Patient Reported Outcomes (PROs) Overview

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Disclosures

- None

Key Objectives

1. Background & Goals of PROs
2. Why PROs for CHANGE AFib?
3. Instructions & Guidance on PRO Administration

Background & Goals of PROs

Pop Quiz (*Raise Your Hands*)

Reduction in quality of life is greatest in which of the following conditions?

A. Heart failure
B. Atrial fibrillation
C. Coronary artery disease/MI

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Pop Quiz

Reduction in quality of life is greatest in which of the following conditions?

A. Heart failure
B. Atrial fibrillation
C. Coronary artery disease/MI

The reductions in QOL are comparable across all 3 conditions.

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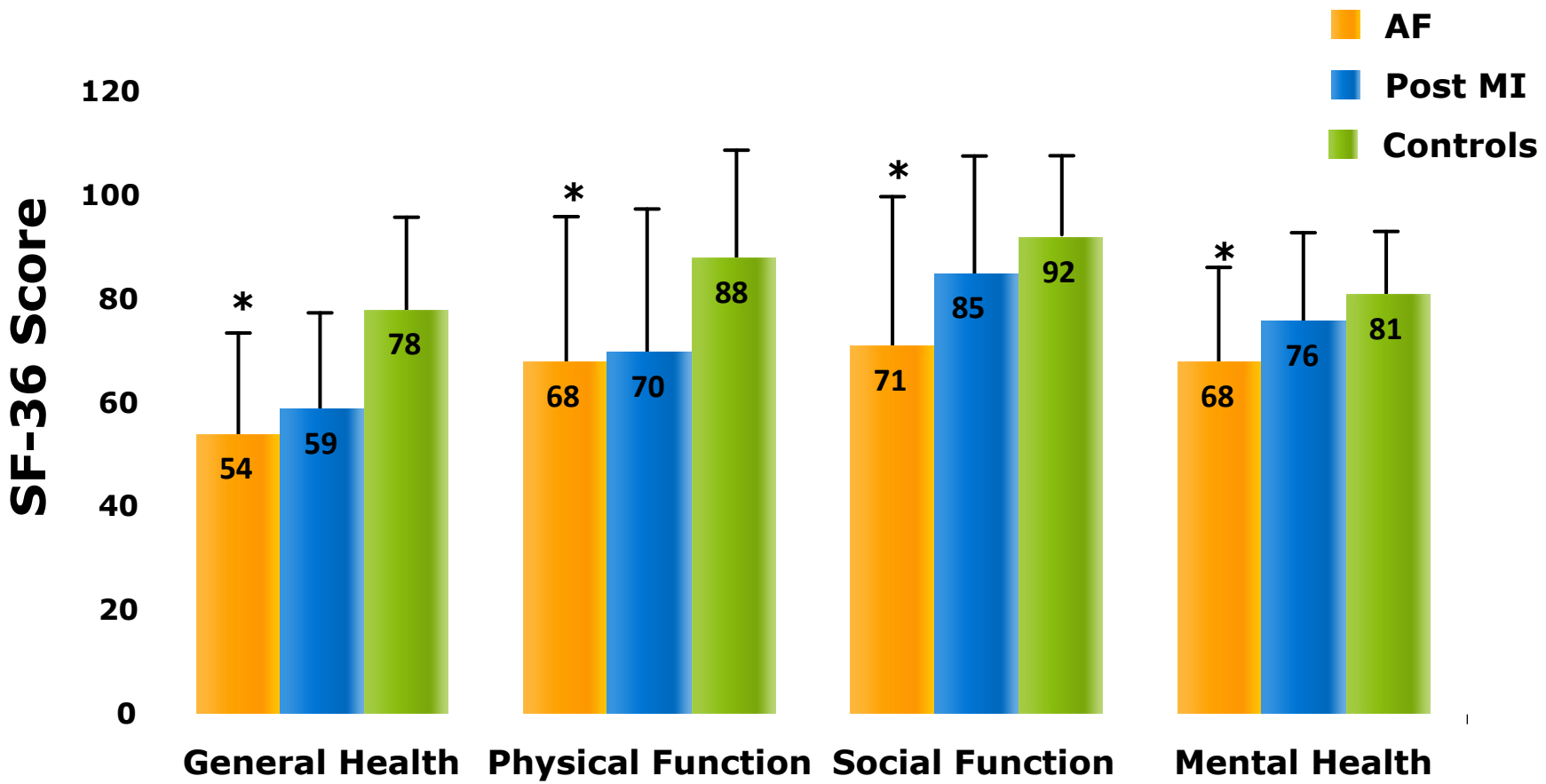
AF Adversely Affects QoL



*$P < .05$ AF vs controls

Dorian P, et al. *J Am Coll Cardiol*. 2000;36:1303-1309.

Background and Goals of PROs

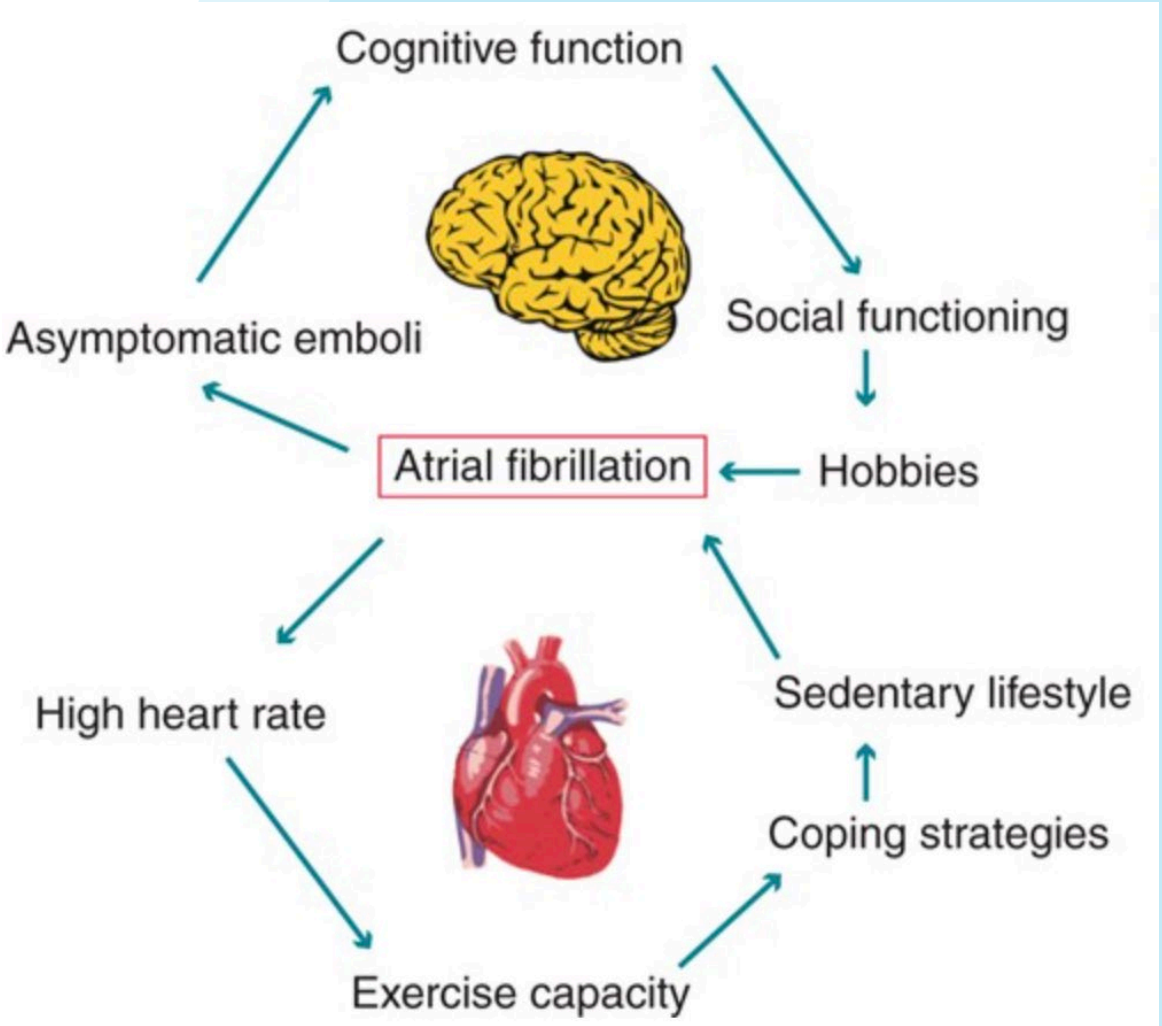
- Any report of the status of a patient's health condition or health behavior that comes directly from the patient **without** interpretation of the patient's response by a clinician or anyone else
- PRO instruments are used to measure the effect of a medical intervention on one or more domains relevant to the disease state
- Can be used to inform patient-centered care, clinical decision making, and health policy[1]

1 Calvert, et al. JAMA 2013

Why PROs for CHANGE AFib?

PROs in CHANGE AFib

- Atrial fibrillation symptoms and their effect on patients are variable, ranging from minimal to incapacitating
- Previous studies with with medical therapy and ablation have shown benefit in PROs
- Important to ensure that PROs do not worsen and ideally, improve with intervention



Aliot, et al. EP Europace, 2014

PROs in CV Trials

The Effects of Antihypertensive Therapy on the Quality of Life

Sydney H. Croog, Ph.D., Sol Levine, Ph.D., Marcia A. Testa, Ph.D., Byron Brown, Ph.D., Christopher J. Bulpitt, M.D., C. David Jenkins, Ph.D., Gerald L. Klerman, M.D., and Gordon H. Williams, M.D.

June 26, 1986

N Engl J Med 1986; 314:1657-1664

DOI: 10.1056/NEJM198606263142602

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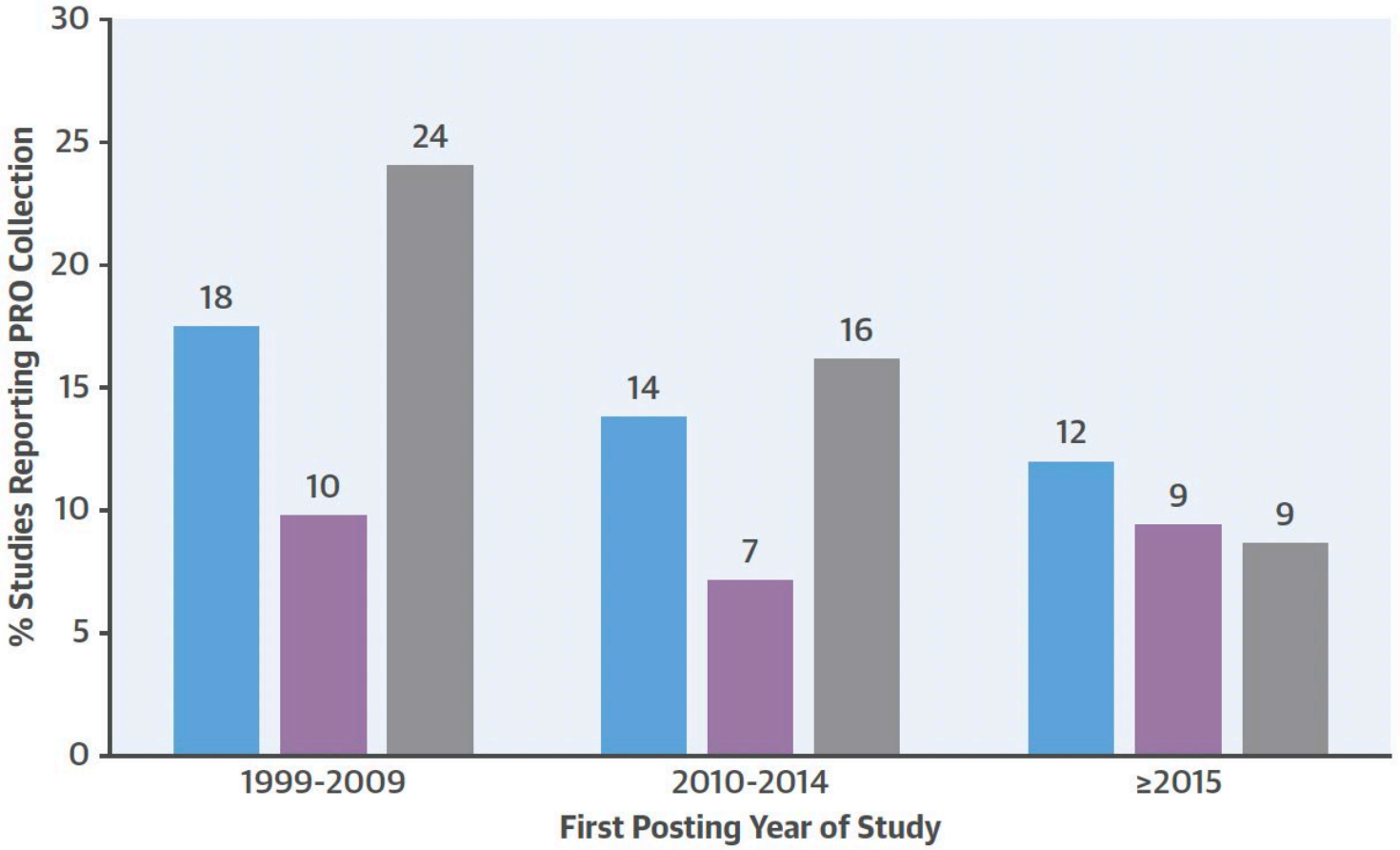
Patient Reported Outcomes: *Often Forgotten*

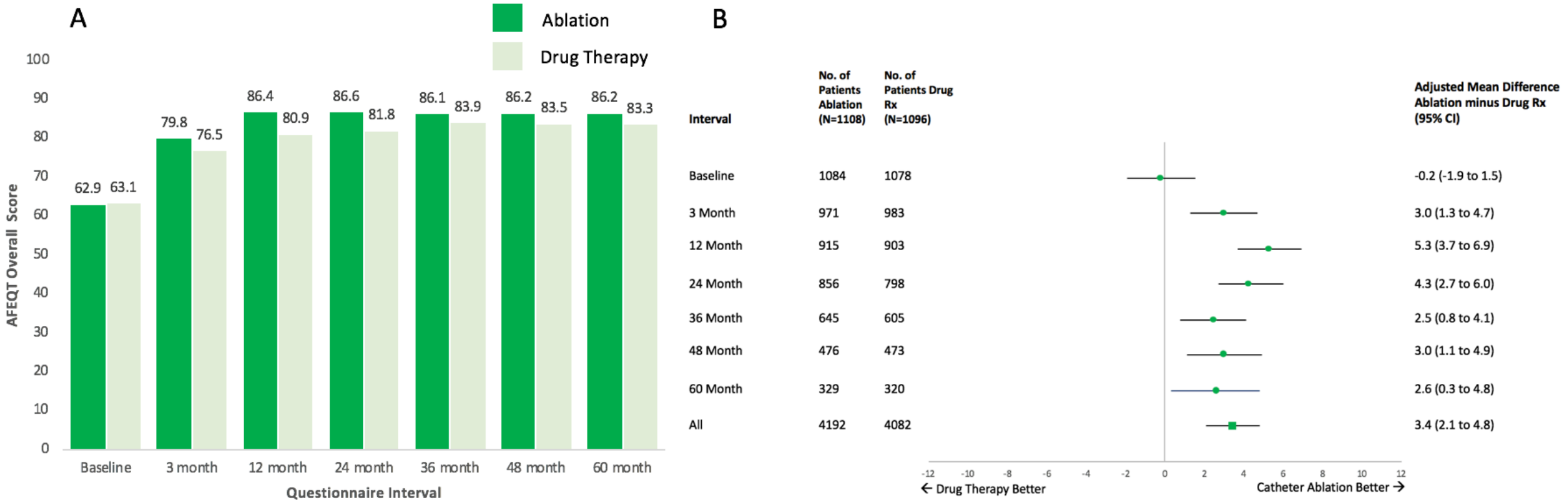


Total n	382	622	705
Drug Only	132	151	138
Procedure or Device Only	137	230	275

Overall Drug Only Procedure or Device Only

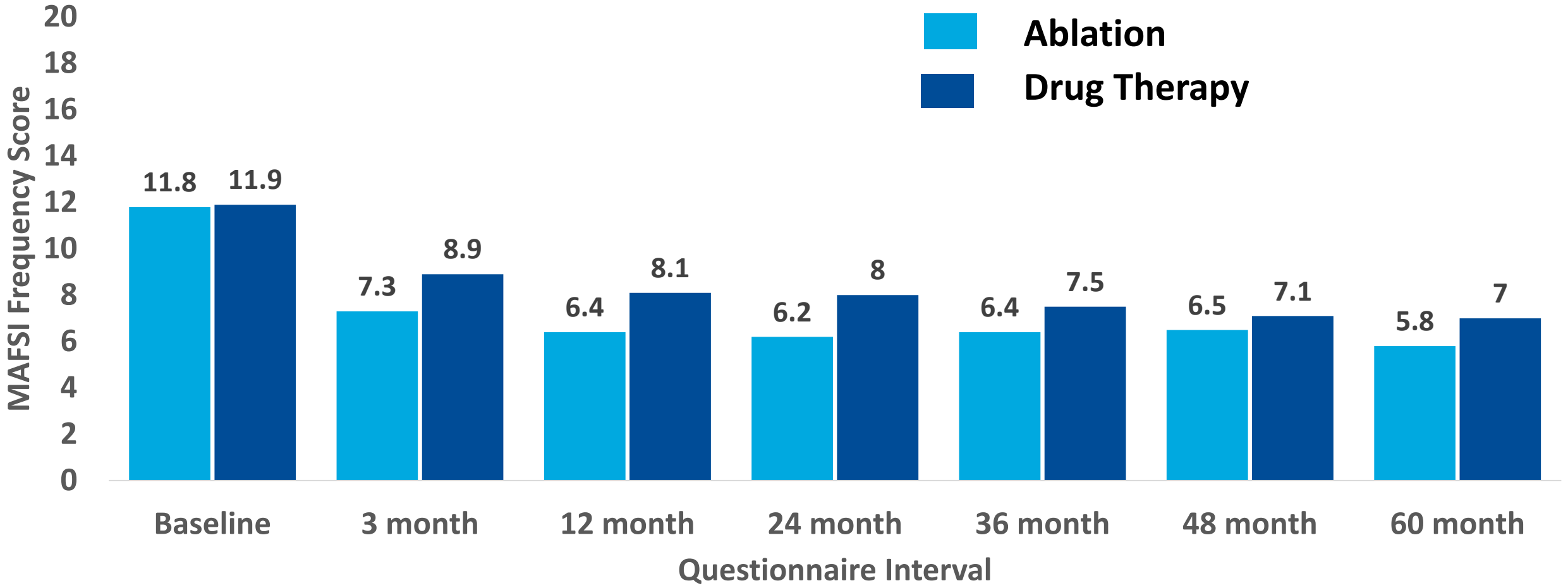
Steinberg, B.A. et al. J Am Coll Cardiol EP. 2019;5(5):599-605.

AF-Related Quality of Life Improved with Rhythm Control: Findings from the CABANA Trial



Mark et al. *JAMA* 2019;321(13):1275-1285.

MAFSI Frequency Score: Intention-to-Treat Analysis



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* 1º endpoint

Mark et al. *JAMA* 2019;321(13):1275-1285.

Instructions & Guidance on PRO Administration

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Quality of Life Scales

The following sections will cover how to correctly administer the following Quality of Life (QOL) Scales. Both scales will be administered at the baseline visit and the 12-month follow-up visit. Total scores for each questionnaire will be calculated for you within GWTG-AFib.

- Atrial Fibrillation Effect on QualiTy-of-life (AFEQT) questionnaire
- Mayo AF-Specific Symptom Inventory (MAFSI)

AFEQT

What is the AFEQT Questionnaire?

- An AFib specific health-related quality of life (HRQoL) questionnaire to assess the impact of atrial fibrillation on patients' HRQOL and possibly assess changes with treatment.

Administration of the AFEQT questionnaire:

- Completion should take approximately 5 minutes
- Intended to be a self-administered questionnaire
- All respondents should be encouraged to answer each question. If the respondent asks for clarification of a particular item, read the question to the subject verbatim. If the respondent still asks for clarification, explain to him/her that he/she should use his/her own interpretation of the question.
- If the patient cannot read, read each question to him/her verbatim.

Baseline & 12-Month Follow-up Visits:

- In-person visits: Provide the questionnaire to the patient to complete.
- Virtual visits: Read the questionnaire, verbatim, document patient responses

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AFEQT (Information obtained from: http://afeqt.org/files/Instruction_Guide_for_AFEQT_Questionnaire-5-18-10.pdf)

For Trial Staff Only. CHANGE AFib Patient ID: _____

Atrial Fibrillation Effect on QualiTy-of-life (AFEQT) Questionnaire

Section 1. Occurrence of atrial fibrillation **Name or ID:**_____

Are you currently in atrial fibrillation? ☐ Yes ☐ No

If **No**, when was the last time you were aware of having had an episode of atrial fibrillation? (Please check one answer which best describes your situation)

__earlier today
__within the past week
__within the past month
__1 month to 1 year ago
__more than 1 year ago
__I was never aware of having atrial fibrillation

Section 2. The following questions refer to how atrial fibrillation affects your quality of life.

On a scale of 1 to 7, over the past 4 weeks, as a result of your atrial fibrillation, how much were you bothered by: (Please circle one number which best describes your situation)

	Not at all bothered Or I did not have this symptom	Hardly bothered	A little bothered	Moderately bothered	Quite a bit bothered	Very bothered	Extremely bothered
1. Palpitations: Heart fluttering, skipping or racing	1	2	3	4	5	6	7
2. Irregular heart beat	1	2	3	4	5	6	7
3. A pause in heart activity	1	2	3	4	5	6	7
4. Lightheadedness or dizziness	1	2	3	4	5	6	7

On a scale of 1 to 7, over the past 4 weeks, have you been limited by your atrial fibrillation in your: (Please circle one number which best describes your situation)

	Not at all limited	Hardly limited	A little limited	Moderately limited	Quite a bit limited	Very limited	Extremely limited
5. Ability to have recreational pastimes, sports, and hobbies	1	2	3	4	5	6	7
6. Ability to have a relationship and do things with friends and family	1	2	3	4	5	6	7

On a scale of 1 to 7, over the past 4 weeks, as a result of your atrial fibrillation, how much difficulty have you had in: (Please circle one number which best describes your situation)

	No difficulty at all	Hardly any difficulty	A little difficulty	Moderate difficulty	Quite a bit of difficulty	A lot of difficulty	Extreme difficulty
7. Doing any activity because you felt tired, fatigued, or low on energy	1	2	3	4	5	6	7
8. Doing physical activity because of shortness of breath	1	2	3	4	5	6	7
9. Exercising	1	2	3	4	5	6	7
10. Walking briskly	1	2	3	4	5	6	7
11. Walking briskly uphill or carrying groceries or other items, up a flight of stairs without stopping	1	2	3	4	5	6	7
12. Doing vigorous activities such as lifting or moving heavy furniture, running, or participating in strenuous sports like tennis or racquetball	1	2	3	4	5	6	7

Atrial Fibrillation Effect on QualiTy-of-life (AFEQT) Questionnaire

On a scale of 1 to 7, over the past 4 weeks as a result of your atrial fibrillation, how much did the feelings below bother you? (Please circle one number which best describes your situation)

	Not at all Bothered	Hardly bothered	A little bothered	Moderately bothered	Quite a bit bothered	Very bothered	Extremely bothered
13. Feeling worried or anxious that your atrial fibrillation can start anytime	1	2	3	4	5	6	7
14. Feeling worried that atrial fibrillation may worsen other medical conditions in the long run	1	2	3	4	5	6	7

On a scale of 1 to 7, over the past 4 weeks, as a result of your atrial fibrillation treatment, how much were you bothered by: (Please circle one number which best describes your situation)

	Not at all bothered	Hardly bothered	A little bothered	Moderately bothered	Quite a bit bothered	Very bothered	Extremely bothered
15. Worrying about the treatment side effects from medications	1	2	3	4	5	6	7
16. Worrying about complications or side effects from procedures like catheter ablation, surgery, or pacemakers therapy	1	2	3	4	5	6	7
17. Worrying about side effects of blood thinners such as nosebleeds, bleeding gums when brushing teeth, heavy bleeding from cuts, or bruising.	1	2	3	4	5	6	7
18. Worrying or feeling anxious that your treatment interferes with your daily activities	1	2	3	4	5	6	7

On a scale of 1 to 7, overall, how satisfied are you **at the present time** with: (Please circle one number which best describes your situation)

	Extremely satisfied	Very satisfied	Somewhat satisfied	Mixed with satisfied and dissatisfied	Somewhat dissatisfied	Very dissatisfied	Extremely dissatisfied
19. How well your current treatment controls your atrial fibrillation?	1	2	3	4	5	6	7
20. The extent to which treatment has relieved your symptoms of atrial fibrillation?	1	2	3	4	5	6	7

Name or ID:_____

For Trial Staff Only. CHANGE AFib Patient ID (as found in REDCap: _____

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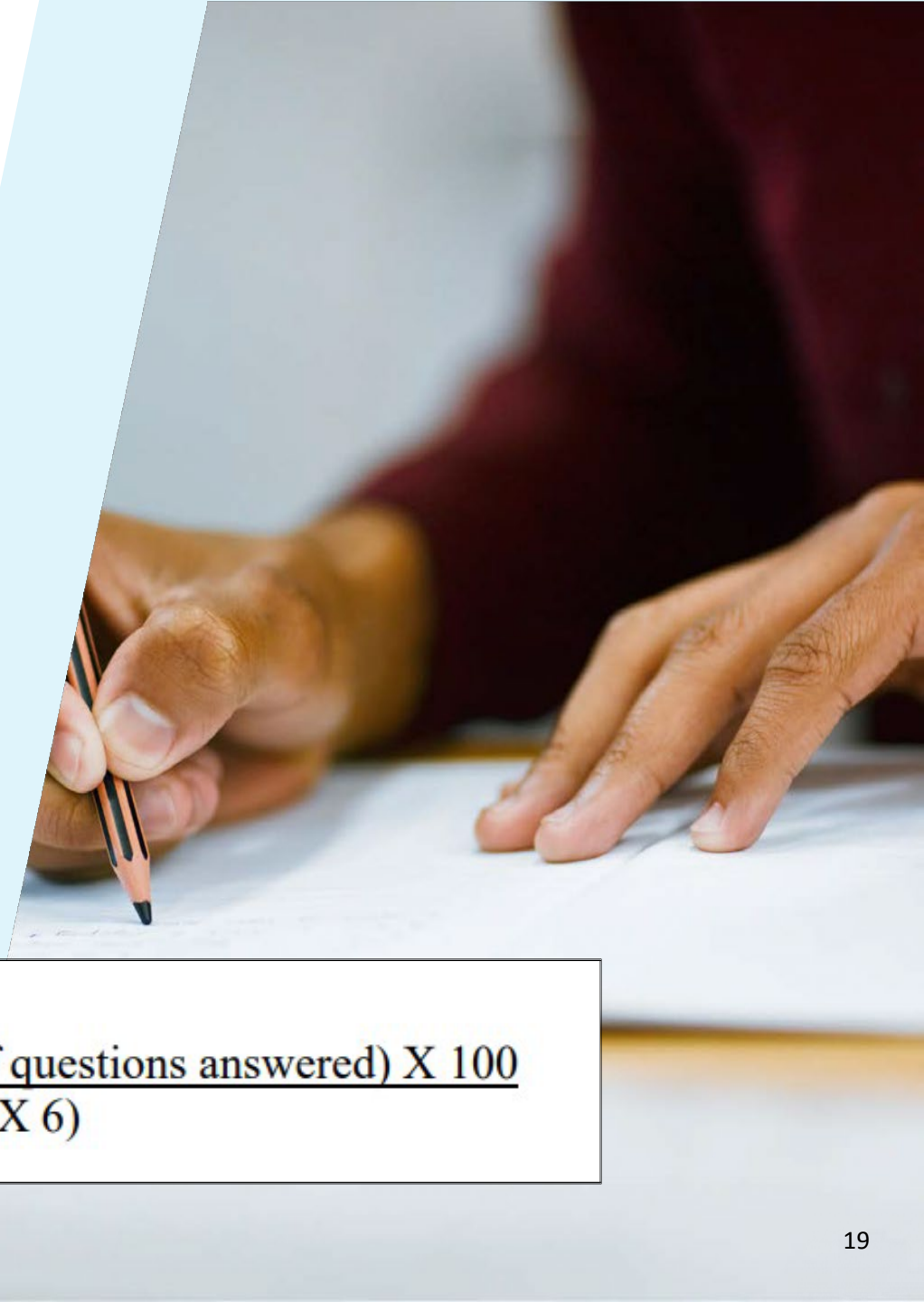
AFEQT Scoring

- General Scoring Information
  - The responses on the AFEQT are scored on a 1 to 7 Likert scale, where for questions 1-18,
    - 1= “Not at all…” to 7 = “Extremely...”.
  - Questions 19- 21 relate to patients’ satisfaction with treatment and are not included in HRQoL score of the AFEQT questionnaire.
- Overall AFEQT score
  - Calculation of the AFEQT score is calculated based on the following formula:



Overall AFEQT score:

$$100 - \frac{(\text{sum of severity for all questions answered} - \text{number of questions answered}) \times 100}{(\text{total number questions answered} \times 6)}$$

http://afeqt.org/files/AFEQT_Questionnaire_Scoring_Guide.pdf

MAFSI

CHANGE AFib is using a modified MAFSI questionnaire comprised of a 10-item AFib symptom checklist asking about both the frequency and severity of each symptom.

Mayo AF-Specific Symptom Inventory (MAFSI)

Subject ID Number: _____ **Write-in the subject's CHANGE AFib Patient ID as found in** REDCap

Assessment Date: _____

Think back over the past month. Please tell us how often you have had each symptom listed below:

	How Often? (mark one)					How Severe? (Leave blank if "Never")		
	Never	Rarely	Sometimes	Often	Always	Mild	Moderate	Extreme
Palpitations heart fluttering/racing	☐	☐	☐	☐	☐	☐	☐	☐
Slow heart beat	☐	☐	☐	☐	☐	☐	☐	☐
Lightheadedness/dizziness	☐	☐	☐	☐	☐	☐	☐	☐
Fainting/blackout/loss of consciousness	☐	☐	☐	☐	☐	☐	☐	☐
Chest pain, pressure or fullness WITHOUT palpitations	☐	☐	☐	☐	☐	☐	☐	☐
Shortness of breath	☐	☐	☐	☐	☐	☐	☐	☐
Unable to exercise	☐	☐	☐	☐	☐	☐	☐	☐
Tired/lack of energy	☐	☐	☐	☐	☐	☐	☐	☐
Weakness	☐	☐	☐	☐	☐	☐	☐	☐
Feeling warm/flushed	☐	☐	☐	☐	☐	☐	☐	☐

Administered by: _____ **Date:** _____

MAFSI

What is the MAFSI Questionnaire?

- The MAFSI was developed as a modification and update of the AF Symptom Checklist.

Administration of the MAFSI questionnaire:

- The frequency of symptoms is recorded as 0 (Never), 1 (rarely), 2 (sometimes), 3 (often), or 4 (always).
- These responses are summed for a total Frequency Score that ranges from 0 (no AF symptoms) to 40 (worst score). Similarly, MAFSI Severity Scores are recorded as 1 (mild), 2 (moderate), or 3 (extreme). Severity scores are summed and range from 0 (no AF symptoms) to 30 (most severe AF symptoms).
- The MAFSI will be collected on the trial case report form and will be administered by site coordinators at baseline and at the 12-month follow-up visit. Patients can self complete the form or trial staff can read the questionnaire, verbatim, to the patients and document his/her responses.

Baseline & 12-Month Follow-up Visits:

- In-person visits: Provide the questionnaire to the patient to complete.
- Virtual visits: Read the questionnaire, verbatim, document patient responses

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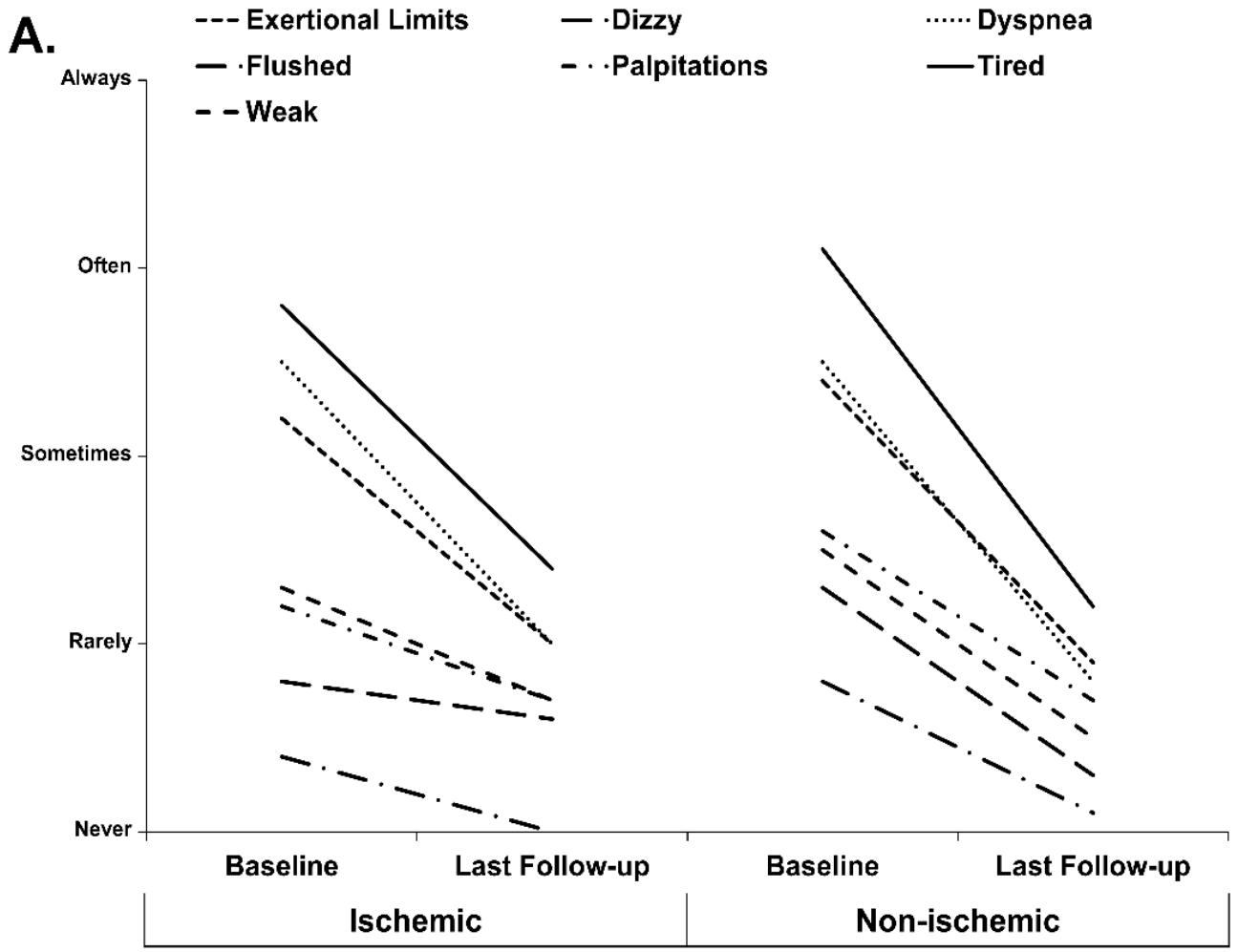
MAFSI Illustrated:

Changes in MAFSI Severity in Patients with Heart Failure Undergoing Rhythm Control



Black-Maier E, et al. *J Arrhythm.* 2020; 36(1): 84–92.

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Thank You