

1

Implementing Patient-Reported Outcomes in Clinical Care: The Final Frontier

John Spertus MD MPH
Professor of Medicine
University of Missouri-Kansas City

2

Saint Luke's MID AMERICA HEART INSTITUTE

Disclosures

- Speaker's Bureaus: None
- Grant Support: BMS, Janssen, Imbria, Lexicon, ACCF
- Consultant: Cytokinetics, Janssen, Imbria, Lexicon, Lexio, Kardigan, BMS, Terumo, BCBS of KC
- Prior Copyrights: SAQ, KCCQ
- Current Copyrights: PAQ/PAQ-CLI

3

Imagine a New, Revolutionary Test

- Defines the status of a medical condition
  - Improves Accuracy
  - Increases Clinical Efficiency
- Risk-stratifies prognosis
- Identifies which patients benefit from treatment
- Monitors responses to treatment
- Supports population health management
- Defines the quality of healthcare

4

It's Patient-Reported Outcomes…



5

A Conceptual Model of Health Status in CAD

Capturing What the Patient Experiences…

Disease	Symptoms	Functional Limitation	Quality of Life
Coronary occlusion Vascular Function Inflammatory State	Angina	Physical Emotional Social	Discrepancy between actual & desired health and functioning

The Range of Health Status

6

Attributes of Health Status Measures

- Validity:
  Does the instrument measure what it is supposed to?
- Reliability:
  Are the results the same when given repeatedly to stable patients?
- Responsiveness:
  Do the results reflect changes in patients' disease status?
- Interpretability:
  What does a given score or change in score mean?
- Translations:
  Are linguistically and culturally appropriate translations available?

7

The Seattle Angina Questionnaire

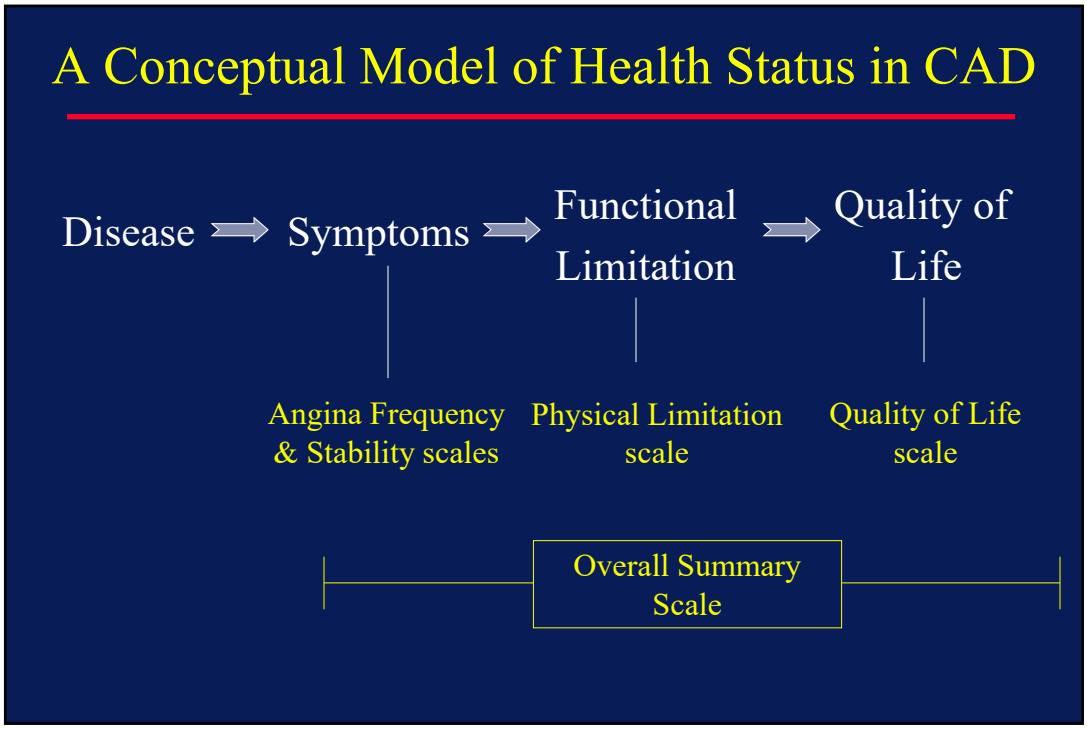
- 19/7 items that measures 5 clinically relevant domains
  - » Physical Limitation
  - » Anginal Frequency
  - » Disease Perception/Quality of Life
  - » Anginal Stability*
  - » Treatment Satisfaction*

  SAQ Summary Score
- Higher Scores = Better Function (Range 0 - 100)
- Established validity, reliability and responsiveness
- Translated into >60 languages/cultures
- Associated with prognosis: Survival, ACS and Costs

* Not in SAQ-7

8

A Conceptual Model of Health Status in CAD



9

The 7-item SAQ

Physical Limitation Scale

Angina Frequency Scale

Quality of Life Scale

The Seattle Angina Questionnaire-7

1. The following is a list of activities that people often do during the week. Although for some people with several medical problems it is difficult to determine what it is that limits them, please go over the activities listed below and indicate how much limitation you have had **due to chest pain, chest tightness or angina** over the past 4 weeks.

2. Over the past 4 weeks, on average, how many times have you had **chest pain, chest tightness or angina**?

   I have had **chest pain, chest tightness or angina…**

4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks
❑	❑	❑	❑	❑	❑

3. Over the past 4 weeks, on average, how many times have you had to take nitroglycerin (nitroglycerin tablets or spray)

4. Over the past 4 weeks, how much has your **chest pain, chest tightness or angina** limited your enjoyment of life?

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not** limited my enjoyment of life at all
❑	❑	❑	❑	❑

5. If you had to spend the rest of your life with your **chest pain, chest tightness or angina** the way it is right now, how would you feel about this?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied
❑	❑	❑	❑	❑

10

The KC Cardiomyopathy Questionnaire

- 23/12 items that measure 5 clinically relevant domains
  - Physical Limitation
  - Symptoms:
    - Frequency
    - Severity
    - Change*
  - Social Limitation
  - Quality of Life
  - Self-Efficacy*

Total Symptom Score

Clinical Summary Score

Overall Summary Score

- Represents the *patient's* perspective of their HF
- Available in over >150 translations
- Established validity, reliability and responsiveness
- Qualified by FDA's CDRH and CDER as a COA

* Not in KCCQ-12

11

Mapping the KCCQ Scales

Disease ⇒ Symptoms ⇒ Functional Limitation ⇒ Quality of Life

Symptom Scales

Physical and Social Function Scales

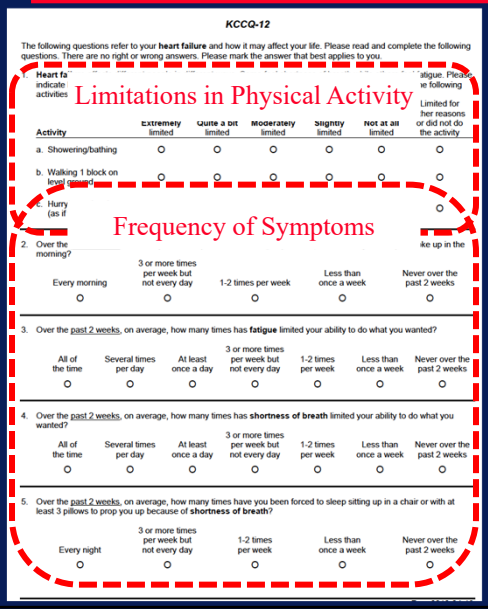
Quality of Life Scale

KCCQ Clinical Summary Scale

KCCQ Overall Summary Scale

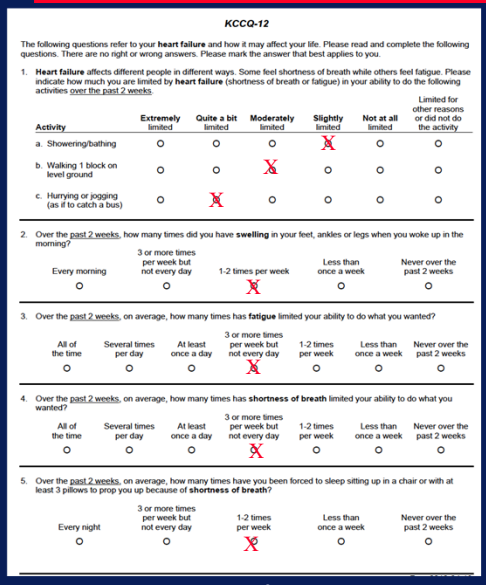
12

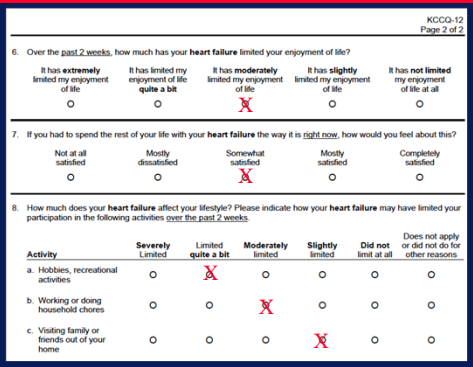
The KCCQ-12



13

The KCCQ-12 – Individual Changes





KCCQ Sxm Freq = 50 → 54 → 62

KCCQ Overall Sum = 50 → 51 → 55

©John Spertus – Privileged and Confidential – Do Not Distribute

14

Imagine a New, Revolutionary Test

- Defines the status of a medical condition
  - Improves Accuracy
  - Increases Clinical Efficiency
- Risk-stratifies prognosis
- Identifies which patients benefit from treatment
- Monitors responses to treatment
- Supports population health management
- Defines the quality of healthcare

15

Evolving Standards in Clinical Care

- The 'Gold Standard' for Cardiac Physiology



Evolution



- Limitations in…
  - Accuracy
  - Reproducibility

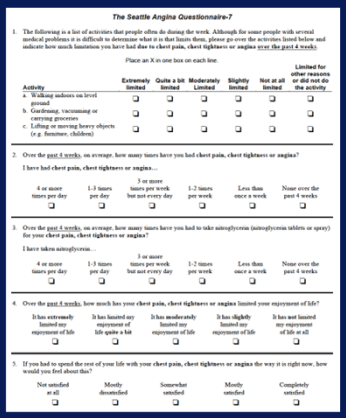
16

A Conceptual Framework for PROs

- The 'Gold Standard' for History of Symptoms and Impact



Evolution



The Seattle Angina Questionnaire-7

1. The following is a list of activities that people often do during the week. Although for some people with several medical problems it is difficult to determine what it is that limits them, please go over the activities listed below and indicate how much limitation you have had due to chest pain, chest tightness or angina over the past 4 weeks:

Place an X in one box on each line.

Activity	Extremely limited	Quite a bit limited	Moderately Limited	Slightly limited	Not at all limited	Limited for other reasons or did not do the activity
a. Walking indoors on level ground	❑	❑	❑	❑	❑	❑
b. Gardening, vacuuming or carrying groceries	❑	❑	❑	❑	❑	❑
c. Lifting or moving heavy objects (e.g. furniture, children)	❑	❑	❑	❑	❑	❑

2. Over the past 4 weeks, on average, how many times have you had chest pain, chest tightness or angina?

I have had chest pain, chest tightness or angina…

4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks
❑	❑	❑	❑	❑	❑

3. Over the past 4 weeks, on average, how many times have you had to take nitroglycerin (nitroglycerin tablets or spray) for your chest pain, chest tightness or angina?

I have taken nitroglycerin…

4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks
❑	❑	❑	❑	❑	❑

4. Over the past 4 weeks, how much has your chest pain, chest tightness or angina limited your enjoyment of life?

It has extremely limited my enjoyment of life	It has limited my enjoyment of life quite a bit	It has moderately limited my enjoyment of life	It has slightly limited my enjoyment of life	It has not limited my enjoyment of life at all
❑	❑	❑	❑	❑

5. If you had to spend the rest of your life with your chest pain, chest tightness or angina the way it is right now, how would you feel about this?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied
❑	❑	❑	❑	❑

- Limitations in…
  - Accuracy
  - Reproducibility

17

Saint Luke's MID AMERICA HEART INSTITUTE

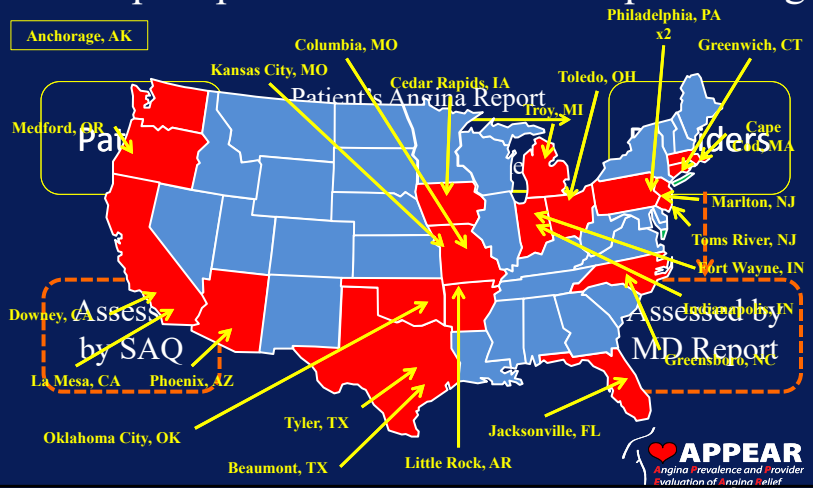
PROMs: Hearing the Patient's Voice



18

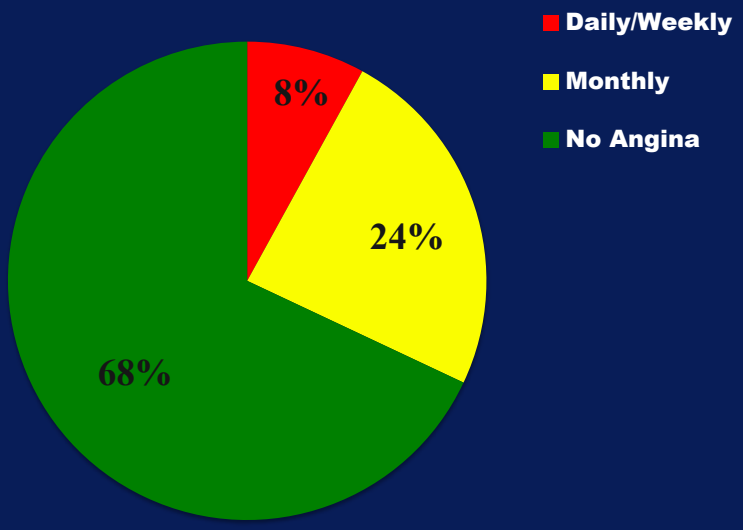
Do MDs Accurately Assess Angina?

- 24-center study of outpatients with CAD (n=1,257)
- To compare patient- and clinician-reported angina



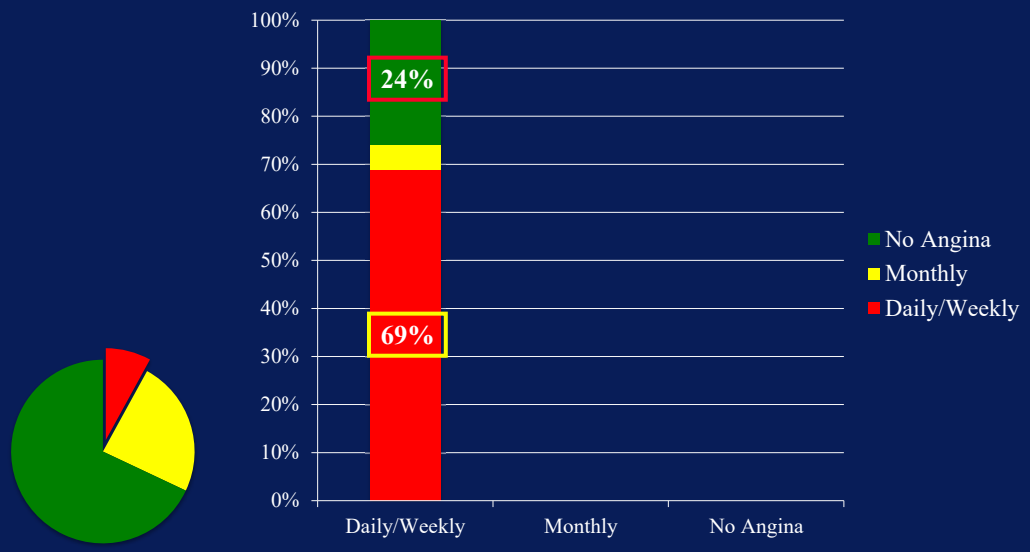
19

Patient-reported Angina Frequency



20

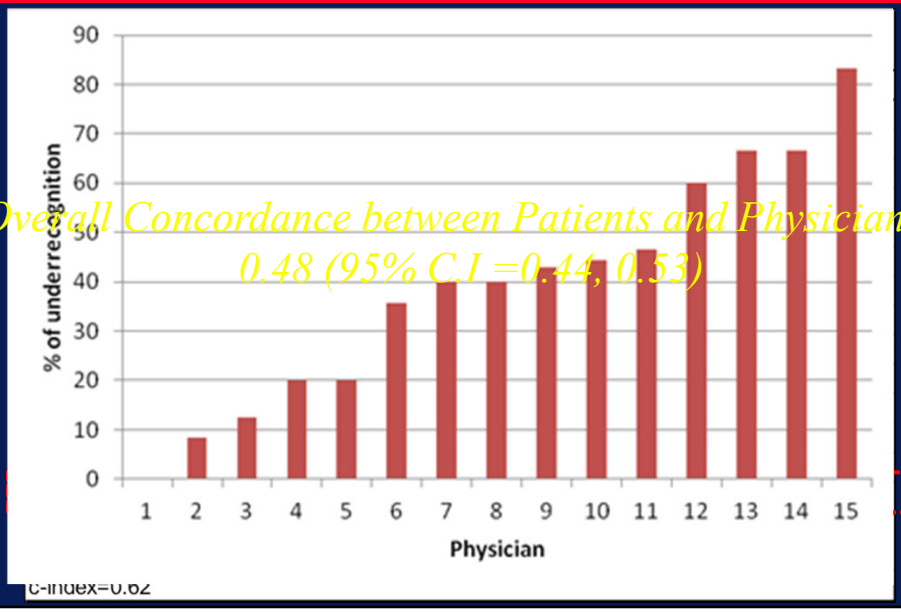
Dr:Pt Discordance – Frequent Angina



21

Predictors of Under-Recognition

Overall Concordance between Patients and Physicians = 0.48 (95% C.I =0.44, 0.53)



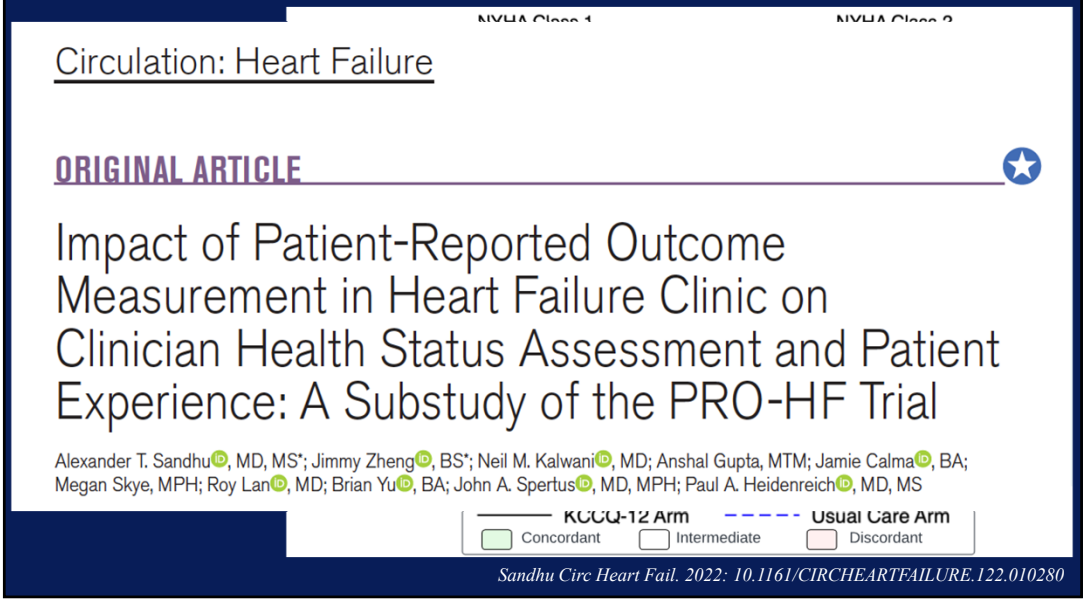
22

Predictors of Not Escalating Treatment

	OR (95% CI)	P value
Under-recognition of angina	0.13 (0.07-0.24)	<0.001
Age (per 5 years)	0.90 (0.80-1.02)	0.102
Male	1.19 (0.68-2.06)	0.533
White race	0.58 (0.24-1.37)	0.216
Avoids care due to cost	0.66 (0.25-1.76)	0.413
History of coronary bypass graft surgery	1.43 (0.80-2.53)	0.217
SAQ Angina Stability (per 25 point decrease)	1.27 (0.96-1.67)	0.092
SAQ Summary Score (per 10 point decrease)	1.05 (0.97-1.15)	0.231
On ≥2 antianginal medications on arrival	0.98 (0.56-1.72)	0.965
Physician specialty: interventional cardiology	1.02 (0.45-2.30)	0.945

23

More Accurate Classification of NYHA



24

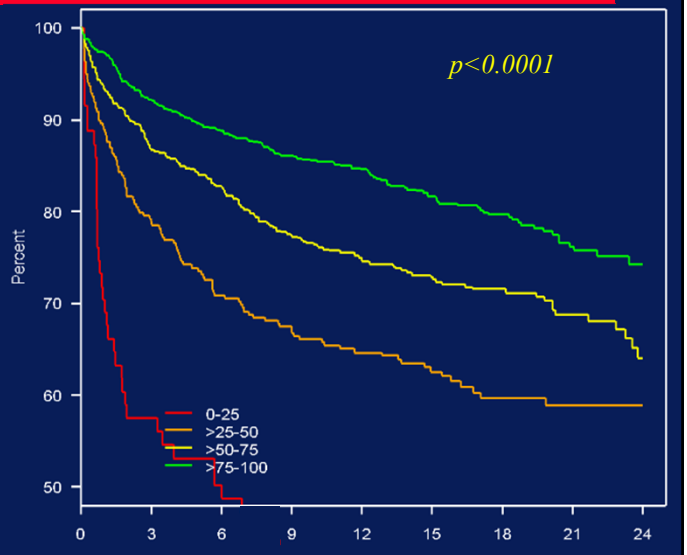
Imagine a New, Revolutionary Test

- Defines the status of a medical condition
  - Improves Accuracy
  - Increases Clinical Efficiency
- Risk-stratifies prognosis
- Identifies which patients benefit from treatment
- Monitors responses to treatment
- Supports population health management
- Defines the quality of healthcare

25

Scores at a Single Point in Time Predict Outcome

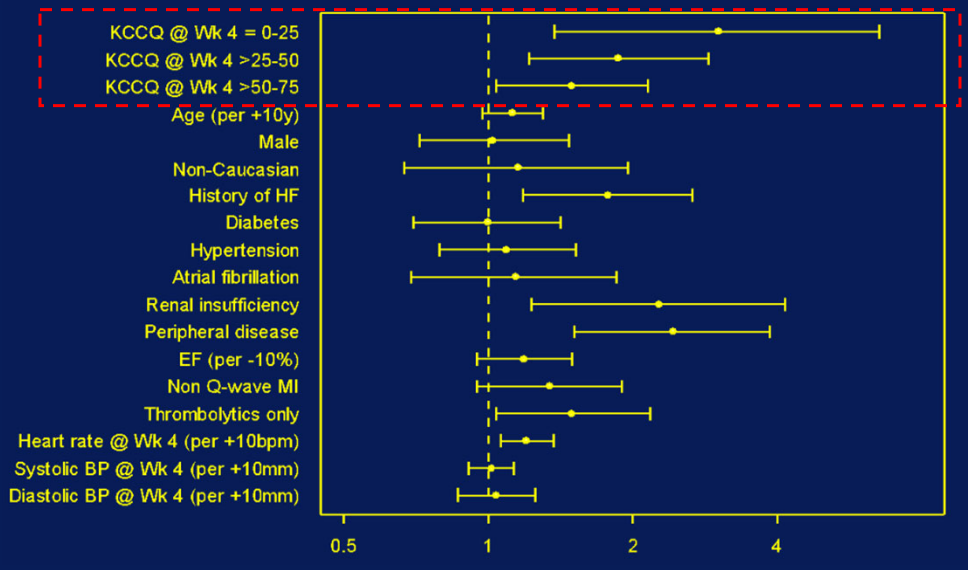
- Freedom from CV Mortality/hospitalization
- n=1,516 outpatients
- Scores grouped in ranges of 25 points
- Graded relationship with lower scores associated with worse outcomes



Soto et al. Circulation 2004;110:546-51

26

Multivariable Model: 1-year CV Death/Hospitalization



27

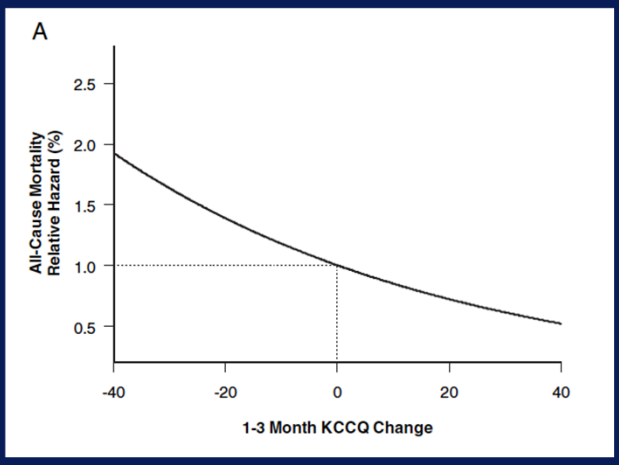
A 5-point Δ in KCCQ = 10% Δ in Death/Hosp

n=1,358 outpatients assessed 2 months apart

Adjusted for >25 covariates, *including initial KCCQ scores*

A linear association between ΔKCCQ and death (HR=1.09/5-pt decrease in KCCQ (95%CI=1.03, 1.18))

Multivariable-adjusted association

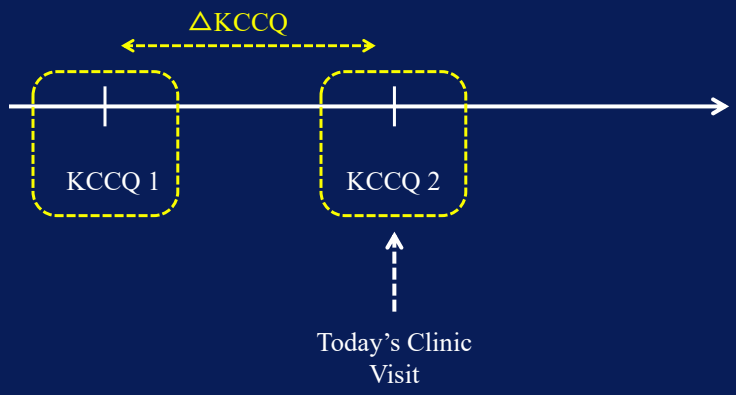


Kosiborod et al. Circulation 2007;115:1975-1981

28

Estimating Prognosis with Serial KCCQs

What best estimates prognosis??



Does the Type of HF (HFrEF vs. HFpEF) Matter??

©John Spertus – Privileged and Confidential – Do Not Distribute

29

Studies to Test Prognosis

HFpEF with 3.3 years of Follow-up



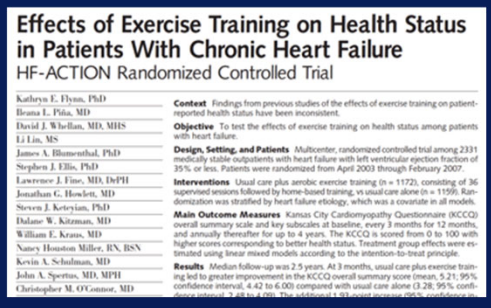
Original Article

Impact of Spironolactone on Longitudinal Changes in Health-Related Quality of Life in the Treatment of Preserved Cardiac Function Heart Failure With an Aldosterone Antagonist Trial

Eldrin F. Lewis, MD, MPH; Hae-Young Kim, DrPH; Brian Claggett, PhD; John Spertus, MD; John F. Heitner, MD; Susan F. Assmann, PhD; Christopher T. Kenwood, MS; Scott D. Solomon, MD; Akshay S. Desai, MD; James C. Fang, MD; Sonia A. McKinlay, PhD; Bertram A. Pitt, MD; Marc A. Pfeffer, MD, PhD; for the TOPCAT Investigators

Background—Heart failure (HF) with preserved ejection fraction patients have equally impaired health-related quality of life (HRQL) compared with those with HF with reduced ejection fraction, but limited studies have evaluated the impact of therapies on changes in HRQL.
Methods and Results—Patients ≥50 years of age, with symptomatic HF and left ventricular ejection fraction ≥45%, were enrolled in Treatment of Preserved Cardiac Function Heart Failure With an Aldosterone Antagonist (TOPCAT) and

HFrEF with 2.6 years of Follow-up



Effects of Exercise Training on Health Status in Patients With Chronic Heart Failure
HF-ACTION Randomized Controlled Trial

Kathryn E. Flynn, PhD
Ileana L. Piña, MD
David J. Whellan, MD, MHS
Li Lin, MS
James A. Blumenthal, PhD
Stephen J. Ellis, PhD
Lawrence J. Fine, MD, DrPH
Jonathan G. Howlett, MD
Steven J. Keteyian, PhD
Dalane W. Kitzman, MD
William E. Kraus, MD
Nancy Houston Miller, RN, BSN
Kevin A. Schulman, MD
John A. Spertus, MD, MPH
Christopher M. O'Connor, MD

Context Findings from previous studies of the effects of exercise training on patient-reported health status have been inconsistent.

Objective To test the effects of exercise training on health status among patients with heart failure.

Design, Setting, and Patients Multicenter, randomized controlled trial among 2331 medically stable outpatients with heart failure with left ventricular ejection fraction of 35% or less. Patients were randomized from April 2003 through February 2007.

Interventions Usual care plus aerobic exercise training (n = 1172), consisting of 36 supervised sessions followed by home-based training, vs usual care alone (n = 1159). Randomization was stratified by heart failure etiology, which was a covariate in all models.

Main Outcome Measures Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary scale and key subscales at baseline, every 3 months for 12 months, and annually thereafter for up to 4 years. The KCCQ is scored from 0 to 100 with higher scores corresponding to better health status. Treatment group effects were estimated using linear mixed models according to the intention-to-treat principle.

Results Median follow-up was 2.5 years. At 3 months, usual care plus exercise training led to greater improvement in the KCCQ overall summary score (mean, 5.21; 95% confidence interval, 4.42 to 6.00) compared with usual care alone (3.28; 95% confi-

©John Spertus – Privileged and Confidential – Do Not Distribute

30

Association of Serial KCCQ – CV Death/Hosp

Adjustment for clinical factors does not alter association with KCCQ

Past, Current and Change in KCCQ all associated with outcome

Current KCCQ most important – a continually updatable means of stratifying risk

KCCQ-os Models	HFpEF HR (95% CI)	HFpEF P value	HFrEF HR (95% CI)	HFrEF P value
Prior, unadjusted	0.94 (0.92-0.96)	<0.001	0.94 (0.91-0.96)	<0.001
Prior, adjusted	0.94 (0.91-0.96)	<0.001	0.95 (0.92-0.97)	<0.001
Current, unadjusted	0.91 (0.89-0.93)	<0.001	0.92 (0.90-0.95)	<0.001
Current, adjusted	0.91 (0.88-0.93)	<0.001	0.94 (0.91-0.96)	<0.001
Change, unadjusted	0.94 (0.91-0.97)	<0.001	0.95 (0.91-0.99)	0.02
Change, adjusted	0.94 (0.91-0.97)	<0.001	0.96 (0.92-1.00)	0.05
Prior and current, unadjusted				
Prior	1.00 (0.97-1.04)	0.70	1.00 (0.95-1.04)	0.84
Current	0.90 (0.88-0.93)	<0.001	0.93 (0.89-0.97)	<0.001
Prior and Current, adjusted				
Prior	1.00 (0.97-1.04)	0.99	1.00 (0.95-1.04)	0.93
Current	0.91 (0.88-0.94)	<0.001	0.94 (0.90-0.98)	0.002
Change and Current, unadjusted				
Change	0.99 (0.96-1.03)	0.70	1.00 (0.96-1.05)	0.84
Current	0.91 (0.89-0.93)	<0.001	0.92 (0.90-0.95)	<0.001
Change and Current, adjusted				
Change	1.00 (0.97-1.03)	0.99	1.00 (0.96-1.05)	0.93
Current	0.91 (0.88-0.93)	<0.001	0.94 (0.91-0.96)	<0.001

0.8 1 1.25 0.8 1 1.25

HR <1 suggests lower CV death or first HF hospitalization and HR >1 suggests higher CV death or first HF hospitalization

©John Spertus – Privileged and Confidential – Do Not Distribute

31

Comparing NYHA vs. KCCQ

Changes in KCCQ Associated with Death and Death/Hospitalization, but not NYHA

KCCQ Much More Sensitive to Clinical Change than NYHA

Figure 2. Associations Between Change in New York Heart Association (NYHA) Class and Kansas City Cardiomyopathy Questionnaire Overall Summary Score (KCCQ-OS) With Clinical Outcomes Among Patients With Heart Failure (HF) With Reduced Ejection in Contemporary US Outpatient Practice

NYHA class: any improvement	Improvement vs no improvement hazard ratio (95% CI)	P value
Death		
Unadjusted	1.23 (0.90-1.69)	.19
Adjusted	1.01 (0.69-1.47)	.97
HF hospitalization		
Unadjusted	1.15 (0.88-1.50)	.31
Adjusted	1.05 (0.76-1.43)	.78
Death or HF hospitalization		
Unadjusted	1.14 (0.93-1.41)	.21
Adjusted	1.02 (0.79-1.32)	.87
KCCQ-OS: ≥5-point improvement		
Death		
Unadjusted	0.75 (0.58-0.98)	.03
Adjusted	0.59 (0.44-0.80)	<.001
HF hospitalization		
Unadjusted	1.06 (0.84-1.36)	.61
Adjusted	0.84 (0.65-1.10)	.20
Death or HF hospitalization		
Unadjusted	0.90 (0.75-1.10)	.31
Adjusted	0.73 (0.59-0.89)	.002

Adverse clinical outcome: Lower risk | Higher risk

0.25 0.5 1 2 4

Hazard ratio (95% CI)

Unadjusted and adjusted hazard ratios indicating the risk of adverse clinical outcomes associated with improvement in NYHA class and improvement in KCCQ-OS. Adjusted models include age, sex, race/ethnicity, total household income, body mass index, systolic blood pressure, heart rate, ejection fraction, glomerular filtration rate, atrial fibrillation, coronary artery disease, diabetes, chronic obstructive pulmonary disease, prior heart failure hospitalization, cardiac resynchronization therapy, implantable cardioverter-defibrillator, angiotensin-converting enzyme inhibitor or angiotensin II receptor blocker, sacubitril/valsartan, evidence-based β-blocker, and mineralocorticoid receptor antagonist.

Figure 1. Cha … Overall Sum … stionnaire

A NYHA cla …

Participants, % 70 60 50 40 30 20 10 0

≥10-Point mprovement

Data reflect t … low-up.

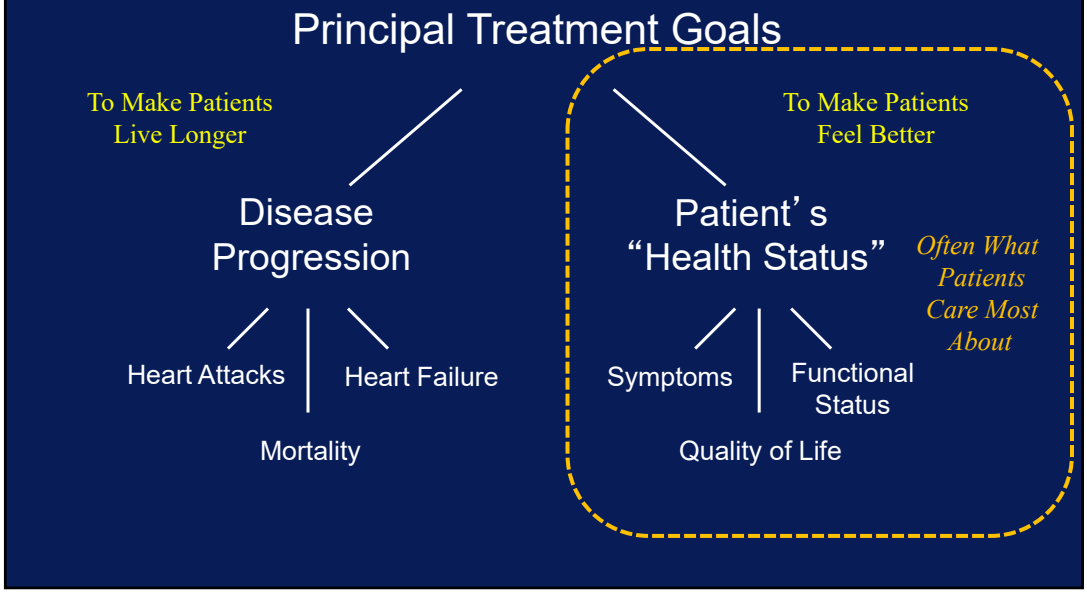
32

Imagine a New, Revolutionary Test

- Defines the status of a medical condition
  - Improves Accuracy
  - Increases Clinical Efficiency
- Risk-stratifies prognosis
- Identifies which patients benefit from treatment
- Monitors responses to treatment
- Supports population health management
- Defines the quality of healthcare

33

Treatment Goals for Stable Ischemic Heart Disease



34

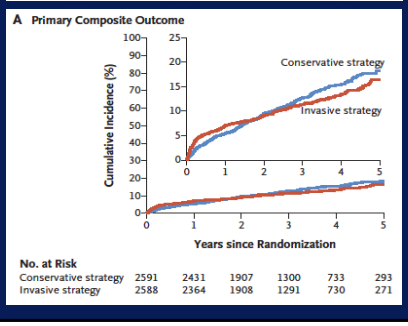
Often the Only Benefits are QoL

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Initial Invasive or Conservative Strategy for Stable Coronary Disease

D.J. Maron, J.S. Hochman, H.R. Reynolds, S. Bangalore, S.M. O'Brien, W.E. Boden, B.R. Chaitman, R. Senior, J. López-Sendón, K.P. Alexander, R.D. Lopes, L.J. Shaw, J.S. Berger, J.D. Newman, M.S. Sidhu, S.G. Goodman, W. Ruzyllo, G. Gosselin, A.P. Maggioni, H.D. White, B. Bhargava, J.K. Min, G.B.J. Mancini, D.S. Berman, M.H. Picard, R.Y. Kwong, Z.A. Ali, D.B. Mark, J.A. Spertus, M.N. Krishnan, A. Elghamaz, N. Moorthy, W.A. Hueb, M. Demkow, K. Mavromatis, O. Bockeria, J. Peteiro, T.D. Miller, H. Szwed, R. Doerr, M. Keltai, J.B. Selvanayagam, P.G. Steg, C. Held, S. Kohsaka, S. Mavromichalis, R. Kirby, N.O. Jeffries, F.E. Harrell, Jr., F.W. Rockhold, S. Broderick, T.B. Ferguson, Jr., D.O. Williams, R.A. Harrington, G.W. Stone, and Y. Rosenberg, for the ISCHEMIA Research Group*

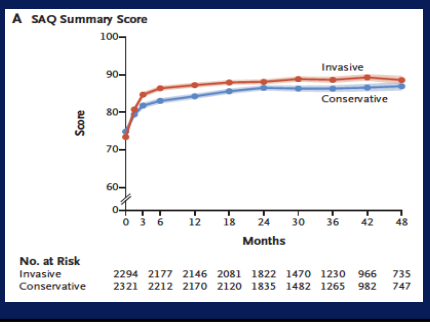


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

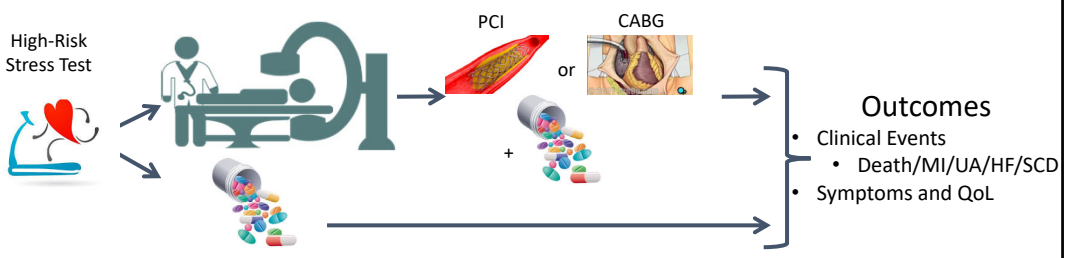
Health-Status Outcomes with Invasive or Conservative Care in Coronary Disease

John A. Spertus, M.D., M.P.H., Philip G. Jones, M.S., David J. Maron, M.D., Sean M. O'Brien, Ph.D., Harmony R. Reynolds, M.D., Yves Rosenberg, M.D., M.P.H., Gregg W. Stone, M.D., Frank E. Harrell, Jr., Ph.D., William E. Boden, M.D., William S. Weintraub, M.D., Khaula Baloch, M.P.H., Kreton Mavromatis, M.D., Ariel Diaz, M.D., Gilbert Gosselin, M.D., Jonathan D. Newman, M.D., M.P.H., Stavroula Mavromichalis, M.S., Karen P. Alexander, M.D., David J. Cohen, M.D., Sripal Bangalore, M.D., M.H.A., Judith S. Hochman, M.D., and Daniel B. Mark, M.D., M.P.H., for the ISCHEMIA Research Group*

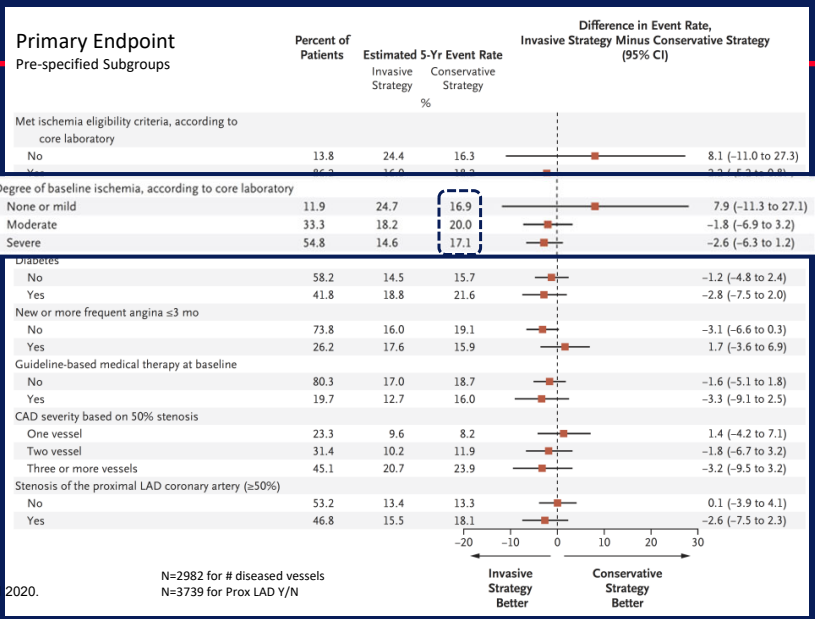


35

Design of the ISCHEMIA Trial



36

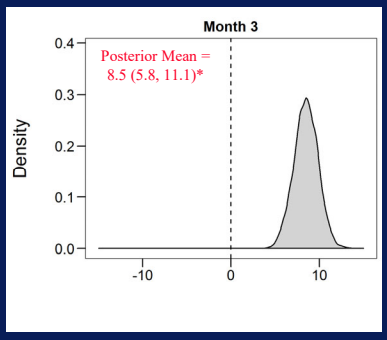


Maron, et al. NEJM 2020.

37

SAQ-SS Benefits of INV Rx by Angina Frequency

Daily to Weekly Angina

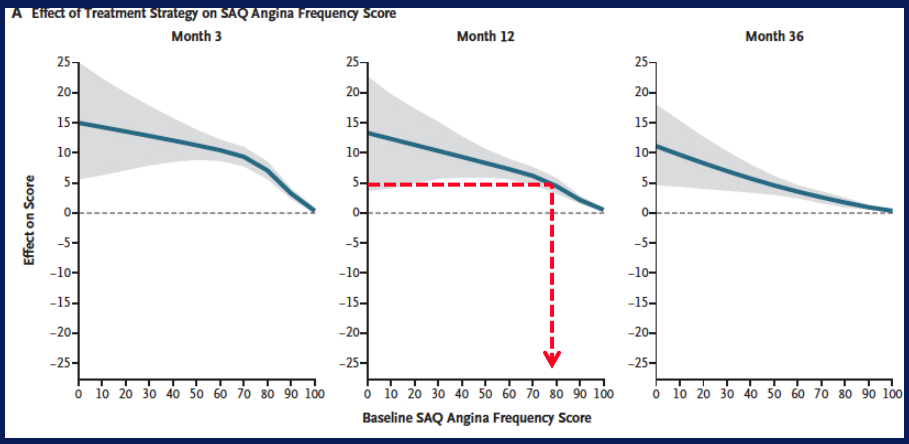


**95% Highest Posterior Density Interval*

Spertus, NEJM 2020

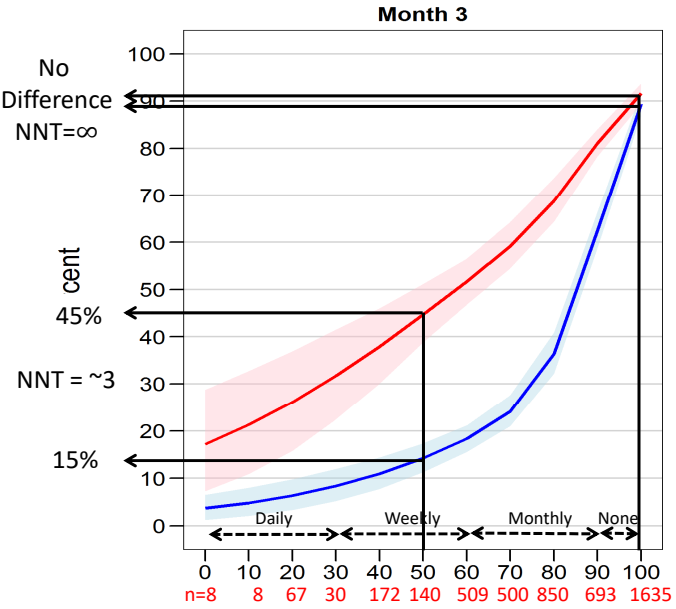
38

Baseline Angina is the Only Thing that Discriminates Benefit in ISCHEMIA



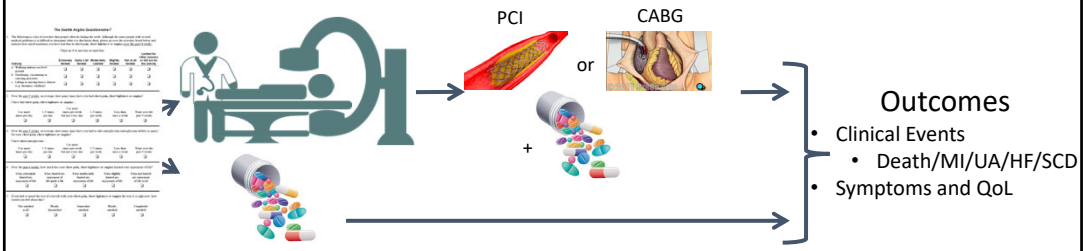
39

Baseline Angina Frequency and Angina Free @ 3m



40

Raises the Question of How to Identify Pts for the Cath Lab and Revascularization



41

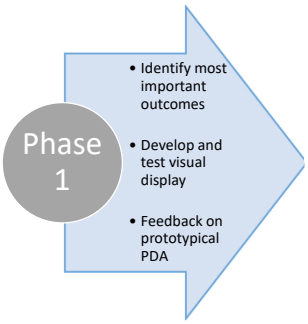
Treatment Decisions in Chronic Coronary Disease

TOP 10 TAKE-HOME MESSAGES

1. Treatment decisions regarding coronary revascularization in patients with coronary artery disease should be based on clinical indications, regardless of sex, race, or ethnicity, because there is no evidence that some patients benefit less than others, and efforts to reduce disparities of care are warranted.
2. In patients being considered for coronary revascularization for whom the optimal treatment strategy is unclear, a multidisciplinary Heart Team approach is recommended. Treatment decisions should be patient centered, incorporate patient preferences and goals, and include shared decision-making.

42

Developing a Patient Decision Aid (PDA)



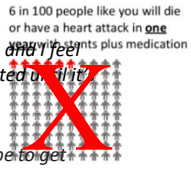
Patients valued **quality of life and longevity**, followed closely by function and symptoms:

"Forget longevity. It's the quality of life today."

"I don't want to die. I want to live and see my grandchildren get older. I want to see my daughter live her life."

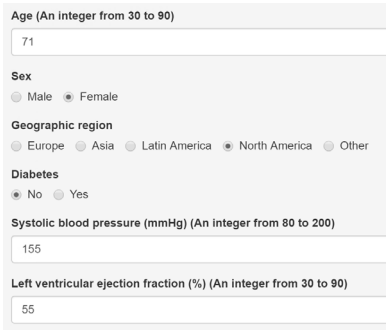
"The [illegible] again and I feel strong [illegible] for granted until it's almo[illegible]"

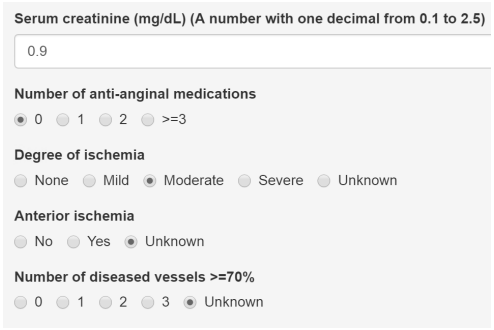
"I've never had another chest pain again nor do I ever hope to get another chest pain again."



43

ISCHEMIA PDA





44

ISCHEMIA

Patient Decisio

Will be made availa
at no cost at
myhealthoutcomes.

How is chronic coronary artery disease treated to prevent heart attacks and death? You can reduce the risk of death or heart attack with diet, exercise, and medicines.

How is chronic coronary artery disease treated to reduce angina, improve function and quality of life? There are two options. One option is to use medicines alone. The other is invasive treatment. This means getting an angiogram where dye is injected through a small catheter to the heart arteries to identify the blockages. These are then treated with either a stent (a metal 'coil' to prop open the blockage) or open-heart bypass surgery.

What are the risks of a coronary angiogram? About 1 in 1000 people have a major complication, such as a

Survival 96% **patients like you are expected to be alive 4 years from now, with either treatment.**

Quality of Life (how much you feel your angina and physical limitations impact your life)



Physical Function (how much your angina limits your physical activities)



Angina Frequency (how often you have symptoms)

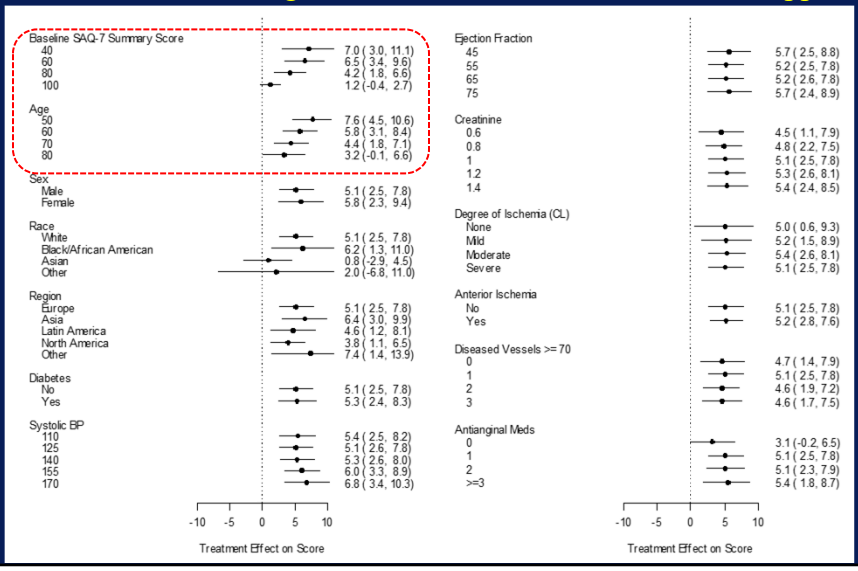


*It is important to discuss these results with your doctor. Sometimes an angiogram can further refine your risks and benefits of a stent or bypass surgery.

45

Predicting SAQ-SS at 1 Year

Baseline Health Status and Age most Differentiate Benefit of INV Approach



46

Imagine a New, Revolutionary Test

- Defines the status of a medical condition
  - Improves Accuracy
  - Increases Clinical Efficiency
- Risk-stratifies prognosis
- Identifies which patients benefit from treatment
- Monitors responses to treatment
- Supports population health management
- Defines the quality of healthcare

47

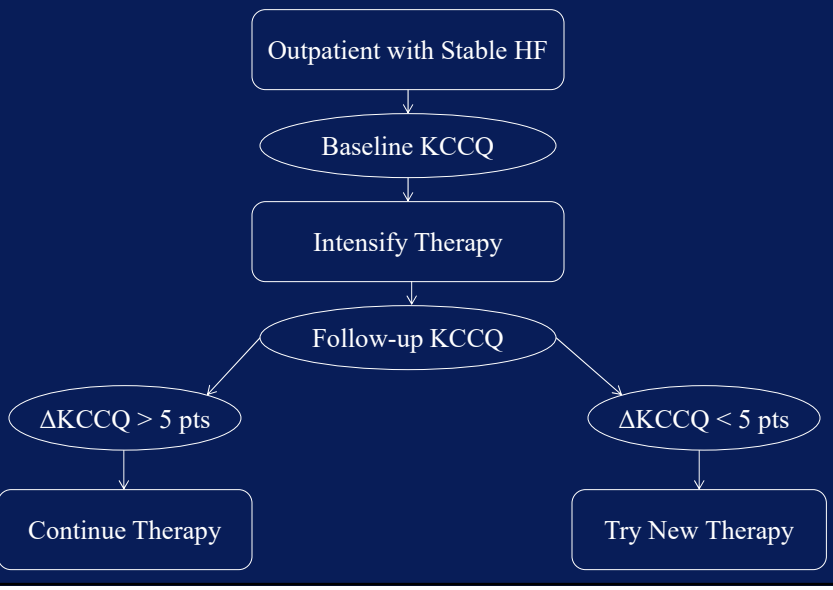
Using the KCCQ to Guide Treatment

- If new HF Treatments (SGLT2i's, verciguat, ARNI's, omecaptiv) have similar RRRs in Death/Hospitalization, why not choose on QoL?
- Can 'test' in individual patients using the KCCQ before and after treatment
- If patient improves….
  - Continue treatment
  - Patient 'knows' the benefits of treatment → Better adherence
- If patient doesn't improve → try something else

©John Spertus – Privileged and Confidential – Do Not Distribute

48

Monitoring Treatment Response with KCCQ



49

Leveraging the KCCQ in Care

Circulation: Cardiovascular Quality and Outcomes

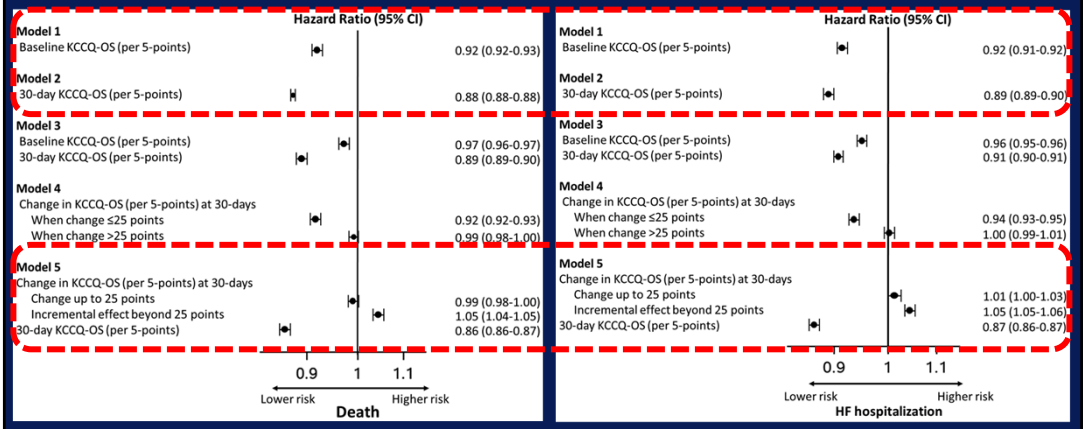
ORIGINAL ARTICLE

Practical Application of Patient-Reported Health Status Measures for Transcatheter Valve Therapies

Insights From the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapies Registry

50

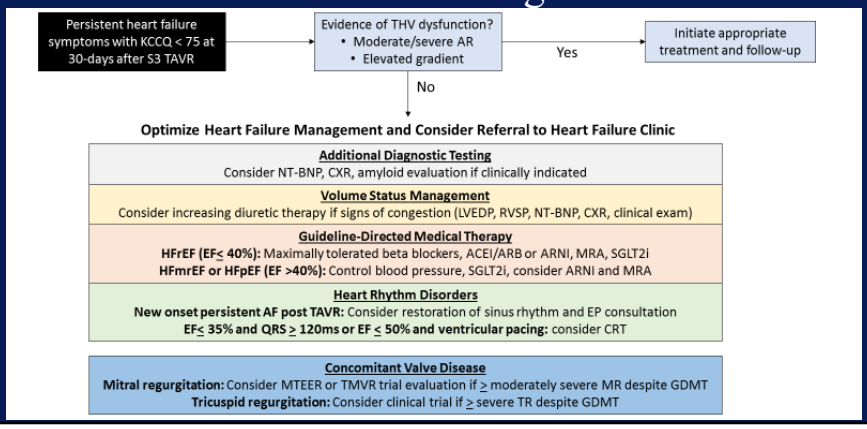
Prognostically Important



51

Using the KCCQ to Improve Patient Care

- Valve Teams focus on the success of the procedure
- While patients can benefit from treatment, they may benefit more from also treating HF

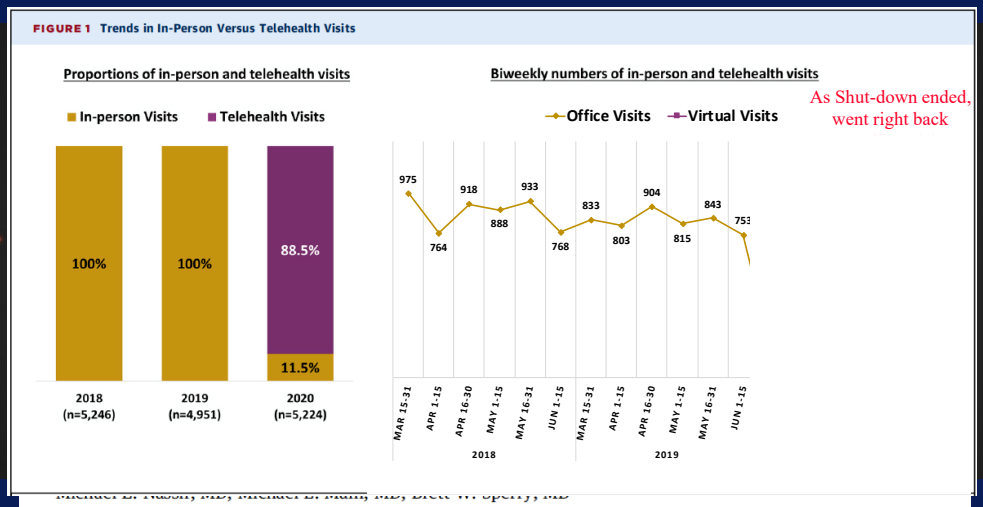


52

Imagine a New, Revolutionary Test

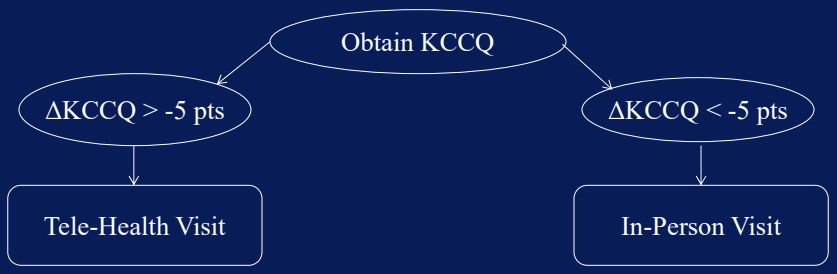
- Defines the status of a medical condition
  - Improves Accuracy
  - Increases Clinical Efficiency
- Risk-stratifies prognosis
- Identifies which patients benefit from treatment
- Monitors responses to treatment
- Supports population health management
- Defines the quality of healthcare

Rationally Implementing Tele-Health



In 2022, we were >95% In-Person

Using KCCQ to Triage In-person Visits?



55

Identifying SIHD Patients for Invasive Rx…

ORIGINAL INVESTIGATION

The Prevalence of Weekly Angina Among Patients With Chronic Stable Angina in Primary Care Practices

The Coronary Artery Disease in General Practice (CADENCE) Study

John F. Beltrame, BSc, BMBS, FRACP, PhD; Andrew J. Weekes, BMedSci, BMBS; Claire Morgan, BPhysio; Rosanna Tavella, BSc(Hons); John A. Spertus, MD, MPH, FACC

Background: Angina, the cardinal symptom of coronary artery disease (CAD), is amenable to a range of therapies, and its routine assessment is considered a performance measure of quality. However, the prevalence of frequent angina among outpatients with CAD is unknown.

Methods: The Coronary Artery Disease in General Practice (CADENCE) Study utilized a cluster-stratified, cross-sectional design to examine angina frequency in patients with stable angina attending Australian primary care practices. The 207 participating primary care practitioners recruited 2031 consecutive patients, irrespective of the purpose of their visit. Angina frequency was quantified with the Seattle Angina Questionnaire (SAQ), and weekly angina was defined as having 1 or more episodes per week over the preceding 4 weeks [hereinafter, "weekly (≥1) angina"].

Results: Among primary care practice patients with stable angina, 29% (95% confidence interval [CI], 26%-31%) experienced weekly (≥1) angina, which was associated with greater physical limitations and worse quality of life (24% and 27% lower SAQ scores, respectively; $P<.05$) compared with those with minimal angina (angina less than once a week over the preceding 4 weeks). The proportion of patients with weekly (≥1) angina within a clinic ranged from none (14% of clinics) to more than 50% (18% of clinics). Patient characteristics associated with weekly (≥1) angina included female sex (odds ratio [OR], 1.42; 95% CI, 1.13-1.78), a history of heart failure (OR, 1.59; 95% CI, 1.22-2.08), and peripheral artery disease (OR 1.89; 95% CI, 1.42-2.51; $P<.001$ for all comparisons).

Conclusions: Almost 1 in 3 patients with stable angina attending primary care practices had angina at least once a week, which was associated with worse quality of life. Moreover, weekly (≥1) angina varied considerably across clinics, possibly reflecting variability in the identification and management of angina. The potential role of an angina performance measure to improve patients' outcomes, including symptom control, warrants further consideration.

Trial Registration: anzctr.org.au Identifier: ACTRN12608000347369

Arch Intern Med. 2009;169(16):1491-1499

56

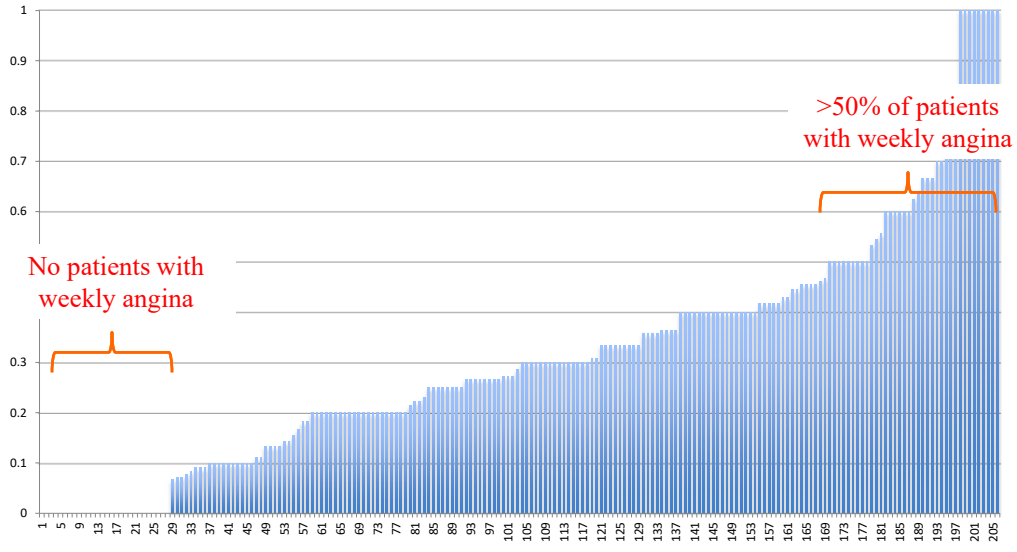
Insights into Underuse of Revascularization

- Survey of 207 Primary Care Practices in Australia
- Consecutive CAD patients completed SAQ
- SAQ Angina Frequency categorized into weekly or more angina
- Percentage of each practices' patients with weekly angina displayed

Beltrame et al. *Arch Intern Med* 2009; 169: 1491-9

57

Prevalence of Weekly Angina in Australian Clinics



58

Imagine a New, Revolutionary Test

- Defines the status of a medical condition
  - Improves Accuracy
  - Increases Clinical Efficiency
- Risk-stratifies prognosis
- Identifies which patients benefit from treatment
- Monitors responses to treatment
- Supports population health management
- Defines the quality of healthcare

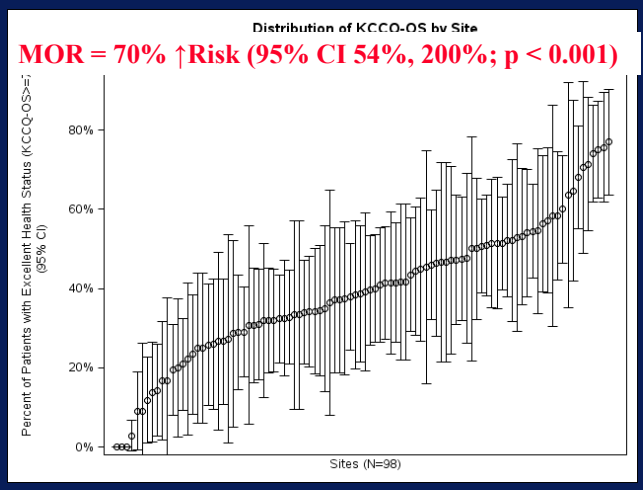
59

PROs as Performance Measures in Heart Failure

- CHAMP-HF – 150-center outpatient US registry of 5000 patients with HFrEF
- Examined the proportion of patients in each practice with Good to Excellent Health Status (KCCQ OS≥75)
- After adjusting for 28 patient characteristics, examined the variability across centers using MOR

60

Proportion with Excellent Health Status



Khariton, *Circ Cardiovasc Qual Outcomes*. 2018; 11: e004668

61

Early Efforts with PRO Performance Measures

- LOINC and CPT Payment Codes Available
- ACC/AHA 2024 Heart Failure Performance Measures
  - KCCQ Collection and Results are Quality Metrics
- International Consortium for Health Outcomes Measurement (ICHOM)
- Center for Medicaid and Medicare Services
  - Developed SAQ as a PCI Performance Measure
  - Created a KCCQ Measure for Chronic Heart Failure
  - Implementing MANDATORY ASM January 2027

62

The Final Frontier….

- *If PROs…*
  - Can increase accuracy and efficiency of patient care
  - Can risk stratify prognosis and treatment benefit
  - Monitor responses to therapy
  - May become a requirement for quantifying quality
- *Then Integrating them into Routine Care Should be Done…*

63

Patients' Perspective of KCCQ – U of Utah

- Qualitative Study of 24 Patients where KCCQ was used
  - 23 strongly/agreed that PROs gave providers better sense of their HF
  - 16 stated with was helpful in doctor-patient communication
  - 22 felt that they improved their care
  - 17 felt that *more attention* should have been given to their KCCQs
- Patients felt that the use of PROs was important, *particularly if their doctors used them in their visit*

Mondesir et al., *Circ Cardiovasc Qual Outcomes. 2020;13:e007027*

64

Insights on Implementation – Qual

- *Engaged Clinical Champion*
  - "[IMPLEMENTATION LEAD] was very hands on with the project. It wasn't like, "Okay, we're going to do this. And here you go." He was very passionate, and he was always providing himself as an available resource, checking in, emails...He was there throughout the whole thing, and I think it helped for sure." (Provider 3)
- *Experience is key*
  - "Yeah. I was just going to say obviously, the more you use it, the more comfortable you get and the better you understand what each individual score means because you've been in more and more positions where you've seen a score in that range, or you've seen a score and heard a similar story." (Provider 14)
- *Integration into Workflow*
  - "I did initially find it time-consuming compared to what the other tools that we have, but now, when I look at it, I don't think it's time-consuming because the information we gather from it is valuable." (Provider 16)
  - "But having the score show up in Epic is fine, because it's easy for us to kind of locate it. And, put it in a place that *when we open the charts*, that we see it." (Provider 7)

Courtesy Alex Sandhu, Stanford University

65

How Providers See it Helps Care - Qual

- *Standardized History Taking*
  - "I think it's very helpful! I think it's very helpful, because, like I said, I think that my history-taking can be a little bit variable from how the APP does it, from how someone else does it. But I think the nice thing about the PRO is, it standardizes that to a larger extent" (Provider 2)
- *Better Patient Communication*
  - "The times that I have, I look to see as a way to see if anything's changed from their baseline, if I know the patient well, and if they've never had issues with fatigue and all of a sudden they've been fatigued for the last month, I would then make sure that I address that in more detail than I normally would." (Provider 16)
- *Engaging Patients in Additional Therapy*
  - "But there are patients who are skeptical. I find that for patients who have skepticism and fear of moving forward with the procedure, especially a procedure that carries risk, having the data can be very helpful. I would kind of explain where they are, and say, "Look, your quality of life is X. I think we can get it to Y. I think we can dramatically improve it. If I were to look at all-comers, this is kind of my concern." I find it very helpful in those patients.

Courtesy Alex Sandhu, Stanford University

66

How Providers See it Helps Care - Qual

- *Getting a More Accurate History*
  - "And I think the other reason it's helpful, is a lot of patients I find want to be perceived as a good patient or want to sort of build rapport with a provider by giving them a very rosy assessment of their symptoms and the medication adherence, et cetera. And so I think a standardized questionnaire can also help bring some honesty to their relationship so that even if something's not going well…" (Provider 8)
- *A More Complete Picture of How Patients are Doing*
  - I think it's helpful for me for patients where their objective data is discordant with how they're feeling. So meaning that from their echo or their lab values or their exam, they seem to be, those things perhaps underestimate the severity of their heart failure. So I think that the KCCQ can be important data point there. I think less so if all the other objective data shows the patient's sick or decompensated, then the KCCQ being concordant with that not necessarily add as much. So yeah. I think it's kind of helpful in that way." (Provider 1)
- *Tracks Patients Over Time*
  - "Yeah. I think, and in the same way that if the person has had several KCCQs, it gives you a sense of longitudinal trajectory and I would use it the same way." (Provider 12)

Courtesy Alex Sandhu, Stanford University

67

Randomized Trial of Routine KCCQ Use

Clinical Impact of Routine Assessment of Patient-Reported Health Status in Heart Failure Clinic: The PRO-HF Trial | CME

Alexander T. Sandhu, Jamie Calma, Megan Skye, Neil Kalwani, Jimmy Zheng, Jessica Schirmer, Natasha Din, Cati Brown Johnson, Anshal Gupta, Roy Lan, Brian Yu, John A. Spertus and Paul A. Heidenreich

Circulation. 2024 | Volume 149, Issue 22: 1717–1728,
originally published April 7, 2024,

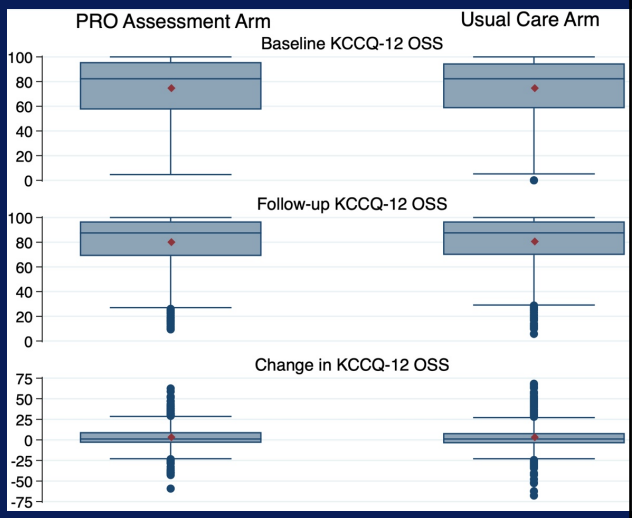
https://doi.org/10.1161/CIRCULATIONAHA.124.069624

- Single-center study
- 625 with routine use vs. 624 without
- Primary Outcome: 1-year Change in KCCQ

68

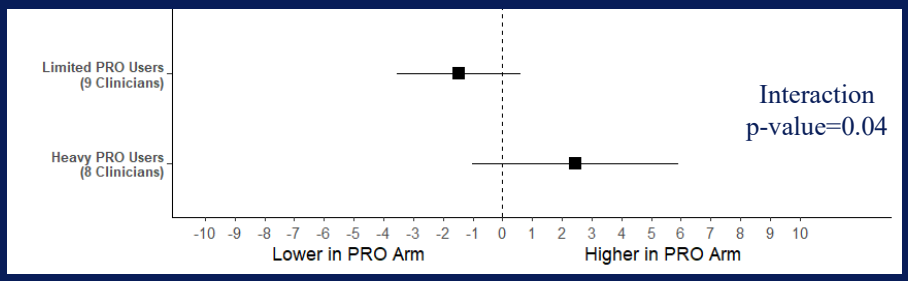
KCCQ-12 Overall Summary Score

- Difference in KCCQ-12 OSS: 0.2 (-1.7 to 2.0); p=0.85
- Results consistent across imputation approaches
- Results consistent across KCCQ-12 domain scores



69

If Providers Use Them, Patients Improve



12-month Change in KCCQ Overall Summary Score

70

Key Considerations in Implementation

- Identifying a Clinical Champion
  - Education and accountability
- Define how to most efficiently collect PROs
  - Portals vs. texts vs. clinic tablets
- Define how best to present the data
  - Graphs vs. tables
  - To patients??
- Define where to place the PROs in the EMR
  - Disease-specific tabs (e.g. with EF, BNP, Meds)
  - On the vitals page?

71

Try It, You'll Like It…



72