Guardwire

Guardwire, is designed to allow cardiologists and other interventional specialists to capture embolic debris that might otherwise block downstream vessels and branches during interventional procedures and damage the heart.

The GuardWire Plus system consists of a balloon-tipped guidewire, which is inflated briefly to occlude blood flow and capture any material dislodged from the wall of the vessel during placement of a stent upstream. Captured material is then withdrawn by using the PercuSurge Export aspiration catheter before the balloon of the GuardWire Plus is deflated and blood flow restored.

The device has been used in over 5,000 procedures since its release in Europe during 1999 and was the first distal protection product to be commercialized there. The product's first targeted indication is for the treatment of degenerated saphenous vein grafts that show signs of disease following heart bypass surgery.

The GuardWire Plus is an investigational device in the United States. This fall, PercuSurge submitted U.S. clinical data from its SAFER study (Saphenous Vein Graft Angioplasty Free of Emboli Randomized Trial) for consideration by the U.S. Food and Drug Administration (FDA). Medtronic expects to receive FDA approval for the GuardWire Plus sometime during the first half of calendar year 2001.

Case series

2016

Transfemoral stenting of common carotid artery stenosis origin is technically difficult because of poor stability of the guiding catheter.

Four patients (5 stenotic lesions) with stenosis of the common carotid artery (CCA) origin underwent transfemoral stenting with a balloon protection device (PercuSurge GuardWire; Medtronic, Santa Rosa, California). These 5 stenotic lesions of the CCA origin included 1 on the right side and 4 on the left side. Two of the stenoses were symptomatic, and 3 were asymptomatic. A balloon-expandable stent (Express LD stent; Boston Scientific, Natick, Massachusetts) was used in all patients.

All stenoses were successfully dilated. With the balloon protection device as an anchor in all patients, the guiding catheter was highly stable during the procedure. There were no intraprocedural or periprocedural ischemic complications in any patients. None of the patients developed a stroke during a mean follow-up period of 8.4 months.

The anchoring technique using a balloon protection device is useful for transfemoral stenting of stenoses at the CCA origin [1)].

For a period of 28 months, 31 patients with carotid artery stenosis , most of whom were considered at high risk for carotid endarterectomy (CEA) (87%), underwent treatment with CAS in conjunction with either the PercuSurge GuardWire (n = 19; Medtronic, Minneapolis, Minn), the Cordis Angioguard filter (n = 7; Cordis, Warren, NJ), or the ArteriA Parodi Anti-embolization catheter (n = 4; ArteriA, San Francisco, Calif) with US Food and Drug Administration-approved investigational device exemptions.

Factors that made CEA high risk included restenosis after CEA (n = 6), hostile neck (n = 6), high or low lesions (n = 4), and severe comorbid medical conditions (n = 11). Preoperative neurologic symptoms were present in 58%, and the mean stenosis was 85% +/- 12%. Data were prospectively recorded and analyzed on an intent-to-treat basis. Neurologic evaluation was performed before and after carotid artery stenting CAS by a protocol neurologist.

CAS was performed with local anesthesia with the Wallstent (n = 23; Boston Scientific Corp, Natick, Mass) or the PRECISE carotid stent (n = 7; Cordis) in conjunction with one of the protection devices in an operating room with a mobile C-arm. Each patient received dual antiplatelet therapy before surgery. The overall technical success rate was 97% (30/31). In one patient, the lesion could not be crossed with a guidewire because of a severely stenosed and tortuous lesion. This patient was not a candidate for CEA and was treated conservatively. In the remaining 30 cases, CAS had a good angiographic result (residual stenosis, <10%). All patients tolerated the protection device well, and no intraprocedural neurologic complications occurred. Macroscopic embolic particles were recovered from each case. One patient (3%) with a severely tortuous vessel had a major stroke immediately after CAS, and no deaths occurred. The combined 30 day stroke/death rate was 3%. During a mean follow-up period of 17 months, one subacute occlusion of the stent occurred but did not result in a stroke. Three other patients had duplex scan-proven in-stent restenosis, and two underwent treatment with repeat percutaneous transluminal angioplasty with a good result. No patient had a stroke during the follow-up period.

CAS with cerebral protection devices can be performed safely with a high technical success rate. Although many patients who underwent treatment with CAS were at high risk, the neurologic complication rate was low and CAS appears to be an acceptable treatment option for select patients at high risk for CEA. Tight lesions and tortuous anatomy may make the use of distal protection devices difficult. Further study is warranted [2].

1)
Tsuji K, Fukawa N, Nakagawa N, Watanabe A, Murakami S, Nagatsuka K, Nakano N, Kataoka K, Kato A. Transfemoral Stenting of Stenoses at the Common Carotid Artery Origin Using an Anchoring Technique With a Balloon Protection Device. Neurosurgery. 2016 Oct;79(4):598-603. doi: 10.1227/NEU.0000000000001312. PubMed PMID: 27309345.

2)
Ohki T, Veith FJ, Grenell S, Lipsitz EC, Gargiulo N, McKay J, Valladares J, Suggs WD, Kazmi M. Initial experience with cerebral protection devices to prevent embolization during carotid artery stenting. J Vasc Surg. 2002 Dec;36(6):1175-85. PubMed PMID: 12469049.