

Clinical Outcomes of FFRangio Guided Treatment for Coronary Artery Disease

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Background

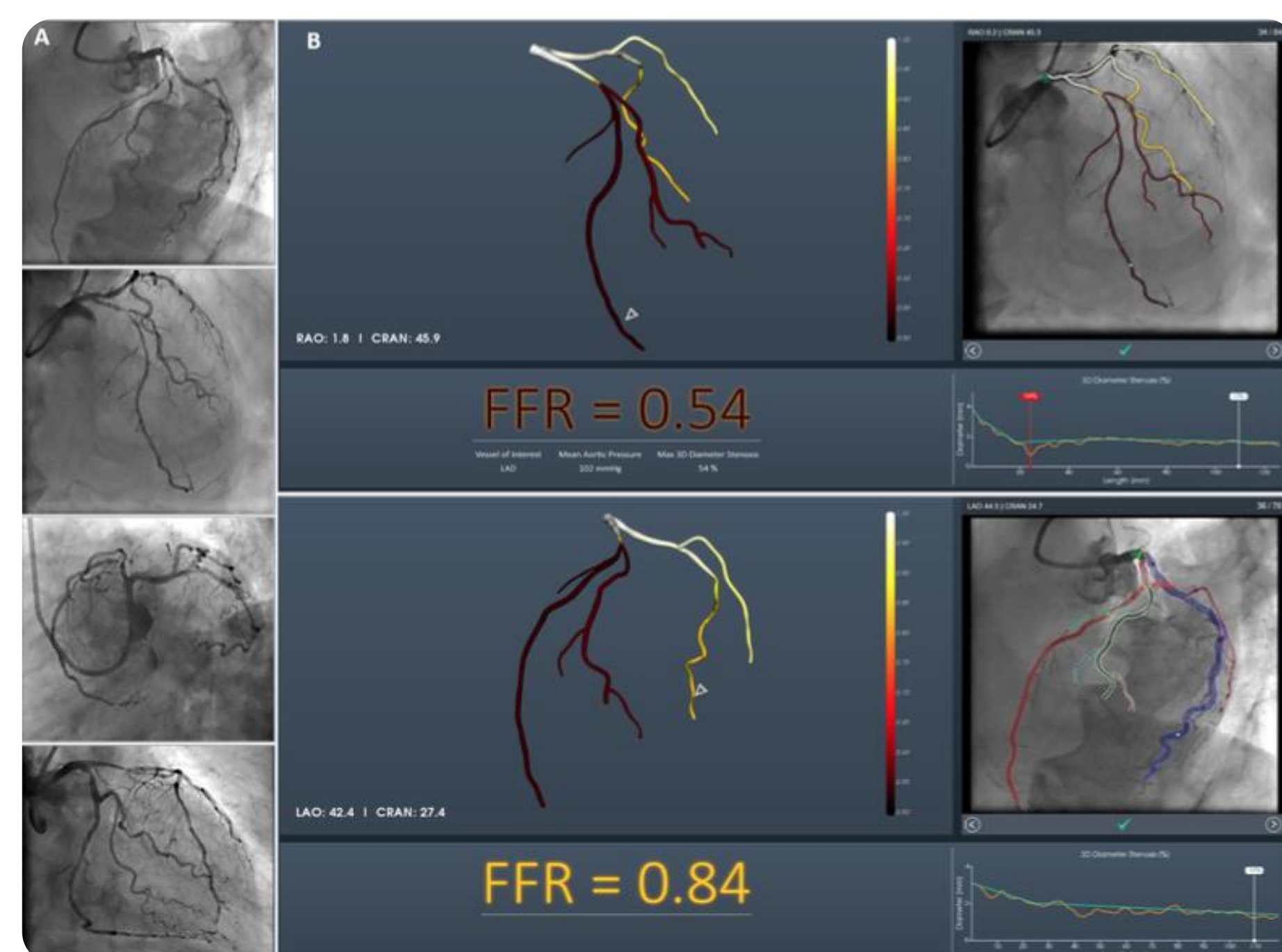
Wire based fractional flow reserve (wbFFR) is the gold standard for physiologic assessment of coronary lesions. In recent years, several angiogram based FFR (abFFR) technologies have been developed and shown good diagnostic performance compared to wbFFR. Unlike wbFFR, scarce data is available regarding clinical outcomes of abFFR guided treatment for coronary artery disease.

Methods

An observational study in two early adopting centers of FFRangio: Rabin Medical Center (Petah-Tikva, Israel), and Gifu Heart Center (Gifu, Japan). At both centers, FFRangio is used in routine clinical practice to assess the physiologic significance of coronary lesions and guide treatment decisions, without the concomitant measurement of wbFFR.

Primary endpoint was 1-year cumulative incidence of cardiovascular (CV) death / myocardial infarction (MI) / repeat revascularization (RR) stratified by treatment strategy (revascularization/deferral).

Figure 1 | Example of FFRangio Analysis



Results

Our cohort included 601 lesions from 518 patients. In 552 lesions (91.8% of all lesions, 265 revascularization, 287 deferral), treatment was concordant with FFRangio results. Mean age was 66 years and 28% were female. Deferred patients were younger, more often female less likely to suffer from diabetics and present with acute coronary syndrome. Mean FFRangio was 0.79 (0.68 and 0.89 in the revascularization and deferred lesions, respectively). Cumulative incidence of the primary endpoint for the revascularization and deferred groups at 1 year was 4.1% and 2.5% (CV death 0.4% and 0.7%, MI 1.4% and 0.9%, RR 3.8% and 2.1%). Vessel level analysis showed excellent results for TVMR and TVR at 1 year for both revascularization (0% for both) and deferral (0.3% and 0.7% respectively).

Graphic overview of the study design

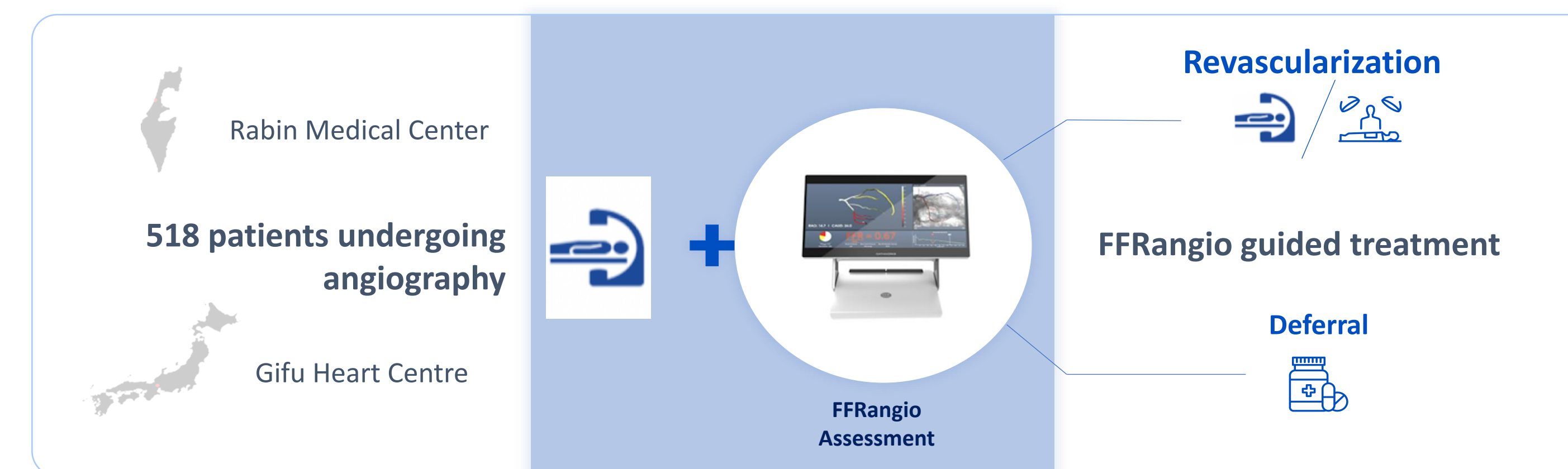


Table 1 | baseline characteristics

	All (n=492)	Deferred (n=256)	Treated (n=236)	P value
Age	66.4±10.7	67.4±9.5	65.4±11.8	0.04
Male	350(71.1%)	160(45.7%)	190(80.5%)	<0.01
Diabetes mellitus	202(41.1%)	89(34.85)	113(47.6%)	<0.01
Hypertension	288(58.5%)	153(59.8%)	135(57.2%)	0.58
Dyslipidemia	285(57.9%)	147(57.4%)	138(58.5%)	0.86
Family history	50(10.2%)	28(10.9%)	22(9.3%)	0.66
PVD	16(3.3%)	8(3.1%)	8(3.4%)	0.56
Previous MI	45(9.1%)	21(8.2%)	24(10.2%)	0.53
Previous PCI	139(28.3%)	67(26.2%)	72(30.5%)	0.32
Previous CVA	18(3.7%)	13(5.1%)	5(2.1%)	0.10
Active smoker	117(24.6%)	53(21.5%)	64(27.8%)	0.26
ACS	263(53.4%)	122(47.6%)	141(59.7%)	0.02
Number vessels disease				<0.01
Single vessel	296(60.1%)	166(69.5%)	130(55.1%)	
Two vessels	115(23.45)	53(20.7%)	61(25.8%)	
Three vessels	81(16.4%)	37(14.4%)	44(18.6%)	
Number vessels assessed by FFRangio				0.11
Single vessel	1(1-1)	1(1-1)	1(1-2)	
Two vessels	409(83.1%)	218(85.2%)	191(80.9%)	
Three vessels	60(12.2%)	30(11.7%)	30(12.7%)	
Three vessels	23(4.7%)	8(3.3%)	15(6.4%)	
Vessels distribution*				0.62
LAD	326(59.1%)	168(58.05)	161(60.2%)	
LCx	110(19.9%)	59(20.5%)	51(19.3%)	
RCA	106(19.2%)	53(8.4%)	53(20.1%)	
Radial access	460(93.6%)	237(92.6%)	223(94.5%)	0.56
FFRangio*	0.79±0.13	0.89±0.04	0.68±0.06	<0.01
Revascularization modality				<0.01
PCI	213(41.9%)	0(0.0%)	213(90.3%)	
CABG	23(6.1%)	0(0.0%)	23(9.7%)	
%Stenosis*	59.5±14.6	50.2±1.3	69.6±10.5	<0.01
Lesion length (mm)			23.6±12.5	
Median number of stents			1(1-1)	
Stent diameter (mm)			3.0±0.45	
Stent length (mm)			26.6±13.0	
Stent type		NA		
EES		NA	122	
SES		NA	73	
ZES		NA	39	
BES		NA	18	
Other/mixed		NA	27	

Figure 2 | KM curves for 1 year MACE

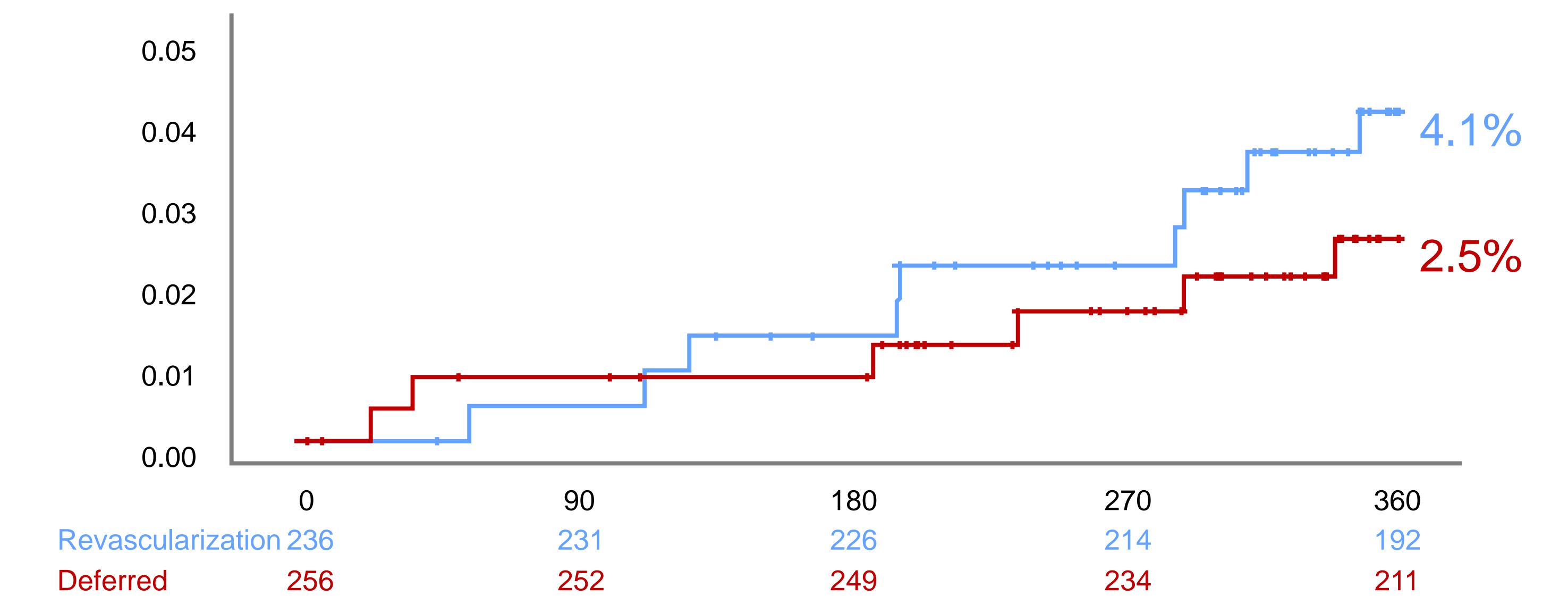


Table 2 | Patient and Vessel Level Analysis

A - Patient level analysis	Deferred (n=256)	Revascularization (n=236)
CV death/MI/RR	6(2.5%)	9(4.1%)
CV death/MI/RR	2(0.7%)	1(0.4%)
MI	2(0.9%)	3(1.4%)
RR	5(2.1%)	9(3.8%)
B - Vessel level analysis	Deferred (n=287)	Revascularization (n=265)
TVMI	1(0.3%)	0(0.0%)
TVR	2(0.7%)	0(0.0%)

Conclusions

In the real-world setting, FFRangio guided treatment yields excellent one-year outcomes for both revascularization and deferred lesion, which are comparable with current data for wbFFR guided treatment. These results demonstrate, for the first time, the clinical utility of FFRangio guided treatment. More data, ideally an RCT for abFFR vs. wbFFR guided treatment is needed to also examine other possible benefits of abFFR, such as time saving, cost effectiveness and resource utilization