

CorMicA

A Randomized Trial of Coronary Function Testing in Angina and Non Obstructive Coronary Disease

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On Behalf of the CorMicA Investigators



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Disclosure Statement of Financial Interest

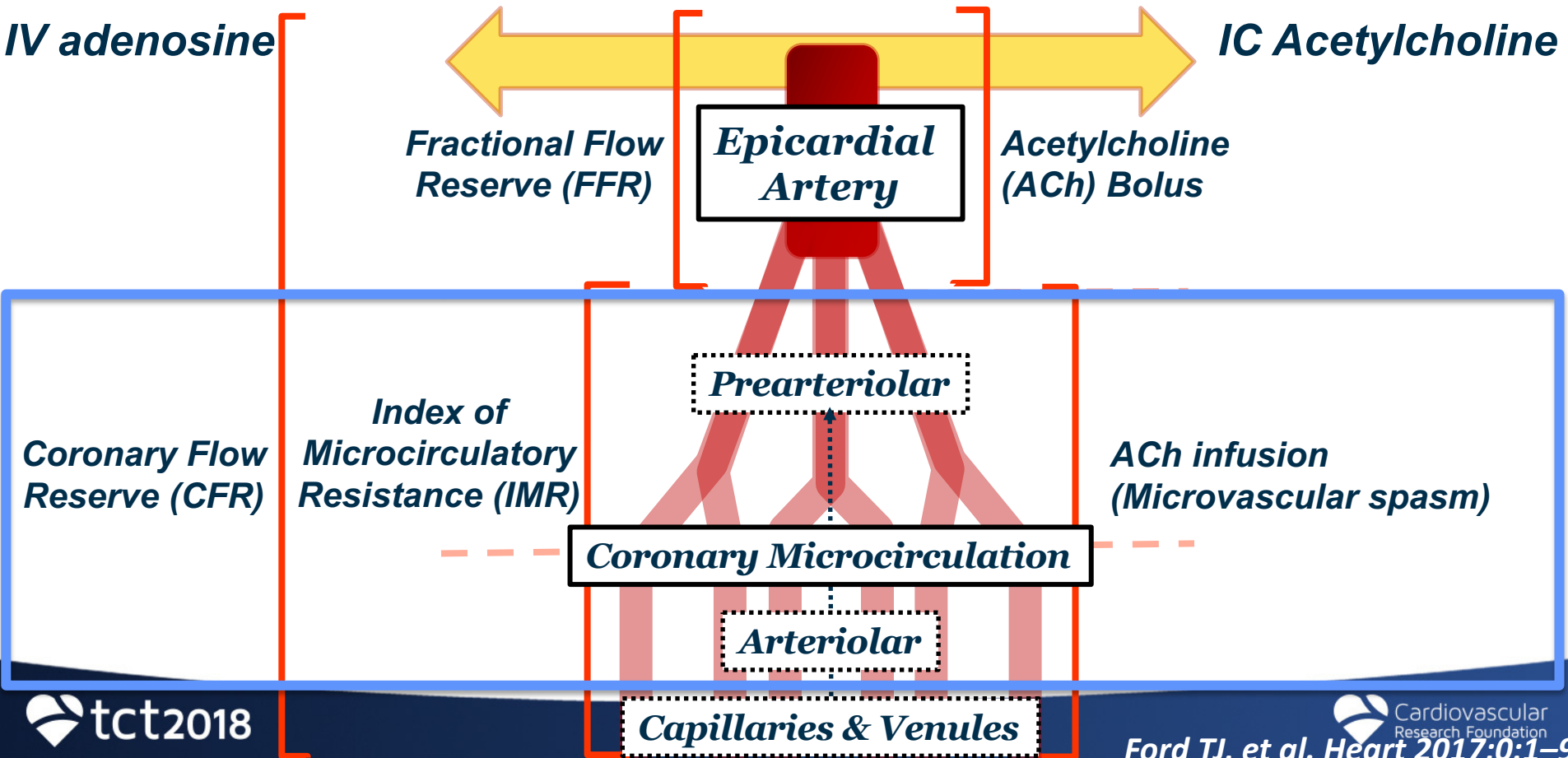
NIL TO DECLARE

I, Tom Ford DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

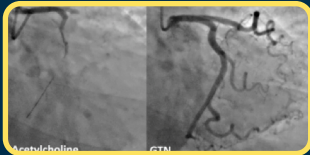
Background

1. Ischemia without obstructive CAD - common
2. Invasive diagnostic tests are available
3. Practice guideline recommendations for therapy ✓ (ESC 2013)
4. No randomized trials
5. No adoption in the clinic
6. Patient outcomes sub-optimal.

Interventional Diagnostic Procedure (IDP)

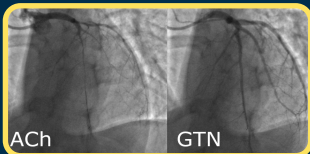


Invasive Diagnosis with Stratified Medicine



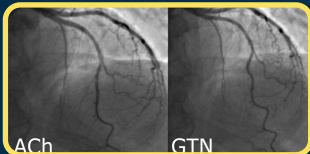
Microvascular Angina

- Guideline directed therapy – e.g. Betablocker & Lifestyle



Vasospastic Angina

- Guideline directed therapy – e.g. CCB & Lifestyle



Non-Cardiac (Normal Function)

- Cease antianginal therapy +/- non-cardiac Ix

Hypothesis

**Stratified medicine guided by an
Interventional Diagnostic Procedure (IDP)
improves angina in patients without
obstructive CAD**

Eligibility Criteria

- **Age ≥ 18 years**
- **Angina (Rose questionnaire)**
 - **Definite or Probable**
- **Clinically-indicated invasive coronary angiography**
- **Written, informed consent**

CorMicA Trial Design

Primary Endpoint = Angina Severity (SAQSS)

Standard Care

Two Large Regional Hospitals (Popⁿ 2.5m)

Referred for Invasive Coronary Angiogram

Baseline (Day 0)

- Consent
- Record Treatment/Diagnosis
- **SAQ**
- EQ-5D-5L
- TSQM9
- BIPQ
- PHQ4

Angiogram

No Obstructive CAD

DS <50%
FFR >0.8

Randomise

Diagnostic procedure
Stratified Therapy, n=75

Blind, Sham Procedure
Standard Care, n=76

6 Months

- **SAQ**
- EQ-5D
- TSQM9
- BIPQ
- PHQ4

Primary Endpoint (6 months vs. baseline)

- **Seattle Angina Questionnaire – Summary Score (SAQSS)**
 - *Between group difference*
 - *Regression model, adjust for the baseline score*
- **Blinded outcome assessment**
- **Blinded statistical analysis**
- **Independent Clinical Trials Unit**

Sample Size

- **Effect size of 9 units in SAQ Summary Score**
- **80% power**
- **Standard deviation, 19 units**
- **140 randomized patients**

Baseline Characteristics

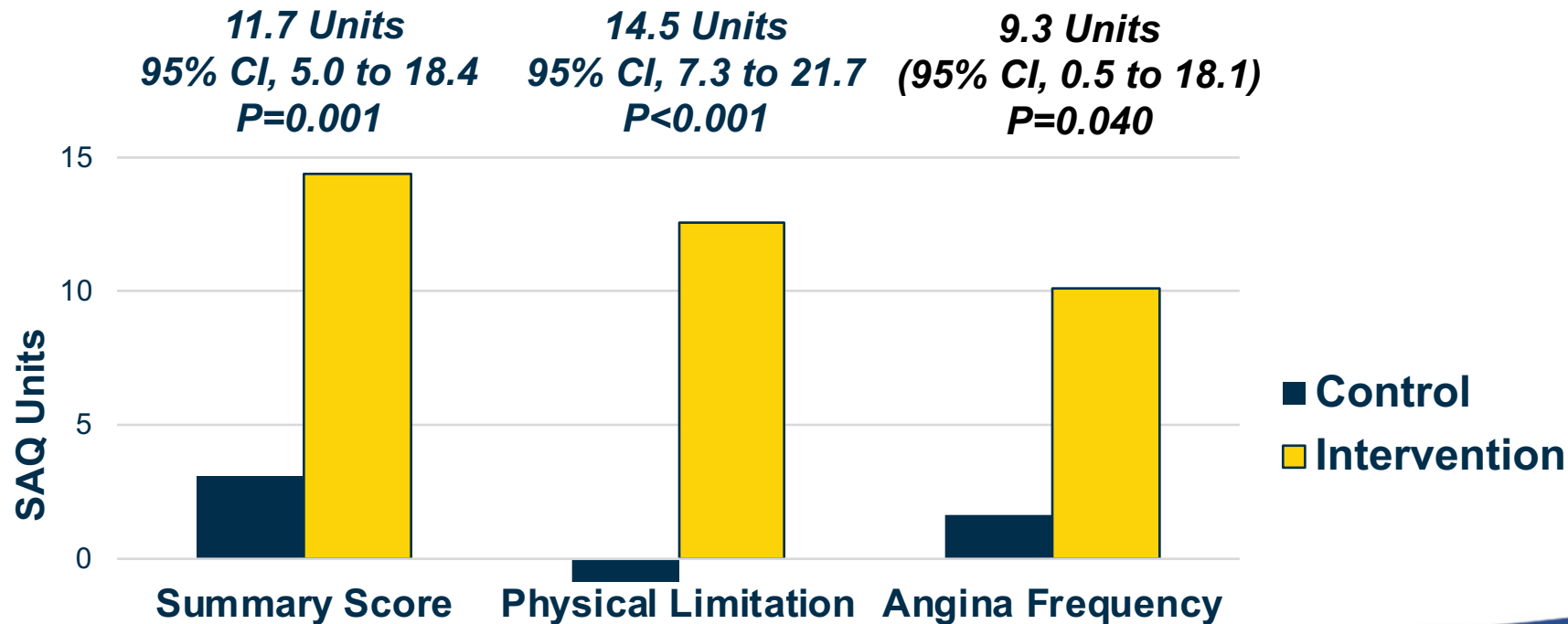
	Control n = 76	Intervention n = 75
Definite Angina	42 (55%)	55 (73%)
Probable Angina	34 (45%)	20 (27%)
Non-Anginal	0	0
SAQ Summary Score	49.0 (17.2)	52.6 (18.9)

Baseline Characteristics

	Control (N=76)	Intervention (N=75)
Age	60 [53, 68]	62 [54, 69]
Female	58 (76%)	53 (71%)
BMI [Q1, Q3]	30 [26, 34]	30 [26, 35]
Current Smoker	14 (18%)	13 (17%)
Diabetes Mellitus	15 (20%)	14 (19%)
Predicted 10-year CHD risk*	18% [10, 28]	19% [12, 39]

Primary Endpoint – 6 month SAQ Change

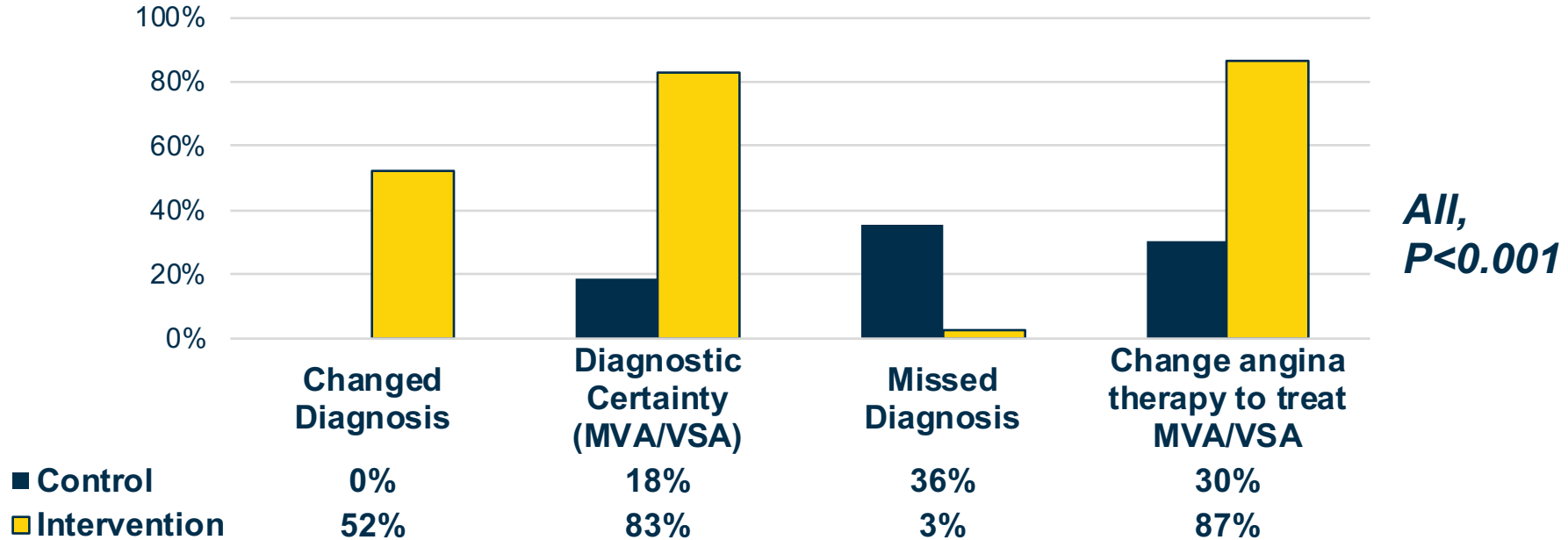
Between-Group Difference



Secondary Endpoints – Health Status

	Intervention Effect	95% CI	P-Value
Quality of Life (EQ5D-5L):			
Index Score	0.1	0.01 – 0.18	0.024
VAS score	14.54	7.77 – 21.31	<0.001
Treatment satisfaction:			
Effectiveness	10.73	2.37 – 19.09	0.013
Convenience	14.34	7.30 – 21.37	<0.001
Global satisfaction	16.47	7.28 – 25.66	0.001

Secondary Endpoints – Post Randomization Diagnostic/Clinical Utility



Safety

No Procedural SAE

- Self-limiting AF (5%), sinus at discharge
- Bradycardia during ACh expected physiological response

MACCE at 6 months

- 2 (2.6%), both groups
- 4 / 151 (2.6%)

Conclusions

1. CorMicA - the first randomised, sham-controlled trial of diagnostic strategy in angina and no obstructive CAD
2. **Adjunctive IDP is routinely safe & feasible**
3. Physician diagnosis changed, half of patients
4. **Stratified medicine guided by the IDP improves health status at 6 months**

↓ angina and ↑ quality of life.

CI – Prof Colin Berry

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Online in JACC, today

ORIGINAL INVESTIGATIONS

Stratified Medical Therapy Using Invasive Coronary Function Testing In Angina: CorMicA Trial

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