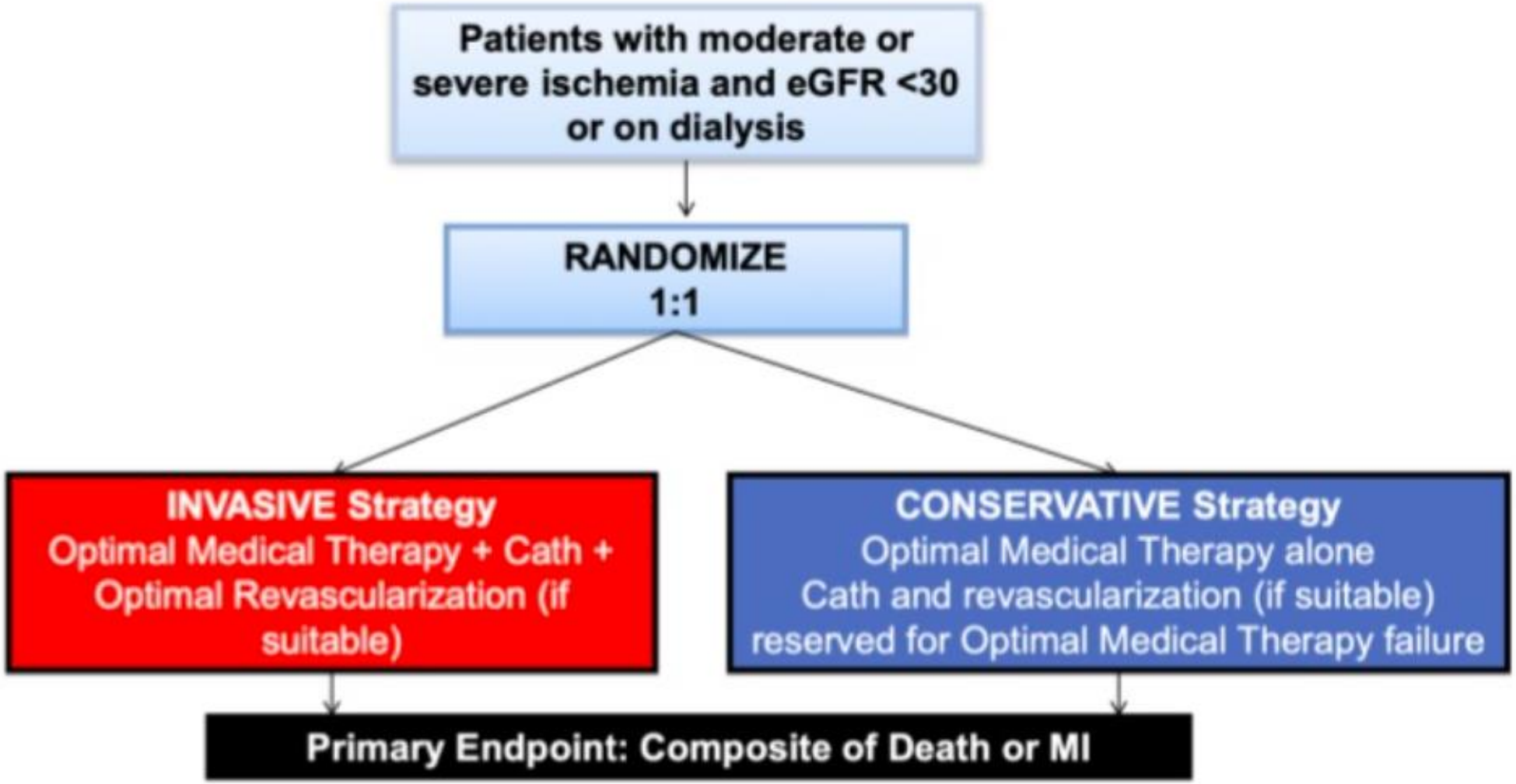
International Study of Comparative Health Effectiveness with Medical and Invasive Approaches - Chronic Kidney Disease

Primary Report of Clinical Outcomes

Study Design



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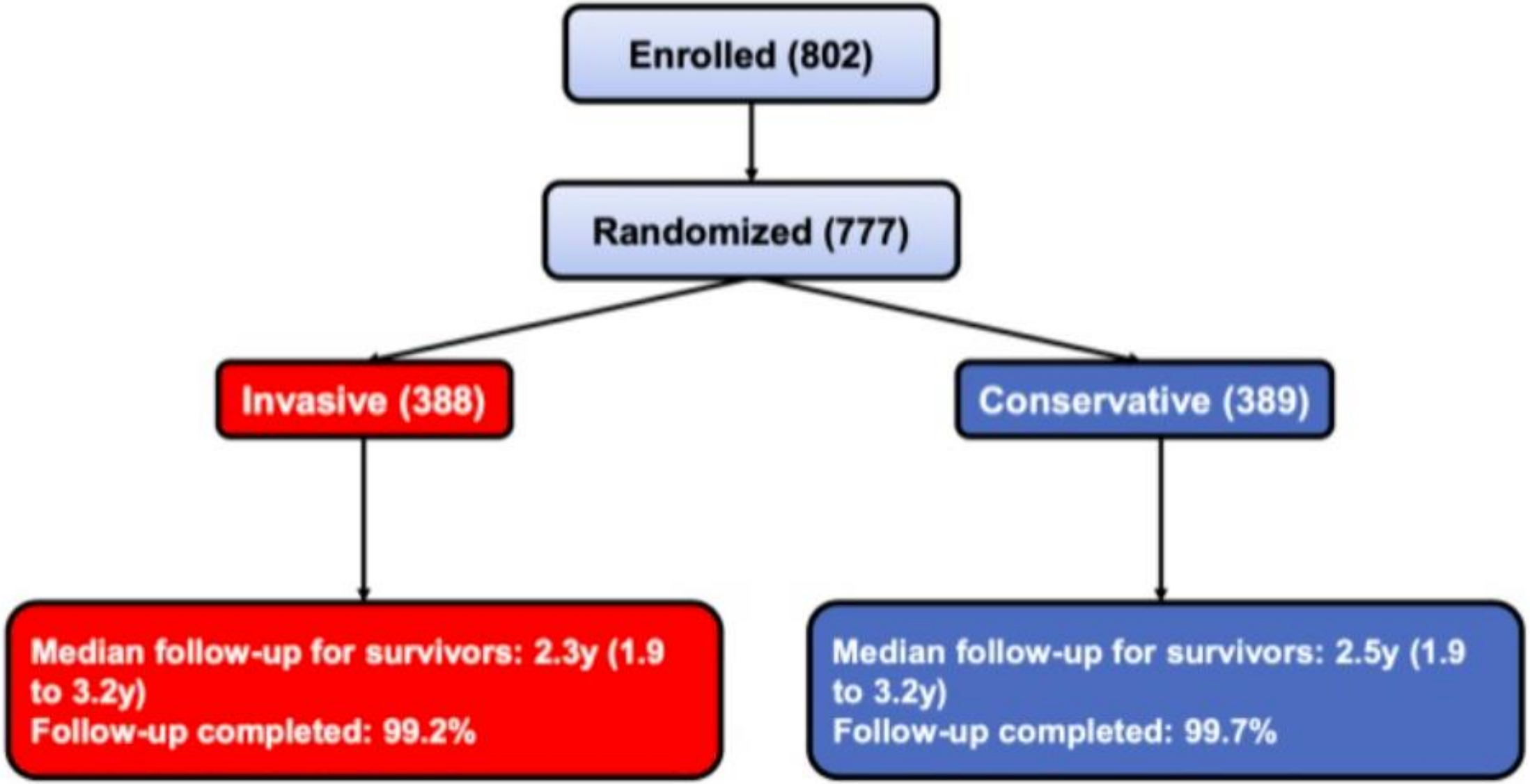
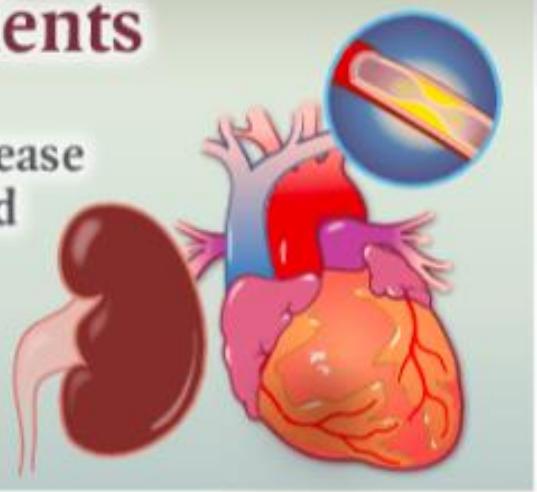
Patient Flow



Managing Coronary Disease in Advanced Kidney Disease

OPEN-LABEL RANDOMIZED, CONTROLLED TRIAL

777 Patients
with stable coronary disease and advanced CKD



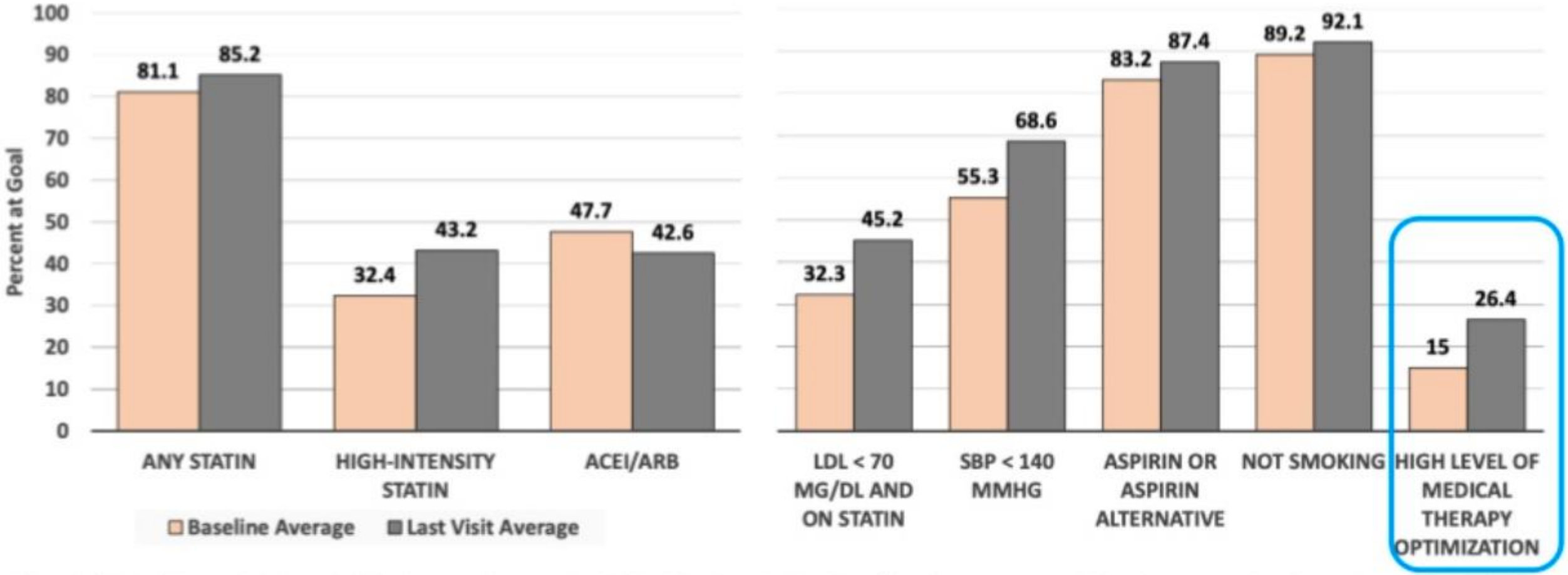
	Invasive Strategy	Conservative Care
	+ Medical therapy	Medical therapy
	(N=388)	(N=389)
Death or nonfatal MI	**123**	**129**
	Adjusted HR 1.01; 95% CI, 0.79–1.29; P=0.95	
Angina-related health status	No difference in Seattle Angina Questionnaire summary score	

Invasive treatment did not reduce the rate of death or nonfatal MI or improve angina-related health status

Characteristic	Total (N=777)	INV (N=388)	CON (N=389)
Age at Enrollment (yrs.)			
Median (25th, 75th)	63 (55, 70)	62 (55, 69)	64 (56, 70)
Female Sex (%)	31	31	31
Hypertension (%)	92	90	93
Diabetes (%)	57	58	56
Prior heart failure (%)	17	17	18
Ejection Fraction			
Median (25th, 75th)	58 (50, 64)	58 (50, 63)	58 (50, 64)
ESRD on Dialysis (%)	53	51	56
Duration of Dialysis (years)	2.0 (1.0, 5.0)	3.0 (1.0, 6.0)	2.0 (1.0, 4.0)
Type of Dialysis			
Hemodialysis (%)	84	83	85
Peritoneal dialysis (%)	15	16	13
eGFR among those not on dialysis			
<15 ml/min/1.73m^2 (%)	14	15	13
15 to <30 ml/min/1.73m^2 (%)	86	85	87

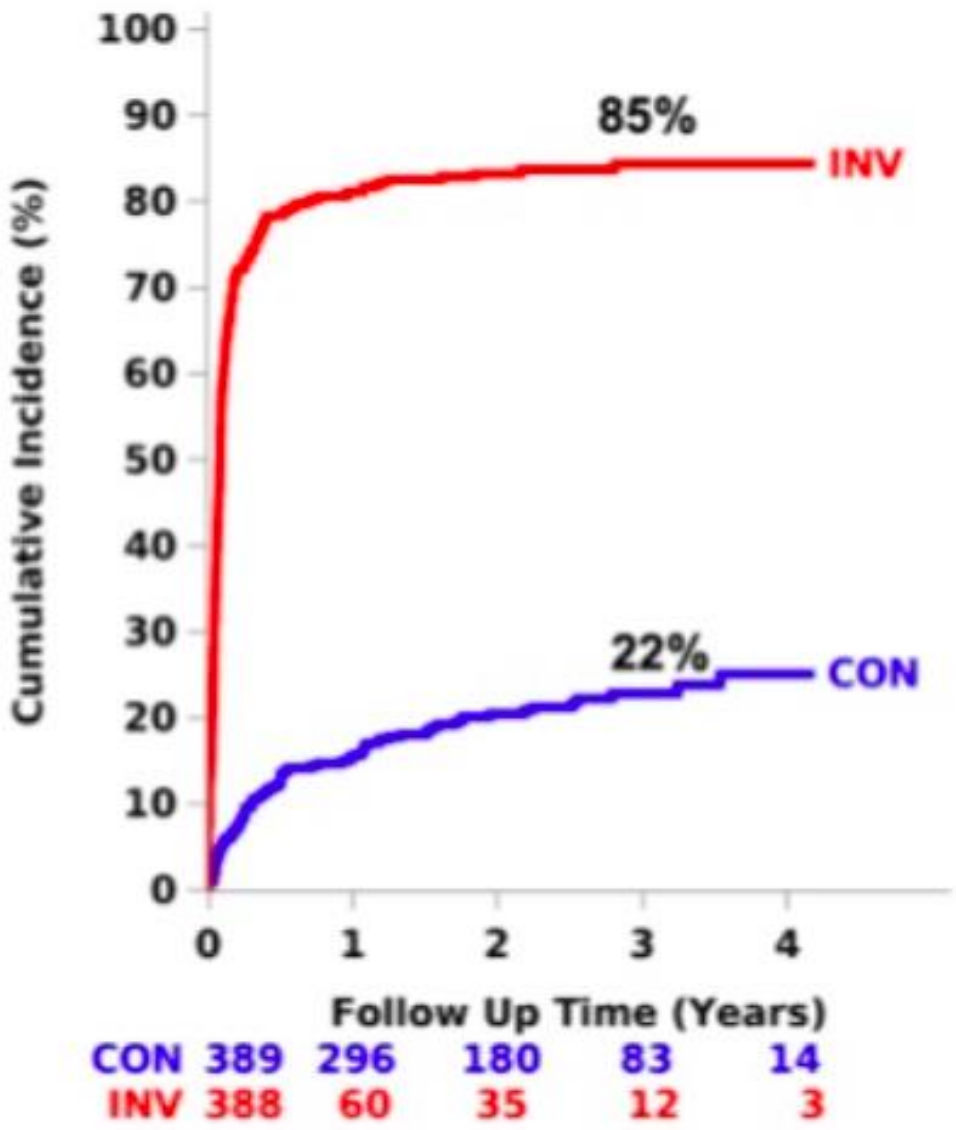
Characteristic	Total (N=777)	INV (N=388)	CON (N=389)
Stress Test Modality			
Stress Imaging (%)	82	81	82
Non-imaging ETT (%)	18	19	18
Stress Test Severity (site determined)			
Severe (%)	38	36	39
Moderate (%)	62	64	61
Number of Native Vessels With ≥ 50% Stenosis (QCA)			
0 (%)		26	
1 (%)		22	
2 (%)		28	
3 (%)		23	
Specific Native Vessels With ≥ 50% Stenosis (QCA)			
Left Main		2	
Left Anterior Descending (LAD)		57	
Proximal LAD		21	
Left Circumflex		44	
Right Coronary artery		45	

No between group differences INV vs CON

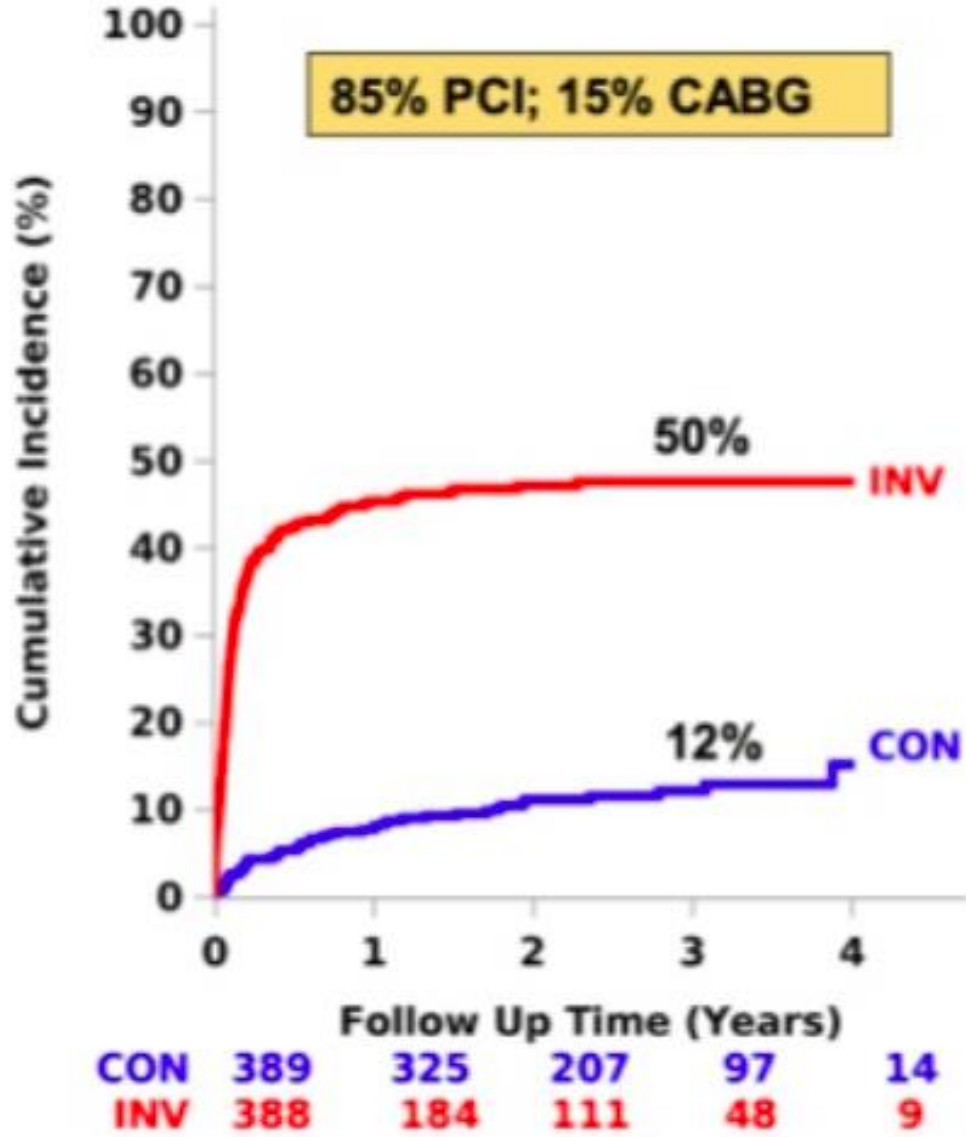


High Level of Medical Therapy Optimization is defined as a participant meeting all of the following goals: LDL < 70 mg/dL and on any statin, systolic blood pressure < 140 mm/Hg, aspirin or other antiplatelet or anticoagulant and not smoking. High level of medical therapy optimization is missing if any of the individual goals are missing.

Coronary Angiography

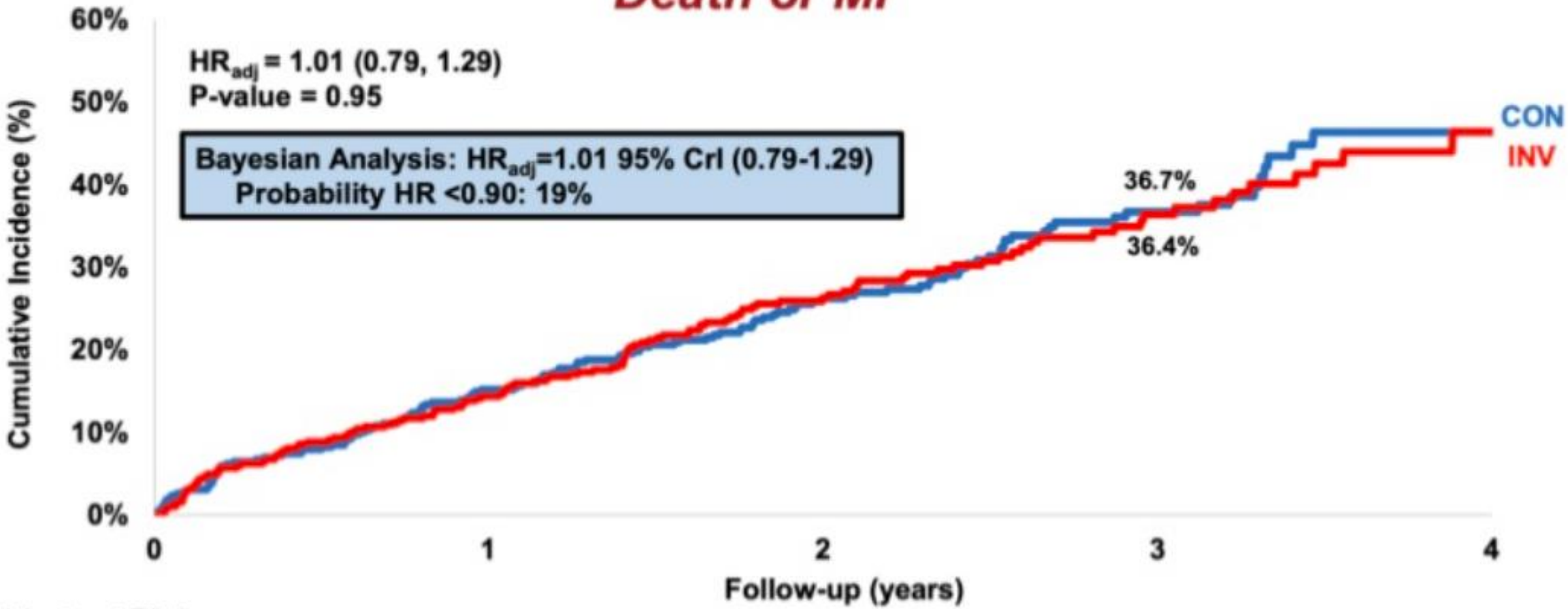


Revascularization



Primary End Point

Death or MI



Subjects at Risk

CON	389	330	213	91	13
INV	388	323	190	80	18

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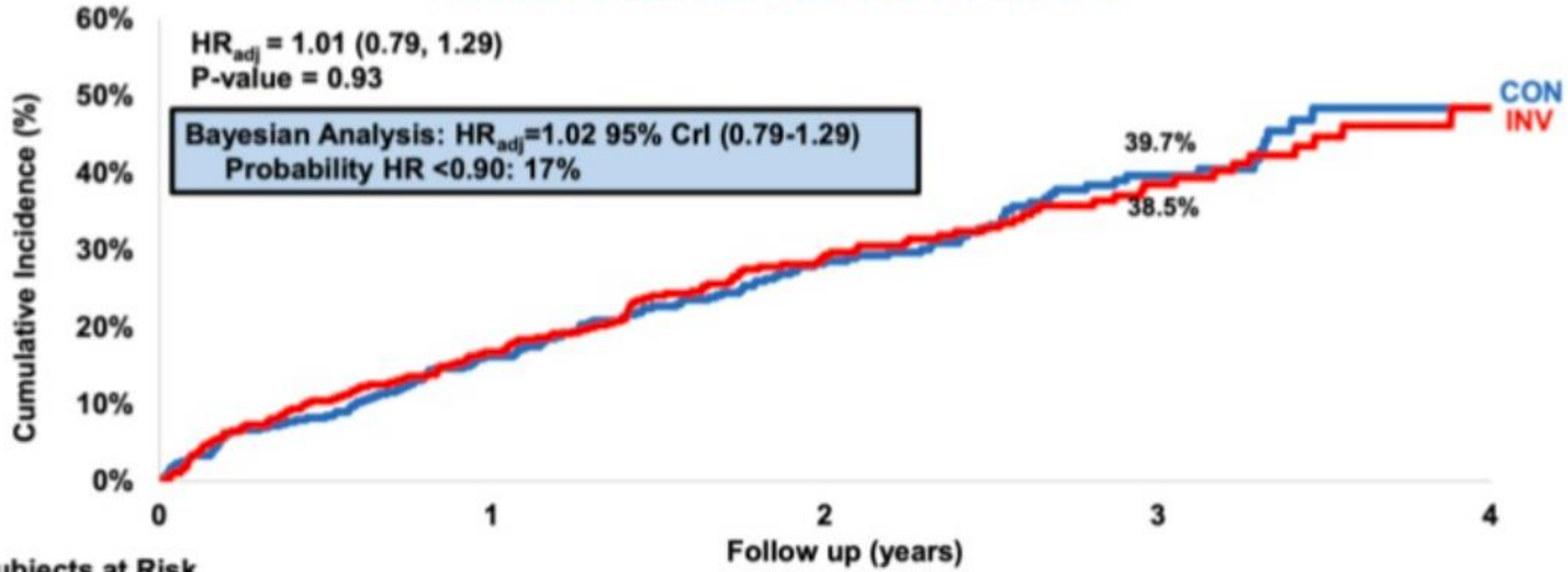
Major Secondary End Point

Death, MI, Hospitalization for Unstable Angina or Heart Failure or Resuscitated Cardiac Arrest



Subjects at Risk					
CON	389	326	206	87	13
INV	388	315	183	77	18

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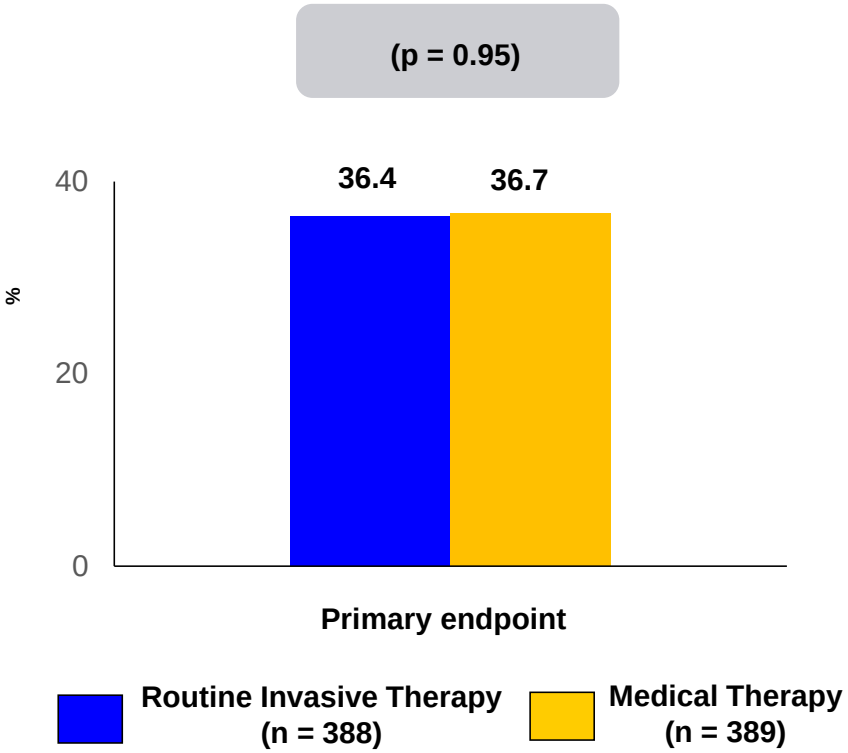
Trial Description: Patients with stable ischemic heart disease, moderate to severe ischemia, and chronic kidney disease were randomized to routine invasive therapy vs. medical therapy.



RESULTS

- Primary efficacy endpoint: Death or MI at 2.3 years, occurred in 36.4% of the routine invasive group vs. 36.7% of the medical therapy group (p = 0.95)
- Improvement in symptoms was not observed irrespective of angina burden

CONCLUSIONS

- Among patients with stable ischemic heart disease, moderate to severe ischemia on noninvasive stress testing, and advanced chronic kidney disease, routine invasive therapy failed to reduce the incidence of death or MI compared with optimal medical therapy
- Routine invasive therapy failed to improve angina symptoms and quality of life compared with medical therapy

Presented by Drs. Sripal Bangalore and John Spertus at AHA 2019