

Physicians' perspectives and attitudes toward surgical bailout in transcatheter aortic valve replacement



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ABSTRACT

Objectives: The incidence of surgical bailout during transcatheter aortic valve replacement (TAVR) is ~1%, with an associated 50% in-hospital mortality. We performed an exploratory qualitative study of TAVR team perceptions regarding routine surgical bailout planning with patients.

Methods: We developed a semistructured interview guide to explore clinician perspectives on the TAVR consent process, managing intraoperative emergencies, and involving patients in surgical contingency planning. We interviewed surgeons, cardiologists, and anesthesiologists involved with TAVR in 4 hospitals. We performed qualitative thematic analysis via independent coding of salient quotations from the transcribed texts. Codes were categorized based on shared meaning and the final themes were derived by identifying key content, and examining its relational nature.

Results: Thirteen interviews were conducted, identifying 4 major themes. Participants agreed that eliciting patient preference for bailout is crucial, particularly when surgical outcome is ambiguous. In those cases, participants offered criteria for determining which patients should be engaged in a more nuanced discussion. The ethos of specialty clinicians impacted anticipation and response to procedural emergencies. Finally, physician attitudes reflected strong emotional responses to patient death/morbidity, particularly in iatrogenic injury. Participants expressed anxiety with performing TAVR without surgical backup, while also demonstrating willingness to respect patients' wishes.

Conclusions: The TAVR team supports engaging patients regarding potential surgical bailout and honoring their preferences in the event of complication. However, clinical judgment about the expected outcome of bailout would frame that discussion. Participants described the emotional weight of not pursuing bailout if indicated and the importance of good coping mechanisms. (JTCVS Open 2022;9:74-81)



Involving patients in surgical bailout planning.

CENTRAL MESSAGE

The TAVR physician team members supported engaging patients regarding potential surgical bailout based on clinical judgment about the expected outcome.

PERSPECTIVE

TAVR complications that require a surgical bailout are associated with a 50% in-hospital mortality and therefore may not align with patient's goals. In this study, TAVR physician team members highlighted the importance of consent conversations, including contingency planning for surgical bailout. Participants called for a standardized approach to ensure goal concordance in surgical bailout planning. The TAVR team will need administrative and peer support to honor these patient's preferences.

See Commentary on page 82.



Video clip is available online.

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The risk of catastrophic complications from transcatheter aortic valve replacement (TAVR) must be discussed during the informed-consent process. There is no current literature on providers' perspectives of how to best include patients

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Abbreviations and Acronyms

STS = Society of Thoracic Surgeons

TAVR = transcatheter aortic valve replacement

in preparing for potential surgical bailout during a TAVR procedure. However, there is abundant research focused on determining which patients with severe aortic stenosis would most benefit from a surgical versus transcatheter approach.¹ In the infancy of the transcatheter approach, TAVRs were strictly performed on patients who were deemed to be inoperable. Over time, the indications have broadened to include high-, intermediate-, and low-risk patients.¹ Based on the 2020 guidelines for management of valvular heart disease, these risks are stratified by a multidisciplinary team and include Society of Thoracic Surgeons (STS)-predicted risk of death, frailty, major organ system compromise, and procedure-specific impediments.²

Complications during TAVR procedures that require emergent conversion to open heart surgery are rare. This situation has been described as surgical bailout in previous work, with a reported incidence of 0.76% to 1.17%.^{3,4} In such instances, Eggebrecht and colleagues⁴ reported an in-hospital mortality rate of 46%, and of those who did survive the index hospitalization, only 40% were alive 1-year postprocedure. Pineda and colleagues³ reported an all-cause 30-day mortality of 60% and in those patients who required cardiopulmonary bypass, mortality doubled. The 1-year incidence of major adverse cardiovascular events was 64%.³ The authors are not aware of any published data about quality-of-life outcomes after surgical bailout during TAVR.

Nurok and colleagues⁵ comment on the paradox of performing a surgical bailout procedure on patients who were deemed too ill for a surgery in the first place. Given the wider range of risk groups in patients undergoing TAVR, the variance in potential postsurgical bailout outcomes continues to grow. Based on outcomes after bailout, patients may wish to forgo a surgical bailout in the event of a severe complication. This may prompt a conversation by the TAVR team comparable with required reconsideration of code status before an operation.^{6,7} This refers to the preoperative conversation with patients who have any restrictions on their code status (everything except full code), to determine collaboratively what perioperative code status would be goal-concordant rather than automatically transitioning patients to be full code for the perioperative period.⁶ According to the American College of Surgeons, patients or patient surrogates and the physician responsible for their care should not only discuss the intra- and perioperative complications of the procedure but also discuss the patient's overall treatment goals.⁶ Required reconsideration of code status ensures the physician's approach to life-threatening

problems during the procedure is consistent with the patient's values and preferences.⁶ Similarly, other authors have encouraged discussing surgical bailout preferences with every patient who is scheduled to undergo TAVR.^{5,8}

There is no published literature on TAVR clinical providers' perspectives on how to best manage surgical bailouts in TAVR. We aimed to deeply explore physician perspectives and attitudes toward surgical bailout during TAVR in an exploratory semistructured interview study. We hoped that these findings might inform which topics we should emphasize in future work including a broader sample of TAVR clinical providers.

METHODS

We performed an exploratory qualitative semistructured interview study.

Approach and Participants

The purpose of this study was to examine physician perspectives and attitudes toward surgical bailout during TAVR. We decided to start with only the physicians on the TAVR team, as they are the decision makers who work together to address how to respond in a TAVR emergency. We conducted semistructured interviews with physician TAVR team members, including cardiothoracic surgeons, interventional cardiologists, and cardiac anesthesiologists, at several tertiary hospital systems in Minnesota.

This study was submitted, reviewed, and determined to be exempt by the institutional review board at The University of Minnesota (STUDY00009632) on May 21, 2020. Because of the exploratory nature of this study, we recruited a convenience sample, which is a sample based on the relationship of an investigator with a small population, via a direct sampling approach. Participants were given a detailed explanation of the study background, purpose, and procedures both in an introductory e-mail and via Zoom. Their verbal agreement to participate before initiating the Zoom interview acted as our informed consent process. Of the potential participants who were approached, all except one participated. The number of interviews required was derived through an iterative process that was used to determine theoretical saturation within the data.⁹ The process for determining saturation involved formal data reviews following the completion of 3 to 4 interviews. These reviews promote active discussion among coders for 2 reasons. The first is to compare data for content and concept relevance and the second is to determine that collecting any new data would not add insight to the question under investigation. As a result, theoretical saturation occurs when all coders believe that insights from data are either repetitive or unnecessary, and determine that further interviews would not provide additional conceptual insight.

Participants were given a detailed explanation of the study background, purpose, and procedures both in an introductory e-mail and verbally via during the interview. Their verbal agreement to participate before initiating the interview acted as our informed-consent process. Participants engaged in a semistructured interview conducted via a remote conferencing platform (Zoom Video Communications, Inc).

Interview Design and Process

We used semistructured interviews, which are well-regarded as an appropriate qualitative method that permits a deeper examination of both specific a priori concepts and research questions that are exploratory in nature.¹⁰ The interviews were all performed and recorded via Zoom by the same interviewer (A.J.R.). An interview guide was used that included 3 main content domains, including the TAVR consent processes, management of TAVR intraoperative emergencies, and perspectives on involving patients in intraoperative decision-making. These domains were chosen

to comprehensively address our research question and drew from the author's clinical experience, and from gaps of knowledge identified on literature review.^{5,8} In each domain, there were specific questions that were asked of every participant, including 3 mock patient scenarios. These can be seen in the interview guide included in [Online Data Supplement](#). Several elicitation probes were included in the guide that could be used if the standard questions did not evoke a robust response. The interview guide was pilot tested for content and face validity in 2 informal interviews before arriving at its final iteration.

Data Analysis

Participants self-reported demographic information about their age, sex, specialty, number of years in practice, and number of hospitals in which they practice. Descriptive statistics were reported as percentages for categorical variables or mean and standard deviation for continuous variables.

The interviews lasted 30 to 60 minutes, depending on the participant. All interviews were recorded via Zoom and transcribed verbatim by one member of the research team. Three researchers performed inductive thematic analysis, reducing the raw transcribed data to portions of text that could be labeled based on certain characteristics.^{11,12} To do this, they independently reviewed each transcript for quotes that highlighted salient points, created context, captured specific language, or reflected a pattern seen throughout the interviews. These quotes were then assigned a code created by the researcher, with each researcher limiting themselves to 15 to 20 codes overall. Examples of codes used include clinical judgment versus patient autonomy, processing mistakes, or coping with patient loss and barriers to shared decision-making. The 3 researchers met several times to assess and compare the codes for consistency.

The researchers then categorized the codes and organized them into broader themes based on shared meaning and contextual relevance. In this way, identified themes characterized a group of concept-linked codes. Thematic analysis allows for a flexible approach to evaluating text and synthesizing concepts that is inductive, rather than a deductive approach that may be required if using an a priori codebook or content analysis.¹³ This approach is also highly effective for generating themes based on narrative patterns constructed in a conversation between a participant and the interviewer.¹⁴

RESULTS

We interviewed 13 TAVR physician members. This included 6 cardiothoracic surgeons, 3 cardiac anesthesiologists, and 4 interventional cardiologists. The demographics of the participants are summarized in [Table 1](#). Thematic analysis of interview transcripts produced 4 major themes ([Table 2](#), [Figure 1](#)). Illustrative quotes for each theme are included in [Online Data Supplement](#).

Clinical Judgment and Expertise in Determining Viability of Surgical Bailout Option

Many of the surgeons and cardiologists described a group of patients who may be appropriate to elicit preferences around surgical contingency planning. Participants described patients who were too high risk for surgical bailout with a low chance of a good outcome, which would preclude the TAVR team from even offering to attempt a surgical repair. Conversely, participants described patients who they felt were likely to have a good outcome with surgical repair in whom it would be negligent not to pursue surgical bailout in the rare event of a complication. Patients not

TABLE 1. Demographics of the participants

Demographic variables	
Age, y, mean (SD)	47 (6)
Sex (female), n (%)	2 (15)
Years in practice, mean (SD)	12 (8)
Number of hospitals worked at,* mean (SD)	2 (1)
Professional role, n (%)	
Anesthesiologist	3 (23)
Cardiothoracic surgeon	6 (46)
Interventional cardiologist	4 (31)

SD, Standard deviation. *These hospitals include a veterans' affairs hospital, a university-affiliated hospital, and local nonprofit hospitals.

covered by either of these extremes were described as a population who should be engaged in a more nuanced consent process where preferences should be elicited about undergoing a surgical bailout or not in the event of a complication.

Where participants differed was in which criteria they used to define this middle group. Some of the objective criteria included age, STS mortality risk scores, or comorbidities as well as technical considerations such as valvular anatomy or previous sternotomy. Other participants factored in a patient's ability to perform activities of daily living, functional status, and what kind of setting of residence.

Importance of Patient Autonomy

Participants agreed that eliciting patient preferences for surgical bailout during TAVR is important, particularly when there is ambiguity about the futility of proceeding with surgical bailout. Other participants noted the importance of exploring any mental health concerns in those patients who stated they would not want surgical repair despite the TAVR team's consensus that they would likely do well. This would be pursued with the aim of elucidating if depression, coercion, lack of decisional capacity, or other temporary influence was unduly influencing their decision.

Many providers discussed wanting to promote patient autonomy while recognizing some of the barriers of involving patients in intraoperative decision making. Some providers highlighted the importance of being able to use clinical judgment in the moment. Others commented on the asymmetry of information between highly trained medical professionals and patients who might not be able to make truly informed choices about responding to intraoperative complications. Some participants discussed the burden that we place on patients and families in asking them to make decisions about these high-stakes circumstances. Overall, participants recognized that it would be reasonable for patients to express that a surgical bailout's risk would outweigh the projected benefit for them. However, the point

TABLE 2. Major themes

Themes	Subthemes	Illustrative quotes
Clinical judgment and expertise in determining viability of surgical bailout option	<ul style="list-style-type: none"> • Futility in high-risk patients • Potential harm in with-holding salvage from low-risk patients 	<p>“If that was my mother (age 88) ...I’d feel like in that case you’re doing more harm than good.”—Anesthesiologist 1</p>
Importance of patient autonomy	<ul style="list-style-type: none"> • Decision-making burden on families • Defer to in-the-moment physician expertise/devaluation of clinical judgment • Do not scare the patient • Respect patient preferences 	<p>“They’re going to the OR and they signed up for the full OR experience. And so, that’s what they’re going to get.”—Anesthesiologist 1</p> <p>“We’re fairly paternalistic, to be quite blunt. I think it’s hard for them to really understand what they’re getting into.”—Cardiologist 1</p> <p>“I feel like a good way to get yourself into trouble is to talk patients into doing things they don’t want to do... those are exactly the kinds of people who have a problem...that’s a level of paternalism that maybe exists in a different generation of physicians, but I am entirely uncomfortable with”—Surgeon 2</p> <p>“But that’s a medical decision that I don’t think a family member should make, and I don’t think they should carry that burden.”—Surgeon 3</p>
TAVR team dynamic vs relative professional roles	<ul style="list-style-type: none"> • Respectful, high-functioning team • Responsibility for outcomes • Who should consent for bailout 	<p>“Surgeons are the people who see these people in clinic...talk to the family... call the family, if something goes wrong, they have to deal with it. It’s something that they have to live with... I genuinely trust what the surgeon is telling me. If they think they can do something, I believe them, because if I didn’t, then it would make my job a whole lot harder.”—Anesthesiologist 1</p> <p>“The cardiologists stayed the whole time, they were right on my shoulder, scrubbed in... and then we’d go to talk to the family together... it’s a shared responsibility... it’s our patient.”—Surgeon 1</p>
Emotional impact on TAVR team	<ul style="list-style-type: none"> • Cope with loss • Anxiety in a non-bailout case 	<p>“I think part of it is ... you don’t want it to fail. You want to ...pull them through, even if the quality of life is not what the patient would have wanted. You don’t want to see it as your failure.”—Cardiologist 1</p> <p>“... imagine I... cut the ... sternum and the wife said, ‘you know, he would have never done this...’ ...that would haunt me for the rest of my life.”—Surgeon 3</p> <p>“... we’re not bringing people to the operating room if we think they’re gonna die...if something does go wrong and we’re not going to do anything, that doesn’t sit well...that’s not my job. My job is to make sure that they live through the whole thing”—Anesthesiologist 3</p>

TAVR, Transcatheter aortic valve replacement.

of contention was how explicitly to involve patients in the preemptive decision-making for all potential scenarios versus using their broad goals of care to guide physician’s contemporaneous decision making in the event of a complication.

TAVR Team Dynamic Versus Relative Professional Roles

Participants discussed the unique TAVR environment, given the multiple disciplines represented in the operating

room. Participants were asked to discuss the process of how the team typically responds to emergencies. This prompted conversations about leadership and collaboration in high-stakes situations. The varying ethos and cultures between the professional roles were discussed. This included how each role was involved in consent, the decision to operate during an intraoperative emergency, and the ultimate responsibility for the outcome of the patient. In general, participants described a current environment of a high-functioning team that worked well together in emergencies

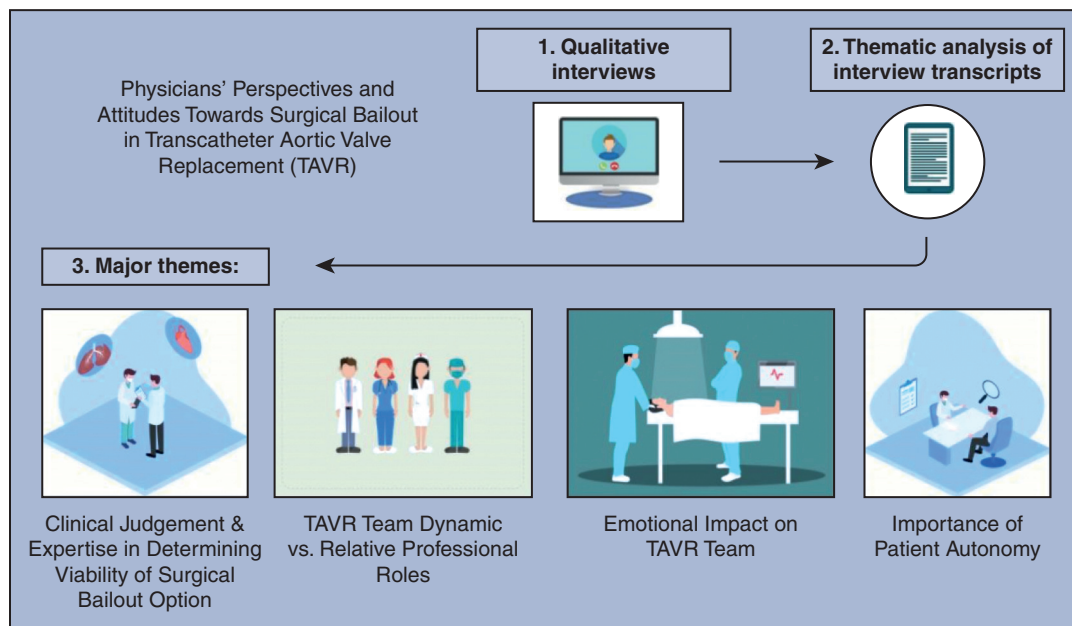


FIGURE 1. The interviewed TAVR physician team expressed a commitment to emphasize patient autonomy while guiding the decision-making based on clinical experience. Despite the multidisciplinary nature of the TAVR team, many participants reported collaborative ownership of intraoperative decisions. Finally, participants discussed the emotional toll of poor outcomes on the TAVR team, particularly if the decision did not seem to be patient goal-concordant in retrospect. Implication Statement: Consent for TAVR should include a more nuanced conversation regarding planning for potential complications. TAVR physician team members should develop a standardized way to approach this. *TAVR*, Transcatheter aortic valve replacement.

and respected each other. Many described shared responsibility for patient outcomes and proper consenting.

Emotional Impact on the TAVR Team

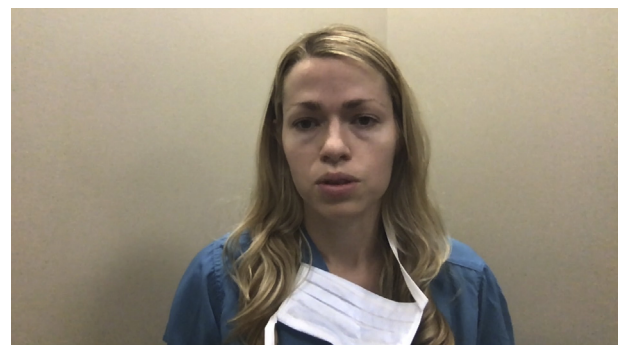
Participants expressed increased anxiety while performing TAVR on high-risk patients without the ability to perform rescue measures. One participant went as far as describing the situation as being handcuffed without the full toolkit to get the patient through the case. Others compared it to the type of contingency planning that is done with patients and families before emergent procedures, in which heroic measures are attempted with firm boundaries of when to stop. Many respondents described the emotional burden associated with patients who have complications and the additional impact if the team was restricted from attempting to repair an iatrogenic injury. Despite this pressure, most participants demonstrated a desire to respect the patient’s preferences to not undergo a surgical bailout. A few participants highlighted the importance of the hospital administration backing up the team in the event of a goal-concordant intraoperative death rather than surgical bailout.

Other participants discussed how it feels when there are concerns that the care was more aggressive than what the patient themselves would have elected to undergo. No matter the circumstances around a case that results in significant morbidity or mortality, participants highlighted the importance of debriefing as a team right after the event. They

also discussed trying to find learning opportunities in these cases and in finding healthy coping mechanisms and support systems.

DISCUSSION

These participants expressed a diversity of beliefs on how to engage patients in surgical bailout planning and highlighted the complexities of assessing risk and team management. To the authors’ knowledge, there is no previous work that explores a multidisciplinary team’s thoughts about surgical bailout for catheter-based procedures (*Video 1*).



VIDEO 1. Author overview of the research question and relevance of the results. Video available at: [https://www.jtcvs.org/article/S2666-2736\(22\)00027-4/fulltext](https://www.jtcvs.org/article/S2666-2736(22)00027-4/fulltext).

The participants in our study were aware of the poor outcomes associated with surgical bailouts, whether this was expressed in anecdote or citing recent literature from the STS/American College of Cardiology Transcatheter Valve Therapy Registry.³ Many participants described patients who died intraoperatively, shortly postoperatively, or had profound morbidity. However, when asked to predict which patients undergoing TAVR would be expected to have poor outcomes with surgical bailout, various criteria were used. There are substantial data to aid in predicting outcomes after TAVR and some regarding who is at risk of surgical bailout.^{2,15} However, there are limited data regarding who is at greatest risk of poor outcomes after surgical bailout. Pineda and colleagues³ looked at several predictors for survival after surgical bailout, including sex, previous *International Classification of Diseases* code, age, previous aortic procedure, and New York Heart Association heart failure class. Interestingly, only increased body surface area was a statistically significant independent predictor. However, Eggebrecht and colleagues⁴ independent predictors of in-hospital mortality included age older than 85 years, annular rupture, and immediate emergency cardiac surgery. Understanding who is at greatest risk of a poor outcome after surgical bailout could help standardize how we discuss this with patients. There was agreement among participants that patients in whom a surgical bailout would be considered futile should not be offered bailout. In patients to whom the team thought surgical bailout would be reasonable, there were concerns that allowing low-risk patients to forgo surgical bailout would be negligent. Some participants were concerned that lower-risk patients might be influenced by mental health crisis or coercion.¹⁶

In patients of moderate risk, participants aimed to engage patients in surgical contingency planning. Some participants emphasized the importance of ensuring intraoperative plans are concordant with the patient's overall goals. This could be thought of as an extension of how patient preferences are incorporated in shared decision-making regarding the treatment choice of surgical aortic valve replacement versus TAVR.^{17,18} Others felt that it was unfair to ask patients to imagine intraoperative emergencies and make truly informed decisions about what should be done in that moment. Rather than offering autonomy, requesting that patients make that choice forfeits our duty to care and act based on our training and experience. The authors suggest that rather than discussing the potential burdens specific to surgical bailout, the TAVR team should determine whether there are certain outcomes that would be unacceptable to the patient. For example, a patient who said that chronic mechanical ventilation would be intolerable versus another that would be willing to endure any condition to make it to an important anniversary would likely willingly undergo differing intensities of care. While it would still require the TAVR team to prognosticate about long-term

outcome during an emergent complication, the broader goals of a patient may help guide the TAVR team while allowing them to use their expertise to determine which plan of action would best align with those aims.

The TAVR team is unique in that it comprises a variety of physician specialties that together work toward the best outcome for the patient.^{19,20} A 2017 survey study of cardiac surgeons found that the majority reported that they were involved in TAVR preoperative planning (91%), regularly contributed to technical aspects (50%), and provided postoperative care (87%).²¹ In an emergency, there were questions of team versus specific role leadership and who should make the final call to perform a surgical bailout. Despite the described differences in training and specialty cultures, the participants described a team with shared pre-, intra-, and postoperative responsibility for the patient's outcome. This appears to reflect the multidisciplinary heart team approach that is recommended for managing many cardiovascular conditions, such as ischemic heart disease or pulmonary embolisms.²²⁻²⁵ A recent issue of *American Medical Association ethics* was dedicated entirely to the anesthesiologist–surgeon relationship. The authors encouraged a shared responsibility for preoperative code status conversations, intraoperative emergency decision-making, disclosures to family, and postoperative outcomes.²⁶⁻²⁸ Recent studies have shown that effective multidisciplinary teamwork improves patient safety and highlights the importance of communication skills.²⁹

As described, there are symptomatic patients who would benefit from TAVR but who are either deemed to be too frail or sick for surgical bailout by the clinical team, or who have declined surgical bailout and are of sound mind. In these instances, perhaps the procedure could be deemed a palliative procedure, meaning that the overarching aim is in symptom alleviation rather than restorative intent.³⁰ Given the responsibility that these participants felt toward their patients, some reported that operating on patients who make a premeditated choice to forgo surgical bailout would require a shift in the TAVR team's perspective. Participants went on to describe the emotional burden associated with a complication or bad patient outcome. Many participants highlighted the importance of team debriefing, good self-care practices and creating learning opportunities when complications do occur.

A limitation of our study is that a sample size of 13 may not be representative of the diverse opinions of TAVR team members. However, it permitted an in-depth probing of attitudes and beliefs. We recognize that perspectives may vary depending on geographic location, patient population, and hospital dynamics. This study was designed to be exploratory as a first step into understanding TAVR team physicians' thoughts on this complex issue. National data with a broader group of TAVR team members, including other operating room staff, other medical disciplines (such as

palliative care, medical ethics or psychologists), and trainees, could help make these results more generalizable. In addition, it would be valuable to gain the perspectives of patients, caregivers and patient advocates.

In summary, TAVR procedures rarely result in an emergent complication that requires a surgical bailout. One half of patients who undergo a surgical bailout die before hospital discharge.³ Participants in this study reflected on the preprocedure risk assessment process of TAVR patient's potential outcomes after surgical bailout. The participant's opinions varied regarding to what extent patient's preferences for surgical contingency planning should be included in the consent process for TAVR. The participants represented all of the physician disciplines involved in TAVR procedures and commented on the unique team dynamic in decision making when addressing TAVR complications. Participants described the emotional toll on physicians when patients have complications, particularly when it feels like they were prevented from doing everything to fix the situation. The authors view the results of this preliminary paper as a call to action, both at our own institution and globally, to discuss and examine the interdisciplinary TAVR the consent process. We specifically recommend that surgeons be involved in discussing surgical bailout planning with patient, as ultimately surgeons are the ones that best understand the risk and potential benefits.

Future research is required on how to best support physicians as they engage patients in these nuanced conversations and then honor patients' preferences in the event of a catastrophic complication. Our group hopes to perform future interview studies to gain the perspectives of the other TAVR team members as well as the patient perspective on this issue. We also aim to validate our study's findings through a national survey of TAVR team providers. We anticipate that each institution will have its own team dynamics, culture and logistics to navigate in creating a system to facilitate this in-depth consent process. We hope that future additional interview studies will be performed in other regions of the country or at varying institutions to potentially corroborate our results and build consensus. Our institution is partnering with palliative care team to develop sensitive and efficient language to elucidate patient's preferences in the event of a TAVR emergency. Our ultimate goal is to help establish guidelines for best practices for involving patients in planning for potential catastrophic TAVR complications.

Conflict of Interest Statement

G.H. is a proctor for Edwards Life Sciences and Medtronic and has received financial compensation from both. All other authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or

reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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