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Mid-term Outcomes of Stent Assisted Balloon Induced Intimal Disruption and Relamination in Aortic Dissection Repair (STABILISE) in Acute Type B Aortic Dissection

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Objectives: This article reports mid-term results of 41 patients treated by the stent assisted balloon induced intimal disruption and relamination (STABILISE) technique for acute type B aortic dissection.

Methods: Between November 2011 and November 2017, 41 patients (10 male; median age 50 years) underwent proximal descending aortic stent grafting plus stent assisted balloon induced intimal disruption of the thoraco-abdominal aorta for acute type B aortic dissection. Serial computed tomography angiography was used to assess aortic remodelling.

Results: There were no intra-procedural complications. Fifteen branch arteries supplied by the false lumen were stented (9% of the visceral branch arteries). The thirty day incidence of death, stroke, and paralysis/visceral ischaemia was 2% ($n = 1$), 0%, 5% ($n = 2$), and 2% ($n = 1$) respectively. During a median follow up of 12 months (range 1–168) eight patients (20%) required re-intervention. Primary visceral stent patency was 93% ($n = 14$). No aortic related deaths occurred. On the most recent computed tomography angiogram, complete false lumen obliteration and aortic remodelling was obtained in all patients at the thoraco-abdominal level, and in 39% ($n = 16$) at the unstented infrarenal aorto-iliac level. The maximum aortic diameter increased in only two patients (5%) at the unstented infrarenal level.

Conclusion: To obtain immediate and durable thoraco-abdominal aortic remodelling in acute type B dissections, the STABILISE technique is safe and reproducible while not compromising the patency of collateral branches.

Keywords: Aortic dissection, Bare stent, Endovascular, TEVAR, STABILISE

INTRODUCTION

Over the past decade, thoracic endovascular aortic repair (TEVAR) has replaced open surgery as the preferred treatment for complicated acute type B aortic dissection.^{1,2} However, TEVAR is associated with up to a 40% re-intervention rate most often due to aneurysmal evolution of the distal dissected aorta with increased risk from the persistent patent false lumen due to distal re-entry tear.^{3,4}

The STABILISE concept was first described in 2014 by Hof-ferberth et al.⁵ as “Sent assisted Balloon induced intimal Disruption and relamination in aortic dissection repair”. This technique has been developed as an adjunct of the staged total aortic and branch vessel endovascular (STABLE) reconstruction technique (or PETTICOAT technique) which consists of bare stent deployment distal to the stent graft to induce remodelling of the distal dissected aorta while preserving the visceral branch arteries and the Adamkiewicz artery.⁶ Where the STABLE technique mid-term results showed a 75% false lumen perfusion rate despite extensive distal aortic repair,^{6–8} STABILISE aimed to achieve false lumen elimination and immediate restoration of uni-luminal thoraco-abdominal aortic flow by balloon inflation of the bare aortic stent.⁵ Although the first report of this

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technique with 11 cases (7 acute type A, 4 acute type B) was promising,⁵ there has been no other report since, and the technique was only described briefly. The aim of this article was to describe the operative technique of the STABILISE approach in this centre, and to report mid-term results of the first 41 patients treated by this technique for an acute type B aortic dissection.

METHODS

The Georges Pompidou European Hospital Ethics Committee approved this retrospective study and waived the need for individual patient consent. All patients gave informed consent to each procedure.

A retrospective review of a prospectively maintained database of acute aortic dissections in the “SOS Aorta” program at Georges Pompidou European Hospital, Paris, was performed from 2011 (first stent assisted balloon induced intimal disruption and relamination in aortic dissection repair performed in this department) to 2017. The medical records of all consecutive patients treated by the STABILISE technique for a complicated acute type B aortic dissection were reviewed for pre-operative patient characteristics, dissection morphology, details of operative strategy, intra-operative events, and post-operative course.

Patients

From November 2011 to November 2017, TEVAR was performed in all patients presenting to the tertiary referral centre with acute type B aortic dissection (ABAD), if complicated according to the 2017 ESVS Guidelines on the Diagnosis and Management of Descending Aorta Diseases,⁹ or if associated with poor prognostic factors involving maximum aortic diameter of the dissected aorta > 40 mm. The STABILISE technique was performed concomitant with proximal entry tear stent grafting for extension of dissection cases to the level of the abdominal aorta, and residual flow in the false lumen of the abdominal aorta distal to the stent graft on per-operative angiography. It was also performed as a second stage procedure for cases of secondary false lumen reperfusion distal to the proximal stent graft on post-operative computed tomography (CT) scan. Conversely, exclusion criteria for STABILISE techniques included dissection limited to the thoracic descending aorta and complete false lumen thrombosis after stent graft closure of the primary entry tear on per-operative angiogram.

Pre-operative management

Baseline CT scan with multiplanar reconstruction was performed in all patients to assess the dissection characteristics such as location of the primary entry tear, extension of the dissection, patency and origin (true or false lumen) of visceral vessels, in order to select the peripheral access site, and to perform sizing of aortic devices.

All patients had a second CT scan 2–3 days before discharge from the Intensive Care Unit, and a third between 7 and 10 days before hospital discharge.

Proximal stent graft choice: adequate proximal and distal sealing

The aim of the proximal stent grafting is both to close the primary entry tear to obtain proximal sealing, and to exclude the dilated proximal half of the descending thoracic aorta. The diameter of the stent graft was sized on the basis of its proximal sealing zone in the arch, and also in order to obtain a distal sealing of both the true and the false lumen at the level of the descending thoracic aorta. Since “off the shelf” stent grafts allow sealing on a maximum aortic diameter of 42 mm with their larger designs (45–46 mm), the distal part of the stent graft should land in an area where the global diameter of the aorta does not exceed 42 mm over at least a 20 mm length. The length of the stent graft should therefore be adapted to fulfill this condition. If no adequate distal landing zone \leq 42 mm can be reached above the coeliac trunk, the STABILISE technique should not be recommended.

Stent graft implantation

All procedures were performed in a hybrid operating suite under general anaesthesia. The femoral artery access side depended on the extent of the dissection within the aortic bifurcation and the iliac arteries on pre-operative CT scan, with the easier access to the true lumen selected. After puncture of the common femoral artery, an angiogram was performed at visceral level through a 5F 120 cm Pigtail catheter to confirm its correct position in the true lumen. The pigtail was then advanced to the ascending aorta, and a Lunderquist Extra Stiff Double Curved Exchange Guide Wire (Cook Medical, Bloomington, IN, USA) placed over the pigtail catheter up to the aortic valve. The proximal stent graft was then advanced and deployed as usual on the landmark of an aortic arch angiogram in order to ensure proximal sealing.

Distal aortic bare stent deployment

An angiogram at the level of the thoraco-abdominal aorta, including the distal part of the stent graft, all visceral arteries, and the distal marker of the 24F Dryseal sheath in the infrarenal aorta was performed to serve as a road map. The delivery system of the Zenith Dissection Endovascular Stent (ZDES) (Cook Medical) was then exchanged and advanced through the 24F Dryseal sheath, on the true lumen extra stiff wire. Its optimal proximal deployment was aimed to provide a one stent body overlap in the stent graft. Distally, the extent of bare stenting was determined by the distal extension of the dissection up to 2–4 cm below the renal arteries. The entire infrarenal aorta was not stented even if the dissection extended to the iliac arteries, to preserve flow in them. A 185 mm length of aortic bare stent usually allowed its deployment from the distal extremity of the stent graft to the infrarenal aorta. Regarding diameter, the 36 mm ZDES was chosen for a maximum external aortic diameter up to 30 mm, and the 46 mm ZDES for a maximum external aortic diameter between 30 and 42 mm. Angiography of the visceral aorta confirmed

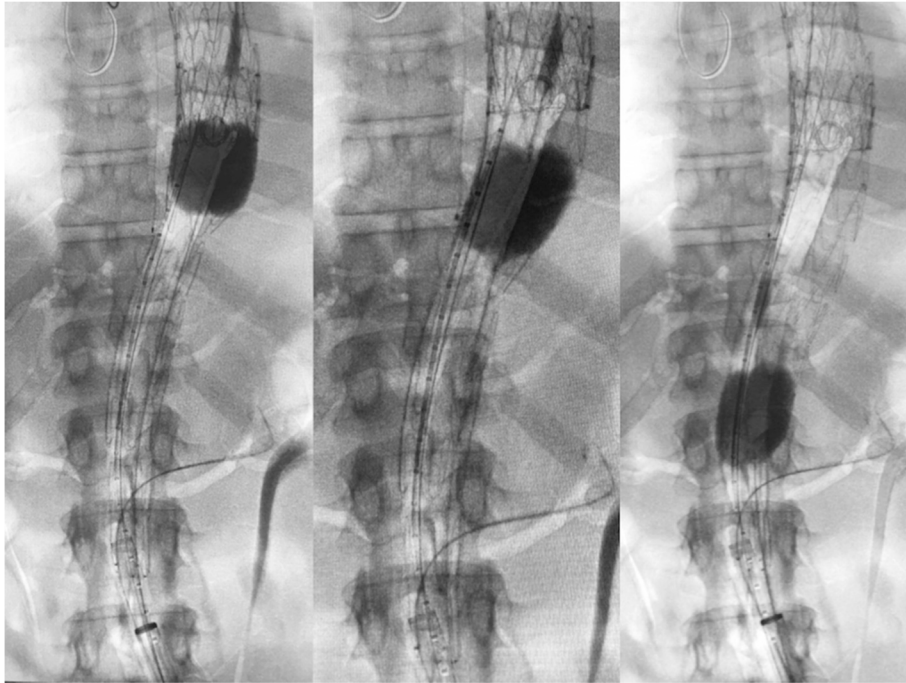


Figure 1. Serial balloon dilatation of the stented true lumen is undertaken in caudal direction to propagate the intimal flap disruption and simultaneously relaminate the intima to the aortic wall.

incomplete expansion of the true lumen with residual and retrograde flow in the false lumen after ZDES deployment.

Management of the visceral arteries supplied by the false lumen

In cases of visceral or renal branches arising from the false lumen, or presenting signs of malperfusion on pre-operative CT scan, it is recommended that the targeted vessels are catheterized through the struts of the aortic bare stent before balloon expansion. An aortogram is performed through the bare stent using a pigtail catheter, before balloon disruption of the lamella. The targeted vessel catheterisation is performed using a curved guide catheter. The guide catheter is manipulated until it is seated in the ostium located on the intimal flap through the struts of the bare stent. The 0.035 guidewire is then advanced within the catheter and manipulated to catheterise the targeted artery. The catheter is advanced into the targeted vessel for swapping the standard 0.035 guidewire for a Rosen 0.035 wire (180 cm) (Boston Scientific, Natick, MA, USA). A 6F 65 cm long sheath is advanced within the vessel ostium to guide the intimal ostium during relamination of the flap in order to realign it on the targeted vessel origin. The 6F long sheath is also placed through the 24F Dryseal Sheath, parallel to the initial aortic Lunderquist. This manoeuvre allows access to the vessel for potential stenting after aortic bare stent dilatation. This introducer allows protected progression of a branch stent if needed.

Balloon dilatation of the bare stent

Subsequently, a tri-lobe balloon catheter (large size for 26–42 mm aortic diameter; Gore Medical, Flagstaff, AZ, USA) is inserted via the 24F Dryseal on the Lunderquist extra stiff

wire, parallel to the potential 6F sheath(s) of the target vessel(s). After accurate positioning at the level of the overlap zone between the distal end of the stent graft and the proximal end of the ZDES, the balloon is manually inflated under fluoroscopic control. Balloon expansion in the stent graft is undertaken to the point of intimal flap disruption, leading to re-apposition of the intimal flap to the aortic wall. Self expansion of the aortic bare stent secures complete relamination of aortic wall. Serial balloon dilatation of the stented true lumen is undertaken in a caudal direction to propagate the intimal flap disruption and simultaneously relaminate the intima to the aortic wall, all the way down to the infrarenal aorta. Balloon pressures range from 1 to 2 atmospheres with manual inflation to enable intimal disruption without applying this pressure to the outer aortic wall (Fig. 1). On completion of balloon angioplasty, an angiogram is performed to ensure an adequate seal of the thoracic false lumen and to assess false lumen obliteration and branch vessel patency in the thoraco-abdominal aorta. For visceral or renal artery malperfusion a nitinol or balloon expandable bare stent can be advanced via the Rosen guidewire, protected in the 6F long sheath, and deployed with ≈ 3 mm protruding beyond the bare stent mesh into the aortic true lumen. Since there are no markers on the aortic bare stent, caution must be taken to deploy the arterial stent perpendicular to the vessel origin, in order to make sure it protrudes well inside the aorta (Fig. 2).

RESULTS

Baseline characteristics

During the study period, 83 patients underwent TEVAR for complicated acute type B aortic dissection. Among them, 41

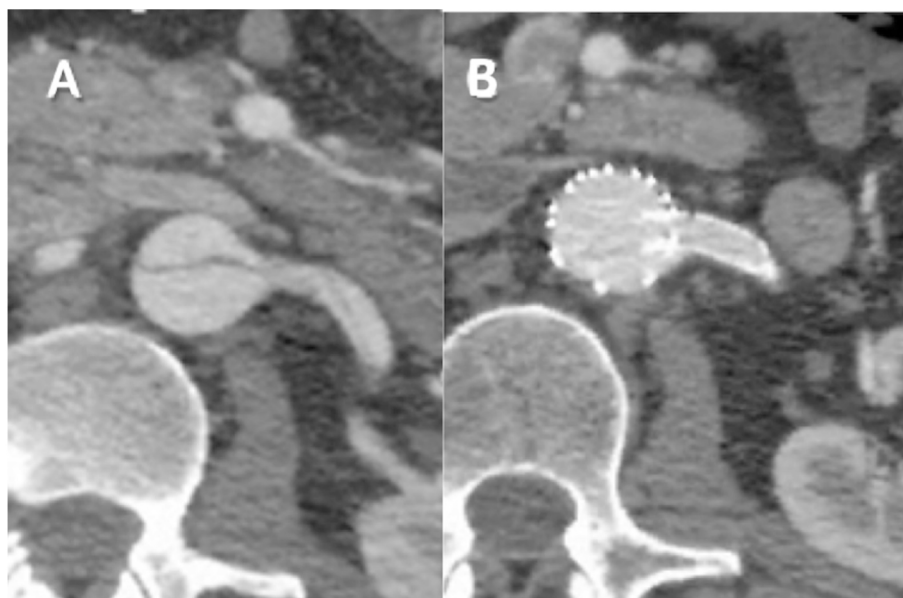


Figure 2. (A) Pre-operative computed tomography (CT) scan showing dissection of the left renal artery. (B) Same patient post-operative CT scan with left renal artery stenting through the mesh of the aortic bare stent.

patients underwent the STABILISE procedure for ABAD for persisting patent false lumen at abdominal aortic level after stent graft deployment on per-operative angiogram. Seven patients were female (17%) and the median age was 61 years (range 23–87 years). Pre-operative patient demographics, anatomical dissection characteristics and selection for STABILISE are shown in [Table 1](#).

Procedural outcomes

The median interval from onset of symptoms to STABILISE procedure was 5 days (range 0–20 days). STABILISE was performed concomitant with TEVAR in 38 patients and as a second stage procedure following dissection evolution on post-TEVAR CT scan in three patients with delays of 2, 11, and 20 days.

The proximal stent graft was a Gore CTAG (Gore Medical) in 34 patients, a Cook TX2 (Cook Medical) in three and a Relay Plus NBS (Bolton Medical, Sunrise, FL, USA) in four.

The median proximal stent graft diameter was 37 mm (range, 31–45 mm). The median length of stent graft aortic coverage was 200 mm (range, 150–300 mm).

Distal to the stent graft, all patients received only one bare stent. The type of bare stent used was a GZSD-46-164 in 16, a ZDES-46-185 in 21, and a ZDES-36-180 in four. The distal end of the bare stent was in the infrarenal aorta in 35 patients. Six patients had bare stenting up to the superior mesenteric artery.

The outcomes after bare stenting of the visceral arteries supplied by the false lumen or dissected are reported [Table 2](#). Overall, 15 visceral branches were stented (9% of the visceral branches) in 13 patients (32%). All stented visceral arteries were dissected or supplied by the false lumen on pre-operative CT scan. The rate of stenting of the visceral arteries was similar whether they were supplied by the false lumen or dissected (dissection extending into the visceral

arteries). The visceral branches the most frequently stented when involved in the dissection pattern (supplied by the false lumen or dissected) were the left renal artery, followed by the right renal artery. The coeliac trunk did not require stenting in this study. No intra-procedural complications occurred in relation to endovascular device deployment or intimal flap disruption. On the completion angiogram, the false lumen was no longer perfused at the stent grafted and bare stented level, no endoleaks were detected, and there was no evidence of aortic or branch vessel injury.

Early < 30 days outcomes

There was no post-operative stroke, no retrograde dissection, and no post-operative renal failure requiring dialysis.

Table 1. Baseline characteristics.

Variable	N (%)
Age, y	61
Female	7 (17)
Hypertension	27 (66)
Previous aortic surgery	9 (22)
Anatomical dissection characteristics	
Infrarenal extension	38 (93)
Coeliac trunk extension	3 (7)
Visceral arteries supplied by false lumen	44 (27)
Indication for STABILISE	
Malperfusion	20 (49)
Intestinal	4 (10)
Renal	11 (26)
Lower limb	5 (12)
Rupture	3 (7)
False lumen aortic growth > 5 mm ^a	3 (7)
Maximum aortic diameter > 40 mm	10 (24)
Refractory pain	3 (7)
Refractory hypertension	2 (5)

y = year.

^a During initial hospitalisation.

Table 2. Layout of the branch visceral arteries stented during the STABILISE procedure according to their pattern of perfusion: supplied by the false lumen or with dissection extending in to the visceral arteries (dissected).

Visceral arteries	False lumen supply, n (%)	Stented, n (%)	Dissected, n (%)	Stented, n (%)	Total involved n (%)	Total Stented, n (% overall) (% involved)
CT	6 (14)	0 (0)	6 (14)	0 (0)	12 (29)	0 (0) (0)
SMA	2 (5)	0 (0)	6 (14)	1 (17)	8 (19)	1 (2) (12)
LRA	8 (19)	4 (50)	9 (21)	5 (55)	17 (40)	9 (21) (53)
RRA	8 (19)	3 (37)	4 (10)	2 (50)	12 (29)	5 (12) (42)
Total	24 (14)	7 (29)	25 (15)	8 (32)	49 (29)	15 (9) (31)

CT = coeliac trunk; SMA = superior mesenteric artery; LRA = left renal artery; RRA = right renal artery; Tot = total; (% overall) = proportion of each visceral artery stented within the whole population; (% involved) = proportion of artery stented when dissected or supply by the false lumen.

Two patients had early post-operative iliac artery thrombosis; one with acute limb ischaemia had femoro-femoral crossover bypass on day 2 and the other had claudication and underwent iliac recanalisation 2 months later. One patient had post-operative ischaemic colitis medically treated, and two other patients had spinal cord ischaemia: one had paraparesis with spontaneous regression, the other developed paraplegia on day 2 post-TEVAR. This was an 82 year old man who had a ruptured acute type B aortic dissection associated with renal malperfusion. He developed post-operative paraplegia on day 2 and died on day 26. The 30 day mortality rate was 2% ($n = 1$). Overall, the 30 day complication rate was 12% ($n = 5$).

Late > 30 days outcomes

The median length of follow up was 12 months (range 1–168 months).

Eight re-interventions (20%) were needed during follow up (Table 3). One patient had left renal artery stent thrombosis at 7 months treated by thrombo-aspiration. There were no other visceral branches or iliac artery occlusions, giving a primary visceral patency rate of 93%, and a secondary patency of 100%. Two patients had open repair of infrarenal aorto-iliac aneurysmal degeneration at 5 and 8 months. There were no all cause deaths reported during follow up.

Table 3. Indication for re-intervention and type of procedure.

N	Time	Indication	Intervention
1	D 3	Iliac thrombosis	Femoro-femoral bypass
2	D 45	Type A dissection	Asc Ao graft replacement
3	D 57	Iliac thrombosis	Recanalisation
4	M 3	EL Ib	Bare stent new inflation
5	M 5	Infrarenal dissecting aneurysm	Open aortic repair
6	M 7	Renal stent thrombosis	Thrombo-aspiration
7	M 8	Iliac dissecting aneurysm	Open aortoiliac repair
8	Y 2	EL Ia	Asc Ao graft replacement

D = day; M = month; Y = year; EL = endoleak; Asc Ao = ascending aorta.

Aortic remodelling

At the last CT scan, all patients had complete aortic remodelling at the stent graft and bare-stent levels. One patient required new bare stent inflation 3 months post-intervention for distal false lumen reperfusion at the bare stent level because of incomplete re-approximation of the intimal layer to the outer thoraco-abdominal aortic wall associated with 3 mm aortic diameter growth.

Sixteen patients (39%) had complete aortic remodelling at the non-stented infrarenal aorto-iliac level. Regarding the 25 patients with persistent false lumen flow at the infrarenal bare-stent level, the aorto-iliac diameter remained stable in 23 (92%). In the whole cohort, only two patients had infrarenal aorto-iliac growth and required secondary infrarenal open repair.

DISCUSSION

In this study the STABILISE technique led to an immediate and extensive remodelling of the thoraco-abdominal aorta with intimal flap delamination in 100% of the cases, which eliminated the risk of persistent false lumen flow in the most critical part of the aorta, the thoracic descending and visceral part. In the unstented infrarenal aorta, the rate of complete aortic remodelling was 39%. These were higher rates of remodelling in comparison with rates reported with TEVAR alone.^{1,10} The INSTEAD-XL trial reported a rate of complete aortic remodelling of 90% at the stent graft level, but did not report the rate of aortic remodelling distally.¹ Leshnowar et al.¹⁰ reported a complete false lumen thrombosis rate after TEVAR in the De Bakey 3b patients of 78% in the mid-thoracic and visceral aorta, and of 22% in the infrarenal aorta.

The technique has been reported once and described briefly in 2014 with promising results in 11 cases with only four with acute type B dissection.⁵ In this first report, four patients were treated at the chronic stage of the dissection (post type A). The 41 patients reported in the present study were all treated at the acute stage of a type B aortic dissection. As reported by Hofferberth et al.,⁵ the technique could be performed at anytime of the dissection, from the very acute to the chronic stage. However, it is assumed that the earlier the procedure is performed, the more the chronic distal complications (such as aneurysm evolution) are prevented, and the more the patients would meet

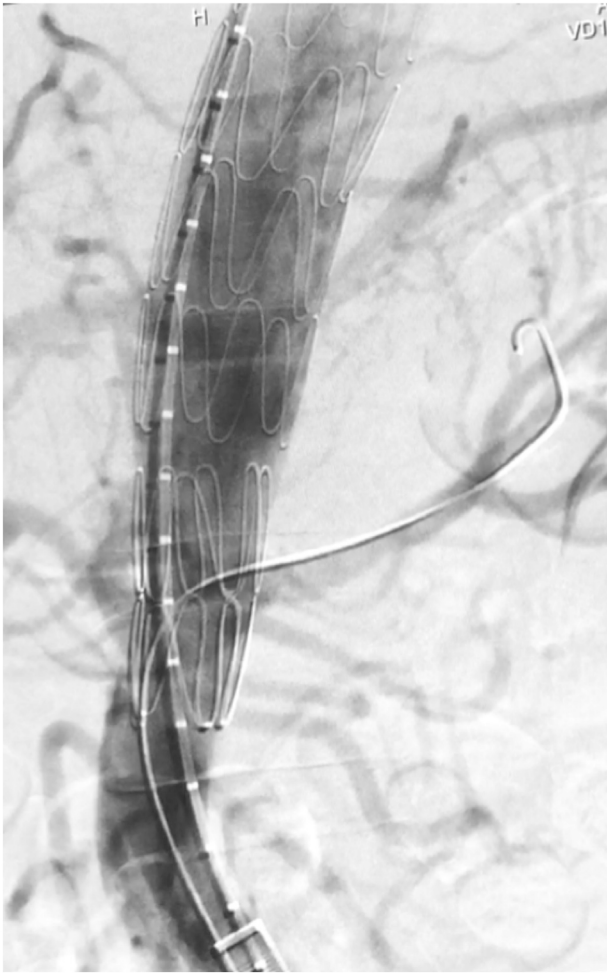


Figure 3. Final angiogram showing adequate seal of the thoracic false lumen, false lumen obliteration and branch vessel patency in the thoraco-abdominal aorta.

eligibility requirements for the technique since the bare stent is inappropriate for treating dissecting aneurysms with a diameter > 42 mm. Here, the median interval from onset of symptoms to STABILISE procedure was 5 days (range 0–20 days) and despite the acute stage of the dissections there was no aortic rupture. Balloon inflation pressures ranged from 1 to 2 atmospheres in this study, which was similar to that reported by Hofferberth et al.⁵ This low pressure was enough to enable intimal disruption and allow the radial force of the self expandable aortic bare stent to fix the intimal flap to the outer aortic wall, but not enough to induce aortic wall damage.

In recent years several techniques, such as the knickerbocker technique or techniques for direct false lumen occlusion using Candyplug, coil or glue, have been developed to address the issue of false lumen reperfusion at the level of the stent grafted descending thoracic aorta by distal re-entry tears.^{11–13} These techniques solved the problem of distal sealing of the stent graft with the false lumen in the setting of TEVAR for chronic dissecting aneurysms but none of them provided extensive remodelling of the thoraco-abdominal aorta up to the infrarenal aorta at the acute stage of the disease as with the STABILISE approach.^{11–13}

One of the critical aspects of this technique is to preserve the aortic branches supplied by the false lumen when the intimal flap was fixed to the aortic wall. This important point is managed by visceral artery catheterisation when arising from the false lumen or when dissected, before inflation of the bare stent, for potential stenting in case of stenosis on the completion angiogram (Fig. 3). Adjunctive intra-operative endovascular procedures to maintain patency of visceral or iliac arteries have been reported in up to 22.5%, even when the bare stent was not inflated (with PETTICOAT technique).⁸ With the STABILISE technique a 32% intra-operative adjunctive procedure rate for visceral artery stenting was achieved. It should be noted however, that the rate of pre-operative malperfusion was 49% and six of the 13 patients (46%) who required visceral stenting had pre-operative malperfusion within the targeted visceral vessels. For these six patients, stent graft closure of the primary entry tear did not allow recovery of flow in these arteries on post-stentent graft deployment angiography, and in any case these arteries would have required selective spot stenting even if the bare stent was not deployed. The rate of stenting of visceral arteries supplied by the false lumen or dissected was 31%, which was less than the 50% rate reported in an experimental ex vivo study.¹⁴ Renal arteries are the most commonly affected visceral arteries whereas the coeliac trunk never required stenting. Catheterisation through the mesh of the bare stent and the dissected flap did not raise technical problem in this study. After bare stent deployment the intimal flap is under tension and the ostia of the targeted vessels are well open so technical difficulty of the intimal flap catheterisation through the ostium is similar to standard visceral artery catheterisation in non-dissected aorta. Once the intimal flap is catheterised with the catheter guide, the ostium of the visceral artery is in line and is easily catheterised with a 0.035 guidewire. In case of catheterisation failure, it is still possible to not inflate the bare stent at visceral branch level and distally, in order to preserve distal false lumen reperfusion. Regarding aortic branch vessels supplied by the true lumen, owing to the large size of the bare stent mesh, their patency was always preserved. There was one visceral artery stent thrombosis reported in this study, successfully treated by thrombo-aspiration.

Another issue is how far the aortic bare stent should be extended distally when the dissection involves iliac arteries. It is not necessary to stent the entire infrarenal aorta: 2–4 cm below the renal arteries is sufficient to preserve flow in the iliac arteries. Regarding late aortic remodelling, the non-stented infrarenal aorto-iliac level remained dissected with patent false lumen flow in 25 patients without any impact on aorto-iliac diameters in 23. Two patients required open infrarenal aorto-iliac repair due to dissecting aneurysm with simple outcomes, indicating the importance of regular follow up for these patients. There was no additional aorto-iliac diameter growth reported in this study. Anyway, the infrarenal aorta should be easier to treat later on, with reasonable operative risk, following aneurysmal evolution in this area.

Cases of misalignment of the stents were reported with the Cook dissection bare stent.¹⁵ Although no serious clinical consequences of this misalignment have been reported, the manufacturer has modified the design of the device with a new suture between each peak of the Cook-Z stent segments of the first and second stent of the proximal and distal end in order to prevent misalignment.¹¹ No case of misalignment was reported in this series.

Limitations

Although short and even mid-term results are quite encouraging, comparative studies with TEVAR alone or the Petticoat technique without balloon disruption of the intimal septum are needed with large scale and long-term follow up.

CONCLUSIONS

The STABILISE technique is safe and reproducible to obtain immediate and durable thoraco-abdominal aortic remodelling in acute type B dissections, while not compromising the patency of collateral branches arising from the true lumen. False lumen supplied visceral branch malperfusion could be managed by preventive catheterisation through the mesh of the bare stent before balloon inflation.

CONFLICT OF INTEREST

None.

FUNDING

None.

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