Patient Risk-Benefit Preferences for Transcatheter versus Surgical Mitral Valve Repair

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Background

- For patients with mitral regurgitation, two repair options include: transcatheter repair and surgical repair.
- Compared to surgical repair, transcatheter repair is a less invasive procedure. However, prior studies suggest that transcatheter repair is potentially associated with a higher risk of needing additional surgery (i.e., re-intervention), higher risk of five-year mortality, and lesser improvement in physical functioning.[1]

Objective

- To quantify patient preferences for risk-benefit tradeoffs for transcatheter and surgical procedure options for mitral regurgitation

Methods

- A discrete-choice experiment survey was developed based on ISPOR best practice guidelines[2-4] and included comprehension questions and a scope test. ***Table 1*** displays the attributes and levels.
- 201 patients (***Table 2***) were recruited via Health Valve Voice US, a patient advocacy organization.
- The internal validity of response data was assessed[5] and two individuals were excluded due to straight-lining (n=199 for analytic sample).
- Mixed-logit regression models were fit to estimate preference weights.
- Maximum-acceptable risks were calculated and a novel SMART approach was applied to showcase simultaneous maximum-acceptable risks.[6]

Table 1. Attributes and Levels

Features (or attributes)	Levels
Type of procedure	Repair with catheter, surgery
Chance of death (in 30 days)	2%, 5%, 10%
Chance of death [a] (in 5 years)	20%, 30%, 45%
Physical functioning [a] (in 5 years)	Improvement from NYHA class III to… class I, class II
Number of hospitalizations (in 5 years)	1, 4, 8
Chance of needing additional surgery (in 5 years)	10%, 20%, 30% (low-risk [b]) OR 10%, 20%, 40% (high-risk [b])

NYHA = New York Heart Association;
[a] Compound attribute—5-year mortality and functional ability were shown together.
[b] Respondents were randomized to the low-risk or high-risk versions of the survey to facilitate a scope test.

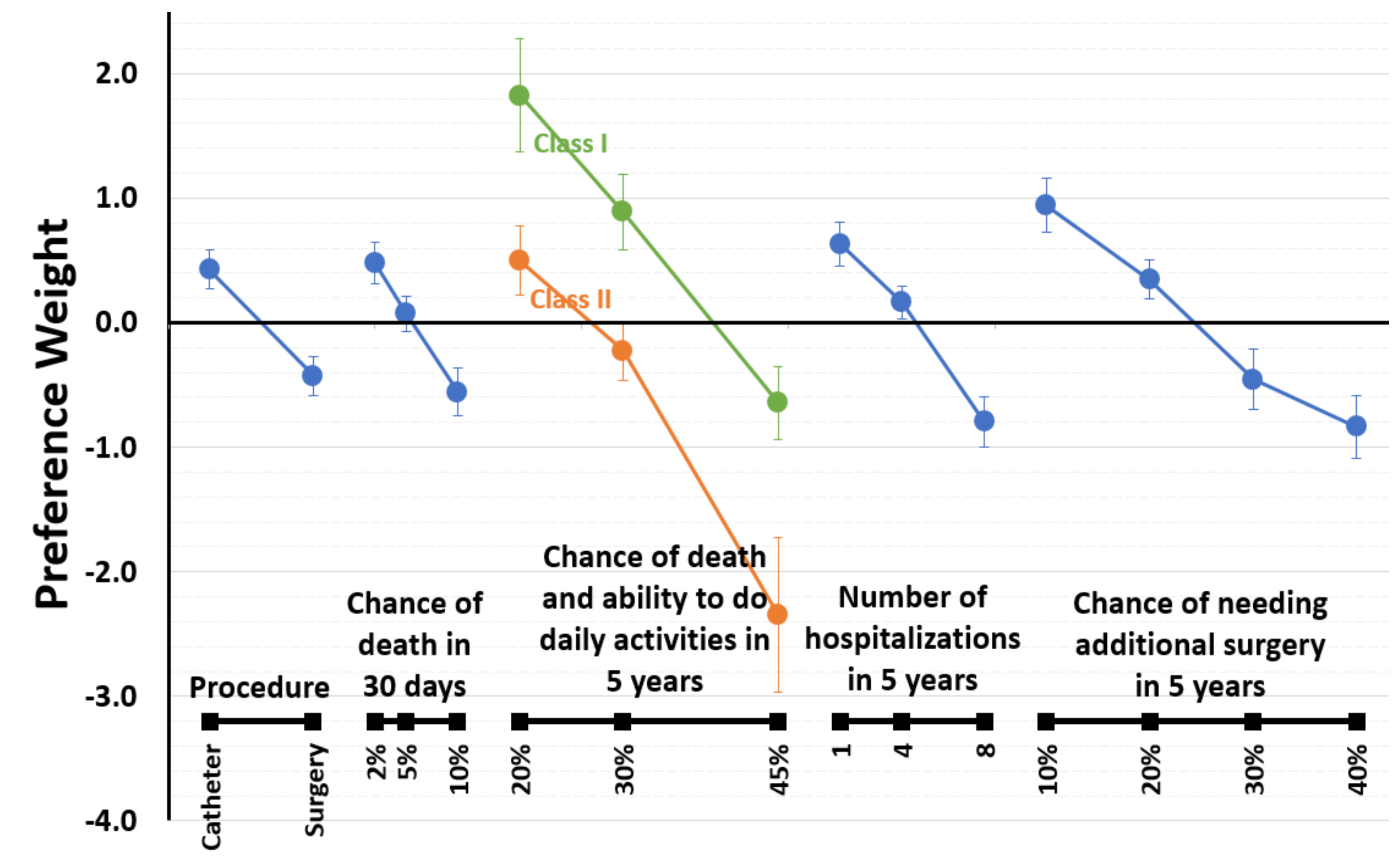
Results

Table 2. Respondent Characteristics (N=201)

DEMOGRAPHICS	N (%) or Mean (SD)
Age in years	73.7 (9.9)
Female [a]	120 (62.8%)
White [b]	176 (94.6%)
Hispanic [b]	2 (1.1%)
Married [b]	120 (64.5%)
At least 4-year college degree [b]	92 (49.5%)
Health literacy (based on Brief Health Literacy Screen[7]) [c]	10.4 (1.1)
Numeracy (based on 3-item version of Subjective Numeracy Scale[8]) [b,d]	15.0 (3.2)
CLINICAL HISTORY	
Comorbidities	201
Atrial fibrillation	92 (45.8%)
Heart failure	62 (30.8%)
Prior MR symptoms	
"Shortness of breath when you have been very active"	131 (65.2%)
Fatigue ("tiredness")	126 (62.7%)
Heart palpitations (sensations of a rapid, fluttering heartbeat)	105 (52.2%)
Prior MR management	
Mitral valve surgery	49 (24.4%)
Catheter-based mitral valve procedure	28 (13.9%)

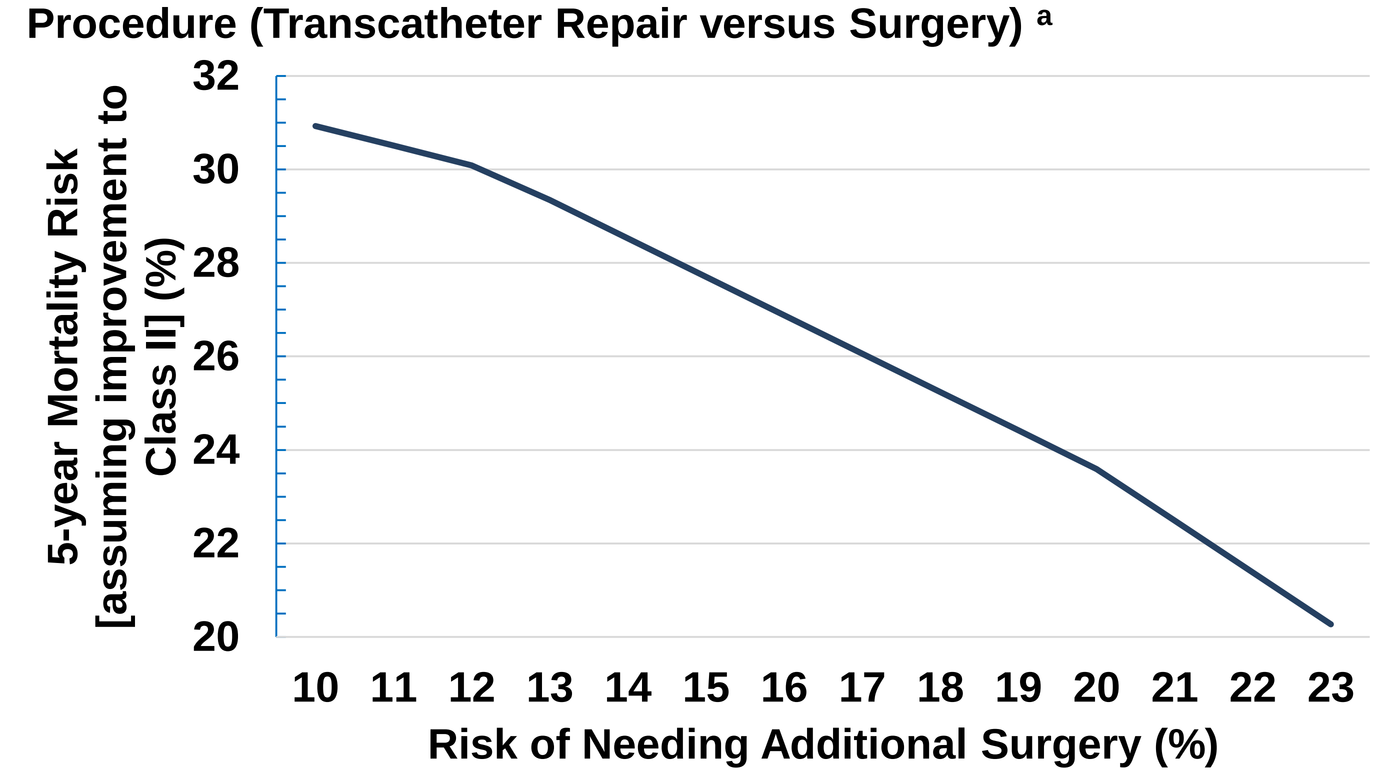
MR = mitral regurgitation; SD = standard deviation
[a] Ten responses were missing (N=191) and two respondents had inconsistent responses (i.e., in the latter survey phase, when respondents were restricted to men, two respondents reported being male in the screener question, but later reported being female in the survey).
[b] Missing responses from 15 respondents who terminated the survey early (but after answering at least one choice question). Percentages are reported out of N=186.
[c] Missing responses from 17 respondents who terminated the survey early (but after answering at least one choice question) and two additional who reported 'prefer not to say' for the health literacy questions (N=184). The score for the three-item Brief Health Literacy Screen ranges from 3 to 15 with higher scores indicating higher subjective health literacy.
[d] The score for the three-item version of the Subjective Numeracy Scale ranges from 3 to 18 with higher scores indicating higher subjective numeracy.

Figure 1. Preference Weight Estimates from Analytic Sample (N=199) [a]



[a] A greater (more positive) preference weight indicates a greater preference toward that level over the other level for a given attribute.

Figure 2. Simultaneous Maximum-Acceptable Risk Thresholds for 5-year Mortality and Needing Additional Surgery for a Less Invasive Procedure (Transcatheter Repair versus Surgery) [a]



[a] Origin starts at (10, 20) because the baseline risk of needing additional surgery was 10% and the baseline 5-year mortality risk was 20%.

Table 3. Maximum Acceptable Harm Estimates for a Less Invasive Procedure (Transcatheter Procedure instead of Surgery)

Harm	Mean Estimate (95% Confidence Interval)	
Risk of needing additional surgery (above a baseline risk of 10%)	**13.3% (8.7% - 18.5%)**	
Number of hospitalizations (above a baseline risk of one hospitalization)	**4.6 (3.1 - 6.2)**	
Risk of 5-year mortality (above a baseline risk of 20%)	**9.3% (5.2% - 14.3%)** with improvement from NYHA class III to I	**10.7% (6.5% - 14.5%)** with improvement from NYHA class III to II
More limited physical functioning (of the difference between NYHA class I and II)	**0.8 (0.5 to 1.3)** with 30% five-year mortality risk	**0.7 (0.4 to 1.1)** with 20% five-year mortality risk

NYHA = New York Heart Association

Conclusions

- Patients in general preferred transcatheter repair over surgical repair (***Figure 1***).
- For a transcatheter repair, patients would accept up to 1 of the following over five years: (***Table 3***)
  - a 13%-point increase in re-intervention risk,
  - an additional 5 hospitalizations,
  - a 9%-point increase in mortality risk, or
  - more limited physical functioning representing nearly one NYHA class.
- Conversely, respondents would undergo surgery if five-year gains in physical functioning were equivalent to achieving NYHA class I versus NYHA class II, or the increase in re-intervention risk, hospitalizations, or mortality risk over five years was higher than 13% points, 5 hospitalizations, or 9% points, respectively.
- When considering simultaneous risks, patients would accept smaller increases of each type of risk to undergo a transcatheter rather than surgical repair:
  - e.g. a 5%-point increase in re-intervention risk along with an 8%-point increase in mortality risk (***Figure 2***)

References

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