SCAI Scientific Session 2019

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A Global Registry of Fractional Flow Reserve (FFR)-Guided Management During Routine Clinical Procedures

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Disclosures

Erick Schampaert, MD

In the past 2 years: Minor Consultant / Speaker fees:
Abbott Vascular, AstraZeneca, Bayer, Medtronic, Volcano-Philips, Sanofi, Servier.

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Background

- Fractional flow reserve (FFR) is the ratio of maximum blood flow in a stenotic coronary artery to maximum blood flow if the same artery was completely normal

- FFR is a gold standard to determine the need for percutaneous coronary intervention (PCI) procedure

- Currently there is limited research conducted on the use of FFR in everyday practice especially patients presenting with Acute Coronary Syndrome (ACS) on culprit and non-culprit lesions

Study Objectives

- To understand routine use of FFR and alternate indices in clinical practice in patients presenting with either stable coronary artery disease, or in patients presenting with Acute Coronary Syndrome (ACS)

- To characterize the frequency of change in treatment plan when FFR is performed compared to a prospectively collected initial decision based on angiography alone and its associated outcomes

Study Design

- PRESSUREwire is a prospective, international multicenter open label observational registry
- 2217 subjects enrolled from 70 hospitals across 15 countries
- Subjects were treated between October 2016 – February 2018
- ClinicalTrials.gov identifier: NCT02935088

Inclusion Criteria:

- Patient with stable CAD, UA, NSTEMI, STEMI or documented silent ischemia
- Patient undergoing clinically indicated coronary angiography, where FFR was performed for further PCI consideration
- Patient with written informed consent

Exclusion Criteria:

- Extremely tortuous or calcified coronary arteries
- Patent coronary artery bypass graft to the target vessel

Baseline Demographic Characteristics

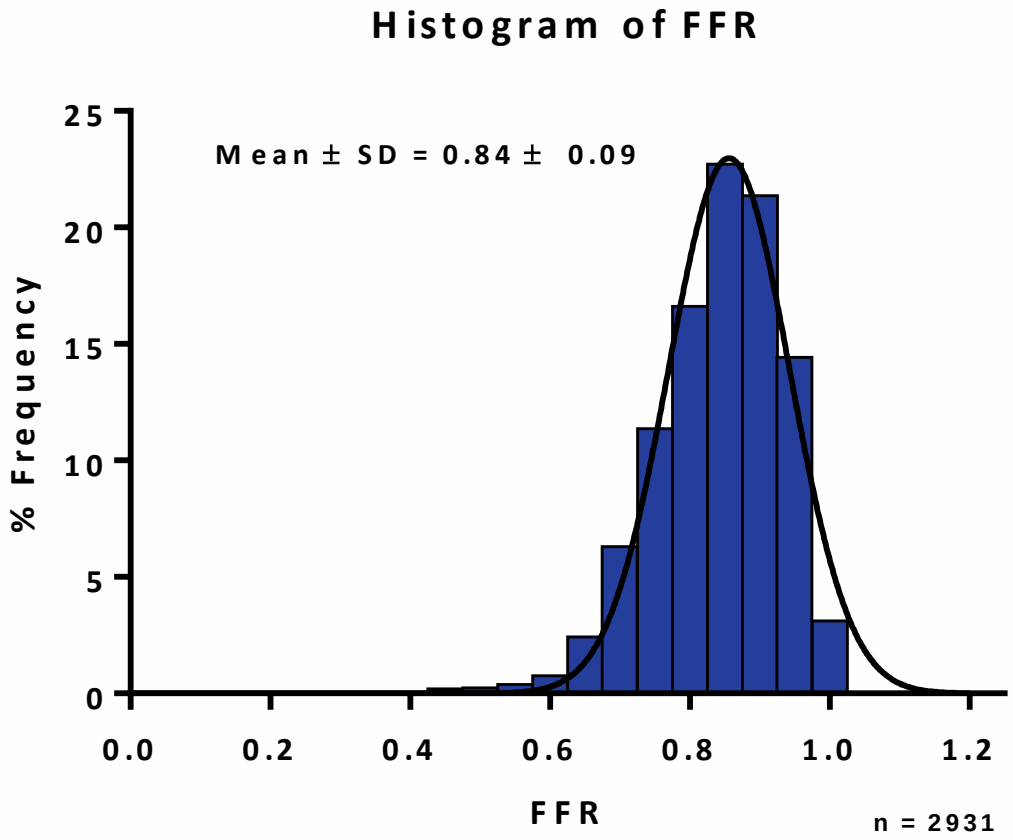
	All Subjects (N=2217)
Baseline Demographics	
Age (years)	65.48 ± 10.47
Gender, Male	74.6%
Medical History	
Diabetes Mellitus	31.3%
Hypertension	66.0%
Previous/Current Smoker	56.9%
Hypercholesterolemia	60.3%
Previous PCI	44.1%
Previous CABG	3.6%
Previous MI	28.1%
% LVEF	54.23 ± 11.74
Pre-Procedure Assessment	
Stable Angina	62.6%
Unstable Angina	16.5%
Non-STEMI	9.8%
STEMI	4.3%
Documented Silent Ischemia on non-Invasive Testing	6.8%

Baseline Lesion Characteristics

	All Subjects (N=2217) (L=2974)
Per Subject analysis	
Multiple Vessel Disease	26.9%
Number of Lesions Treated per Patient	1.35 ± 0.65
Per Lesion Analysis	
Target Lesion	
LAD	54.8%
Circumflex or Ramus	21.7%
RCA	20.4%
LMCA	3.1%
Lesion Severity	
< 50%	20.4%
50-69%	54.1%
70-90%	23.8%
> 90%	1.2%
Total Occlusion	0.5%

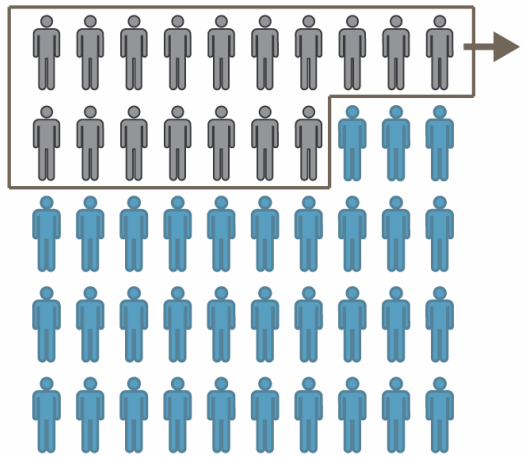
N= Number of Subjects; L = Number of Lesions

Frequency Distribution of FFR



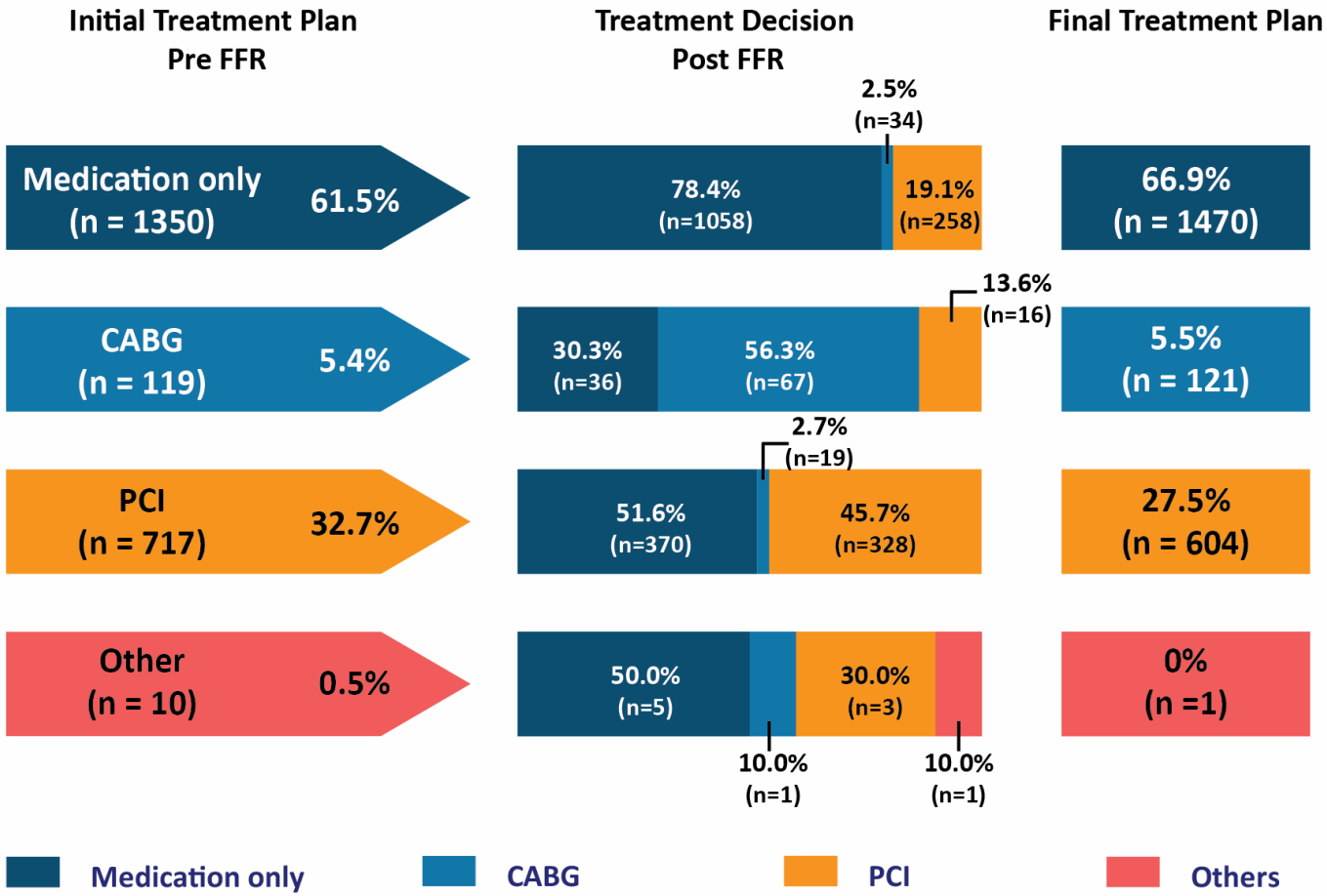
Change in Treatment Plan (Per Subject)

Per Patient Analysis **(n = 2196)**



Treatment plan changed in **34.7%** of patients after FFR

(n=763)



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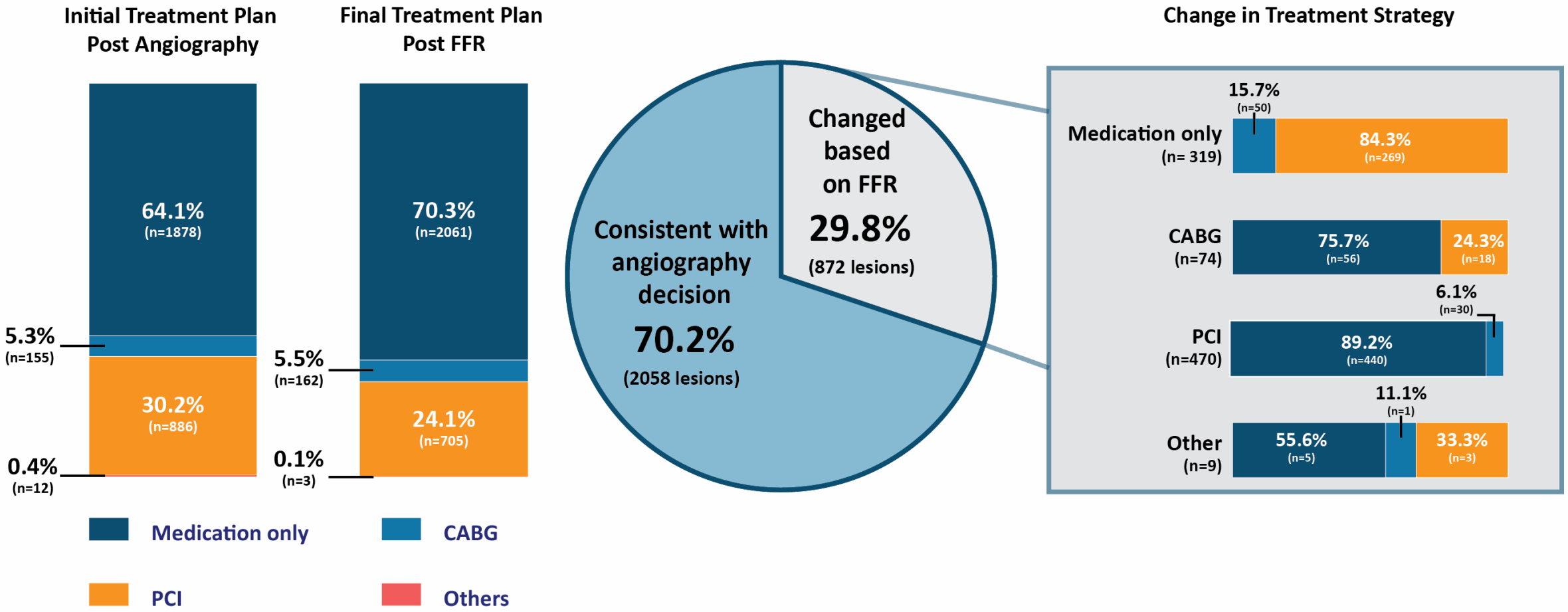
Change in Treatment Plan (Per Lesion)

Per Lesion Analysis **(n = 2931)**



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ACS vs Stable CAD Patients

	ACS Patients (N=677, L=894)	Stable CAD Patients (N=1536, L=2074)	P-Value*
Initial Treatment Plan, for non-culprit lesions			
Medication Only	59.0%	65.5%	**<0.01**
CABG	8.2%	3.9%	**<0.01**
PCI	32.6%	30.1%	0.174
Other	0.2%	0.5%	0.529
% Change from Initial Treatment Based on FFR	35.5%	28.4%	**<0.01**
Changes from Initial Treatment Based on FFR			
Medication Only	52.9%	57.9%	0.152
CABG	9.4%	8.9%	0.835
PCI	37.1%	32.3%	0.150
Other	0.6%	0.9%	1.000
Final Treatment Plan			
Medication Only	64.5%	72.0%	**<0.001**
CABG	7.2%	4.8%	**0.011**
PCI	28.3%	23.0%	**0.002**
Other	0.0%	0.1%	0.559

*From Chi-square Test

Conclusions

- Use of FFR in real-world global clinical practice changes the treatment plan in more than one third of all-comers, both ACS and stable CAD, selected for physiology-guided assessment

- FFR measurement is very useful, providing additional information beyond coronary angiography, to guide treatment decisions