

Systematic Review and Meta-Analysis of Published Studies on Endovascular Repair of Abdominal Aortic Aneurysm With the p-Branch

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Wu H, Zhang L, Li M, Wei S, Zhang C and Bai H (2022) Systematic Review and Meta-Analysis of Published Studies on Endovascular Repair of Abdominal Aortic Aneurysm With the p-Branch. Front. Surg. 9:879682. doi: 10.3389/fsurg.2022.879682 **Background:** Endovascular treatment of juxtarenal or pararenal abdominal aortic aneurysms is more popular than open surgery, mainly because it reduces perioperative mortality and morbidity. The custom-made fenestrated devices need to be tailored to each patient, so these devices require extra manufacturing and shipping time. The increased wait time may increase the risk of aneurysm rupture in some patients. In some situations, "Off-the-shelf" (OTS) fenestrated grafts can be used. The Cook Zenith p-Branch device (William Cook Australia, Brisbane, Australia) is a relatively common OTS. This study aimed to systematically evaluate all published experiences with p-Branch.

Methods: We searched PubMed, Embase, and Cochrane to find works of literature that reported on the outcomes of patients treated with the p-Branch stent-grafts. Then we conducted an assessment of quality and meta-analysis of the results. The primary endpoints were the application rate of p-Branch stent-graft (type A, B), technical success rate, and early re-intervention rate. We estimated pooled proportions and 95% CIs.

Results: Initial search of the literature included 111 articles, of which 7 studies were included in the end. A total of 260 patients were enrolled in these studies, and 218 patients were eventually treated with p-Branch. The pooled application rate of type A devices was 48% (95% CI, 29–67%), and pooled application rate of type B devices was 30% (95% CI, 16–44%). The pooled technical success rate was 87% (95% CI, 75–98%). The early re-intervention rate was 10% (95% CI, 3–17%). Midterm renal infarct rate (after 30 days) was 3% (95% CI, 0–6%). Midterm re-intervention rate (after 30 days) was 6% (95% CI, 2–10%).

Conclusions: This pooled analysis indicated an acceptable technical success rate after p-Branch stent-graft implantation, with early and midterm re-intervention rate and renal failure rate that cannot be ignored. The p-Branch repair of juxtarenal abdominal aortic aneurysms may be an appropriate and safe option, especially in emergency situations.

Keywords: p-Branch, off-the-shelf, branched endovascular aortic aneurysm repair, juxtarenal abdominal aortic aneurysm, pararenal abdominal aortic aneurysm

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INTRODUCTION

Endovascular treatment is often preferred over open surgical aneurysm repair for repairing juxtarenal or pararenal abdominal aortic aneurysms (AAA). Some studies have pointed out that the short- and medium-term mortality and morbidity rates of endovascular treatment were lower (1– 3). In addition, unfavorable neck anatomy with insufficient infrarenal sealing zone poses a great challenge for endovascular treatment of AAA. Fenestrated and branched stent-grafts could be used to treat complex aortic aneurysms at high risk (4).

In the past few years, device technology and operator experience in endovascular aortic repair have achieved tremendous improvement, resulting in improved outcomes with fenestrated and branched endografts (5). And current studies suggested fenestrated endovascular aneurysm repair (FEVAR) was a safe and effective treatment for juxtarenal

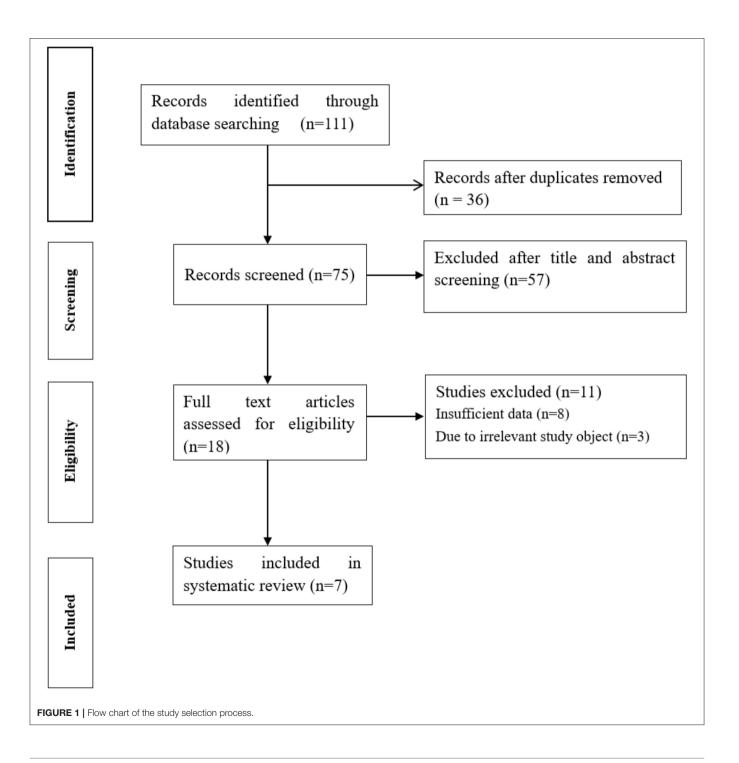


TABLE 1 | Quality appraisal checklist for the included studies.

	Study objective		Study	design			S	Study population		Intervention and	l cointervention
Studies	1. Was the hypothesis/aim/obj of the study clearly stated?		collected	in more rec	Were patients ruiter nsecutively?	chara the p includ	acteristics of e atients (i ded in the e described? for s	Were the eligibility criteria i.e., inclusion and exclusion criteria) or entry into the study clearly stated?	7. Did patients enter the study at a similar point in the disease?	8. Was the intervention of interest clearly described?	9. Were additional interventions (cointerventions) clearly described?
Bargay-Juanet al. (15)	Y	Ν	Ν	Y		Partia	al/unclear F	Partial/unclear	Ν	Partial/unclear	Ν
Sveinsson et al. (16)	Y	Υ	Ν	Y		Υ	Y	(Ν	Υ	Υ
Farber et al. (17)	Y	Y	Ν	Y		Υ	Y	(Ν	Υ	Partial/unclear
Farber et al. (18)	Y	Y	Y	Y		Y	Y	(Ν	Y	Y
Farber et al. (19)	Y	Y	Y	Y		Y	Y	(Partial/unclear	Y	Ν
Kitagawa et al. (20)	Y	Partial/unc	lear Partial/u	nclear Y		Y	F	Partial/unclear	Ν	Υ	Y
Ou et al. (21)	Υ	Y	Partial/u	nclear Y		Partia	al/unclear F	Partial/unclear	Partial/unclear	Y	Partial/unclear
	Outcome n	neasures		Statistical analysis				Results and conc	lusions		Competing interests and sources of support
10. Were relevant outcome measures established a priori?	assessors blinded r to the intervention r that patients r received?		13. Were the relevant outcome measures made before and after ethe intervention?	14. Were the statistical tests used to asses relevant outco appropriate?	s long enoug s the important	gh for events	16. Were losses follow-up reported?	to 17. Did the stur provide estimat of random variability in the data analysis o relevant outcomes?	es adverse events reported?	19. Were the conclusions of the study supported by the results?	20. Were both competing interests and sources of suppor for the study reported?
Partial/unclear	N Y	(Partial/unclear	Y	Y		Partial/unclear	Ν	Y	Y	Partial/unclear
	N Y	(Υ	Υ	Y		Ν	Ν	Υ	Υ	Υ
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Wu et al.

TABLE 2 | Baseline characteristics of studies not funded by Cook.

Study	Country	Study type	Study period	Type of stent Zenith	No. of patient	s No.ofp	No. of patients who received a p-Branch			
Bargay-Juanet al. (15)	Espana	Retrospective, single center	2008–2015		41		30		NA	
Sveinsson et al. (16)	Denmark	Prospective, single center	2012–2015	Zenith	23		23		11	
Farber et al. (18)	USA, Europe	Prospective, multiple center	2011–2015	Zenith	76		76		11	
Ou et al. (21)	China	Prospectively	2006–2013	Zenith	51	31			NA	
Study	Mean age, years	Male, (%)	CAD, (%)	Smokers, (%)	Congestive heart failure	МІ	Hypertension	COPD, (%)	CKD, (%)	
Bargay-Juanet al. (15)	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Sveinsson et al. (16)	69 (52–81)	18 (78)	6 (26)	19 (83)	1 (4)	4 (17)	14 (61)	6 (26)	3 (13)	
Farber et al. (18)	71.8 (52–92)	62 (82)	34 (45)	24 (34)	6 (7.9)	21 (28)	63 (83)	24 (32)	15 (20	
Ou et al. (21)	76.8	43	NA	NA	NA	NA	NA	NA	NA	
Study	Diabetes m	ellitus CVD, (%) Hospi	tal days	ICU days	Endoleak	Funding	Fo	ollow-up	
Bargay-Juanet al. (15)	NA	NA	NA		NA	NA	NA	NA		
Sveinsson et al. (16)	3 (13)	2 (9)	8 (4–5	7)	1 (0–22)	311	NA	48	45 ± 24.4	
Farber et al. (18)	8 (11)	10 (13)	1.9 (0-	-22)	7.5 (1–57)	2l 18ll	NA	25 ± 13		
Ou et al. (21)	NA	NA	NA		NA	NA	NA	NA		

CAD, coronary artery disease; MI, myocardial infarction; COPD, chronic obstructive pulmonary disease; CKD, chronic kidney disease; CVD, cerebrovascular disease; ICU, intensive care unit.

TABLE 3 | Baseline characteristics of studies funded by Cook.

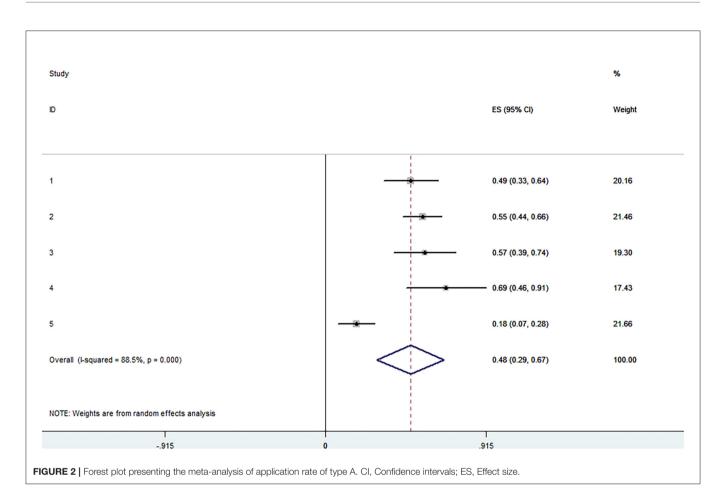
Study	Country Study type Study period Type of sten		No. of patien	ts No.ofp	No. of patients who received a p-Branch				
Farber et al. (17)	USA	Prospective, single center	2012–2013	Zenith	23		14		
Farber et al. (19)	USA	Prospective, multiple center	2013–2015	Zenith	30		28		NA
Kitagawa et al. (20)	NA	NA	2011-2012	Zenith	16	16			2
Study	Mean age, years	Male, (%)	CAD, (%)	Smokers, (%)	Congestive heart failure	МІ	Hypertension	COPD, (%)	CKD, (%)
Farber et al. (17)	72	14 (87.5)	7 (43.8)	NA	1 (6.3)	4 (25)	13 (81.3)	10 (62.5)	3 (18.7
Farber et al. (19)	73	28 (93.3)	10 (33.3)	9 (30)	5 (16.7)	6 (20)	27 (90)	11 (36.7)	2 (6.7)
Kitagawa et al. (20)	75 (59–87)	15 (94)	13 (81)	14 (88)	NA	9 (56)	15 (94)	6 (38)	1 (6)
Study	Diabetes m	nellitus CVD, (%) Hospi	tal days	ICU days	Endoleak	Funding	Fol	low-up
Farber et al. (17)	NA	NA	NA		NA	0	Cook		6.5
Farber et al. (19)	5 (16.	7) 2 (6.6)	NA		NA	NA Cook		29 ± 12.5	
Kitagawa et al. (20)	4 (25) 4 (25)	NA		NA	NA	Cook	4.3	

CAD, coronary artery disease; MI, myocardial infarction; COPD, chronic obstructive pulmonary disease; CKD, chronic kidney disease; CVD, cerebrovascular disease; ICU, intensive care unit.

and pararenal AAA (6, 7). These custom-made fenestrated devices, which need to be tailored to each patient, require extra manufacturing and shipping time, making them unavailable to patients requiring emergency interventions. At the same time,

this also puts large-diameter aneurysms at a heightened risk of rupture (8, 9).

Physician-modified fenestrated stent-grafts (PMSGs) save the time required for graft manufacture and delivery, but there are



still technical challenges and concerns about such uncontrolled device modifications (10–12). "Off-the-shelf" (OTS) fenestrated grafts can be used in emergency situations due to a degree of standardized design in planning and deployment. The emergence of OTS solves the dilemma faced by the above devices to a certain extent. The Cook Zenith p-Branch device (William Cook Australia, Brisbane, Australia) is a relatively common OTS.

The aim of our study was to perform a systematic review and meta-analysis of published reports concerning technical success rate and early and midterm clinical outcomes of the p-Branch stent graft use for the treatment of juxtarenal or pararenal AAA.

METHODS

The present systematic review and meta-analysis was written based on the Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) Statement (13).

Eligibility Criteria

This analysis included original research studies that reported outcomes of applications of the p-Branch stent graft for the treatment of juxtarenal or pararenal AAA. The article was considered for inclusion when the target population was patients with aortic aneurysm receiving p-Branch stent-graft treatment and the AAA was objectively diagnosed. Studies examining insufficient data were excluded, as were review articles and studies whose data was incomplete.

Search Strategy

The databases search was updated last on January 2022 in the PubMed, Embase, and Cochrane Library. No restriction on language was required. Search terms included "p-Branch", "off-the-shelf", "aortic aneurysm", "aneurysm", and "Zenith". Moreover, we enriched the search by manually reviewing the reference lists of all retrieved articles.

Study Selection

Three review authors (HW, LZ, and ML) screened the titles and abstracts of each search result independently. Then we read the full text to review for eligibility and quality of selected articles. Disagreements were resolved by consensus if necessary.

Data Extraction and Management

Two review authors (SW and CZ) independently extracted data from each study using standard forms. We collected the following data: number, sex, and age of enrolled patients, types of studies, and number of patients. The main endpoints of the analysis were the application rate of the p-Branch stent-graft (type A, B), technical success rate, and early re-intervention rate. Secondary endpoints included midterm renal infarct rate, re-intervention rate, and renal failure (14).

Assessment of Methodological Quality

The quality of studies was assessed based on The Quality Appraisal of Case Series Studies Checklist (**Table 1**) (22). We evaluated quality based on it with discrepancies resolved by a third author.

Statistical Analysis and Data Synthesis

All analyses were conducted using Stata statistical software version 14 (StataCorp LP, College Station, TX, USA). According to the data collected, we generated pooled rates and 95% CIs. The software produced forest plots and the heterogeneity of included studies was evaluated by providing inconsistency (I²) statistics. Publication bias was assessed by generating funnel plots.

RESULT

Study Characteristics

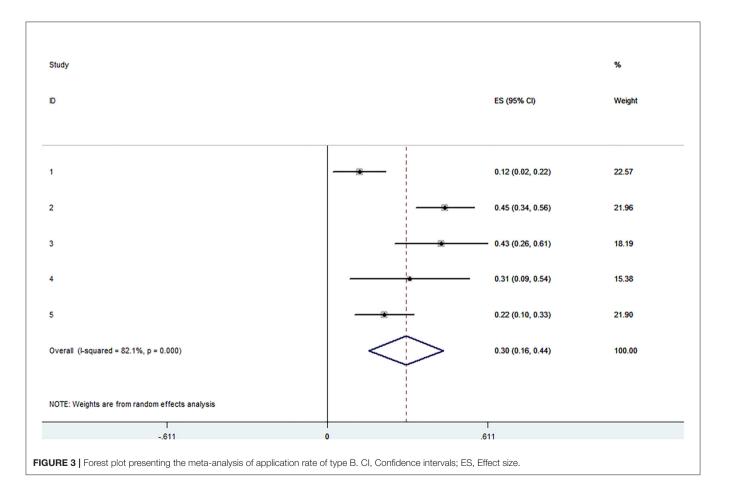
A total of 111 results were retrieved from databases. After excluding 36 duplicated studies, the remaining 75 studies were potentially eligible. After scanning titles and abstracts and removing 57 irrelevant studies, 18 studies were further evaluated. After reading the full text, 7 eligible studies were finally included,

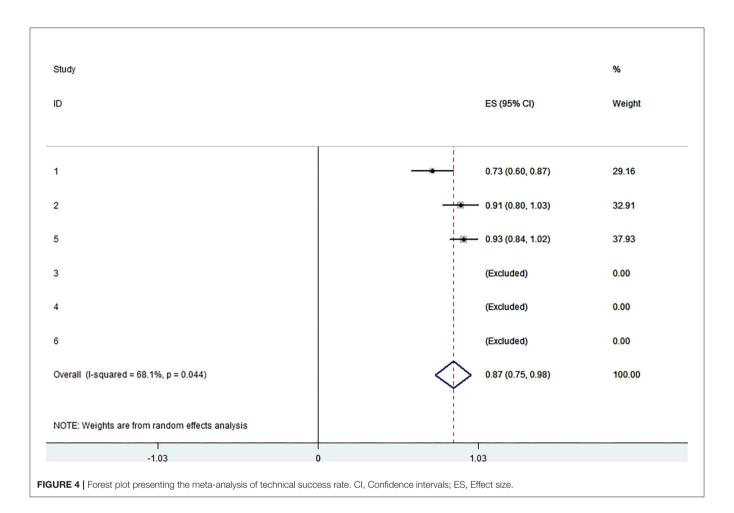
(15–21) 8 studies were excluded due to insufficient data, and 3 studies were excluded due to irrelevant study objects (**Figure 1**).

The baseline characteristics of the 7 eligible studies included in the present review are shown in **Tables 2**, **3**. A total of 260 patients were enrolled in these studies, and 218 patients were eventually treated with p-Branch. The mean age was 73.1 years; 180 of 219 (82.2%) were men (results from 6 studies). One included publication was a retrospective single-center study, five publications were prospective studies, and one did not specify the nature of the study. Three studies identified a total of 24 patients who received emergency procedures, seventeen of the patients underwent emergent surgery for ruptured aneurysms, three had symptoms, one had a mycotic aneurysm, and the rest were with no information available. In these studies, no death at 30-days was mentioned. The technical success rate was 91.7% (22/24) in the emergent group and 92.6% (162/175) in the elective group.

Meta-Analysis

The pooled application rate of type A was 48% (95% CI, 29– 67%) (**Figure 2**), and pooled application rate of type B was 30% (95% CI, 16–44%) (**Figure 3**). The pooled technical success rate was 87% (95% CI, 75–98%) (**Figure 4**). Early re-intervention rate was 10% (95% CI, 3–17%) (**Figure 5**). Early renal infarct rate was 15% (95% CI, 8–22%). Early occlusion rate of a fenestrated renal vessel was 2% (95% CI, -1 to 4%). Midterm death rate (after 30





days) was 15% (95% CI, 8–22%). Midterm occlusion rate of a fenestrated renal vessel (after 30 days) was 8% (95% CI, 3–14%). Midterm renal infarct rate (after 30 days) was 3% (95% CI, 0–6%). Midterm re-intervention rate (after 30 days) was 30% (95% CI, 3–57%). Midterm renal failure rate (after 30 days) was 6% (95% CI, 2–10%).

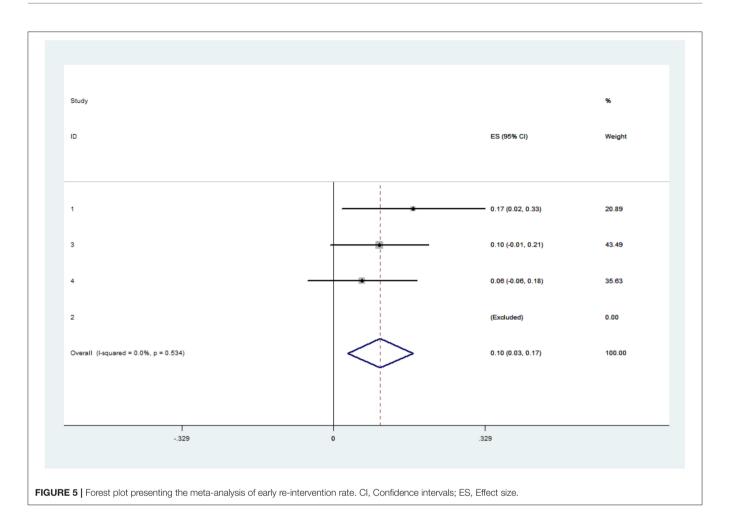
DISCUSSION

In the present systematic review and meta-analysis, we collected and analyzed the data on standardized, off-the-shelf stent graft (p-Branch) implantation for the treatment of AAA. The results show that type A p-Branch is more used than type B. We found a pooled success rate of 87% with a lower pooled early re-intervention rate and midterm renal infarct rate of 10 and 3%, respectively.

Specifications and characteristics of the stent-graft for type A and type B have been described in detail in previous studies (16, 23). In brief, it is a tubular stent-graft with a scallop for the celiac artery consisting of one 8-mm superior mesenteric artery (SMA) and two renal artery pivot fenestrations (p-Branches). Differences in the position of the p-Branches relative to the renal artery pivotal fenestration at the origin of the SMA led to two types of p-Branches. In type A, the two branches are

at the same level, while in type B, the longitudinal position of the two branches is staggered, and the left renal pivot fenestration is 4 mm lower than the right renal pivot fenestration (20). This study on p-Branch also indicated that type A was available in 54% of patients and type B was available in 49%, which is similar to our results (20). In addition, one study suggested that "OST" devices were suitable for 50–80% of patients anatomically and another study showed p-Branch stent graft was not able to incorporate visceral arteries in 40% of patients (24, 25).

The pooled technical success rate was 87%. This success rate was satisfactory; it was lower than that of off-the-shelf stents in other studies (11). Juan et al. evaluated 11 of 41 patients who were unsuitable for this stent-graft (15). Farber et al. observed 2 failures, one due to difficulty in cannulating the renal arteries and the other due to the inability to place a renal stent (19). Sveinsson et al. suggested that technical failure occurred in two emergency ruptured AAA cases where renal arteries were left unstented (16). Vessel access anatomy may also play a role in technical failure cases. Unfortunately, due to data limitations, we cannot analyze the success rates of the two types of p-Branches separately. The technical success rate of the emergent population (91.7%) is similar to that of the elective population (92.6%), which also requires more data to confirm.



The results of follow-up showed that p-Branch is not only safe and effective in selected patient populations, but also can be used in emergency situations (16). More research is needed to see if p-Branch works differently in selective and emergency settings. In addition, three studies have shown reasons for re-intervention. There were eight early interventions, two due to type III endoleak, one due to type Ic endoleak, one due to limb occlusion, one due to completion of the primary intervention, one due to SMA occlusion, one due to left renal artery occlusion, and one due to observed lower extremity ischemia. Furthermore, there were twelve late interventions, one due to type Ib endoleak, one due to type III endoleak, one due to device migration, one due to left lower extremity claudication and left femoral artery stenosis, one due to left renal stent kink, one due to hip and buttock claudication, two due to limb stenosis, three due to renal artery occlusion, three due to type II endoleak, four due to SMA stenosis, and five due to renal artery stenosis (16, 19, 20). Interestingly, there was no early intervention in the elective patient population, but there were different reasons for early and late interventions between the elective and the emergent population (16).

In our results, there was no death event in three studies. One systematic review compared the safety and efficacy of off-the-shelf fenestrated/branched grafts and physician-modified stent-grafts for the treatment of complex AAA also showed that no death at 30 days in the OTS group (11). There were 8 midterm death events, but all deaths were related to the device and procedure. Hence, the safety of the device is satisfactory.

Chuter et al. compared the results of multibranched custommade stent-grafts with standard stent-grafts for repairing aortic aneurysms. Their results showed no significant differences in branching morphology and perioperative outcomes between the two groups, and "OTS" standard stents expanded the treatment population due to delays in the absence of manufacturing (26). However, "OST" devices may be difficult to implant due to their relative mismatch with the aortic anatomy compared to the customized stents (25). In addition to implantation problems, "OTS" devices have a higher risk of complications, such as loss of target vessels, endoleaks, and the need for open surgery, due to their lower matching with the native aortic anatomy than custom-made devices (27). In addition, branch instability can also cause issues (28). As a study pointed out, the durability of fenestructions and branches depends on the patency of the target vessels and renal impairment (11). Early and midterm renal infarct rate and occlusion rate of a fenestrated renal vessel were low. More studies and patients are needed to confirm it strongly. There are also some limitations in this review. Firstly, the small number of published studies and patients included in the analysis as well as the high levels of heterogeneity between the included studies limit the quality of the results. Secondly, we did not include unpublished studies, such as the gray literature. Thirdly, three studies were funded by Cook Medical, which might potentially have an impact on the results.

CONCLUSION

Our results showed an acceptable technical success rate of p-Branch stent graft implantation with re-intervention rate and renal failure rate that cannot be ignored. Considering these, p-Branch is a promising technology for the repair of emergent AAA, but for selective cases, it is an option that needs careful preoperative evaluation.

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DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

AUTHOR CONTRIBUTIONS

HB and HW designed experiments, performed data analysis, wrote, and revised the manuscript. LZ, ML, SW, and CZ compiled data. HB obtained funding. All authors contributed to the article and approved the submitted version.

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