Orbital atherectomy versus balloon angioplasty before drug-eluting stent implantation in severely calcified lesions eligible for both treatment strategies (ECLIPSE): a multicentre, open-label, randomised trial

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Summary

Background Coronary artery calcification is common among patients undergoing percutaneous coronary intervention (PCI), and severe coronary artery lesion calcification is associated with increased procedural complexity, stent under-expansion, and high rates of intraprocedural complications and out-of-hospital adverse events. Whether calcium ablation before stent implantation can mitigate these adverse events is not currently established. We aimed to prospectively compare orbital atherectomy with a balloon angioplasty-based strategy before stent implantation for the treatment of severely calcified coronary lesions.

Methods In this multicentre, open-label, randomised controlled trial conducted at 104 medical centres in the USA, patients (aged ≥18 years) with severely calcified coronary lesions were randomly assigned (1:1) to orbital atherectomy or balloon angioplasty before PCI with drug-eluting stents using a web-based system (block sizes of four and six) and stratified by intended treatment of single versus multiple lesions and enrolling site. Randomly assigned lesions were deemed by operators to be eligible for both treatment strategies. Operators and patients were not masked to treatment. The two powered coprimary study endpoints were target vessel failure at 1 year (a composite of cardiac death, target vessel myocardial infarction, or ischaemia-driven target vessel revascularisation) and post-procedural minimal stent area at the site of maximal calcification, as assessed by intravascular optical coherence tomography in an imaging patient cohort. Primary analyses were by intention-to-treat. The trial is registered at ClinicalTrials.gov NCT03108456, and 2-year follow-up is ongoing.

Findings From March 27, 2017, to April 13, 2023, 2005 patients with 2492 lesions were randomly assigned to lesion preparation with orbital atherectomy (1008 patients with 1250 lesions) or balloon angioplasty (997 with 1242 lesions) before stent implantation. Median patient age was 70·0 years (IQR 64·0–76·0). 541 (27·0%) of 2005 patients were female and 1464 (73·0%) were male. Angiographically severe calcium was confirmed by the core laboratory in 1088 (97·1%) of 1120 lesions assigned to orbital atherectomy and 1068 (97·0%) of 1101 lesions assigned to balloon angioplasty. PCI was guided by intravascular imaging in 627 (62·2%) of 1008 patients in the orbital atherectomy group and 619 (62·1%) of 997 in the balloon angioplasty group. Target vessel failure events within 1 year occurred in 113 of 1008 patients in the orbital atherectomy group (1-year target vessel failure 11·5% [95% CI 9·7 to 13·7]) and in 97 of 997 patients in the balloon angioplasty group (10·0% [8·3 to 12·1]; absolute difference 1·5% [96% CI −1·4 to 4·4]; hazard ratio 1·16 [96% CI 0·87 to 1·54], p=0·28). Among those in the optical coherence tomography substudy cohort (276 patients with 286 lesions in the orbital atherectomy group and 279 patients with 292 lesions in the balloon angioplasty group), the mean minimal stent area at the site of maximal calcification was 7·67 mm² (SD 2·27) in the orbital atherectomy group and 7·42 mm² (2·54) in the balloon angioplasty group (mean difference 0·26 [99% CI −0·31 to 0·82]; p=0·078). Cardiac death events within 1 year occurred in 39 of 1008 patients in the orbital atherectomy group and in 26 of 997 in the balloon angioplasty group.

Interpretation Routine treatment with orbital atherectomy before drug-eluting stent implantation did not increase minimal stent area or reduce the rate of target vessel failure at 1 year compared with a balloon angioplasty-based approach in severely calcified lesions deemed eligible for both treatment strategies. These data support a balloon-first approach for most calcified coronary artery lesions that can be crossed and dilated before stent implantation, guided by intravascular imaging.

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See Online for appendix

Research in context

Evidence before this study

The incidence of coronary artery calcification is increasing as the population ages, and because coronary artery calcification impedes vessel dilation and stent delivery during percutaneous coronary intervention, severe calcification is associated with procedural complications, stent under-expansion, and increased rates of early and late adverse clinical outcomes. Although additional technologies (beyond balloon angioplasty alone) have been specifically designed to modify coronary calcium before stent implantation, comparative clinical outcome data supporting the use of these technologies are scarce. We searched PubMed on Jan 5, 2025, with the search terms "atherectomy", "orbital OR rotational OR laser", "coronary", and "calc*" for randomised trials published in English and identified two randomised trials comparing atheroablation with balloon angioplasty alone for preparation of severely calcified lesions. In these studies, rotational atherectomy before stent implantation in severely calcified lesions had higher rates of strategy success than balloon angioplasty alone but did not improve event-free survival. Data for other advanced calcium-modification devices, including orbital atherectomy and intravascular lithotripsy, are largely limited to intravascular imaging-based observations alone (one randomised trial of lithotripsy compared with rotational atherectomy) or observational studies without a randomised control group.

Added value of this study

In this multicentre, randomised clinical trial in patients with severely calcified lesions for which the operator believed atherectomy was not absolutely required, calcium modification with orbital atherectomy did not increase minimal stent area or reduce the 1-year rate of target vessel failure compared with balloon angioplasty alone before drug-eluting stent implantation. Consistent with the 2024 European Society of Cardiology guidelines, most procedures in this trial were guided by intravascular imaging, which has been shown to improve clinical outcomes after stenting of complex lesions. These findings indicate that adequate stent expansion and low rates of adverse outcomes are achievable with a balloon angioplasty-based strategy in a large proportion of severely calcified lesions if meticulous attention is paid to lesion preparation before contemporary stent implantation. These data further suggest that the conventional definition of severe calcification based on the coronary angiogram alone might be insufficient to identify lesions that might optimally benefit from advanced calcium modification strategies.

Implications of all the available evidence

These findings support a balloon-first approach to most calcified coronary artery lesions that can be crossed and dilated before stent implantation, guided by intravascular imaging.

Introduction

Approximately a third of patients undergoing percutaneous coronary intervention (PCI) have calcified coronary lesions.[1–3] With an ageing population, the incidence of coronary artery calcification is increasing, and because coronary artery calcification impedes vessel dilation and stent delivery, it is associated with stent under-expansion and high rates of intraprocedural complications and out-of-hospital adverse events among patients who undergo PCI.[2–9] Whether advanced calcium modification strategies that aim to ablate and fracture coronary calcium can mitigate these adverse events is not currently known.

The aim of balloon angioplasty for lesion preparation before stent implantation is to dilate and potentially fracture intracoronary calcium through application of pressure to the artery wall. By contrast, coronary atherectomy is a lesion preparatory technique designed to ablate calcium, thereby facilitating its fracture and improving lesion compliance, enabling stent delivery and stent expansion. Although coronary atherectomy is an essential tool to treat balloon-uncrossable or non-dilatable calcified coronary stenoses,[9–11] it is used in only a small proportion of PCI procedures with rates of use varying substantially between operators and hospitals.[12,13] This variability might be due to unfamiliarity with the technology, a desire to avoid complications, increased costs, and the paucity of adequately powered randomised trials supporting its use.[14–17] We aimed to prospectively compare orbital atherectomy with a balloon angioplasty-based strategy before stent implantation for the treatment of severely calcified coronary lesions.

Methods

Study design and participants

This multicentre, open-label, randomised trial was conducted in 104 medical centres in the USA (details on the participating sites and investigators are provided in the appendix [pp 4–6]). The trial protocol and statistical analysis plan were designed by the steering committee and sponsor of the study (Cardiovascular Systems, an affiliate of Abbott, Santa Clara, CA, USA).[18] Study protocol and statistical analysis plan versions (initial versions and final versions, with changes between all versions) are provided in the appendix (pp 62–251). The trial was approved by the institutional review board at each site (appendix pp 252–57).

Eligible patients included adults (aged ≥18 years) with chronic or acute coronary syndromes undergoing PCI of one or more native de novo coronary artery target lesions with angiographic or intravascular imaging evidence of severe calcium, and an estimated survival of ≥1 year. Severe angiographic calcification was defined (per convention)[19,20] as the presence of radiopacities noted

without cardiac motion involving both sides of the arterial wall, with a total length of ≥15 mm calcium extending into the target lesion. Severe calcification by intravascular imaging was defined as ≥270° of calcium in at least one imaging cross-section. Exclusion criteria included absence of treatment equipoise (ie, the investigator's opinion was that the target lesion required atherectomy or was contraindicated for atherectomy), target lesions with thrombus, severe tortuosity, lesion in a bypass graft, or true bifurcations (unless disease extension into the side branch was ≤5 mm, the side branch was not heavily calcified, and intended treatment of the side branch was either provisional balloon only or no treatment). Full inclusion and exclusion criteria are listed in the appendix (p 9). All patients provided written informed consent.

Randomisation and masking

After successful guidewire crossing of the target lesions, patients were randomly assigned (1:1) to orbital atherectomy or balloon angioplasty before stent implantation using a web-based system (with block sizes of four and six), stratified by intended treatment of single versus multiple lesions and enrolment site. Operators and patients were not masked to treatment. The target vessel could contain more than one eligible lesion requiring treatment. For multivessel procedures, if more than one vessel contained eligible lesions, investigators could declare multiple vessels for random assignment and all eligible lesions were treated in the same treatment group according to random assignment. However, if investigators considered that non-target vessel lesions were required to be treated with a specific strategy, it was permissible to treat other vessels as a non-target vessel according to investigator discretion before the patient was randomly assigned.

Procedures

In the orbital atherectomy group, orbital atherectomy was performed as per manufacturer instructions using the Diamondback 360 Coronary Orbital Atherectomy System (Cardiovascular Systems, an affiliate of Abbott) with the 1·25 mm classic crown.[21] A description of the device and its mechanism of action is provided in the appendix (p 12). Balloon predilatation was permitted, if necessary, before orbital atherectomy and was mandatory after atherectomy before stent implantation. Post-stent dilatation with a non-compliant balloon, sized 1:1 to the vessel diameter at ≥18 atmospheres, was also mandatory.

In the balloon angioplasty group, lesions were prepared using balloon angioplasty catheters, including cutting and scoring balloons but excluding intravascular lithotripsy, before stent implantation and for post-stent expansion. PCI was otherwise performed using standard techniques.

Treatment crossovers between study groups were strongly discouraged; an expert committee classified crossovers as acceptable or unacceptable according to prespecified criteria (appendix p 15). Rotational or laser atherectomy or intravascular lithotripsy were not permitted in either treatment group unless the target lesion was refractory to the assigned treatment; if rotational or laser atherectomy or intravascular lithotripsy was used, the patient was considered to have crossover treatment.

Demographic data were collected by study coordinators from medical records and patient interviews. If data on sex were self-reported, the options provided were male or female. Clinical follow-up was conducted at 30 days, 90 days, and 1 year; 2-year follow-up is ongoing. At selected sites, patients were prospectively enrolled in an optical coherence tomography substudy to characterise the effect of randomised treatment strategy on stent expansion. In this cohort, following stent implantation and optimisation, a final post-stent optical coherence tomography run was performed to assess the minimal stent area and other parameters.

Outcomes

The powered coprimary endpoints were target vessel failure (a composite of cardiac death, target vessel myocardial infarction, or ischaemia-driven target vessel revascularisation assessed in all patients at 1 year) and acute post-procedural minimal stent area at the maximal calcification site, assessed by optical coherence tomography in a prespecified cohort of approximately 500 patients. All centre-identified clinical events were centrally adjudicated by an independent committee, and angiography and optical coherence tomography imaging results were assessed at independent laboratories at a core site (Cardiovascular Research Foundation Clinical Trials Center, New York, NY, USA). All secondary endpoints were powered and were procedural success (defined as successful stent delivery with normal flow in the target vessel and angiographic in-stent diameter stenosis ≤20% in all treated lesions, and with the absence of stent loss, coronary perforation, or intra-procedural death) and strategy success (procedural success without crossover to an alternative treatment). A complete list of all study endpoints and their definitions are provided in the appendix (p 16).

All clinical events were assessed by interviews at follow-up and examining medical records.

Statistical analysis

For the coprimary endpoints, type I error was controlled by splitting α. For the coprimary imaging endpoint of post-procedural minimal stent area, 376 evaluable samples would provide 90% power to demonstrate a 1 mm² difference in the post-procedural minimal stent area at the site of maximal calcification between groups with an estimated minimal stent area of 4·5 mm² (SD 2·5) with balloon angioplasty alone with a two-sided type I error rate of 0·01. For the coprimary clinical endpoint of target vessel failure, assuming 14% of patients treated with balloon angioplasty alone and 9% treated with orbital atherectomy

would have target vessel failure within 1 year, and assuming 10% loss to follow-up, 1989 patients provided 90% power with a two-sided type I error rate of 0·04 using a test of binomial proportions. The trial incorporated an adaptive design based on the zone approach with an interim analysis performed in 700 patients. An independent unmasked statistician recommended that the study size remain unchanged based on the conditional power evaluated in the first 701 patients.

For the coprimary clinical endpoint of target vessel failure, 1-year Kaplan–Meier time-to-first-event estimates of target vessel failure were generated, and hazard ratios (HRs) and 96% CIs with associated p values were derived from a Cox proportional hazards model and Wald test, after confirming that proportional hazards assumption was satisfied on the basis of a standardised Score Process test. For the coprimary imaging endpoint of post-procedural minimal stent area at the site of maximal calcification, the between-group difference with 99% CI was calculated using a linear mixed-effects model accounting for clustering of multiple lesions per patient.

Missing data were not replaced for the coprimary outcomes; data are presented as a complete case analysis without imputation. As sensitivity analyses, the coprimary clinical endpoint of target vessel failure was analysed using multiple imputation to account for patients who withdrew or were lost to follow-up to 1 year, and the risk of target vessel failure was analysed using a Fine–Gray subdistribution model to account for the competing risk of non-cardiac death. Target vessel failure was also reported using prespecified alternative definitions of myocardial infarction, and in the per-protocol and as-treated populations. All randomly assigned patients contributed data to the primary endpoint analysis of target vessel failure, including complete in-hospital data.

For all secondary endpoints, HRs and 95% CIs were calculated and a two-sided p value of <0·05 was considered statistically significant. However, adjustments were not made for multiplicity for these outcomes and these findings should be considered hypothesis-generating. Formal interaction testing was used to assess the relative differences in treatment effects for the coprimary endpoints across 16 prespecified subgroups. Descriptive categorical data are reported as counts and percentages and compared with a χ^2 test or Fisher's exact test. Descriptive continuous data are reported as mean (SD) if normally distributed or median (IQR) if not normally distributed and compared with a *t* test or Wilcoxon test, respectively. All analyses were performed in the intention-to-treat population. All statistical analyses were performed with SAS, version 9.4, or R, version 4.4.

An independent data safety and monitoring committee consisting of three independent cardiologists oversaw the conduct of the study with data reported at regular intervals based upon enrolment milestones. The trial is registered at ClinicalTrials.gov NCT03108456, and 2-year follow-up is ongoing.

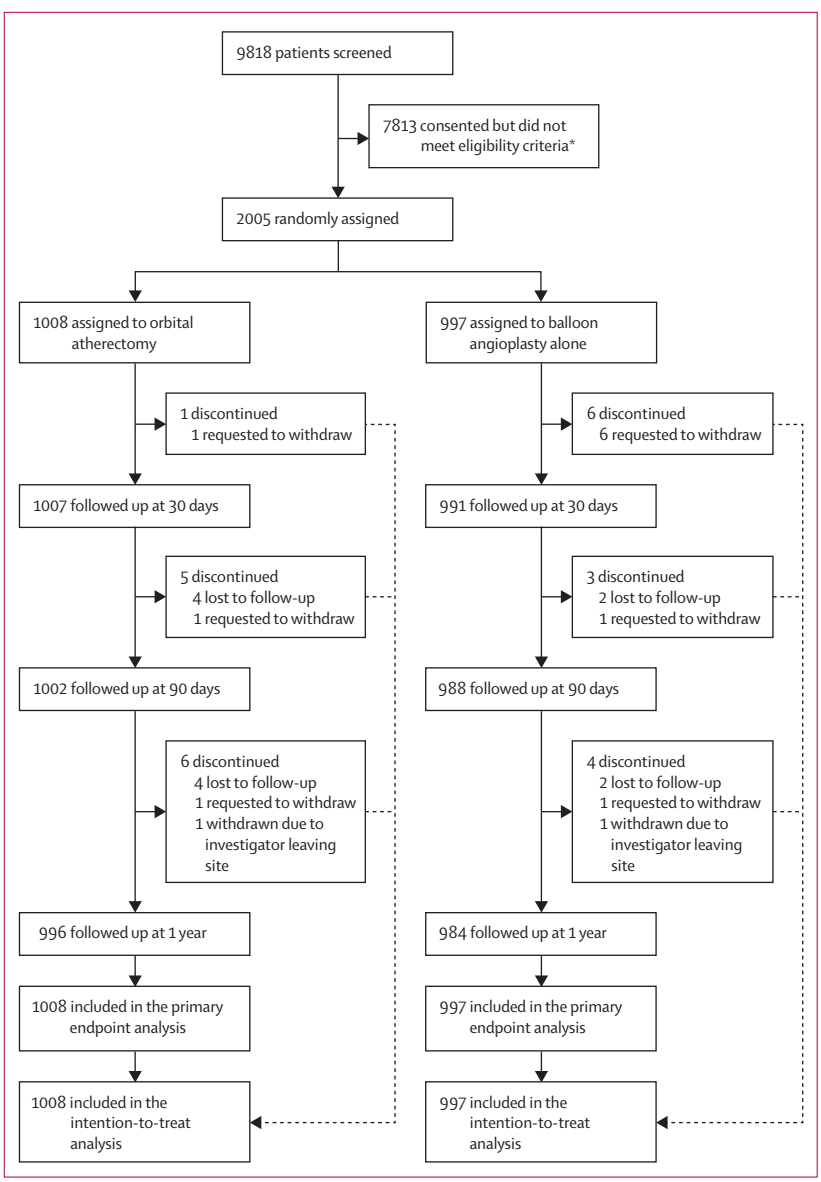

Figure 1: **Trial profile**
Patients who were lost to follow-up or withdrew were censored at the time of last data availability. *Reasons for ineligibility were not captured.

Role of the funding source

The funder of the study had a role in the study design, data collection, data analysis, data interpretation, and writing of the report.

Results

From March 27, 2017, to April 13, 2023, 9818 patients were screened and 2005 patients with 2492 lesions were randomly assigned to lesion preparation with orbital atherectomy (1008 patients with 1250 lesions) or balloon angioplasty alone (997 patients with 1242 lesions) before stent implantation (figure 1). Four patients in the orbital

atherectomy group and nine in the balloon angioplasty group withdrew from the study. Eight patients in the orbital atherectomy group and four patients in the balloon angioplasty group were lost to follow-up. 996 (98·8%) patients in the orbital atherectomy group and 984 (98·7%) in the balloon angioplasty group were followed up to 1 year (median follow-up 365 days [IQR 365–365]).

Baseline clinical and angiographic characteristics were well matched between the groups (table 1; appendix p 31). Median patient age was 70·0 years (IQR 64·0–76·0). 541 (27·0%) of 2005 patients were female and 1464 (73·0%) were male. 881 (43·9%) of 2005 patients had diabetes and 479 (23·9%) had chronic kidney disease (including 112 [5·6%] on haemodialysis). As assessed by the independent angiographic core laboratory, the mean reference vessel diameter of treated lesions was 3·0 mm (SD 0·4), mean lesion length was 28·7 mm (15·1), and mean calcium length was 41·8 mm (19·9), as angiographic calcium often extended beyond the stenotic lesion. Angiographically severe calcium was confirmed in 1088 (97·1%) of 1120 lesions assigned to orbital atherectomy and 1068 (97·0%) of 1101 lesions assigned to balloon angioplasty. Representative angiograms are shown in the video. A total of 555 patients with 578 treated lesions at 39 sites were enrolled in the optical coherence tomography substudy cohort (276 patients with 286 lesions in the orbital atherectomy group and 279 patients with 292 lesions in the balloon angioplasty group); their baseline characteristics were also balanced between groups (appendix pp 33–36).

Orbital atherectomy was attempted in 997 (98·9%) of 1008 patients and crossing of one or more lesions by orbital atherectomy occurred in 990 (98·2%) patients who were randomly assigned to that strategy. 25 (2·0%) of 1250 lesions in 20 (2·0%) patients in the orbital atherectomy group required crossover to an alternative lesion preparation strategy (appendix p 37). In the balloon angioplasty group, cutting ballons were used in 125 (10·1%) of 1242 lesions and scoring balloons were used in 137 (11·0%) lesions (appendix p 38). 61 (4·9%) lesions required crossover in 46 (4·6%) patients in the balloon angioplasty group. Of the lesions treated by crossover to the alternative strategy, 16 (64·0%) of 25 lesions in the orbital atherectomy group and 40 (65·6%) of 61 lesions in the balloon angioplasty group were adjudicated as acceptable.

PCI was guided by intravascular imaging in 627 (62·2%) of 1008 patients in the orbital atherectomy group and 619 (62·1%) of 997 in the balloon angioplasty group (table 2). A femoral access site was used in 480 (47·6%) of 1008 patients in the orbital atherectomy group and 465 (46·6%) of 997 patients in the balloon angioplasty group. The total number of guidewires and ancillary equipment including microcatheters and temporary pacemakers placed prophylactically was greater in the orbital atherectomy group, although fewer balloon catheters were used in this group. Stents were implanted in 1235 (98·8%) of 1250 lesions in the orbital atherectomy group and in 1226 (98·7%) of 1242 lesions in the balloon angioplasty group. Post-stent dilatation was performed in 1140 (91·2%) and 1089 (87·7%) lesions at a mean of 19·1 (SD 3·3) and 18·7 (4·0) atmospheres in the two groups, respectively. Contrast use and total procedure times were higher in the orbital atherectomy group than in the ballon angioplasty group (table 2). Patients were treated with durable polymer everolimus-eluting stents, durable polymer zotarolimus-eluting stents, bioabsorbable polymer everolimus-eluting stents, bioabsorbable polymer sirolimus-eluting stents, and durable polymer ridaforolimus-eluting stents, with similar frequency of use of these stent types between

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	Orbital atherectomy group (n=1008)	Balloon angioplasty group (n=997)
Age, years	70·0 (65·0–76·0)	71·0 (64·0–76·0)
Sex		
Male	742 (73·6%)	722 (72·4%)
Female	266 (26·4%)	275 (27·6%)
Ethnicity		
Hispanic or Latino*	90 (8·9%)	81/994 (8·1%)
Not Hispanic or Latino*	918 (91·1%)	913/994 (91·9%)
Race		
Native American or Alaska Native	5/995 (0·5%)	2/989 (0·2%)
Asian	22/995 (2·2%)	18/989 (1·8%)
Black or African American	93/995 (9·3%)	100/989 (10·1%)
Native Hawaiian or other Pacific Islander	3/995 (0·3%)	2/989 (0·2%)
White	848/995 (85·2%)	828/989 (83·7%)
Other	21/995 (2·1%)	33/989 (3·3%)
More than one race selected	3/995 (0·3%)	6/989 (0·6%)
BMI, kg/m²	29·2 (25·8–33·4)	29·3 (25·7–33·1)
History of hypercholesterolemia	886/1007 (88·0%)	869/996 (87·2%)
History of hypertension	910 (90·3%)	900 (90·3%)
History of diabetes	434 (43·1%)	447 (44·8%)
Treated with insulin	185 (18·4%)	179 (18·0%)
Current smoker (within 1 month of enrolment)	129 (12·8%)	125 (12·5%)
History of chronic kidney disease	234 (23·2%)	245 (24·6%)
Requiring haemodialysis	60 (6·0%)	52 (5·2%)
eGFR, mL/min per 1·73 m²	70·1 (53·5–83·2)	67·9 (52·3–83·4)
Left ventricular ejection fraction	55·0% (50·0–61·0%)	55·0% (50·0–61·0%)
Previous myocardial infarction	262 (26·0%)	272 (27·3%)
Previous stroke or transient ischaemic attack	88 (8·7%)	112 (11·2%)
Peripheral vascular disease	138 (13·7%)	146 (14·6%)
Previous PCI	440 (43·7%)	466 (46·7%)
Previous coronary artery bypass surgery	92 (9·1%)	109 (10·9%)
Presentation with stable angina or ACS without elevated biomarker	789 (78·3%)	798 (80·0%)
Presentation with recent myocardial infarction or biomarker positive ACS	219 (21·7%)	199 (20·0%)

Data are n (%) or median (IQR). ACS=acute coronary syndrome. PCI=percutaneous coronary intervention. *These were the terms used at the time of data collection.

Table 1: **Baseline demographics and clinical characteristics**

	Orbital atherectomy group (n=1008)	Balloon angioplasty group (n=997)	Difference (95% CI)	p value
Number of target lesions treated	1·0 (1·0 to 1·0)	1·0 (1·0 to 1·0)	0·0 (–0·1 to 0·0)	0·44*
Two or more	170 (16·9%)	180 (18·1%)	–1·2% (–4·5 to 2·1)	0·48
Number of target vessels treated	1·0 (1·0 to 1·0)	1·0 (1·0 to 1·0)	0	0·046*
Two or more	23 (2·3%)	38 (3·8%)	–1·5% (–3·0 to 0·0)	0·046
Non-target vessels treated during the index procedure	126 (12·5%)	117 (11·7%)	0·8% (–2·1 to 3·6)	0·60
Any femoral artery access site†	480 (47·6%)	465 (46·6%)	1·0% (–3·4 to 5·3)	0·66
No femoral access site	528 (52·4%)	532 (53·4%)	–1·0% (–5·3 to 3·4)	0·66
Haemodynamic support	8 (0·8%)	7 (0·7%)	0·1% (–0·7 to 0·8)	0·81
Temporary pacemaker‡	45 (4·5%)	19 (1·9%)	2·6% (1·0 to 4·1)	0·0011
Guide extension catheter used	216 (21·4%)	222 (22·3%)	–0·8% (–4·5 to 2·8%)	0·65
Number of guide wires used	2·7 (1·4)	2·2 (1·4)	0·6 (0·4 to 0·7)	<0·0001*
Number of balloon catheters used	3·6 (2·3)	4·0 (2·8)	–0·4 (–0·6 to –0·2)	0·017*
Orbital atherectomy attempted	997 (98·9%)	37 (3·7%)	95·2% (93·9 to 96·5)	..
Orbital atherectomy performed	990 (98·2%)	37 (3·7%)	94·5% (93·1 to 95·9)	..
Microcatheter or over-the-wire balloon used	424 (42·1%)	165 (16·5%)	25·5% (21·7 to 29·3)	<0·0001
Any intravascular imaging performed§	627 (62·2%)	619 (62·1%)	0·1% (–4·1 to 4·4)	0·96
Optical coherence tomography	408 (40·5%)	411 (41·2%)	–0·7% (–5·1 to 3·6)	0·73
Intravascular ultrasound	258 (25·6%)	255 (25·6%)	0·0% (–3·8 to 3·8)	0·99
Total contrast volume, mL	165·0 (120·0 to 220·0)	150·0 (100·0 to 200·0)	19·4 (11·4 to 27·3)¶	<0·0001‖
Total procedure time, min	68·0 (49·0 to 90·5)	52·0 (36·0 to 74·0)	13·1 (10·1 to 16·2)¶	<0·0001‖

Data are median (IQR), n (%), or mean (SD), unless otherwise specified. *p values based on a *t* test or Wilcoxon test. †Any femoral access used. ‡43 pacemakers in the orbital atherectomy group and 18 pacemakers in the control group were placed prophylactically (pre-percutaneous coronary intervention). §Optical coherence tomography and intravascular ultrasound were used in some patients. ¶Differences between continuous variables are differences between mean values with 95% CIs. ‖p values based on Chi squared test or Fisher's exact test.

Table 2: **Procedural characteristics**

treatment groups (appendix p 40); antiplatelet regimens were also similar between treatment groups at discharge, 30 days, 90 days, and 1 year (appendix p 41).

Among 578 lesions in the optical coherence tomography substudy cohort with evaluable images (appendix p 29), the mean minimal stent area at the site of maximal calcification was 7·67 mm² (SD 2·27) in the orbital atherectomy group versus 7·42 mm² (2·54) in the balloon angioplasty group (mean difference 0·26 [99% CI –0·31 to 0·82]; p=0·078; figure 2A). Results were consistent across prespecified subgroups (appendix p 30). The minimal stent area across the entire stent length was also similar between the orbital atherectomy group and balloon angioplasty group (mean 6·13 mm² [SD 2·01] *vs* 5·87 mm² [2·04]; p=0·10; appendix p 46).

Target vessel failure events within 1 year occurred in 113 of 1008 patients in the orbital atherectomy group (1-year target vessel failure 11·5% [95% CI 9·7 to 13·7]) and in 97 of 997 patients in the balloon angioplasty group (10·0% [8·3 to 12·1]; absolute difference 1·5% [96% CI –1·4 to 4·4]; HR 1·16 [96% CI 0·87 to 1·54]; p=0·28; figure 2B). The results were similar using multiple imputation to account for missing follow-up data, after accounting for the competing risk of non-cardiac death, with use of alternative myocardial infarction definitions, and in the per-protocol and as-treated populations (appendix pp 47–50). Outcomes were consistent across most prespecified subgroups, although nominal interactions between treatments were present according to diabetes, target lesion calcification length, access site, and follow-up in relation to the COVID-19 pandemic (figure 3).

855 (85·5%) of 1000 patients in the orbital atherectomy group and 848 (86·1%) of 985 patients in the balloon angioplasty group had a successful procedure (difference –0·6% [95% CI –3·7 to 2·5]; appendix p 43). Strategy success occurred in 840 (84·0%) of 1000 patients and 816 (82·8%) of 985 patients in the two groups, respectively (difference 1·2% [95% CI –2·1 to 4·4]). Post-procedure quantitative coronary angiographic measures were similar with both approaches (appendix p 44). Angiographic complications were infrequent in both groups and largely similar, apart from a slightly greater incidence of (transient) slow flow in the orbital atherectomy group than in the balloon angioplasty group (14 [1·4%] events *vs* four [0·4%] events; appendix p 45).

Cardiac death events within 1 year occurred in 39 of 1008 patients in the orbital atherectomy group (1-year cardiac death 4·0% [95% CI 3·0–5·5]) and in 26 of 997 in the balloon angioplasty group (2·7% [1·9–4·0]). Within the first 30 days, cardiac death occurred in eight patients in the orbital atherectomy group and in no patients in the balloon angioplasty group. Among these eight early cardiac death events, the clinical events committee adjudicated

two related to the orbital atherectomy device, two possibly related to the orbital atherectomy device, and four unrelated to the orbital atherectomy device (appendix pp 52–56). Within 1 year, target vessel-related myocardial infarction events occurred in 55 of 1008 patients in the orbital atherectomy group (1-year target vessel-related myocardial infarction 5·6% [95% CI 4·3–7·2]) and in 43 of 997 patients in the balloon angioplasty group (4·4% [3·2–5·8]), ischaemia-driven target vessel revascularisation events occurred in 40 patients (1-year ischaemia-driven target vessel revascularisation 4·2% [3·1–5·7]) and 41 patients (4·4% [3·2–5·9]), and stent thrombosis events occurred in 11 patients (1-year stent thrombosis 1·1% [0·6–2·0]) and four patients (0·4% [0·2–1·1]; table 3; details are provided in the appendix p 57). Other outcomes occurred at similar rates in both groups.

Discussion

This multicentre, randomised trial examined two strategies for routine upfront treatment of severely calcified coronary lesions, a lesion subset that is increasing in prevalence in clinical practice, and for which adverse outcomes are among the highest. Notably, eligible lesions met the standard definition for severe calcification and investigators deemed them eligible for preparation with either atherectomy or a balloon angioplasty-based strategy before stent implantation. Despite enrolling a high-risk patient cohort with a prevalence of angiographically severe calcium that exceeded 97%, orbital atherectomy did not result in a greater minimal stent area or reduce the 1-year rate of target vessel failure compared with balloon angioplasty alone before drug-eluting stent implantation.

With a growing elderly population with multiple comorbidities, the effective treatment of severe coronary artery calcification has become increasingly important.[10,11] Severe lesion calcification is associated with an increase in procedural complications including major dissections and perforations.[12] Furthermore, coronary artery calcium impairs device delivery and stent expansion and might damage the stent drug-delivery polymer leading to adverse outcomes, including stent thrombosis and repeat revascularisation procedures.[1–8]

Predilatation with non-compliant balloons is the conventional approach to treat most severely calcified lesions before stent implantation. Specialty cutting or scoring balloons might further improve lesion compliance to facilitate stent expansion in calcified lesions but have not been shown to improve clinical outcomes.[22–24] Advanced calcium modification devices, including atherectomy (orbital, rotational, or laser) and intravascular lithotripsy were developed to ablate and fracture calcium to enhance stent delivery and expansion. In cases of balloon uncrossable or non-dilatable lesions, these technologies are essential.[9–11] However, randomised data supporting the more widespread use of these technologies in severely calcified lesions in which atheroablation is not considered absolutely mandatory, are scarce. In two previous randomised trials,[14,16] rotational atherectomy before stent implantation was associated with higher rates of strategy success than balloon angioplasty for routine lesion preparation of severely calcified lesions, but rotational atherectomy did not improve event-free survival. However, longer-term follow-up of one trial[17] demonstrated an improvement in target lesion revascularisation.[14–17] Additionally, coronary atherectomy is more complex than balloon angioplasty alone,[25] and complications might be greater after atherectomy if the procedure were to be performed by a less experienced interventional cardiologist. Atherectomy has therefore remained infrequent, being used in only 1% to 5% of PCIs in most catheterisation laboratories.[12,13]

One of the primary hypotheses underlying this trial was that more liberalised use of advanced calcium modification devices would improve long-term

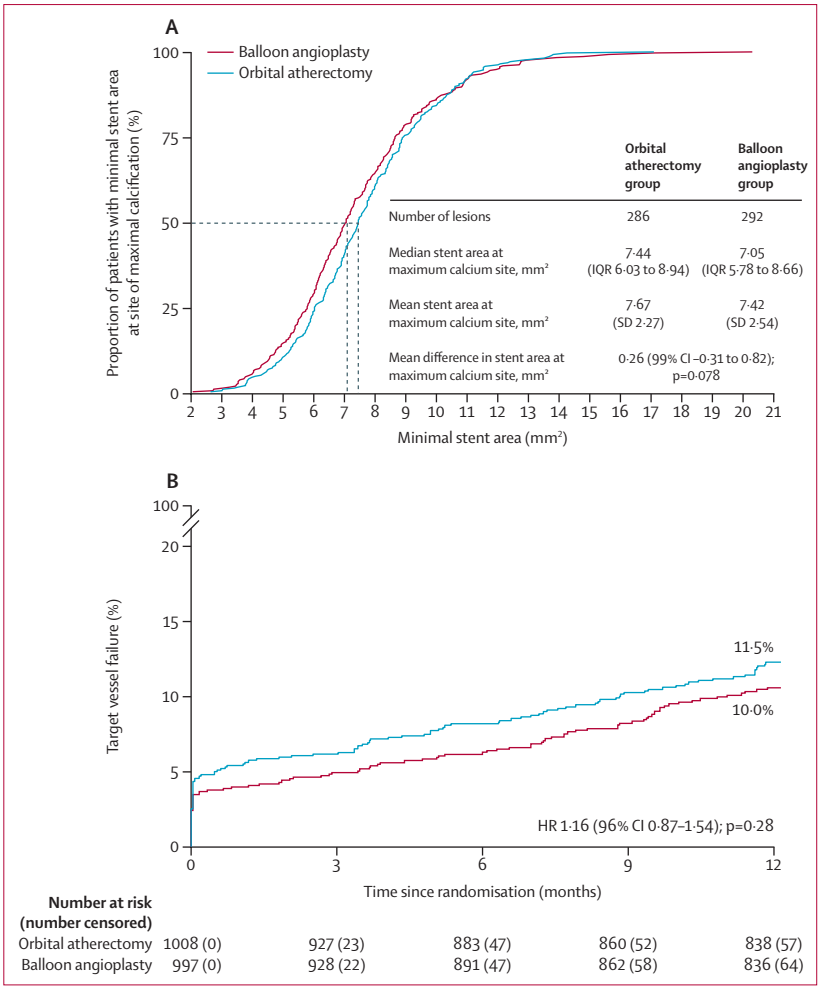

Figure 2: **Primary outcome results**
(A) Cumulative distribution function of minimal stent area at the site of maximal calcification. The y-axis is the proportion of patients with minimal stent area equal to or lesser than the corresponding minimal stent area on the x-axis. (B) Kaplan–Meier estimates of the percentage of patients with target vessel failure at 1-year follow-up.

	Orbital atherectomy group, N/n (%)	Balloon angioplasty group, N/n (%)	HR (95% CI)	$p_{interaction}$
OCT cohort				0·95
Yes (n=555)	21/276 (7·8%)	18/279 (6·6%)	1·18 (0·63–2·21)	
No (n=1450)	92/732 (12·9%)	79/718 (11·4%)	1·15 (0·85–1·56)	
Age (years)				0·68
<65 (n=517)	26/243 (11%)	28/274 (10·5%)	1·05 (0·62–1·79)	
≥65 (n=1488)	87/765 (11·7%)	69/723 (9·9%)	1·20 (0·88–1·65)	
Sex				0·084
Male (n=1464)	70/742 (9·7%)	69/722 (9·9%)	0·99 (0·71–1·37)	
Female (n=541)	43/266 (16·4%)	28/275 (10·5%)	1·64 (1·02–2·63)	
History of diabetes				0·042
Yes (n=881)	50/434 (12%)	58/447 (13·5%)	0·89 (0·61–1·30)	
No (n=1124)	63/574 (11·2%)	39/550 (7·3%)	1·57 (1·05–2·34)	
Clinical presentation				0·30
Recent MI or biomarker positive ACS (n=418)	21/219 (9·9%)	22/199 (11·6%)	0·87 (0·48–1·59)	
Stable angina or biomarker negative (n=1587)	92/789 (11·9%)	75/798 (9·7%)	1·25 (0·92–1·70)	
eGFR				0·29
<30 mL/min per 1·73 m² (n=163)*	22/88 (27%)	14/75 (19·9%)	1·49 (0·76–2·91)	
30–60 mL/min per 1·73 m² (n=537)	35/258 (14%)	26/279 (9·7%)	1·48 (0·89–2·46)	
>60 mL/min per 1·73 m² (n=1301)	56/660 (8·6%)	57/641 (9·1%)	0·95 (0·66–1·37)	
Total target lesion length†				0·95
<30 mm (n=1051)	52/511 (10·4%)	47/540 (9%)	1·17 (0·79–1·73)	
≥30 mm (n=941)	60/489 (12·6%)	49/452 (11·2%)	1·15 (0·79–1·67)	
Total median target lesion length†				0·72
<28·8 mm (n=999)	47/482 (10%)	46/517 (9·2%)	1·09 (0·73–1·64)	
≥28·8 mm (n=993)	65/518 (12·9%)	50/475 (10·8%)	1·21 (0·84–1·75)	
Target lesion length of longest lesion†				0·98
<30 mm (n=1126)	58/553 (10·7%)	52/573 (9·4%)	1·16 (0·80–1·68)	
≥30 mm (n=866)	54/447 (12·4%)	44/419 (10·8%)	1·16 (0·78–1·73)	
Target median lesion length of longest lesion†				0·29
<27·2 mm (n=990)	47/481 (10%)	50/509 (10·2%)	0·99 (0·67–1·48)	
≥27·2 mm (n=1002)	65/519 (12·9%)	46/483 (9·8%)	1·34 (0·92–1·95)	
Total median target lesion calcification length†				0·022
<41·6 mm (n=1003)	35/496 (7·3%)	45/507 (9·2%)	0·78 (0·50–1·21)	
≥41·6 mm (n=998)	78/511 (15·7%)	51/487 (10·8%)	1·51 (1·06–2·15)	
Number of target lesions treated†				0·46
1 (n=1808)	93/905 (10·6%)	84/903 (9·6%)	1·11 (0·83–1·49)	
>1 (n=197)	20/103 (19·9%)	13/94 (14·2%)	1·47 (0·73–2·97)	
Smallest median target lesion RVD†				0·33
<2·9 mm (n=987)	59/476 (12·7%)	49/511 (9·9%)	1·32 (0·91–1·93)	
≥2·9 mm (n=1010)	53/525 (10·4%)	48/485 (10·2%)	1·01 (0·68–1·49)	
Smallest target lesion RVD†				0·17
≤2·5 mm (n=352)	31/184 (17·4%)	16/168 (10%)	1·88 (1·03–3·43)	
2·5–3·0 mm (n=880)	44/410 (11%)	46/470 (10·1%)	1·10 (0·73–1·66)	
>3·0 mm (n=765)	37/407 (9·3%)	35/358 (10%)	0·92 (0·58–1·46)	
Worst tortuosity of any treated lesion†				0·11
None (n=1937)	111/970 (11·7%)	93/967 (9·9%)	1·20 (0·91–1·58)	
Moderate or severe (n=62)	1/33 (3·1%)	4/29 (14·1%)	0·20 (0·02–1·80)	
Worst angulation of any treated lesion†				0·78
>45° (n=196)	12/92 (13·1%)	13/104 (12·7%)	1·04 (0·48–2·28)	
≥45° (n=1795)	99/909 (11·2%)	83/886 (9·7%)	1·17 (0·87–1·57)	
Access site				0·044
Any femoral (n=945)	69/480 (14·8%)	46/465 (10·3%)	1·51 (1·04–2·19)	
No femoral (n=1060)	44/528 (8·5%)	51/532 (9·8%)	0·86 (0·57–1·28)	
Worst treated lesion calcium severity†				0·92
None, mild, or moderate (n=33)	2/16 (12·9%)	2/17 (12·2%)	1·03 (0·15–7·33)	
Severe (n=1971)	111/991 (11·5%)	95/980 (10%)	1·16 (0·89–1·53)	
1-year follow-up relative to COVID-19				0·034
During COVID-19 (n=887)	43/447 (9·9%)	50/440 (11·7%)	0·84 (0·56–1·26)	
Not during COVID-19 (n=1118)	70/561 (12·8%)	47/557 (8·7%)	1·51 (1·05–2·19)	
All patients (n=2005)	**113/1008 (11·5%)**	**97/997 (10·0%)**	**1·16 (0·87–1·54)**	

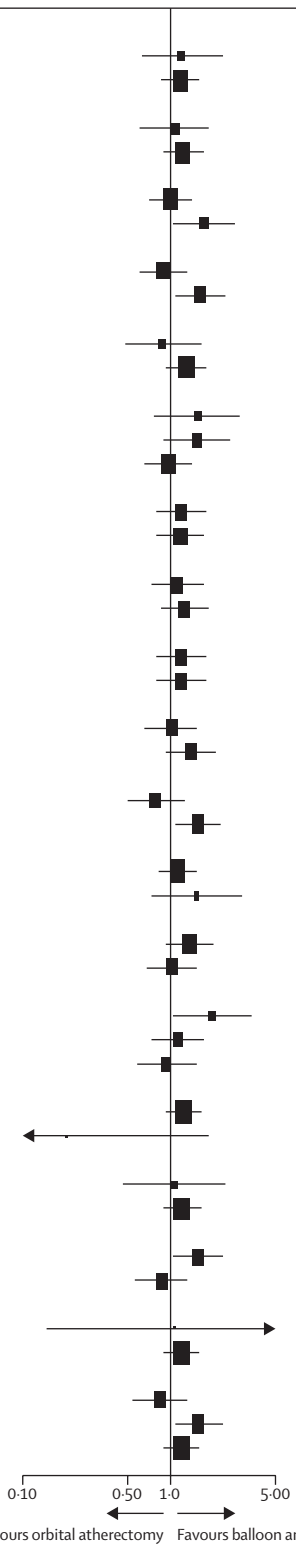

Figure 3: **1-year rates of target vessel failure in prespecified subgroups**
ACS=acute coronary syndrome. eGFR=estimated glomerular filtration rate. MI=myocardial infarction. OCT=optical coherence tomography. RVD=reference vessel diameter. *Patients with eGFR <30 mL/min per 1·73m² includes those on chronic haemodialysis. †Angiographic core laboratory-reported variables.

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outcomes after PCI of calcified coronary lesions. Compared with rotational atherectomy, in which a diamond-coated burr is advanced linearly at high-speed over a guidewire, the orbital atherectomy crown was designed to take an elliptical path through the coronary artery to sand the calcified surface, potentially leading to greater calcium ablation with less thermal injury.[19,26] Additional modifications of precedent atherectomy systems have been incorporated into the design of the orbital atherectomy device to facilitate ease of use. However, in this trial, which was conducted in patients representative of a population in the USA undergoing PCI of severely calcified lesions (appendix p 26), routine use of orbital atherectomy did not provide greater stent expansion (with the 99% CIs excluding a 1 mm² difference between groups) or improve clinical outcomes compared with a balloon-based approach to lesion preparation before stent implantation. Further, orbital atherectomy did not lessen procedural complexity; PCI procedures in the atherectomy group were longer and required a greater number of guidewires and ancillary equipment, such as microcatheters and temporary pacemakers, as well as more contrast. Similarly to observations in smaller trials,[25] the results of this trial argue against more widespread use of atherectomy in calcified lesions that are crossable and dilatable by a balloon-based approach.

Although 2156 (97·1%) of 2221 lesions were verified as severely calcified, only 61 (4·9%) lesions in 46 patients in the balloon angioplasty group required crossover to atherectomy or lithotripsy to enable stent delivery or expansion. This crossover rate is lower than in previous trials,[14,16] which probably reflects the differences in case selection and improvements in contemporary balloons, stents, and other adjunctive PCI equipment and techniques. Although the lesions within this trial were severely calcified, operators did not believe atherectomy was absolutely necessary to cross them or enable adequate stent expansion.

Despite the angiographic severity of lesion calcification, the rate of target vessel failure (especially target lesion revascularisation) was lower than expected following lesion preparation with balloon angioplasty alone, and the minimal stent area in this group was greater than anticipated. These findings indicate that adequate stent expansion and low rates of adverse outcomes are achievable with a balloon angioplasty-based approach alone in a large proportion of severely calcified lesions if meticulous attention is paid to lesion preparation before contemporary stent implantation. Outcomes (in both groups) were probably further improved through the high rate of intravascular imaging observed within the trial,[27,28] a practice recently afforded a class I guideline recommendation for complex PCI.[29,30] These data suggest that the conventional definition of severe calcification based on the angiogram alone, which has been in use for several decades, might currently be insufficient to identify lesions that could benefit from advanced calcium modification strategies.[31–33]

The results of this study do not apply to lesions so extensively calcified that they pose a major risk for stent non-delivery or under-expansion and were excluded from randomisation. For these lesions, calcium-modifying devices, such as coronary atherectomy or lithotripsy, are necessary to perform PCI, and scoring systems might be of use in determining a threshold for when these devices are necessary.[31–34] It is reassuring that, in this study, there was no excess of severe angiographic complications including major dissections or perforation among patients treated with orbital atherectomy, partly due to the experience of the participating investigators. Nevertheless, eight early cardiac deaths occurred in the orbital atherectomy group, compared with none in the balloon angioplasty group. Although this comparison was underpowered, and not all deaths were attributable to the atherectomy device or procedure, it is nonetheless concerning and reinforces the need for greater training, improved case

	Orbital atherectomy group (n=1008)	Balloon angioplasty group (n=997)	Hazard ratio (96% or 95% CI)*	p value
Primary endpoint				
Target vessel failure	113 (11·5%)	97 (10·0%)	1·16 (0·87–1·54)†	0·28
Components and other endpoints				
All-cause death	61 (6·2%)	53 (5·5%)	1·14 (0·79–1·65)	0·48
Cardiac	39 (4·0%)	26 (2·7%)	1·49 (0·91–2·45)	0·12
Vascular	4 (0·4%)	2 (0·2%)	1·99 (0·36–10·84)	0·43
Non-cardiovascular	18 (1·9%)	25 (2·6%)	0·71 (0·39–1·31)	0·28
All myocardial infarction	80 (8·1%)	74 (7·6%)	1·07 (0·78–1·47)	0·65
Procedural	41 (4·1%)	34 (3·4%)	1·19 (0·76–1·88)	0·45
Non-procedural	41 (4·3%)	40 (4·2%)	1·02 (0·66–1·57)	0·94
Target vessel-related	55 (5·6%)	43 (4·4%)	1·27 (0·85–1·89)	0·24
Non-target vessel-related	27 (2·8%)	32 (3·4%)	0·84 (0·50–1·39)	0·49
Ischaemia-driven revascularisation, any	81 (8·5%)	76 (8·1%)	1·06 (0·78–1·45)	0·70
Ischaemia-driven TVR	40 (4·2%)	41 (4·4%)	0·97 (0·63–1·49)	0·88
Ischaemia-driven TLR	32 (3·4%)	32 (3·4%)	0·99 (0·61–1·62)	0·98
Ischaemia-driven TVR (non-TLR)	15 (1·6%)	16 (1·7%)	0·93 (0·46–1·88)	0·84
Ischaemia-driven non-TVR	57 (6·0%)	44 (4·7%)	1·30 (0·88–1·92)	0·19
Stent thrombosis (definite or probable)	11 (1·1%)	4 (0·4%)	2·74 (0·87–8·59)	0·085
Definite	8 (0·8%)	4 (0·4%)	1·99 (0·60–6·61)	0·26
Probable	3 (0·3%)	0	..	..
Timing of stent thrombosis				
Acute (ie, <24 h)	1 (0·1%)	2 (0·2%)	0·49 (0·04–5·45)	0·57
Subacute (ie, 24 h–30 days)	6 (0·6%)	1 (0·1%)	5·97 (0·72–49·59)	0·10
Late (ie, >30 days–1 year)	4 (0·4%)	1 (0·1%)	3·99 (0·45–35·73)	0·22

Data are number of events (Kaplan–Meier estimates), unless otherwise specified. p values are based on a Cox proportional hazards model. TLR= target lesion revascularisation. TVR=target vessel revascularisation. *The only hazard ratio with a 96% CI is target vessel failure (primary endpoint), all others have 95% CIs. †The estimated hazard ratio for target vessel failure at 1 year was 1·16 (96% CI 0·89–1·52).

Table 3: **Clinical outcomes at 1 year**

selection, and haemodynamic optimisation of patients who require atherectomy.[12,13]

This trial has several limitations. First, as noted, patients with extremely calcified lesions for which investigators believed atherectomy was required and those in whom atherectomy might not have been safe (eg, extreme vessel tortuosity or lesion angulation) were excluded from enrolment. The proportion of screened patients excluded for these reasons was not recorded. Second, operators and patients were not masked to treatment, which might have affected early and late outcomes through differences in practice relating to knowledge of treatments administered. Third, the frequent use of femoral access (945 [47·1%] of 2005 patients) might reflect differences in practice within the USA compared with other countries, but probably also reflects the need for improved guide support during the treatment of complex calcified coronary lesions. Fourth, although there were borderline interactions observed in prespecified subgroups according to diabetes, target lesion calcification length, access site, and follow-up in relation to the COVID-19 pandemic, subgroup analyses were not adjusted for multiplicity; as such, they should be considered hypothesis-generating. Fifth, at operator discretion, intravascular imaging guidance was performed in 1246 (62·1%) of 2005 patients. The effect of this non-randomised practice on the outcomes of PCI in this patient population with severely calcified lesions will be reported separately. Detailed analyses from the randomised optical coherence tomography cohort beyond the post-procedural minimal stent area are also ongoing and will be reported separately. Finally, trial enrolment occurred over 6 years, during which changes in treatment practices occurred and new calcium-modifying devices were introduced. The results of this study apply only to lesion preparation with orbital atherectomy compared with balloon angioplasty using non-compliant, scoring and cutting balloons. Ultra-high pressure balloons and intravascular lithotripsy were not available in the USA during most of the enrolment period of this trial. It is unknown whether routine use of these balloon-based devices might improve outcomes before stent implantation in severely calcified coronary lesions that are crossable and dilatable by a standard balloon-based approach, and it warrants further study.

In conclusion, routine treatment with the calcium modification strategy of orbital atherectomy before drug-eluting stent implantation did not increase the minimal stent area or reduce the rate of target vessel failure at 1 year compared with a balloon angioplasty-based approach in severely calcified lesions deemed eligible for both treatment strategies. These findings support a balloon-first approach to most calcified coronary artery lesions that can be crossed and dilated before stent implantation, guided by intravascular imaging.

Contributors

AJK, PG, and GWS designed the trial. AJK and GWS supervised the trial and accessed and verified the data. AJK, PG, BL, RAS, SD, JC, TD, AMP, and KS enrolled participants. PG, AM, AP, BR, and ZAA were involved in core laboratories, trial design, or data management (or all these). AJK, PG, MK, EA, DEK, WO, and GWS were steering committee members. CK, KMS, DEJ, and JC were involved in data management and trial supervision. AJK and GWS drafted and revised the manuscript. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Declaration of interests

AJK reports research grants and consulting fees paid to Columbia University or the Cardiovascular Research Foundation from Medtronic, Boston Scientific, Abbott Vascular, Amgen, CathWorks, Concept Medical, Philips, ReCor Medical, Neurotronic, Biotronik, Chiesi, Bolt Medical, Magenta Medical, SoniVie, and Shockwave Medical; equity options in Bolt Medical; and support for meeting attendance from Amgen, Medtronic, Biotronik, Boston Scientific, Abbott Vascular, CathWorks, Concept Medical, Novartis, Philips, Abiomed, ReCor Medical, Chiesi, Zoll, Shockwave, and Regeneron. PG reports consultancy, advisor, and speaker fees from Abbott Vascular; consultancy, advisor, and speaker fees from Abiomed; consultancy fees from Boston Scientific; consultancy, advisor, and speaker fees, a proctor role, and an institutional research grant from Edwards Lifesciences; consultancy, advisor, and speaker fees from Medtronic; consultancy fees from Haemonetics; equity and consultancy fees from Pi-Cardia; equity and consultancy fees from Puzzle Medical; consultancy and speaker fees from Shockwave; equity and consultancy fees from Soundbite Medical; consultancy fees from Teleflex; consultancy fees from 4C Medical; consultancy and advisor fees from Egnite; and was a coprimary investigator for the ECLIPSE trial (funded by Abbott Vascular), a primary investigator for the EARLY-TAVR and PROGRESS trials (funded by Edwards Lifesciences), and a primary investigator for the ALTA Valve Feasibility study (funded by 4C Medical). RAS is a Chairman of Cardiology at St Francis Hospital. SD reports fellowship grants from Abbott Vascular and Cardiovascular Systems paid to Cedars Sinai Medical Center and Smidt Heart Institute, and payment for lectures on complex PCI and optical coherence tomography from Abbott Vascular. TD reports honoraria for lectures, presentations, speakers bureaus, manuscript writing, or educational events from Cardiovascular Systems; and participation on the ECLIPSE crossover committee and the advisory board for Abbott Vascular for the ECLIPSE study. AMP reports consulting fees and support for meeting attendance from Cardiovascular Systems. KS reports grants or contracts paid to institution from Cardiovascular Systems (for the ECLIPSE trial), Boston Scientific, and Idorsia; royalties with Johns Hopkins for transoesophageal MRI; consulting fees from PercAssist and TransAortic Medical; payment or honoraria for being a faculty lecturer from Cardiovascular Innovations; support for meeting attendance from PercAssist; participation on a data safety monitoring board or advisory board for Syntactx, TransAortic Medical FIM, and the ENGULF trial; a role as Chair for the CathPCI Steering Committee (American College of Cardiology) Ex officio; and stock or stock options with PercAssist. AM reports consulting fees paid to Cardiovascular Research Foundation from Boston Scientific, Abbott Vascular, and Philips; consulting fees from Amgen; and payments for participation on a data safety monitoring board or advisory board for SpectraWave. AP reports grants or contracts from Abbott/Cardiovascular Systems to the Cardiovascular Research Foundation for the coordination of the core laboratories, clinical events committee, and the academic research organisation in the ECLIPSE study. ZAA reports institutional grants from Abbott, Abiomed, Acist Medical, Amgen, AstraZeneca, Boston Scientific, Cardiovascular Systems, Chiesi, Gore, HeartFlow, Inari, Medtronic, Nipro, Philips, Shockwave, and Siemens; personal fees from Acist Medical, AstraZeneca, Boston Scientific, Philips, and Shockwave; and equity from Elucid, Lifelink, Spectrawave, and Vital Connect. MK reports research funding paid to the institution from CSI and Abbott Vascular, and grants, consulting fees, lecturer fees, and support for meeting attendance from CSI and Abbott Vascular. EA reports consulting fees from Abbott Vascular, Boston Scientific, Medtronic, and Shockwave Medical; and is a board member with the VIVA Foundation. DEK reports grants or contracts from Medtronic,

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Data sharing

The data from this study will not be made publicly available. The authors will consider requests for collaborative research. Any relevant inquiries should be emailed to the corresponding author (gregg.stone@mountsinai.org).

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