

BEACH Trial: 1-Year Outcomes of Carotid Wallstent and FilterWire EX/EZ Distal Protection System Placement for Treatment of High-Surgical-Risk Patients

NOTES

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Background

Carotid artery stent (CAS) placement with distal protection has been investigated as an alternative to carotid endarterectomy (CEA) for stroke prevention. The BEACH trial is a multicenter, prospective registry to evaluate outcomes of patients with carotid artery stenosis at high risk for CEA using the Carotid Wallstent and FilterWire EX/EZ distal protection system.

Methods

The cohort consisted of a total of 747 patients at high surgical risk for CEA owing to prespecified anatomic criteria or medical comorbidities who had a stenosis of > 50% in symptomatic (Sx) and > 80% in asymptomatic (ASx) patients. The cohort was divided into three groups. The “roll-in” (R) group (n = 189) included up to 5 patients per site for initiation and familiarization; the “pivotal” (P) group (n = 480) is the primary group; and the “bilateral” (B) group (n = 78) included those with treatment of both carotids. The study patients were compared to an objective performance criteria (OPC) derived from historic controls for patients undergoing CEA (12.6% ± 4%). The results of the P group are reported in Table 1.

Conclusions

The patients undergoing CAS with the Carotid Wallstent and FilterWire EX/EZ who are at high risk for surgical intervention compare favorably to an objective performance criteria for patients at high risk for CEA. CAS was performed with a high degree of procedural and technical success. CAS in this study has had favorable hemodynamic and clinical durability through 1 year.

Table 1. Study Results with Pivotal Group

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Primary End Point Measures	Pivotal (n = 480)*
Non Q wave MI (through 24 h)	0.9% (4/438)
Death, stroke, Q wave MI (through 30 d)	5.5% (24/438)
Death	1.6% (7/438)
Stroke	4.6% (20/438)
Q wave MI	0.2% (1/438)
Neurologic death, ipsilateral stroke (31-360 d)	3.2% (14/438)
Neurologic death	1.6% (7/438)
Ipsilateral stroke	2.5% (11/438)
Total 1 yr morbidity and mortality	9.1% (40/438)

MI = myocardial infarction.

*438 evaluable.