



Australian Government
Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

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AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summary

Filterwire embolic protection system

May 2008



**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**

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ISBN

Publications Approval Number:

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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from departments in all states and territories, the Australia and New Zealand governments; and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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PRIORITISING SUMMARY

REGISTER ID

S000077

NAME OF TECHNOLOGY

FILTERWIRE EMBOLIC PROTECTION SYSTEM

PURPOSE AND TARGET GROUP

TO CONTAIN AND REMOVE EMBOLIC MATERIAL WHILE PERFORMING ANGIOPLASTY AND STENTING PROCEDURES

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|---|-------------|-----|
| <input type="checkbox"/> Yes | ARTG number | N/A |
| <input checked="" type="checkbox"/> No | | |
| <input type="checkbox"/> Not applicable | | |

INTERNATIONAL UTILISATION

| COUNTRY | LEVEL OF USE | | |
|---------------|------------------------------|-------------|-----------------|
| | Trials Underway or Completed | Limited Use | Widely Diffused |
| Canada | ✓ | | |
| Europe | ✓ | | |
| Israel | ✓ | | |
| United States | ✓ | | |

IMPACT SUMMARY

Boston Scientific (Natick, United States) provides the FilterWire EX and FilterWire EZ distal protection system with the aim of improving clinical outcomes following angioplasty and stenting in coronary saphenous vein grafts and carotid arteries. The device is approved for use in the United States and Europe, however it is not yet available in Australia.

BACKGROUND

Percutaneous coronary intervention (PCI), also known as angioplasty, in combination with coronary stent placement, is a successful technique for the restoration of epicardial blood flow in patients who have suffered acute myocardial infarction (AMI) (Kastrati et al. 2000; Stone et al. 2002). PCI with stenting is also the preferred method for patients with saphenous vein graft (SVG) disease (Stephan et al. 1996; Morrison et al. 2002). Similarly, in cases of carotid artery disease, carotid artery stenting has become a widely used minimally invasive alternative to prevent stroke resulting from extracranial bifurcation carotid artery stenosis (Roubin et al. 2006).

In addition to ischemic microvascular damage and reperfusion-induced regional inflammatory responses, distal embolisation of plaque and thrombus material presents a major source of insufficient reperfusion in patients who undergo primary PCI with stenting for AMI (Gick et al. 2005). The situation repeats itself in the case of diseased SVGs as embolisation of plaque and thrombus material occurs commonly during PCI of diseased SVGs, which can result in periprocedural AMI (Hong et al. 2001; Holmes et al. 1995). Similarly, there exists concern that cerebral embolisation of carotid plaque material during carotid artery stenting may create adverse events for the carotid artery disease patient (Iyer et al. 2007).

Given the potential for embolisation in the above settings (and others) distal protection devices able to prevent embolisation during primary PCI have been hypothesised to lead to improved clinical outcomes in patients.

The FilterWire EX system is a distal protection system designed for use as a guidewire and embolic protection (including the containment and removal of embolic material) during angioplasty and stenting procedures in coronary saphenous vein grafts and carotid arteries. The system consists of a distal polyurethane filter with 110 µm diameter pores mounted on a 0.014 inch steerable guide wire via a spinner tube, allowing unrestricted wire rotation and steering. The filter is attached to an elliptical, eccentric self-expanding radiopaque nitinol loop, deployed following crossing of the lesion by retracting a restraining 3.9F delivery sheath. The elliptical loop allows the system to maximise the cross sectional area exposed to the bloodstream and allows for apposition of vessels between 3.5 and 5.5 mm in diameter. PCI can then be performed over the guide wire with maintained antegrade perfusion carrying the liberated atherosclerotic and thrombotic debris distally into the filter. Using a retrieval sheath the filter is closed with a retrieval sheath and removed along with the retained debris.

The FilterWire EZ is the next generation FilterWire system and differs from the FilterWire EX in terms of the collection filter, which moves independently of the guide wire shaft. Additionally, the EZ model is a lower profile (3F) and is more flexible.

CLINICAL NEED AND BURDEN OF DISEASE

Evidence of distal embolisation in AMI patients following primary PCI has been reported in 9% to 15% of patients although it is possible that the true incidence may be higher, in

line with autopsy studies and experience using distal protection devices (Giri et al. 2000; Henriques et al. 2002; Saber et al. 1993).

In patients who have undergone SVG angioplasty without distal protection, a poor late prognosis characterised by high rates of death, MI and target vessel revascularisation (TVR) has been reported (Hong et al. 2001; Keeley et al. 2001; Nishida et al. 2000). The three year rates of mortality and major adverse cardiac events (MACE) in patients not treated with distal protection have been reported at 9% and 43%, respectively (Hong et al. 2001 and Keeley et al. 2001).

In the setting of carotid artery stenting, it has been reported that protected CAS has a combined stroke and death rate of 2.0%, in comparison to unprotected CAS which has a combined stroke and death rate of 3.2% (Eckert and Zeumer 2003). Additionally, balloon occlusion based protection systems (proximal or distal) have been reported to be associated with cerebral intolerance in 5% to 10% of cases (Powell et al. 2006; Whitlow et al. 2002).

DIFFUSION

The FilterWire EZ distal protection device has received approval from the United States Food and Drug Administration for SVG procedures in 2004 and for carotid artery procedures in 2006.

The device has been in use in Europe since September 2003.

COMPARATORS

Various devices for embolic protection are currently available on the market. These types of protection devices usually fit into the categories of either proximal or distal and filter based or occlusion/aspiration based systems.

Filter based protection devices include:

Spider (ev3, Plymouth, United States)

Emboshield (Abbott Vascular, Redwood City, United States)

Angiogard (Cordis, United States)

Trap (ev3)

Accunet (Abbott Vascular)

Occlusion based protection devices include:

NPS (W.L. Gore & Associates, Flagstaff, United States)

Mo.Ma (Invatec, Roncadelle, Italy)

Percusurge GuardWire (Medtronic, Santa Rosa, United States)

SAFETY AND EFFECTIVENESS ISSUES

Four studies, representing the areas for which the FilterWire system has been approved internationally have been included in this summary. The studies include three randomised controlled trials and one comparative retrospective review. Due to the FilterWire's measure of effectiveness being its impact on clinical outcome, which primarily relates to the occurrence of adverse events, safety and effectiveness issues will be reported together.

The FIRE trial included 651 patients > 21 years old (mean age 69.5 ± 10 years) at 66 institutions in the United States and Canada, scheduled to undergo PCI in conjunction with stenting of one or more de novo lesions in diseased SVG's (Halkin et al. 2006). Patients were randomised to undergo treatment with distal embolic protection using either the FilterWire EX (n = 332) or the GuardWire¹ device (n = 319). With the exception of the number of stents used per patient (1.4 ± 0.9 vs. 1.6 ± 0.9 , $p = 0.04$) and post-procedural in-lesion diameter stenosis ($12.2\% \pm 9.5\%$ vs. $13.7\% \pm 10.7\%$, $p = 0.04$) both patient populations were comparable. The sample size was chosen to demonstrate the FilterWire EX device's non-inferiority (i.e. equivalent or superior) to the GuardWire.

Guetta et al. 2007 investigated the effect of the FilterWire EZ device on tissue perfusion during urgent ST-segment elevation myocardial infarction (STEMI) stent-based PCI. The study was an Israeli multicenter, prospective, randomised trial, named 'Use of Protective FilterWire to improve Flow in Acute Myocardial Infarction' (UpFlow MI). The study included patients with STEMI scheduled to undergo revascularisation < 24 hours after the onset of chest pain. Patients were randomised to one of two groups, PCI with distal protection using the FilterWire EZ group (n = 51) or a control group using regular guidewires (n = 49). With the exception of the time from chest pain onset to emergency room arrival, and the number of patients recording TIMI grade 0/1 flow, both patient groups were comparable. Epicardial and myocardial reperfusion were compared between groups. Additionally, in the FilterWire EZ group, following completion of PCI and retrieval of the FilterWire EZ device, the filter was fixed in formaldehyde and subjected to microscopic inspection.

Glick et al. (2005) conducted the 'Protection Devices in PCI treatment of Myocardial Infarction for Salvage of Endangered Myocardium' (PROMISE) randomised, controlled study to investigate the effects of the FilterWire EX on myocardial perfusion. Two hundred MI patients with and without ST-segment elevation undergoing PCI within 48 hours of pain onset were included. All patients had at least one episode of typical anginal pain lasting over 30 minutes and a coronary artery lesion suitable for stent placement and use of the FilterWire EX device. In addition, patients had at least one of the following:

1. ST segment elevation of at least 1 mm in ≥ 2 contiguous leads,
2. Elevation in creatine kinase to at least three times the upper limit of normal with a concomitant rise in MB isoenzyme, or
3. Coronary artery occlusion with angiographic appearance of fresh thrombus.

¹ The GuardWire is a transient distal balloon occlusion device used during angioplasty or stent placement and permits the recovery of any liberated plaque by aspiration before restoration of antegrade flow.

Patients were randomised to receive distal protection using the FilterWire EX device (n = 100) or to a control group (n = 100). Both patient groups were comparable. Following PCI in the FilterWire group, the filters were retrieved and inspected visually. A further 10 randomly selected filters were fixed in formaldehyde, embedded in paraffin and processed for microscopic examination.

Iyer and colleagues (2007) conducted an analysis reviewing their experience using embolic protection devices during CAS. The study aimed to verify the importance of embolic protection devices and compare adverse neurological event rates between different devices and types of protection devices. Existing institutional databases of four centres were reviewed. The patients included had lesions appropriate for treatment (symptomatic lesions $\geq 50\%$, asymptomatic lesions $\geq 80\%$) and underwent CAS with one of nine different protection devices (3030 procedures) or unprotected (130 procedures). Of the protected procedures, the FilterWire was the most commonly used device (n = 1640). Therefore procedural and 30 day events were reported as absolute risks and risks relative to the FilterWire.

Safety and Effectiveness

In the FIRE trial, clinical follow-up after discharge was available for 624 patients (317 and 307 patients in the FilterWire EX and GuardWire groups, respectively). There was no in-hospital mortality reported in either group. The pooled mortality rates were 0.9% and 3.7% for the period between discharge and 30 days, and cumulative to six months, respectively. There were no statistically significant differences between groups in terms of in-hospital, post-discharge and cumulative six month rates of death, MI, TVR and composite MACEs.

A regression analysis was performed to identify independent predictors of late clinical events. The results showed mortality was independently predicted by proximal location of the target lesion, pre-PCI TIMI 0/1 flow in the treated graft and reduced baseline ventricular function. In-hospital MI was predicted by lesion length and SVG degeneration score while no predictive factors were identified for out of hospital MI. The type of device used (including the number and length of stents deployed) and distal protection device used was not an independent correlate of any six month MACE.

The study demonstrated the six month non-inferiority of the FilterWire EX compared with the GuardWire device, supporting the 30 day results presented in a previous publication (Stone et al. 2003). According to the authors, despite the reduction in complications using distal protection devices, the absolute out of hospital death, MI and TVR rates were significant.

In the UpFlow MI study, the FilterWire EZ was successfully placed as the first and only wire used in 23 patients (56%). In six patients (12%) a second 'buddy wire' was required and in eight (16%) pre-dilatation using an undersized balloon was necessary. In eight patients (16%) the FilterWire EZ could not be advanced beyond the lesion primarily as a result of vessel tortuosities and/or calcification.

Microscopic inspection of the filters demonstrated the presence of captured debris in 52% of them. However, no differences in post procedural TIMI flow grades or myocardial blush scores between groups were recorded. Although captured debris was found in all examined filters, angiographically visible distal embolisation occurred in 2% of FilterWire EZ patients compared to 15% on the control group ($p = 0.03$).

In terms of percent ST-segment resolution at 60 and 90 minutes, there were no statistically significant differences displayed between both groups ($p = \text{NS}$). Similarly, the mean percent ST-segment resolution from last contrast injection was not significantly different between groups. At 240 minutes from the last contrast injection, the mean percent ST resolution in the control group was 86.1% compared to 83.6% in the FilterWire group.

During 30 day follow up, four MACE were reported. Two deaths occurred in the FilterWire group, compared to no deaths in the control ($p = 0.17$). One of these patients developed a hemorrhagic stroke on day 1 and died within a week and while the other died of septic shock on day 4. Recurrent MI was observed in one patient (2.3%) in the control group compared to none in the FilterWire group ($p = 0.33$). Finally, angina pectoris after MI was observed in one (2.4%) patient in the FilterWire group compared to none in the control group ($p = 0.30$).

The study demonstrated that use of the FilterWire EZ device did not result in significant clinical improvements despite lower angiographically visible distal embolisation in the FilterWire EZ group.

Of the 200 patients enrolled in the PROMISE study, 61% had an occluded infarct-related artery (TIMI flow grade 0/1). The FilterWire was successfully deployed in 95 patients, however, pre-dilatation was required in 42 of these. In the five patients in whom the device could not be advanced, vessel tortuosities and/or calcification were given as the reason. The procedural time recorded was significantly longer in the FilterWire group by 11.7 ± 3.9 minutes ($p = 0.003$). The PCI procedure was completed with a mean residual stenosis of less than 10% for both patient groups ($8.7 \pm 5.9\%$ in the FilterWire group vs. $9.0 \pm 6.4\%$ in the control group, $p = 0.47$).

Flow velocity measurements to assess coronary perfusion demonstrated that maximal time-averaged peak velocity (maximal APV) in the recanalised infarct-related artery was similar between the two groups (34 ± 17 cm/s in the FilterWire group vs. 36 ± 20 cm/s, $p = 0.46$). Similarly, the point estimate for coronary flow reserve did not demonstrate any statistically significant difference between the two groups (1.85 ± 0.64 in the FilterWire group vs. 1.94 ± 0.70 in the usual care group, $p = 0.37$). The FilterWire reduced the incidence of angiographically visible distal embolisation by trend compared to usual care, however this was not statistically significant (3 vs. 8, $p = 0.12$). The FilterWire and the usual care group also did not statistically differ in regards to TIMI flow grade, or myocardial blush grade ($p = \text{NS}$). Visual inspection of the filters showed captured debris

in one third of filters and found plaque material in six out of 20 histologically examined filters.

There was no significant difference in delayed enhancement as a measure of infarct size between the FilterWire (n = 78) and the control group (n = 82) either in absolute volume or as a percent of LV mass (p = NS for both). Similarly, peak creatine kinase was elevated to 11 ± 10 times the upper limit of normal in the FilterWire group and to 9 ± 8 times in the control group, although there was no significant difference between the groups (p = 0.13).

Five deaths were reported by the 30 day follow-up. This included two patients in the FilterWire and three patients in the control group (p = 1.0). The causes of death of these patients were not reported. However, no further revascularisation procedures were required and no patient experienced recurrent MI, stroke or stent thrombosis within 30 days.

In the analysis performed by Iyer et al. (2007), of the 3160 CAS procedures performed without protection or with one of nine protection devices, 29 (0.9%) procedural and 90 (2.8%) 30 day events were reported. Twenty-six protected patients and three unprotected patients experienced procedural adverse events, while 87 protected patients and three unprotected patients experienced 30 day adverse events. The relative risk compared with protected stenting was 0.38 (95% Confidence interval [CI]: 0.12 – 1.24, p = 0.12) for procedural adverse events and 1.25 (95% CI: 0.40 – 3.88, p = 1.00) for 30 day adverse events.

A comparison of the various protection devices used demonstrated a statistically significant 30 day adverse event rate for the AccUNET (Abbott Vascular) concentric filter with a relative risk compared with FilterWire of 2.67 (95%CI: 1.41-5.04, p = 0.005). A similar analysis of procedural adverse events did not reveal any statistically significant relative risk compared to the FilterWire with any of the other eight devices. This review did not demonstrate a statistically significant clinical benefit of the use protection devices in terms of procedural or 30 day events in line with the studies presented above.

COST IMPACT

The cost of the FilterWire device was not revealed in the searches performed.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

No issues were identified from the retrieved material.

SUMMARY OF FINDINGS

The evidence presented on the FilterWire EX and FilterWire EZ device have suggested that little clinical benefit is conferred through the use of the device. Whilst the FilterWire has been demonstrated to capture debris and thrombus material, the device does not

appear to offer a clear benefit in clinical outcomes when compared to other embolic protection devices.

HEALTHPACT ACTION

Due to contrasting results to previous studies on the benefits of neuroprotection during carotid angioplasty (MSAC Assessment 1065), HealthPACT recommends that a full health technology assessment should be conducted to determine the true effectiveness of embolic protection devices during carotid artery angioplasty and stenting.

NUMBER OF STUDIES INCLUDED

| | |
|-----------------------------------|---|
| Total number of studies | 4 |
| Level II intervention evidence | 3 |
| Level III-2 intervention evidence | 1 |

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SEARCH CRITERIA TO BE USED

FilterWire

Filter wire

Embolic protection
EPD
Distal protection