

Comparing Maximum-Acceptable Risk Estimates from two Preference-Elicitation Methods: A Discrete-Choice Experiment and a Threshold-Technique Exercise



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FROM THOUGHT LEADERSHIP
TO CLINICAL PRACTICESutphin J¹, Wallace M¹, Yang J-C¹, Corriere MA², Secemsky EA³, Johnson R¹, Gonzalez JM⁴, Tarver ME⁵, Saha A⁵, Gebben D⁵, Chen A⁵, Farb A⁵, Malone M⁵, Babalola O⁵, Rorer E⁵, Buckley D⁵, Capanna K⁵, Reed SD¹¹Duke Clinical Research Institute, Durham, NC, USA, ²University of Michigan, Ann Arbor, MI, USA, ³Beth Israel Deaconess Medical Center, Boston, MA, USA, ⁴Duke University, Durham, NC, USA, ⁵U.S. Food and Drug Administration, Silver Spring, MD, USA

OBJECTIVES

- Quantify patients' benefit-risk preferences for alternative devices used in revascularization procedures for peripheral arterial disease (PAD)
- Test whether a discrete-choice experiment (DCE) and threshold-technique (TT) exercise would yield similar maximum-acceptable-risk (MAR) estimates at the sample and individual levels
- Test whether alternative approaches to conveying complex risk information impact risk-tolerance estimates

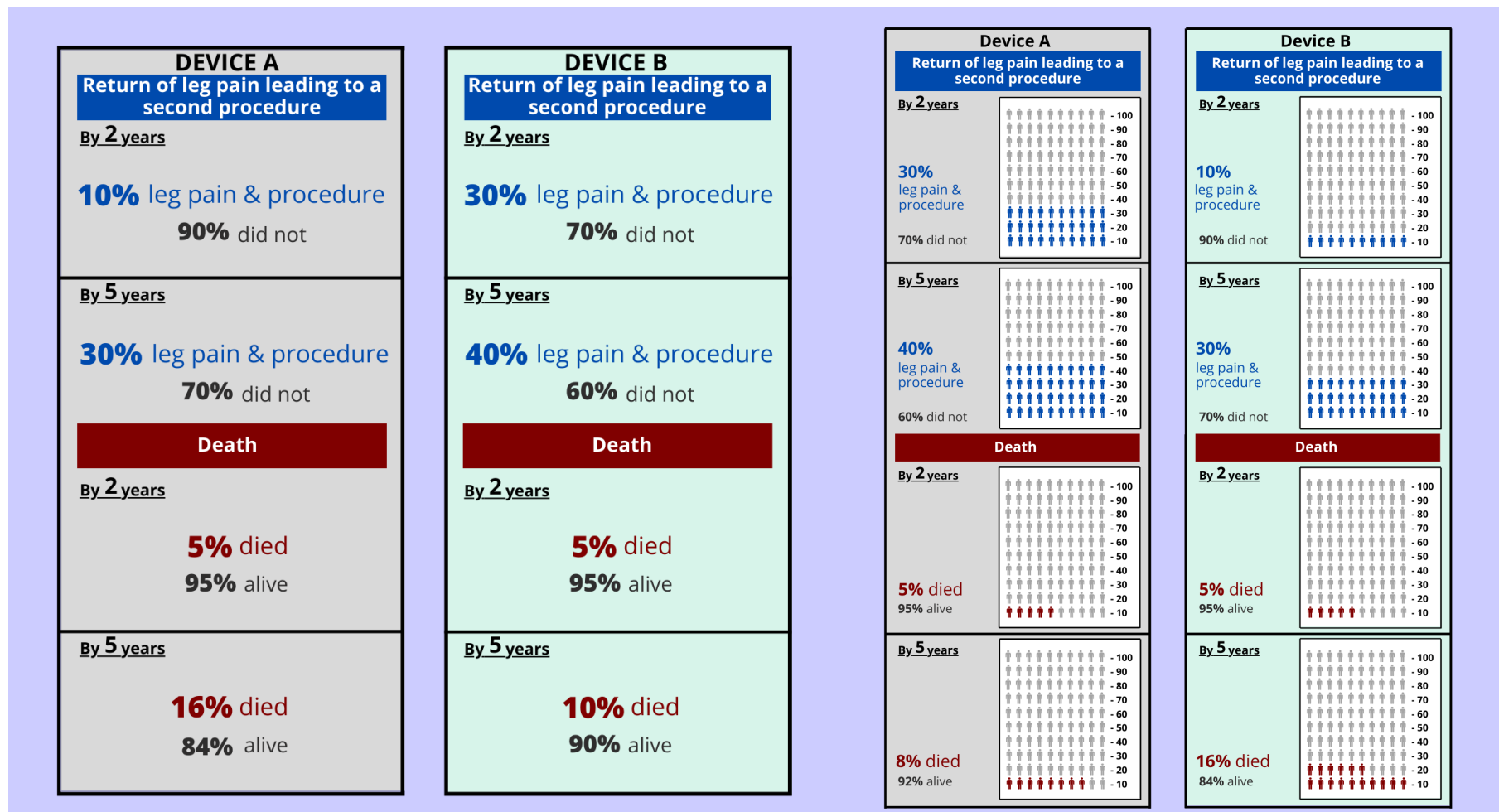
METHODS

- Recruited patients with physician-confirmed PAD from 7 U.S. medical centers
- DCE and TT questions offered patients a choice between 2 device options for a revascularization procedure for PAD
- Used the same task layout for DCE and TT questions (**Figure 1**)
- Randomized the order of DCE and TT exercise
- Risks were a repeat procedure and mortality at 2 and 5 years (**Table 1**)
- Randomized the risk presentation with or without icon arrays (**Figure 1**)
- The TT offered patients a device that
 - reduces the risk of needing another procedure by 2 years from 30% to 10%, and by 5 years from 40% to 30%, and
 - increases the 5-year mortality by 2 percentage points from 8%, up to 20%
- Sample-level and individual-level DCE MARs were estimated with mixed-logit models¹ with linear functional forms for all attributes
- Individual-level DCE MARs higher than 20% were censored at 20%
- Individual-level MARs from the TT are each respondent's lower-bound (i.e. conservative) risk threshold (direct response)
- Sample-level MARs also were estimated using interval regression

RESULTS

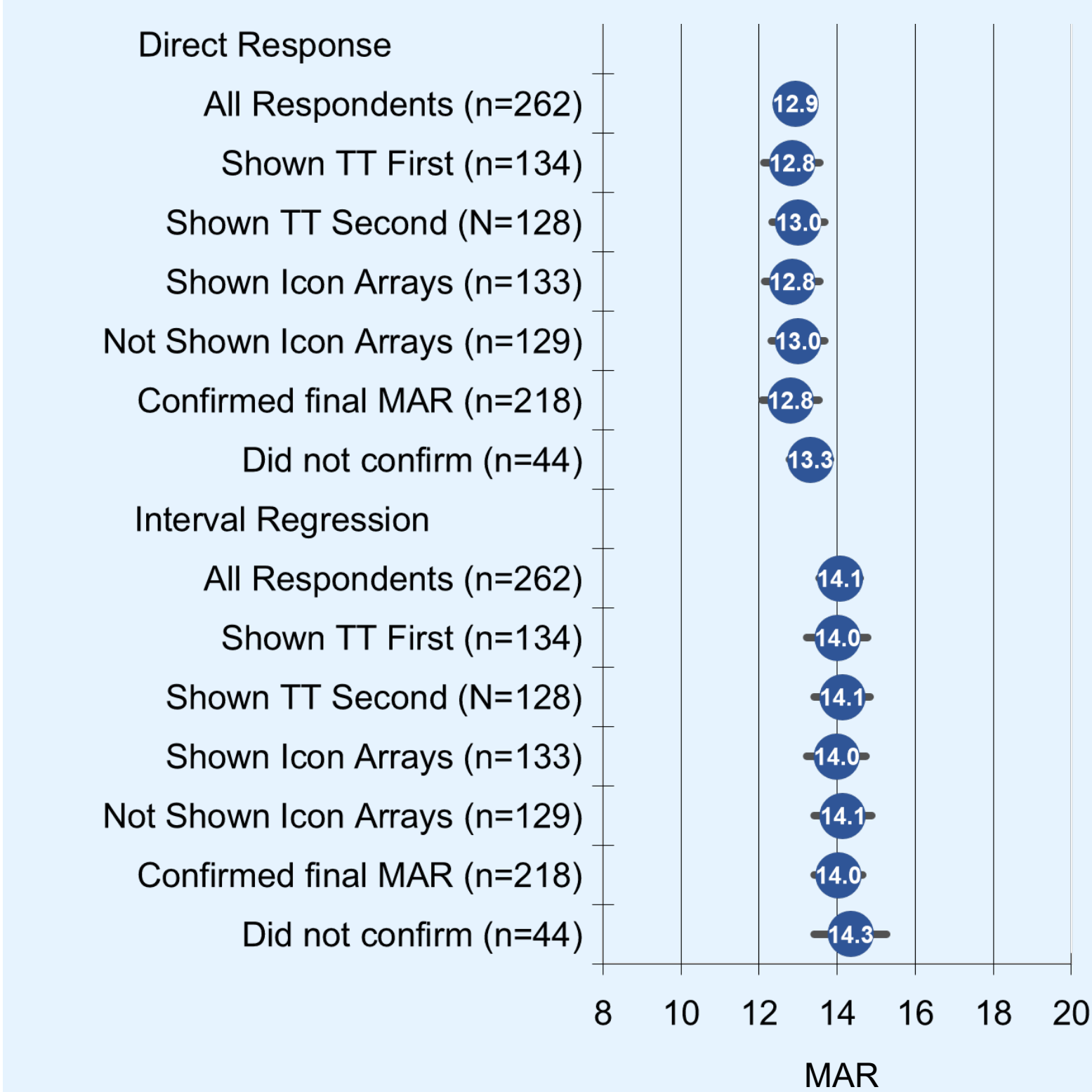
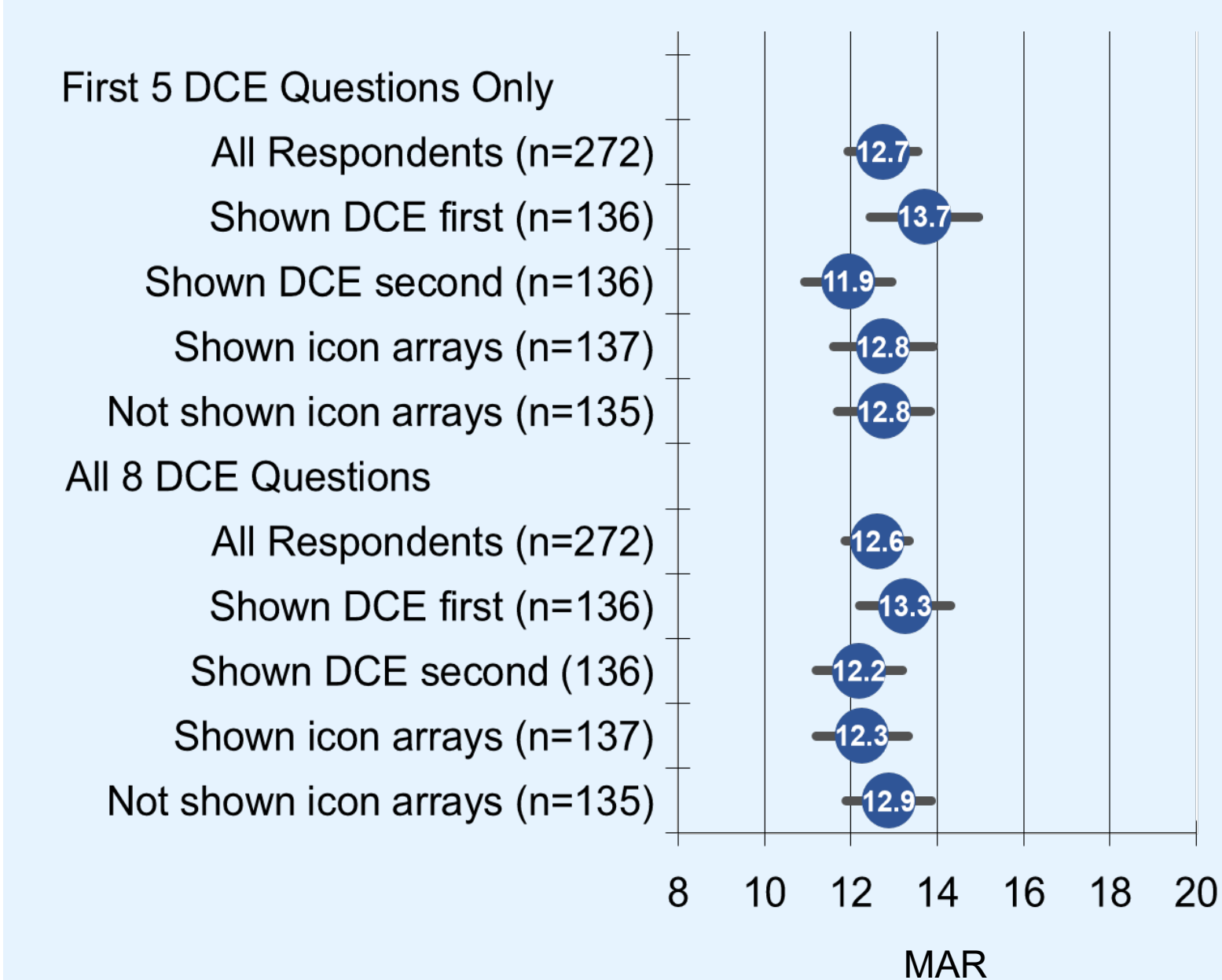
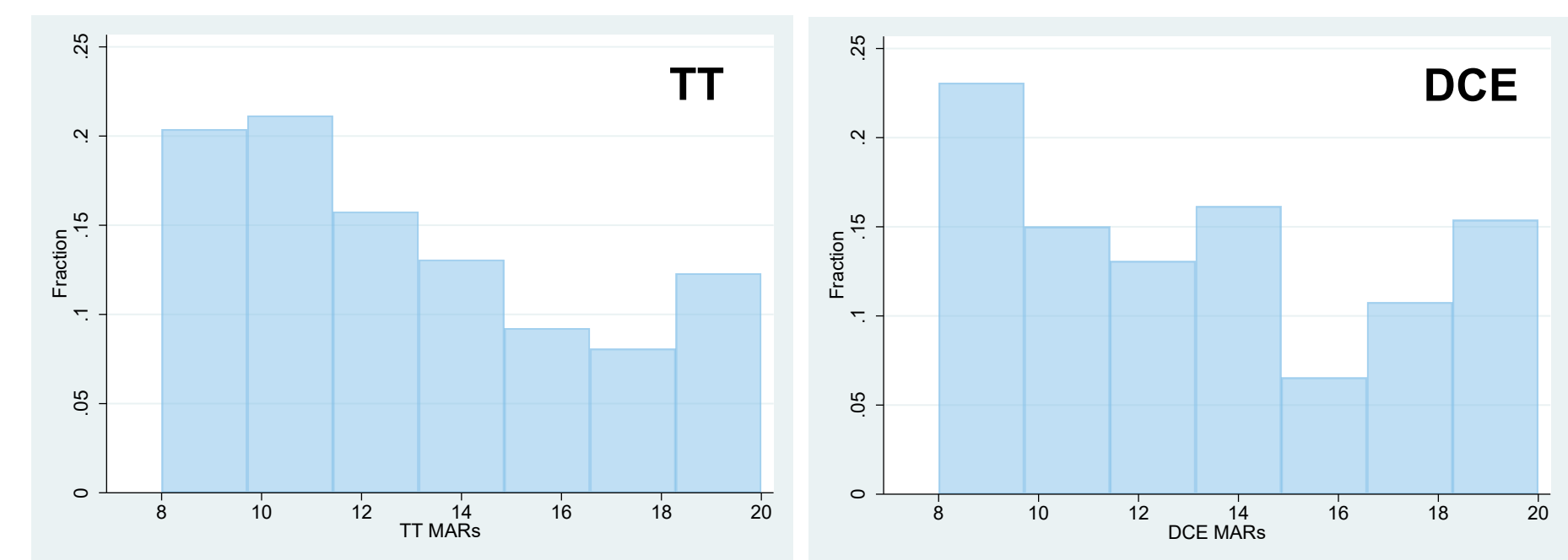
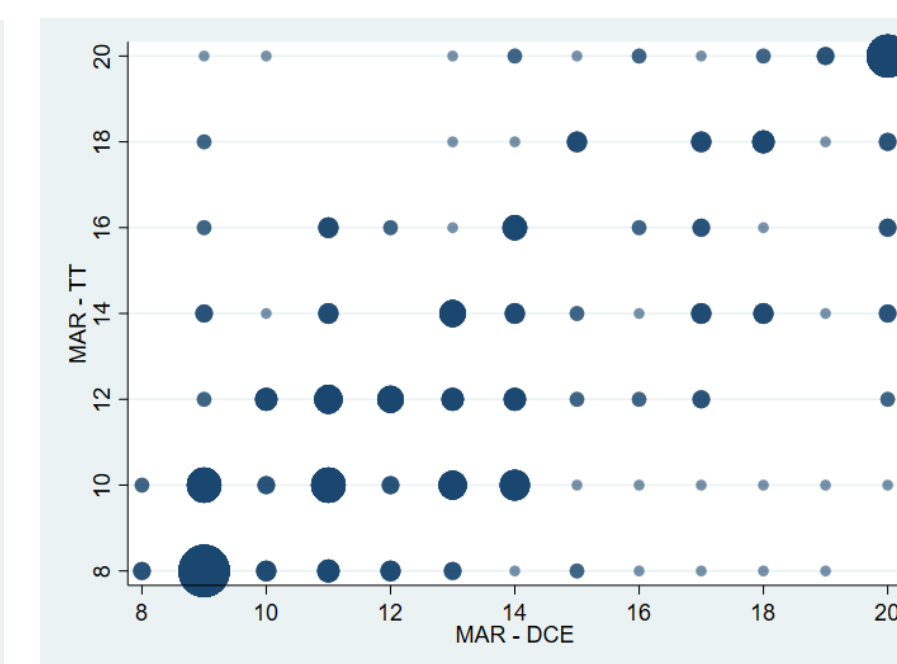
- N=272, median survey completion time was 29 minutes
- 68% male, 92% white, mean age 70 years, 53% previously had a revascularization procedure
- 83% confirmed their final MAR in the TT exercise
- DCE mean parameter estimates were negative ($p<0.000$) indicating that respondents preferred less risk

Risk tolerance estimates from different methods were similar at the aggregate level, but not at the individual level.

Figure 1. Example DCE/TT Questions**Table 1. Attributes, levels and DCE experimental Design**

Attribute	Levels for Experimental Design 1 First 5 Questions	Levels for Experimental Design 2 3 Additional Questions
2-year repeat procedure risk	10%	10%
	30%	30%
5-year repeat procedure risk	30%	30%
	40%	40%
2-year mortality risk	Not shown	50%
	Not shown	2%
5-year mortality risk	5%	5%
	8%	8%
	10%	10%
	16%	16%
	20%	20%

The experimental design (Table 1) included 2 parts: 1) a saturated design of 6 blocks of 5 questions for comparison with the TT by restricting the levels shown to those that were also evaluated in the TT; and 2) a fractional experimental design of 48 questions split into 16 blocks of 3 questions.

Figure 2. TT Sample-level MARs**Figure 3. DCE Sample-level MARs****Figure 4. Distribution of Individual-level MARs****Figure 5. Comparing TT and DCE Individual-level MARs**

- Respondents preferred devices with lower 5-year mortality risk
 - An increase in 5-year mortality risk from 8% to 20% was the most important attribute ($\beta = -3.95$), followed by 2-year mortality risk ($\beta = -0.058$), 2-year repeat procedure risk ($\beta = -0.062$) and 5-year repeat procedure risk ($\beta = -0.058$)
 - 63% chose the device with the lowest 5-year mortality risk in at least 6 of the 8 DCE questions
- At the sample level:
 - Mean sample-level MARs were similar. TT: 12.9% [95% CI: 12.4, 13.4], DCE: 12.7% [11.9, 13.5]
 - TT estimates were consistent across order shown, risk-communication approach, and whether they confirmed their final TT choice (**Figure 2**)
 - DCE estimates were consistent across experimental designs, order shown, and risk-communication approach (**Figure 3**)
- At the individual level (**Figures 4 & 5**):
 - The distributions of MARs differed between the two methods
 - 53% of respondents had a difference of less than 2 percentage-points between the TT and DCE MARs
 - Discordance between DCE and TT MARs ranged from 0 to 12 percentage-points with a mean absolute difference of 2.5 (SD 2.4)

CONCLUSIONS

- On average, starting at a baseline of 8%, respondents would accept an increase in 5-year mortality risk of 4 to 6 percentage-points for a device that reduces the risk of a repeat procedure by 2 years from 30% to 10%, and by 5 years from 40% to 30%
- Concordance between DCE and TT MARs occurred at the sample level, but there was less concordance the individual level
- The range of responses at the individual level indicate a fair degree of heterogeneity across both preference methods with regard to the acceptability of increases in mortality risk
- Limitations include measurement error associated with individual-level MARs estimated using DCE data, potential influence of the starting point for the TT, selection of attribute levels, and model selection and assumptions

REFERENCES & FUNDING

¹ The method used was first proposed by Revelt and Train (2000). See Train (2003), Chapter 11 for a full discussion of the method. [Revelt D, Train K. 2000. Customer-specific taste parameters and mixed logit: Households' choice of electricity supplier. Working Paper, Department of Economics, University of California, Berkeley.] [Train KE. 2003. Discrete Choice Methods with Simulation. Cambridge: Cambridge University Press.]

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