THERAPEUTICS

Percutaneous transluminal coronary angioplasty improved long-term angina status more than medical therapy in coronary artery disease

Henderson RA, Pocock SJ, Clayton TC, et al. **Seven-year outcome in the RITA-2 trial: coronary angioplasty versus medical therapy.** J Am Coll Cardiol. 2003;42:1161-70.

QUESTION

In patients with coronary artery disease, how do the long-term outcomes of percutaneous transluminal coronary angioplasty (PTCA) compare with conservative medical therapy?

METHODS

Design: Randomized controlled trial (Second Randomized Intervention Treatment of Angina [RITA-2] Trial).

Allocation: {Concealed}†.*

Blinding: Blinded (outcome assessors).*

Follow-up period: Median 7 years.

Setting: 20 centers in the United Kingdom and Ireland.

Patients: 1018 patients > 18 years of age (median age 58 y, 82% men) with arteriographically proven coronary artery disease who were considered suitable for either PTCA or medical therapy. Exclusion criteria were previous myocardial revascularization, left main stem disease, recent acute coronary syndrome, hemodynamically significant valve disease, life-threatening noncardiac disease, or need for revascularization.

Intervention: Patients were allocated to PTCA (*n* = 504) or conservative medical therapy consisting of appropriate antiangina medication for symptom relief (*n* = 514).

Outcomes: Composite endpoint of death or definite nonfatal myocardial infarction (MI). Secondary outcomes included all-cause mortality, MI, cardiac death, and angina.

Patient follow-up: 98% (intention-to-treat analysis).

MAIN RESULTS

471 patients (93%) who were allocated to the PTCA group received the intended PTCA at a median 5 weeks after the time of randomization. Patients in the PTCA and conservative medical therapy groups did not differ for rates of the composite endpoint of death or definite nonfatal MI, or for all-cause mortality, definite nonfatal MI, or cardiac death (Table). Angina decreased from baseline (53%) in both groups, but decreased more rapidly in the PTCA group than in the medical therapy group (19.4% vs 35.9% at 3 mo). At 5 years, the difference between groups was much smaller (15% vs 21%), but this attenuation of benefit was at least partially due to patients in the medical group with severe symptoms crossing over to have PTCA.

CONCLUSIONS

In patients with coronary artery disease, percutaneous transluminal coronary angioplasty (PTCA) and conservative medical therapy did not differ for rates of all-cause mortality or definite myocardial infarction. An initial strategy of PTCA improved angina control and exercise tolerance, but this benefit was attenuated over the subsequent 7 years because patients assigned to medical therapy with severe symptoms crossed over to have revascularization.

For correspondence: Dr. R.A. Henderson, Nottingham City Hospital, Nottingham, England, UK. E-mail rhender1@ncht.trent.nhs.uk. ∎

*See Glossary.

†Information provided by author.

Percutaneous transluminal coronary angioplasty (PTCA) vs conservative medical therapy for coronary artery disease at median 7 years‡

Outcomes	PTCA	Medical	RRI (95% CI)	NNH
Death or definite nonfatal MI	14%	12%	18% (−14 to 62)	Not significant
All-cause mortality	8.5%	8.4%	2% (−32 to 52)	Not significant
Definite nonfatal MI	6%	4%	42% (−15 to 138)	Not significant
			RRR (CI)	NNT
Cardiac death	3%	4%	40% (−17 to 69)	Not significant

‡MI = myocardial infarction. Other abbreviations defined in Glossary; RRI, RRR, NNH, NNT, and CI calculated from data in article.

COMMENTARY

Randomized trials comparing PCTA with medical therapy are comparisons of an initial treatment strategy. 35.4% of patients receiving medical therapy in the RITA-2 trial required revascularization within 7 years of enrollment. Although unavoidable, such crossover limits the ability to detect benefit from the strategy to which patients cross over.

Bare-metal stents (BMSs) reduce restenosis and repeated revascularization procedures by about 50% below that seen with balloon angioplasty (BA), which was used in the RITA-2 trial. Drug-eluting stents (DESs) reduce revascularization by about 70% below that seen with BMSs. BMSs probably reduce death or infarction compared with BA (when bail-out stenting is not available) (1). DESs do not reduce death or infarction below that seen with BMSs (although by reducing repeated revascularization, they probably reduce future procedural infarctions). The effects of BMSs and DESs must be considered when applying the RITA-2 results to current practice.

Many asymptomatic patients with normal ventricular function were enrolled. No data exist to show that revascularization improves the outcome of such patients, which is excellent; including such low-risk patients reduced the chances of showing the ability of either therapy to reduce adverse events or angina. Patients with severe angina believed to require revascularization were understandably also excluded from enrollment. However, revascularization is most beneficial in the "sickest" patients; excluding such patients also reduced the chance that PTCA could reduce death or infarction in the trial.

These issues should not detract from the credit due to the RITA-2 investigators who did a large and complex randomized trial at a time when it was critically important to do so. Finally, the most appropriate application of percutaneous revascularization is being scrutinized.

Peter B. Berger, MD
Duke Clinical Research Institute
Durham, North Carolina, USA

Reference

1. **Al Suwaidi J, Holmes DR Jr., Salam AM, Lennon R, Berger PB**. Impact of coronary artery stents on mortality and nonfatal myocardial infarction: meta-analysis of randomized trials comparing a strategy of routine stenting with that of balloon angioplasty. Am Heart J. 2004;147:815-22.