Dual lumen intervention for aortic dissection: Long-term impact on aortic remodelling

Xun Yuan[1,2] MBBS, MMED; Andreas Mitsis[1] MD; Thomas Semple[3] FRCR, MBBS, BSc; Michael Rubens[3] MD; Christoph A. Nienaber[1,2] MD, PhD

1 Cardiology and Aortic Centre, Royal Brompton & Harefield NHS Foundation Trust, London, SW3 6NP

2 National Heart and Lung Institute, School of Medicine, Imperial College London

3 Radiology Department, Royal Brompton & Harefield NHS Foundation Trust, London, SW3 6NP

Corresponding to: Prof Christoph A. Nienaber. Cardiology and Aortic Centre, Royal Brompton & Harefield NHS Foundation Trust; Imperial College London, London, SW3 6NP. C.Nienaber@rbht.nhs.uk

Key words: Remodelling; False lumen; Thoracic endovascular aortic repair; coils; occluder devices; vascular plug

Word count: 3033

Conflicts of interest: No potential conflicts exist for all authors.

Funding: No funding was provided for this work

Abstract

Objective

Thoracic endovascular aortic repair (TEVAR) has changed the management of aortic dissection and enabled the dissected segment to remodel. In this report we describe the concept of dual lumen intervention with both stent-grafts in the true lumen and thrombus promoting interventions to the false lumen in the attempt to remodel dissected aorta regardless of location.

Methods

A total of 10 patients with aortic dissection (5 type A; 5 type B) underwent dual lumen intervention using a combination of patent foramen ovale (PFO) or atrial septal defect (ASD) occluders, coils and glue in addition to endovascular stenting of the true lumen. Patients were followed by computed tomography (CT) angiogram prior to, 6 months and 2 years following discharge to evaluate the status of aortic remodelling. The analysis comprised successful device delivery, completeness of false lumen thrombosis and aortic remodelling and procedure related complications.

Results

Dual lumen interventions have induced aortic remodelling in all cases of proximal dissection, with aortic shrinkage from 63.8 ± 7.5 pre-intervention, to 50.2 ± 6.6 mm (p=0.057) and an increase in true lumen area from 5.8±3.6 to 11.4±2.5 cm^2 (p=0.006). In distal dissection (after previous TEVAR with residual false lumen flow), false lumen intervention induced false lumen thrombosis in 4 of 5 cases upon first attempt (1 case required additional coiling of the gutter between left subclavian artery and stent-graft for complete thrombosis). While maximal aortic diameter remained unchanged (55.6 ±9.1 pre-intervention and 54.4±13.7 mm

at 2 years follow-up), true lumen area increased from 7.8±2.3 pre-procedure, to 10.6±1.5 cm^2 at follow-up (p=0.016), consistent with stable remodelling.

Conclusion

Interventional false lumen management of both lumens in case of subacute/chronic aortic dissection is feasible, promotes false lumen thrombosis and induces successful remodelling with or without previous endografting.

Introduction

Aortic dissection is a life-threatening condition with an incidence of 2.6-3.5 cases per 100,000 person-years (1,2) and usually is caused by an intimal tear of the intima or media, resulting in dissection of layers of the aortic wall. Proximal or type A dissection originates from the ascending aorta, while in type B dissection the tear originates at or distal to the origin of the left subclavian artery. Traditionally, surgery is the treatment of choice of proximal aortic dissection, with a perioperative mortality of 15% to 30% in elderly patients with comorbidities (3). Thoracic endovascular aortic repair (TEVAR) is attracting interest for managing type B dissection by excluding the false lumen from circulation and placing a stent-graft across the tear. According to guidelines, TEVAR is the treatment of choice for complicated type B aortic dissection (class I, level of evidence C), while pre-emptive TEVAR should be considered in uncomplicated cases, because it improves long-term outcome by remodelling (class IIa/IIb, level of evidence B) (4,5). Thus, TEVAR as a true lumen intervention has changed the management algorithm for patients with type B aortic dissection since successful remodelling of dissected aorta carries a long-term benefit (6). Conversely, with persistent flow into the false lumen (e.g. endoleak after TEVAR or retrograde flow via distal re-entry tears), reinterventions become necessary due to false lumen expansion (7). Independently, incomplete or partial false lumen thrombosis has been associated with increased mortality (8); elevated diastolic false lumen pressure will increase both wall tension, and the risk of distal aneurysmal degeneration and rupture. Thus, dual lumen intervention may be useful to promote false lumen thrombosis and mitigate aneurysmal degeneration which help to stabilise the aorta (9, 10). False lumen management has been reported with devices such as a “candy-plug” in the false lumen (11,12) or overexpansion of stent-graft (13) in the true lumen. Our dual lumen intervention relies on an alternative, minimalistic, percutaneous concept to manage the false lumen by inducing

thrombosis, both proximally and distally, by virtue of occluder devices, vascular plugs, selective distal stent-grafts to the true or coils and glue applied to the false lumen. This report of a series of cases with previous type A and B dissection illustrates the concept of dual lumen interventions to promote remodelling of dissected aorta when true (single) lumen interventions alone failed.

Study Protocol/Methods

Patients population

A total of 10 patients were identified with sustained false lumen flow (5 cases of type A, and 5 cases of type B dissection) after previous attempts of endovascular interventions to the true lumen with closure of thoracic entry tears. One patient with type A dissection underwent surgical interposition grafting; the remaining patients with proximal dissection had not undergone any prior intervention. Patients were selectively chosen as their risk for any open repair or even branched or fenestrated graft implantation was considered to be prohibitively high (Euroscore II: 6-31%) not withstanding anatomic suitability.

Of those 10 patients, 7 were male, with a mean age of 72.3±12.5 years. All were initially treated in the subacute or chronic phase of dissection and considered unsuitable for surgery (Euroscore II of 12.8±7.7%). The Charlson Comorbidity Index ranged from 2 to 10 (mean 5.8) with an estimated 10-year survival ranging from 0 to 90% (mean 42%). The duration from onset to the dual lumen intervention varied between 1 and 6 months; in 5 cases the procedure was performed to dissection or false aneurysm of the ascending aorta and in 5 cases after pervious true lumen TEVAR for chronic type B dissection. Evidence of perfused or retrogradely pressurised false lumen was obtained from serial ECG-triggered CT or

dynamic magnetic resonance imaging (MRI) demonstrating false lumen flow and ≥ 5mm expansion per 6 months.

With Ethics Committee approval and multidisciplinary board decisions, off-label use of occluder devices applied to both the false and the true lumen, and various plugs or coils was sanctioned. Each patient had provided written informed consent for all primary and additional/ancillary procedures. In the context of aortic dissection, demographics, comorbidities (represented by EuroScore II and Charlson Comorbidities Index), procedure-related details, complications, peri-interventional characteristics, management, peri-interventional events and follow-up were reviewed and extracted from medical records. Both strategy and device selection were subject to multidisciplinary discussion including interventional cardiologists, cardiac surgeons and radiologists using pre-procedure enhanced CT aortic angiograms and other essential examinations such as coronary and aortic angiograms and transoesophageal echocardiography (TOE).

Embolization and sealing techniques

The decision to proceed with percutaneous means to induce false lumen thrombosis and eventually remodelling was based on the presence of both active (re)-entries and false lumen flow / expansion. Entry points were identified by CT angiography, and further assessed by flow sensitive MR sequences or colour Doppler TOE. In addition, prior to occlusion, entry sites were confirmed on contrast fluoroscopy; intraprocedural TOE was used in all cases as it has proven useful to guide procedures and quality-control results by notion of colour Doppler flow signal disappearance in the false lumen and signs of thrombosis in evolution confirmed by final aortography as previously described. (14) All embolization and closure procedures were aimed to access the false lumen percutaneously, under local or general anaesthesia, via either femoral and/or brachial arterial access:

1st. Promotion of false lumen thrombosis by sealing the entry tear or communication using a combination of coils deployed in the false lumen and an Amplatzer™ PFO or ASD occluder with the distal umbrella deployed in the false lumen and the proximal umbrella in the true lumen.

2nd. Retrograde catheterisation of the false lumen via distal re-entry tears and induction of thrombosis by coils, duct occluder in addition to true lumen scaffolding with bare metal stent and/or re-entry occlusion by short stent-graft.

3rd. Selective application of Onyx® glue and/or coils in the false lumen and sealing of re-entry site by use of a local stent-graft.

In a scenario of type A dissection, the false lumen was instrumented via the proximal entry tear at the level of the ascending aorta. In type B dissection, the false lumen could best by navigated/instrumented via a distal re-entry tear. All chronic type A/DeBakey II dissection cases had either a contraindication for open surgery or denied open surgery. In essence, the approach to proximal and distal dissection was fundamentally the same. Initially, a 5F coronary diagnostic catheter was advanced into the target entry. If possible selective coil deployment into the false lumen was performed with spiral coils directly detached via 5F catheter (William Cook Europe, Bjæverskov, Denmark). The number of coils varied between 5 and 10 per case and between 5mm x 5cm and 15mm x 15cm in dimension. In all type A cases, coiling of the false lumen was followed by definitive sealing of the proximal tear using a PFO or ASD-occluder (st. Jude Medical, Minnesota, USA), with the distal umbrella deployed in the false lumen and the proximal umbrella in the true lumen. Ethylene vinyl alcohol copolymer (Onyx® glue, ev3, California, USA) was injected via conventional 6F MP coronary guide catheter in 2 cases into the false lumen followed by true lumen stenting. All

cases were performed in a state-of-the-art hybrid theatre offering latest imaging technology and simultaneous TOE.

Analysis

All categorical data were counted by frequency and percentages, and descriptive variables displayed as mean and standard deviation or median and inter-quartile range. Paired t-tests were used to compare pre- and post-procedure lumen diameters. All statistical analyses were performed using IBM SPSS® Statistics 23 (IBM Corp, New York, USA). Procedural success was assessed from fluoroscopy and intra-procedural TOE, while aortic remodelling was quantified based on serial CT angiography. Analysis included aortic dimensions before and after induction of false lumen thrombosis and was performed according to an established method (15).

Results

Procedural Outcomes

The mean interval between confirmation of flow in the false lumen and the dual lumen intervention was 3.6 ± 2.5 months; in all 5 type A dissection cases, the false lumen was closed and thrombosed by PFO or ASD occluders with umbrella sizes between 18 mm and 40 mm and additional coils. False lumen coils and vascular entry occluders were applied in 3 type B dissection patients who revealed residual false lumen inflow post-TEVAR. The remaining 2 cases with re-entry tears distal to a previously implanted stent-graft were sealed by Onyx® and coils (between 5 and 8 coils) in the false lumen. In all 10 cases, the target goal was achieved with successfully sealing the tear and subsequent false lumen thrombosis (Figure 1 and 2). In four cases, brachial access was used, while femoral access was used in all

others ranging between 7 and 9 F introducer. In 1 case a transient access complication (local hematoma), due to a large size delivery system (10F) via the right brachial artery, was encountered. There were no other periprocedural complications. In addition, there was no periprocedural vascular events within 30 days, and a total follow-up duration ranging from 34 to 81 months with no relapse or late events.

Late outcomes

The median follow-up duration was 13.5 (IQR 9.75-51.0) months with no adverse cardiovascular and cerebrovascular events. All patients had follow-up CT images at 6 months after procedure and in annual intervals. Compared to aortic dimensions at baseline (pre-procedure) or discharge, total diameter of the affected aortic segments decreased, while true lumen area expanded (aorta remodelling) in all 10 cases. There was no case of visceral or lower limb malperfusion over the entire period of observation. (Figure 1 and 2)

All but 1 case demonstrated complete false lumen thrombosis. Patient no.7 revealed backflow from the distal re-entry tear, opposite to the celiac trunk, which was first addressed by placing coils and an occluder in the false lumen, via the distal re-entry site. This manoeuvre, however, lead to only partial false lumen thrombosis, as residual antegrade false lumen flow was documented through the gutter between a Viabahn in the carotid artery and the aortic stent-graft. Longer follow-up will show whether interventions may become necessary to complete false lumen thrombosis (including Onyx® or coils) in this patient. Figure 3 and 4 summarises the remodelling process over time, showing both an increasing true lumen area and decreasing total aortic diameter after the dual lumen intervention.

Anatomic aspects

Our series proved that dual lumen interventions can be applied in both proximal and distal dissection of the aorta, thus representing a novel conceptual approach to induce remodelling after previous dissection or unsatisfactory TEVAR results. Patients with highly selected type A and type B dissections were subjected to dual lumen procedures and eventually showed successful remodelling. Although the effect only reached borderline statistical significance (p=0.057), in terms of total diameter reduction, complete false lumen thrombosis was induced in all cases of type A dissection, and importantly, the true lumen area nearly doubled from 5.8±3.6 to 11.4±2.5 cm^2 (p=0.006).

In the setting of type B dissection (after previous TEVAR with residual false lumen flow), the dual lumen intervention was successful in 4 of 5 cases on first attempt. As described previously one case required secondary intervention and complete plugging of the left subclavian artery to fully interrupt communication with the false lumen. While maximal aortic diameter was essentially unchanged (55.6±9.1 before intervention versus 54.4±13.7 mm at follow-up), no expansion was seen. The true lumen area at index level (maximal aortic diameter), however, increased from 7.8±2.3 pre-procedure to 10.6±1.5 cm^2 at 6-month follow-up (p=0.016), consistent with aortic remodelling. Figure 1 and 2 summarises the anatomic changes in all patients (both type A and B dissections) as a sign of successful remodelling.

Discussion

TEVAR has become a cornerstone of primary management of aortic dissection, improving long-term prognosis by initiating false lumen thrombosis and aortic remodelling. In patients with organ or limb malperfusion, coverage of the proximal entry tear will usually expand the

true lumen and re-perfuse ischaemic organs. Residual patency of the false lumen, however, is not uncommon and is considered to herald unfavourable long-term outcomes. (8,9) Conversely, successful remodelling and complete false lumen portend an excellent prognosis, (16) and vice versa (17-19). As known predictors of poor outcomes include an aortic diameter of >44mm, a false lumen diameter >22mm and patency of the false lumen (20, 21), it appears logical to induce complete thrombosis of the false lumen to safely manage aortic dissection and improve long-term outcomes (22), also realizing that incomplete or partial false lumen thrombosis and a patent false lumen promote further expansion and possibly late rupture (RR 2.69, P=0.002) (8).

Therapeutic induction of complete thrombosis would be desirable to avoid false lumen dilatation and rupture. The classic endovascular approach aims for the occlusion of connections between true and false lumen by stent-graft coverage in the true lumen, potentially followed late by custom-made fenestrated and branched endografts at the level of abdominal re-entries. (23) such true lumen endovascular approach produces false lumen thrombosis throughout the dissected thoraco-abdominal aorta (24), but carries significant risks of spinal cord ischemia, as many segmental arteries may be covered. Recently, alternatives were introduced including the “candy-plug” and “knickerbocker” techniques, relying on obstruction of the false lumen by prohibiting distal false lumen backflow (11,12). The “knickerbocker technique” intends to block retrograde false lumen flow by deploying an oversized stent-graft in the true lumen followed by controlled rupture of the dissection membrane with a non-compliant balloon expanding the graft to prevent backflow through abdominal entry tears (13). Both techniques have drawbacks, have not been tested in larger series and are considered more traumatic and potentially risky. Similarly, the use of multilayer stent technology would not be safe or appropriate as side branch or communications are likely to stay open (25, 26). More interestingly, a recent “true lumen

intervention" suggests tackling distal re-entry sites by small stent-grafts to promote thrombosis of the false lumen (27).

While the beneficial effect of remodelling is undebated, the technical execution of various procedures to promote remodelling is individually different ranging from injection of embolizing material to deployment of coils, and plugs alone or in combination with coils or glue applied to the false lumen (28,29). Onyx® is the most common embolizing agent and has previously been used with coils to promote false lumen thrombosis and seal endoleaks (30,31). When Onyx® is exposed to blood, it precipitates swiftly from liquid to solid state; this agent has drawbacks as it potentially migrates into visceral vessels and causes iatrogenic ischemia. Furthermore, Onyx® is radiopaque, causes image artefacts and disguises true endoleaks while it is costly. (30-32).

Dual lumen interventions have proven safe and feasible even in 5 cases of chronic proximal dissection and are certainly less traumatic than other techniques including stenting of ascending aorta (29). Closure of entry tears, restoration of single-lumen blood flow and enhanced false lumen thrombosis may reap long-term benefits (33), without the risks of stent-grafting the ascending aorta (Figure 3 and 4). Hence, the false lumen channel is an alternative pathway to allow a catheter to reach the tear to deploy coils and the distal umbrella of Amplatzer ™ vascular occluder devices in the false lumen. In our series, 2 Amplatzer ™ Septal Occluders, 2 Amplatzer ™ PFO Occluders, 1 Amplatzer ™ Vascular Plug II and 1 Amplatzer ™ Duct Occluder II were eventually used. The criteria to choose these devices were individualised to anatomical characteristics of a given patient, and to the access sites needed for different sizes of delivery systems for those devices. Advanced interventional skills, with formal training in interventional cardiology, are essential for safe interventions. Finally, timing of any false lumen intervention as complimentary intervention remains an

open question, and better understanding of CT imaging may help to identify patients likely to benefit (34).

Limitations

The presented results of dual lumen interventions in dissection were generated in a single centre as a series of proximal and distal dissections (post-TEVAR in type B aortic dissection) with limited follow-up. Moreover, our cases were highly selected and subjected to an individualised approach. Interventions were performed in the subacute, chronic phase of dissection only, and all occlusive devices were used off-label, however, followed for more than 2 years. More experience and longer follow-up is certainly warranted.

Outlook

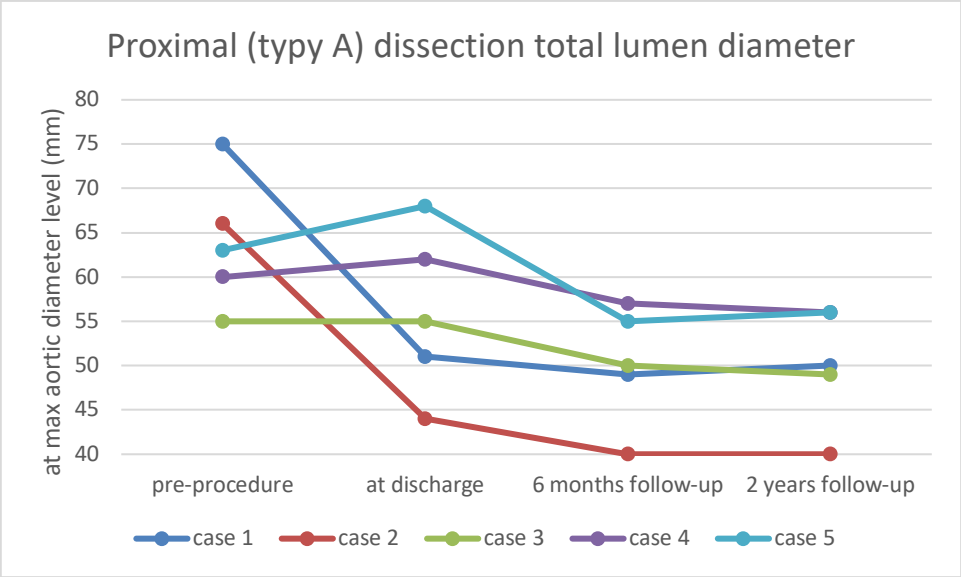
Endovascular interventions for aortic dissection, without the trauma of open surgery, especially in the light of our ageing comorbid population, will be in clear demand for both distal and even proximal aortic dissection. We have demonstrated that interventional management of the false and the true lumen, to induce remodelling, is feasible in selected cases of aortic dissection regardless of location. Further studies and longer follow-up are needed to prove the sustainability and safety of such manoeuvres.

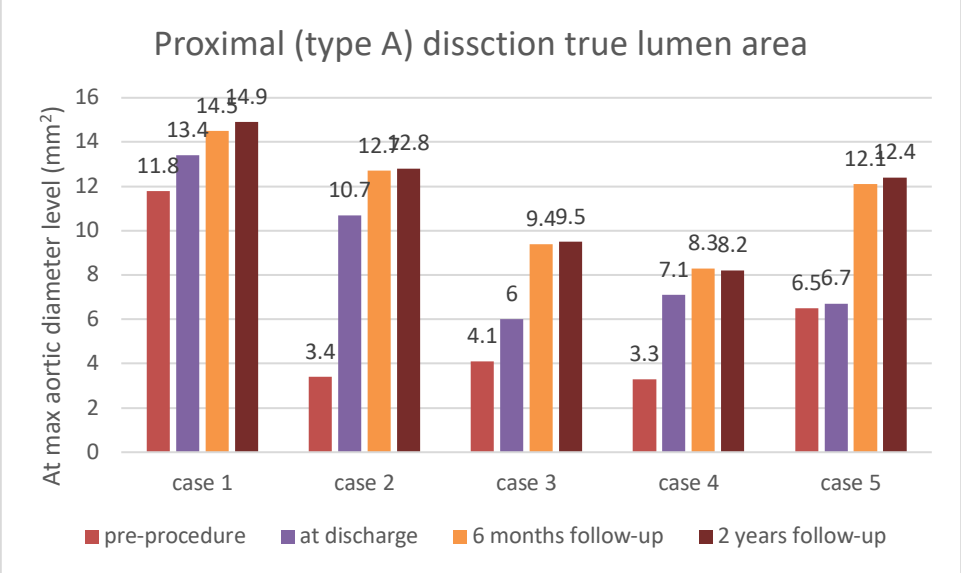
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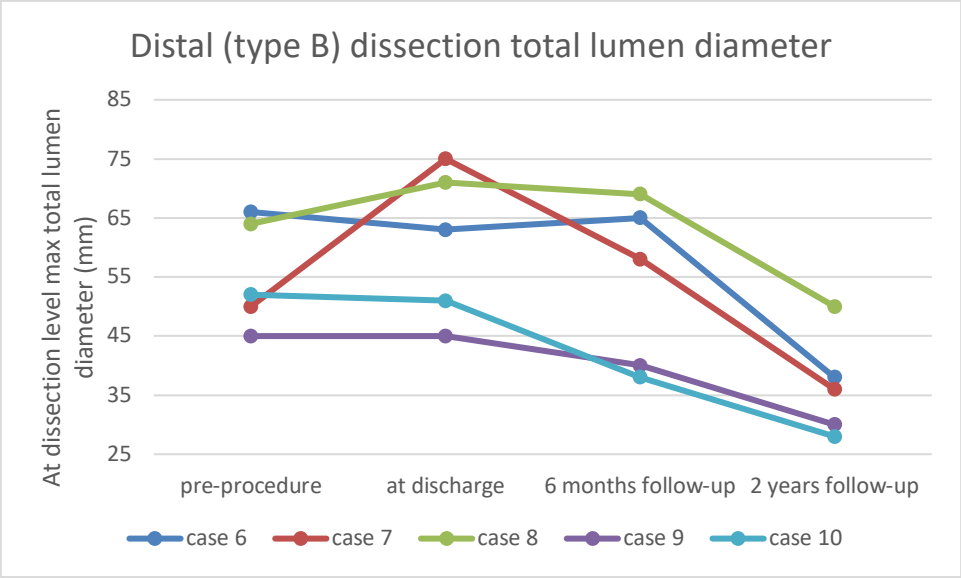
Figure 1

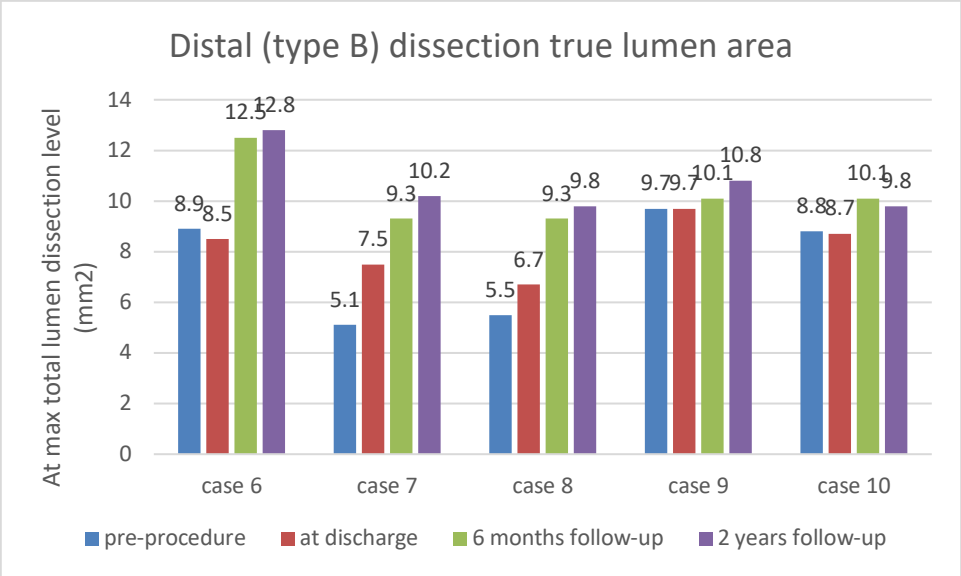




Individual display of total lumen diameter in cases of proximal aortic dissection over time of follow up; the lower panel displays true lumen area over time post-intervention.

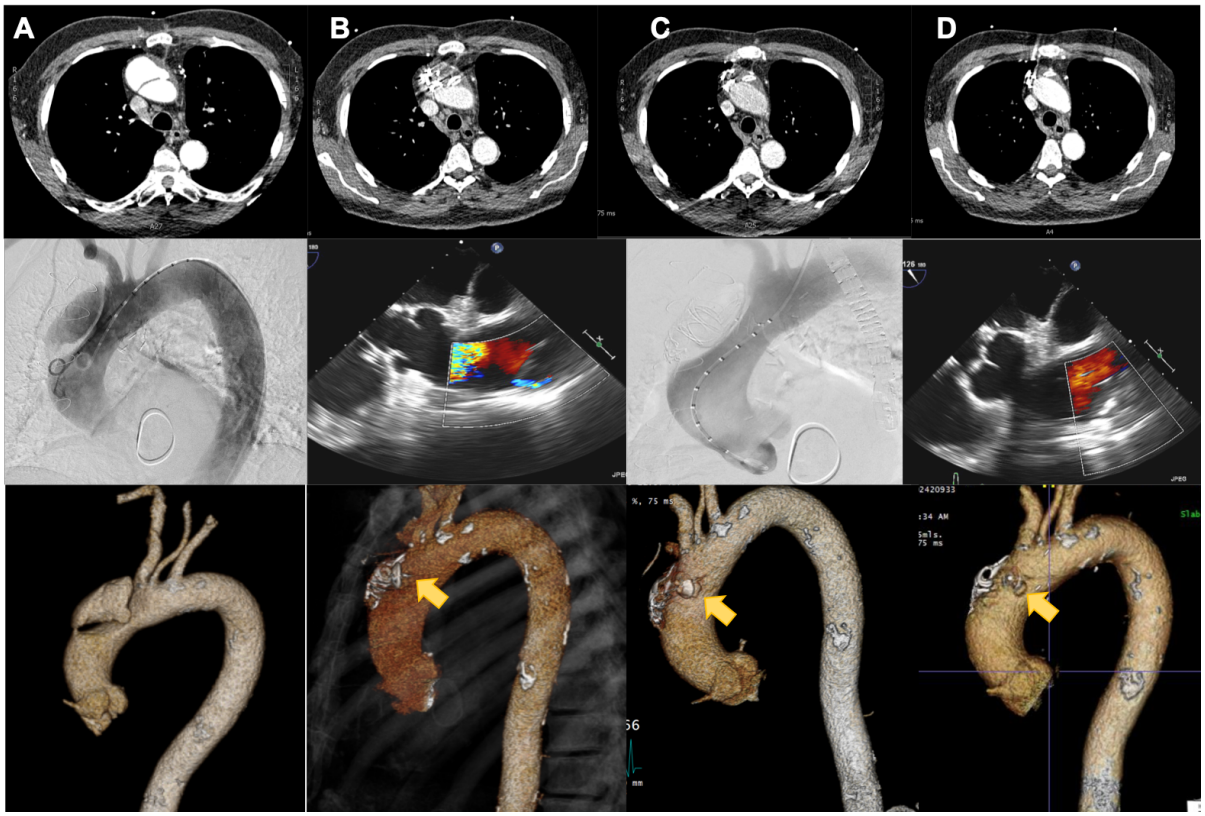
Figure 2





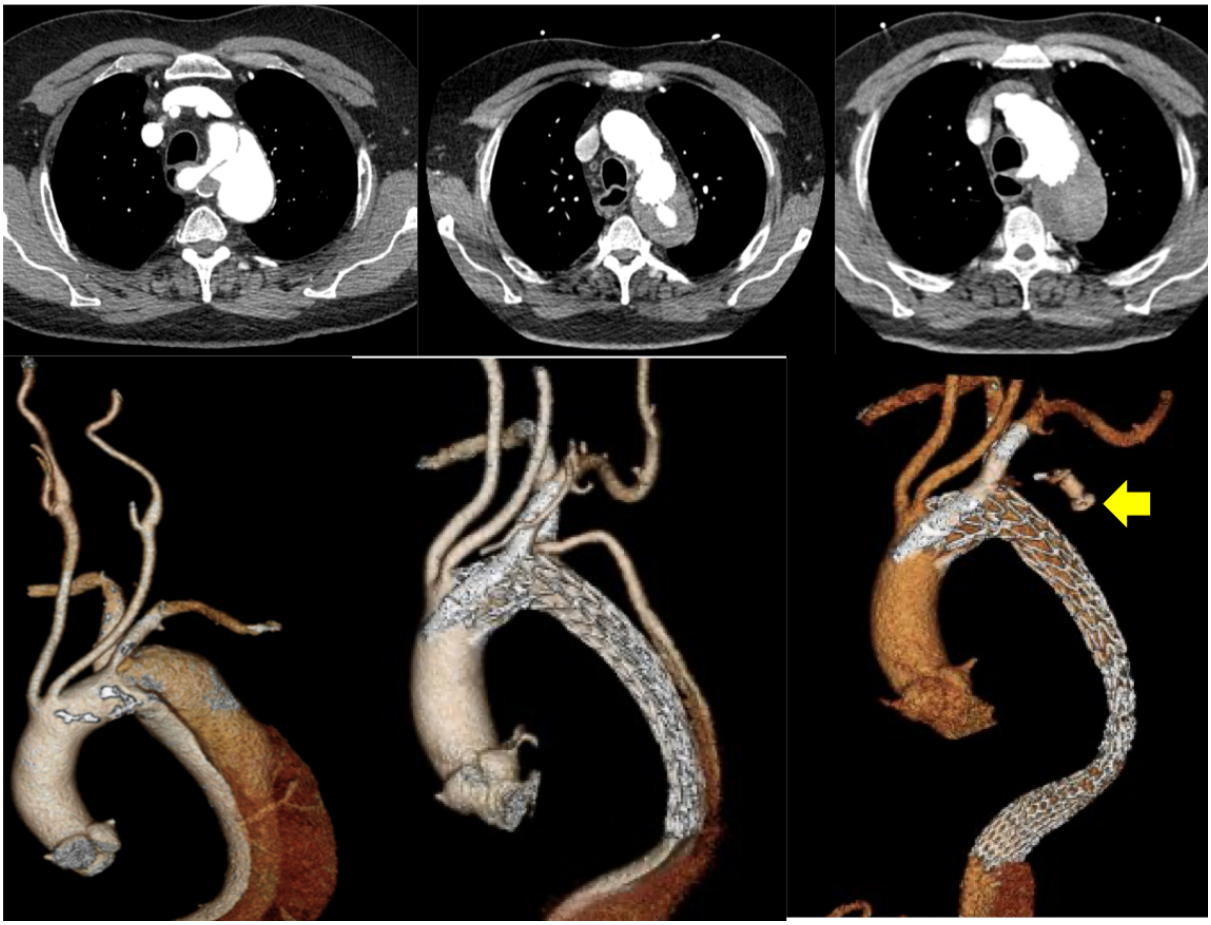
Individual display of total lumen diameter in cases with distal dissection over time; the lower panel displays true lumen area over time.

Figure 3



CT, angiogram and echo images pre-procedure (A), at discharge (B), 6-month follow-up (C) and 2-year follow-up (D) showing entry closure false lumen thrombus and shrinkage with true lumen expansion (remodelling). Arrows shows the ASD occluder.

Figure 4



CT images pre-procedure (A), post-TEVAR (B) and 6-month follow-up after dual lumen intervention (C) showing entry closure false lumen thrombus and shrinkage with true lumen expansion (remodelling). Arrows shows the Amplatzer Plug II.