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# Safety and feasibility of rotational atherectomy (RA) versus conventional stenting in patients with chronic total occlusion (CTO) lesions: a systematic review and meta-analysis

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# **Abstract**

**Background and aim** Interventional cardiologists face challenges in managing chronic total occlusion (CTO) lesions, with conflicting results when comparing rotational atherectomy (RA) to conventional PCI. This meta-analysis aims to provide a critical evaluation of the safety and feasibility of RA in CTO lesions.

**Methods** PubMed, Scopus, Web of Science, Ovid, and Cochrane central library until April 2023 were searched for relevant studies. MACE was our primary outcomes, other outcomes were all cause of death, cardiac death, MI, and TVR. Also, we reported angiographic outcomes as technical success, procedural success, and procedural complications in a random effect model. The pooled data was analyzed using odds ratio (OR) with its 95% CI using STATA 17 MP.

**Results** Seven studies comprising 5494 patients with a mean follow-up of 43.1 months were included in this metaanalysis. Our pooled analysis showed that RA was comparable to PCI to decrease the incidence of MACE (OR=0.98, 95% CI [0.74 to 1.3], p=0.9). Moreover, there was no significant difference between RA and conventional PCI in terms of other clinical or angiographic outcomes.

**Conclusion** Our study showed that RA had comparable clinical and angiographic outcomes as conventional PCI in CTO lesions, which offer interventional cardiologists an expanded perspective when addressing calcified lesions.

PROSPERO registration CRD42023417362.

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# Keywords RA, CTO lesions, Non-CTO lesions, PCI

# Introduction

A chronic total occlusion (CTO) of coronary vessel is defined a complete blockage of the vessel, with no blood flow through the blocked segment according to the Thrombolysis in Myocardial Infarction (TIMI) grading system, and an estimated occlusion duration of  $\geq 3$  months [1–3]. CTOs are commonly seen in practice, accounting for approximately 20% of all patients referred for coronary angiography [4, 5]. Between 30 and 50% of patients with established coronary artery disease (CAD) have CTOs [5], and their prevalence is higher in patients who have undergone coronary artery bypass graft (CABG) surgery [4–6].

In general, percutaneous coronary intervention (PCI) for patients with CTO is a challenging procedure and requires not only patience during manipulation, but also requires experience with various instruments and interventional techniques [7, 8]. With the advent of hybrid treatment strategies, the recent success rate for treating CTO using conventional procedures has reached 60–92% when performed by skilled interventionists [9, 10]. However, heavily calcified stenoses present a challenge due to their refractory plaque burden and uneven lesion surface. This can be a contributing factor in the failure of stent delivery or insufficient stent expansion [11-14]. During CTO PCI, the most common retrograde CTO crossing technique is reverse controlled antegrade and retrograde subintimal tracking (reverse CART) [15]. When performing retrograde CTO-PCI in severely calcified lesions, the use of retrograde crossing techniques, in particular reverse CART, has been thought to carry a relatively high risk of dissection and perforation after rotational atherectomy (RA) in these lesions [16].

Rotational atherectomy has been considered to be the most promising intervention in the treatment of CTO lesions and might improve the procedure success rate and it is increasingly applied for the preparation of certain calcified CTOs [17, 18]. Rotational atherectomy is a process that involves cutting a portion of the obstructive atheroma to enable balloon dilatation, plaque fracture, stent delivery, and expansion [19, 20]. It is utilized for complete lesion preparation prior to stenting as well as device passage [21]. However, despite the potential for short-term results of CTO PCI, it has been observed that it might be consistent with a higher possibility of periprocedural complications [22]. Moreover, the long-term clinical outcome of CTO lesions treated by RA-assisted PCI remains unclear.

At present, the optimal treatment for CTO lesions is still debatable due to conflicting results from the randomized controlled trials (RCTs) comparing RA to

non-RA strategies in managing CTO lesions. To date, no systematic review and meta-analysis has compared the preparation of calcified coronary lesions with an atherectomy-based strategy to non-RA PCI in the treatment of CTO lesions. Therefore, we conducted a systematic review and meta-analysis to compare the outcomes and efficacy of these approaches.

# **Methods**

We followed the preferred reporting items for systematic reviews and meta-analysis (PRISMA) statement guidelines when performing this systematic review and meta-analysis [23]. The method was carried out in accordance with the Cochrane handbook of systematic reviews and meta-analysis of interventions (version 5.1.0).

# Eligibility criteria

We considered all relevant trials that reported RA as the interventional group and conventional PCI method as the comparable group in patients with chronic total occlusion and reported our primary and secondary outcomes of interest. We excluded irrelevant papers of animal studies, non-English studies, data of unpublished studies, or data from conference abstracts.

# Primary and secondary outcomes

The primary outcome of interest was the incidence of major adverse cardiac events (MACE) as a clinical outcome of interest. Other secondary outcomes were all cause of death, cardiac death, myocardial infarction (MI), and target vessel revascularization (TVR). Also, we reported angiographic outcomes as technical success, procedural success, and procedural complications. The definitions of these outcomes were based on the descriptions provided by the authors of the individual studies.

# Literature search

We performed a comprehensive literature search on PubMed, Scopus, Web of Science, and Cochrane Library, from inception until April 2023, using this search query: ("rotational atherectomy" OR RA) AND ("coronary artery disease" OR "chronic total occlusion" OR CTO OR "CTO lesions" OR "CTO-PCI") AND ("non-RA" OR "without RA" OR "stenting without RA" OR "conventional PCI" OR "standard PCI") AND ("percutaneous coronary intervention" OR PCI OR "drug-eluting stent\*" OR DES). All duplicates were removed by EndNote and manual backward citation analysis was done for all the references of the included studies.

# Screening of the literature search results

The literature search results were screened in a twostep process. Initially, the titles and abstracts of all articles were assessed for eligibility. Subsequently, full-text screening was conducted for the studies that met the eligibility criteria.

### Data extraction

Data from the included studies was extracted and recorded in a standardized data extraction sheet. The extracted data encompassed four main categories: (1) Characteristics of the included studies, (2) Characteristics of the study population, (3) Risk of bias domains, and (4) Outcome measures, which included MACE, All-Cause Death, TVR, MI, stent thrombosis, and cardiac death.

### Synthesis of results

For outcomes that involved dichotomous data, the frequency of events and the total number of patients in each group were combined to calculate the odds ratio (OR) with its 95% confidence interval (CI) using the DerSimonian-Laird random-effect model, moreover, a *P* value less than 0.05 was considered as a significant result. In cases where studies reported data at multiple time points, the last endpoint was considered for the primary analysis. All statistical analyses were conducted using StataMP version 17 for Mac.

### Assessment of Heterogeneity

Statistical heterogeneity among studies was evaluated by the Chi-square test (Cochrane Q test). Next, the chi-square statistic, Cochrane Q, was used to calculate the I-squared according to the equation:  $I2=\left(\frac{Q-df}{Q}\right)x\ 100\%$ . A Chi-square P value less than 0.1 was considered as significant heterogeneity. I-square values  $\geq 50\%$  were considered to indicate high heterogeneity. In scenarios of significant heterogeneity, we employed the leave-one-out sensitivity analysis model to address the reported heterogeneity. Moreover, we used the Galbraith plot to detect any heterogeneity across studies.

# **Quality assessment**

To assess the quality of the clinical trials included in our analysis, we utilized the Cochrane Risk of Bias 2 (ROB-2) tool for randomized controlled trials (RCTs) [24]. This tool evaluates the risk of bias in five domains, namely, selection bias, performance bias, detection bias, attrition bias, and reporting bias. The authors' decisions were categorized as 'High risk of bias', 'Some concerns', or 'Low risk of bias'. Observational studies were assessed using the Newcastle–Ottawa Scale (NOS) [25] which involves three domains (selection, comparability, and outcome).

To investigate publication bias across studies, we employed the DOI plot model to analyze the relationship between effect size and standard error [26]. We assessed evidence of publication bias using Egger's regression test [27].

### **Results**

### Literature search

Our electronic search on four databases yielded 1507 articles of which seven studies were finally included in this meta-analysis after title, abstract, and full text screening. The flow chart of included studies is illustrated in PRISMA flow diagram, as shown in Fig. 1.

### Characteristics of included studies

Our meta-analysis included seven studies with a total of 5494 patients. Of the included studies, 5 were observational studies [8, 28]– [31], and only two were randomized controlled trials [13, 14]. The baseline summary and characteristics of all included studies is summarized in Table 1.

### Risk of bias assessment

The Five observational studies were truly representative of the patients included. The non-exposed group was selected from the same community and the ascertainment of exposure was confirmed by secure records. Furthermore, the two groups included in all the studies were comparable. They also showed adequate periods of follow-up except for Pagnotta 2010. However, the overall quality of all the studies is good, as shown in Table 2.

The two RCTs Abdel-Wahab 2013 and Abdel-Wahab 2018 showed low risk of bias in almost all the five domains of Rob2. However, Abdel-Wahab 2013 showed protocol deviation in 3 patients. They demonstrated adequate randomization process, allocation concealment, appropriate analysis, appropriate outcome measurement, and no baseline difference between the two groups, as shown in Fig. 2.

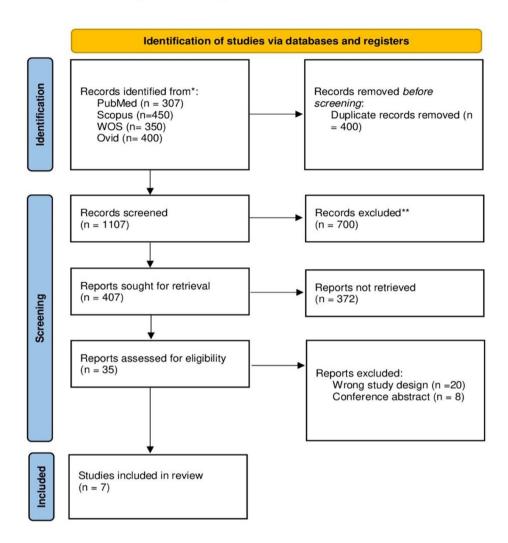
# **Clinical outcomes**

# MACE

Six studies assessed our primary outcome, MACE, with an incidence rate of 15.91% (78 of 490) in RA group compared to 15.36% (669 of 4356) in the conventional PCI group. The pooled OR did not detect any significant difference between the two studied groups regarding MACE (OR=0.98, 95% CI [0.74 to 1.3], p=0.9); the pooled studies were homogenous ( $I^2$ =0.00%, p=0.62), as shown in Fig. 3.

We assessed the statistical heterogeneity using Galbraith plot, and by inspection, all studies were within the 95% CI of the precision area, indicating that there no heterogeneity across studies, as shown in Fig. 4.

### PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only



\*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: http://www.prisma-statement.org/

Fig. 1 PRISMA flow diagram

We used DOI plot to detect possible publication bias, and by inspection, there was a major asymmetry with a LFK of -4.7, indicating possible publication bias and further studies are needed to achieve stability, as shown in Fig. 5.

# Secondary outcomes

Our pooled analysis showed no significant difference between RA and conventional PCI according to all-cause death (OR=1.34, 95% CI [0.8 to 2.25], p=0.26), or cardiac death (OR=1.46, 95% CI [0.54 to 3.95], p=0.46); the pooled studies were homogenous with the following

<sup>\*\*</sup>If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

 Table 1
 Summary and baseline of all included studies

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**Table 2** NOS scale for observational studies

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values, respectively (I<sup>2</sup>=0.00%, p=0.69; and I<sup>2</sup>=0.00%, p=0.43), as shown in Figs. 6 and 7.

Sensitivity analysis was done by excluding Pagnotta et al., in which the pooled studies did not favor RA over conventional PCI regarding either all-cause death (OR=1.29, 95% CI [0.77 to 2.17], p=0.33) or cardiac death (OR=1.25, 95% CI [0.45 to 3.51], p=0.67), as shown in Supplementary Figs. 1, 2.

Moreover, our pooled analysis showed no superior effect of RA compared to conventional PCI regarding the incidence of TVR (OR=1.01, 95% CI [0.74 to 1.36], p=0.97), or incidence of MI (OR=1.42, 95% CI [0.92 to 2.18], p=0.11); the pooled studies were homogenous with the following values, respectively ( $I^2$ =0.00%, p=0.58; and  $I^2$ =0.00%, p=0.47), as shown in Figs. 8 and 9.

### **Angiographic outcomes**

Four studies assessed technical success in which the pooled analysis did not favor RA over conventional PCI (OR=1.06, 95% CI [0.89 to 1.25], p=0.53); the pooled studies were homogenous (I $^2$ =0.00%, p=0.87), as shown Supplementary Fig. 3. Regarding procedural success, the pooled analysis of six studies showed no superior effect of RA over conventional PCI (OR=1.08, 95% CI [0.94 to 1.24], p=0.29); the pooled results were homogenous (I $^2$ =0.00%, p=0.98), as shown in Supplementary Fig. 4.

The incidence rate of procedural complications was 5.05% (15 of 297) in the RA group compared to 5% (88 of 1760) in the conventional PCI group. The pooled OR did not show any superiority of RA over conventional PCI (OR=1.72, 95% CI [0.64 to 4.61], p=0.28); the pooled studies were homogenous ( $I^2$ =18.04%, p=0.11), as shown in Supplementary Fig. 5.

A sensitivity analysis model was performed, and upon excluding Huang et al., the pooled analysis, yet, did not detect any difference between the two studied groups (OR=1.34, 95% CI [0.55 to 3.28], p=0.52), as shown Supplementary Fig. 6.

# Discussion

We conducted this meta-analysis to evaluate the safety and feasibility of RA in patients with CTO lesions compared to conventional CTO PCI. Our findings revealed that there was no significant difference between the two procedures in clinical outcomes, including MACE, all-cause death, cardiac death, incidence of TVR, and the incidence of MI. Similarly, we found no significant difference in angiographic outcomes, including technical success, procedural success, and complications.

Revascularization of CTO lesions can enhance longterm survival rates and quality of life, especially in patients with CTO in the left anterior descending territory and extensive ischemic areas [32]. Multiple studies have demonstrated the clinical benefits of successful

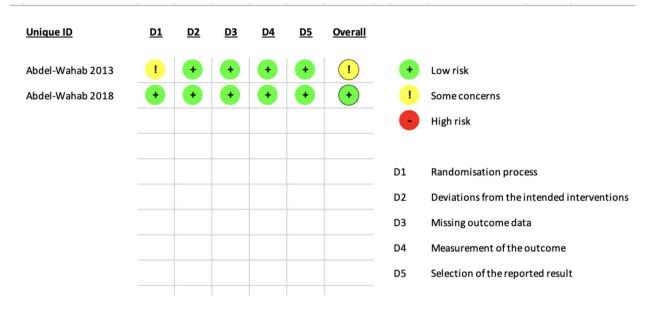


Fig. 2 Risk of bias assessment tool-2 (ROB-2) for RCTs

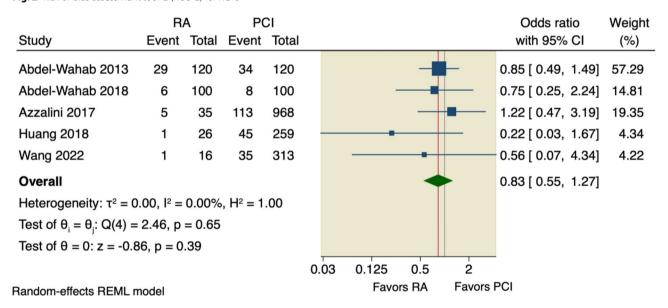


Fig. 3 Forest plot of MACE. RA: rotational atherectomy, PCI: percutaneous coronary intervention, CI: confidence interval

canalization of CTO lesions in improving anginal pain, survival rate, and left ventricular systolic function [33, 34]. Given the numerous advantages of revascularization, it is essential to properly recanalize resistant CTO lesions.

CTO interventions represent around 25% of patients undergoing coronary angiography, and many interventional cardiologists are committed and enthusiastic about performing CTO PCIs. With well-trained physicians and technical advancements, the success rate for CTO PCIs has increased to over 80% after 15 years of follow-up. However, the mortality rate within 30 days of CTO PCI

was 1.3%, and perforation occurred in 4.8% of cases [35, 36]. Another study with a 20-year follow-up found that successful CTO-PCI approaches were associated with a 10-year survival benefit [37].

Despite improvements in PCI technology and techniques, some lesions remain uncrossable or undilatable by balloon [38]. According to a previous multicenter CTO PCI registry, 9% of all lesions are considered uncrossable and are characterized by moderate to severe coronary calcification, moderate to severe coronary tortuosity, and higher J-CTO scores. Additionally, 12% of CTO lesions are undilatable, with most of them associated with a

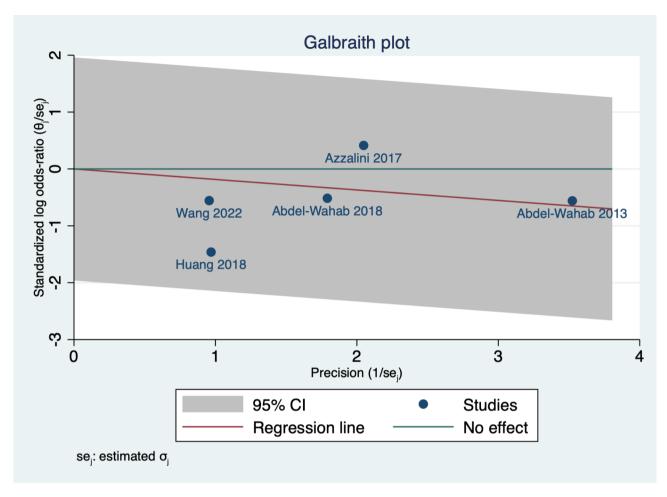


Fig. 4 Galbraith plot assessing heterogeneity across studies assessed MACE

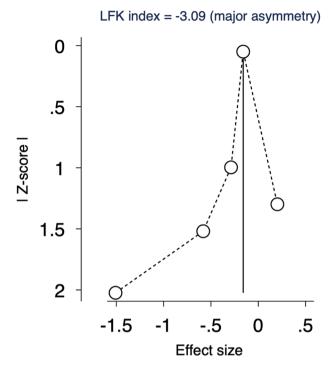
history of CAD, heart failure, diabetes, and higher J-CTO scores [39]. Uncrossable CTO lesions are associated with a lower success rate and more complications. Prolonged procedures also increase the amount of fluoroscopy time required [40].

The uncrossable CTO lesions can be successfully managed by special approaches such as deep seating of the guiding catheter, anchoring balloon technique, buddy wire technique, manual rotation of the Tornus catheter, and child-in-mother guiding catheters [41, 42]. Additionally, higher ballooning pressure, excimer laser, and RA showed a high success rate [38].

One of the most effective managements for resistant CTOs and heavy calcific lesions is RA [43]. Practice guidelines recommend using RA to prepare highly fibrous or calcified lesions that cannot be properly crossed by a balloon or dilated before stenting [36]. Fang et al. conducted a study to compare the feasibility and safety of RA versus a penetrating catheter (Tornus catheter) for treating heavy calcific lesions and it was found that RA was superior to the Tornus catheter in terms of in-hospital and 30-day follow-up outcomes. RA was

associated with a higher device and angiographic success rate and a shorter procedural duration. However, both procedures showed similar results regarding major and minor complications [44]. Another study by Pagnotta et al. reported that the RA was superior to the penetrating catheter (Tornus catheter) with a predicted success rate of over 45%. In addition, the RA with a bail-out approach can increase the predicted success rate to 91% in CTO patients [45].

Previous randomized controlled trials reported that there were no significant differences between CTO-PCI and RA, which is in line with our results [13, 14, 46, 47]. The randomized ROTAXUS trial assessed the effect of the RA technique on heavily calcified lesions and fixation of a drug-eluting stent (DES), and they found that RA was not superior to other PCI procedures in terms of in-hospital outcomes and after 9 months of follow-up [13]. At 2-year clinical follow-up, there was no difference in MACE rates between patients with complicated calcified lesions undergoing RA and those undergoing standard PCI before DES implantation. However, the rate of MACE increased to one-third of total patients, which



 $\textbf{Fig. 5} \ \ \text{DOI plot assessing publication bias of MACE. LFK= -3.09, indicating major asymmetry }$ 

may be associated with the time-dependent occurrence of MACE [46].

The Randomized PREPARE-CALC trial showed similar rates of in-hospital and 9-month lumen loss when modified balloons or RA were used with a heavily calcific lesion [14]. Recently, a post hoc analysis of this trial showed that RA-based lesion preparation had a higher success rate than the modified balloon strategy-based lesion preparation in heavy calcific lesions in the left anterior descending artery. The major cause of this

discrepancy was a greater rate of crossover and stent failure in the modified balloon group [47].

The ARTIST trial evaluated the efficacy and safety of RA followed by balloon angioplasty with balloon percutaneous transluminal coronary angioplasty, and no significant difference was found in the short-term success rate compared to other procedures. However, RA was associated with minimal luminal diameter after 6 months, considering that the operators used low-pressure inflations [48].

The wide range of atherectomy application rates during CTO PCI, ranging from 3.5 to 9%, is most likely due to variations in equipment accessibility and operator expertise [8, 31]. A previous retrospective study conducted in Europe and Russia on 3540 patients found that the currently used RA procedure, which is mostly utilized for complex lesions, has similar technical success rate compared to CTO-PCI, but carries a higher risk of donor vascular damage and tamponade, requiring pericardiocentesis. Additionally, after excluding failed crossing instances and those where the successful crossing technique was unclear. However, procedural success (94% vs. 96%, p=0.358) and MACE (5% vs. 3%, p=0.195) rates were similar [49]. Another study reported the similarity in success rate and MACE between both procedures inhospital and after 1 year. Nevertheless, this benefit was lost when the multivariate Cox regression analysis was adjusted for confounding factors (HR 1.25, 95% CI, 0.33-1.94, p=0.242) [8].

A previous study assessed the risk of RA and found that RA was associated with more dissections; however, there were no significant differences between CTO and non-CTO groups [50]. Additionally, the CTO-PCI has a higher rate of dissection, especially with the retrograde method compared with the antegrade method [51].

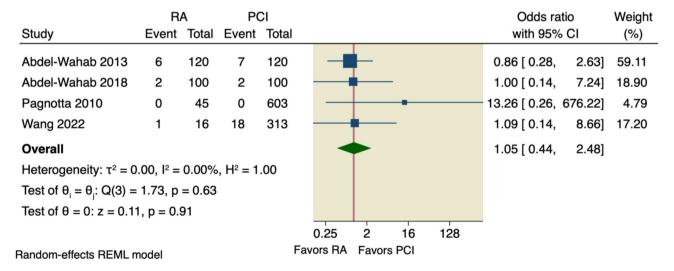


Fig. 6 Forest plot of all-cause death. Cl: Confidence interval, RA: rotational atherectomy, PCI: percutaneous coronary intervention

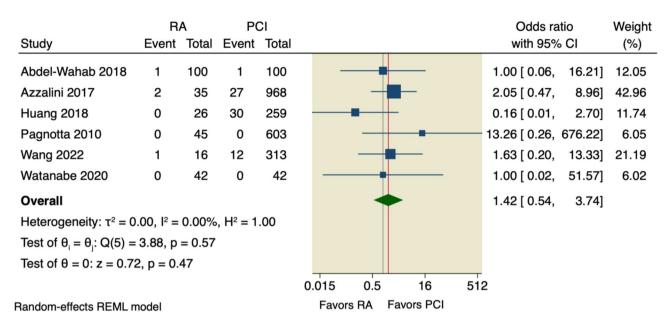


Fig. 7 Forest plot of cardiac death. Cl: Confidence interval, RA: rotational atherectomy, PCI: percutaneous coronary intervention

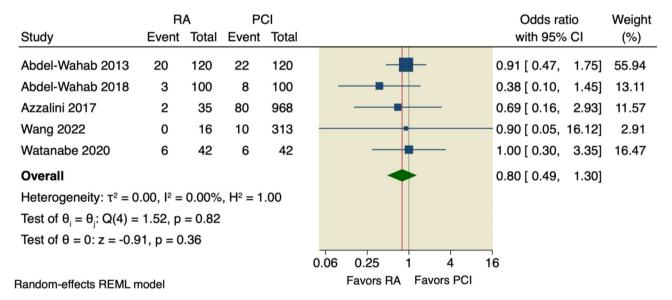


Fig. 8 Forest plot of TVR. CI: Confidence interval, RA: rotational atherectomy, PCI: percutaneous coronary intervention

Moreover, a recent meta-analysis addressed the clinical outcomes of PCI in CTO lesions reported that PCI in CTO lesions was associated with higher odds of vessel perforations and cardiac tamponade during in-hospital stay, while high rates of MACE was noted during long-term outcomes highlighting the challenges and adverse endpoints related to PCI in CTO lesions [52].

In terms of clinical implications, our findings suggest that RA is an important procedure for managing uncrossable or undilatable lesions with a high success rate and less fluoroscopy time. However, CTO-PCI has comparable success rates and complications. Therefore, while RA may not be the preferred first choice for CTO

lesions, it remains a practical and viable alternative for difficult-to-treat lesions.

The study has several strengths. It is the first metaanalysis to compare the effectiveness of RA to CTO-PCI in heavy and complex CTO lesions, and we obtained consistent results by combining data from studies with similar characteristics. Our findings have important clinical implications for the management of CTO lesions. However, the study also has some limitations. Firstly, most of the included studies were observational, which may have introduced bias. Secondly, the number of included studies was relatively small, and there was evidence of publication bias. Therefore, we suggest that more prospective clinical trials with larger sample sizes are needed to

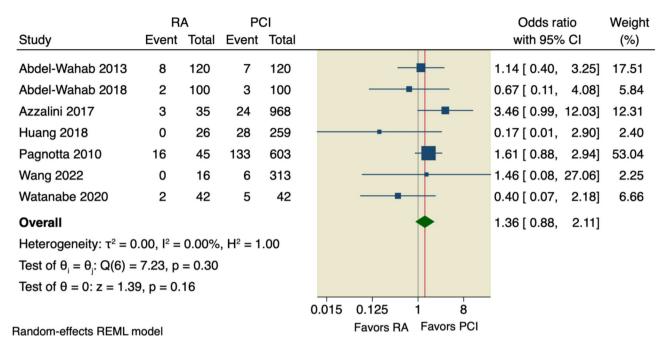


Fig. 9 Forest plot of MI. Cl: Confidence interval, RA: rotational atherectomy, PCI: percutaneous coronary intervention

evaluate the short-term and long-term outcomes associated with RA and CTO-PCI, as well as to compare the different procedures within CTO-PCI and RA.

In conclusion, our results demonstrate that patients who underwent RA and CTO-PCI experienced comparable in-hospital outcomes. In cases where the lesion was heavily calcified and challenging to treat using retrograde CTO-PCI, RA can be a viable option for experienced operators.

# **Supplementary Information**

The online version contains supplementary material available at https://doi.org/10.1186/s12872-023-03673-2.

Supplementary Material 1

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### **Author contributions**

Ahmed Abdelaziz: Conceptualization, Supervision, data collection revision, statistical analysis, writing – original draft and editing. Hanaa Elsayed: screening, data collection, original draft writing. Aboalmagd Hamdaalah: data collection, data validation. Karim Atta: Full-text screening, data collection, data validation. Mohamed Abdelaziz: screening, data collection, revision of data collection, quality assessment. Hallas Kadhim: data collection, quality assessment. Ahmed Mechi: data collection, data validation, Final version. Ahmed Elaraby: quality assessment, full-text screening, data collection, writing – revision. Mahmoud Ezzat: screening, data collection, data revision for analysis. Aya Moustafa Aboutaleb: summary and characteristics, quality assessment, writing – revision. Fayed Mohamed Rzk: quality assessment, manuscript drafting and writing. Mahmoud Eid: screening, data collection, quality assessment. Abdelrahman H. Hafez: summary and characteristics, quality assessment, writing – revision. Mohamed Hatem Ellabban: data collection, manuscript drafting and writing. Hadeer Elsaeed Aboelfarh:

data collection, quality assessment. Rahma Abdelfattah: data collection, quality assessment, summary and characteristics. Shaimaa Fadel: data collection, quality assessment, summary and characteristics. Hazem S. Ghaith: Conceptualization, screening, writing – original draft. Emad Addin Zawaneh: quality assessment, TSA analysis, summary and characteristics. Mustafa Suppah: writing – original draft, data revision, Manuscript revision.

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# **Data Availability**

The data underlying this article are available in the article and in its online supplementary material.

### **Declarations**

### **Ethical approval**

Not applicable.

### **Competing interests**

There was no conflict of interest among all authors.

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