# COMPLETE Trial QoL

## Effects of Complete Revascularization on Angina-Related Quality of Life in Patients with ST-Segment Elevation Myocardial Infarction

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for the COMPLETE trial Investigators

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# Disclosures

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Coordinated by the Population Health Research Institute, Hamilton, Canada

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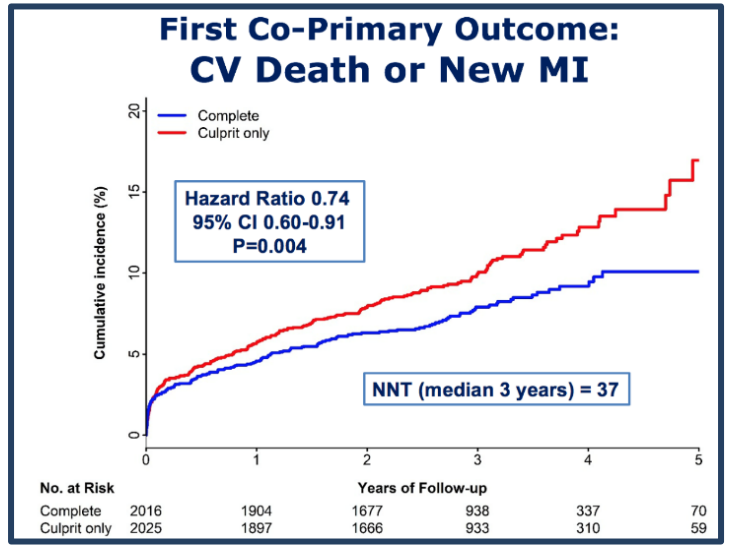
# Background

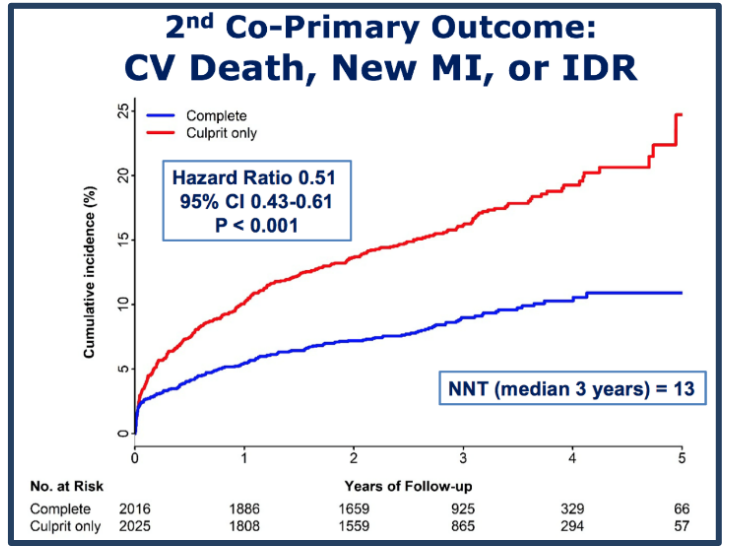
- The goals of treatment in patients with STEMI and multivessel CAD are to reduce major cardiovascular events AND improve quality of life

- The COMPLETE trial demonstrated that complete revascularization reduced CV death or new MI and this led to a Class 1A recommendation for complete revascularization in the 2021 ACC/AHA/AATS/STS/SCAI Guideline for Coronary Artery Revascularization[2]

- ***However, the effect of complete revascularization on angina-related quality of life is uncertain and*** *has not previously been evaluated in a RCT*

## COMPLETE Trial Main Results






1. Mehta SR et al. N Engl J Med 2019; 381, 1411-1421
2. Lawton JS et al. J Am Coll Cardiol. 2022;79:e21-e129

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# Primary Objective

To determine whether complete revascularization improves angina-related quality of life compared with culprit-lesion only PCI in patients with STEMI and multivessel CAD.

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# SAQ, Outcomes and Analysis

- Pre-specified analysis of the COMPLETE trial*
- Seattle Angina Questionnaire was administered at baseline (randomization), 6 months and final visit (median 3 years).
- SAQ is a a 19-item questionnaire completed by the patient that assesses frequency of angina, treatment satisfaction, angina stability, physical limitation, and quality of life.
- Scores range from 0 to 100 for each domain with higher scores indicating better health status and fewer symptoms.
- **Main outcomes:** SAQ-AF score as a continuous variable and SAQ-AF score=100 (proportion free of angina)
- **Analysis:** Intention-to-treat, mixed model repeated measures analysis (MMRM) for SAQ and GLMM for proportion angina-free



*Mehta SR et al. *Am Heart J* 2019; 215:157-166.

# COMPLETE QoL Design

## STEMI WITH MULTIVESSEL CAD AND SUCCESSFUL PCI TO THE CULPRIT LESION

MVD defined as at least one additional non-culprit lesion ≥ 2.5 mm diameter and ≥70% stenosis or 50-69% with FFR ≤0.80

### Randomized to COMPLETE REVASCULARIZATION (Staged Non-Culprit Lesion PCI plus Optimal Medical Therapy)

n=2016

- Received Allocated Intervention (n=1881)
- Did not receive Allocated Intervention (n=135)
  - Crossover to Culprit Lesion-Only Revascularization (n=122)
  - Death prior to intervention (n=13)
- Lost to Follow-up (n=18)
- Withdrew Consent (n=3)

**SAQ FREQUENCY SCORE Completed/Expected**

Baseline: n=1905/2016 (94.5%)
Month 6: n=1734/1981 (87.5%)
End of study: n=1666/1920 (86.8%)

### Randomized to CULPRIT LESION-ONLY REVASCULARIZATION (Optimal Medical Therapy Only)

n=2025

- Received Allocated Intervention (n=1634)
- Did not receive Allocated Intervention (n=391)
  - Met protocol criteria for Complete Revascularization (n=198)
  - Did not meet protocol criteria for Complete Revascularization (n=193)
- Lost to Follow-up (n=15)
- Withdrew Consent (n=6)

**SAQ FREQUENCY SCORE Completed/Expected**

Baseline: n=1925/2025 (95.1%)
Month 6: n=1730/1995 (86.7%)
End of study: n=1632/1919 (85.0%)

**MEDIAN FOLLOW-UP: 3 YEARS**

Population Health Research Institute
HEALTH THROUGH KNOWLEDGE

Hamilton Health Sciences
McMaster University HEALTH SCIENCES

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# Baseline Clinical Characteristics and SAQ Score

| | Complete N=2016 | Culprit-only N=2025 |
|---|---|---|
| Age (yrs) | 61.6 | 62.4 |
| Gender (% male) | 80.5 | 79.1 |
| Diabetes (%) | 19.1 | 19.9 |
| Chronic renal insuff. (%) | 2.0 | 2.3 |
| Prior MI (%) | 7.3 | 7.6 |
| Current smoker (%) | 40.6 | 38.9 |
| Hypertension (%) | 48.7 | 50.7 |
| Dyslipidemia (%) | 37.9 | 39.4 |
| Prior PCI (%) | 7.0 | 7.0 |
| Prior stroke (%) | 3.2 | 3.1 |

| | Complete N=2016 | Culprit-only N=2025 |
|---|---|---|
| SAQ score | | |
| Angina frequency | 87.1±17.8 | 87.2±18.4 |
| Daily | 34/1905 (1.8) | 39/1925 (2.0) |
| Weekly | 211/1905 (11.1) | 211/1925 (11.0) |
| Monthly | 719/1905 (37.7) | 675/1925 (35.1) |
| None | 941/1905 (49.4) | 1000/1925 (51.9) |
| Physical limitation | 84.9±20.4 | 84.4±20.8 |
| Treatment satisfaction | 93.0±12.4 | 92.5±12.5 |
| Quality of life | 66.9±23.0 | 66.3±23.5 |
| Summary score* | 79.6±15.7 | 79.3±16.7 |

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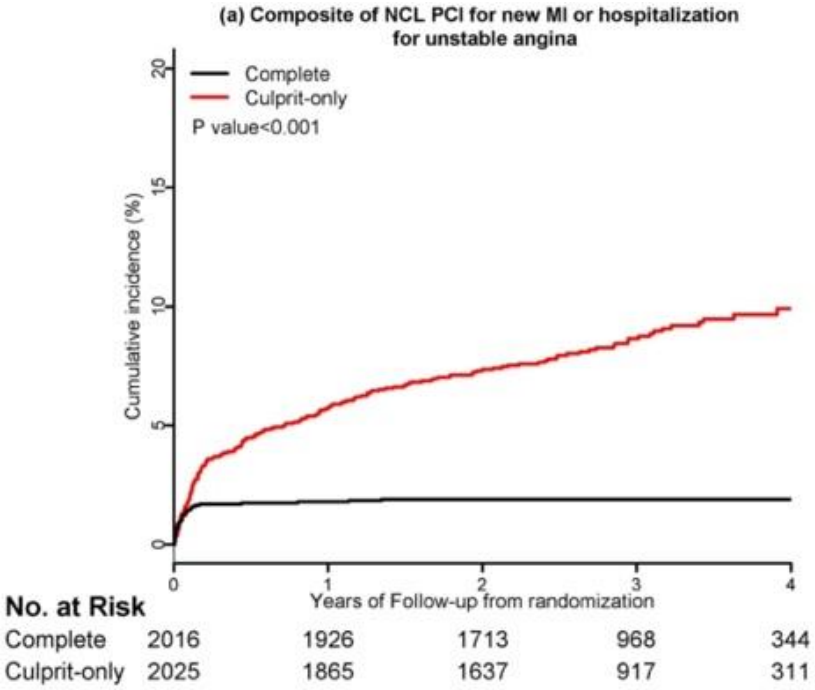
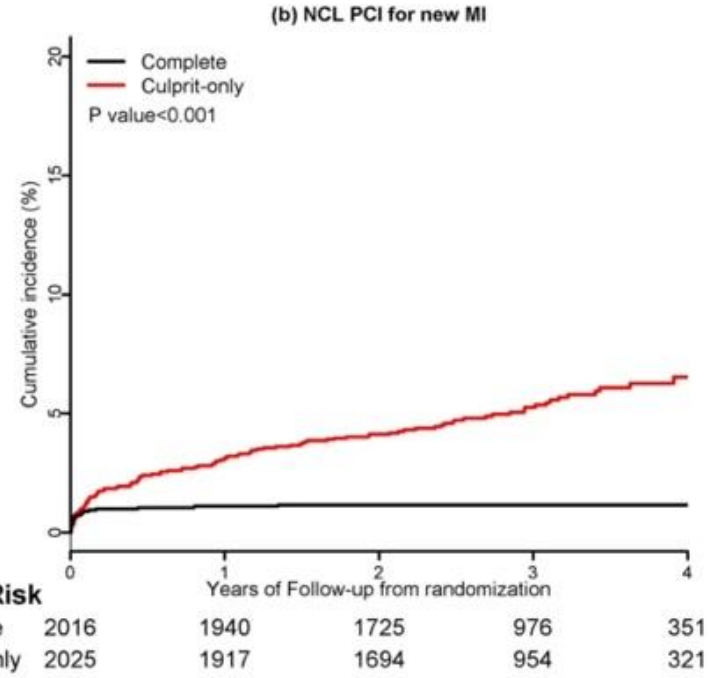
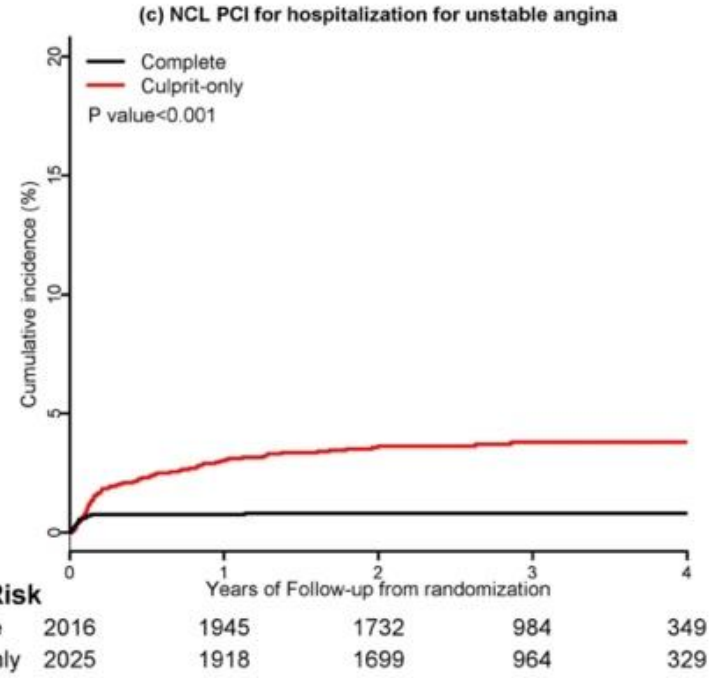
# Crossover PCI of Non-culprit Lesion after Angina-Related Clinical Event




| No. at Risk | | | | | |
|---|---|---|---|---|---|
| Complete | 2016 | 1926 | 1713 | 968 | 344 |
| Culprit-only | 2025 | 1865 | 1637 | 917 | 311 |




| No. at Risk | | | | | |
|---|---|---|---|---|---|
| Complete | 2016 | 1940 | 1725 | 976 | 351 |
| Culprit-only | 2025 | 1917 | 1694 | 954 | 321 |




| No. at Risk | | | | | |
|---|---|---|---|---|---|
| Complete | 2016 | 1945 | 1732 | 984 | 349 |
| Culprit-only | 2025 | 1918 | 1699 | 964 | 329 |

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# SAQ Subscale Scores at Follow-up (6 months)

| SAQ Subscale | Score at Follow-up | | Δ from Baseline | | Difference (95% CI) | P Value |
|---|---|---|---|---|---|---|
| | Complete | Culprit | Complete | Culprit | | |
| Angina frequency | 94.6±13.0 | 93.6±14.7 | 7.3±20.2 | 6.4±21.6 | 0.96 (0.05-1.88) | 0.039 |
| Physical limitation | 88.8±17.7 | 88.0±18.0 | 3.3±19.7 | 3.3±21.1 | 0.83 (-0.39-2.04) | 0.18 |
| Treatment satisfaction | 93.7±11.1 | 92.2±12.7 | 0.7±13.8 | -0.2±15.0 | 1.44 (0.65-2.23) | <0.001 |
| Quality of life score | 80.4±18.9 | 78.0±20.7 | 13.2±24.0 | 11.5±27.0 | 2.26 (0.94-3.58) | <0.001 |
| Summary score | 80.4±18.9 | 78.0±20.7 | 13.2±24.0 | 11.5±27.0 | 2.26 (0.94-3.58) | <0.001 |

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# SAQ Subscale Scores at Follow-up (Median 3 Years)

| SAQ Subscale | Score at Follow-up | | Δ from Baseline | | Difference (95% CI) | P Value |
|---|---|---|---|---|---|---|
| | Complete | Culprit | Complete | Culprit | | |
| Angina frequency | 97.1±9.7 | 96.3±10.9 | 9.8±18.9 | 8.6±19.9 | 0.97 (0.27-1.67) | 0.006 |
| Physical limitation | 91.1±15.7 | 89.9±17.4 | 4.2±20.0 | 4.3±22.3 | 1.41 (0.24-2.59) | 0.018 |
| Treatment satisfaction | 93.3±12.4 | 92.5±13.2 | 0.6±15.1 | 0.2±16.2 | 0.97 (0.10-1.84) | 0.028 |
| Quality of life score | 83.6±18.0 | 82.5±18.4 | 16.3±25.6 | 15.9±27.2 | 1.25 (0.01-2.48) | 0.048 |
| Summary score | 90.7±11.4 | 89.5±12.2 | 9.8±15.8 | 9.6±18.0 | 1.27 (0.44-2.11) | 0.003 |

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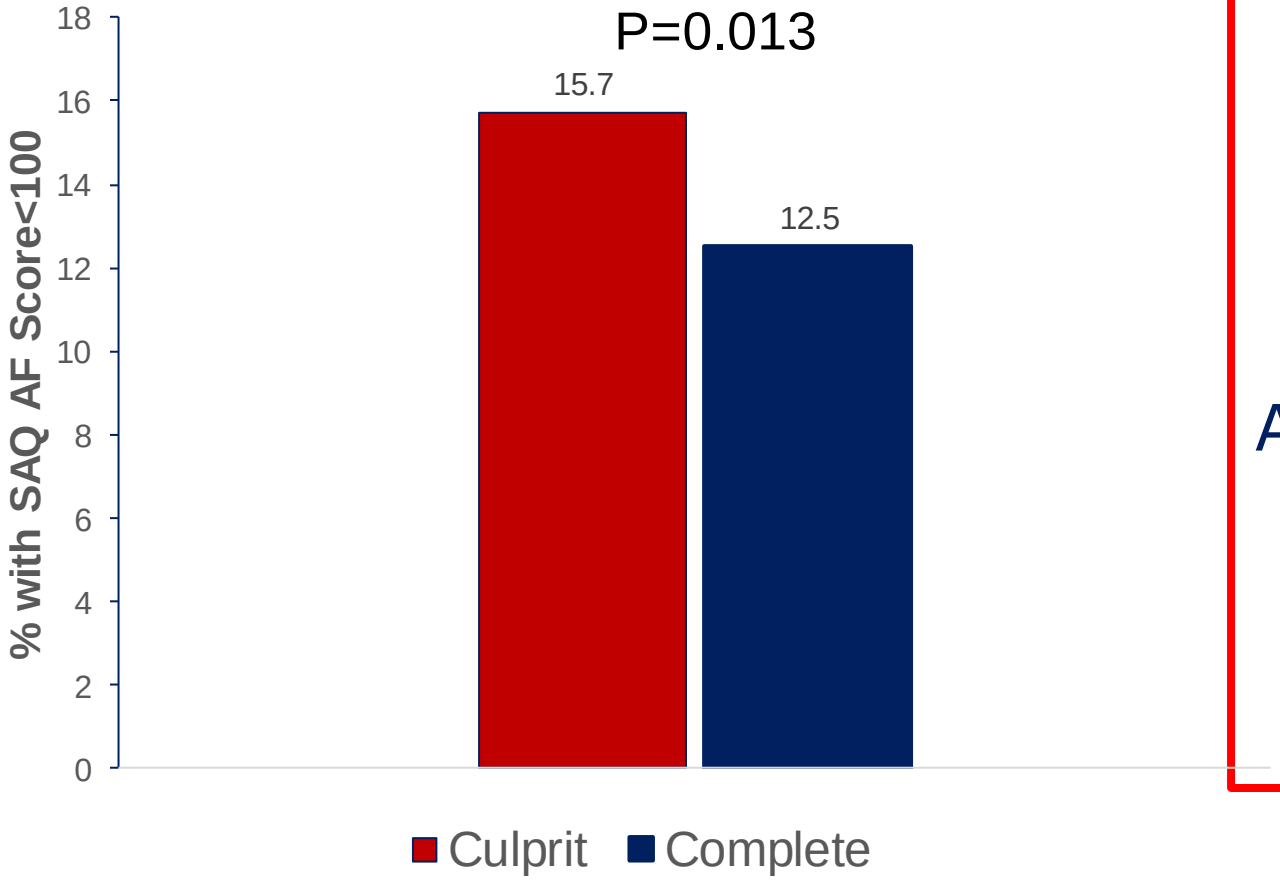
# Angina Status at Study End

## Residual Angina

Absolute Difference 3.21%
P=0.013




## Proportion Angina Free

(SAQ-AF Score=100)

87.5% Complete Revasc
vs
84.3% Culprit-Lesion-only

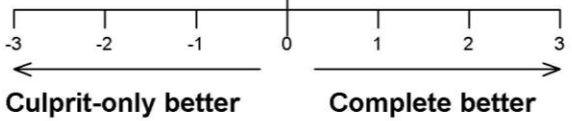
ARD=3.2%  95% CI  0.7-5.7%

Number Needed to Treat=31

P=0.013

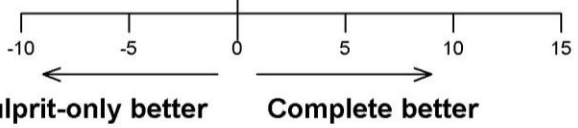
# Pre-Defined Subgroups (SAQ-AF Score)

| Subgroup | Score at 3 years | | | | Change from baseline | | | | Absolute difference (95% CI) | P value for interaction |
|---|---|---|---|---|---|---|---|---|---|---|
| | Complete | | Culprit-only | | Complete | | Culprit-only | | | |
| | *N* | *mean±SD* | *N* | *mean±SD* | *N* | *mean±SD* | *N* | *mean±SD* | | |
| Overall | 1666 | 97.1±9.7 | 1632 | 96.3±10.9 | 1587 | 9.8±18.9 | 1572 | 8.6±19.9 | 0.97 (0.27-1.67) | |
| **Intent to perform non-culprit lesion PCI** | | | | | | | | | | 0.80 |
| During initial hospitalization | 1132 | 97.5±8.7 | 1120 | 96.7±10.4 | 1072 | 10.0±18.7 | 1074 | 9.2±19.9 | 0.91 (0.07-1.76) | |
| After initial hospitalization | 534 | 96.4±11.4 | 512 | 95.4±11.8 | 515 | 9.2±19.5 | 498 | 7.3±19.7 | 1.11 (-0.13-2.35) | |
| **Proximal/mid LAD non-culprit stenosis** | | | | | | | | | | 0.86 |
| Presence | 700 | 97.2±9.9 | 686 | 96.1±11.2 | 670 | 9.0±18.5 | 663 | 8.7±20.0 | 1.03 (-0.05-2.11) | |
| Absence | 894 | 97.3±9.3 | 882 | 96.3±10.8 | 853 | 10.2±18.8 | 846 | 8.5±20.1 | 1.16 (0.21-2.11) | |
| **Non-culprit stenosis severity ≥ 80% visual or ≥ 60% core lab** | | | | | | | | | | 0.05 |
| Presence | 1379 | 97.2±9.6 | 1313 | 96.0±11.1 | 1311 | 9.7±18.6 | 1267 | 8.9±20.5 | 1.29 (0.51-2.06) | |
| Absence | 285 | 96.8±10.4 | 318 | 97.5±9.6 | 274 | 9.9±20.4 | 304 | 7.4±16.9 | -0.50 (-2.14-1.13) | |
| **Residual SYNTAX score** | | | | | | | | | | 0.10 |
| <6(median) | 730 | 97.3±9.1 | 710 | 96.9±9.6 | 693 | 10.1±18.4 | 682 | 8.4±19.0 | 0.44 (-0.62-1.49) | |
| ≥ 6(median) | 865 | 97.2±9.9 | 863 | 95.7±11.9 | 831 | 9.3±18.9 | 831 | 8.7±20.8 | 1.63 (0.67-2.60) | |
| **Angina frequency at baseline** | | | | | | | | | | 0.88 |
| Daily/weekly | 203 | 94.0±15.4 | 193 | 93.5±14.4 | 203 | 43.4±21.3 | 193 | 44.6±21.1 | 0.64 (-1.38-2.67) | |
| Monthly | 598 | 96.7±10.2 | 563 | 95.6±12.1 | 598 | 13.6±12.2 | 563 | 12.7±13.7 | 1.21 (0.02-2.39) | |
| None | 786 | 98.1±7.4 | 816 | 97.3±8.9 | 786 | -1.9±7.4 | 816 | -2.7±8.9 | 0.93 (-0.08-1.94) | |



# Pre-Defined Subgroups (Angina-Free at 3 Years)

| Subgroup | Complete | Culprit-only | Difference in proportions (%) with 95% CI | P value for Interaction |
|---|---|---|---|---|
| | *no. of events/total no. (%)* | | | |
| Overall | 1457/1666 (87.5) | 1376/1632 (84.3) | 3.21 (0.69-5.73) | |
| **Intent to perform non-culprit lesion PCI** | | | | 0.16 |
| During initial hospitalization | 997/1132 (88.1) | 967/1120 (86.3) | 1.73 (-1.02-4.49) | |
| After initial hospitalization | 460/534 (86.1) | 409/512 (79.9) | 6.26 (1.72-10.80) | |
| **Proximal/mid LAD non-culprit stenosis** | | | | 0.97 |
| Presence | 616/700 (88.0) | 577/686 (84.1) | 3.90 (0.13-7.67) | |
| Absence | 789/894 (88.3) | 747/882 (84.7) | 3.96 (0.61-7.30) | |
| **Non-culprit stenosis severity ≥ 80% visual or ≥ 60% core lab** | | | | 0.017 |
| Presence | 1210/1379 (87.7) | 1093/1313 (83.2) | 4.71 (1.95-7.48) | |
| Absence | 245/285 (86.0) | 283/318 (89.0) | -3.16 (-8.69-2.37) | |
| **Residual SYNTAX score** | | | | 0.09 |
| <6(median) | 641/730 (87.8) | 615/710 (86.6) | 1.32 (-2.28-4.92) | |
| ≥ 6(median) | 765/865 (88.4) | 714/863 (82.7) | 6.01 (2.56-9.45) | |
| **Angina frequency at baseline** | | | | 0.96 |
| Daily/weekly | 167/203 (82.3) | 149/193 (77.2) | 5.55 (-2.66-13.76) | |
| Monthly | 508/598 (84.9) | 454/563 (80.6) | 4.32 (-0.16-8.79) | |
| None | 710/786 (90.3) | 718/816 (88.0) | 2.52 (-0.65-5.70) | |



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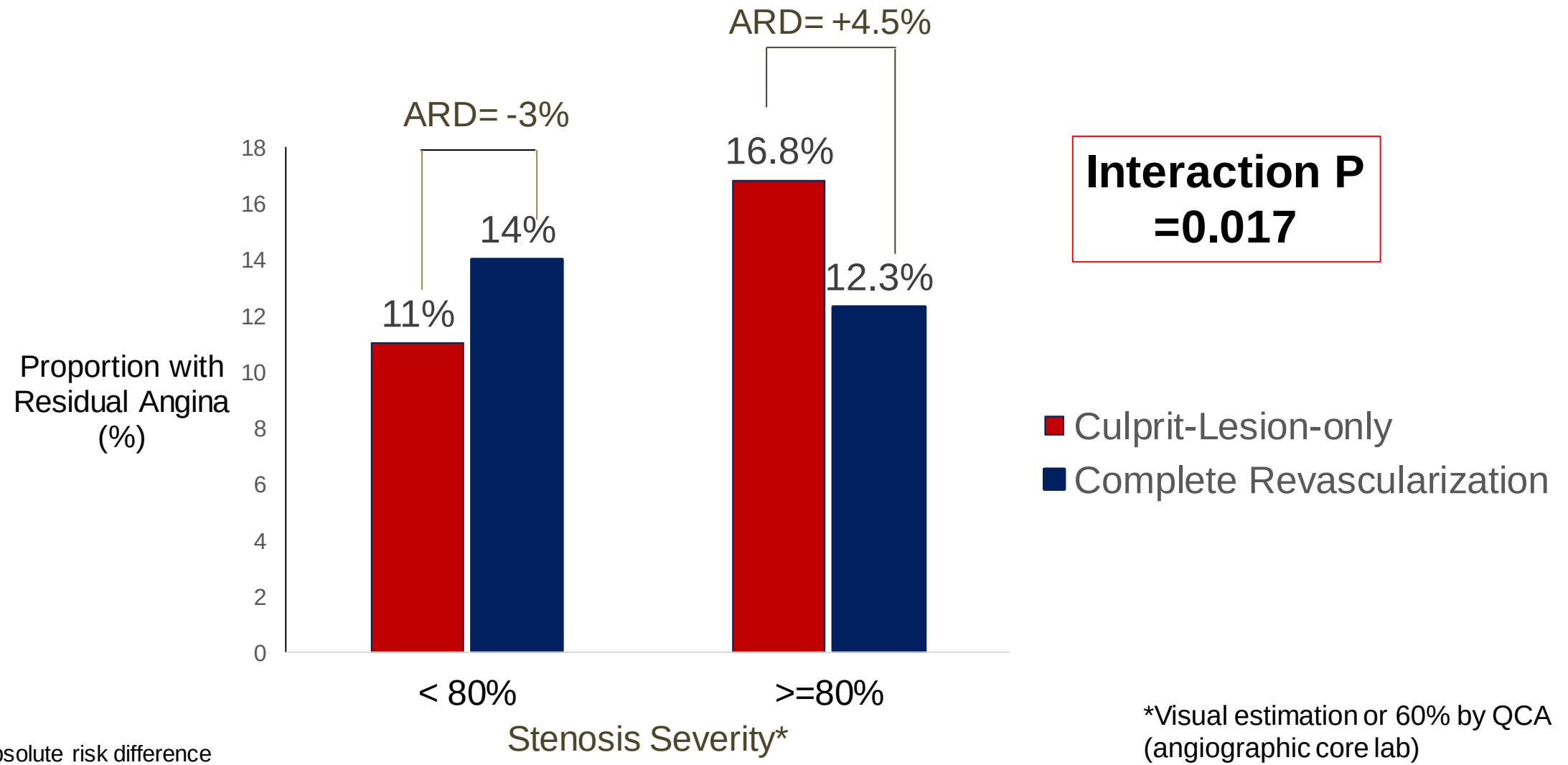
# Residual Angina at Study End (Median 3 Years) According to Non-Culprit Lesion Stenosis Severity




**Interaction P =0.017**

ARD=absolute risk difference

*Visual estimation or 60% by QCA (angiographic core lab)

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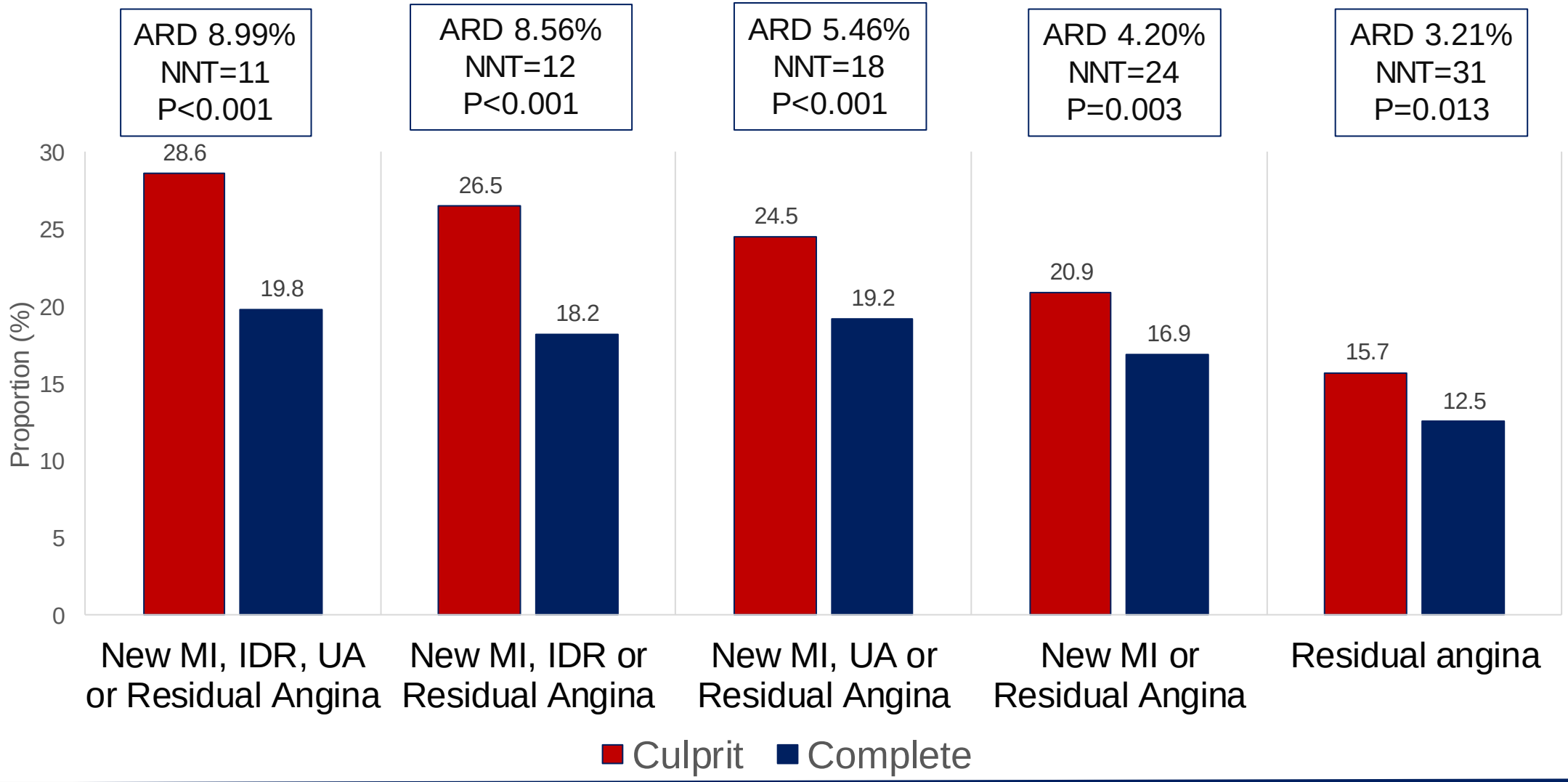
# Total Angina Burden Randomization to Follow-up



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# Limitations

1. 14% of health status measurements were missing at final follow-up. Sensitivity analyses, including multiple imputation were consistent with the primary results

2. SAQ measured at only 3 timepoints. More interim assessments would have allowed for a more granular assessment of angina status in the intervening time periods.

3. Approximately 13% of patients crossed over from culprit-lesion only PCI to complete revascularization after experiencing an angina-related outcome event (MI, ischemia-driven revascularization or unstable angina), which may have narrowed the difference in angina status at study end as measured by the SAQ.

To address #2 and #3, we evaluated total angina burden, which included not only residual angina at study end, but also any angina-associated events over the course of the trial, and this demonstrated a consistent benefit of complete revascularization.

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# Conclusions

**In Patients with STEMI and MVD:**

- Both a complete revascularization and a culprit-lesion-only strategy resulted in substantial improvements in overall angina-related quality of life compared with baseline.
- At a median follow-up of 3 years, a greater proportion of patients were free of angina in the complete revascularization group than in the culprit-lesion-only group, translating into a number needed to treat of 31 patients to prevent one patient from experiencing angina at a median follow-up of 3 years.

- The benefit of CR was observed entirely in patients with NCL stenosis severity $\geq$80%.
- This difference is notable given crossover to NCL PCI in the culprit lesion only group after an angina-related ischemic event
- Total angina burden from randomization to follow-up (including all angina-related events and residual angina at study end) was substantially reduced with complete revascularization

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# Implications

- Complete revascularization improves overall patient-reported health status in addition to its established benefit in reducing major cardiovascular events

- These data also provide important new information for physicians to consider in the context of shared decision making as it relates to coronary artery revascularization in patients with STEMI.

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# Acknowledgments

## COMPLETE QoL Sub-Committee

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