# Health Technology Assessment (HTA) of Percutaneous Transluminal Coronary Angioplasty (PTCA) with Rotational Atherectomy (RA)

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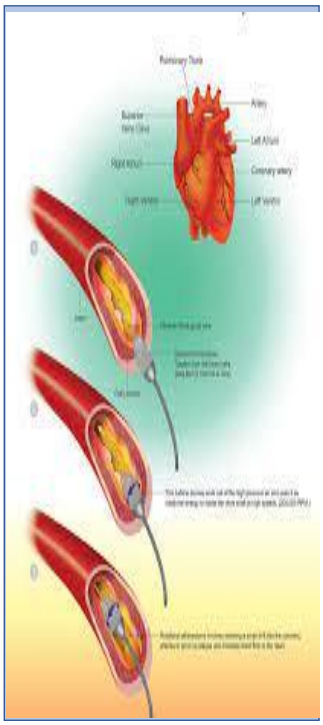
POLICY BRIEF

## Summary

- 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.
- This health technology assessment study aims to ccompare the clinical and cost-effectiveness of rotational atherectomy with cardiac stenting/balloon angioplasty, in calcified undilatable lesions of the coronary artery.
- 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.



## Policy Recommendations

- 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. Hence, the clinical effectiveness of rotational atherectomy over other PTCA procedures is not established.

**Background**

- Rotational atherectomy (RA) is a lesion preparation technique. 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.

**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.1

***Methodology***

*A narrative review was conducted for the duration June 2022 to September 2022.*

***Population***

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

***Intervention***

Rotational atherectomy

***Comparators***

Cardiac stenting

Balloon angioplasty

Cardiac stenting/balloon angioplasty

***Outcome***

*Clinical effectiveness study:*

Outcomes were assessed at 6 months or later

1.Major adverse cardiovascular events (MACE)

2.Instant revascularization

3.Repeat revascularization

***Results***

- 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.
- ROTAXUS trial was conducted in 2013. In this trial, rotablation followed by stenting was compared to stenting without prior rotablation as standard therapy. They found After 9 months of follow -up, the overall mortality was not significantly different between the two groups.
- ERBAC trial was conducted in 1997 to test whether coronary revascularization with ablation of either excimer laser or RA can improve the initial angiographic and clinical outcomes compared with dilatation (balloon angioplasty). They 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.
- 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. They also found cumulative long-term death rates were not significantly different between the ablative group and the coronary angioplasty group.

***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.