USING REAL WORLD EVIDENCE TO EVALUATE MANAGEMENT STRATEGIES FOR ISCHEMIC HEART DISEASE: AN OBSERVATIONAL REPLICATION OF THE ISCHEMIA TRIAL

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OBJECTIVES

The aims of this study were to use real world evidence to:

1. Replicate the parameters of the ISCHEMIA clinical trial evaluating outcomes among patients with ischemic heart disease (IHD) treated with routine invasive therapy (INV) and optimal medical therapy (OMT) in comparison with OMT on its own.[1]
2. Characterize outcomes of INV for patients experiencing certain ischemic events.

METHODS

Data from an EMR research network representing over 58M patient-lives was used to examine outcomes after treatment for two initial ischemic indications, angina pectoris and non-ST elevation myocardial infarction (NSTEMI), newly incident in the past five years. INV was defined as cardiac catheterization, coronary artery bypass grafting, or percutaneous coronary intervention, and OMT constituted several cardiovascular medications. INV+OMT cohorts were treated with at least one INV and one OMT within the month after the incident ischemic event. OMT cohorts were treated with OMT alone in the first month. We matched on demographic factors, comorbid ischemic events, and other risk factors, and we compared outcomes (cardiac arrest, all-cause mortality, STEMI, NSTEMI, unstable angina, heart failure, and all-cause hospitalization) occurring any time after treatment between cohorts using risk ratios and 95% confidence intervals.

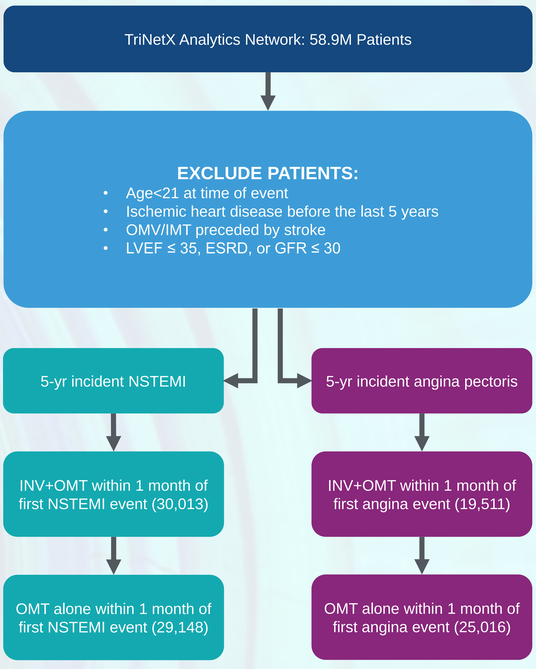

Figure 1. Patient flow diagram

Table 1. Patient demographics before matching

	Age		Male
	Mean	SD	Percentage
NSTEMI			
INV+OMT	61.9	12.2	64
OMT alone	64.8	14.0	57
Angina pectoris			
INV+OMT	62.0	11.3	63
OMT alone	62.2	12.7	55

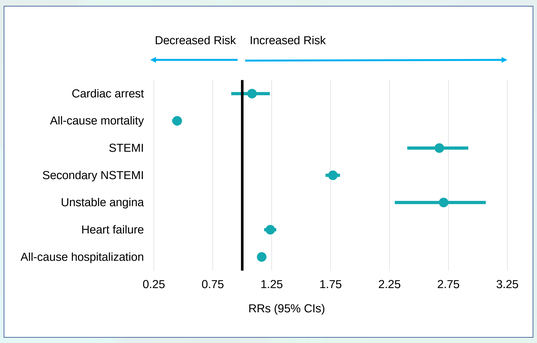

Figure 2. Risk ratio of ischemic events occurring after 5-year incident NSTEMI between patients treated with INV+OMT vs. OMT alone

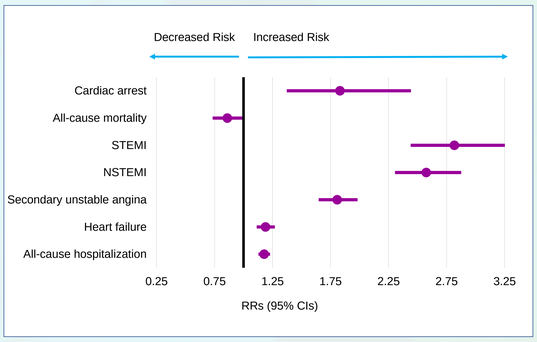

Figure 3. Risk ratio of ischemic events occurring after 5-year incident angina pectoris between patients treated with INV+OMT vs. OMT alone

RESULTS

The risk of STEMI, a second NSTEMI, unstable angina, heart failure, and all-cause hospitalization was significantly greater among primary NSTEMI patients treated with INV+OMT vs. those treated with OMT alone. There was no difference in risk of cardiac arrest between the two patient groups, and those treated with INV+OMT had significantly less risk of all-cause mortality than those treated with OMT alone (Figure 2). The risk of cardiac arrest, STEMI, NSTEMI, a second occurrence of unstable angina, heart failure, and all-cause hospitalization was significantly greater among primary unstable angina patients treated with INV+OMT vs. those treated with OMT alone. There was no difference in risk of all-cause mortality between the two patient groups (Figure 3).

CONCLUSIONS

Routine INV may be beneficial in reducing all-cause mortality among patients with an NSTEMI event. Otherwise, this study suggests INV+OMT treatment has the same or greater risk for other relevant outcomes than OMT alone, matching some preliminary conclusions seen from the ISCHEMIA trial.[2]

REFERENCES

1. NYU Langone Health. International Study of Comparative Health Effectiveness With Medical and Invasive Approaches (ISCHEMIA) (ISCHEMIA). First posted 11 Feb 2020. NCT01471522.
2. Hochman, JS, Bavry, AA, and Bhatt, DL. International Study of Comparative Health Effectiveness With Medical and Invasive Approaches – ISCHEMIA. American College of Cardiology 16 Nov 2019.

Table 2. Baseline patient characteristics before and after matching for each initial ischemic indication
Note: p-values >0.05 for all factors except for ethnicity for the NSTEMI cohort and age at index for the angina pectoris cohort.

	NSTEMI				Angina pectoris			
	Before Matching		After Matching		Before Matching		After Matching	
	INV+OMT	OMT alone	INV+OMT	OMT alone	INV+OMT	OMT alone	INV+OMT	OMT alone
Total N	**30,013**	**29,148**	**22,190**	**22,190**	**19,511**	**25,016**	**13,803**	**13,803**
Age at Index, mean (SD)	62 (12.2)	65 (14.0)	62 (12.6)	62 (12.9)	62 (11.3)	62 (12.7)	61 (11.6)	61 (11.8)
21-40 years (%)	4.0	5.1	4.5	4.6	2.8	4.5	3.3	3.4
40-60 years (%)	37.1	28.4	35.5	35.1	39.4	38.5	40.0	41.2
60-70 years (%)	30.7	26.0	30.2	30.1	32.3	29.0	31.2	30.7
70-75 years (%)	11.8	12.4	12.0	12.1	12.2	11.2	11.7	11.7
75-80 years (%)	8.5	11.1	9.0	9.2	7.7	8.4	7.8	7.3
80-85 years (%)	5.7	10.7	6.1	6.3	4.3	5.9	4.6	4.4
At least 85 years (%)	2.1	6.3	2.6	2.7	1.2	2.5	1.4	1.3
Male (%)	63.6	57.4	61.1	61.1	62.0	54.5	58.8	59.1
Not Hispanic or Latino (%)	58.5	48.1	51.2	52.4	66.7	52.1	60.3	59.5
Unknown Ethnicity (%)	37.1	48.0	44.8	43.5	28.2	41.5	34.1	34.9
Hypertensive diseases (%)	44.7	31.5	34.9	34.3	50.8	34.7	42.1	41.6
Acute myocardial infarction (%)	41.4	22.7	25.2	25.3	9.6	1.1	1.8	2.1
Other forms of heart disease (%)	28.7	20.7	21.2	21.4	30.6	17.2	23.3	22.6
Hyperlipidemia, unspecified (%)	30.5	16.3	19.8	19.2	37.2	19.6	27.1	26.4
Diabetes mellitus (%)	20.6	13.9	15.6	15.4	20.9	14.8	18.0	17.7
Chronic ischemic heart disease (%)	28.2	8.1	10.5	10.5	28.8	6.0	10.4	10.9
Other acute ischemic heart diseases (%)	4.6	1.2	1.5	1.5	2.8	0.5	0.8	0.8
Angina pectoris (%)	5.5	0.6	0.8	0.8	56.9	22.6	39.1	38.8