Stent-Assisted Balloon-Induced Intimal Disruption and Relamination in Aortic Dissection Repair (STABILISE): A Meta-Analysis of Early Outcomes

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Background: This meta-analysis aims to determine the early clinical outcomes and rate of complete false lumen obliteration associated with the stent-assisted balloon-induced intimal disruption and relamination in aortic dissection repair (STABILISE) technique in the management of aortic dissection.

Methods: Electronic databases searches were performed on PubMed, Embase, and the Cochrane Library to identify studies reporting early outcomes of the STABILISE technique. In addition, we retrospectively analyzed all patients treated with the STABILISE technique for aortic dissection at our institution. The case series data were pooled with relevant studies to perform a meta-analysis of proportions using random-effects models.

Results: One hundred and ninety two patients from 9 relevant studies were pooled with an additional 13 patients undergoing STABILISE at our institution over a 3-year period. Pooled in-hospital mortality rate was 6% [95% confidence interval (CI); 3%–10%, $I^2 = 0.00\%$] and the overall rate of intraoperative aortic rupture was 4% [95% CI; 2%–8%, $I^2 = 0.00\%$]. The rate of in-hospital reintervention was 8% [95% CI; 5%–14%, $I^2 = 13.37\%$]. Median follow-up ranged from 8 to 36 months. Pooled cumulative mortality at follow-up was 8% [95% CI; 4%–18%, $I^2 = 23.15\%$]. The overall rate of late reintervention was 11% [95% CI; 7%–17%, $I^2 = 0.00\%$]. Complete obliteration of the false lumen in the thoracic aorta was achieved in 93% of patients [95% CI; 84%–97%, $I^2 = 47.49\%$] and in the abdominal aorta in 86% of patients [95% CI; 79%–91%, $I^2 = 0.00\%$].

Conclusions: The STABILISE technique carries an acceptable operative safety profile with low in-hospital morbidity and mortality and excellent complete false lumen obliteration.

INTRODUCTION

Since the introduction of thoracic endovascular aortic repair (TEVAR) and its application to thoracic aortic dissection, there have been considerable advances to endovascular management of aortic dissection. Aortic dissection remains a challenging condition to treat, with substantial acute and long-term morbidity and mortality, and patency of the false lumen is an independent risk factor of long-term reintervention and mortality.[1,2] Traditionally managed conservatively, in recent years, the advancement of endovascular techniques has led to extended indications for surgical intervention in dissection of the thoracoabdominal aorta, with some literature suggesting a long-term benefit of surgery.[3] The Provisional Extension to Induce

Author contributions: All authors contributed to the conception, data collection, data analysis, manuscript drafting, and final versions of this manuscript. The literature searches were performed by A Bennett and N Bayfield.

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Ann Vasc Surg 2024; 98: 146–154
https://doi.org/10.1016/j.avsg.2023.06.028

Manuscript received: April 16, 2023; manuscript accepted: June 21, 2023; published online: 15 July 2023

Complete Attachment (PETTICOAT) concept of covered thoracic stent deployment followed by bare metal stent deployment in the visceral abdominal aorta was introduced in 2006[4] but has not demonstrated improved short-term or mid-term survival or improved positive remodeling in the abdominal aorta when compared with TEVAR alone.[5]

First described by Hofferberth et al. in 2014,[6] the stent-assisted balloon-induced intimal disruption and relamination in aortic dissection repair (STABILISE) technique aims to completely obliterate the false lumen with covered stent deployment in the descending thoracic aorta and bare metal stent deployment in the visceral abdominal aorta followed by balloon postdilation of the entire length of the stented aorta to disrupt the distal delaminated intimal flap, reapproximating the intimal flap to the outer aortic wall and completely obliterating the false lumen. The aim is to enhance aortic remodeling. Despite promising results in early case series, the STABILISE technique has not yet been widely adopted,[7] which may be due to concern regarding risk of aortic rupture during balloon postdilation, particularly in acute dissection when tissues are inflamed and weakened.[8] Although several case series of the STABILISE technique have now been published, there remains a lack of evidence of the short-term and mid-term procedural outcomes surrounding the technique. No prospective comparative trials have been published, hence this meta-analysis of proportions aims to establish the short-term clinical outcomes and rate of complete false lumen obliteration associated with the STABILISE technique. Our institutional experience with the STABILISE technique was retrospectively assessed to pool our data with the published figures from the literature.

METHODS

Literature Search

Electronic databases searches were performed on PubMed, Embase, and the Cochrane Library (Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Trials) from inception through to November 2022 to identify relevant studies. A broad search strategy was used to maximize the scope of the search. The search term was ''dissection [Title/Abstract]'' AND ("STABILISE" [Title/Abstract] OR "stent-assisted balloon-induced" [Title/Abstract]). The reference lists of pertinent studies were manually searched for additional relevant studies. The literature search was independently conducted by 2 authors, and disagreements in inclusion were settled by a third author after review of the article in question.

Selection Criteria

Primary inclusion criteria included any observational or interventional studies reporting on the short-term of mid-term outcomes following use of the STABILISE technique to treat thoracic aortic dissection. Only studies with a full-text publication were considered for inclusion. No language restrictions were applied. Case reports and case series with less than 5 patients were excluded to minimize the influence of publication bias. Studies including duplicated patients from other manuscripts were excluded after confirmation with the original author.

Early clinical postoperative outcomes included in-hospital or 30-day mortality, operative aortic rupture, stroke, spinal cord ischemia, visceral ischemia, and reintervention. Clinical outcomes at follow-up included mortality, type 1 endoleak, aneurysmal dilatation of the aorta requiring reintervention, and overall late reintervention. Outcomes associated with aortic remodeling included complete obliteration of the thoracic, abdominal, and aorto-iliac false lumen on postoperative computed tomography (CT).

Quality Assessment

Study quality was assessed using the Quality Appraisal Checklist for Case Series Studies (Canadian Institute for Health Economics). Each study was independently assessed by 2 authors and scored using a 16-point metric. Studies were then judged to be of good quality (13−16 points), fair quality,[9,10] or poor quality (0−10 points). Disagreements in score were resolved by discussion and mutual agreement.

Patient Selection (Perth Experience)

We retrospectively obtained demographic, operative, clinical, and anatomical data of all patients with thoracic aortic dissection managed at a large tertiary vascular center in Perth, Western Australia via TEVAR combined with the STABILISE technique. Indications for operation during the index admission with acute aortic dissection included malperfusion syndrome, rapid aneurysmal dilatation of the false lumen, or concern for impending aortic rupture. Otherwise, patients were readmitted for elective surgery approximately 6 weeks following the index admission. All patients received postoperative CT aortogram postoperatively while in hospital

and were reassessed up to 24 months postoperatively with CT prior to clinic appointments. Aortic diameters were measured at the carinal level (thoracic diameter), celiac axis level (abdominal), and immediately superior to the aorto-iliac bifurcation. Ethical approval was obtained through the Hospital Quality Control process (Quality Activity 47,874).

Operative Technique (Perth Experience)

True lumen access was obtained via bilateral femoral arteries and confirmed via transesophageal echocardiography and digital subtraction angiography. In acute cases with simultaneous debranching, frozen elephant trunk (FET) implantation, TEVAR, and STABILISE, additional antegrade true lumen access was obtained via direct cannulation of inflow limb of the trifurcated supra-aortic Dacron graft (TAPP graft, Vascutek Ltd., Renfrewshire, Scotland, the United Kingdom) prior to closure of the sternum. Covered stents were deployed in the thoracic aorta from a sufficient proximal landing zone to a convenient location proximal to the celiac artery origin and sparing distal intercostal arteries where possible, followed by deployment of the Zenith Dissection Endovascular Stent (Cook Medical Inc., Bloomington, Indiana) in the visceral abdominal aorta. Visceral arteries coming off the false lumen were cannulated prior to balloon postdilation via the true lumen and a wire left in situ. A Coda balloon (Cook Medical Inc., Bloomington, Indiana) was then used to postdilate the full extent of the stented thoracic and visceral abdominal aorta. When thought feasible, bare metal stents were extended into the common iliac arteries. The STABILISE technique is described in detail elsewhere.[6]

Data Extraction and Statistical Analysis

Demographic data were pooled as meta-analysis of proportions or means as appropriate. Where demographic data were presented as median and range, the sample mean and standard deviations were estimated using the approach described by Hozo et al.[11] Data from the Perth series were incorporated under the title ''Ritter 2022''.

For postoperative outcomes of all patients, a meta-analysis of proportions was performed to generate a pooled effect size (expressed as a percentage) with an associated 95% confidence interval (CI). As baseline heterogeneity was assumed, a random-effects model was used to compute the pooled estimate. Statistical heterogeneity was assessed using the I^2 statistic and considered to be present when $I^2 > 50\%$. Publication bias was tested in thoracic and abdominal false lumen obliteration using funnel plots. Meta-analyses were performed using Stata 18 software (StataCorp LLC, College Station, Texas: 2023).[12]

RESULTS

Literature Search

The electronic literature search identified 75 articles, after exclusion of 39 duplicates. Following application of the inclusion and exclusion criteria, 9 studies were included in the statistical meta-analysis, incorporating 192 patients. Eight studies were of retrospective single-arm case series design;[6,9,10,13–17] there was 1 comparative retrospective case series.[18] One study contained patients who were duplicated in other manuscripts and were excluded after confirmation with the original author.[19] All studies were of good quality.

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart of the literature search is presented in Supplementary Figure 1, and the characteristics of the included studies including quality assessment are presented in Table I.

Patient Demographic and Operative Details

In the 9 studies retrieved from the literature, STABILISE repairs were undertaken in 192 patients of which 35 had acute or subacute type A dissection, 37 had chronic type A dissection, 107 had acute or subacute type B dissection, and 11 had chronic type B dissection. Eighty six patients had undergone prior open repair of type A dissection, and 12 patients had connective tissue disorders including Marfan syndrome. There were no reports of operative technical failure. In addition to thoracoabdominal TEVAR grafts, 68 visceral stents and 6 iliac stents were implanted at time of TEVAR. Demographic and perioperative factors are presented in Table II.

Perth Experience (Demographics, Operative Details, and Outcomes)

The STABILISE technique was used for 13 patients over a 3-year period. Indications included Stanford type A ($n = 4$) and type B ($n = 9$) aortic dissections; 6 patients underwent STABILISE during the index admission, including 2 performed in the same sitting as the open aortic arch replacement. The distal extent of dissection was beyond the aorto-iliac bifurcation in 11/13 (84.6%) patients. Aortic arch replacement was undertaken prior to TEVAR in 9

Table I. Study characteristics

Author	Year	Country	Patient number	Multicenter	Median follow-up (months)	Quality
Mitreski[9]	2022	Australia	16	0	36	good
Vecchini[10]	2022	France	58	1	8	good
Zhong[18]	2021	UK	11	0	-	good
Soler[16]	2021	France	8	0	15	good
Faure[13]	2021	France	17	0	17	good
Kahlberg[15]	2019	Italy	14	0	12	good
Faure[14]	2019	France	16	0	8	good
Faure[17]	2018	France	41	0	20	good
Hofferberth[6]	2014	Australia	11	0	19	good

Table II. Demographic and perioperative data

Demographic	Perth cohort ($n = 13$)	Overall cohort
Male	11 (84.6%)	153/205 (74.6%)
Age (mean ± std.)	49.5 ± 11.1	57.3 ± 10.9
Connective Tissue Disorder	2 (15.4%)	14/194 (7.2%)
Preoperative Malperfusion	4 (30.8%)	80/194 (41.2%)
Acute or Subacute TAD	4 (30.8%)	39/205 (19.0%)
Chronic TAD	0	37/205 (18.0%)
Acute or Subacute TBD	9 (69.2%)	118/205 (57.6%)
Chronic TBD	0	11/205 (5.4%)
Prior Aortic Surgery	9 (69.2%)	95/194 (49.0%)
Prior Frozen Elephant Trunk	4 (30.8%)	-

Std., standard deviation; TAD, Type A Dissection; TBD, Type B dissection.

patients, and 5 of those patients underwent FET deployment. Indications for immediate on-table STABILISE following aortic arch replacement included concern for impending rupture ($n = 1$, rapid development of large right pleural effusion on CT) and malperfusion syndrome ($n = 1$). Of the 8 patients without FET, 7 underwent staged or simultaneous left carotid to subclavian bypass grafting at time of TEVAR. Demographic and perioperative factors are presented in Table II.

Technical success was obtained in all cases. In 1 case, intraoperative distal migration of a thoracic covered stent was observed after balloon dilatation requiring an additional covered stent to be deployed across the proximal landing zone. No visceral vessels required stenting and flow to all visceral vessels was preserved and/or restored in all cases. Uncovered stenting was extended into the common iliac arteries for 5 patients. One patient required emergency intraoperative subxiphoid drainage of a hemorrhagic pericardial effusion after temporary pacing wire removal and recovered uneventfully. There were no in-hospital mortalities. Notable morbidities included 1 case of transient spinal cord ischemia and 2 cases of acute kidney injury requiring temporary dialysis. Median postoperative length of stay was 9.5 days. There was 1 postoperative return to theater for a patient who developed an acutely ischemic leg and required common femoral embolectomy day 1 post STABILISE for acute type B dissection. The patient recovered fully.

On postoperative CT, complete obliteration of the false lumen was achieved in 8/13 (61.5%) patients in the thoracic aorta and 11/13 (84.6%) patients in the abdominal aorta. Eleven of 13 (84.6%) patients had residual aortic dissection distal to the bare stent limit. In 1 case, a small type 1b endoleak was noted on the postoperative CT at the distal aspect of the covered thoracic stent graft, which was managed conservatively and not expanding on follow-up CT. Three patients had small type 2 endoleaks from lumbar or intercostal vessels sustaining mild contrast enhancement in the thoracic false lumen; all were stable on follow-up. At a median of 7.5 (range 1−34) months follow-up, there were no late reinterventions and 1 late mortality (31 months postoperatively, unknown cause) in a patient who had complete false lumen obliteration and satisfactory postoperative CT on last imaging at 28 months postoperatively. Postoperative

Table III. Postoperative clinical and aortic remodeling outcomes

Outcome	Perth event rate ($n = 13$)	Overall event rate	Effect size [95% CI]
In-hospital outcomes			
In-hospital mortality	0	8/205	0.06 [0.03−0.10]
Aortic rupture	0	3/205	0.04 [0.02−0.08]
Stroke	0	2/178	0.03 [0.01−0.07]
Spinal cord ischemia	1	7/189	0.06 [0.03−0.11]
Visceral ischemia	0	4/194	0.04 [0.02−0.08]
In-hospital reintervention	1	13/205	0.08 [0.05−0.14]
Follow-Up Outcomes			
Cumulative mortality at follow-up	1	7/136	0.08 [0.04−0.18]
Type 1 endoleak	1	8/205	0.06 [0.03−0.12]
Aneurysmal dilatation	0	5/205	0.05 [0.03−0.11]
Late reintervention	0	19/205	0.11 [0.07−0.17]
Thoracic false lumen obliteration	8	175/184	0.93 [0.84−0.97]
Abdominal false lumen obliteration	11	164/184	0.86 [0.79−0.91]
Aorto-iliac false lumen patent	11	87/141	0.69 [0.51−0.83]

CI, confidence interval.

outcomes and aortic remodeling outcomes are presented in Table III.

Pooled In-Hospital Clinical Outcomes

The pooled in-hospital mortality rate was 6% [95% CI; 3%−10%, $I^2 = 0.00\%$] inclusive of 2 intraoperative deaths due to suspected or confirmed aortic rupture on balloon inflation. The overall rate of intraoperative aortic rupture was 4% [95% CI; 2%−8%, $I^2 = 0.00\%$], and 1 case of intraoperative aortic rupture was salvaged by deployment of a covered stent leading to survival. Other perioperative morbidities included a stroke rate of 3% [95% CI; 1%−7%, $I^2 = 0.00\%$], spinal cord ischemia rate of 6% [95% CI; 3%−11%, $I^2 = 0.00\%$], and a postoperative visceral ischemia rate of 4% [95% CI; 2%−8%, $I^2 = 0.00\%$]. There was 1 reported retrograde aortic dissection leading to pericardial tamponade and subsequent mortality. The rate of in-hospital reintervention was 8% [95% CI; 5%−14%, $I^2 = 13.37\%$].

Postoperative outcomes and aortic remodeling outcomes are presented in Table III. Forest plots of in-hospital mortality and reintervention are presented in Figure 1. Forest plots of aortic rupture, in-hospital stroke, spinal cord ischemia, and visceral ischemia are presented in Supplementary Figures 2 and 3.

Pooled Follow-Up Clinical Outcomes

Pooled cumulative mortality at follow-up was 8% [95% CI; 4%−18%, $I^2 = 23.15\%$] with median follow-up ranging from 8 to 36 months. The overall rate of late reintervention was 11% [95% CI; 7%−17%, $I^2 = 0.00\%$]. The rate of type 1 endoleak was 6% [95% CI; 3%−12%, $I^2 = 0.00\%$], and the rate of aneurysmal dilatation requiring reintervention was 5% [95% CI; 3%−11%, $I^2 = 9.65\%$]. Forest plots of follow-up clinical outcomes are presented in Supplementary Figures 4 and 5.

Pooled Aortic Remodeling Outcomes

Follow-up CT results were available for 184/205 patients. Obliteration of the false lumen in the descending thoracic aorta was achieved in 93% of patients [95% CI; 84%−97%, $I^2 = 47.49\%$], and obliteration of the false lumen in the abdominal aorta at the level of the bare stent was achieved in 86% of patients [95% CI; 79%−91%, $I^2 = 0.00\%$]. False lumen patency distal to the bare stent was 69% [95% CI; 51%−83%, $I^2 = 71.89\%$], although this information was reported in only 141 patients across 5 studies including Vecchini et al. and Faure et al. which included 87.5% (42/48) of the chronic aortic dissections. The publication bias was assessed using funnel plots, which showed symmetrical patterns (Supplementary Figure 6). Forest plots of aortic remodeling outcomes are presented in Figure 2.

DISCUSSION

The results of the present meta-analysis suggest that the STABILISE technique carries an excellent operative safety profile despite initial concerns regarding operative aortic rupture during balloon

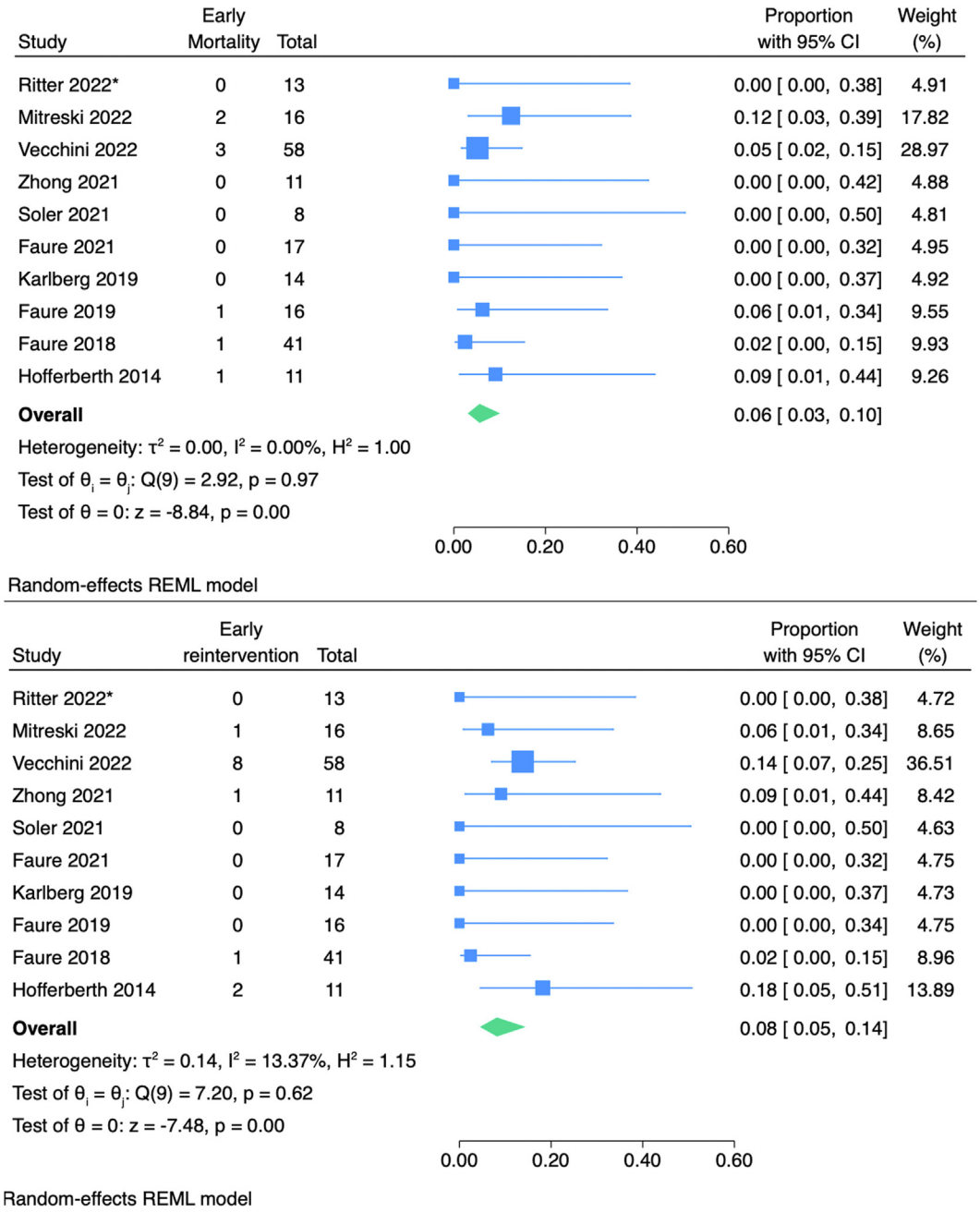

Fig. 1. Forest plots of in-hospital mortality and in-hospital reintervention.

postdilation[20] and potential visceral vessel occlusion. The pooled rate of operative aortic rupture was 4%, and the cohort was comprised of 76.6% (157/205) acute or subacute aortic dissection. Other postoperative morbidity rates were satisfactory across the pooled cohort. By comparison, a meta-analysis of proportions of the PETTICOAT technique for acute type B dissection[5] demonstrated across 143 patients an in-hospital mortality of 4.9%, a retrograde aortic dissection rate of 5.6%, and a type 1 endoleak rate of 4.9%, while a meta-analysis comparing TEVAR to the PETTICOAT technique[21] suggested that PETTICOAT carries favourable outcomes compared with TEVAR alone with a reduced rate of overall adverse events (14.1% vs. 17.6%, $P = 0.02$) and secondary intervention (5.1% vs. 12.5%, $P = 0.004$).

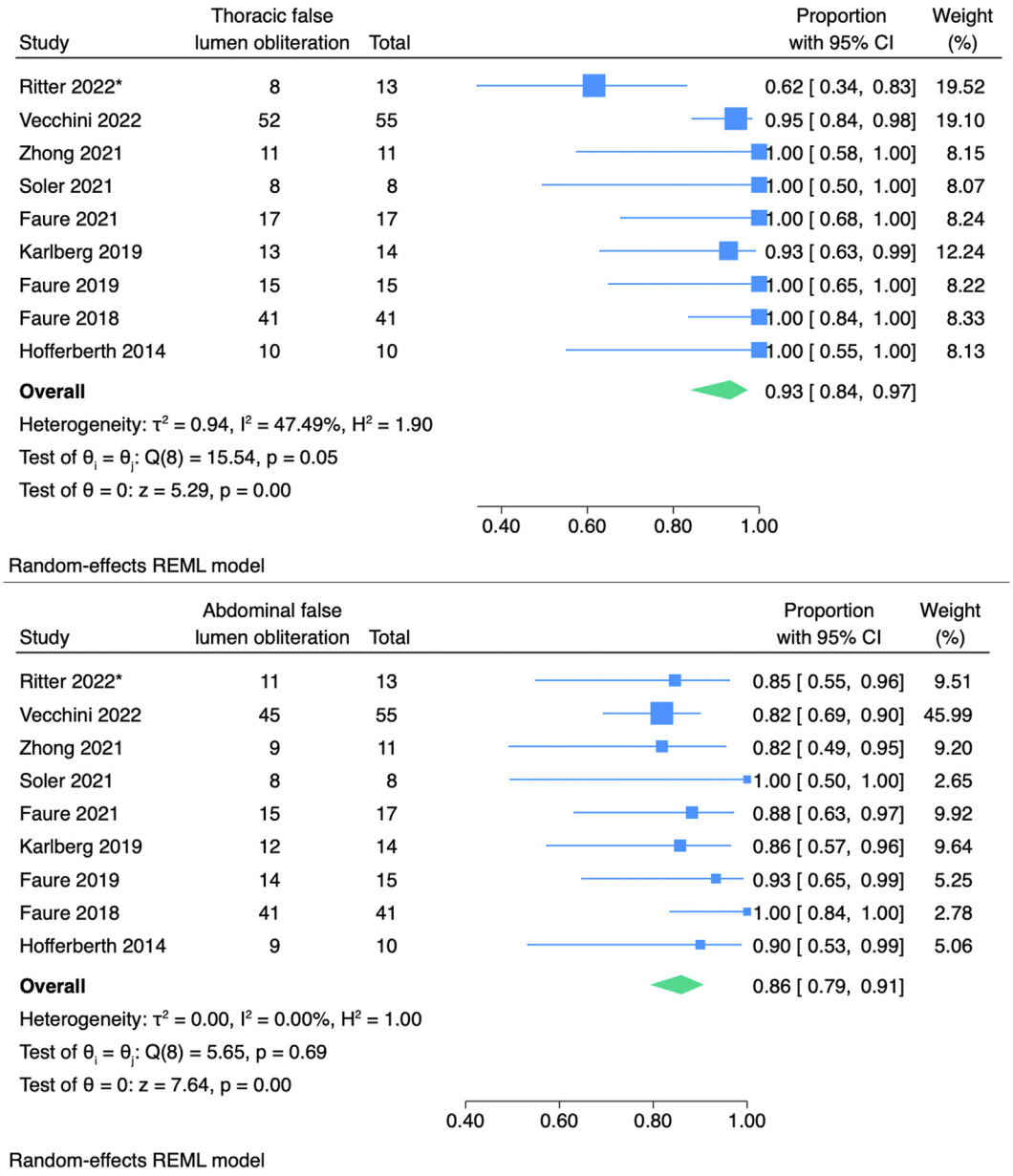

Fig. 2. Forest plots of aortic remodeling outcomes.

The primary aim of the STABILISE technique is total obliteration of the false lumen to facilitate long-term aortic remodeling. The Perth results demonstrate a higher than usual incidence of type II endoleak resulting in small areas of thoracic false lumen perfusion, with 3/11 (27.3%) of patients developing thoracic type II endoleak on postoperative CT, while the pooled cohort rate of contrast enhancement in the thoracic false lumen was 7%. A possible explanation is that aggressive proximal dilatation of the thoracic component was avoided to minimize the risk of a retrograde dissection in those patients, which all but one had their proximal landing zone in native vessel. Type II endoleaks have a reported incidence of 5.7%–8.7% following TEVAR[22,23] and are thought to have a higher risk of occurring with long lengths of aortic stenting. The literature suggests type II endoleak carries an extremely low rate of requiring reintervention, and none of this institution's patients with type II endoleak have demonstrated aneurysmal degeneration in the affected portion of the aorta.

The fate of the false lumen is critical in the long-term outcomes of aortic dissection patients, as patency or partial thrombosis of the false lumen is an independent predictor of late reintervention and mortality following repair of type A dissection[2] and for type B dissection.[24–26] The results of this meta-analysis demonstrate excellent aortic remodeling outcomes, with a 93% rate of complete false lumen obliteration in the descending thoracic aorta and an 86% rate of complete false lumen obliteration in the stented visceral abdominal aorta in the short term. By comparison, the Study of Thoracic Aortic Type B Dissection Using Endoluminal Repair trial[27] investigated the results of the PETTICOAT technique following type A dissection repair and demonstrated a 5.9% and 31.3% rate of postoperative complete thoracic false lumen thrombosis at 1 month and 12 months, respectively, and a 3.2% and 3.1% rate of complete thrombosis in the abdominal aorta at 1 month and 12 months. The Study of Thoracic Aortic Type B Dissection Using Endoluminal Repair II trial of PETTICOAT in acute type B dissection showed better radiological outcomes (thoracic complete thrombosis 52.1% and 69.6% at 1 and 12 months, abdominal complete thrombosis 5.6% and 15.4% at 1 and 12 months). Long-term complete aortic remodeling following TEVAR alone is estimated at only 40%.[26] It is as yet unclear what long-term effect this favourable rate of complete false lumen obliteration in STABILISE will have, due to limited evidence.

The present study has several limitations. Due to the relatively low number of patients and heterogeneity of duration of follow-up, mid-term clinical outcomes were pooled and should be interpreted with caution. Mid-term aortic remodeling data such as diameter and area of thoracic and abdominal aorta were reported heterogeneously and could be not pooled for analysis. Only one study was comparative in design, and this was a retrospective study without propensity matching. Prospective comparative studies should be performed to enhance the quality of the underlying evidence base. However, while more experience and data with this technique are gathered, this analysis gives an indication of procedural safety and outcomes suggesting that further studies especially in view of long-term outcomes are warranted.

CONCLUSION

The results of the present meta-analysis suggest that the STABILISE technique carries an excellent operative safety profile with low in-hospital morbidity and mortality. Early radiological data suggest a 93% rate of complete false lumen obliteration in the descending thoracic aorta and an 86% rate of complete false lumen obliteration in the stented visceral abdominal aorta.

SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi.org/10.1016/j.avsg.2023.06.028.

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