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Cost-effectiveness analysis of the orbital atherectomy system: Two-year follow-up☆,☆☆

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ABSTRACT

Background: The presence of coronary artery calcification is associated with a significant burden of coronary artery disease along with being a predictor of increased adverse ischemic events. The Diamondback 360® Coronary Orbital Atherectomy System (OAS) is a novel device designed to facilitate treatment of calcified lesions. This study aimed to evaluate the cost-effectiveness of OAS compared to standard treatment.
Methods: A decision tree model utilizing ORBIT II clinical trial and Medicare data from the health system perspective was constructed. Target population was U.S. patients age ≥ 65 with coronary atherosclerosis due to a calcified coronary lesion, both inpatients and outpatients, and combined over a time horizon of two years for costs and lifetime for mortality. OAS was compared to standard treatment (use of balloon angioplasty to prepare stent-placement site). Outcomes were costs of index event and target vessel revascularization in two years, life–years gained, and incremental cost-effectiveness ratios (ICERs).
Results: On average, OAS was projected to cost $1702 less than standard treatment for inpatients, $2360 more than standard treatment for outpatients, and $959 more than standard treatment overall; the projected mortality reduction implies 0.41 life–years gained. Compared to standard treatment, OAS was dominant in an inpatient setting, had an ICER of $5759 per QALY in the outpatient setting, and had an ICER of $2340 per QALY overall. These ICERs are below the accepted threshold for highly cost-effective interventions of $50,000 per QALY.
Conclusions: Compared to standard treatment, OAS is likely to be cost-effective and was projected to be cost-saving in an inpatient setting.
Summary: A decision tree from the health system perspective was used to evaluate the cost-effectiveness of Diamondback 360® Coronary Orbital Atherectomy System (OAS), a novel device designed to facilitate treatment of calcified lesions. OAS was projected to cost $1702 less than standard treatment for inpatients, $2360 more than standard treatment for outpatients, and $959 more than standard treatment overall; the projected mortality reduction implies 0.41 life–years gained. Compared to standard treatment, OAS was dominant in an inpatient setting, had an ICER of $5759 per QALY in the outpatient setting, and overall had an ICER of $2340 per QALY.

1. Background

Coronary artery calcification (CAC) is a well-established risk factor for the occurrence of adverse ischemic events, generating an annual burden of illness approaching $1.3 billion among patients undergoing a percutaneous coronary intervention (PCI) [1]. In October 2013, the U.S. Food and Drug Administration (FDA) approved the Diamondback 360® Coronary Orbital Atherectomy System (OAS) technology for coronary use. The covered indication is "to facilitate stent delivery in patients with coronary artery disease who are acceptable candidates for percutaneous transluminal coronary angioplasty or stenting due to *de novo*, severely calcified coronary artery lesions [2]."

A previous analysis which evaluated the potential cost-effectiveness of OAS projected it to be cost-saving and life-saving compared to standard treatment [3]. That study was based on one-year outcomes in the pivotal ORBIT II clinical trial as well as Medicare data. Recently, two-year results of the ORBIT II trial were reported. In this study, we

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evaluated the two-year potential cost-effectiveness of OAS with Medicare data and also compared to standard treatment for severely calcified lesions, which is the use of balloon angioplasty to prepare the stent-placement site, using additional data.

2. Methods

The target population for this analysis was patients in the U.S. age 65 or over who experienced an index event, defined here as a *de novo* PCI. Those particular patients were diagnosed with coronary atherosclerosis due to a calcified coronary lesion (ICD-9 code 414.4). Patients with a CABG or PCI within six months prior to the index event were excluded.

We evaluated the costs and outcomes of OAS compared to standard treatment. OAS included those who received the Diamondback 360® Coronary OAS in the pivotal single-arm clinical study, the ORBIT II trial [4–6], conducted at 49 U.S. sites. Because the clinical trial did not include a comparator population, standard treatment included Medicare beneficiaries [7] in the target population with an index event between October 1, 2011 and December 31, 2013. Appreciating the current substantial under-coding of coronary calcification, we opted to utilize data obtained from "top coding hospitals" as more reflective of the prevalence of true coronary calcification in the Medicare population. The 65 top coding hospitals were those that reported at least 10% of the patients diagnosed with coronary atherosclerosis as having coronary atherosclerosis due to a calcified coronary lesion. Standard treatment patients generally underwent balloon angioplasty without atherectomy to prepare the stent placement site, though a small percentage of cases may have used a rotational atherectomy device, which is not coded in the claims data [8].

The time horizon for this analysis was two years for costs and lifetime of the patient for health outcomes. A discount rate of 3% per year was applied to health outcomes, which is the standard practice in cost-effectiveness analyses with a lifetime patient horizon in the U.S. [9].

2.1. Health outcomes

The health outcome of each intervention was all-cause mortality within two years of the index event. Disease-specific mortality data are unavailable in the Medicare Statistical Analytical Files claims data; therefore, all-cause mortality was compared using the ORBIT II and Medicare data. Probability of surviving the two years following index event was applied to the expected remaining life–years for the target population to calculate life–years gained.

2.2. Costs

Costs included (1) cost of the index event, and (2) cost of any subsequent target vessel revascularization (TVR) within two years of the index event. Costs of index event were derived from ORBIT II for inpatients and outpatients receiving OAS, and from Medicare data for inpatients and outpatients receiving standard treatment. Index event costs included only costs related to the PCI. For subsequent costs, only costs of TVR were included. TVR rate for OAS patients was obtained from Kaplan–Meier based estimates from the ORBIT II data. Medicare reports total revascularization rate, but not TVR. In order to approximate TVR rate in the standard treatment population, we applied the ratio of TVR to total revascularization from the ADAPT-DES study [10,11] to the total revascularization rate in the Medicare target population. Cost of a revascularization event was obtained from Medicare data.

The manufacturer's suggested list price of the OAS device in this analysis was $3795 and did not vary in the analysis. It is a disposable, one-time use device. Cost estimates associated with each intervention were derived from the health system perspective.

2.3. Economic model

We constructed a simple decision tree to compare costs and health outcomes of each intervention (Fig. 1). Patients were in either the OAS or standard treatment arm, and then could have a TVR, death, or neither within two years of the index event. We assumed that there was no difference in mortality between those with and without a TVR, and that death or TVR occurred immediately following the index event. For each arm (OAS and standard treatment) we calculated expected costs and expected remaining life–years. We believe there may be important differences in populations and costs for inpatients *versus* outpatients; therefore, we chose to model these patients separately. The model calculated results for inpatients only, outpatients only, and all patients combined. We then computed an incremental cost-effectiveness ratio

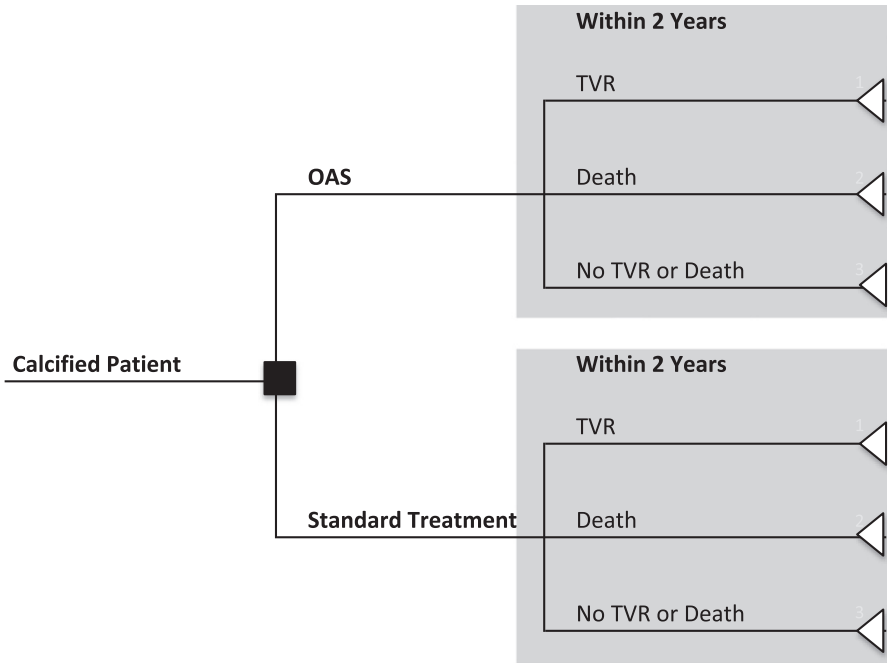

Fig. 1. Simple decision tree representing costs and outcomes of OAS compared to standard treatment.

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