by the interquartile range (IQR), were calculated. Indications with a median rating of 7–9 and no disagreement were classified as appropriate. Those with a median rating of 4–6 or any median accompanied by disagreement were categorised as uncertain. Indications with

a median rating of 1–3 and no disagreement were deemed inappropriate.[11]

The level of agreement is expressed as the disagreement index (DI) that is based on the interpercentile range (IPR) (difference between the 66th and 33rd centiles appropriateness score) with a correction factor for asymmetry. To ensure equitable participation, all eight panellists had equal voting rights, irrespective of their specialty. The potential impact of asymmetry in panel composition was addressed using the RAND/UCLA Appropriateness Method's formal procedure for detecting disagreement. Specifically, disagreement was evaluated by calculating the DI, defined as the ratio between the IPR and the IPR adjusted for symmetry (IPRAS). The IPRAS was derived by adjusting a reference IPR (IPRr) according to the degree of asymmetry in the ratings, using the asymmetry index and a correction factor for asymmetry, as outlined in the RAND/UCLA Appropriateness Method manual. A DI >1 indicated the presence of disagreement among panellists. In such cases, regardless of the median score, the intervention was not classified as appropriate. The writing group used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) network classification for strength of recommendation (I=strong; II=weak) and for quality of evidence (a=high; b=moderate; c=low). The maximum achievable quality of evidence was 'c' if the results were solely based on the consensus process. A median appropriateness score of >7.9 and DI <0.5 indicated a strong recommendation (GRADE Ic). Disagreement was identified if DI was >1.[12,13]

Results

The round one survey consisted of 37 items and 994 initial statements in different clinical scenarios. In total, 334 statements (34%) were rated as appropriate, 269 (27%) as inappropriate, and 391 (39%) as uncertain. After the group discussion, two new items and 52 new statements were added to the survey, and one item and 14 statements were removed. Thus, 38 items for a total of 1032 statements were included in round two of the survey (Supplementary Material 3). The 1032 statements examined in round two resulted from the combination of 38 clinical items with the predefined clinical scenarios and risk classes. For instance, the use of an arterial catheter (item) was assessed in patients with haemodynamic instability and LVEF <30% in the high-risk class (scenario), or the appropriateness of central venous catheterisation (item) was evaluated in patients with untreated CAD and LVEF >30% in the low-risk class (Supplementary Table 1). After the second round of voting, 289 statements (28%) were rated as appropriate, 506 (49%) as inappropriate, and 237 (23%) as uncertain (Tables 1 and 2). All recommendations were informed by the structured literature review, which included 72 randomised or propensity score-matched studies. This evidence was reviewed by all panellists and integrated into the appropriateness ratings, alongside clinical expertise, using the RAND/UCLA Appropriateness Method.

Monitoring

The placement of an additional arterial catheter received a strong recommendation in high-risk patients with haemodynamic instability and in all (high- and low-moderate-risk) patients with RV dysfunction and an LVEF <30% (strong recommendation, GRADE Ic). The placement of an additional arterial catheter was still deemed appropriate, but with a weak recommendation (weak recommendation, GRADE IIc) in patients with haemodynamic instability (irrespective of surgical risk or LVEF), in high-risk patients with specific comorbidities (liver cirrhosis with LVEF <30%, untreated CAD, RV dysfunction, severe COPD with LVEF <30%, and chronic kidney disease stage 3 or higher).

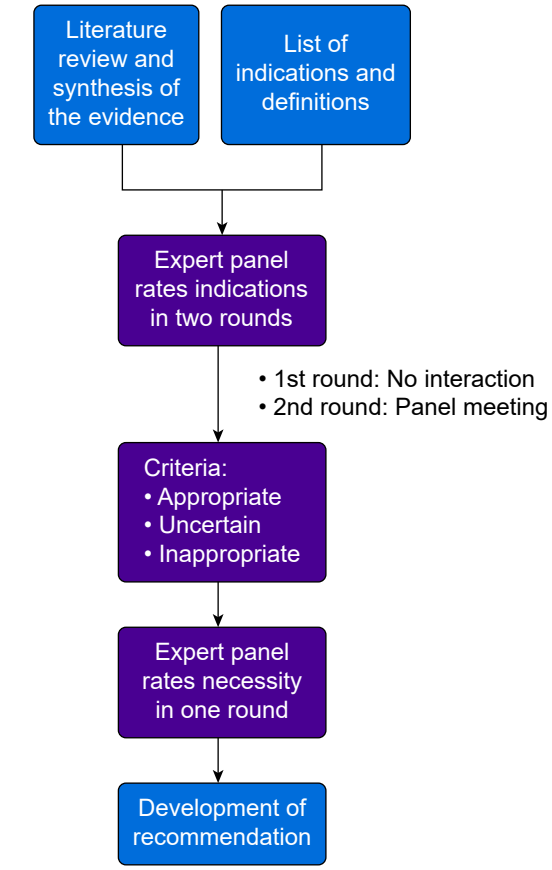

Fig 1. Flowchart of Italian consensus guidance for anaesthetic management in transcatheter aortic valve implantation.

Central venous catheter placement was strongly recommended (GRADE Ic with clinical benefit considered clear and substantial) in: high-risk patients with haemodynamic instability; in all patients with RV dysfunction or untreated CAD when combined with an LVEF <30%; low-risk patients presenting with both haemodynamic instability and LVEF <30%. Conversely, central venous catheter placement was deemed appropriate, but with a weak recommendation (GRADE IIc) in high-risk patients with haemodynamic instability, untreated CAD, or RV dysfunction. Central venous catheter placement was judged inappropriate (strong recommendation, GRADE Ic) in low- to moderate-risk patients with cognitive impairment or significant functional limitations, where the potential risks of catheterisation were outweighed by the expected benefits.

Urinary catheterisation was considered appropriate only in high-risk patients with severely reduced LVEF and advanced chronic kidney disease (weak recommendation, GRADE IIc). In low- to moderate-risk patients with limited mobility, cognitive

Table 1 Consensus-based recommendations for periprocedural management in patients undergoing transcatheter aortic valve implantation. Appropriate: indications with a median rating of 7–9 and no disagreement. Uncertain: indications with a median rating of 4–6 or any median accompanied by disagreement. Inappropriate: indications with a median rating of 1–3 and no disagreement. ACT, activated clotting time; BIS, bispectral index; CAD, coronary artery disease; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; ECMO, extracorporeal membrane oxygenation; F_{IO_2}, fraction of inspired oxygen; LVEF, left ventricular ejection fraction; RV, right ventricular; TAVI, transcatheter aortic valve implantation.

	Statement	Appropriateness	GRADE
1	Use of an additional arterial catheter in high-risk patients with haemodynamic instability and RV dysfunction with LVEF <30%.	Appropriate	Ic
2	Use of central venous catheter in high-risk patients with haemodynamic instability, RV dysfunction, untreated CAD, and LVEF <30%, or in low-risk patients with haemodynamic instability and LVEF <30%.	Appropriate	Ic
3	Use of conscious sedation technique in patients with allergy to local anaesthetics, liver cirrhosis, untreated CAD, RV dysfunction, severe COPD, or CKD stage ≥3.	Appropriate	Ic
4	Use of local anaesthesia technique in patients with haemodynamic instability, liver cirrhosis, untreated CAD, RV dysfunction, severe COPD, and CKD stage ≥3.	Appropriate	Ic
5	Adoption of a minimally invasive approach in patients with limited mobility, allergy history, cognitive impairment, liver cirrhosis, severe COPD, CKD stage ≥3, and in low-risk patients with haemodynamic instability, untreated CAD, or RV dysfunction.	Appropriate	Ic
6	Use of remimazolam in patients undergoing TAVI.	Appropriate	Ic
7	Use of rapid pacing is appropriate in patients undergoing TAVI.	Appropriate	Ic
8	Use of left ventricular pacing in patients undergoing TAVI.	Appropriate	Ic
9	Use of bivalirudin in patients with heparin allergy or heparin-induced thrombocytopenia and thrombosis.	Appropriate	Ic
10	Use of an additional arterial catheter in high-risk patients with specific comorbidities (e.g. liver cirrhosis with LVEF <30%, untreated CAD, RV dysfunction with LVEF >30%, severe COPD with LVEF <30%, CKD stage ≥3).	Appropriate	IIc
11	Use of central venous access in high-risk patients with haemodynamic instability, untreated CAD, RV dysfunction, or severe COPD with LVEF <30%.	Appropriate	IIc
12	Use of urinary catheterisation in high-risk patients with severely reduced LVEF and advanced CKD.	Appropriate	IIc
13	Use of conscious sedation in patients undergoing TAVI.	Appropriate	IIc
14	Use of local anaesthesia technique in patients undergoing TAVI.	Appropriate	IIc
15	Use of deep sedation in patients with limited mobility, allergy history, or cognitive impairment in high-risk patients with LVEF >30%.	Appropriate	IIc
16	Adoption of a minimally invasive approach in patients undergoing TAVI.	Appropriate	IIc
17	Use of propofol in patients with cognitive impairment, dementia, or poor cooperation, limited mobility, liver cirrhosis, CKD stage ≥3, severe COPD, or untreated CAD requiring revascularisation.	Appropriate	IIc
18	Use of dexmedetomidine for conscious sedation in patients with cognitive impairment, dementia, poor cooperation, limited mobility, liver cirrhosis, CKD stage ≥3, severe COPD, untreated CAD requiring revascularisation, haemodynamic instability, LVEF <30%, or RV dysfunction.	Appropriate	IIc
19	Use of dexmedetomidine for general anaesthesia in patients with cognitive impairment, dementia, poor cooperation, limited mobility, liver cirrhosis, CKD stage ≥3, severe COPD, or untreated CAD requiring revascularisation.	Appropriate	IIc
20	Use of ACT-based heparin administration in patients undergoing TAVI.	Appropriate	IIc
21	Preoperative darbepoetin alfa with iron optimisation in patients undergoing TAVI.	Appropriate	IIc
22	Use of high-flow nasal oxygen in high-risk patients with haemodynamic instability and untreated coronary artery disease requiring revascularisation.	Appropriate	IIc
23	Use of low *vs* high F_{IO_2} target in patients with COPD, cognitive impairment, dementia, poor cooperation, disorders limiting prolonged immobilisation, haemodynamic instability, liver cirrhosis, CKD stage ≥3, or RV dysfunction.	Appropriate	IIc
24	Use of physiotherapy in patients undergoing TAVI.	Appropriate	IIc
25	Use of audiovisual distraction in patients with disorders limiting prolonged immobilisation.	Appropriate	IIc
26	Use of central venous access in low- to moderate-risk patients with cognitive impairment or significant functional limitations.	Inappropriate	Ic
27	Use of urinary catheterisation in low- to moderate-risk patients with conditions such as limited mobility, cognitive impairment, liver disease, RV dysfunction with LVEF >30%, severe COPD, or untreated CAD.	Inappropriate	Ic
28	Use of the RenalGuard system.	Inappropriate	Ic
29	Use of pulse contour analysis.	Inappropriate	Ic
30	Use of Swan–Ganz catheterisation.	Inappropriate	Ic
31	Use of BIS monitoring in low-risk patients undergoing TAVI.	Inappropriate	Ic
32	Use of local anaesthesia technique in patients with a documented allergy to local anaesthetics.	Inappropriate	Ic
33	Use of deep sedation in patients with untreated CAD, liver cirrhosis, RV dysfunction, severe COPD, haemodynamic instability, or in high-risk settings.	Inappropriate	Ic
34	Use of general anaesthesia in patients with haemodynamic instability, liver cirrhosis, renal failure, RV dysfunction, severe COPD, or untreated CAD.	Inappropriate	Ic
35	Nurse-administered anaesthesia in patients undergoing TAVI.	Inappropriate	Ic
36	Use of supraglottic airway devices in haemodynamic instability, liver cirrhosis, renal failure stage ≥3, right ventricular dysfunction.	Inappropriate	Ic
37	Use of regional anaesthesia technique in patients undergoing TAVI.	Inappropriate	Ic
38	Use of adenosine in all clinical contexts and risk category.	Inappropriate	Ic
39	Use of prophylactic ECMO in all clinical contexts and risk category.	Inappropriate	Ic
40	Use of remote ischaemic preconditioning in patients undergoing TAVI.	Inappropriate	Ic
41	Use of bivalirudin instead of heparin in patients undergoing TAVI.	Inappropriate	Ic
42	Use of protamine 0.5 mg, instead of 1 mg, per 100 IU of heparin in patients undergoing TAVI	Inappropriate	Ic
43	Withheld anticoagulation in patients undergoing TAVI.	Inappropriate	Ic
44	Use of bioimpedance spectroscopy-guided decongestion in patients undergoing TAVI.	Inappropriate	Ic
45	Use of intracardiac echography in patients undergoing TAVI.	Inappropriate	Ic
46	Use of mild hypothermia in patients undergoing TAVI.	Inappropriate	Ic
47	Use of transoesophageal echocardiography in patients undergoing TAVI.	Inappropriate	Ic

Table 2 Summary of appropriateness ratings across main intervention categories. ACT, activated clotting time; ECMO, extracorporeal membrane oxygenation; UFH, unfractionated heparin.

Item	Number of clinical scenario	Number of areas of appropriateness	Number of areas of inappropriateness	Number of areas of uncertainty
Anaesthetic technique				
Conscious sedation	36	36	0	0
Deep sedation	36	6	13	17
General anaesthesia	36	0	17	19
Local anaesthesia	36	33	1	2
Minimally invasive approach	36	36	0	0
Nurse anaesthesia	36	0	36	0
Regional anaesthesia	36	0	29	7
Supraglottic airway device	36	0	9	27
Monitoring				
Arterial catheter	32	12	0	20
Urinary catheter	32	1	20	11
Central venous catheter	32	9	4	19
Bispectral index	32	0	13	19
Pulse contour analysis	32	0	32	0
Pulmonary artery catheterisation	32	0	32	0
Renal guards	32	0	32	0
Medication and interventions				
Adenosine	36	0	36	0
Corticosteroids	36	0	36	0
Prophylactic ECMO	36	0	36	0
Propofol	36	20	0	16
Rapid pacing	36	36	0	0
Remimazolam	36	36	0	0
Remote ischaemic preconditioning	36	0	36	0
Antithrombotic management				
0.5 mg *vs* 1 mg protamine	14	0	14	0
ACT-based *vs* weight based heparin administration	14	14	0	0
Bivalirudin *vs* UFH	16	2	14	0
Continued *vs* withheld anticoagulation	14	0	14	0
Intraprocedural and periprocedural strategy				
Preoperative darbepoetin alpha + iron	14	14	0	0
Bioimpedance spectroscopy-guided decongestion	16	0	14	0
High-flow oxygen	14	3	11	0
Intracardiac echography	14	0	14	0
Low *vs* high F_{IO_2} target	14	7	0	7
Mild hypothermia	14	0	14	0
Audiovisual distraction	8	0	1	7
Physiotherapy	8	8	0	0

impairment, liver disease, RV dysfunction with LVEF >30%, severe COPD, or untreated CAD, urinary catheterisation was deemed inappropriate (strong recommendation, GRADE Ic).

Both pulse wave analysis and pulmonary artery catheterisation were considered always inappropriate, regardless of risk profile or cardiac function (strong recommendation, GRADE Ic). Bispectral index monitoring and the use of renal guards were generally rated inappropriate, especially in low-risk patients (strong recommendation, GRADE Ic).

The results of consensus on monitoring are reported in Supplementary Table 1 and Supplementary Figures 2 and 3. Figure 2 shows an algorithm for invasive monitoring during TAVI.

Anaesthetic technique

Conscious sedation received a strong recommendation (GRADE Ic) in patients with allergy to local anaesthetics, liver cirrhosis, untreated CAD, RV dysfunction, severe COPD, and stage 3 or higher chronic kidney disease. In the broader population, conscious sedation was judged appropriate across almost all clinical scenarios and risk groups, although with a weak recommendation (GRADE IIc).

Local anaesthesia without sedation received a strong recommendation (GRADE Ic) in patients with haemodynamic instability, liver cirrhosis, untreated CAD, RV dysfunction, severe COPD, and chronic kidney disease stage 3 or higher. Local anaesthesia technique was rated as inappropriate in patients with a documented allergy to local anaesthetics (strong recommendation, GRADE Ic).

More broadly, local anaesthesia alone was judged appropriate in most clinical scenarios, although with a weak recommendation (GRADE IIc). It is important to clarify that 'local anaesthesia' in this context refers to procedures performed under local infiltration without additional sedation, but always with an anaesthesiologist readily available on site according to local and regional practice arrangements.

Deep sedation was considered inappropriate in most clinical scenarios (strong recommendation, GRADE Ic), with

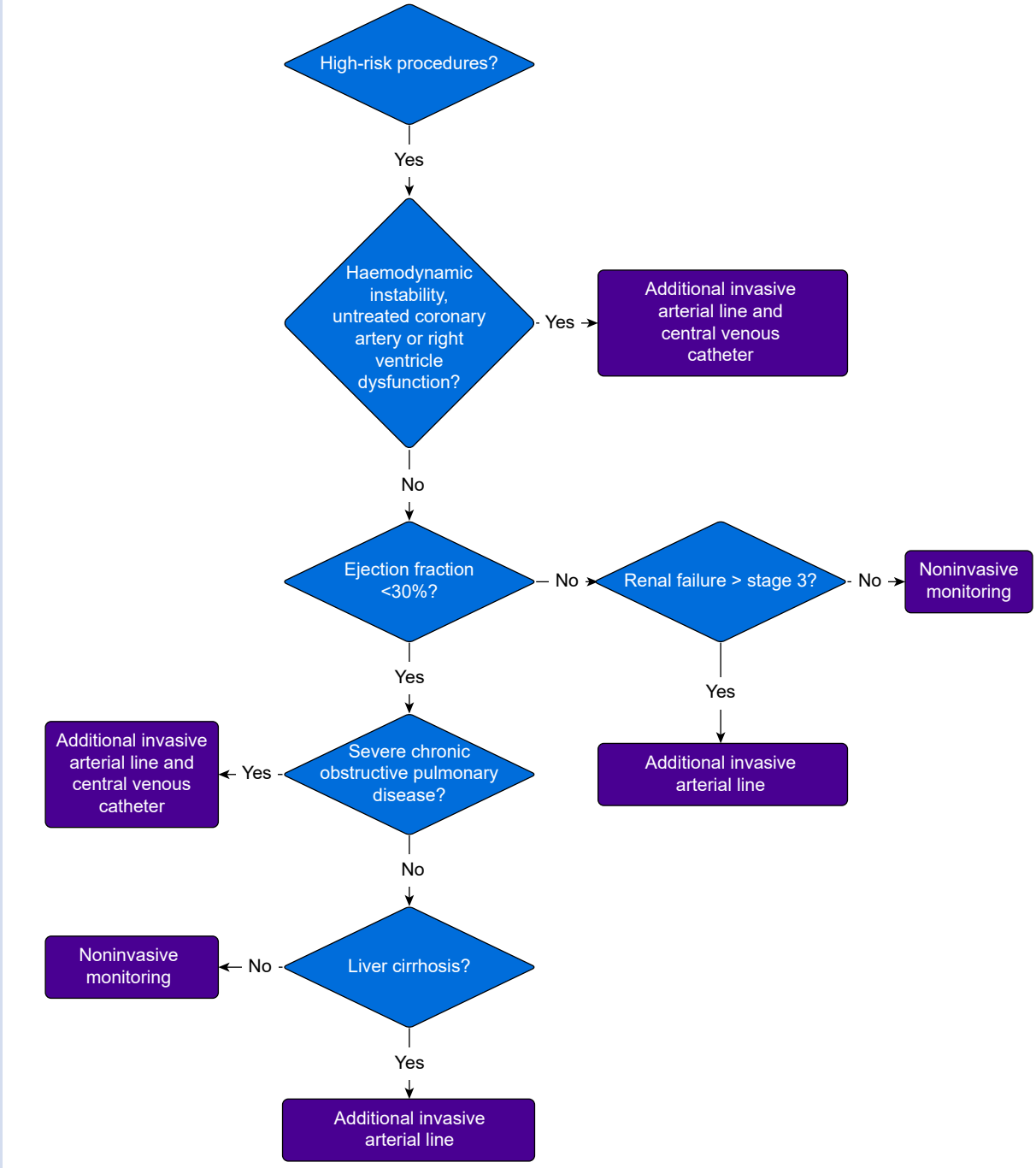

Fig 2. Algorithm for invasive monitoring during percutaneous valvular procedures in high-risk procedure.

appropriateness limited to patients with disorders limiting prolonged immobilisation, history of allergy to local anaesthetics or cognitive impairment (weak recommendation, GRADE IIc).

General anaesthesia was rated inappropriate in patients with haemodynamic instability, liver cirrhosis, renal failure, RV dysfunction, severe COPD, or untreated CAD (strong recommendation, GRADE Ic). No case of appropriateness was identified, while uncertainty was frequent.

The minimally invasive approach (defined in Supplementary Material 4) received a strong recommendation (GRADE Ic) across all clinical scenarios and patient categories, except in high-risk patients with haemodynamic instability, untreated CAD, and RV dysfunction where the rating was weak (weak recommendation, GRADE IIc). No scenarios were rated as inappropriate.

Supraglottic airway device was rated inappropriate in haemodynamic instability, liver cirrhosis, stage 3 or higher

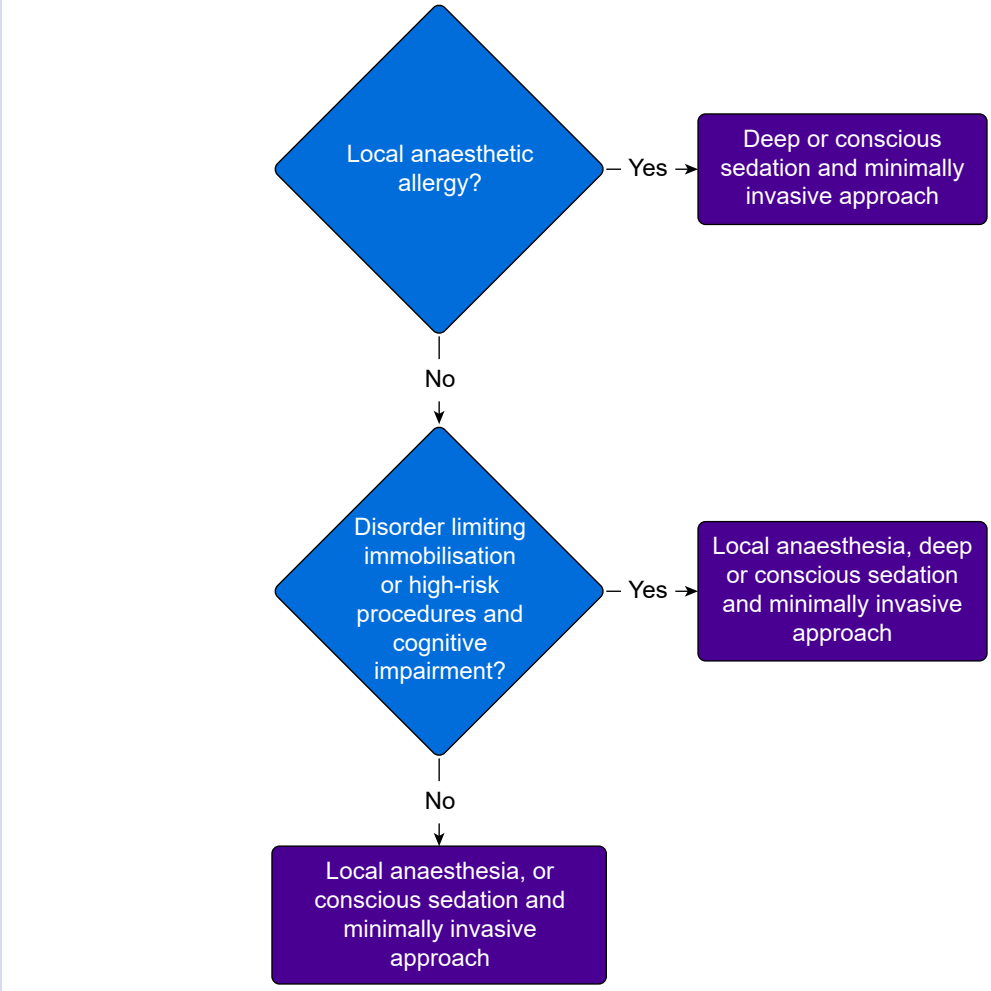

Fig 3. Algorithm for anaesthetic technique during percutaneous valvular procedures.

chronic kidney disease, and RV dysfunction (strong recommendation, GRADE Ic).

Nurse anaesthesia and regional anaesthesia were rated inappropriate in all evaluated clinical contexts (strong recommendation, GRADE Ic). Results of consensus on anaesthetic technique are reported in Supplementary Table 2 and Supplementary Figures 4 and 5. Figure 3 and Supplementary Figure 6 show the algorithm for anaesthetic technique during TAVI.

Medications

The use of propofol was rated as uncertain in patients with LVEF <30%, haemodynamic instability, or RV dysfunction, but appropriate in other conditions, with a weak recommendation (weak recommendation, GRADE IIc). The use of remimazolam received a strong recommendation (GRADE Ic). Dexmedetomidine was also considered appropriate in most evaluated clinical contexts, although the recommendation remained weak (GRADE IIc). Both rapid pacing and left ventricular pacing were strongly recommended in patients undergoing TAVI (strong recommendation, GRADE Ic). Conversely, the use of adenosine, prophylactic extracorporeal membrane oxygenation (ECMO), and remote ischaemic preconditioning was deemed inappropriate in all evaluated clinical scenarios, with a strong recommendation against their use (strong recommendation, GRADE Ic). Results of consensus on medication are reported in Supplementary Table 3.

Antithrombotic management

Activated clotting time (ACT)-based heparin management and preoperative optimisation with darbepoetin alfa combined with iron were considered appropriate across all evaluated clinical contexts, although the recommendation was weak (weak recommendation, GRADE IIc). The use of bivalirudin was judged appropriate only in patients with a documented allergy to heparin or in cases of heparin-induced thrombocytopenia and thrombosis. In these specific scenarios, the use of bivalirudin was strongly recommended (strong recommendation, GRADE Ic).

The administration of protamine 0.5 mg per 100 IU of heparin, instead of 1 mg per 100 IU of heparin, and withholding or continuing anticoagulation without adjustment,

were considered inappropriate in all evaluated clinical contexts, with a strong recommendation against their use (strong recommendation, GRADE Ic). Results of consensus on antithrombotic management are reported in Supplementary Table 4.

Intraprocedural and periprocedural strategy

The use of high-flow nasal oxygen was considered appropriate in haemodynamic instability and untreated CAD requiring revascularisation in high-risk patients (weak recommendation, GRADE IIc). Low *vs* high F_{IO_2} target was considered appropriate in most scenarios (weak recommendation, GRADE IIc); however, it was rated uncertain in patients with untreated CAD requiring revascularisation.

The use of bioimpedance spectroscopy-guided decongestion, intracardiac echography, mild hypothermia, and transoesophageal echography were considered inappropriate in all evaluated clinical contexts (strong recommendation, GRADE Ic).

Among periprocedural strategies, physiotherapy was considered appropriate in all clinical scenarios (weak recommendation, GRADE IIc), while audiovisual distraction was considered uncertain. Results of consensus on intraprocedural strategy were reported in Supplementary Tables 5 and 6.

Rating of necessity

Interventions rated as necessary represent the minimum acceptable standard of care. According to the RAND/UCLA Appropriateness Method, an intervention is deemed necessary when the expected benefits clearly outweigh the risks to such an extent that not performing at least this level of care would be considered poor clinical practice. While these interventions define the baseline level of care that cannot be compromised, they do not exclude the possibility of providing additional or more intensive treatments when clinically justified.

According to the RAND/UCLA Appropriateness Method, several interventions were rated as necessary in defined clinical contexts. The placement of an additional arterial catheter was deemed necessary in high-risk patients with haemodynamic instability, and in low-risk patients with haemodynamic instability and LVEF <30%. Central venous catheterisation was rated necessary in all patients presenting with haemodynamic instability, regardless of risk profile. Performing the procedure under local anaesthesia alone was judged necessary in all patients, except those with contraindications such as allergy to local anaesthetics, cognitive impairment, poor cooperation, or severely limited mobility. In these cases, conscious sedation was considered the minimum necessary technique. Adoption of a minimally invasive approach was judged necessary across all patient categories. Similarly, the use of rapid pacing and ACT-based heparin administration were both considered necessary in all evaluated patients.

Discussion

This Italian expert consensus statement provides a comprehensive evaluation of anaesthesiological management strategies for patients undergoing TAVI. The panel reached strong consensus on several key issues. In a limited number of cases, uncertainty remained, likely reflecting the heterogeneity of the expert panel and the diversity of clinical perspectives across specialties. This multidisciplinary composition, while enriching the consensus process, may have contributed to areas of disagreement where the balance of risks and benefits remains unclear. Nearly 40% of clinical scenarios in the first round and 23% in the second round were classified as uncertain. These uncertainties point to critical areas for future research.

Conscious sedation and a minimally invasive approach were broadly endorsed across nearly all patient profiles and clinical scenarios. Although appropriateness ratings were determined without considering economic implications, the panel judged that, in selected scenarios, a minimalist approach may be appropriate indicating that the expected benefits outweigh the risks according to expert evaluation. This judgement reflects the structured consensus process in areas where high-quality evidence is limited (level of evidence 'c').

Similarly, the selective use of invasive monitoring—such as placement of an additional arterial catheter or a central venous catheter—was deemed appropriate only in specific high-risk contexts. The use of an additional arterial catheter was rated as appropriate in most clinical scenarios, with no instances of inappropriateness, reflecting broad expert consensus on its utility and the absence of clinical conditions where its use was considered to pose greater risks than benefits. The use of a central venous catheter was rated as appropriate in several high-risk scenarios, while in many others consensus was not reached, reflecting variability in clinical judgement among panellists from different specialties. Notably, central venous catheter placement was rated as inappropriate only in low-risk procedures when based solely on the presence of cognitive impairment, dementia, poor cooperation, or disorders limiting prolonged immobilisation, in the absence of additional risk factors.

The use of remimazolam, dexmedetomidine, and rapid or left ventricular pacing also received strong recommendations. Conversely, general anaesthesia, nurse-administered anaesthesia, supraglottic airway devices, and some advanced monitoring techniques (e.g. bispectral index and pulmonary artery catheterisation) were consistently rated as inappropriate.

The panel did not assess contraindications or prescriptive indications, but rather the balance between expected benefits and risks when based solely on the defined clinical scenario. In particular, for general anaesthesia, the existing literature remains overall neutral when compared with conscious sedation. Nonetheless, the panellists judged its routine use as inappropriate in specific scenarios, based on their interpretation of the evidence and clinical experience. The final anaesthetic strategy remains the responsibility of the treating physician, considering each patient's individual characteristics and procedural complexity. Local anaesthesia alone was rated as appropriate in most scenarios, including cases of haemodynamic instability, based on the panel's judgement that the expected benefits outweigh the potential risks. This does not imply that local anaesthesia is mandatory, and the final anaesthetic strategy remains under the responsibility of the treating physician.

Our findings reflect a growing trend towards fast-track TAVI protocols that prioritise patient safety, procedural efficiency, and resource optimisation. Although 30-day mortality after TAVI has substantially decreased to ~1–2% in most countries, procedure-related morbidity remains significant.[14] Recent data indicate that major or life-threatening complications may occur in up to 10% of cases, with a relevant

incidence of surgical conversion and permanent pacemaker implantation.[14] Therefore, while a minimalist anaesthetic approach is increasingly adopted, it should not be viewed as universally applicable. Differences in national practice patterns and institutional readiness must be considered, and anaesthetic strategies should remain tailored to patient- and procedure-specific risks.[15] The DOUBLE-CHOICE trial was published after the completion of our Delphi process and, therefore, was not included in the evidence reviewed by the panellists.[16] This multicentre, randomised, non-inferiority trial enrolled 752 patients undergoing transfemoral TAVI and compared a minimalist approach with isolated local anaesthesia with standard of care with conscious sedation. At 30 days, the minimalist approach was non-inferior to standard of care for the composite primary endpoint of all-cause mortality, vascular and bleeding complications, infections requiring antibiotic therapy, and neurological events.[16] However, almost 20% of patients assigned to the minimalist strategy required conversion to conscious sedation, most frequently because of pain or agitation, and self-reported stress and anxiety levels during the procedure were significantly higher compared with the standard of care.[16] These findings confirmed the feasibility and safety of minimalist strategies but also underscored the importance of careful patient selection and the role of structured monitoring and collaboration between cardiologists and anaesthesiologists. As this trial was not available at the time of the consensus process, its results could not influence the panel's voting, but they represent an important addition to the evolving evidence base.

The endorsement of conscious sedation and reduced invasiveness aligns with broader efforts to minimise perioperative complications and facilitate early mobilisation and discharge. The recommendations also clarify the role of specific interventions, providing structured guidance to assist centres in decision-making processes and protocol development.

The use of urinary catheters was rated as appropriate in patients with severely reduced LVEF or advanced chronic kidney disease, where accurate fluid monitoring may be essential. In contrast, in many other scenarios, particularly in lower-risk patients, the appropriateness was rated as uncertain or inappropriate. These ratings reflect that routine catheterisation may not be justified based solely on isolated comorbidities. However, the final decision remains at the discretion of the treating clinician, considering individual patient history and procedural duration. This aligns with current evidence discouraging routine catheter use in short procedures unless clinically indicated.[17,18]

Haemoglobin optimisation with darbepoetin alpha and iron was rated as appropriate in all scenarios. The intervention was assigned a level of evidence 'IIc', reflecting limited supporting data and expert agreement that the expected benefits may outweigh the risks, though it was not considered mandatory (rating for necessity). The panel evaluated the appropriateness of bispectral index monitoring as a routine intervention across all TAVI procedures, independent of anaesthetic technique. However, the specific context of general anaesthesia with total intravenous anaesthesia was not separately assessed. It is acknowledged that, in the setting of total intravenous anaesthesia, the use of bispectral index or comparable depth-of-anaesthesia monitoring is widely recommended and often considered standard of care. The routine use of transoesophageal echocardiography in standard TAVI procedures was rated as inappropriate, based on expert consensus and in the absence of robust supporting evidence. However, clinicians may still consider its use appropriate in selected emergency scenarios or complex cases where additional imaging guidance is deemed clinically beneficial.[19] Although rapid pacing is a procedural prerequisite for TAVI, the inclusion of specific pacing strategies—particularly left ventricular pacing as an alternative to the more commonly used RV approach—was intended to address their potential implications. The panel was asked to evaluate whether, in selected clinical scenarios, left ventricular pacing might offer a favourable perioperative risk–benefit profile, especially in terms of haemodynamic tolerance and anaesthetic management.

Notably, all interventions rated as inappropriate received a median score of 1, indicating a very high degree of consensus among panellists. This uniformity reflects a shared perception across specialties that, in the specified clinical scenarios, the potential risks of these interventions consistently outweigh their anticipated benefits.

Despite growing interest in optimising anaesthetic strategies for TAVI,[20–22] most available studies are observational, retrospective, or single-centre experiences, with limited external validity and heterogeneity in reported outcomes.[23] While meta-analyses have suggested potential benefits of minimalist approaches, including local or conscious sedation techniques,[23–25] randomised evidence remains scarce and often inconclusive.[26] In particular, trials such as SOLVE-TAVI demonstrated clinical equipoise between general and conscious sedation, reinforcing the need for individualised decision-making.[26] Current guidelines for cardiac surgery procedures offer minimal anaesthetic-specific guidance,[27] and there is no internationally accepted framework for procedural monitoring or supportive care in high-risk subsets. This consensus effort attempts to address that gap by providing systematically derived appropriateness ratings across a range of realistic clinical scenarios, thereby complementing rather than replacing clinical judgement.

This consensus document was developed using a modified Delphi methodology, a well-recognised approach that has been applied successfully in numerous similar initiatives. By integrating targeted literature review with multidisciplinary expert input, the aim was to generate practical guidance in areas where clinical uncertainty remains. While the process did not involve a formal meta-analysis, it was grounded in comprehensive discussion and the collective expertise of the panel. Although the RAND/UCLA Appropriateness Method ensures a rigorous and transparent process, the consensus is inherently influenced by expert opinion. The limited number of panellists, despite their recognised expertise, may not fully capture the diversity of clinical practice. Moreover, the absence of randomised controlled trials for several scenarios limited the strength of supporting evidence, with most recommendations rated as GRADE IIc. Given the limited and heterogeneous nature of the available data, all statements were conservatively rated as level of evidence 'c'. While this reflects a limitation in terms of the underlying evidence base, it also represents a strength of the consensus process, ensuring that recommendations are grounded in a cautious, balanced interpretation of the literature. This consensus specifically focuses on the anaesthesiologic management of patients undergoing *transfemoral* TAVI, which currently represents the predominant access route. Other alternative approaches (e.g. transapical, transaxillary) were not within the

scope of this work. RV dysfunction, defined as tricuspid annular plane systolic excursion (TAPSE) <18 mm, was included among the prespecified risk factors guiding anaesthetic strategy. While other important determinants, such as pulmonary hypertension,[28] may significantly impact perioperative risk, it was not feasible to incorporate every possible clinical variable into the structured consensus process. Given the limited availability of high-quality evidence in several of the clinical scenarios considered, all recommendations were classified as level of evidence 'c' according to the GRADE framework, reflecting reliance on structured expert consensus. However, the underlying literature review includes 72 randomised trials or propensity score-matched studies—representing all relevant trials published to date on anaesthetic management in TAVI. The RAND/UCLA Appropriateness Method was applied specifically to address areas of uncertainty and variability, allowing integration of this evidence with multidisciplinary expert judgement. Although the panel was composed exclusively of Italian experts, this experience reflects a robust practice environment: Italy performs approximately 171 TAVI procedures per million inhabitants, a rate above the current European average of around 138 cases per million.[29] The participating centres represent a spectrum of institutional models and procedural volumes, thereby mirroring elements common to high-performing programmes internationally. Moreover, the RAND/UCLA Appropriateness Method emphasises the evaluation of appropriateness in relation to clinical contexts rather than institutional norms, making the resulting recommendations broadly adaptable. The use of a structured, scenario-based RAND/UCLA Appropriateness Method supports generalisability and offers a reproducible framework for application in diverse healthcare systems with varying levels of anaesthesiology involvement. The panel consisted of only eight members, which, despite their recognised expertise, may not fully capture the breadth of nationwide clinical practice. However, this aligns with the RAND/UCLA Appropriateness Method, which is specifically designed for structured consensus among small, multidisciplinary groups of seven to 15 experts.

A formal grading system for the strength of evidence was used, and the recommendations reflect the group's collective assessment of the underlying evidence. Areas with limited evidence or ongoing debate have been explicitly identified and addressed throughout the document.

This consensus provides a practical foundation for national and institutional protocols aimed at optimising anaesthetic care during TAVI. Further research should prioritise the uncertain or controversial areas identified by the panel, ideally through randomised controlled trial, to generate more definitive guidance in the future. Given the predominance of expert consensus-based recommendations (evidence level c), this document also serves to identify important gaps in current knowledge. Future prospective or randomised studies are particularly warranted to clarify the optimal anaesthetic approach in patients with high-risk comorbidities, the role of advanced monitoring modalities, and the impact of perioperative strategies—such as minimally invasive approach and vascular access management—on clinical outcomes.

Authors' contributions

Study concept and design: VA, SF, FD, GF, TA, MB, PB, MD, PM, FM, MP, FS, CS, SS, MR, SS
Data collection: VA, SF, FD, GF, TA, MB, PB, MD, PM
Data analysis: FM, MP, FS, CS, SS, MR, SS, VA, SF
Data interpretation: VA, SF, FD, GF, GF, LG, FG, MN, EP, LW, GL, GP
Manuscript drafting: VA, SF, FD, GF, LG, FG, MN, EP, LW, GL, GP
Moderators: FD, SF, GF
Panellist: VA, LG, FG, MN, EP, LW, GL, GP
Critical revision of the manuscript: TA, MB, PB, MD, PM, FM, MP, FS, CS, SS, MR, SS
All authors approved the final version of the manuscript. They agree to be accountable for all aspects of the work, ensuring that any questions related to the accuracy or integrity of any part are appropriately investigated and resolved.

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Declaration of interest

The authors declare that they have no conflicts of interest.

Appendix A. Supplementary data

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