



ISCHEMIA

**International Study of Comparative Health Effectiveness with
Medical and Invasive Approaches
Primary Report of Quality of Life Outcomes**

Funded by National Heart, Lung, and Blood Institute

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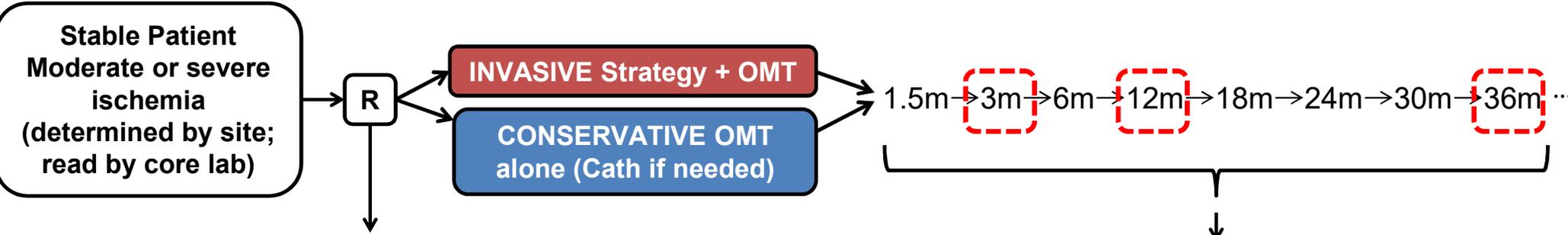
On behalf of the ISCHEMIA Research Group

ISCHEMIA QoL Research Question

In a stable patient with at least moderate ischemia, does an invasive strategy...

improve patients' health status (their symptoms, function and quality of life)?

Study Design



Brief QoL Assessment

Brief QoL Assessment:

- Seattle Angina Questionnaire – 7
 - Angina Frequency**
 - Quality of Life**
 - Physical Limitations

SAQ Summary Score*

Completion Rates

Con:	91%	88%	94%	93%	92%	90%	91%	89%
Inv:	88%	89%	93%	92%	92%	91%	90%	88%

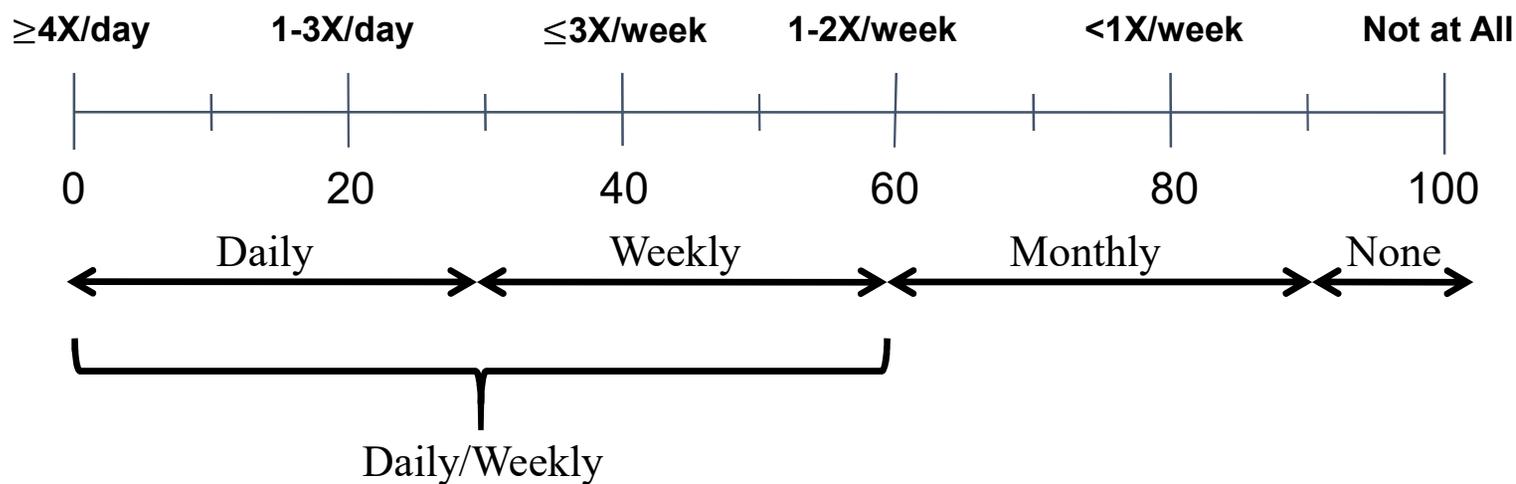
*Primary QoL Outcome
 **Secondary QoL Outcome



Interpreting and Stratifying SAQ Scores

SAQ Angina Frequency Scale:

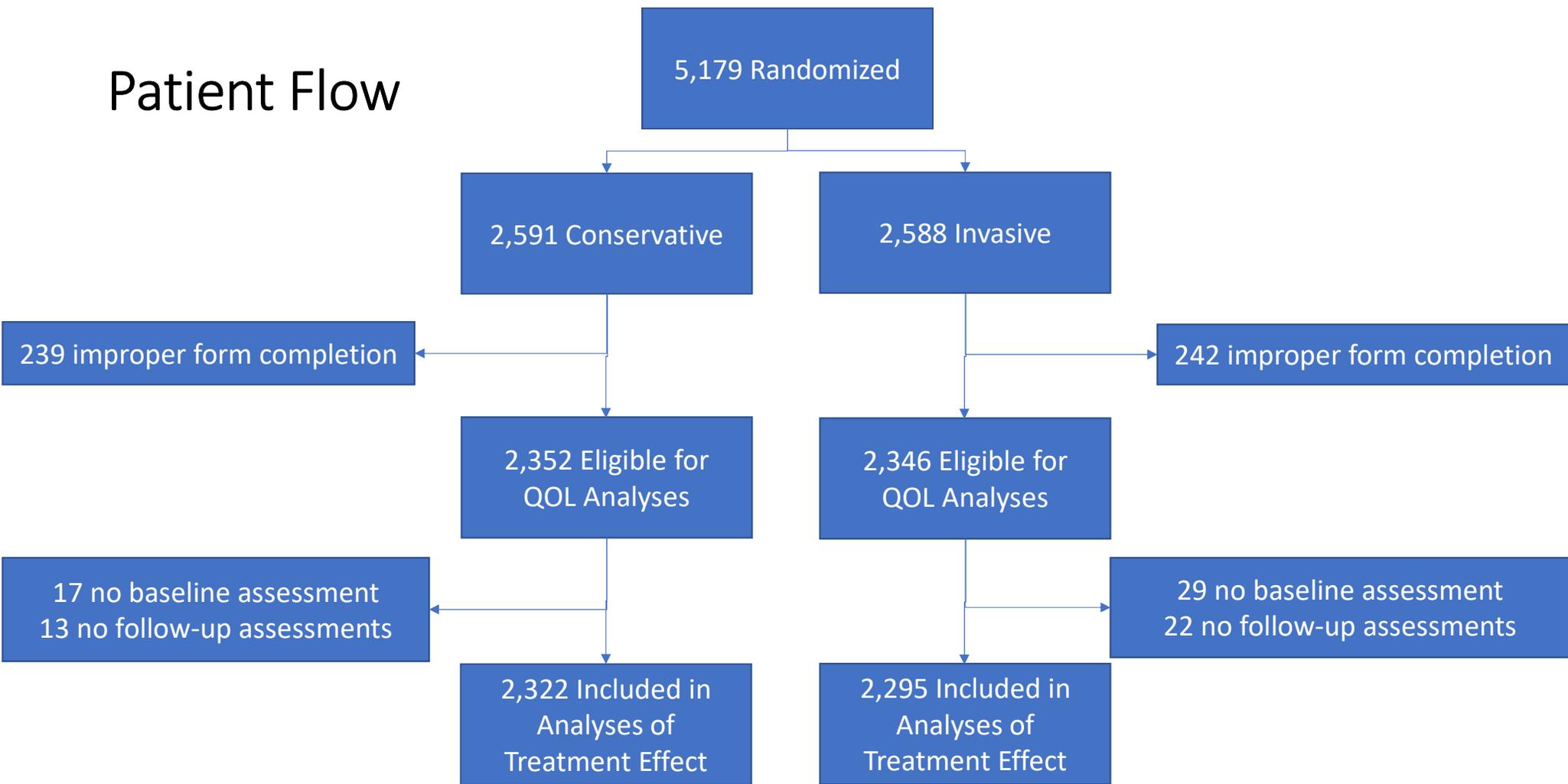
Over the past 4 weeks, how often have you had angina?



Statistical Methods

- Simple descriptive statistics of observed mean scores
- Mixed-effect proportional odds models for all QOL scales
 - Treatment effect = Odds ratio for $QOL \geq X$, at each time point
 - Results transformed to individual SAQ scales
- Bayesian methods used for all models to directly estimate probability of treatment effect with posterior means and 95% posterior density intervals
- Analyses performed for all patients and stratified by baseline angina
 - e.g. daily/weekly vs. several times per month vs. no angina

Patient Flow

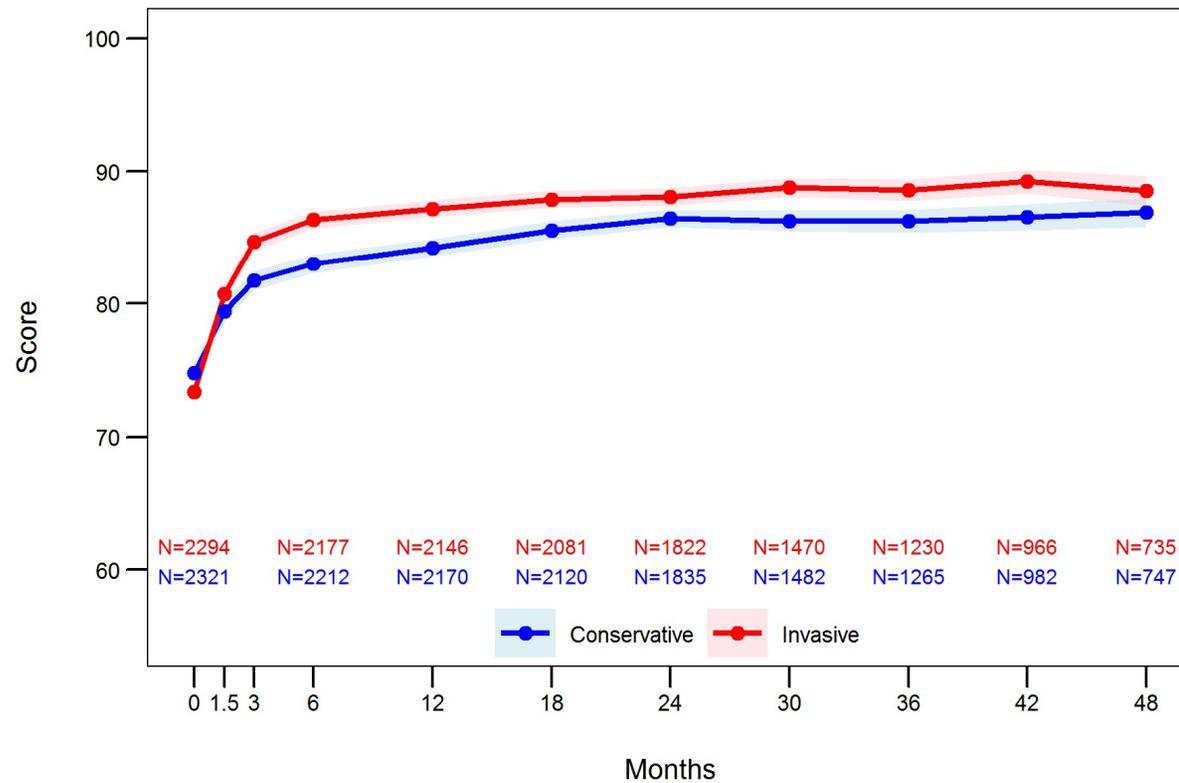


Baseline Health Status

Scale	Invasive	Conservative
SAQ Summary Score	73.3±19	74.8±19
SAQ Quality of Life Score	60.9±27	62.7±26
SAQ Angina Frequency Score	80.8±20	82.1±19
Daily/Weekly Angina	21.6%	19.0%
Several Times per Month	44.1%	44.5%
No Angina	34.3%	36.6%

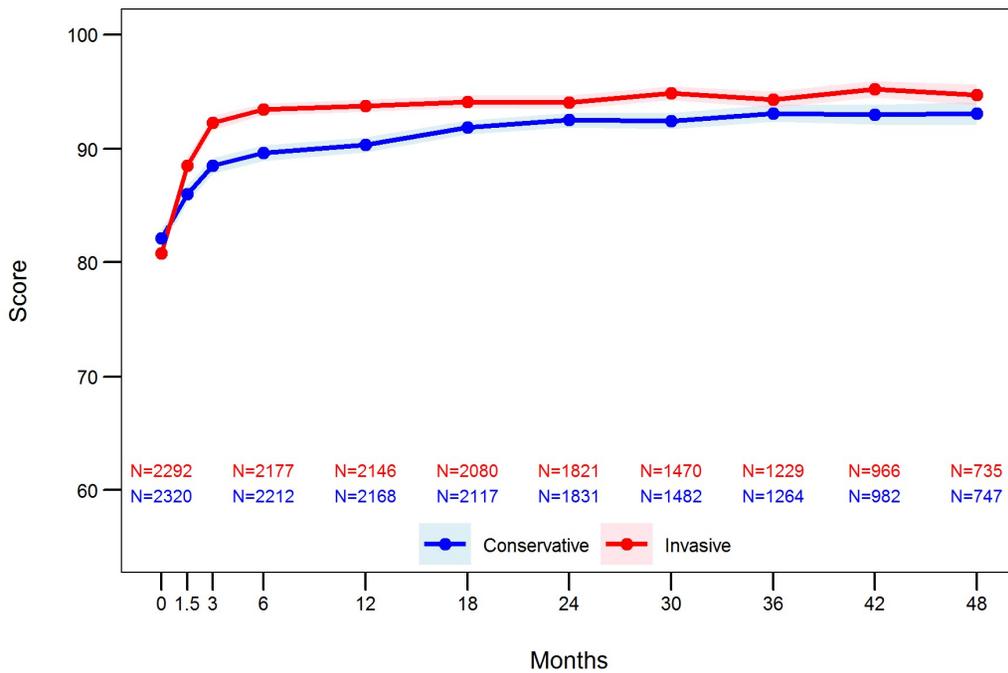
Description of Observed Data

SAQ Summary Score

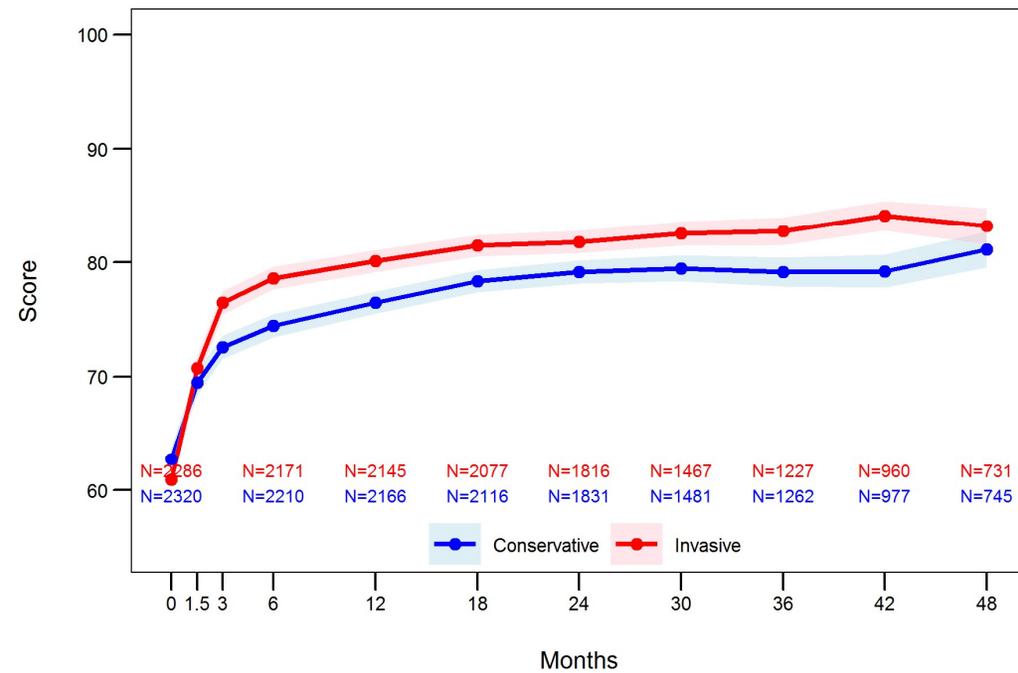


Description of Observed Data

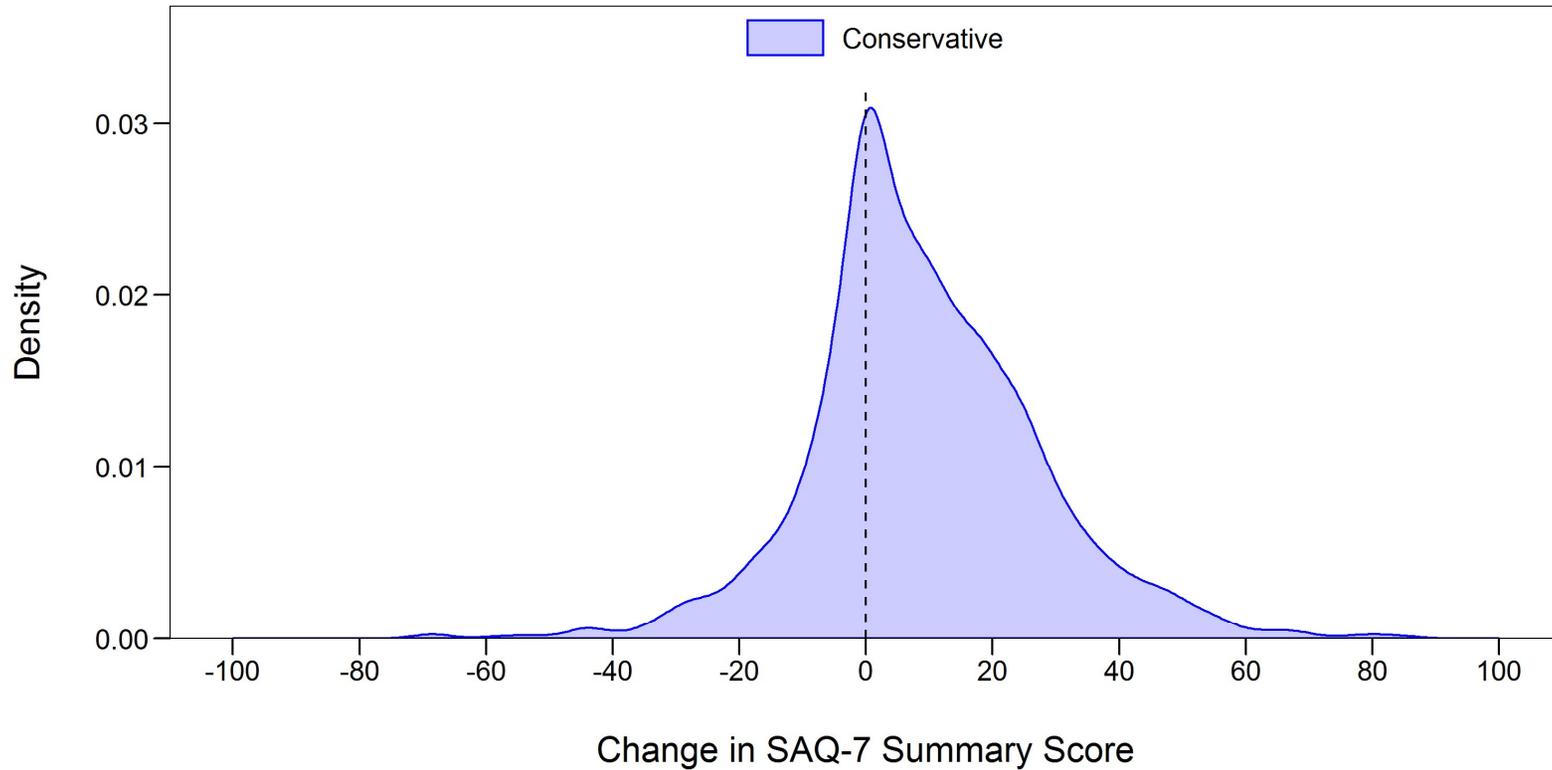
SAQ Angina Frequency



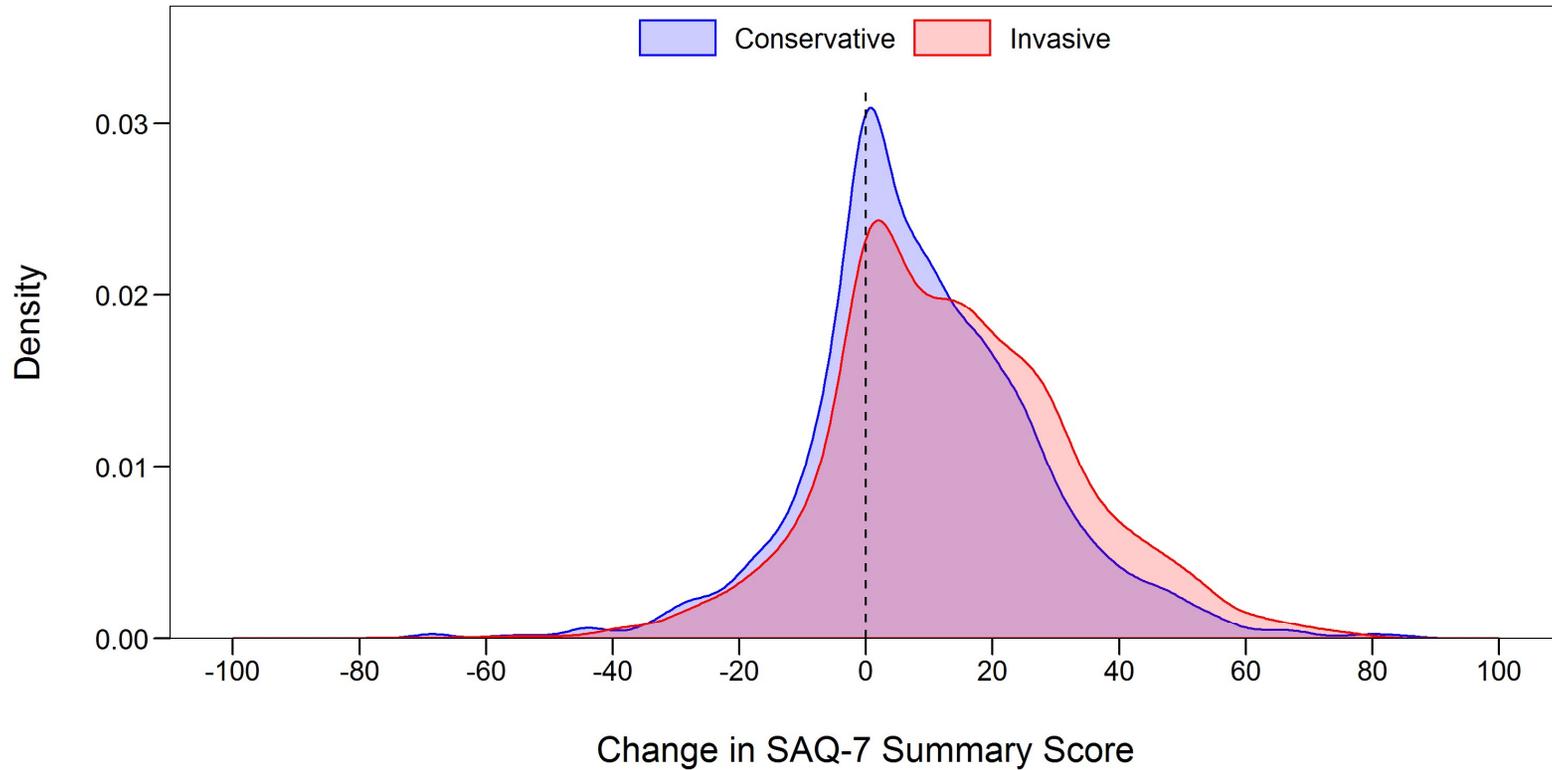
SAQ Quality of Life



Improvement in SAQ Summary Score at 12 Months

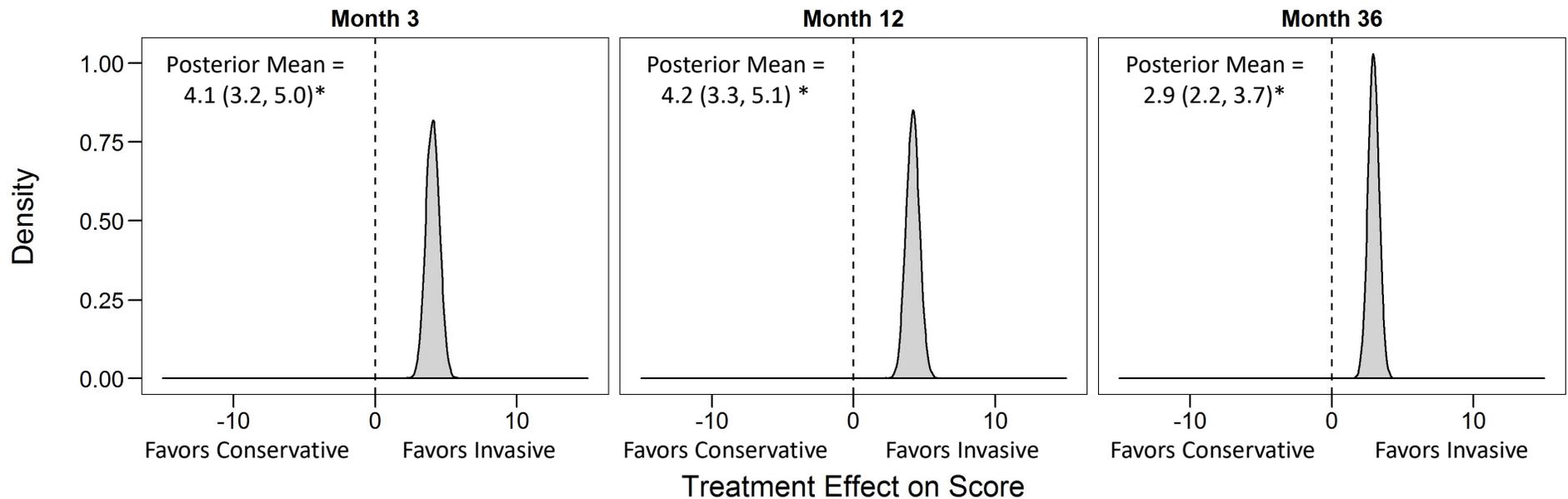


Improvement in SAQ Summary Score at 12 Months



Primary Outcome: Benefit of Invasive Rx on SAQ Summary Score

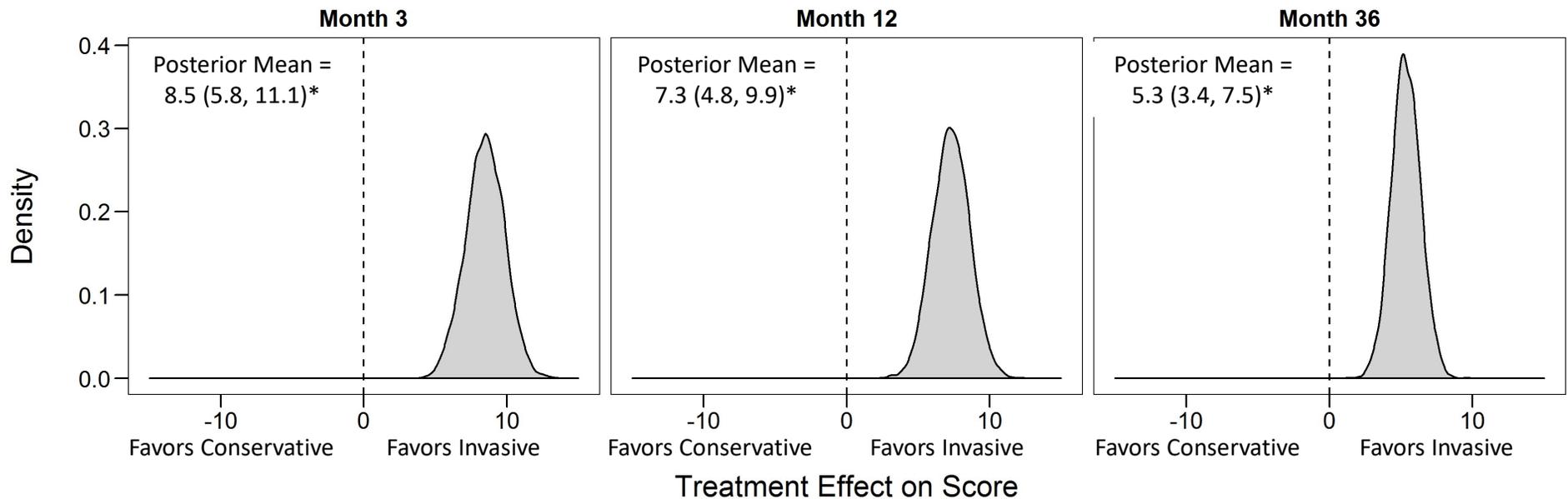
Typical Patient in ISCHEMIA



**95% Highest Posterior Density Interval*

Primary Outcome: Benefit of Invasive Rx on SAQ Summary Score

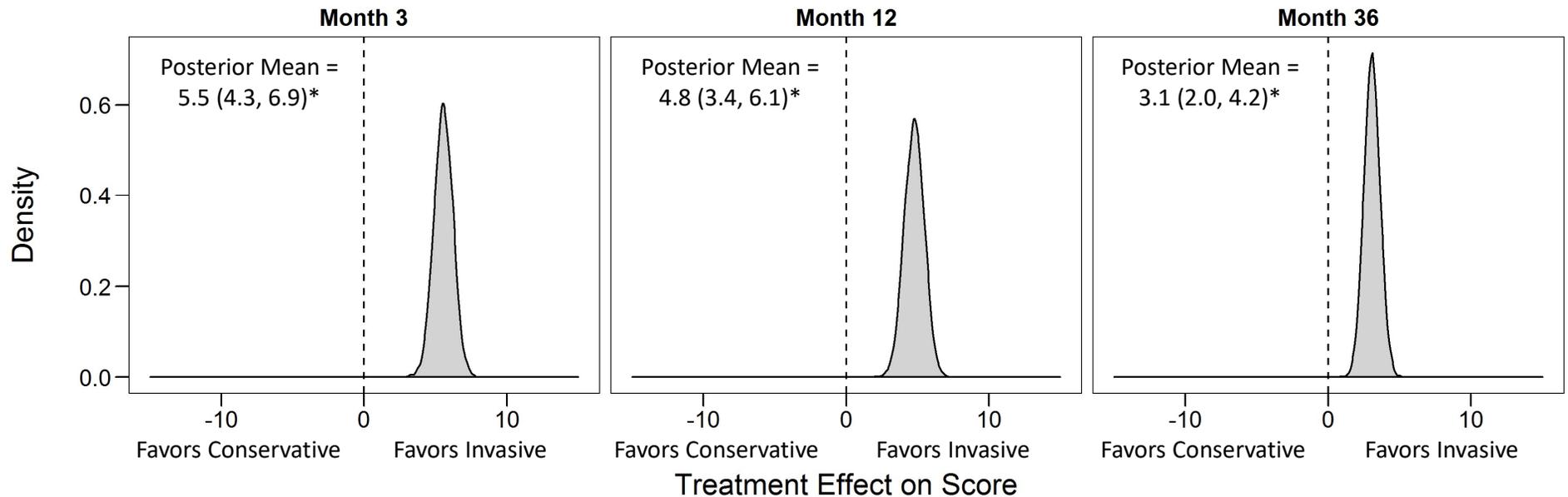
Typical Patient with Daily to Weekly Angina



**95% Highest Posterior Density Interval*

Primary Outcome: Benefit of Invasive Rx on SAQ Summary Score

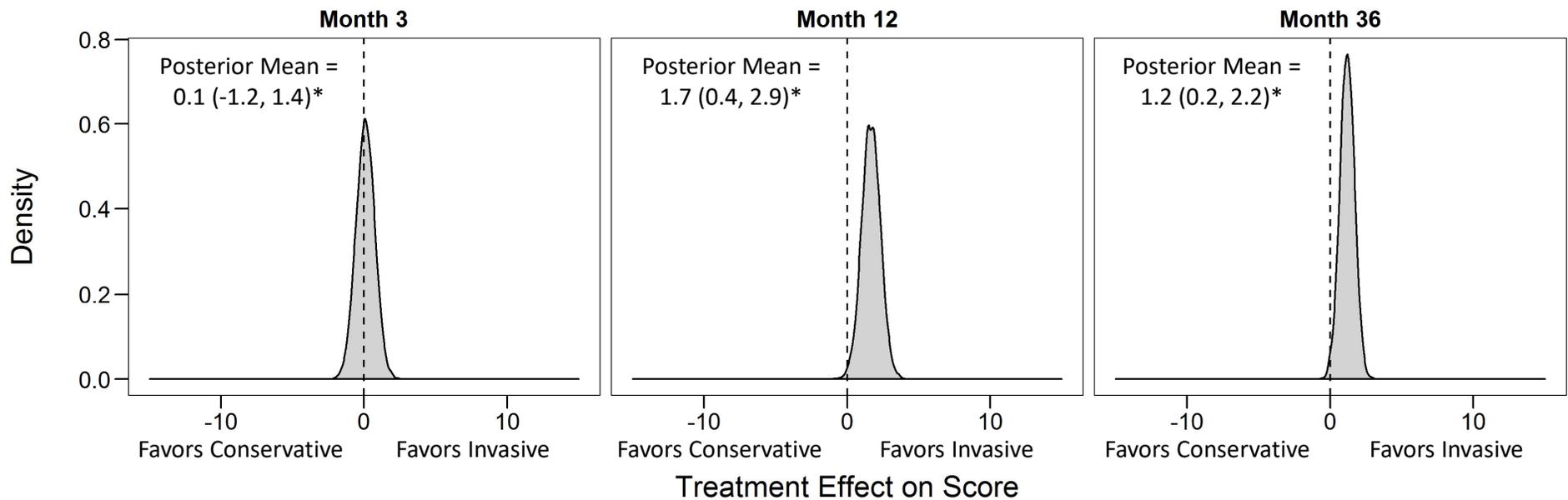
Typical Patient with at least Monthly Angina



**95% Highest Posterior Density Interval*

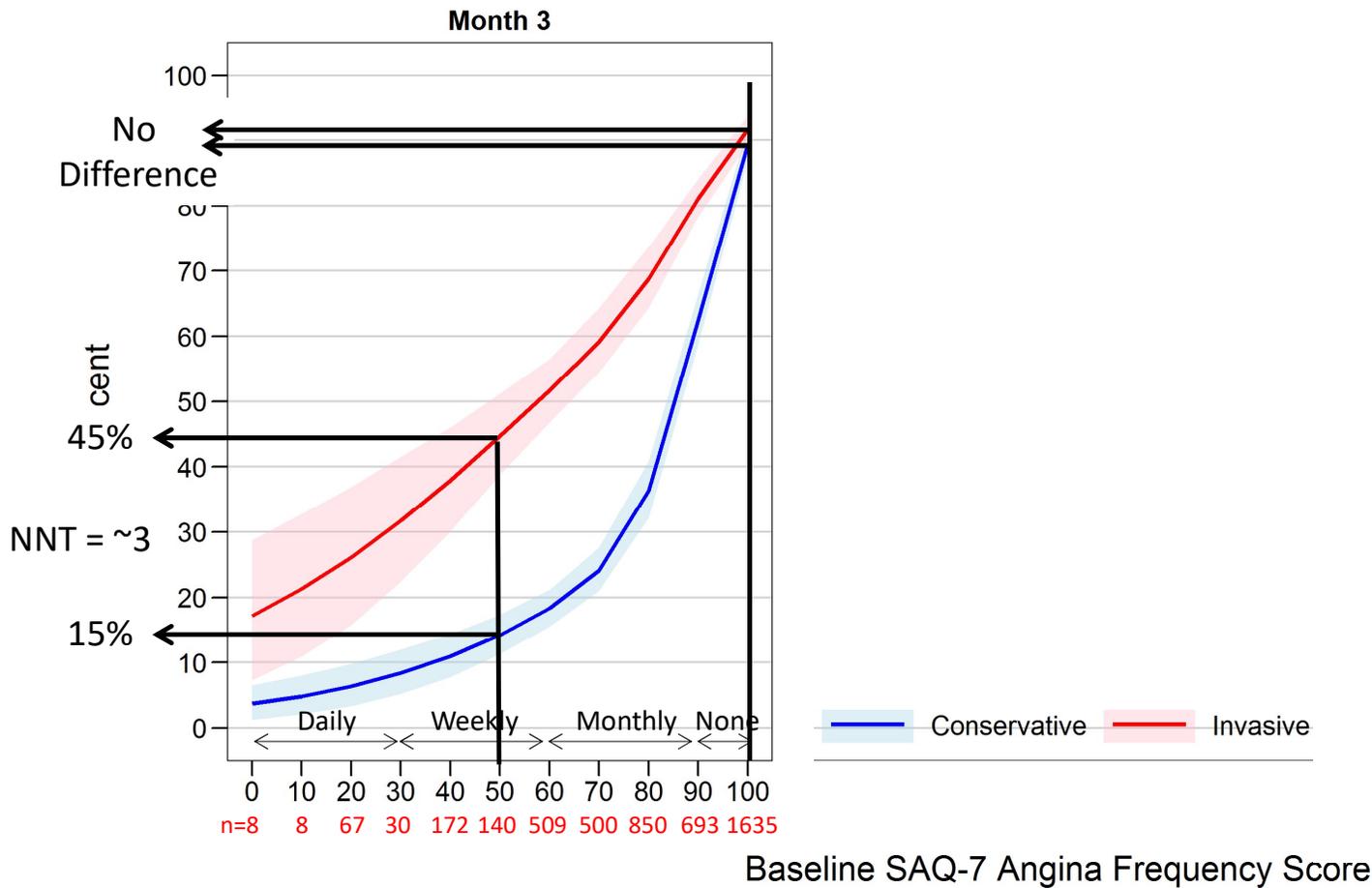
Primary Outcome: Benefit of Invasive Rx on SAQ Summary Score

Typical Patient with No Angina



**95% Highest Posterior Density Interval*

Probability of No Angina by Baseline Angina Frequency



Limitations

- Missing SAQ data, although small (<10%)
- Skewed enrollment towards less symptomatic patients
 - The larger effects in more symptomatic still clearly assessable
- No sham group
 - Nonetheless, angina-free benefits comparable with that seen in ORBITA

Conclusions

- Patients with stable CAD and moderate to severe ischemia had significant, durable improvements in angina control and quality of life with an invasive strategy *if they had angina* (daily/weekly or monthly)
- In patients without angina, an invasive strategy led to minimal symptom or quality of life benefits, as compared with a conservative strategy
- In patients with angina, shared decision-making should occur to align treatment with patients' goals and preferences

Thank you....

- Quality of Life Core Lab: Philip Jones, Dan Mark, Khaula Baloch, Lisa Hatch
- ISCHEMIA Trial Chair & Co-Chair: Judith Hochman, David Maron
- ISCHEMIA Analytic Center and DSMB: Sean O'Brien, Frank Harrell
- ISCHEMIA Site PIs and Data Coordinators
- The Patients volunteering to participate in ISCHEMIA

Backup Slides

SIHD Management after ISCHEMIA

