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A Systematic Review of Randomized Controlled Trials of Different Types of Patch Materials During Carotid Endarterectomy

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Patch angioplasty performed during carotid endarterectomy may reduce the risk of re-stenosis and consequently reduce the long-term risk of recurrent stroke. However, there is uncertainty as to the optimal patch material.

Objectives

We sought to determine whether any particular patch material was associated with a lower risk of perioperative and/or long-term complications than any other.

Search Strategy

Two reviewers independently searched MEDLINE (1996 to April 2003), EMBASE (1980 to 2002), and Index to Scientific and Technical Proceedings (1980 to 1994). We also searched the Stroke Group trials register (April 2003), hand-searched 13 relevant journals up to 2002, and searched the reference lists of articles identified.

Selection Criteria

We sought to identify all randomized and quasi randomized trials in which one type of carotid patch was compared with another.

Data Collection and Analysis

Thirty-day and long-term risks of stroke, death, restenosis (>50%), and wound complications were independently extracted by 2 reviewers (R.B., K.R.). Proportional risk reductions were calculated using the Peto method. Heterogeneity between trial results was tested using the standard χ^2 test.

Main Results

Eight trials (1480 operations) were included in the review. Four compared vein to polytetrafluoroethylene (PTFE) closure, 3 compared vein to Dacron, and 1 compared PTFE with

Dacron. There were several flaws in the trials. Three failed to use adequate randomization techniques. Three failed to perform blind follow-up and 1 study used heparin reversal at the end of surgery in 30% of their synthetic closures but none of their vein closure patients.

Figure 1 summarizes the results. The absolute risks of perioperative stroke (1.7%, 19/1122), death (1.1%, 12/1122) and combined stroke and death (2.4%, 27/1122) were all very low, and consequently it was not possible to determine reliably whether there was any difference between the vein and Dacron patches for perioperative stroke, death, and arterial complications. During follow-up of >1 year, no difference was shown between the 2 types of patch for the risk of stroke, death, or arterial restenosis. However, there were significantly fewer pseudoaneurysms associated with synthetic patches than vein (odds ratio, 0.07; 95% confidence interval, 0.02 to 0.49). However, the clinical significance of this finding is uncertain because of small numbers and poor definitions of pseudoaneurysm. One study compared Hemoshield Dacron and PTFE patches. PTFE was associated with a lower risk of combined stroke and transient ischemic attack ($P=0.03$) and restenosis at 30 days ($P=0.01$), and perioperative stroke ($P=0.06$).

Implications for Practice

This review found no differences in the risks of perioperative or long-term stroke, death, or local complications experienced by patients receiving synthetic or venous patches. There is still little evidence to guide surgeons on which patch material to use. Synthetic patches do spare the morbidity associated with vein harvesting and leave vein for future bypass grafting. However, PTFE may increase the operation

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Outcome	Synthetic Events / Patients	Vein closure Events / Patients	Odds Ratio	95% CI	Significance
Ipsilateral stroke	8 / 406 (2.0)	3 / 391 (0.8)	2.60	0.7-9.9	P=0.27
All death	3 / 562 (0.5)	8 / 560 (1.4)	0.37	0.1-1.4	P=0.26
Fatal stroke	0 / 295 (0.0)	4 / 294 (1.4)	0.02	0.0-12.7	P=0.16
Any stroke	11 / 588 (1.9)	8 / 585 (1.4)	1.38	0.5-3.4	P=0.65
Stroke or death	15 / 562 (2.7)	12 / 560 (2.1)	1.25	0.6-2.7	P=0.70
Return to theatre	21 / 585 (3.6)	12 / 583 (2.1)	1.77	0.9-3.6	P=0.17
Arterial rupture	2 / 359 (0.6)	3 / 348 (0.9)	0.64	0.1-3.9	P=0.97
Wound infection	4 / 242 (1.7)	10 / 236 (4.2)	0.38	0.1-1.2	P=0.16
Cranial nerve injury	10 / 319 (3.1)	9 / 311 (2.9)	1.09	0.4-2.7	P=0.98
Long term Follow up					
Ipsilateral stroke	17 / 389 (4.4)	12 / 387 (3.1)	1.43	0.7-3.0	P=0.75
All death	41 / 457 (9.0)	46 / 463 (9.9)	0.89	0.6-1.4	P=0.95
Pseudoaneurysm	1 / 389 (0.3)	14 / 387 (3.6)	0.07	0.0-0.5	P=0.001
Any stroke	23 / 457 (5.0)	18 / 463 (3.9)	1.31	0.7-2.5	P=0.71
Infection	1 / 118 (0.9)	0 / 118 (0.1)	11.09	0.0-7,223.8	P=0.50
Stroke or death	57 / 457 (12.5)	56 / 463 (12.1)	1.04	0.7-1.5	P=0.99
Restenosis	33 / 451 (7.3)	33 / 450 (7.3)	1.00	0.6-1.6	P=0.93

Summary estimates of treatment effect from all meta-analyzed outcomes from 7 trials (1280 operations) comparing vein with synthetic patch angioplasty that were included in the review. Data were not available for all outcomes from all trials, and there was significant loss to follow-up.

time because of increased bleeding. There is limited evidence that PTFE has a lower 30-day stroke, transient ischemic attack, and restenosis rate than Hemoshield Dacron.

Implications for Research

The risk of major arterial complications such as rupture or infection was very low in both treatment groups in all trials. Any trials designed to detect a reduction in risk would,

therefore, need to be very large, and differences in risks between patch types are likely to be small.

Note: The full text of this review is available in the Cochrane Library (for subscribers <http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME>). The full article should be cited as: Bond R, Rerkasem K, Naylor R, Rothwell PM. Patches of different types for carotid patch angioplasty. *Cochrane Database Syst Rev.* 2004, Issue 2.