Cardiovascular Revascularization Medicine xxx (2017) xxx–xxx

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Efficacy of a heparin based rota-flush solution in patients undergoing rotational atherectomy☆

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ARTICLE INFO

Article history:
Received 9 July 2017
Received in revised form 18 August 2017
Accepted 22 August 2017
Available online xxxx

Keywords:
Rotational atherectomy
Percutaneous coronary intervention
Coronary artery disease

ABSTRACT

Introduction: The efficacy of heparin based flush solutions in rotational atherectomy (RA) has not been validated. Recently, a single center study demonstrated the feasibility of an alternative flush solution with 10,000 U of unfractionated heparin (UFH) in 1 L of normal saline. We aimed to evaluate the safety and efficacy of an alternative flush solution intermittently utilized at our institution.

Methods: We retrospectively identified 150 patients undergoing RA over a three year period. One hundred cases utilized an alternative flush solution containing 10,000 U UFH, 400mcg nitroglycerin, and 10 mg verapamil in 1 L normal saline and fifty cases utilized RotaGlide Lubricant (Boston Scientific) in addition to heparin and vasodilators in the same dose. The primary end point was to compare rates of procedural success. Secondary endpoints were to report procedural characteristics including the incidence of major adverse cardiac events (MACE) and minor periprocedural complications.

Results: Procedural success was achieved in 98% (98/100) of cases utilizing the alternative Rota-Flush solution compared to 100% (50/50) in the Rota-Glide group ($P = 0.553$). A total of 292 lesions (200 Rota-Flush vs 92 Rota-Glide) were targeted for intervention. MACE occurred in 13 (13%) and 4 (8%) cases in the Rota-Flush and Rota-Glide groups, respectively ($P = 0.425$).

Conclusion: Rotational atherectomy performed with the previously defined Rota-Flush or Rota-Glide solutions resulted in similar rates of procedural success. There were no significant disparities in incidence of MACE and minor periprocedural complications between the two groups. Heparin based rota-flush solutions can be effective alternatives to traditional solutions containing RotaGlide Lubricant.

1. Introduction

Coronary artery calcium is a marker of advanced coronary artery disease and is a predictor of adverse clinical outcomes including stroke and myocardial infarction [1–5]. Severely calcified coronary lesions increase the intricacy of percutaneous coronary intervention (PCI) and are associated with increased procedural risk and adverse clinical outcomes [6–11]. These lesions can be resistant to adequate predilatation, impair stent delivery and expansion, and lead to an increased rate of stent thrombosis and/or restenosis [1,12]. Current guidelines indicate that rotational atherectomy (RA) is a reasonable approach to heavily calcified lesions which cannot be crossed by a balloon catheter or adequately dilated before stent implantation [13]. RA is a technique which was introduced by Jerome Ritchie and David Auth and first utilized in human cases by Fourrier et al. in 1988 [14,15]. The technique relies on the principle of "orthogonal displacement of friction" and utilizes a rotating diamond shaped burr to modify calcified coronary lesions and reduce plaque burden [16]. The resulting luminal morphology of treated lesions is smooth and nonendothelialized, which differs from lesions treated with balloon angioplasty [17–21].

The Rotablator Rotational Atherectomy System (Boston Scientific, Marlborough, MA) is a device approved for percutaneous rotational coronary angioplasty. The system utilizes a pressurized flush solution to lubricate the drive shaft in order to reduce friction, heat generation, and sudden drops in revolutions per minute [22]. The standard flush solution includes vasodilators such as nitroglycerin and verapamil in addition to RotaGlide Lubricant (Boston Scientific Marlborough, MA) which contains olive oil, egg yolk, phospholipids, sodium deoxycholate, L-histidine, disodium EDTA, sodium hydroxide, and water [22]. Known clinical complications of rotational atherectomy are similar to those common to PCI and include the need for urgent coronary artery bypass graft surgery, myocardial infarction, stroke, and death. Angiographic complications include coronary vasospasm, dissection, side branch loss, and slow-flow/no-reflow phenomenon [16,18].

☆ Disclosure statement: The authors report no financial relationships or conflicts of interest regarding the content herein.

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https://doi.org/10.1016/j.carrev.2017.08.013
1553-8389/

RotaGlide Lubricant has been studied in a small population of twenty patients following failed stent placement [23]. It was reported to facilitate stent delivery in complex lesions in addition to being safe and biocompatible with drug-eluting stents. The efficacy of alternative rota-flush solutions has not been thoroughly investigated. In a recent case series, Lee et al. evaluated the safety and feasibility of a heparin based rota-flush solution in the absence of vasodilators [24]. The authors report that the use of a heparin based rota-flush solution without vasodilators is a reasonable alternative to RotaGlide and vasodilators. These findings have not yet been validated. We sought to evaluate the safety and procedural success rate of an alternative rota-flush solution intermittently utilized at our institution and its potential impact on both major adverse cardiac events (MACE) and minor periprocedural complications.

2. Methods

2.1. Study population

Following institutional review board approval, we identified all patients who underwent rotational atherectomy at the Medical College of Georgia/Augusta University Medical Center between January 1st 2014 and December 31st 2016, using an institutional database. One hundred and fifty patients met inclusion criteria and data was extracted from the electronic medical record system in accordance to the study protocol.

2.2. Procedural technique and medical intervention

Patients underwent percutaneous coronary intervention (PCI) with rotational atherectomy performed by one of six operating physicians. Standard techniques were utilized to perform PCI via a transradial or transfemoral approach. Dual-antiplatelet therapy with a $P2Y_{12}$ inhibitors and aspirin was administered prior to PCI. Unfractionated heparin was administered intravenously throughout the procedure to achieve an activated clotting time (ACT) >250 s. Intravascular ultrasound (IVUS) was utilized prior to intervention in all but one case and fractional flow reserve (FFR) was utilized to evaluate coronary lesions with 50–70% stenosis. The selection of arterial access sheath, burr size, and stent type (bare-metal vs drug-eluting) was determined by the operating physician. In addition, the decision to utilize a temporary pacemaker and/or provide hemodynamic support with an intra-aortic balloon pump (IABP) or percutaneous left ventricular assist device (pLVAD) was operator dependent, based on patient and target lesion profile.

Rotational atherectomy was performed using one of two rota-flush solutions based on operator preference. The "Rota-Glide" solution contained one $20cm^3$ vial of RotaGlide Lubricant, 10 mg verapamil, 400 mcg nitroglycerin, and 10,000 U unfractionated heparin in 1 L of normal saline. The alternative "Rota-Flush" solution contained 10 mg verapamil, 400 mcg nitroglycerin, and 10,000 U unfractionated heparin in 1 L of normal saline. The target lesion was crossed using a 0.014″ work-horse wire followed by wire exchange for a 0.009"Rota-floppy wire (Boston Scientific, Marlborough, MA) via an over-the-wire balloon or microcatheter. A pressure bag infusion containing either Rota-Glide or the alternative Rota-Flush solution was utilized based on operator preference. The flush solution was started and the burr was advanced through the lesion using a pecking technique. The duration of each pass with the burr was less than or equal to 20 s. Following rotational atherectomy, the decision to proceed with coronary angioplasty and/or stent placement was routinely guided by IVUS.

All patients were treated with dual antiplatelet therapy following PCI. In addition, all patients were prescribed an angiotensin-converting enzyme inhibitor or angiotensin II receptor blocker, beta-blocker, and statin at the time of discharge unless clinically contraindicated.

2.3. Data extraction

A detailed chart review was conducted to collect demographic data including cardiac risk factors, echocardiographic data, procedural characteristics, and the incidence of MACE and minor periprocedural complications. All physician notes were reviewed up until the time of discharge in order to extract both subjective and objective data such as the development of anginal symptoms or hematoma at arterial access site. All data was entered into a dedicated rotational atherectomy database.

2.4. Study endpoints

The primary end point was procedural success defined as Thrombolysis in Myocardial Infarction (TIMI) flow grade 3 and residual stenosis ≤ 30% after final percutaneous transluminal coronary angioplasty (PTCA) and/or stent placement. If stent loss, death, or an indication for emergent PCI and/or coronary artery bypass graft surgery developed during the first 24 h, the procedure was considered a failure. Secondary endpoints were the development of major and minor periprocedural complications prior to hospital discharge. Major adverse cardiac events were defined as: bradycardia requiring transvenous pacing, hypotension requiring vasopressors or placement of mechanical hemodynamic support (IABP or pLVAD), sustained ventricular arrhythmia, need for target lesion revascularization, non-fatal myocardial infarction, stroke, and cardiac death.

Target lesion revascularization was defined as the development of ischemia due to a stenosis of ≥ 50% of the luminal diameter either within the stent or within 5 mm of its borders which required surgical or percutaneous revascularization. Acute and subacute stent thrombosis was defined according to the Academic Research Consortium definition [25]. Myocardial infarction was defined as the development of new ST-segment elevation or an increase in cardiac biomarkers either ≥2× the upper limit of normal or above the previously documented value in addition to the development of ischemic symptoms. Death was to be considered cardiac in origin unless a non-cardiac origin was documented in the electronic medical record. Minor periprocedural complications were defined as: development of hematoma or pseudoaneurysm at the vascular access site or reported systemic blood loss from any source.

2.5. Statistical analysis

Statistical analysis was performed with R© version 3.3.1 (2016-06-21) -The R Foundation for Statistical Computing Platform. The difference between means for continuous variables was tested by two-tailed *t*-test. For categorical values, the Fishers exact test was utilized in testing the significance of dependent variables on independent variables. P-values < 0.05 were considered statistically significant. Descriptive statistics were used to analyze procedural characteristics. Continuous variables are reported as a mean and standard deviation while categorical variables are reported as a value and percentage.

3. Results

3.1. Population demographics and procedural characteristics

Patient demographics and cardiac risk factors for both the Rota-Flush and Rota-Glide groups are documented in Table 1. A total of 292 lesions (200 Rota-Flush vs 92 Rota-Glide) were targeted for intervention and the distribution of target lesions are listed in Table 2. Unprotected left main disease was targeted in 19 (19%) and 4 (8%) cases in the Rota-Flush and Rota-Glide groups, respectively ($P = 0.095$). A complete list of procedural characteristics including: burr size, number of stents utilized, type of stent deployed, and application of IVUS is provided in Table 3.

Please cite this article as: Whiteside HL, et al, Efficacy of a heparin based rota-flush solution in patients undergoing rotational atherectomy, Cardiovasc Revasc Med (2017), https://doi.org/10.1016/j.carrev.2017.08.013