

Use of percutaneous transluminal renal angioplasty in atherosclerotic renal artery stenosis: a systematic review and meta-analysis

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Abstract

Objective: For patients with atherosclerotic renal artery stenosis (ARAS), the role of percutaneous transluminal renal angioplasty (PTRA) remains inconclusive. This study aimed to comparatively evaluate the benefits of best medical therapy (BMT) plus PTRA and BMT alone in treating ARAS.

Methods: We performed a systematic review and meta-analysis, and searched for all randomized, controlled trials that reported patients with ARAS. The effectiveness and safety in the BMT plus PTRA and BMT alone groups were estimated, taking into account hypertension, stroke, renal events, cardiac events, and mortality.

Results: Nine randomized, controlled trials involving 2309 patients were included. In the BMT plus PTRA group, the incidence of refractory hypertension was significantly lower compared with that in the BMT alone group (odds ratio 0.09; 95% confidence interval 0.01, 0.70). However, there were no significant differences in the rates of stroke, renal events, cardiac events, cardiac mortality, and all-cause mortality between the two groups.

Conclusions: PTRA plus BMT improves blood pressure in patients with ARAS, but there is insufficient evidence for this therapy in improving stroke, renal events, cardiac events, and cardiac and all-cause mortality.

Keywords

Atherosclerotic renal artery stenosis, renal event, cardiac mortality, percutaneous transluminal renal angioplasty, best medical therapy, stroke, all-cause mortality

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Introduction

Renal artery stenosis is caused by atherosclerotic disease in 90% of cases and by fibromuscular dysplasia in 10%.¹ Among patients aged older than 66 years, the incidence of atherosclerotic renal artery stenosis (ARAS) has reached 6.8%.² ARAS is defined as at least 50% to 70% stenosis.³ Hemodynamically significant ARAS is a leading cause of refractory hypertension, progressive deterioration of renal function, ischemic renal events, cardiac diseases, such as aortic syndrome, recurrent hyperemia heart failure, and acute coronary syndrome, and even death.⁴⁻⁷ In patients with refractory hypertension, ARAS is the most common secondary cause of refractory hypertension (2%–5%) which could lead to severe stroke. However, there is frequently no indication of any cause of ARAS.^{2,8} Approximately more than half of these patients show aggravation of stenosis within 5 years of diagnosis, of whom 15% to 20% develop end-stage renal failure or require replacement therapy.⁹ Among patients undergoing cardiac catheterization owing to suspected coronary artery disease, the prevalence of ARAS varies from 25% to 30%.¹⁰⁻¹⁴

The treatment of ARAS includes medical therapy and surgery. Currently, open surgery has been increasingly replaced with endovascular surgery because of severe trauma.^{15,16} Generally, percutaneous transluminal renal angioplasty (PTRA) is regarded as endovascular surgery, and is commonly accompanied by stenting. Nevertheless, the indications of PTRA remain debatable. Previous observational studies have shown that PTRA might be beneficial¹⁷⁻¹⁹ or detrimental^{20,21} to patients with ARAS. Therefore, this systematic review aimed to comparatively assess the effectiveness and safety between best medical therapy (BMT) plus PTRA and BMT alone.

Methods

Search strategy

The review protocol was developed by the steering committee and approved by the ethics review committee of Tianjin Medical University General Hospital. This meta-analysis was registered with PROSPERO (CRD42020150880). The PRISMA statement²² was followed in our literature research. Following Population, Intervention, Comparison, Outcomes, and Study design, different researchers (Y-HC and H-RP) searched PubMed, EMBASE, Web of Science, Wanfang database, and the Cochrane Library using various combinations of key words, such as “stents”, “endovascular”, “angioplasty”, “drug”, “medicine”, “medical”, “renal”, “kidney”, “stenosis” and “randomized”. Detailed search strategies are shown in Supplemental Tables 1 to 5. We were able to access five databases, including Core Collection, KCI-Korean Journal Database, Medline, Russian Science Citation Index, and SciELO Citation Index through searching the Web of Science. Additionally, a reference search was carried out to identify additional publications by screening reference lists. Only studies written in English were considered in this meta-analysis.

Inclusion and exclusion criteria

The inclusion criteria were as follows: (1) diagnosis of ARAS; (2) the experimental group was BMT plus PTRA (with stents necessary) and the control group was BMT alone; (3) randomized, controlled trials (RCTs); and (4) published studies. The exclusion criteria included the following: (1) no information was available; (2) there was a significant difference in variables at baseline; (3) repeated publication data; and (4) non-RCTs. Studies that met

none of the inclusion criteria or any of the exclusion criteria were excluded.

To ensure the accuracy and completeness of the data, two researchers (Y-HC and H-RP) screened all studies independently. Additionally, a third researcher (G-ZL) intervened in case of dispute arising between inclusion and exclusion criteria.

Data extraction

Data were extracted from the patients at baseline, as well as bias risk indicators, endpoint events, and conclusions. For those studies that lacked some requisite information, the author was contacted by e-mail. We also focused on baseline differences, hemodynamic assessment during follow-up, determination of endpoint events, laboratory or imaging assessment, withdrawal, and funding sources.

Statistical analysis

Review Manager 5.3 software (Cochrane Collaboration, London, United Kingdom) was used for analysis. The quality of selected studies was evaluated using the risk of bias as recommended by the Cochrane instructions. Odds ratios (ORs) and 95% confidence intervals (CIs) were adopted to evaluate the outcomes. The evaluation methods for heterogeneity used in this study included the forest plot (showing Q and I^2 statistics) and the funnel chart. The fixed model was applied if I^2 was $<50\%$. Conversely, if I^2 was $>50\%$, the level of heterogeneity was treated as significant. In this circumstance, the random model was used for meta-analysis. The full text was reviewed to identify the source of the heterogeneity and subgroup analysis was conducted. Subgroup analysis was also implemented in RCTs at different follow-up time and baselines.

Results

Study selection and characteristics

A total of 4410 studies were selected from various online databases, including 1559 articles in PubMed/Medline, 356 articles in Embase, 1271 articles in the Web of Science databases, 1214 articles in the Wanfang database, and 10 articles in the Cochrane Library. One record was identified in a search of references. A total of 9 RCTs (EMMA,²³ SNRASCG,²⁴ DRASTIC,²⁵ STAR,²⁶ RASCAD,²⁷ CORAL,²⁸ RADAR,²⁹ NITER,³⁰ and ASTRAL³¹) involving 2309 patients were chosen. Figure 1 shows a flowchart illustrating the search strategy for RCTs on PTR and BMT in patients with ARAS.

The baseline participants' characteristics are shown in Table 1. There was a difference in sample size among the studies. Except for the total sample of the CORAL²⁸ and ASTRAL³¹ studies, which exceeded 800, most of the other studies (EMMA,²³ SNRASCG,²⁴ RASCAD,²⁷ and RADAR²⁹) included less than 100 people. With regard to the mean degree of stenosis of the kidney, the RADAR study²⁹ exceeded 80% and DRASTIC exceeded 70%, while the others showed a similar degree of stenosis $>50\%$. The remaining features were not significantly different among the studies. The patients' inclusion criteria in each selected study are shown in Table 2.

Risk of bias

The risk bias of the nine RCTs was determined by the risk of bias as recommended in the Cochrane instructions (Figure 2). Most of the items were identified as low in risk, except for some studies that were assessed as posing a high risk in performance bias and detection bias.

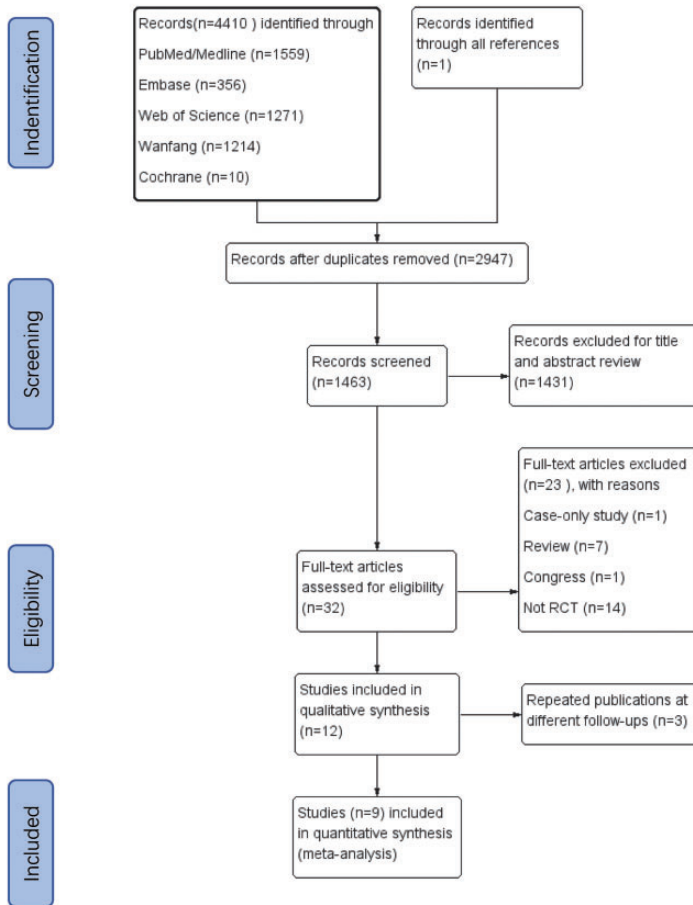


Figure 1. Detailed flowchart showing the search strategy for randomized, controlled trials on percutaneous transluminal renal angioplasty and best medical therapy in patients with atherosclerotic renal artery stenosis.

Meta-analysis results

We found that BMT plus PTRAs significantly reduced the incidence of refractory hypertension compared with BMT alone within 2 years of follow-up (OR 0.09; 95% CI 0.01, 0.70; $P=0.02$) (Figure 3). There was no significant difference in stroke at 1 year (OR 0.44; 95% CI 0.11, 1.79) or with at least 2 years of follow-up (OR 0.87; 95% CI 0.57, 1.34) between BMT plus PTRAs and BMT alone (Figure 4).

There was no significant difference in renal events at 1 year (OR 0.85; 95% CI 0.32, 2.31) or with at least 2 years of follow-up (OR 0.99; 95% CI 0.78, 1.25) between the two groups (Figure 5). There was also no significant difference in renal events in patients with balloon angioplasty only (OR 0.68; 95% CI 0.22, 2.10) or additional stent placement (OR 1.02; 95% CI 0.80, 1.29) (Figure 6).

There was no significant difference in cardiac events within 1 year (OR 0.91;

Table 1. Participants' baseline characteristics of nine included randomized, controlled trials.

Studies	EMMA	SNRASCG	DRASTIC	STAR	RASCAD	CORAL	RADAR	NITER	ASTRAL															
Year of study	1998	1998	2000	2009	2012	2016	2017	2018	2020															
Country	France	UK	The Netherlands	The Netherlands, France	Italy	USA	Germany	Italy	UK, Australia, New Zealand															
Group	BMT PTRA	BMT PTRA	BMT PTRA	BMT PTRA	BMT PTRA	BMT PTRA	BMT PTRA	BMT PTRA	BMT PTRA															
Patients (n)	26	30	25	50	56	64	76	64	472	459	45	41	43	472	459	45	41	28	24	403	403			
Mean age (%)	59.2	59.5	61	61	59	67	66	66	69	69	69	69	69	69	69	68.3	71.1	74	69	71	70	70		
Men (%)	69	78	60	56	66	59	67	67	54	51	51	51	51	51	51	64.8	67.2	61	58	63	63	63		
DM (%)	15	26	NM	NM	6	5	31	30	44	32	32	32	44	34	32	39	31.1	57	67	29	31	31	31	
Smoking history (%)	62	65	50	36	70	82	68	72	47	60	47	60	47	32.2	28	48.8	55.6	64	63	55	51	51	51	
Mean SBP (mmHg)	165	165	175	182	180	179	163	160	133	131	150	150	150	150	150	NM	NM	149	148	152	149	149	149	
No. of drugs	NM	NM	2.4	2.4	2	2	2.9	2.8	2-3	2-3	2.1	2.1	2.1	2.1	2.1	2.8	2.4	3.3	3.3	2.8	2.8	2.8	2.8	
Bilateral (%)	0	0	53	48	22	23	46	50	5	9	18.1	22	22	18.1	22	NM	NM	46	50	61	58	58	58	
Degree of stenosis >50%	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
Degree of stenosis >70%	NM	NM	NM	NM	70	79	68	66	NM	NM	NM	NM	NM	NM	NM	97.4	97.9	100	100	100	100	100	100	100
PTRA only, (%)	91.3	91.3	80	80	96.4	96.4	96.4	NM	NM	NM	0	0	0	0	0	NM	NM	0	0	58	60	60	60	
Mean FU (months)	6	6	6	12	12	12	24	24	12	12	43	12	43	43	43	12	12	43	43	60	60	60	60	

BMT, best medical therapy; PTRA, percutaneous transluminal renal angioplasty; DM, diabetes mellitus; SBP, systolic blood pressure; NM, not mentioned; FU, follow-up.

Table 2. Brief inclusion criteria in each selected study.

Selected study	Inclusion criteria
EMMA	<ul style="list-style-type: none"> • Diastolic office blood pressure >95 mmHg on anti-hypertensive medication • Ccr \geq50 mL/minute • A reduction in arterial diameter of >60% • A functional kidney on the opposite side with a normal main artery
SNRASCG	<ul style="list-style-type: none"> • A minimum diastolic blood pressure of 95 mmHg on two or more anti-hypertensive medications • Stenosis of \geq50% in the arteries
DRASTIC	<ul style="list-style-type: none"> • Difficult-to-treat hypertension • Diastolic blood pressure remained at \geq95 mmHg • Unilateral or bilateral renal artery stenosis of at least 50%
STAR	<ul style="list-style-type: none"> • Ccr <80 mL/minute • A reduction in the renal artery of \geq50%
ASTRAL	Substantial anatomical atherosclerotic stenosis in at least one renal artery
RASCAD	<ul style="list-style-type: none"> • Ischemic heart disease • Renal artery stenosis >50% and \leq80%
CORAL	<ul style="list-style-type: none"> • Hypertension on two or more anti-hypertensive medications • Renal dysfunction (\geqstage 3 chronic kidney disease) • Renal artery stenosis >60%
RADAR	<ul style="list-style-type: none"> • Renal artery stenosis >70% • Estimated glomerular filtration rate >10 mL/minute • Hypertension
NITER	<ul style="list-style-type: none"> • Glomerular filtration rate \geq30 mL/minute • Hypertension • Renal artery stenosis >70%

Ccr, creatinine clearance.

95% CI 0.42, 1.97) or with at least 2 years of follow-up between the two groups (OR 0.97; 95% CI 0.78, 1.21) (Figure 7). There was also no significant difference in the incidence of cardiac mortality beyond 2 years of follow-up between the two groups (OR 0.90; 95% CI 0.61, 1.32) (Figure 8). There was no significant difference in all-cause mortality at 1 year (OR 0.76; 95% CI 0.23, 2.50) or with at least 2 years of follow-up between the two groups (OR 0.93; 95% CI 0.74, 1.16) (Figure 9).

For a degree of ARAS >70%, BMT plus PTRAs did not significantly reduce the incidence of renal events at 1 or 2 years of follow-up (OR 1.28; 95% CI 0.52, 3.15) compared with BMT alone (Figure 10).

We also found no significant difference in renal events in patients with grade 2 hypertension between the two groups within 2 years of follow-up (OR 0.69; 95% CI 0.35, 1.37) (Figure 11).

Discussion

In this study, we found that BMT plus PTRAs significantly reduced the incidence of refractory hypertension within 2 years of follow-up compared with BMT alone. The ability of BMT plus PTRAs to reduce resistant hypertension was proven by three previous RCTs.^{24,31,32} Our results also support recommendations of the American College of Cardiology and American Heart Association guidelines³³ and the

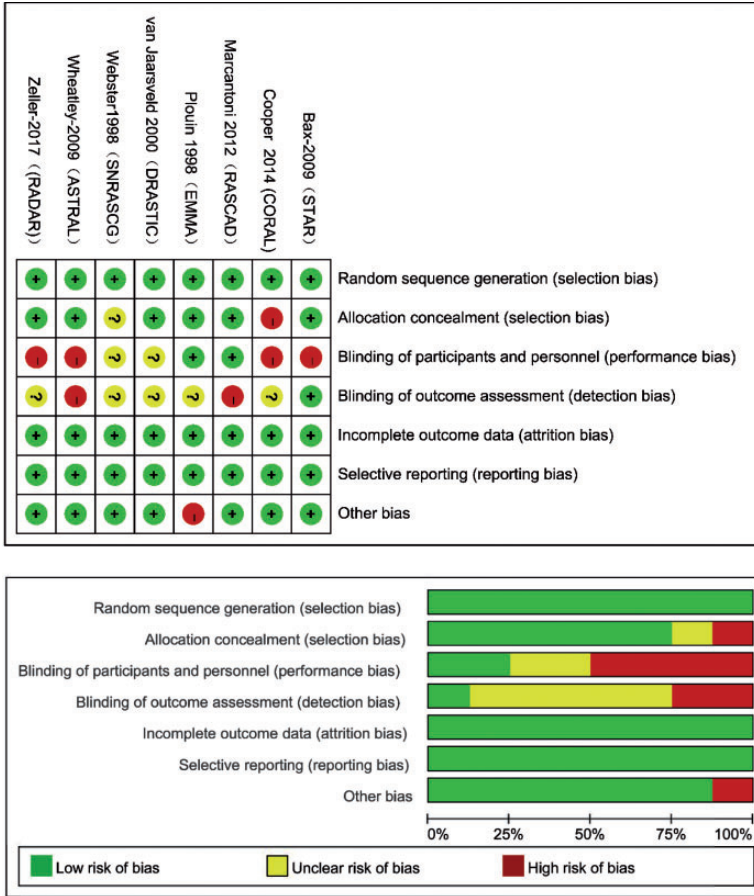


Figure 2. Risk of bias graph of the nine included randomized, controlled trials.

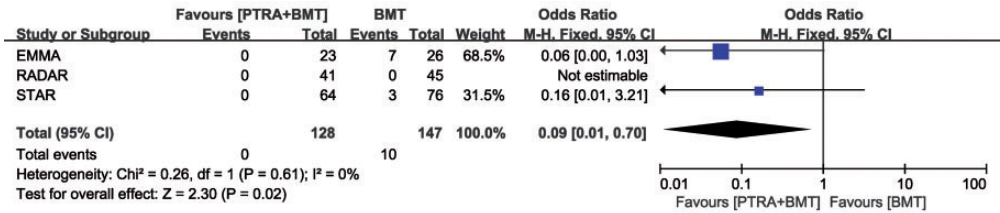


Figure 3. Refractory hypertension within 2 years of follow-up
 PTRA, percutaneous transluminal renal angioplasty; BMT, best medical therapy; M-H, Mantel-Haenszel; CI, confidence interval.

Society for Cardiovascular Angiography and Interventions appropriate use criteria³⁴ that PTRA is beneficial in patients with resistant hypertension. Many researchers

have suggested that patients showing renal blush grade,³⁶ an abnormal renal frame count,^{35,36} unstable angina or congestive heart failure,^{37,38} or flash pulmonary

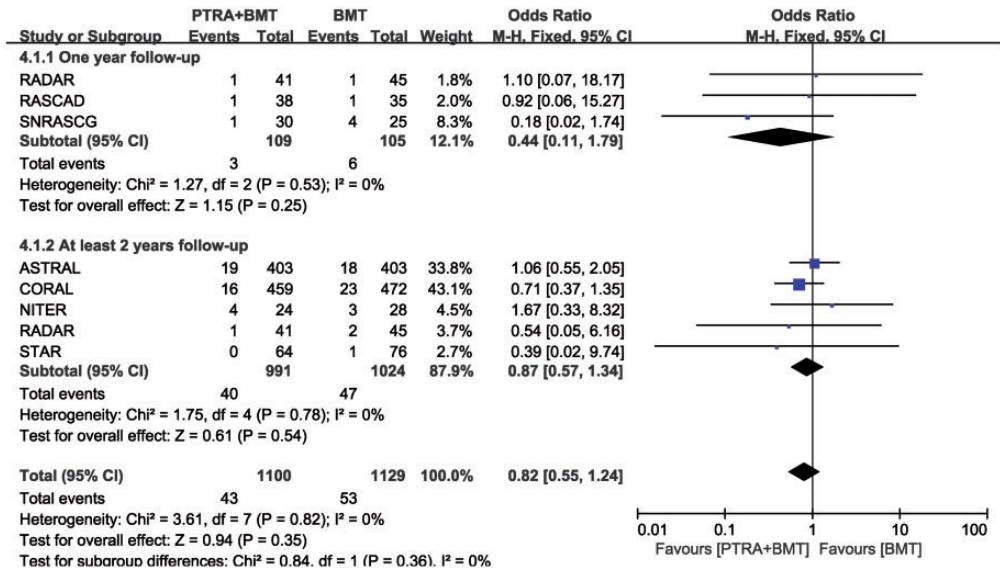


Figure 4. Stroke in 1 year and with at least 2 years of follow-up
 PTRA, percutaneous transluminal renal angioplasty; BMT, best medical therapy; M-H, Mantel -Haenszel; CI, confidence interval.

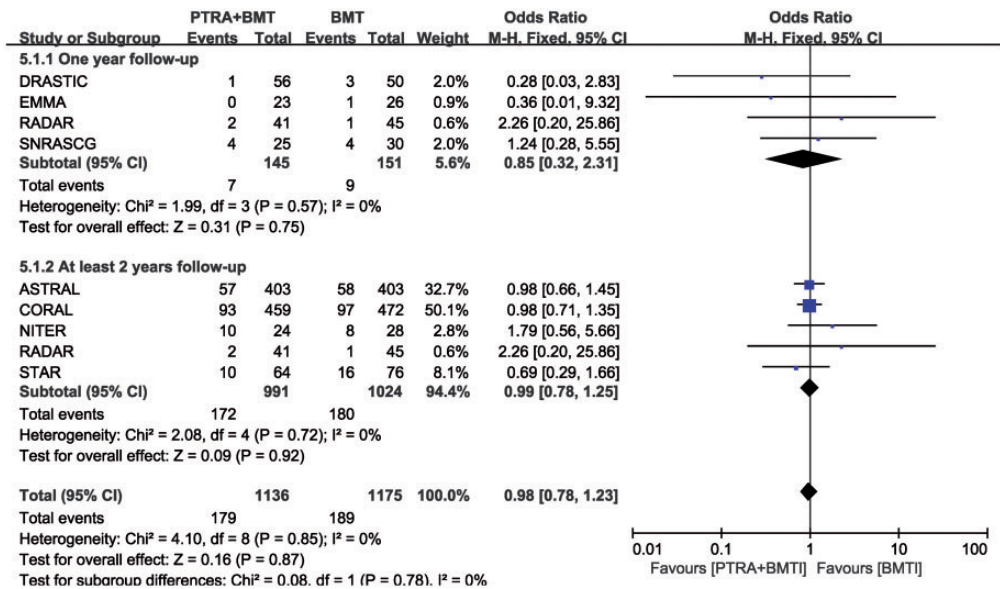


Figure 5. Renal events in 1 year and with at least 2 years of follow-up
 PTRA, percutaneous transluminal renal angioplasty; BMT, best medical therapy; M-H, Mantel -Haenszel; CI, confidence interval.

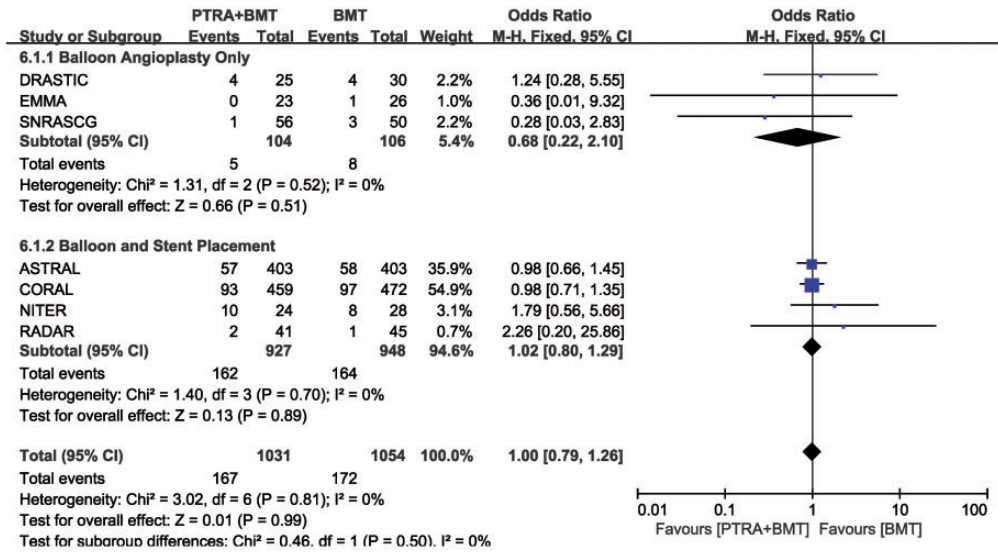


Figure 6. Renal events between balloon angioplasty only and additional stent placement
 PTRA, percutaneous transluminal renal angioplasty; BMT, best medical therapy; M-H, Mantel -Haenszel; CI, confidence interval.

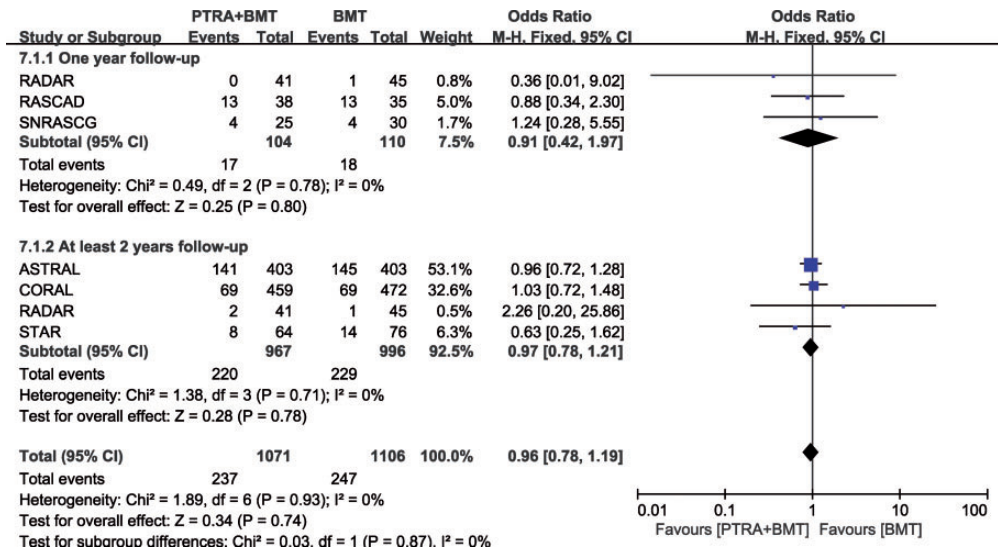


Figure 7. Cardiac events in 1 year and with at least 2 years of follow-up
 PTRA, percutaneous transluminal renal angioplasty; BMT, best medical therapy; M-H, Mantel -Haenszel; CI, confidence interval.

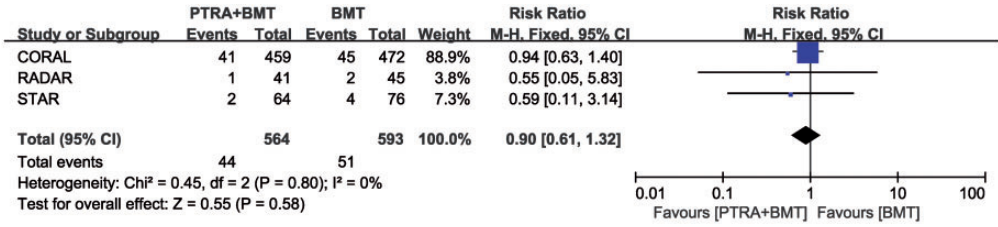


Figure 8. Cardiac mortality after 2 years of follow-up
 PTRA, percutaneous transluminal renal angioplasty; BMT, best medical therapy; M-H, Mantel -Haenszel; CI, confidence interval.

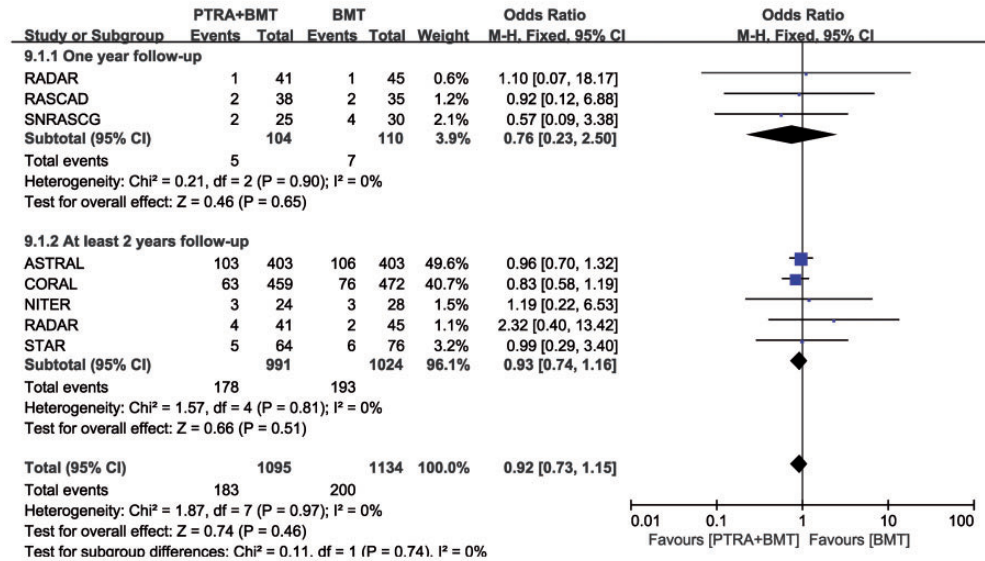


Figure 9. All-cause mortality in 1 year and with at least 2 years of follow-up
 PTRA, percutaneous transluminal renal angioplasty; BMT, best medical therapy; M-H, Mantel -Haenszel; CI, confidence interval.

edema³⁸ have a significantly improved prognosis of hypertension.

In our meta-analysis, there was no reduction in renal events for BMT plus PTRA during the follow-up in patients with balloon angioplasty only, additional stent placement, or grade 2 hypertension. For patients with a degree of stenosis of 70% in the kidney, we still could not find any obvious reduction in renal events. Additionally, renal events resulted from diabetes, nephritis, nephropathy, heart

failure, and a solitary functioning kidney. In a previous meta-analysis,³⁹ 7 studies focused on the efficacy of PTRA on patients with a solitary functioning kidney, involving 253 cases. This previous meta-analysis showed that a renal artery stent was beneficial for patients with a solitary functioning kidney regarding improved or stabilized renal function. The benefit rate was 0.77. The authors of some recent retrospective studies⁴⁰⁻⁴² reached the conclusion that PTRA might be conducive

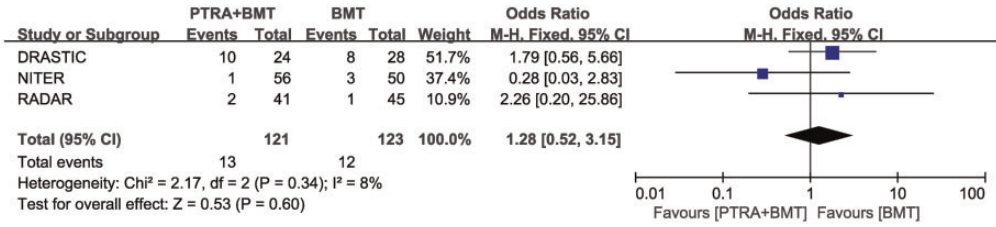


Figure 10. Degree of stenosis >70% in 1 year of follow-up
 PTRA, percutaneous transluminal renal angioplasty; BMT, best medical therapy; M-H, Mantel -Haenszel; CI, confidence interval.

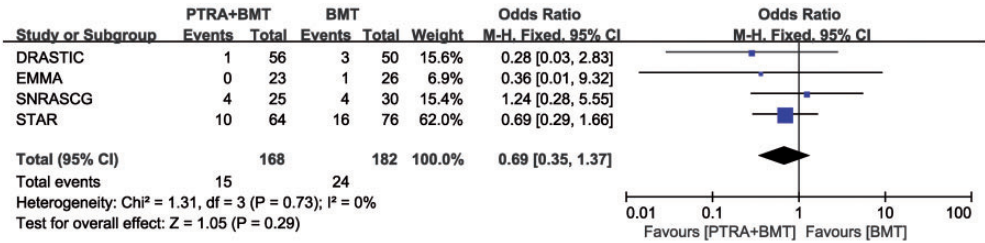


Figure 11. Grade 2 hypertension within 2 years of follow-up
 PTRA, percutaneous transluminal renal angioplasty; BMT, best medical therapy; M-H, Mantel -Haenszel; CI, confidence interval.

to refractory control of blood pressure and kidney function, but only for those with high-risk clinical manifestations, including rapid deterioration of kidney function, episodic pulmonary edema, and post-transplant renal artery stenosis. Nevertheless, our results showed little evidence of the benefits of PTRA in improving renal function.

In our study, we did not find any significant difference in cardiac events, cardiac mortality, or all-cause mortality between PTRA plus BMT and BMT alone. Authors in a previous study found that almost half of the patients who had congestive heart failure had ARAS.⁸ Therefore, determining the hemodynamic significance simply by the degree of anatomical stenosis is limited.^{20,43,44} When ARAS is compounded by heart failure, determining which factor contributes more significantly to the occurrence of renal events is

extremely difficult. Some other studies^{27,45} were unable to detect a clinically significant benefit from PTRA on left ventricular mass in patients with ARAS of 50% to 80%. When stenosis was $\geq 80\%$ in a recently published RCT,²⁹ there was improvement in clinical outcomes in cardiac events in 3 years after PTRA. Iwashima et al.⁴⁵ found that fibromuscular dysplasia, severe ARAS ($\geq 90\%$), and a higher left ventricular mass index were independent predictors of better cardiac outcomes.

Several previous meta-analyses evaluated the role of PTRA in ARAS as follows. In a meta-analysis by Natalie et al., 210 patients were recruited from three randomized studies (EMMA,²³ SNRASC,²⁴ and DRASTIC²⁵). They showed a more significant reduction in systolic/diastolic blood pressure ($P=0.02/P=0.03$) and a trend in improvement of creatinine levels in the PTRA arm ($P=0.06$). Shetty et al.⁴⁶

identified five RCTs (EMMA,²³ SNRASCg,²⁴ DRASTIC,²⁵ STAR,²⁶ and ASTRAL³¹) and discovered an upward trend in systolic blood pressure ($P=0.07$), diastolic blood pressure ($P=0.12$), or serum creatinine levels ($P=0.07$) in patients who underwent PTRa compared with those who had BMT only.

There are some limitations of our review. First, in the studies that we summarized, different criteria were used to select patients for angiography. Therefore, we included a heterogeneous population. Potential confounding factors between randomly assigned treatment groups might have reduced the chance of identifying advantages of PTRa over BMT. Second, some RCTs (EMMA,²³ SNRASCg,²⁴ DRASTIC,²⁵ STAR,²⁶ RASCAD,²⁷ CORAL,²⁸ and ASTRAL³¹) included many patients with stenosis $<70\%$ who might not have obtained a benefit from PTRa. Third, the NITER study was terminated prematurely because of an insufficient inclusion. Finally, the criteria to preserve renal function in our included RCTs varied from each other. Therefore, we could not perform a meta-analysis on the effect of PTRa on renal function.

In conclusion, our study shows that PTRa plus BMT reduces the incidence of refractory hypertension, but does not improve the rates of stroke, renal events, cardiac events, cardiac mortality, and all-cause mortality compared with BMT alone. Because of the low strength of the meta-analysis for these findings, we believe that if candidates for PTRa are carefully selected, PTRa will have more effect.

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Author contributions

Research idea and study design: Y-HC, H-RP, and X-CD; data acquisition: Y-HC and H-RP; data analysis/interpretation: H-RP; statistical analysis: Y-HC and H-RP; manuscript writing: Y-HC, H-RP, G-ZL, and X-CD.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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Supplemental material

Supplemental material for this article is available online.

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