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Filter no reflow during percutaneous coronary interventions using the Filterwire distal protection device

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Abstract

Background: Distal protection devices are increasingly used to prevent embolization during percutaneous coronary interventions (PCI) in saphenous vein grafts (SVG) and native coronary arteries (NV). During interventions with the Filterwire device we have observed reduced flow that is reversible following removal of the filter (filter no reflow, FNR), which might be erroneously interpreted as true no reflow and might be associated with reduced capture efficiency of the basket.
Methods: We analyzed the incidence of FNR in 58 patients (60 lesions) at high risk of embolization undergoing PCI of either a SVG or a NV using the Filterwire (Boston Scientific, Natick, MA). Qualitative and quantitative angiographic analysis was performed, and the volume of collected debris was estimated using a photographic technique.
Results: In our population, about 1/3 of the cases showed FNR, which was associated with angiographically visible filling defects within the basket, indicating macroembolism. However some patients (especially those undergoing vein graft interventions) showed filling defects without FNR, and some others FNR without filling defects. Thus we tried to understand the predictors of FNR: FNR was associated with higher amount of collected debris (36.97 ± 42.98 mm^3 vs. 11.31 ± 18.47 mm^3, $p = 0.005$), was neither prevented by abciximab, nor predicted by high thrombotic burden, increasing stent volume or need for predilatation. When patient with and without angiographically evident macroembolisation were separately analyzed, a linear correlation of FNR with the quantity of debris was only apparent in the macroembolization group.
Conclusions: Interventionalists should be aware of the "Filter No Reflow", a common but reversible angiographic complication when the Filterwire device is used. Reduced flow seen during these procedures should be treated conservatively. Mechanical obstruction of the filter, but also other mechanisms (pharmacologically active debris? platelet aggregates?) play a role in this phenomenon.

Keywords: Distal protection; No-reflow; Stenting

1. Background

Protecting the distal microcirculation is now considered critical during percutaneous coronary interventions (PCI). Microvascular damage has been observed after up to 35% of coronary procedures [1], and a recent metanalysis of outcome data has showed that even a slight increase in CK–MB, possible after an elective PCI, is associated with increased mortality at medium-term follow up [2]. Although myocardial enzyme elevation is a multifactorial process, involving both obstruction of microvessels and leukocyte infiltration with tissue oedema (related to reperfusion injury and generation of oxygen radicals), the importance of mechanically preventing distal embolization has been clearly demonstrated during saphenous vein graft interven-

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tions [3,4]. The main mechanisms to prevent embolism involve either an active "suction" of the debris in the culprit vessel (with or without balloon occlusion) or a passive shielding of the distal vascular bed with a variety of filter devices. Interestingly, while preliminary reports of benefit during primary PCI in native coronary arteries have been published [5], a large trial has suggested no significant benefit for distal balloon occlusion and aspiration [6].

Among the filter devices, the Filterwire (Boston Scientific Corp., Natick MA) is increasingly popular, mainly due to its easy, monorail-based delivery and retrieval system. Technical correlates of efficacy have been previously reported for SVG [7] and during primary PCI [8]. The Filterwire can be used safely even in very small vessels [9].

Here we investigate a still under recognized complication of Filterwire use, the "filter no-reflow" (FNR) [10]. We have called FNR the transient impairment of epicardial flow, possibly due to "plugging" of the capture device full of embolic material, which may occur during the procedure and may be associated with clinical deterioration (i.e., chest pain, ECG changes) and can also be misinterpreted as a true no-reflow, thus triggering unnecessary pharmacological interventions. Moreover, a blocked filter may have reduced capture capacity, due to the loss of perfusion drive, and may preferentially direct flow towards unprotected side branches. Recently, in a subanalysis of the FIRE trial, transiently impaired flow has been associated with significantly higher 30-day mortality [11].

We evaluated the relationship of FNR with various angiographic and clinical variables.

2. Materials and methods

2.1. Patients and setting

We analyzed 58 consecutive patients (mean age 65 years, 52 males) that presented for vein graft PCI or for native coronary PCI at our institutions (John Radcliffe Hospital, Oxford, UK, 50 patients, and Policlinico A. Gemelli, Rome, Italy, 8 patients) during the same time frame (Apr 2002–Oct 2003) (Table 1). PCI were performed by experienced operators (KC and AB for Oxford, CT and FB for Rome).

Inclusion criteria were a PCI to vein graft body or non-primary PCI to a native coronary artery when features suspect for high thrombus burden (thrombus >3 reference vessel diameter or cut-off pattern, persistent angiographic stain with vessel occlusion, fluctuating thrombus or proximal thrombus >5 mm) [12] were evident at pre-PCI angiogram and the visually-estimated vessel diameter was predicted to be 3.5–5.5 mm.

Clinical exclusions criteria were: cardiogenic shock, contraindications to anticoagulation or anti-platelet therapy. Patients with vessels presenting severe proximal tortuosity or more than mild calcification were also excluded.

Table 1
Baseline features of the 58 patients included in the analysis

Baseline characteristics of 58 patients	
Age, years	65±3
Male sex *n* (%)	52 (90)
SVG treated *n* (%)	28 (48)
Average graft age, years	13.2
NV treated *n* (%)	30 (52)
Rescue PCI *n* (%)	12 (40)
Dyslipidemia *n* (%)	53 (92)
Hypertension *n* (%)	46 (80)
Diabetes *n* (%)	13 (22)
Smokers *n* (%)	21 (36)
Pre PCI Abciximab *n* (%)	44 (73%)

Among the 28 SVG patients, two had two lesions treated in two different grafts (60 lesions total). Use of Abciximab was relatively high at 73%. Average graft age was high at 13 years.
Abbreviations: SVG=saphenous vein graft, NV=native vessel, PCI=percutaneous coronary intervention.

Clinical information were collected from clinical notes and procedural reports.

2.2. The Filterwire

The Filterwire EX consists of a distal polyurethane filter with 80 μm pores, mounted on a 0.014-inch steerable guidewire. The system allows for free and independent rotation of guide and filter. On top of the filter and attached to it, a self-expandable, radiopaque, and elliptically shaped nitinol loop is designed to assume the profile of the vessel and to afford compatibility with different vessel size (from 3.5 to 5.5 mm in diameter). The collapsed filter has a crossing profile of 3.9 Fr. During the course of this study, the new and improved Filterwire EZ has become available, the main differences being the increased diameter of the pores (120 μm), the ability of the nitinol loop to remain centered in the vessel also in tortuous segments due to the absence of fixed connection with the wire, and the reduced crossing profile (2.3 Fr). Only the last five patients included in this analysis were treated with the new device.

2.3. Percutaneous coronary intervention

Before PCI, all patients received aspirin, oral clopidogrel (with a loading dose of 300 mg in cases of new instigation) or ticlopidine and intravenous heparin ≥5000 IU. Use of the glycoprotein IIb/IIIa receptor antagonist abciximab was at the discretion of the operator, and was used preprocedurally in 44 patients (73%). PCI was routinely performed with 6 F access through the right femoral artery. Where feasible, the FW was passed directly beyond the lesion. Alternatively, passage of a standard guidewire followed by pre-inflation with a small balloon was permitted in order to facilitate passage of the FW (43%). The FW was positioned at least 1.5 cm beyond the target lesion in a non-tortuous segment of vessel proximal to major branch points or