Health Technology Assessment in India (HTAIn)

Health Technology Assessment of Rotational Atherectomy for Undilatable Lesions

2023

Supervised by:

Dr. Ayush Lohiya

Dr. Manish Kumar Singh

Compiled by:

Dr. Pooja Dwivedi

Dr. Dahy Sulaiman

Health Technology Assessment (HTA) Resource Hub

(Funded by Department of Health Research, Ministry of Health & Family Welfare, Government of India)

Department of Public Health

Kalyan Singh Super Specialty Cancer Institute (KSSSCI)

Lucknow, Uttar Pradesh (India)

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List of Abbreviations

CAD	Coronary artery disease
DALYs	Disability Adjusted Life Years
CTO	Chronic total occlusions
MI	Myocardial infarction
RA	Rotational atherectomy
CABG	Coronary artery bypass graft
DES	Drug-eluting stent
PTCA	Percutaneous transluminal coronary angioplasty
PES	Paclitaxel-eluting stent
TVR	Target vessel revascularization
MB	Modified balloons
POBA	Plain old balloon angioplasty
CBA	Cutting-balloon angioplasty
HCCL	Heavily calcified coronary lesions
MACE	Major Adverse cardiac events
ICER	Incremental cost-effectiveness ratio

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Introduction

Coronary artery disease (CAD) is a common heart condition that involves atherosclerotic plaque formation in the vessel lumen leading to an inadequate supply of blood and oxygen to the myocardium (Shahjehan RD, 2022). The disease is very common in both developed and developing worlds (Shahjehan RD, 2022). CAD is the foremost single cause of mortality and loss of Disability Adjusted Life Years (DALYs) globally (Ralapanawa, U, 2021). Much of the mortality burden falls on low and middle-income countries accounting for nearly 7 million deaths and 129 million DALYs annually (Ralapanawa, U, 2021).

The treatment of CAD is highly dependent on percutaneous coronary intervention (PCI) along with medical management (Iftikhar SF, 2022). PCI techniques have advanced significantly over time and are used to stent even difficult lesions (Iftikhar SF, 2022). There are, however, some lesions that present challenges via the conventional PCI route (Iftikhar SF, 2022). These lesions, termed complex coronary lesions, are categorized as such based on various anatomic, physiological, or functional difficulties (Iftikhar SF, 2022). Four specific coronary anatomic features are commonly considered to be markers of interventional procedural complexity: 1) the presence of calcium; 2) severe tortuosity; 3) high thrombus content; and 4) diffuse atherosclerotic burden with the variable caliber and an absence of a plaque-free landing zones, to facilitate safe stent placement (De Maria, G. L., 2019). Of these, lesions with high calcium content are probably the most challenging and most likely to impact adversely on both the acute and the long-term results of PCI (De Maria, G. L., 2019). Some of the complex lesions in coronary vessels include bifurcation lesions, calcified lesions, chronic total occlusions (CTO), unprotected left main coronary artery lesions, ostial lesions, or stenosis of the saphenous vein graft (Truesdell A G, 2020; Wilensky R L, 2002).

Moderate-to-severe coronary calcification is encountered in up to one-third of coronary lesions, is commonly associated with a greater degree of lesion complexity to include coronary bifurcations and chronic total occlusions and is expected to increase in prevalence with increasing patient age, chronic kidney disease, and diabetes (Truesdell A G, 2020). Heavily calcified lesions are difficult to dilate and are associated with complications like coronary dissection and perforation, failure to deliver stents, stent under expansion and malposition, polymer disruption and impaired drug delivery with drug-eluting stents, and higher rates of target lesion failure, restenosis, stent thrombosis, myocardial infarction (MI), and death

(Truesdell A G, 2020). The incidence of coronary calcification at 93% for men aged over 70 years and 77% for women aged greater than 70 (Goel M, 1992).

Uncross able lesions are those that cannot be crossed with a balloon after successful guidewire crossing (McQuillan C, 2021). These lesions are challenging and are commonly encountered in day-to-day PCI, particularly in tortuous and calcified arteries as well as chronic total occlusions (CTO) (McQuillan C, 2021). Uncross able lesions are encountered in up to 9% of all CTO interventions and are the second most common barrier to successful PCI in CTO intervention after the inability to cross the CTO segment with a guidewire (McQuillan C, 2021). Once the lesion has been crossed, it is essential to get adequate lesion preparation prior to stent implantation (McQuillan C, 2021). Stent deployment prior to effective lesion preparation leaves limited and challenging therapeutic interventions to achieve a good result if the stent remains under expanded (McQuillan C, 2021).

Rationale

Rotational atherectomy (RA) is a lesion preparation technique (McQuillan C, 2021; Truesdell A G, 2020). The long-term effect of introducing rotational atherectomy in moderate-severely calcified undilatable lesions compared with cardiac stenting and/or balloon angioplasty needs evidence synthesis. The existing literature indicates that the cost-effectiveness of rotational atherectomy is very less, especially in the Indian context. To fill this gap, there is a need to generate evidence regarding the clinical and cost-effectiveness of rotational atherectomy in India which will aid in policymaking.

Aim

The review aims to compare the clinical and cost-effectiveness of rotational atherectomy for undilatable lesions in coronary artery disease.

Objectives

1. To compare the clinical outcomes of rotational atherectomy with cardiac stenting/balloon angioplasty, in calcified undilatable lesions of the coronary artery.
2. To evaluate the cost-effectiveness of rotational atherectomy with cardiac stenting/balloon angioplasty, in calcified undilatable lesions of the coronary artery.

Methodology

Study design

A narrative review was conducted.

Study duration

June 2022 to September 2022.

Inclusion and exclusion criteria

Population

Coronary artery disease (CAD) patients with moderate - severely calcified/ undilatable lesions undergoing percutaneous transluminal coronary angioplasty (PTCA).

Intervention

Rotational atherectomy

Comparators

For primary objective:

1. Cardiac stenting
2. Balloon angioplasty
3. Cardiac stenting/balloon angioplasty

Outcome

a) ***Clinical effectiveness study****:*

Outcomes were assessed at 6 months or later

1. Major adverse cardiovascular events (MACE)
2. Instant revascularization
3. Repeat revascularization

b) ***Cost-effectiveness study:***

1. Cost of treatment
2. Life years gained (LY)
3. Incremental cost-effectiveness ratio (ICER)

Data sources and searches

The search strategy was done in following steps in the review:

1. The initial search was done through PubMed, where terms such as “rotablation”, “atherectomy”, “calcified lesions”, and “undilatable lesions” was used through Boolean operators like AND, OR, and NOT for the retrieval of the initial few articles.
2. This search was followed by an exploration of the MeSH words and text words contained in the titles and abstracts.
3. Furthermore, articles describing index terms were also assessed. Subsequent searches using all identified keywords and index terms were then carried on to PubMed, Cochrane Library, and Google Scholar.
4. Additionally, the reference list of all identified papers, reports, and articles were explored for bibliographic search. Studies published till July 2022 fitting the inclusion criteria were included in the review.

Types of study to be included

Any observational and experimental study fitting the inclusion criteria was taken for review.

Data synthesis

All studies fitting the inclusion criteria were included in the study. The studies were grouped into following categories:

1. **Clinical effectiveness studies:** The studies where the outcome was MACE or instant revascularization or repeat revascularization were grouped into this category.
2. **Systematic reviews:** In this section, we described all the systematic reviews related to this topic.
3. **Cost-effectiveness:** The studies where the outcome was cost of treatment or life years gained or ICER were grouped into this category.

Ethical Justification

There was no primary data collection involved in the study. Data from available literature was used and henceforth, ethical approval was not required.

Results

Search results and characteristics

After conducting a thorough search on RA from multiple sources, a total of 12 articles were obtained. Out of these, 11 articles were identified as potentially relevant for the clinical effectiveness review following a careful screening of their titles and abstracts. These studies were conducted in Germany and/or the United States and included six trials, one sub-group analysis of a trial, three systematic reviews, and an observational study. Furthermore, we retrieved one article for the cost-effectiveness review, which was conducted in Japan.

Clinical effectiveness

1. ROTAXUS trial

The ROTAXUS trial was conducted by Abdel-Wahab and his colleagues in 2013, in Germany to determine the effect of rotational atherectomy (RA) on drug-eluting stent (DES) effectiveness among patients with documented myocardial ischemia and complex calcified native coronary artery lesions. In this trial, rotablation followed by stenting was compared to stenting without prior rotablation as standard therapy.

Findings from the study:

After 9 months of follow-up, the overall mortality was not significantly different between the two groups. In the group that received RA along with paclitaxel-eluting stent (PES), overall mortality was 5.0%, while in the standard therapy group, it was 5.8%. Similarly, the rates of myocardial infarction (MI) and target vessel revascularization (TVR) were not significantly different between the two groups. MI occurred in 6.7% of patients in the RA + PES group compared to 5.8% in the standard therapy group, while TVR occurred in 16.7% of patients in the RA + PES group compared to 18.3% in the standard therapy group resulting in a cumulative major adverse cardiac events rate of 24.2% versus 28.3%, respectively. In-stent binary restenosis, target lesion revascularization, definite stent thrombosis, and major adverse cardiac events were similar in both groups. The RCT concluded that routine rotablation before PES implantation in complex calcified coronary lesions was not superior to PES implantation without rotablation, indicating that rotablation does not increase the efficacy of drug-eluting stent in calcified lesions.

2. PREPARE-CALC trial

The PREPARE-CALC was conducted by Abdel-Wahab and his colleagues in 2018, in Germany to assess the comparative performance of RA and modified balloons (MB) strategies in a randomized trial conducted in patients with severely calcified coronary lesions receiving current-generation DES. In this trial, MB (cutting or scoring) followed by DES implantation was compared to RA followed by DES implantation.

Findings from the study:

The overall mortality rate was found to be the same (2%) in both RA and MB groups at 9 months. However, between the time of discharge and the 9-month follow-up, two patients in the MB group experienced a spontaneous MI while none occurred in the RA group. Although clinically indicated TVR rates were twice as high in the MB group, the event rates were low and not statistically significant between both groups. The trial concluded that lesion preparation with upfront RA before DES implantation is feasible in nearly all patients with complex calcified coronary lesions and is more commonly successful as a primary strategy compared with MB. The strategy of provisional MB remains feasible, safe, and effective as long as bailout RA is readily available and may offer the advantages of compatibility with smaller-sized catheters, relatively shorter procedural time, and less irradiation.

3. ERBAC trial

ERBAC trial was conducted by Reifart and his colleagues in 1997, in Germany to test whether coronary revascularization with ablation of either excimer laser or rotational atherectomy can improve the initial angiographic and clinical outcomes compared with dilatation (balloon angioplasty) alone among patients with type B or type C de novo stenoses in the native coronary arteries.

Findings from the study:

During the 6-month follow-up, revascularization of the original target lesion was performed more often in the rotational atherectomy group (42.4%) and the excimer laser group (46.0%) than in the angioplasty group (31.9%). Out of the total number of patients, 70 patients (36.6%) underwent angioplasty, 101 patients (47.9%) underwent excimer laser, and 94 patients (45.9%) who underwent RA, reached a clinical endpoint, which included death, Q-wave myocardial infarction, coronary bypass surgery, or repeated angioplasty. The three-group comparison showed no significant difference (p=0.57); however, when comparing PTCA with ELCA, the difference was significant (p=0.015), and the difference was also significant when comparing PTCA with RA (p=0.04). The trial concluded that the procedural success of RA is superior to laser angioplasty and balloon angioplasty, however, it does not result in better late outcomes.

4. DART trial

DART trial was conducted by Mauri and colleagues in 2003 in the United States to assess the incidence of target vessel failure after rotational atherectomy compared with conventional balloon angioplasty of lesions in small coronary arteries in patients having a target lesion on angiography of 70% diameter stenosis and evidence of myocardial ischemia caused by the target lesion.

Findings from the study:

At 360 days, the incidence of MACE was comparable between the rotational atherectomy arm (26%) and the balloon angioplasty arm (25%). In both arms, most of the events were due to target lesion revascularization. There were no cases of Q-wave myocardial infarction in either treatment arm, but there were 5 cases (2.2%) of non-Q-wave myocardial infarction in the rotational atherectomy arm compared to 3 cases (1.4%) in the balloon angioplasty arm. The balloon angioplasty arm had a higher number of deaths (5 or 2.3%) than the rotational atherectomy arm (2 or 0.9%). The primary endpoint of the study was target vessel failure at 360 days which was similar in the rotational atherectomy arm (30.5%) and the balloon angioplasty arm (31.2%). The trial concluded that rotational atherectomy was not superior to conventional balloon angioplasty in preventing restenosis in small coronary vessels. Although rotational atherectomy was deemed safe for treating obstructed small arteries, it did not result in lower rates of target vessel failure compared to balloon angioplasty.

5. COBRA trial

The COBRA trial was conducted by Dill and colleagues in 2000 in Germany to compare short- and long-term effects of percutaneous transluminal coronary angioplasty (PTCA) and rotablation in patients with angiographically pre-defined complex coronary artery lesions

Findings from the study:

At 6 months, there was no difference in the symptomatic outcome, restenosis rates, and target vessel re-interventions between patients who underwent PTCA (51%) and those who underwent rotablation (49%). However, premature angiograms were performed more frequently in the angioplasty group than in the rotablator group. Target vessel revascularizations were necessary for 23% of patients in the angioplasty group and 21% of patients in the rotablator group, and 6.5% and 4.2%, respectively, required bypass surgery. Only 63.8% of patients who underwent angioplasty and 59.4% of patients who underwent rotablation were free of angina (CCS class 1) or had mild angina (20.8% and 30.7%, respectively). Exercise tolerance did not differ significantly between the treatment groups. The study concluded that complex coronary artery lesions can be treated with a high level of success and low complication rates either by PTCA with adjunctive stenting or rotablation and their long-term clinical outcome is comparable.

6. ADAPT-DES trial

The ADAPT-DES trial was conducted by Redfors and colleagues in 2017 in Germany and the United States to report adverse event rates after RA with contemporary drug-eluting stent (DES) implantation and compare RA to cutting balloon (CB) angioplasty and balloon-only angioplasty (BA) in the all-comers ADAPT-DES trial among patients with moderate or severe coronary calcification and who received only second-generation DESs.

Findings from the study:

During the 2-year study period, it was found that 20.8% of the RA patients, 24.1% of the CB patients, and 17.9% of the BA patients experienced Target-vessel failure (TVF), which was mainly due to target-vessel revascularization, accounting for 13.8%, 11.4%, and 10.2% respectively. Notably, RA patients with acute coronary syndromes exhibited slightly higher 2-year TVF rates compared to RA patients with stable coronary artery disease. The trial concluded that adverse ischemic events are common after contemporary PCI of calcified lesions regardless of whether RA is used.

7. Subgroup analysis from the PREPARE-CALC trial

Hemetsberger and colleagues conducted a subgroup analysis from the randomized PREPARE-CALC trial in Germany in 2021 to investigate the impact of calcified lesion complexity on the treatment effect with either MB or RA among patients with severely calcified coronary artery lesions.

Findings from the study:

The success rate of using RA was found to be higher than MB in patients with at least one Type-C lesion, but this advantage was not seen in patients with non-type-C lesions. Bail-out RA was required more frequently in patients with Type-C lesions than those with non-type-C lesions. Interestingly, lesion complexity and the upfront lesion preparation strategy did not have a significant impact on target lesion revascularization at 9 months. The study concluded that for patients with calcified non-Type-C lesions, the success rates of using RA or MB before DES implantation are similar. However, in the case of Type-C lesions, the upfront use of RA appears to be a superior strategy.

8. Tian W et. al, 2015

The observational study conducted by Tian and colleagues in the United States in 2015 was to compare the clinical outcomes of lesion preparation with rotational atherectomy (ROTA), plain old balloon angioplasty (POBA), or cutting-balloon angioplasty (CBA) in patients with heavily calcified coronary lesions (HCCL) who were treated with DES.

Findings from the study:

At the 12-month follow-up, the results for all-cause death were 9.8% for RA, 8.2% for POBA, and 4.5% for CBA. The incidence of cardiac death was 3.1% for RA, 2.5% for POBA, and 1.3% for CBA. The occurrence of Q-wave MI was not found for patients treated with RA or POBA, but 0.7% for those treated with CBA. The incidence of TLR was 5.2% for RA, 3.5% for POBA, and 3.9% for CBA. None of the patients treated with RA or POBA experienced ST during the study, while 0.6% of patients treated with CBA did. The occurrence of MACE was higher for patients treated with RA (14.6%) and POBA (12.3%) compared to CBA (8.3%). The study found that the 1-year MACE-free survival rates were also similar among the three cohorts. The study concludes that using RA, POBA, or CBA for lesion preparation in HCCL may result in similar clinical outcomes in patients undergoing percutaneous intervention with DES. However, it should be noted that the RA group had a slightly higher trend in MACE, death, and TLR compared to the other groups.

Table 1 Trials and observational studies

No	Author, Year	Objective	Patients	Intervention	Comparator	Outcome	Results
1	Abdel-Wahab M et. al, 2013 (ROTAXUS trial)[1]	To determine the effect of rotational atherectomy (RA) on drug-eluting stent (DES) effectiveness.	Patients with documented myocardial ischemia and complex calcified native coronary artery lesions.	Rotablation followed by stenting	Stenting without prior rotablation (standard therapy)	9 months' outcomes – clinical and angiographic follow-up (In-stent late lumen loss (LLL), Death, MI, TVR, MACE, stent thrombosis, in-segment LLL, binary restenosis, angiographic success, strategy success, procedural duration, and contrast amount)	At 9 months, in-stent late lumen loss was higher in the rotablation group (0.44 $\pm$ 0.58 vs. 0.31 $\pm$ 0.52, p = 0.04), despite an initially higher acute lumen gain (1.56 $\pm$0.43 vs. 1.44 $\pm$ 0.49 mm, p = 0.01). In-stent binary restenosis (11.4% vs. 10.6%, p = 0.71), target lesion revascularization (11.7% vs. 12.5%, p = 0.84), definite stent thrombosis (0.8% vs. 0%, p = 1.0), and major adverse cardiac events (24.2% vs. 28.3%, p = 0.46) were similar in both groups.
2	Abdel-Wahab M et. al, 2018 (PREPARE-CALC trial)[2]	To assess the comparative performance of the strategies conducted in patients with severely calcified coronary lesions receiving current-generation DES.	Patients with myocardial ischemia and severely calcified native coronary artery lesions	Modified Balloons (cutting or scoring) followed by DES implantation	RA followed by DES implantation	Clinical outcome at 9months- Death (Cardiac and non-cardiac), MI, (Target vessel, Periprocedural, Spontaneous), Stent thrombosis, TLR, TVR, clinically indicated TVR, Any revascularization, Target vessel failure.	Two hundred patients were enrolled at 2 centres in Germany (n=100 in each treatment group). At 9 months, mean in-stent late lumen loss was 0.16±0.39 mm in the MB group and 0.22±0.40 mm in the RA group (P=0.21, P=0.02 for no inferiority). Target lesion revascularization (7% versus 2%; P=0.17), definite or probable stent thrombosis (0% versus 0%; P=1.00), and target vessel failure (8% versus 6%; P=0.78) were low and not significantly different between the MB and RA groups.
3	Reifart, N. et.al, 1997 (ERBAC trial)[3]	To test whether ablation of either excimer laser or rotational atherectomy can	Patients with type B or type C de novo stenosis in the native	Excimer Laser, Rotational Atherectomy (coronary revascularization with	Balloon Angioplasty (dilatation alone)	Late Clinical Follow-up - composite clinical end point (0 to 360 days) (whichever event occurred 1st -death, Q-wave myocardial infarction, target lesion	At the 6-month follow-up, revascularization of the original target lesion was performed more frequently in the rotational atherectomy group (42.4%) and the excimer laser group (46.0%) than in the angioplasty group (31.9%, P = .013).

No	Author, Year	Objective	Patients	Intervention	Comparator	Outcome	Results
		improve the outcomes compared with dilatation (balloon angioplasty) alone.	coronary arteries	ablation of either excimer laser or rotational atherectomy)		revascularization or bypass surgery	
4	Mauri L et. al, 2003 (DART trial) [4]	To assess the incidence of target vessel failure after rotational atherectomy compared with conventional balloon angioplasty of lesions in small coronary arteries.	Patients having a target lesion on angiograph y of 70% diameter stenosis and evidence of myocardial ischemia caused by the target lesion.	Conventional balloon angioplasty	Rotational atherectom y	Primary endpoint- target vessel failure at 12 months secondary end points- acute procedural success, acute device success, binary angiographic restenosis, target lesion revascularization, target vessel revascularization, myocardial infarction,	At 8 months, there were no significant differences in minimum lumen diameter (1.28 +/- 0.63 mm vs 1.19 +/- 0.54 mm, P =.26), percent diameter stenosis (28% +/- 12% vs 29% +/- 15%, P =.59), binary restenosis rate (50.5% vs 50.5%, P = 1.0), or late loss index (0.57 vs 0.62, P =.7). No Q-wave myocardial infarctions occurred in either arm of the study, and non-Q-wave myocardial infarctions (defined as creatine kinase level >2 times normal with an elevated creatine kinase-myocardial band isoenzyme level) occurred in 2.2% and 1.4% of the patients in the rotational atherectomy and balloon angioplasty groups, respectively (P =.72).
5	Dill T et. al, 2000 (COBR A study) [5]	To compare effects of percutaneous transluminal coronary angioplasty (PTCA) and rotablation in patients with angiographicall	Patients with coronary artery disease and clinical symptoms of angina or angina-	Percutaneous transluminal coronary angioplasty (PTCA)	Rotational atherectom y	6 months restenoses in the treated segment, major cardiac events during the follow-up period. Secondary end-points- clinical outcome, exercise tolerance scale	At 6 months, symptomatic outcome, target vessel reinterventions and restenosis rates (PTCA 51% versus rotablation 49%, P=0.33) were not different.

No	Author, Year	Objective	Patients	Intervention	Comparator	Outcome	Results
		y pre-defined complex coronary artery lesions.	equivalent symptoms				
6	Redfors B et. al, 2017 (ADAPT-DES trial) [6]	To report adverse event rates after rotational atherectomy (RA) with contemporary drug-eluting stent (DES) implantation and compare RA to cutting balloon (CB) angioplasty and balloon-only angioplasty (BA) in the all-comers ADAPT-DES trial.	Patients with moderate or severe coronary calcification and who received only second-generation DESs	(1) Patients in whom RA was used for lesion preparation	(2) Patients in whom no RA was used but a CB was used (3) Patients who had balloon-only angioplasty	Target-vessel failure (TVF, defined as any death, myocardial infarction, or target-vessel revascularization [TVR]) MACE, (defined as any cardiac death, myocardial infarction, or stent thrombosis), death, myocardial infarction, stent thrombosis, and TVR	Among the 2644 patients, RA and CB were used in 150 patients (5.7%) and 53 patients (2.0%), respectively. TVF occurred in 20.8% of the RA patients, 24.1% of the CB patients, and 17.9% of the BA patients over the 2-year study period (P=.41) and was primarily driven by target-vessel revascularization (13.8%, 11.4%, and 10.2%, respectively). RA patients with acute coronary syndromes had nominally higher 2-year TVF rates than RA patients with stable coronary artery disease.
7	Hemetsberger, R et. al, 2021 (Subgroup-analysis from PREPA	To investigate the impact of calcified lesion complexity on the treatment effect with either MB or RA.	Patients with severely calcified coronary artery lesions.	Modified balloon (MB) – (Type-C and non-type-C lesions)	Rotational atherectomy (RA) – (Type-C and non-type-C lesions)	Need for bail-out RA, acute lumen gain, and late lumen loss (LLL) at 9 months.	The need for bail-out RA was higher in patients with Type-C lesions (n = 15) as compared with non-Type-C lesions. Acute lumen gain, LLL, and target lesion revascularization at 9 months were not dependent on lesion complexity and upfront lesion preparation strategy.

No	Author, Year	Objective	Patients	Intervention	Comparator	Outcome	Results
	RE-CALC) [7]						
8	Tian W et. al, 2015 (Observational) [8]	To compare the clinical outcomes of lesion preparation with rotational atherectomy, plain old balloon angioplasty, or cutting-balloon angioplasty in patients with HCCL who were treated with DES.	Patients undergone RA, POBA, CBA for Heavily calcified coronary lesions	(1) RA	(2) Plain old balloon angioplasty (POBA) (3) Cutting-balloon angioplasty (CBA)	1-month, 6-month, and 12-month rates of death, Q-wave myocardial infarction (MI), target-lesion revascularization (TLR), definite stent thrombosis (ST), and major adverse cardiac event (MACE), defined as the composite of death, Q-wave MI, or TLR.	The 12-month results were all-cause death (RA = 9.8%; POBA = 8.2%; CBA = 4.5%; P=.18), cardiac death (RA = 3.1%; POBA = 2.5%; CBA = 1.3%; P=.61), Q-wave MI (RA = 0%; POBA = 0%; CBA = 0.7%; P>.99), TLR (RA = 5.2%; POBA = 3.5%; CBA = 3.9%; P=.76), ST (RA = 0%; POBA = 0%; CBA = 0.6%; P=.63) and MACE (RA = 14.6%; POBA = 12.3%; CBA = 8.3%; P=.20). The 1-year MACE-free survival rates were also similar among the three cohorts (log-rank P=.20).

Systematic reviews

1. Goel S et. al, 2020

A systematic review and meta-analysis conducted by Goel and colleagues in 2020 compared the performance of orbital atherectomy (OA) versus RA in patients with calcified coronary artery disease (CAD) undergoing PCI, including five articles.

Findings from the study:

The study compared the 30-day outcomes between patients treated with OA and RA for calcified CAD undergoing PCI. There was no statistically significant difference observed in the 30-day mortality or the incidence of MI, TVR, and MACE between the two groups. However, the study did find that OA was associated with a lower fluoroscopy time compared to RA. In summary, the study concluded that OA and RA had similar procedural, peri-procedural, and thirty-day outcomes, with the exception of lower fluoroscopy time for OA among patients with calcified CAD undergoing PCI.

2. Khan, A. A. et. al, 2020

A systematic review and meta-analysis conducted by Khan and colleagues in the year 2020 compared the short and long-term outcomes of patients undergoing RA versus OA in heavily calcified coronary vessels, including 8 articles.

Findings from the study:

The study found no significant differences in MACE, MI, all-cause mortality, or TVR between OA and RA. However, OA was associated with lower long-term MACE rates (at 1 year), lower long-term TVR rates, and lower short-term MI rates (during hospitalization and at 30 days) compared to RA. On the other hand, OA was noted to have a higher incidence of coronary artery dissections and device-related coronary perforations compared to RA. Additionally, the study found that OA was associated with significantly lower fluoroscopy time compared to RA. In conclusion, the study suggests that although there were no differences in MACE, MI, all-cause mortality, or TVR, OA may have some advantages over RA in terms of lower long-term MACE and short-term MI rates, as well as lower fluoroscopy time.

3. Bittl, J. A. et. al., 2004

A meta-analysis conducted by Bittl and colleagues in the year 2004 evaluated the randomized trials of balloon angioplasty versus coronary atherectomy, laser angioplasty, or cutting balloon atherectomy to evaluate the effects of plaque modification during the percutaneous coronary intervention, including 16 trials.

Findings from the study:

Among the included trials, MI rates remained significantly higher in the ablative group than in the coronary angioplasty group up to one year after treatment in the 15 studies that reported long-term event rates. However, cumulative long-term death rates were not significantly different between the ablative group and the coronary angioplasty group. No significant improvement in cumulative MACE was seen for ablative devices compared to coronary angioplasty up to one year after treatment. The overall rate of MACE was 27.8% in the ablative group and 26.1% in the coronary angioplasty group. The study concludes that ablative devices did not achieve predefined clinical and angiographic outcomes, and the meta-analysis does not support the hypothesis that routine ablation or sectioning of atheromatous tissue is beneficial during percutaneous coronary interventions.

Table 2 Systematic Reviews

No	Author, Year	Objective	Population/Patient	Comparator	Outcome	Results
1	Goel S et. al, 2020[9]	To compare OA versus RA in patients with calcified coronary artery disease (CAD) undergoing PCI.	Patients with calcified coronary artery disease undergoing PCI.	Orbital atherectomy Vs rotational atherectomy	• The endpoints assessed were: 1. Thirty-day outcomes include all-cause mortality, MI, TVR, and MACE.	A total of five observational studies (total number of patients=1872; OA=535, RA=1337) were included in the final analysis. There was no difference between the two techniques in terms of in-hospital mortality, 30-day mortality, 30-day MI, 30-day target vessel revascularization (TVR), and 30-day major adverse cardiovascular events (MACE).
2	Khan, A. A. et. al, 2020[10]	To compare the short and long-term outcomes of patients undergoing RA versus OA in heavily calcified coronary vessels	Patients undergoing RA and OA for calcified native coronary artery lesions	Orbital Vs Rotational Atherectomy	• Myocardial infarction (MI), all-cause mortality, major adverse cardiac events (MACE), target vessel revascularization (TVR), cardiac tamponade, coronary artery dissection, and device-induced perforation.	Eight observational studies were included in the analysis. Overall, there were no significant differences in Major-adverse-cardiac-events/MACE (OR: 0.81, CI: 0.63–1.05, p = .11), myocardial-infarction/MI (OR: 0.75, CI: 0.56–1.00, p = .05), all-cause mortality (OR: 0.82, CI: 0.25–2.64, p = .73) or Target-vessel-revascularization/TVR (OR: 0.72, CI: 0.38–1.36, p = 31). However, OA was associated with lower long-term MACE (1-year), (OR: 0.66, CI: 0.44–0.99, p = .04), long-term TVR (OR: 0.40, CI: 0.18–0.89, p = .03), and short-term MI (in-hospital and 30-day) (OR: 0.64, CI: 0.44– 0.94, p = .02).
3	Bittl, J. A. et. al., 2004[11]	To evaluate the effects of plaque modification during percutaneous coronary intervention.	Patients	Atherectomy, laser, or cutting balloon atherectomy versus balloon angioplasty	• Death, myocardial infarction (MI), and revascularization at an early time point (<31 days) and at a late time point (180 to 365 days).	Short-term death rates (<31 days) were not improved using ablative procedures (0.3% vs. 0.4%, odds ratio [OR] 0.94 [95% confidence interval 0.46 to 1.92]), but peri-procedural myocardial infarctions (4.4% vs. 2.5%, OR 1.83 [95% CI 1.43 to 2.34]) and major adverse cardiac events (5.1% vs. 3.3%, OR 1.54 [95% CI 1.25 to 1.89]) were increased. No reduction in revascularization rates (25.2% vs. 24.5%, OR 1.04 [95% CI 0.94 to 1.14]) or cumulative adverse cardiac events rates up to one year after treatment were seen with ablative devices (27.8% vs. 26.1%, OR 1.09 [95% CI 0.99 to 1.20]).

Cost-effectiveness

1. Pietzsch J B et. al., 2018

Pietzsch and colleagues conducted the study in the year 2018 to explore the potential cost-effectiveness of OA compared to RA treatment of severely calcified coronary artery lesions in the Japanese healthcare setting, based on the latest cost and clinical data. The study computed incremental cost-effectiveness in Japanese Yen (JPY) per life year (LY) gained based on differences in 1-year cost and projected long-term survival, assuming OA device cost between JPY 350,000 and JPY 550,000.

Findings from the study:

According to the study, the use of OA in the treatment of severely calcified coronary artery lesions was associated with improved clinical outcomes and projected survival gain, based on 1-year mortality. Moreover, the total 1-year costs were lower for devices with a cost of JPY 430,000 or less, and the highest incremental cost-effectiveness ratio (ICER) was JPY 753,445 per LY at the highest assumed device cost. As a result, OA was considered cost-effective or dominant across the range tested, with ICERs substantially below the willingness-to-pay threshold. Therefore, the study concludes that compared to rotational atherectomy, the use of OA for the treatment of severely calcified coronary artery lesions in the Japanese healthcare system is a cost-effective treatment approach due to its improved clinical performance.

Table 3 Cost-effectiveness studies

No	Author, Year	Country	Objective	Outcome	Results
1	Pietzsch J B, 2018 [12,13]	Japan	To explore the cost-effectiveness of OA compared to RA treatment of severely calcified coronary artery lesions in the Japanese healthcare setting, based on latest cost and clinical data	ICER	OA was found to be associated with improved clinical outcomes (12-month TLR rate 5.0 vs. 15.7%) and projected survival gain (8.34 vs. 8.16 Lys (+0.17), based on 1-year mortality of 5.5 vs. 6.8%). Total 1-year costs were lower for device cost of JPY 430,000 or less and reached a maximum ICER of JPY 753,445 per LY at the highest assumed device cost, making OA dominant or cost-effective across the tested range, at ICERs substantially below the willingness-to-pay threshold.

Summary and Conclusions

In terms of the studied clinical outcomes at 6 months or later time point, rotational atherectomy was not superior to other percutaneous transluminal coronary angioplasty (PTCA) procedures including cardiac stenting and balloon angioplasty, in calcified undilatable lesions of the coronary artery. Hence, the clinical effectiveness of rotational atherectomy over other PTCA procedures is not established. Since the clinical effectiveness of rotational atherectomy is not established, the primary cost-effectiveness analysis was not done for the Indian context.

There is no conclusive evidence regarding the clinical superiority (at 6-month post-procedure or later) of rotational atherectomy over other angioplasty procedures, in calcified undilatable lesions of the coronary artery. In the absence of clinical efficacy, cost-effectiveness analysis of rotational atherectomy is not recommended.

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