ORIGINAL CONTRIBUTIONS:
Initial Experience with a Novel Coronary Rinsing and
Thrombectomy System: “Rinspiration”
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background. Intracoronary thrombus is often problematic during percutaneous coronary intervention. Rinspiration™ is a new thrombectomy catheter system designed to mechanically disrupt and remove intravascular thrombus. Methods. “Rinspiration” thrombectomy was performed in 15 patients with angiographically visible thrombus in native coronary arteries (10 cases) and in saphenous grafts (5 cases). Indications included acute myocardial infarction in 11 patients and postinfarction ischemia in 4 patients. Results. The Rinspiration system appeared relatively simple to use. There were no device-related complications. Thrombectomy resulted in an improvement in thrombus grade from $3.8 \pm 1.6$ to $2.5 \pm 1.7$ ($p = 0.02$), and TIMI flow from $1.5 \pm 1.3$ to $2.2 \pm 1.0$ ($p = 0.047$). Stenting further improved thrombus grade to $0.8 \pm 1.6$ and TIMI flow to $2.6 \pm 0.8$. At 30-day follow up all patients remained free of repeat revascularization and reinfarction; 1 patient died from hemorrhagic stroke. Conclusions. The Rinspiration system appears capable of safely removing intracoronary thrombus
Percutaneous coronary intervention (PCI) plays a prominent role in the management of acute myocardial infarction (MI). However, intracoronary thrombus often contributes to suboptimal angiographic results, morbidity and mortality. Approaches to the management of intracoronary thrombus include anticoagulation and pharmacologic fibrinolysis, aspiration, proximal and distal protection, mechanical thrombolysis and thrombectomy. We describe a new catheter system designed to mechanically disrupt and remove intravascular thrombus.

**Methods**

**Patient population.** Patients were considered eligible for study enrollment when angiography suggested the presence of thrombus as assessed by the angiographer in an artery or graft greater than or equal to 3.0 mm in diameter. Written informed consent was obtained from all patients. The device was approved for clinical use by the Therapeutic Products Directorate, Canada. Clinical data were prospectively collected. Patients were pretreated with aspirin, clopidogrel and eptifibatide when possible. Heparin was administered to maintain an activated clotting time above 250 seconds.

**Device description.** The Rinspiration™ System (Kerberos Proximal Solutions Inc., Sunnyvale, California) is intended for use in the setting of intravascular thrombus. The system consists of two components: a Rinspiration catheter and a Rinspirator™ device.

The Rinspiration catheter has three lumens (Figure 1). A monorail wire lumen is 25 cm in length and allows passage over a standard 0.014-inch coronary guidewire. A second lumen allows distal aspiration. A third lumen allows injection of a rinsing solution through perforations located proximal to the aspiration lumen. The perforations are distributed circumferentially along a short length of the catheter. The catheter includes a small radiopaque marker band at the distal tip adjacent to the aspiration port, and two radiopaque marker bands designating the infusion portion of the catheter. The multilumen catheter has a working length of 135 cm and a diameter of 5.3 French (Fr), or 1.78 mm.

The hand-activated Rinspiration device allows for simultaneous irrigation and aspiration at the treatment site (Figure 2) by activating two syringes, one for infusion and one for aspiration. This coordinated action of both rinsing and aspirating has been designated as “rinspiration”.

The infusion delivery syringe is fed from a reservoir of heparinized Ringer’s lactate solution or saline. As the handle of the Rinspirator is released, the infusion syringe is automatically filled from the reservoir, while the aspirant is emptied into a second reservoir bag. This allows for temporary storage, inspection, analysis, transport and/or disposal of the aspirated materials.

**Procedure.** The currently available Rinspiration catheter is compatible with a 7 Fr large lumen (internal diameter 0.078 inch) guiding catheter. A standard 0.014-inch wire is advanced into the vessel and across the treatment site. The catheter and hand-held activator system
are assembled and flushed. The rapid exchange catheter is introduced over the wire into the guiding catheter. The catheter is advanced into the vessel until the distal tip marker is situated just proximal to the target lesion. The hand-held activator is squeezed and then released. It is necessary to pause slightly while the handle is in the fully squeezed position during each rinspiration cycle to allow the aspirating syringe to fill. The distal tip of the device is advanced a few millimeters every few rinspiration cycles.

**Angiographic analysis.** Angiograms were analyzed at an independent core laboratory (CIRCL, CardiABC, Vancouver, Canada), using previously validated software (Discovery, Quinton Cardiology Systems, Bothell, Washington). Assessment of the standard angiographic parameters including TIMI flow grade, frame count, thrombus grade, blush, no-reflow and distal embolization has been previously described.

**Histopathologic analysis.** Aspirate was collected and passed through a 40-mcg filter. Samples were preserved in formalin, embedded in paraffin, stained with hematoxylin and eosin and Movat's pentachrome. Pathologic analysis was performed at the CAPTURE Centre, University of British Columbia.

**Results**

**Patients.** Rinspiration was performed in 15 patients. Indications were acute MI in 11 cases and post-MI ischemia in 4 cases. Vessels were native coronary arteries in 10 acute MI patients and ulcerated saphenous vein grafts in 5 patients, 1 of whom was suffering from an acute MI. Patient baseline characteristics are summarized in Table 1.

**Device performance.** Although the Rinspiration catheter was compatible with a 7 Fr large lumen, 0.078-inch internal diameter guiding catheter, contrast opacification was improved when used with an 8 Fr, 0.084-inch lumen guiding catheter. The catheter was readily advanced to the intended treatment site in all patients.

Thrombus removal appeared to be most effective if initiated just proximal to angiographically visible thrombus, with gradual advancement during continued rinspiration. Fresh thrombus associated with acute infarction was relatively readily disrupted and removed. Older thrombus, as seen several days following acute infarction, appeared more resistant. Retrograde flushing of thromboembolic material into proximal branches was not observed. On occasion, the aspiration syringe was noted to fill slowly or incompletely during rinspiration. Three potential causes were identified: occlusion of the catheter aspiration lumen by bulky thrombus, placement of the catheter tip and aspiration port beyond a tight stenosis, and an over-tightened rotating hemostatic valve. Continued rinsing in the absence of aspiration would seem undesirable. In this situation, our standard approach was to loosen the rotating hemostatic valve slightly, withdraw the catheter a few millimeters and re-attempt rinspiration. If the aspirating syringe still did not fill readily, then the catheter was removed from the patient and manually flushed to remove occlusive thrombus within the catheter lumen. Rinspiration was stopped when there was no visible residual thrombus in the culprit vessels or when there was no more retrievable thrombus despite multiple attempts (using different techniques, as explained above).

**Procedural and clinical outcomes.** Procedural results are detailed in Table...
2. Telephone follow up at 30 days documented no reinfarction or repeat target vessel revascularization. One death occurred the day following the procedure as a consequence of intracranial hemorrhage.

**Histopathologic analysis.** Grossly visible thrombus was recovered in 2 of 15 cases in which the aspirate was filtered. Pathologic analysis demonstrated red blood cells, fibrin, platelets and thrombus. Embolic material was identified by FilterWire basket analysis, consisting of platelet-rich material, fibrin, occasional cholesterol and trapped white blood cells.

**Angiographic analysis.** TIMI flow grade, frame count and thrombus grade improved following rinspiration and improved further following stent implantation (Table 3). Changes in TIMI flow grade are illustrated in Figure 3.

**Case description.** In an illustrative case, a 56-year-old male presented with an inferior MI and cardiogenic shock refractory to dopamine and intra-aortic balloon support. Angiography revealed thrombotic occlusion of a 5-year-old saphenous vein graft anastomosed sequentially to the intermediate, obtuse marginal and posterior descending branches of the dominant circumflex artery (Figure 4A). The thrombotic occlusion was crossed with a wire. The Rinspiration catheter was advanced up to the thrombus. “Rinspiration” was initiated just proximal to the thrombus, and the catheter was slowly advanced. There was immediate restoration of patency and normalization of flow (Figure 4B). Following stenting, the vessel was widely patent, with normal TIMI 3 flow (Figure 4C). A large amount of visible clot was aspirated (Figure 5). Continuous digital 12-lead monitoring demonstrated rapid ST-segment normalization (Figures 6). The patient was discharged home 4 days later.

**Discussion**

**The Rinspiration device.** Use of the Rinspiration thrombectomy system appeared feasible and safe in this initial experience. Preparation and deployment of the system was relatively intuitive. The manual activation mechanism is disposable and self-contained, avoiding the capital outlay and maintenance concerns associated with an external drive unit.

The catheter appeared capable of disrupting and removing fresh thrombus. Some larger, well-organized particles were recovered from the Rinspiration catheter’s aspiration lumen and removed whole, while smaller fragments were recovered from filtered aspirate. Displacement of thrombus into the proximal vessel or branches was not observed.

The Rinspiration catheter used in the study was compatible with a 7 Fr large lumen (internal diameter 0.078 inch) guiding catheter. More recently, a 6 Fr guiding catheter-compatible version has become available.

**Acute MI and thrombectomy.** Acute ST-segment elevation MI is usually the consequence of thrombotic occlusion of an epicardial coronary artery. Despite the relative success of PCI in restoring epicardial coronary flow, the majority of patients in whom normal flow is achieved have evidence of suboptimal myocardial perfusion. Myocardial perfusion is a major determinant of infarct size, cardiac function and mortality. Thromboembolism with microvascular and macrovascular obstruction may play a significant role in reducing myocardial perfusion. By implication, removal of coronary thrombus at the time of acute MI intervention has the potential to improve myocardial perfusion and clinical outcome.

The thrombectomy devices with the most clinical data are the AngioJet™ rheolytic system (Possis Medical, Inc., Minneapolis, Minnesota), and the X-Sizer™ mechanical extraction system (ev3, Inc., Plymouth, Minnesota). Both have been
shown to reduce thrombus burden. However, clinical benefit has not been demonstrated.\textsuperscript{10–15}

**Embolic protection.** In contrast to thrombectomy devices, embolic protection devices are intended to address the issue of blood-borne particulate. Three general types of embolic protection devices have been utilized in the setting of coronary arterial thrombus: a distally-placed occlusive balloon in conjunction with an aspiration catheter (e.g., GuardWire™ and Export™, Medtronic AVE Inc., Santa Rosa, California),\textsuperscript{16,17} a proximally-placed occlusive balloon, also used in conjunction with aspiration (e.g., Proxis™, Velocimed Inc., Minneapolis, Minnesota), and a distally-placed filter (e.g., FilterWire™, Boston Scientific Corp., Natick, Massachusetts). Despite favorable preliminary experience with distal protection in the setting of acute MI,\textsuperscript{18–22} randomized trials have failed to demonstrate benefit.\textsuperscript{23, 24}

**Combined thrombectomy and distal protection.** An inherent concern with thrombectomy is the risk of unprotected thrombus disruption and thromboembolism. The combined use of the GuardWire distal occlusion balloon and Export aspiration catheter (Boston Scientific) represent the prototypical system intended to provide both embolic protection and thrombus removal. The use of mechanical thrombectomy in combination with distal protection has also been described.\textsuperscript{25} In our experience with the Rinspiration system in the setting of acute MI, where distal protection with a FilterWire was utilized at the operator’s discretion, small amounts of dislodged thrombus were often recovered within the distally-placed filter. Although both thrombectomy and embolic protection would seem complementary, it remains to be seen if a combined approach improves outcome.

**Conclusions**

Rinspiration appears to offer potential for the removal of intracoronary thrombus. Further study is indicated to evaluate efficacy and safety.


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