Percutaneous coronary intervention plus optimal medical therapy was not more effective than medical therapy alone in stable CAD

Boden WE, O'Rourke RA, Teo KK, et al. **Optimal medical therapy with or without PCI for stable coronary disease.** N Engl J Med. 2007;356:1503-16.

Clinical impact ratings: GIM/FP/GP ★★★★★★★ Hospitalists ★★★★★★☆ Cardiology ★★★★★★☆

QUESTION

In patients with stable coronary artery disease (CAD), is percutaneous coronary intervention (PCI) plus optimal medical therapy (OMT) more effective than OMT alone for preventing cardiovascular events?

METHODS

Design: Randomized controlled trial (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation [COURAGE] trial).

Allocation: Unclear allocation concealment.*

Blinding: Blinded (outcome adjudication committee).*

Follow-up period: Median 4.6 years (range 2.5 to 7.0 y).

Setting: 50 centers in the United States and Canada.

Patients: 2287 patients (mean age 62 y, 85% men) with stable CAD (stenosis ≥ 70% in ≥ 1 proximal epicardial coronary artery and objective evidence of myocardial ischemia, or ≥ 1 coronary stenosis ≥ 80% and classic angina without provocative testing). Exclusion criteria included persistent class IV angina, a markedly positive stress test, refractory heart failure or cardiogenic shock, ejection fraction < 30%, revascularization in ≤ 6 months, and coronary anatomy not suitable for PCI.

Intervention: PCI (with bare-metal stents in most patients) plus OMT (antiischemic therapy, aggressive therapy to optimize lipid levels, and a lifestyle intervention) (n = 1149) or OMT alone (n = 1138).

Outcomes: Composite endpoint of death or nonfatal myocardial infarction (MI). Secondary outcomes were a composite endpoint of death, MI, or stroke; hospitalization for unstable angina with negative biomarkers; and additional revascularization procedures.

Patient follow-up: 91% (intention-to-treat analysis).

MAIN RESULTS

Groups did not differ for the composite endpoint of death or MI; the composite endpoint of death, MI, or stroke; or hospitalization for unstable angina (Table). Risk for additional revascularization procedures was lower in the PCI plus OMT group (Table).

CONCLUSION

In patients with stable coronary artery disease, initial management with percutaneous coronary intervention plus optimal medical therapy was not more effective than optimal medical therapy alone for preventing cardiovascular events.

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*See Glossary.

Percutaneous coronary intervention (PCI) plus optimal medical therapy (OMT) vs OMT alone in stable coronary artery disease at median 4.6 years†

Outcomes	PCI plus OMT	OMT alone	RRI (95% CI)	NNH
Death or MI	19.0%	18.5%	4.5% (–12 to 24)	Not significant
Death, MI, or stroke	20.0%	19.5%	4.5% (–12 to 23)	Not significant
Hospitalization for ACS	12.4%	11.8%	6.5% (–15 to 34)	Not significant
			RRR (CI)	NNT (CI)
Additional revascularization	21%	33%	35% (25 to 44)	9 (7 to 13)

†MI = myocardial infarction; ACS = acute coronary syndrome; other abbreviations defined in Glossary. RRI, RRR, NNH, NNT, and CI calculated from hazard ratios in article.

COMMENTARY

Most MIs occur from minimally occlusive CAD (1). Thus, it is not surprising that PCI of high-grade CAD is more effective than medical therapy in relieving angina pectoris but not in reducing MI or death in patients with chronic stable CAD (2). However, many clinicians refer patients with stable CAD to PCI without attempting OMT, for fear of litigation should the patient have an MI without PCI. The results of the COURAGE trial by Boden and colleagues suggest that these fears are unfounded. Although approximately 30% of patients randomized to OMT had subsequent PCI, the incidence of death or MI did not differ between groups. Early in the trial, a small decrease in prevalence of angina was shown in patients randomized to PCI; however, by 5 years results for the 2 groups were similar.

Some critics have pointed out that the use of drug-eluting stents in COURAGE was suboptimal; however, no evidence exists that drug-eluting stents decrease the incidence of death or MI compared with bare-metal stents. Others say that the results are less applicable to non–Veterans Administration centers. Yet others object to the decision for randomization being made after a diagnostic coronary angiogram was done—once the angiogram reveals a stenosis suitable for PCI according to guidelines, they claim that the risk associated with PCI is small, and the patient will benefit from immediate relief of angina. However, if one follows current guidelines for evaluation of patients with stable CAD (3) and excludes those with severe left ventricular dysfunction, evidence of left main CAD, or the acute coronary syndrome, most patients should be safely controlled on OMT, as defined in COURAGE. Such patients need to be referred for angiography only if they show evidence of progressive angina or myocardial ischemia. Even in patients with the acute coronary syndrome, the ICTUS trial recently suggested that a strategy of selective, symptom-determined angiography and revascularization may be as good as routine revascularization (4).

Only time will tell whether we can put the interests of our patients above our own economic interests and have the courage to implement OMT, as defined in COURAGE, with its resultant cost savings. If we fail this challenge, we risk having the decision imposed upon us, which would probably not benefit our patients or ourselves.

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