International Subarachnoid Aneurysm Trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomised trial.

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BACKGROUND: Endovascular detachable coil treatment is being increasingly used as an alternative to craniotomy and clipping for some ruptured intracranial aneurysms, although the relative benefits of these two approaches have yet to be established. We undertook a randomised, multicentre trial to compare the safety and efficacy of endovascular coiling with standard neurosurgical clipping for such aneurysms judged to be suitable for both treatments. METHODS: We enrolled 2143 patients with ruptured intracranial aneurysms and randomly assigned them to neurosurgical clipping (n=1070) or endovascular treatment by detachable platinum coils (n=1073). Clinical outcomes were assessed at 2 months and at 1 year with interim ascertainment of rebleeds and death. The primary outcome was the proportion of patients with a modified Rankin scale score of 3-6 (dependency or death) at 1 year. Trial recruitment was stopped by the steering committee after a planned interim analysis. Analysis was per protocol. FINDINGS: 190 of 801 (23.7%) patients allocated endovascular treatment were dependent or dead at 1 year compared with 243 of 793 (30.6%) allocated neurosurgical treatment (p=0.0019). The relative and absolute risk reductions in dependency or death after allocation to an endovascular versus neurosurgical treatment were 22.6% (95% CI 8.9-34.2) and 6.9% (2.5-11.3), respectively. The risk of rebleeding from the ruptured aneurysm after 1 year was two per 1276 and zero per 1081 patient-years for patients allocated endovascular and neurosurgical treatment, respectively. INTERPRETATION: In patients with a ruptured intracranial aneurysm, for which endovascular coiling and neurosurgical clipping are therapeutic options, the outcome in terms of survival free of disability at 1 year is significantly better with endovascular coiling. The data available to date suggest that the long-term risks of further bleeding from the treated aneurysm

are low with either therapy, although somewhat more frequent with endovascular coiling.