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Clinical Investigations

FilterWire™ Distal Embolic Protection Device for Vein Graft Stenting: Initial Single-Center Experience

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Summary

Background: Saphenous vein graft (SVG) intervention is associated with a significant incidence of major adverse cardiac events (MACE) related to distal vessel embolization. The FilterWire™ distal embolic protection device has recently been approved as an adjunct to SVG intervention. We report here our initial experience in a single center in 30 consecutive patients using this device in SVG stenting.

Hypothesis: This study examined the outcomes and complications associated with these devices, as well as whether proficiency with the devices increased with greater experience and whether there were measurable outcome differences between devices.

Methods: We retrospectively identified all patients in whom a FilterWire device was placed at our hospital between June 2001 and June 2004.

Results: The device was successfully deployed in 29 of 30 patients, and all patients were stented successfully. Overall MACE rate was 6.6%, consistent with reports in larger multicenter clinical trials. Transient decreases in flow were noted while the device was in place in six patients, but improved in five patients with device removal.

Conclusions: This early experience in a single center using FilterWire embolic protection indicates that excellent clinical results can be obtained by the adoption of filter protection for SVG intervention, without evidence for a detrimental learning curve.

Key words: distal protection, saphenous vein graft, angioplasty, coronary stent

Introduction

Saphenous vein graft (SVG) intervention is associated with a 15–20% incidence of major adverse cardiac events (MACE),[1–4] particularly related to distal vessel embolization and reduced antegrade flow.[5] Hence, it has been postulated that distal embolic protection would result in decreased MACE. Two devices are currently approved for use as an adjunct in percutaneous coronary intervention (PCI) of SVG, FilterWire (FilterWire EX™ and FilterWire EZ™, Boston Scientific Corp., Natick, Mass., USA) and GuardWire™ (Medtronic, Minneapolis, Minn., USA). Compared with not using a protection device, the GuardWire is associated with a 42% reduction in the incidence of 30-day MACE when used in SVG intervention.[6] Similar rates of in-hospital and 30-day MACE were demonstrated in a randomized comparison of the GuardWire and FilterWire devices,[7] and a follow-up study of the same trial demonstrated a significant 71% reduction in 30-day MACE for FilterWire compared with GuardWire devices for smaller vessel sizes, with similar MACE rates for larger vessel sizes.[8]

Currently, the majority of published experience regarding outcome with these devices is from multicenter trials, with one report detailing experiences from three institutions.[9] In addition, the FilterWire device has undergone further development with progressively different configurations. The first-generation FilterWire EX device was approved for SVG intervention in the United States in June 2003 in vein grafts with a reference vessel diameter (RVD) of 3.5–5.5 mm. The second-generation FilterWire system, the FilterWire EZ, was developed in two sizes.

We report here our single-center experience with these devices over a period of 3 years. We were interested in the outcomes and complications associated with these devices, as

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they were adopted at our institution, as well as whether proficiency with the devices increased with greater experience, and whether there were measurable outcome differences between devices.

Materials and Methods

Patient Selection

We retrospectively identified all patients in whom a FilterWire device was placed at our hospital between June 2001 and June 2004. All patients received the device as part of an initial FDA-approved investigative study. The Investigational Review Board at our hospital approved the following protocols, and all patients provided informed written consent.

FilterWire EX Randomized Evaluation (FIRE): The details of this study have been described previously.[7] Between October 2001 and September 2002, 651 patients were enrolled at 66 clinical sites. Of these, 332 were randomized to the FilterWire EX arm of the study, with the remaining patients receiving a GuardWire (Medtronic) balloon occlusion and aspiration device. In brief, patients aged ≥ 21 years undergoing planned PCI for a de novo lesion in diseased SVG were eligible for enrollment. Exclusion criteria included acute or recent myocardial infarction (MI), elevated creatinine phosphokinase (CPK)-MB enzyme at the time of treatment, SVG age < 6 months, left ventricular ejection fraction < 25%, impaired renal function (creatinine ≥ 2.5 mg/dl), RVD < 3.5 or > 5.5 mm, patient requiring treatment in a native coronary vessel at the time of procedure, allergy or contraindication to any study medication, need for angioplasty or stent in > 1 vessel that does not qualify for study eligibility, stroke or transient ischemic neurological attack (TIA) within the preceding 2 months, expected inability to deliver FilterWire device distal to target lesion for reasons such as excessive tortuosity or vessel calcification, and patient participation in another drug or device study.

Filter Wire High-Risk Saphenous Vein Graft Registry: This registry consisted of a subset of FIRE patients who were at higher risk for peri- and postprocedural complications. Patients with left ventricular ejection fraction < 25% and creatinine > 2.5 mg/dl were included in the study. All other exclusion criteria for this study were similar to those of FIRE described above.

BLAZE: The BLAZE study is a recently completed randomized, prospective clinical trial investigating the two configurations of the FilterWire EZ device. The registry consisted of 76 patients undergoing SVG intervention with the FilterWire EZ configuration at 22 clinical sites. The criteria for inclusion and exclusion are similar to those of FIRE described above.[10] Registries have been established for the larger EZ configuration (BLAZE 1) and the smaller version (BLAZE 2).

FilterWire System

The FilterWire EX device consists of a distal polyurethane filter with 110 mm diameter pores mounted on a percutaneous 0.014" steerable guidewire using a spinner tube (Fig. 1A). The filter is attached to a 3 cm steerable self-expanding radiopaque elliptical loop, which is deployed distal to the lesion by retraction of a 3.9 Fr delivery sheath. Percutaneous coronary intervention is performed over the device guidewire, over which other catheters and stents can pass. The filter serves to trap embolic debris that travels with antegrade flow distally into the filter. A retrieval sheath is then used to close and retract the filter. The FilterWire EX device is designed for use in vessels ranging from RVD 3.5 to 5.5 mm.

The second-generation FilterWire device has been evaluated as well. The FilterWire EZ consists of an improved guidewire, a central suspension arm that conforms the filter to vessel wall curvature, 3.2 Fr crossing profile, and modified retrieval sheath.[10] The FilterWire EZ device in the 3.5–5.5 mm RVD (Fig. 1C) has recently been approved by the FDA for the treatment of SVG stenosis, and a smaller 2.25–3.5 mm RVD FilterWire EZ device is also under development (Fig. 1B).

Interventional Protocol

Standard coronary interventional protocols were followed. All patients were pretreated with aspirin and were treated with intravenous heparin for the intervention. Activated clotting time (ACT) targets of 200–250 s were used for patients receiving a glycoprotein IIb/IIIa inhibitor in addition to heparin, and 300 s for those receiving heparin alone. Procedures were carried out using 6 Fr or 7 Fr sheaths via a femoral approach. All patients who received stents were also treated with clopidogrel for at least 4 weeks following the procedure.

Data Acquisition

All procedural data were collected prospectively at the point of care by health providers and entered into a clinical research folder (CRF) that serves as a patient record for the investigative study. The CRF contains details regarding patient

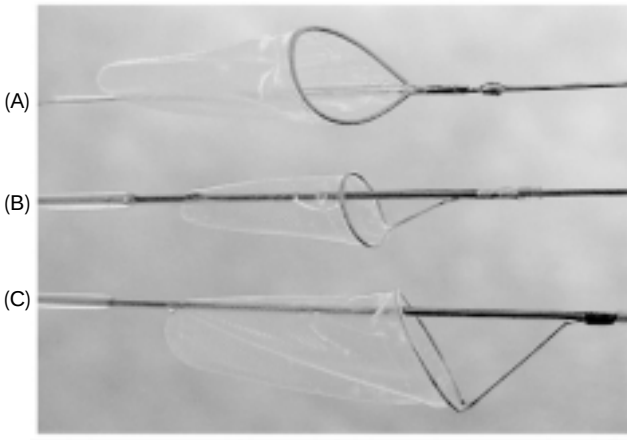

FIG. 1 Different configurations of the FilterWire distal embolic protection device. FilterWire EX (A); 2.25–3.5 mm reference vessel diameter (RVD) FilterWire EZ (B); 3.5–5.5 mm RVD FilterWire EZ (C).

demographics, past personal and family medical history, procedural data, laboratory data, and outcome data.

Data for this study were collected from the CRFs in a standardized manner, including patient characteristics, lesion characteristics, equipment utilized, procedural success, and 30-day clinical outcomes. All data were collected as part of the research trials described above. In this study, we collected data from all patients irrespective of the trial.

Data Analysis

All analyses were performed using Intercooled Stata 7.0 (Stata Corporation, College Station, Tex., USA).

Results

Patient Population

Between June 2001 and June 2004, 30 patients received either a FilterWire EX or EZ device at our institution as part of investigative studies. Of these patients, 15 received a device as part of the FIRE registry: 6 patients were in FIRE High-Risk, 3 patients in BLAZE 1, and 6 patients in BLAZE 2. Our study consisted of an elderly male population that was mostly Caucasian. There was a high incidence of hypertension, smoking, hyperlipidemia, diabetes mellitus, and prior MI (Table I).

Angiographic Characteristics and Procedural Outcomes

Thirty patients were treated with one of the devices. There was no significant difference in baseline patient characteristics or intraprocedural or 30-day clinical outcomes in the patients in whom the 21 EX and 9 EZ devices were used. Similarly, when patients were stratified by three 12-month intervals, no significant difference in baseline or intraprocedural or 30-day outcomes could be identified based on early or later experience with the devices, and no obvious "learning curve" was seen. Grafts to all three major coronary beds were represented, and lesions were identified in proximal, mid, or distal graft locations (Table II). Lesion characteristics are described as well in Table II. The reference vessel diameter was 3.79 mm, and thrombus was angiographically visible in 17%. Embolic material, as assessed visually upon removal of the FilterWire device, was recovered after use in 72% of cases. Devices could be placed in all 30 patients. However, in one patient, there was an inadequate distance between the lesion and the device to allow stent placement, and therefore the FilterWire device was removed and stenting was performed without embolic protection. The remaining 29 patients all had stents placed with FilterWire protection.

In general, one device was used per patient; however, a second FilterWire device was required in three patients for the following reasons. In one patient with two sequential graft lesions, the first FilterWire EX device was placed beyond the second lesion in the graft, and a stent was deployed across the proximal lesion. There was a decrease in Thrombolysis In Myocardial Infarction (TIMI) flow and therefore the EX device was removed, with prompt restoration of normal flow. A second FilterWire EX device was placed in the same position

TABLE I Baseline clinical demographics

Number of patients	30
Age (years)	69.7 ± 9.4
Male sex (%)	100
Race (%)	
Caucasian	83
Other	17
Body mass index (kg/m^2)	27.3 ± 4.5
Current/ former smoking (%)	43
CCS Class III or IV (%)	37
Diabetes mellitus (%)	30
Hypertension (%)	73
Hyperlipidemia (%)	93
Prior myocardial infarction (%)	53

Abbreviation: CCS = Canadian Cardiovascular Society.

TABLE II Baseline angiographic findings and procedural outcomes

Number of patients	30
Grafted vessel (%)	
LAD	27
LCx	53
RCA	20
SVG lesion location (%)	
Proximal	47
Mid	30
Distal	23
Lesion length (mm)	13.5 ± 7.6
Reference vessel diameter (mm)	3.79 ± 0.60
Pretreatment stenosis (%)	86.3 ± 7.9
Post-treatment stenosis (%)	2.4 ± 4.9
Pretreatment TIMI flow (%)	
0/1	3.3
2	3.3
3	93.4
Visible thrombus (%)	16.6
Target vessel tortuosity (%)	
None/mild	73
Moderate	20
Severe	7
Successful overall FilterWire delivery (%)	100
Successful stent delivery (%)	100
Stent delivered over FilterWire (%)	96.7
Distal wire dissection requiring stent (%)	3.3
Visible embolic material recovered (%)	72.4
Final TIMI flow (%)	
0/1	3.3
2	3.3
3	93.4

Abbreviations: LAD = left anterior descending artery, LCx = left circumflex artery, RCA = right coronary artery, SVG = saphenous vein graft, TIMI = Thrombolysis In Myocardial Infarction.

as the first device and the second graft lesion was stented. Again there was a decrease in TIMI flow, believed possibly to be secondary to distal wire trauma. The device was removed, and a distal dissection was identified. A standard coronary wire was used (without FilterWire use), and a stent was placed across this distal lesion resulting in improved flow. In a second patient, there was decreased flow after stenting and post dilating, and flow improved after device removal. A second FilterWire EX device was used to place an additional stent in the vessel, and at the conclusion flow was also normal. In a third patient, after placing a FilterWire EZ device, there was initial difficulty in crossing the stenosis with a stent, and there was loss of position of the FilterWire EZ; a second device was then placed and stenting was accomplished successfully.

Six patients were noted to have decreased flow in the graft after FilterWire placement and initial balloon inflation or stent deployment. In five cases, the flow improved to preprocedural TIMI flow levels after FilterWire device removal. It was presumed that the decreased flow was related to appropriate debris collection in the device. At the time of these early studies, aspiration catheters were not routinely used when decreased flow was noted. There were no clinical consequences related to this transient decrease in flow. Only one patient, who had a very degenerated SVG, experienced a marked reduction in flow during the procedure that persisted despite removal of the device and treatment with pharmacologic agents. This was considered an unsuccessful procedure (see below) with concomitant ST-segment changes on electrocardiogram (ECG) and cardiac enzyme elevations.

Another patient as noted above had marked decrease in TIMI flow, probably related to both debris accumulation in the filter and a distal dissection. Flow improved after appropriate stenting of all sites. This was also the only example of possible distal disruption secondary to the FilterWire. This patient did not sustain an MI related to the procedure.

Thirty-Day Major Adverse Cardiac Events

The clinical outcome up to 30 days was examined (Table III). There was a total of three major complications. Two patients experienced MIs. One patient had sustained a recent ST-elevation MI (STEMI), and despite FilterWire use and stent placement he had poor flow and transient recurrent ST-segment elevation with enzyme elevation. One other patient who received a FilterWire EX device experienced a periprocedural non-STEMI with positive enzymes and anterior T-wave inversions on ECG. As noted, there was one patient with distal graft dissection possibly related to the distal edge of the FilterWire and this was successfully treated with a stent. There was no other MACE either in the hospital or at 30-day follow-up. There were no episodes of target lesion revascularization, emergency coronary artery bypass graft (CABG), or death.

No additional complications were identified at 30-day follow-up. One patient was hospitalized for anginal symptoms secondary to noncompliance with his medical regimen. Following hospitalization, his symptoms resolved and his cardiac enzymes and ECG were negative for MI.

Arteriovenous fistulae occurred in two patients at the time of 30-day follow-up, and gastrointestinal bleeding occurred in one patient who subsequently required rehospitalization within 30 days for colectomy secondary to colon cancer.

Discussion

These data represent an early single-center series of 30 consecutive patients receiving a FilterWire device for distal protection in a vein graft during a time of device evolution. There was a high success rate and a low rate of adverse cardiac events, with all patients having successful device delivery. One patient with a recent STEMI had an unsuccessful PCI with resultant persistent vessel occlusion, and one patient sustained a non-STEMI. The overall MACE rate in these 30 patients was 6.6%, which is consistent with the FilterWire-associated MACE reported in an initial randomized trial[7] and a recent report of 35 patients at three centers,[9] both of which examined outcomes in patients undergoing SVG intervention. One additional patient had evidence of distal wire trauma related to the device. This was treated with a stent and did not lead to enzyme elevation or other consequences. The pivotal trials of embolic protection devices for SVG intervention have shown decreases in MACE with the use of these devices. Widespread adoption of their use will require specific training and experience, but as these data indicate, the real-world experience in individual centers should mirror the randomized trial results. Our device placement success rate was high, and in our relatively limited number of patients we did not identify trends in success related to a learning curve or related to the two different devices utilized here. We did find that we had decreased flow in several patients during stenting because of debris accumulation; flow improved after device removal. Currently, we would address that situation with the use of an aspiration catheter, which was not done at the time of the initial studies. In addition, we occasionally found it helpful to use a second coronary wire to facilitate passage of the FilterWire. The prevalence of distal wire trauma was also quite low despite the fact that this was a new device used by different surgeons. These studies also relate only to SVGs, and additional experience and trials must be performed in selected settings in native coro-

TABLE III Postprocedural and 30-day major adverse cardiac events (MACE) outcomes

Number of patients	30
Q-wave MI n, (%)	1 (3.3) [a]
Non Q-wave MI, n, (%)	1 (3.3)
Repeat target lesion revascularization	0
Emergency CABG	0
Death	0
Total MACE n, (%)	2 (6.6)

[a] Patient with prior Q-wave MI with recurrent ST-elevation periprocedure.

Abbreviations: CABG = coronary artery bypass graft, MI = myocardial infarction.

nary intervention. Studies examining distal embolic protection devices in native vessels for acute MI are ongoing, although early randomized clinical trials have not been promising.[11, 12]

Study Limitations

Our case series of 30 patients examined FilterWire outcomes in patients undergoing SVG intervention at a single center. The devices were not used or evaluated in patients undergoing native vessel intervention, and, since it was a new device, the sample size is limited. Furthermore, the study size did not allow adequate power to compare outcomes between the evolving devices comprehensively, although complications were low with all devices. By chance, women were not represented in this study and should be included in additional registries.

Conclusions

This early experience of a single center using FilterWire embolic protection indicates that excellent clinical results can be obtained with adoption of filter protection for SVG intervention, without evidence for a detrimental learning curve. Transient decreases in flow related to debris accumulation may occur, and there is a low incidence of device-related wire trauma. Additional post-FDA approval studies are warranted to evaluate efficacy of these devices.

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