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Outcomes after thrombus aspiration for ST elevation myocardial infarction: 1-year follow-up of the prospective randomised TOTAL trial

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Summary

Background

Two large trials have reported contradictory results at 1 year after thrombus aspiration in ST elevation myocardial infarction (STEMI). In a 1-year follow-up of the largest randomised trial of thrombus aspiration, we aimed to clarify the longer-term benefits, to help guide clinical practice.

Methods

The trial of routine aspiration ThrOmbecTomy with PCI versus PCI ALone in Patients with STEMI (TOTAL) was a prospective, randomised, investigator-initiated trial of routine manual thrombectomy versus percutaneous coronary intervention (PCI) alone in 10â€ˆ732 patients with STEMI. Eligible adult patients (aged â‰¥18 years) from 87 hospitals in 20 countries were enrolled and randomly assigned (1:1) within 12 h of symptom onset to receive routine manual thrombectomy with PCI or PCI alone. Permuted block randomisation (with variable block size) was done by a 24 h computerised central system, and was stratified by centre. Participants and investigators were not masked to treatment assignment. The trial did not show a difference at 180 days in the primary outcome of cardiovascular death, myocardial infarction, cardiogenic shock, or heart failure. However, the results showed improvements in the surrogate outcomes of ST segment resolution and distal embolisation, but whether or not this finding would translate into a longer term benefit remained unclear. In this longer-term follow-up of the TOTAL study, we report the results on the primary outcome (cardiovascular death, myocardial infarction, cardiogenic shock, or heart failure) and secondary outcomes at 1 year. Analyses of the primary outcome were by modified intention to treat and only included patients who underwent index PCI. This trial is registered with ClinicalTrials.gov, number NCT01149044.

Findings

Between Aug 5, 2010, and July 25, 2014, 10â€ˆ732 eligible patients were enrolled and randomly assigned to thrombectomy followed by PCI (n=5372) or to PCI alone (n=5360). After exclusions of patients who did not undergo PCI in each group (337 in the PCI and thrombectomy group and 331 in the PCI alone group), the final study population comprised 10â€ˆ064 patients (5035 thrombectomy and 5029 PCI alone). The primary outcome at 1 year occurred in 395 (8%) of 5035 patients in the thrombectomy group compared with 394 (8%) of 5029 in the PCI alone group (hazard ratio [HR] 1Â·00 [95% CI 0Â·87â€“1Â·15], p=0Â·99). Cardiovascular death within 1 year occurred in 179 (4%) of the thrombectomy group and in 192 (4%) of 5029 in the PCI alone group (HR 0Â·93 [95% CI 0Â·76â€“1Â·14], p=0Â·48). The key safety outcome, stroke within 1 year, occurred in 60 patients (1Â·2%) in the thrombectomy group compared with 36 (0Â·7%) in the PCI alone group (HR 1Â·66 [95% CI 1Â·10â€“2Â·51], p=0Â·015).

Interpretation

Routine thrombus aspiration during PCI for STEMI did not reduce longer-term clinical outcomes and might be associated with an increase in stroke. As a result, thrombus aspiration can no longer be recommended as a routine strategy in STEMI.

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