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Planned *versus* bailout rotational atherectomy: A systematic review and meta-analysis☆

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ABSTRACT

Background/purpose: Rotational atherectomy (RA) plays a central role in the treatment of heavily calcified coronary artery lesions. Our aim was to compare periprocedural characteristics and outcomes of planned (PA) *vs.* bailout (BA) rotational atherectomy.

Methods: We conducted a systematic review and performed a meta-analysis on studies which compared PA *vs.* BA strategy.

Results: Five studies fulfilled the inclusion criteria, pooling a total of 2120 patients. There was no difference in procedural success, PA *vs.* BA risk ratio (RR) 1.03 and 95% confidence interval (95% CI) 0.99–1.07. Compared to BA, PA was associated with a shorter procedural time [mean difference (MD) -25.88 min, 95% CI -35.55 to −16.22], less contrast volume (MD -43.71 ml, 95% CI -69.17 to −18.25), less coronary dissections (RR 0.50, 95% CI 0.26–0.99), fewer stents (MD -0.20, 95% CI -0.29 to −0.11), and a trend favouring less periprocedural myocardial infarctions (MI) (RR 0.77, 95% CI 0.54–1.11). There was no difference in major adverse cardiovascular events on follow-up (RR 1.04, 95% CI 0.62–1.74), death (RR 0.98, 95% CI 0.59–1.64), MI (RR 1.16, 95% CI 0.62–2.18), target vessel revascularization (RR 1.40, 95% CI 0.83 to 2.36), stroke (RR 1.50, 95% CI 0.46–4.86) or stent thrombosis (RR 0.82, 95% CI 0.06–10.74); all PA *vs.* BA comparisons.

Conclusions: Compared to bailout RA, planned RA resulted in significantly shorter procedural times, less contrast use, lesser dissection rates and fewer stents used. The bailout RA approach appears to enhance periprocedural risk, but there is no difference on mid-term outcomes.

1. Introduction

Over the last five decades percutaneous coronary intervention (PCI) transformed the management of coronary artery disease (CAD). With the aging population, advancement of PCI technology, and increasing public expectation, operators increasingly encounter patients with complex coronary anatomy with heavily calcified CAD. Despite availability of multiple calcium modification strategies, involving cutting balloons, intravascular lithotripsy, orbital atherectomy or laser, rotational atherectomy (RA) remains one of the corner stone techniques to target calcified plaques. In the late 1980's during the pre-stent era, rotational atherectomy emerged as an adjunct to balloon angioplasty and was first performed by Hansen et al. [1,2]. Over the later years' RA found its stable place in calcified lesion modification prior to stent implantation. In contemporary practice, RA use varies widely and ranges from <1% up to 10% of all PCIs at select centres [3].

In daily clinical practice, RA is dominantly implemented during the elective or semi-elective cases, rather than emergency procedures. Recently, a variety of calcium modification algorithms were suggested by the experts in the field [4,5]. Operators use either a planned approach (PA), defined as RA performed immediately before balloon predilation, or as bailout (BA) RA after failure to expand a predilating balloon [6]. Several retrospective single and multicentre observational studies analysed procedural and clinical outcomes [6–10]. Whereas most of these studies show that PA strategy leads to decreased procedural

Abbreviations: BA, bailout (approach) rotational atherectomy; MACE, major adverse cardiovascular events; MD, mean difference; MI, myocardial infarction; PA, planned (approach) rotational atherectomy; PCI, percutaneous coronary intervention; RA, rotational atherectomy (rotablation); RR, risk ratio; TVR, target vessel revascularisation.

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(and/or fluoroscopy) times and less contrast use when compared to BA, data on important periprocedural in-hospital outcomes are scarce and heterogeneously reported across studies. Such outcomes include rates of periprocedural complications including coronary dissections, number of stents used, periprocedural MIs, in-hospital MACE and post-discharge follow-up events. There is no consensus or society recommendation onto which approach - PA or BA is safer or whether both approaches might be equally safe.

In order to answer the question on safety and clinical outcomes of the two different RA approaches, we reviewed literature and performed a meta-analysis on all previously published procedural and clinical outcome data comparing PA and BA rotational atherectomy.

2. Methods

This systematic review and meta-analysis of observational studies was conducted in accordance to the recommendations of the MOOSE criteria [11]. A search of MEDLINE from 1946 and EMBASE from 1974 to 14 May 2021 was performed to identify studies of planned *versus* bailout RA in patients undergoing PCI. The exact search terms were "*rotational atherectomy*" and "*planned OR bailout OR bail-out*". There was no restriction based on the inclusion of studies based on country of origin or language and the bibliography of studies that met the inclusion criteria were reviewed for additional studies. There was no need for contacting authors as the reports included had sufficient detail for data collection.

Studies that were included all evaluated a group of patients who underwent PCI with RA. In addition, there had to be two groups where one had to have RA as a planned or primary procedure and the other has RA as a bailout or secondary procedure. There was no restriction on design of study whether it was a randomized control trial or observational study but there had to be parallel groups. The included studies also had to report results for both groups in the form of in-hospital or follow-up outcomes.

The search results were screened independently by KS and CSK for studies that met the inclusion criteria. Data was extracted by SL and CSK onto predefined tables which collected information on study design, patient characteristics, PCI procedural characteristics and patient outcomes. Both in-hospital and available follow-up data were collected.

In addition, quality assessment was performed considering a number of domains which were: i) reliable ascertainment of bailout and planned RA, ii) reliable outcome ascertainment, iii) low loss to follow up, iv) consideration of adjustments for confounders and v) generalizability of the cohort of PCI patients who have RA.

The results of the studies were synthesized narratively and by statistically pooling with meta-analysis. The random-effects meta-analysis was performed on Review Manager 5.4 (Nordic Cochrane Centre). The Mantel-Haenszel method for dichotomous data was used to determine risk ratios for adverse outcomes for patients who had planned *versus* bailout RA. Continuous data was pooled using the inverse variance methods in a random effects model utilizing mean difference as the effect measure. We used the I^2 statistic to assess statistical heterogeneity

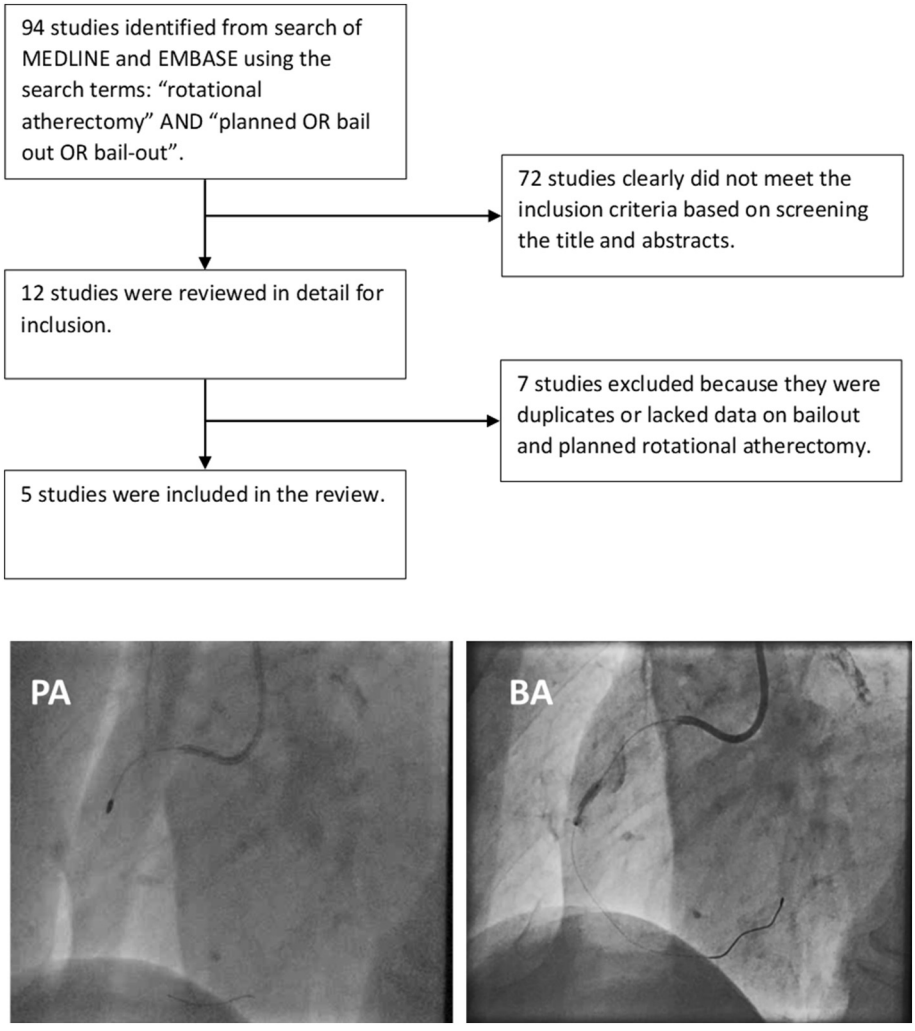

Fig. 1. Flow diagram of literature search and study selection. PA Planned rotational atherectomy, BA Bail out rotational atherectomy.

and values of 30–60% represent moderate levels of heterogeneity [12]. We performed leave-one-out sensitivity analysis in order to identify the studies which contributed to statistical heterogeneity in the pooled estimates. This was performed for pooled estimates where there were more than two studies and I^2 values were > 50%. Publication bias was assessed by asymmetry testing with funnel plots if the dataset contained more than 10 studies and there is no evidence of statistical heterogeneity [13].

3. Results

The search yielded 94 results and after detailed review of titles and abstracts a total of 5 studies met the predefined inclusion criteria (Fig. 1). All five studies were retrospective cohort studies that were undertaken in Germany, China and Italy between 2002 and 2018 (Table 1). There were a total of 2120 patients whose average mean age was 71 years and proportion of male patients was 69%.

The risk of bias assessment of the included studies is available in the Supplementary Table 1. All studies had likely reliable methods to ascertain exposure to RA. Three of the five studies used reliable methods for follow-up and in the other two studies it was not clear how follow-up data was collected. All studies had low loss to follow-up and only one study did not consider adjustments in their analysis. In terms of generalizability, all the studies were representative of a general PCI cohort which underwent RA.

The characteristics of patients included in the analysis are shown in Supplementary Table 2. For study by Allali et al., there was a greater proportion of patients with prior myocardial infarction in the planned RA group (27.9% *vs.* 18.1%). In Cao et al., the only difference between groups was observed for the use of intravascular imaging where intravascular imaging with ultrasound (IVUS) or optical coherence tomography (OCT) were used in 25.4% and 11.5% of patients with planned and bailout RA, respectively. Both studies by Gao and Qi showed no difference in patient characteristics in both groups. Kawamoto and colleagues found that patients with bailout compared to planned RA had greater proportion of patients who were smokers (24.3% *vs.* 15.9%), had family history of CAD (29.4% *vs.* 19.0%) and had ACS (30.7% *vs.* 22.3%) but less had insulin dependent diabetes (10.7% *vs.* 16.2%), fewer had eGFR <60 ml/min/1.73m^2 (15.9% *vs.* 33.2%), hemodialysis (6.1% *vs.* 12.8%), previous PCI (31.4% *vs.* 39.4%) and peripheral vascular disease (16.8% *vs.* 24.0%).

The angiographic, procedural characteristics, in-hospital outcomes and mid-term follow-up outcomes found in individual studies are shown in Supplementary Tables 3–6. The results of the sensitivity analysis exploring statistical heterogeneity is shown in Supplementary Table 7.

Our meta-analysis of pooled data showed risk ratios (RR, 95% CI) favouring PA compared to BA rotational atherectomy in several of the periprocedural outcomes. These included shorter procedural time MD -25.88 min (95% CI -35.55 to −16.22); lower contrast volume use −43.71 ml (−69.17 to −18.25), less coronary dissections RR 0.50 (95% CI 0.26–0.99), fewer stents implanted MD -0.20 (−0.29 to −0.11), and a trend favouring less periprocedural myocardial infarctions RR 0.77 (95% CI 0.54–1.11); PA *vs.* BA, respectively (Fig. 2). The follow-up time ranged from 1 year to 3.5 years. There was no difference on follow-up in MACE (RR 1.04, 95% CI 0.62–1.74), death (RR 0.98, 95% CI 0.59–1.64), acute MI (RR 1.16, 95% CI 0.62–2.18), TVR (RR 1.40, 95% CI 0.83–2.36), stroke (RR 1.50, 95% CI 0.46–4.86) or stent thrombosis (RR 0.82, 95% CI 0.06–10.74); all PA *vs.* BA comparisons (Fig. 3).

In our analysis, we intended to compare outcomes regarding the fluoroscopy time with respect to RA strategy. However, this analysis could not be performed reliably due to paucity of data as only two studies reported fluoroscopy time and one study reported skin radiation dose. We did not report on in-hospital MACE, as though Allali and Kawamoto, both reported significantly higher numbers in the BA group and Qi reported numerically, but statistically not significant higher numbers in the BA group, Gao reported an in-hospital MACE which was not different to PA group. Gao et al. reported MACE rates of around 2% for both parallel groups which were significantly lower compared to other studies which reported in-hospital MACE rates around 10 to 13%. The reason for Gao's low numbers stems from definition of MACE which was used in that particular study. Their definition did not include periprocedural MIs. This is very unusual, as MI in most studies comprised the main component of described in-hospital MACE.

4. Discussion

The key findings of our meta-analysis are that PA, when compared to BA rotational atherectomy results in shorter procedural time, less contrast volume use, reduced incidence of coronary dissections, decreased total number of stents used, and a trend to reduced periprocedural MIs. There was no observed difference with respect to post-discharge outcomes.

A shortened procedural time could be explained by more efficient planning of the catheterisation laboratory set up with the PA strategy, having the team and RA equipment ready to go. Further time can be saved by avoiding the initial ballooning step used in BA strategy. Shorter procedural time is likely associated with shorter total fluoroscopy time. Indeed, both Allali and Kawamoto reported the use of about half fluoroscopy time needed in PA *vs.* BA rotational atherectomy [7,10]. This is supported with findings by Cao who described significantly lower fluoroscopy skin dose in PA group [9]. Shorter fluoroscopy time leads to less radiation exposure to both the patient and the operator. This can result in an important safety advantage in complex lengthy procedures, such as encountered during PCIs for heavily calcified coronary arteries needing RA, which are associated with higher skin radiation dose [14].

Higher contrast volume used in BA, could possibly be explained by contrast volume used for initial balloon placement during predilation, or by dealing with complications resulting from coronary dissections. Contrast volume used during coronary angiography and PCI procedure is one of the modifiable factors contributing to contrast induced nephropathy [15,16]. Patients presenting with heavily calcified disease

Table 1
Study design and participant characteristics.

Study ID	Study design; Country; Year	No. of patients	Mean age	% male	Patient inclusion criteria
Allali 2016	Retrospective cohort study; Germany; 2002 to 2014.	512	71	74%	Patients underwent PCI using RA for heavily calcified and/or fibrotic lesions.
Cao 2020	Retrospective cohort study; China; 2017 to 2018.	190	70	64%	Patients underwent PCI using RA because of heavily calcified lesions.
Gao 2021	Retrospective cohort study; China; 2015 to 2019.	540	70	67%	Patients underwent PCI using RA because of heavily calcified lesions.
Kawamoto 2016	Retrospective cohort study; Italy; 2002 to 2013.	667	71	77%	Patients with calcified coronary lesions treated by RA at 8 different institutions in the ROTATE registry.
Qi 2020	Retrospective cohort study; China; 2011 to 2018.	211	73	62%	Patients with PCI using RA.

PCI = percutaneous coronary intervention; RA = rotational atherectomy.

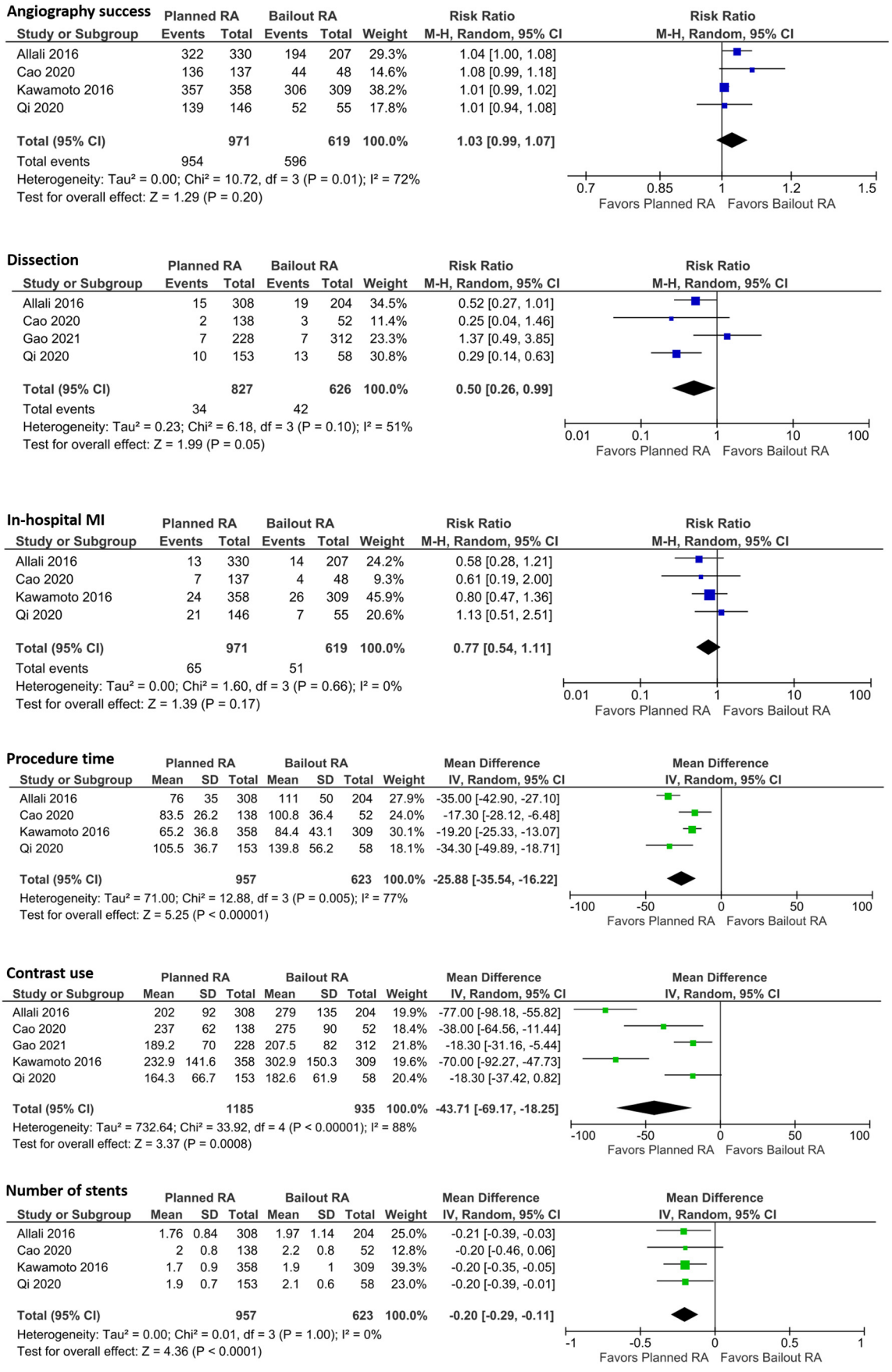

Fig. 2. Forest plot reporting pooled outcomes for angiography success, coronary dissection, in-hospital myocardial infarction (MI), procedure time, contrast use and number of stents.

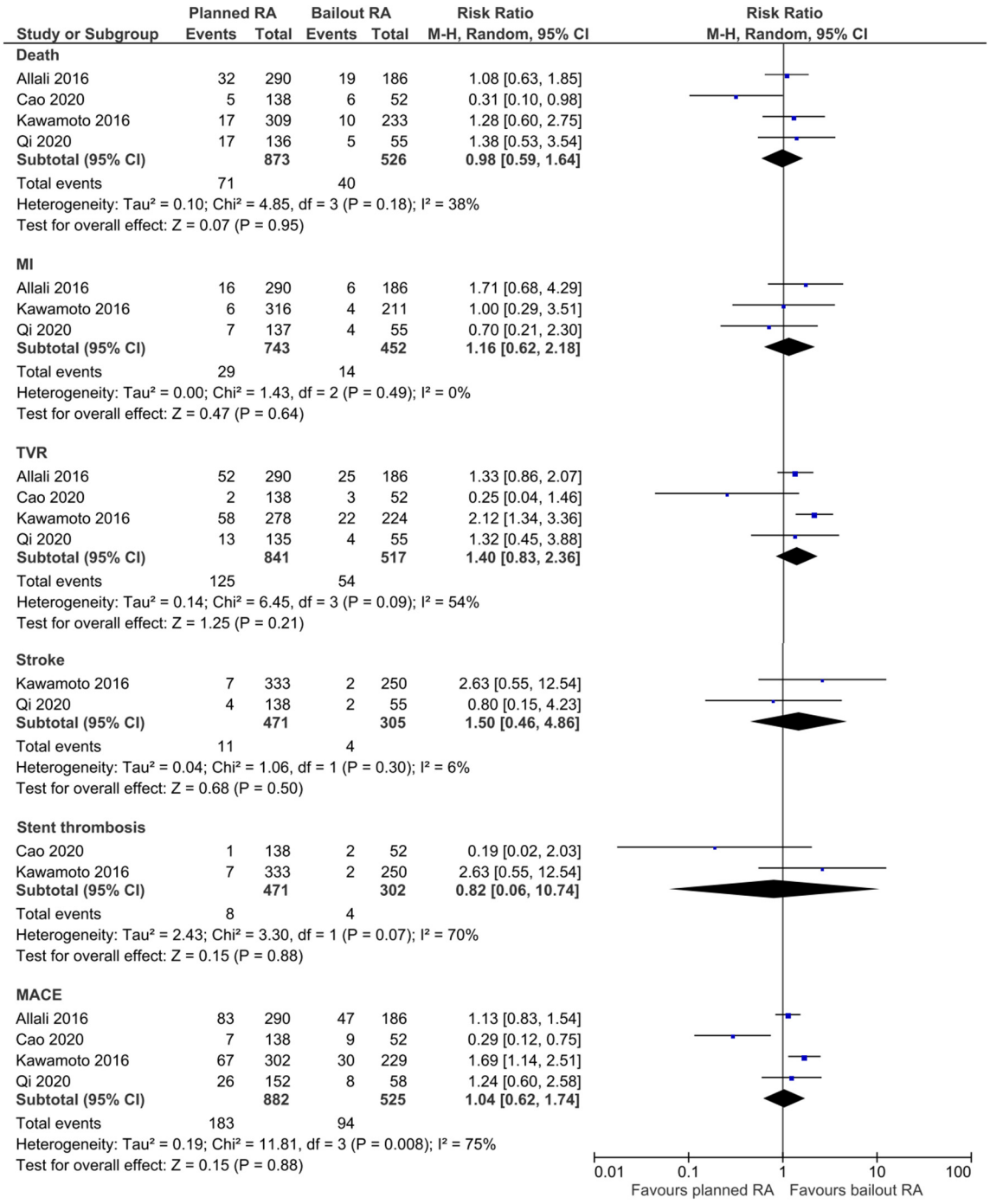

Fig. 3. Forest plot reporting pooled analysis of follow up outcomes including death, myocardial infarction (MI), target vessel revascularization (TVR), stroke, stent thrombosis and major cardiovascular events (MACE).

often present elderly with multiple comorbidities including impaired renal function. Every attempt to reduce their risk of contrast induced nephropathy should be of utmost importance.

A potential risk with BA strategy may be reflected by an increased risk of propagating dissection or lost flow induced by balloon predilation and the following bail out RA. This may lead to the need to use more stents and higher incidence of periprocedural MIs as suggested by our pooled analysis. Shorter procedural times can add to better catheterisation laboratory work flow efficiency, resulting in time and cost saving. Further cost saving can be expected by lower numbers of implanted stents. Whereas our meta-analysis was comprised of retrospective cohort studies comparing directly PA *vs.* BA strategy, Dill et all randomized in an older pre-drug eluting stent era prospective COBRA trial 502 patients with complex coronary artery lesions to either balloon angioplasty or rotablation [17]. There were no differences in Q wave infarctions, emergency bypass surgery or death, but procedural success was higher in the rotablation arm (84%) compared to balloon angioplasty arm (73%, $p = 0.006$), and more stents were used in balloon angioplasty group ($p < 0.002$), predominantly for bailout or unsatisfactory results. In the more recently published PREPARE-CALC trial 200 patients with severely calcified coronary arteries were randomized either to modified (scoring or cutting) balloons (MB) or rotablation (RA) [18].

Procedural success was higher in the RA (98%) *vs* MB (81%) group and the relative risk of failure with the MB strategy more common 9.5 (95% CI 2.3–39.7, $p < 0.001$).

These results are in-line with the finding of our meta-analysis where though rotablation was used in each case, however worse periprocedural outcomes and more stent use were observed if initial balloon angioplasty was attempted (bailout group). The results for the post-discharge follow-up are shown in Supplementary Table 5. It is notable that the follow up for the 4 studies varied from 1 year to a median of 44 months. These results were pooled in meta-analysis and showed no statistical differences in any of the evaluated outcomes at follow up (Fig. 3). This finding suggests, that once a patient is discharged, there is no mid-term difference on which RA strategy was used during his procedure.

Treatment of heavily calcified arteries is challenging, and recommendations are based mainly on expert consensus. Over the last few years, intracoronary imaging has greatly evolved and in the opinion of many experts is finding its place in the centre of decision making as to which calcium modification strategy is best placed to deal with a particular coronary calcification pattern. Intracoronary imaging is not only intended to help with the most suited calcium modification tool, but optimization of stent expansion impacts on long term outcome [19]. Intracoronary imaging demonstrates coronary calcium burden in better detail than angiography, and could lead to an increase in a PA rather than a BA strategy. There are cases when an imaging catheter (OCT or IVUS) cannot be placed through the most calcified lesions and needs a certain lesion preparation first. In other cases, the lesion can be so tight that no balloon can cross the tightest lesion. In light of our finding, we propose a pragmatic approach. If it is clear that a lesion is angiographically or on basis of intracoronary imaging highly likely to need RA, then a planned rotational atherectomy is preferable. Prior to stent placement, further modification strategies (*e.g.,* high pressure balloons, cutting balloons or intravascular lithotripsy) may be needed in adjunction to initial RA. Intracoronary imaging should be attempted ideally already prior to lesion preparation, but if not possible to pass an imaging catheter through a very tight lesion, then after initial modification a final imaging run following stent placement and post-dilation should complete the procedure.

5. Limitation

Approximately half of the patients originated from China and half from Europe. Racial differences and local practice may potentially limit some generalization of the results of this meta-analysis, however as the effects of the two different RA approaches were compared in each population against each other mostly utilizing propensity matching, such influence should be fairly small. The included studies were of limited size, non-randomized and the varying lengths of follow-up should be acknowledged as a potential limiting factor (1 year to 3.5 years). Study by Gao et al. (8) reported solely on in-patient outcomes and did not report on periprocedural MIs. Therefore, outcomes of this study were included only for the analysis where the appropriate endpoints were reported.

Most of the 5 studies reported varying information on high lesion complexity comparing the two retrospectively observed arms. These characteristics included proportions of ACC/AHA type B2/C lesions, bifurcation lesions or CTOs. Interestingly, Allali et all reported significantly more ACC/AHA type B2/C lesions in the BA *vs.* PA. arm (89.6 *vs.* 80.8%, $p = 0.005$), but the largest study of Kawamoto (91.3 *vs.* 88.8%, $p = 0.26$) and smaller by Cao (82.7 *vs.* 79.7%, $p = 0.56$) did not, Supplementary Table 3. Two of the studies reported presence of bifurcation lesions, both showing higher implementation of PA *vs.* BA strategy in such lesions (Kawamoto et al. 34.2% *vs.* 20.3%, $p \leq 0.001$; Allali et al. 41.1 *vs.* 28.5%, $p = 0.002$, PA *vs.* BA). Four out of 5 studies reported significantly higher proportion of CTOs in the BA (range 7.7–23.7%) *vs.* PA group (2.4–5.3%), Supplementary Table 3. The higher proportion of CTO lesions could potentially contribute to observed higher incidence of periprocedural complications in the BA group. *Vice versa*, presence of bifurcation lesions would not support this bias. High variation of pre-existing lesion complexity within the two groups in the presented meta-analysis of retrospective studies is a limitation of our finding and allows descriptive rather than causal relationship between the incidence of periprocedural complications and the choice of rotablation strategy.

Furthermore, our study cannot answer clinical implications or financial costs of a strategy which includes a provisional pre-dilation of a heavily calcified coronary artery, and if successful is not followed by RA. Neither can we answer the long-term benefit (cost saving) or harm by such provisional strategy when RA was kept as a bailout, but for some reason (such as large dissection) RA became contraindicated during the procedure and poorly modified lesion might have later resulted in target lesion failure. To answer these important questions, a prospective randomized trial would be needed. Such trial could involve three arms: 1) planned RA or a provisional RA, which itself may result into either a 2) bailout RA or 3) no need for RA at all.

6. Conclusion

In heavily calcified coronary arteries, with high likelihood of the need for RA, planned approach is preferable to bailout strategy. This approach saves time and reduces periprocedural complications. Once, the patient is discharged, there is no impact on the long-term outcome of the RA strategy used during the procedure.

CRediT authorship contribution statement

Konstantin Schwarz: conceptualization, visualization, data curation, writing – original draft, editing & review. Saul Lovatt: data curation, editing & review. Josip A. Borovac: writing- review and editing, Sathish Parasuraman: writing- review and editing. Jun Shing Kwok: supervision, methodology, data curation, writing-review & editing.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.carrev.2021.09.013.

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