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Safety of Same-Day Discharge after Percutaneous Coronary Intervention with Orbital Atherectomy

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ABSTRACT

Background: Severely calcified lesions present many challenges to percutaneous coronary intervention (PCI). Orbital atherectomy (OA) aids vessel preparation and treatment of severely calcified coronary lesions. Same-day discharge (SDD) after PCI has numerous advantages including cost savings and improved patient satisfaction. The aim of this study is to evaluate the safety of SDD among patients treated with OA in a real-world setting.
Methods: This was a single-center retrospective analysis of patients undergoing OA. In-hospital and 30-day outcomes were assessed for major adverse cardiac events (MACE), device-related events and hospital readmissions.
Results: There were 309 patients treated with OA of whom 94 had SDD (30.4%). Among SDD patients, there were no acute procedural complications and all patients were safely discharged on the day of the procedure. MACE at 30 days occurred in 1 patient (1.06%) due to major bleeding in the setting of a gastric arteriovenous malformation. There were 8 patients with unplanned 30-day readmissions (8.5%).
Conclusion: SDD after OA in patients with heavily calcified lesions appears to be safe, with low rates of adverse events and readmissions in select patients. In patients with SDD treated with OA, unplanned readmission occurred at a similar rate to the statewide average 30-day PCI readmission rate. Larger studies are needed to confirm the safety of this treatment paradigm and the potential cost savings.

1. Background

Coronary artery calcification presents many challenges to successful percutaneous coronary intervention (PCI). Increasing calcification has been associated with worse procedural results and long-term outcomes [1,2]. Specifically, procedural risks include vessel dissection, perforation, balloon rupture, inability to dilate the lesion and failure to deliver a stent [3–8]. Additionally, stents delivered in calcified segments can have incomplete stent expansion which is associated with an increased incidence of stent thrombosis and target vessel revascularization [9–11].

Lesion preparation prior to stent implantation can address several of the limitations of treating calcified lesions. Orbital atherectomy (OA) is the first coronary device approved for use in the United States for the treatment of de novo, severely calcified lesions to facilitate stent delivery [12]. Orbital atherectomy (OA) aids vessel preparation and treatment of severely calcified coronary lesions and has been showed to be safe and effective with favorable outcomes reported up to 3-years [12,13].

Same-day discharge (SDD) after PCI has numerous advantages including cost savings and improved patient satisfaction. The safety and feasibility of SDD after PCI in appropriate patients have been demonstrated in numerous studies [14]. Nonetheless, nationwide rates of SDD remain low with only 6.8% of PCIs being performed in the ambulatory setting [15]. The outcomes of patients treated with OA and discharged the day of procedure is unknown. The aim of this study is to evaluate the prevalence and safety of SDD among patients treated with OA in a real-world setting. We retrospectively evaluated the feasibility and safety of SDD after orbital atherectomy for the treatment of severely calcified lesions.

2. Methods

2.1. Study population

This was a single-center retrospective registry analysis of patients undergoing OA between October 2013 and July 2015 at St. Francis Hospital (Roslyn, NY). Severe coronary artery calcification was defined by the presence of radio-opacities on fluoroscopy involving both sides of the vessel

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wall or >270° of calcification on intravascular imaging. The institutional review board approved the review of the data.

2.2. Device description

The Diamondback 360° Coronary Orbital Atherectomy system (Cardiovascular Systems, Inc. [CSI], St Paul, MN) has been previously described in detail [16]. In brief, the device consists of a 1.25-mm eccentrically mounted crown that is coated with 30-micron diamonds and rotates on a 0.014" ViperWire (CSI). The OA mechanism of action is differential sanding which modifies and ablates hard, calcified plaque modifying lesion compliance to facilitate stent expansion. The OA crown orbits bi-directionally and expands laterally with centrifugal force.

2.3. Procedure

The decision to perform orbital atherectomy was at the operator's discretion. Low speed (80,000 rpm) was initiated for all cases of OA, with high-speed atherectomy (120,000 rpm) performed at the operator's discretion in selected lesions. The choice of arterial access, stent type, antithrombotic therapy, use of a hemodynamic support device, and intravascular imaging was at the discretion of the operator. The decision for same-day discharge was made by the treating physician.

2.4. Endpoints

The primary endpoint was the rate of 30-day readmissions. Readmissions were assessed if they were planned (for staged procedures) or unplanned. Thirty-day readmission was defined as hospital admission within 30 days of discharge from the index procedure when the second admission was not for the purpose of staged PCI, or transcatheter aortic valve replacement (TAVR). A procedure was considered staged, when the overall treatment plan at the time of the first procedure included an expectation for the patient to return at a later date for an additional PCI or TAVR. Also categorized as readmission is any non-staged PCI within 30 days of discharge, even if the second procedure is technically performed on an outpatient basis. In-hospital, procedural and 30-day outcomes were assessed for major adverse cardiac events (MACE), defined as the composite of death, myocardial infarction (MI), target vessel revascularization (TVR), stroke or major bleeding and device-related events. Myocardial infarction was defined as recurrent ischemic symptoms with new ST-segment elevation or re-elevation of cardiac markers to at least twice the upper limit of normal. Cardiac enzymes were checked when clinically indicated. TVR was defined as repeat revascularization of the target vessel. Stent thrombosis was defined according to the Academic Research Consortium definition [17]. Patient data and clinical outcomes were obtained from medical records and entered into a dedicated PCI database. Continuous variables were presented as the mean value.

3. Results

3.1. Baseline demographic and procedural characteristics

There were 309 patients treated with OA during the study period, of whom 94 were discharged on the day of their procedure and included in this study (30.4%). Baseline demographics are presented (Table 1). Mean age was 73.0 years. 78.7% of patients were male and 39.4% had diabetes.

3.2. Procedural results

All patients were treated via femoral access and heparin was used for most cases (97.9%) (Table 2). Intravascular imaging was used in 86.2%; there were a mean of 3.4 OA runs per patient and in 47.8% of cases, high speed was used. Vascular access closure devices were used in 90.3% of patients. In patients discharged on day of the procedure there were no angiographic complications including perforation, dissection, or no reflow.

Table 1
Baseline characteristics.

Variable	$N = 94$
Age (years)	73.0 [range 49–90]
Male	78.7%
Weight	179.9 lbs
Diabetes	39.4%
Hypertension	77.7%
Dyslipidemia	78.7%
Prior CABG	10.6%
Prior PCI	43.6%
Chronic kidney disease	3.2%
Prior myocardial infarction	11.7%
Prior stroke	7.4%
Peripheral vascular disease	6.4%

CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention.

3.3. Readmissions

There were 8 patients with readmissions during the 30-day follow-up (8.5%) (Table 3). One patient presented with syncope and was found to have significant gastrointestinal bleeding requiring intervention. One readmission was for access site related discomfort that was medically managed. Four patients with either shortness of breath or chest pain with a negative work-up with discharge home. Two non-procedure related readmissions occurred. Description and timeline for each unplanned readmission is presented (Table 4). There was no significant difference in unplanned readmission based on SDD compared to those patients hospitalized after OA (8.5% vs. 8.4%, p = ns).

3.4. Thirty-day clinical outcomes

30-day MACE occurred in no patients with SDD after OA (Table 5). There was one adverse clinical event (1.06%), due to major bleeding in the setting of a gastric arteriovenous malformation.

4. Discussion

The principal finding of our study was that same-day discharge was feasible and safe in select patients with heavily calcified coronary artery

Table 2
Procedural characteristics.

Femoral access	100%
Heparin	97.9%
Transvenous pacemaker	4.3%
# Vessels treated	1.1
Vessel treated	
Left main coronary artery	2.1%
Left anterior descending artery	73.4%
Left circumflex artery	13.8%
Right coronary artery	18.1%
# Stents used	2.1
Total stent length	40.4 mm
Intravascular imaging used	86.2%
Pre-stent imaging	54.2%
Post-stent imaging	50%
Optical coherence tomography	68.1%
# OA runs	3.4
High speed used	47.8%
Direct stenting after OA	87.9%
Highest pressure used	15.3 atm
Contrast usage	192.8 mL
Fluoroscopy time	17.6 min
Closure device	90.3%

OA, orbital atherectomy.

Table 3
Readmission breakdown.

24 hour readmissions ($n = 3$)	3.2%
48 hour readmissions ($n = 4$)	4.3%
30-day readmissions ($n = 8$)	8.5%

disease treated with orbital atherectomy during PCI. Readmission after orbital atherectomy in patients with same-day discharge occurred 8.5%, below the New York state (NYS) average 30-Day PCI readmission rate. The NYS 30-day readmission rate was 9.85% for all PCIs in 2014, the most recently available data [18]. The Healthcare Cost and Utilization Project National Readmission Database reported 12% 30-day readmission after PCI, with a range of 6–17% across hospitals [19].

Though same day discharge has been safely reported in numerous diverse patient cohorts, it has not been previously evaluated exclusively in patients with high-risk calcified disease requiring treatment with orbital atherectomy [20]. Rates of same-day discharge after alternative atherectomy devices have been reported as 6% in the United States, and 19% world-wide [21]. Here, we report the use of orbital atherectomy with same-day discharge in over 30% of patients treated. Despite an increased procedural risk in patients with calcified coronary disease, orbital atherectomy can be performed and if patients are clinically stable post-PCI, they can be safely discharged home on the day of their procedure.

Orbital atherectomy allows for lesion preparation prior to stent implantation. By changing lesion compliance, greater stent expansion may occur in lesions properly pre-treated. This may improve procedural results in patients treated with orbital atherectomy. While no patients treated with OA and discharged day of intervention had angiographic complications, angiographic complications have been shown to be low with orbital atherectomy [22]. Rates of readmission lower than the state-wide average for all PCI, demonstrates the viability of same-day discharge. Additionally, 30-day complications and major adverse cardiovascular events were low.

Intravascular imaging was used in the majority of the procedures (86.2%) which may impact the physician's assessment, ensuring an optimal endpoint has been reached at the conclusion of the procedure. Knowing adequate results were achieved with confirmation of adequate stent expansion, and exclusion of procedural complications including thrombus, dissection, and geographic miss may allow for increased confidence in same-day discharge and may have impacted patient selection for SDD. However, in this study there was case-by-case variability in the use of intravascular imaging and specific imaging based parameters were not pre-specified for determining same-day discharge.

Orbital atherectomy can be safely used with a 6 French catheter. This may have an impact on the high rates of SDD after OA, as compared to alternative atherectomy devices that require larger catheter sizes. Though discussion on same-day discharge has largely been focused on radial access, safe same-day discharge can also occur with routine femoral access [23–26]. This registry demonstrates that despite femoral access, and the use of adjunctive treatment devices, SDD can be effectively implemented and safely realized in complex PCI.

Table 4
Unplanned readmissions.

Time post-PCI	Details of readmission presentation
24 h	Shortness of breath with repeat catheterization with patent stents
24 h	Syncope in setting of gastrointestinal bleed, found to have gastric arteriovenous malformation and underwent endoscopic clipping
24 h	Shortness of breath, monitored overnight and discharged home
48 h	Shortness of breath, computed tomography scan of chest negative and patient discharged home
6 days	Chest pain, negative non-invasive stress test
6 days	Groin discomfort, treated with medical therapy
12 days	Deep venous thrombosis
17 days	Dizziness, found to have an arrhythmia and underwent bi-ventricular defibrillator implantation

PCI, percutaneous coronary intervention.

Table 5
Adverse events.

30-day death	0%
30-day MI	0%
30-day TVR	0%
30-day stroke	0%
30-day stent thrombosis	0%

MI, myocardial infarction; TVR, target vessel revascularization.

As procedural complications related to PCI and OA are usually evident within 6 h of intervention, SDD can largely be met in patients that are clinically stable [27,28]. After 6 h of event-free observation, the prospect of procedural related complications is low making overnight hospitalization unwarranted in most cases. An algorithm to assist in the identification of patients who may be candidates for SDD following OA is presented in Fig. 1. In patients who meet our proposed criteria, patients may be safely discharged the day of OA, with a follow-up phone call the next day to assess the patient and reinforce adherence to optimal medical therapy and ensure a follow-up appointment.

While all patients are not candidates for SDD, it is important that future studies focus on further developing algorithmic approaches to determining which patients may most benefit from SDD. A consensus statement from the society for cardiovascular angiography and interventions (SCAI) proposed that same-day discharge after PCI should be reserved for single-vessel PCI with stents <28 mm with no other interventional device used [29]. The consensus statement cautioned that patients who have had directional or rotational atherectomy should be excluded from same-day discharge. A recent update to the SCAI consensus recommendations classified treatment with atherectomy as a factor that was unfavorable for same-day discharge [30]. Updated guidelines and consensus statements however should reflect the role newer devices including orbital atherectomy may play with same-day discharge after PCI. Aside

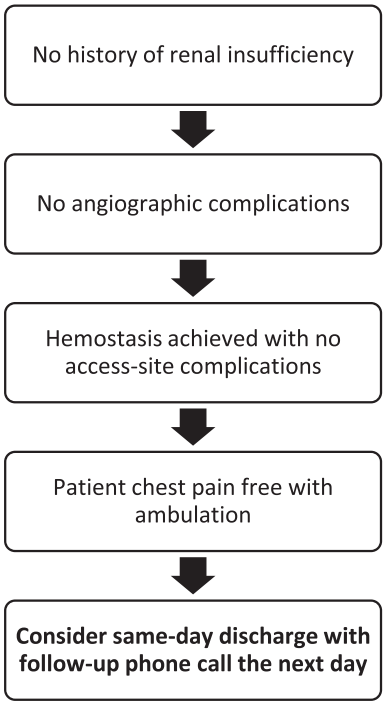

Fig. 1. Screening criteria for same-day discharge following orbital atherectomy. Screening criteria for identification of patients who may be candidates for same-day discharge following orbital atherectomy.

from improving patient comfort, appropriate same-day discharge after PCI improves costs and is feasible after orbital atherectomy.

There are several important study limitations. This was a retrospective analysis with limited follow-up. Patients with SDD were not compared with those hospitalized, as they were pre-selected by the operator as suitable for same-day discharge and inherently represented a lower risk cohort than those the treating physician decided to hospitalize for at least one night as opposed to sending home due to procedural complications, increased perceived risk or co-morbidities. The decision for SDD was at the operator's discretion and therefore subject to selection bias. As a result of the inherent bias, the clinical outcomes of patients with SDD were not compared with those who were admitted in this study. Imaging was not reviewed by a core laboratory and the diagnosis of severe coronary artery calcification was left to the operator's discretion, as is routine in clinical practice. Cardiac biomarkers were not obtained on all patients post-PCI, which likely led to the under-diagnosis of periprocedural myocardial infarction.

5. Conclusion

Same-day discharge after orbital atherectomy appears to be safe, and is associated with low rates of adverse events and readmissions in select patients. In patients with SDD, readmission occurred in 8.5%, which is below the NYS average 30-day PCI readmission rate (9.85%). Larger studies are needed to confirm the safety of this treatment paradigm and assess the potential cost savings.

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