Uncomplicated Type B Aortic Dissection - A European Multicentre Cross-Sectional Evaluation

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1. Introduction

Stanford Type B aortic dissection (TBAD) accounts for nearly 40% of aortic dissections. Based on specific clinical and radiological features, such as malperfusion and rupture, it is categorized as complicated (coTBAD) or uncomplicated (uTBAD). Although uTBAD cases represent a higher incidence, coTBAD requires urgent and often invasive treatment. The preferred treatment is thoracic endovascular aortic repair (TEVAR), which has shown positive clinical outcomes.

Management of uTBAD is less clear, and there is ongoing debate. Most uTBAD cases are initially managed with optimal medical therapy (OMT) to control heart rate and blood pressure and prevent disease progression. However, some patients are lost to follow-up until the disease progresses to coTBAD, at which point TEVAR is considered.

The standard of care and surgical practice for uTBAD worldwide still needs to meet clinical needs. There is a discrepancy between different guidelines [1, 2]. For example, there is controversy surrounding the identification of 'high risk' uTBAD patients who may benefit from preemptive TEVAR, supported by emerging observational data, compared to the durability of OMT [3]. Moreover, there is evidence suggesting that treating all uTBAD patients as a single pathological group and following the same treatment pathway is misleading. Additional risk stratification and classification are necessary [4].

A multicenter European randomized control trial – European Uncomplicated Type B Aortic Repair (EU-TBAR) is being developed to compare pre-emptive TEVAR with custom-made devices vs conventional OMT. The pre-trial set-up is confluent on different pillars, including evaluation of 1) European activity, trends, and governance, 2) outcome reporting, and 3) cost evaluation. This article aimed to demonstrate the observational cross-sectional survey results from participating centres and highlight the risk assessment, activity, practices, and governance of uTBAD.

2. Materials and Methods

2.1. Study Design

This observational cross-sectional survey used a questionnaire that examined the understanding, risk assessment, local governance oversight, and clinical activity of uTBAD. The survey was electronically distributed between Oct 17, 2023, and Nov 18, 2023, across European hospitals amongst surgeons working directly in interventional treatment for TBAD patients. The survey was sent to surgeons via electronic mail with a link to a secure web application. Because uTBAD is a rare disease, the selection of sites and participants was based on an evaluation model that allowed broader coverage of patients from different geographical indices and disparities, including ethnicity and inclusivity.

2.2. Data Collection

The data were collected and managed using Research Electronic Data Capture (REDCap), a secure, web-based software platform hosted at Swansea University. The survey was divided into four sections. The first section detailed 1) the volume of uTBAD the surgeons encounter each year, 2) the commonest month/season of the year to encounter uTBAD, 3) the choice of intervention (pre-emptive TEVAR vs. OMT), and 4) the timing of intervention being acute (< 14 days), subacute (14 days – 3 months) and chronic (> 3 months), as well as the average follow-up duration.

The second section enquired about the types of devices used and whether custom devices were available and used. The third section quantitatively evaluated the surgeon's understanding of risk factors. Hence, participants were asked to rank eight anatomical risk factors for complications from 'Most Important' to 'Least Important' and five technical risk factors from 'Most Important' to 'Least Important'.

Participants were instructed only to rank the factors they regularly use daily. The last section explored the governance of different aspects of TBAD management that are followed locally at every participating surgical site, such as protocols, radiology, emergency, transfer services availability, documentation, review, and research conduct.

3. Results

37 out of 43 (86%) surgeons answered the survey within one month of receiving it. The replies were collected from 14 European countries; Figure 1 illustrates a European geo-scheme map with the participating countries and the number of replies from each.

3.1. Case Volume

A total of 26 (70.2%) participants reported less than 25 uTBAD encounters per year. While nine (24.4%) reported between 25 and 50 encounters per year, two (5.4%) reported more than 50 encounters per year (Table 1). In terms of time of year, autumn was the most reported as the commonest season to encounter uTBAD by 13 (35.1%) of the participants. In comparison, winter was reported by 12 (32.4%) of the participants as the commonest season, spring by eight (21.6%) participants, and summer by only one (2.7%) participant (Figure 2).

Sixteen (43.2%) participants recommended pre-emptive TEVAR for uTBAD. These 16 participants reported a median of 50% of patients treated with pre-emptive TEVAR at their centres. The preferred timing for intervention for uTBAD was subacute (14 days – 3 months) in 19 (51.4%) of participants, acute (< 14 days) in 14 (37.8%) of participants, and chronic (> 3 months) in 4 (10.8%) of participants (Table 2). All participants reported following up with their patients after the intervention, with 33 (89.2%) reporting follow-up for more than 24 months (Table 3).

3.2. TEVAR Data

Figure 3 illustrates the most common devices used in TEVAR, as reported by the participants. The Gore TAG was the most used device by 25 (67.5%) professionals, with the Cook Zenith Alpha and Medtronic Valiant following at 17 (46%) and 12 (32.5%), respectively. 27 (73%) participants reported the availability of custom-made devices. Table 4 represents the different custom graft manufacturers used by the participants. Participants reported they used a median of two stents per patient.

3.3. Risk Factors Assessment

Figure 4 illustrates participants' responses to ranking eight anatomical risk factors from most important to least important. 'Rapid Aortic Enlargement' was voted the most important or second most crucial anatomical risk factor, with only three (8%) participants reporting not using it as a risk factor. 'Fusiform index ≥0.64' was the most voted least important, with another 14 (37.8%) participants reporting not using it as a risk factor. 'Maximal total aortic diameter ≥40mm' was the second most voted as the most critical risk factor. The rest of the anatomical risk factors had a roughly equal distribution among all ranks.

Figure 5 illustrates participants' responses to ranking five technical risk factors from most important to least important. 'Proximal sealing zone length <20mm requiring multiple OR single vessel debranching' were voted as the most important and second most important risk factors. 'Poor vessel access' was voted the third most important risk factor, 'Distal extension' as the fourth, and 'Custom graft required' as the least essential technical risk factor. Moreover, 'Custom graft required' was the most not used as a technical risk factor.

3.4. Governance

Twenty-nine (78.4%) professionals reported that their centre had protocols for uTBAD management as well as the availability of a multidisciplinary team (MDT). 28 (96.5%) participants reported cardiac and vascular surgeons as part of the MDT, 17 (58.6%) reported interventional radiologists as part of the team, and eight (27.5%) reported other components (Table 5). Additionally, 21 (56.7%) participants reported the presence of a specifically appointed team for uTBAD, one (2.7%) participant reported the presence of a rota, and five (13.5%) reported the presence of both.

A Standard Operative Protocol (SOP) was present in 17 (45.9%) centres. Table 6 summarises what each SOP covers. Radiology services were reported as readily available on-site in 35 (94.5%) participants, and only one (2.7%) reported a tertiary radiology service. 34 (91.9%) participants reported that their radiology service was available 24 hours a day, and 32 (86.5%) reported that it was available 7 days a week (Table 6). The great majority of participants (n=33, 89.2%) reported the presence of a single point of contact (SPC) for emergencies around the clock. 28 (84.5%) of these were also readily available for research. Moreover, 27 (81.8%) reported having an SPC Backup, and two (6%) reported available rota systems (Table 6).

Only 17 (45.9%) participants reported the availability of transfer services to a specialized centre at their institution. The travel distance covered by these services was 0-25km in seven (41.1%) participants, 25-50km in four 23.5(%) participants, and >50km in six (35.3%) participants. All the participants reported that it is the same transfer service for complicated and uncomplicated TBAD cases. 14 (82.3%) of the participants reported the presence of protocols for management during transfer (Table 7).

Documentation was reported as a mix of electronic and paper in 18 (48.6%) participants, while 16 (43.2%) reported complete electronic documentation, and two (5.4%) reported purely paper documentation. 25 (67.5%) of participants review performance every set period. 14 (56%) conduct a review every 6-12 months, five (24%) every 3-6 months, and six (20%) every 0-3 months. Only four (10.8%) participants reported involvement in national annual governance reviews. 27 (72.9%) participants reported that their centre supports research data collection (Table 8). Seven (18.9%) participants reported new protocols set during the COVID-19 pandemic, while only one (14.3%) reported that the protocols were still intact.

4. Discussion

The results of this European observational cross-sectional survey represent the uncertainty regarding optimum initial management in those classified as uTBAD. There was an almost equal split between those supporting pre-emptive TEVAR (43.2%) and those opposing it (56.8%) for uTBAD. However, the prior group offered pre-emptive TEVAR in a median of 50% of patients at their centres. Also, it may well be that uTBAD is underdiagnosed, with 70.2% reporting a volume of up to 25 confirmed cases per annum. The pathological nature of uTBAD is dynamic and can rapidly progress to become complicated. This is relevant as the literature has shown delays of up to 14 days from initial diagnosis of uTBAD to progression to coTBAD [5]. In addition to progression to complicated disease, data suggests that nearly 40% of those discharged to their communities with an initial diagnosis of uTBAD later develop aneurysmal dilatation of the thoracic aorta at a mean of 18 months [6, 7]. Accurate and timely identification of 'high risk' uTBAD patients and subsequent early intervention with TEVAR are of utmost clinical importance to prevent disease progression and reduce long-term morbidity. These 'high risk' anatomical/radiological uTBAD features include a >40mm maximal thoracic aortic diameter, a primary entry tear of >10mm length or a location on the inner curve of the aortic arch, a false lumen (FL) diameter >22mm, a partially thrombosed FL and a free-floating true lumen.

However, given the encouraging results, there is a call to expand the TEVAR criteria to include a wider uTBAD population, and at least 25% of these patients will progress to complicated pathology [1-4].

Over the past decade, emerging evidence has supported pre-emptive TEVAR in acute/subacute uTBAD with favourable short-, mid-and long-term results superior to OMT alone. Several randomized controlled trials (RCTs) and observational studies have been conducted to compare TEVAR and OMT in uTBAD. The investigation of STEnt Grafts in Aortic Dissection (INSTEAD) trial is a significant example of this. 140 uTBAD patients were randomly allocated to either a TEVAR+OMT group (n=72) or an OMT-alone group (n=68). The primary outcome was all-cause mortality at two years. Secondary outcomes were aorta-related deaths, aortic remodelling, and dissection progression. The results showed no significant differences between the two groups in terms of cumulative survival (95.6 ± 2.5% with OMT vs. 88.9 ± 3.7% with TEVAR; p=0.15), aorta-related death (97.0 ± 2.0% with OMT vs. 94.4 ± 2.7% with TEVAR; P=0.44), and dissection progression (72.5 ± 5.5% with OMT vs. 77.2 ± 5.0 with TEVAR; p=0.65) at 2-years follow-up. Furthermore, there was no difference in the incidence of persistent paraplegia/paraparesis and significant stroke at the endpoint (p=0.90 and p=0.53, respectively). More importantly, TEVAR patients showed substantially improved aortic remodelling compared to the OMT group (91.3% and 19.4%, respectively, p<0.001) [8]. The investigators expanded the follow-up period to 5 years, producing the INSTEAD-XL trial. In contrast to its predecessor, this trial showed a significant reduction in aorta-related mortality (6.9% vs 19.3%; p=0.04) and progression of dissection (27.0% vs 46.1%; p=0.04) as well as significantly higher FL thrombosis with TEVAR compared to OMT alone at 5 years [9].

Furthermore, multiple studies summarised in our recent scoping review reflected similar results and supported the conclusion that pre-emptive TEVAR yields favourable outcomes in a select uTBAD population [3]. Despite this, further large RCTs are required to solidify the current evidence base and drive a paradigm shift in the clinical management of uTBAD.

A European trial is essential from various points of view, including a diverse population and geographical index. The advent of custom-made device technology and its use in uTBAD is increasingly encouraging; however, the evidence is still lagging, opening a broad spectrum for future research in this field.

In addition to the above, there is an abundance of observational data from recent years confirming the above RCT findings and further affirming the pivotal role of pre-emptive TEVAR in what once was a very debatable clinical scenario. For example, a 10-year propensity-score-matched study of 290 acute uTBAD patients compared pre-emptive TEVAR (n=145) and OMT (n=145), with both groups similar at baseline. Whilst early mortality was also identical, the long-term results demonstrated the superiority and longevity of the endovascular solution. Both the freedom from all-cause death (p=0.028) and aorta-related death (p=0.044) were significantly higher with TEVAR at 1, 3 and 5 years. In addition, the cumulative incidence of rupture over 5 years was considerably lower with TEVAR than with OMT (5.1% vs. 13.7%; p=0.024). Meanwhile, the cumulative incidence of retrograde type A AD, endoleak and reintervention also favoured TEVAR; the difference did not reach statistical significance [10].

Our results stress the importance of long-term follow-up of uTBAD patients due to the deficit that OMT shows over time, with 89.2% of our participants reporting a follow-up period of >24 months. Another 10-year study with 5-year follow-up data by Iannuzzi et al. [11] further confirmed the improved survival benefit of TEVAR (76%, p<0.01) compared to OMT (60%) and open surgical repair (67%).

Further expanding on the variability surrounding the radiological uTBAD features classed 'high risk', these included a maximal thoracic aortic diameter of >40mm. Yet, in their 2016 study looking at mortality predictors of uTBAD, Ray et al. [12] demonstrated lower survival (p<0.36) and significantly high intervention rate (p<0.01) over 10 years in those with an aortic diameter >44mm, as well as being an independent risk factor for mortality (hazard ratio, 8.6; p<0.01).

The same study reported a significant association between an FL diameter >22mm and decreased intervention-free survival ($p<0.04$) [12].

A further ongoing debate is the timing of TEVAR in uTBAD. A recent report revealed an unofficial consensus that the optimal timeframe for intervention is the subacute phase of dissection (15-90 days since onset), as the dissection flap is more compliant at this stage [13]. The latter aligns with our results and most observational studies identified in the literature. A long-term study comparing pre-emptive TEVAR in acute (n=130) versus chronic (n=137) high-risk uTBAD was identified. The overall 30-day mortality and cumulative mortality rates were 2.2% and 5.9%, demonstrating the high efficacy of this management strategy. Whilst the acute group showed higher 30-day mortality and complication rates, this did not reach significance. With a medical follow-up period of 48.2 ± 25.9 months, late outcomes were favourable and similar between the two groups, including all-cause death, dissection-related death, intervention, and aortic-related events [14]. Becket al. [15] presented similarly optimal outcomes using the Society for Vascular Surgery Vascular Quality Initiative data. An interesting finding in this study is the 0% 30-day and 1-year mortality rates in the 'urgent' (<24 hours) group despite higher complications than the acute and subacute counterparts.

Despite its well-established clinical efficacy, TEVAR is not without risks but is associated with multiple complications which may necessitate secondary intervention. These include endoleak, adverse aortic remodelling, retrograde type A AD, endograft migration and malperfusion [16, 17]. Risk stratification based on individual preoperative patient factors, such as demographics and comorbidities, is essential for optimizing the post-operative profile [18-20]. A recent original study investigated the disparity in clinical outcomes based on sex and ethnicity in this clinical context. The authors split their cohort of 58 patients into a male group (n=41, 70.7%; Causacian 95%) and a female group (n=17, 29.3%; Caucasian 88%) and looked at disease and interventional characteristics and clinical outcomes, including mortality, complications, and reinterventions. The majority of males (58%) presented with coTBAD, whilst females had uTBAD mainly (41%).

The number of stents used was significantly higher in females (p = 0.041), but Zone 2 was the most common stent landing zone in both groups. Males overall had worse outcomes with more complications (17% vs. 12%) and reinterventions (22% vs. 6%, P=0.136). However, females experienced higher mortality (41% vs. 24%, P=0.201). Nevertheless, this result can be explained by the logistic regression analysis, which showed that the number of stent grafts was inversely correlated with mortality with an odds ratio of 0.367 (95% CI: 0.145 – 0.927; p=0.034) [18]. Two other scoping review articles investigated 15 different preoperative patient characteristics including, but not limited to, age, sex, ethnicity, comorbidities such as diabetes and hyperlipidaemia, smoking and ASA grade, as well as a range of laboratory markers and radiological features that can be utilized in risk stratification tools for results optimization of uTBAD patients undergoing TEVAR [19, 20].

It is also essential to mention intraoperative factors such as arch debranching and left subclavian artery (LSA) management strategy. Several studies have investigated supra-aortic debranching procedures; however, most are small-numbered and focus on chronic aneurysmal disease rather than TBAD. Despite conflicting evidence, most suggest that LSA coverage during TEVAR with a revascularisation strategy increases the risk of complications, primarily neurological [21].

Cost-effectiveness is essential in the applicability equation for any medical innovation introduced into clinical practice. Several cost analyses have been conducted in the case of TEVAR in TBAD. Our narrative review dwelled on the optimal cost-benefit of TEVAR in this clinical scenario, offering superior cost-effectiveness relative to both open surgical repair and OMT in the long term [22]. As such, the European trial aims to derive a cost-effective model that compares the intervention arms, i.e., custom-made device applications versus OMT.

5. Conclusion

In conclusion, uTBAD remains a misnomer of a dynamic, ongoing disease process requiring early diagnosis and intervention. Pre-emptive TEVAR in high-risk uTBAD is becoming more common, with encouraging results prompting an expansion of indication criteria to a broader uTBAD population managed conservatively. Nevertheless, further evidence is needed through large RCTs, mainly European collaboratives, to reach a definitive conclusion on the optimum surgical management of uTBAD.

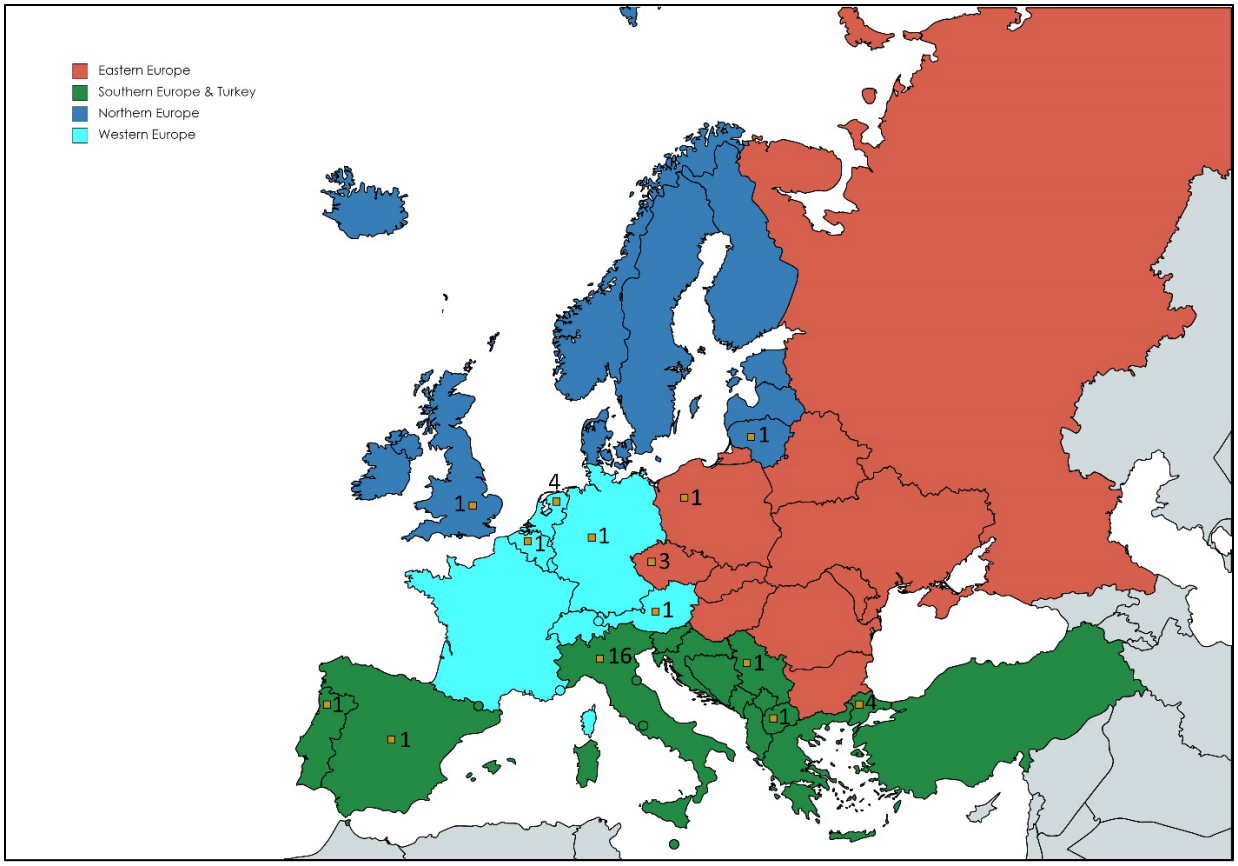

Figure 1: Participating Countries

Table 1: Number of Uncomplicated TBAD per Year	**N (%)**
0-25	26 (70.2%)
25-50	9 (24.4%)
>50	2 (5.4%)

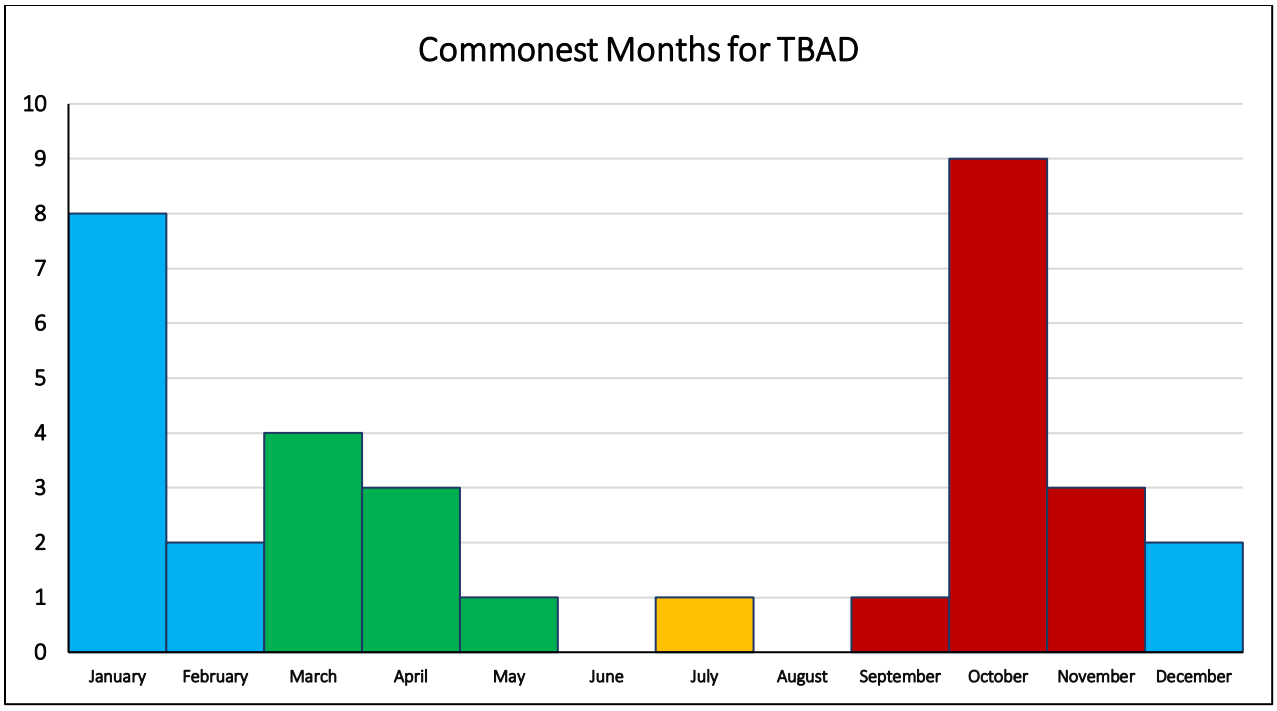

Figure 2: Commonest Month for TBAD (Blue: Winter, Green: Spring, Yellow: Summer, Red: Autumn)

Table 2: TEVAR for Uncomplicated TBAD		**N (%)**
1. Recommendation	With Pre-emptive TEVAR	16 (43.2%)
	Against Pre-emptive TEVAR	21 (56.8%)
2. Median % of patients treated with pre-emptive TEVAR (IQR)		50% (30-90)
3. Preferred Timing	Acute (<14 Days)	14 (37.8%)
	Subacute (14 Days - 3 Months)	19 (51.4%)
	Chronic (>3 Months)	4 (10.8%)

Table 3: Follow-Up After Intervention for Uncomplicated TBAD		N (%)
1. **Follow-up for Uncomplicated TBAD after intervention**		37 (100%)
2. Length of Follow-up	0 – 6 Months	2 (5.4%)
	6 – 12 Months	1 (2.7%)
	12 – 24 Months	1 (2.7%)
	>24 Months	33 (89.2%)

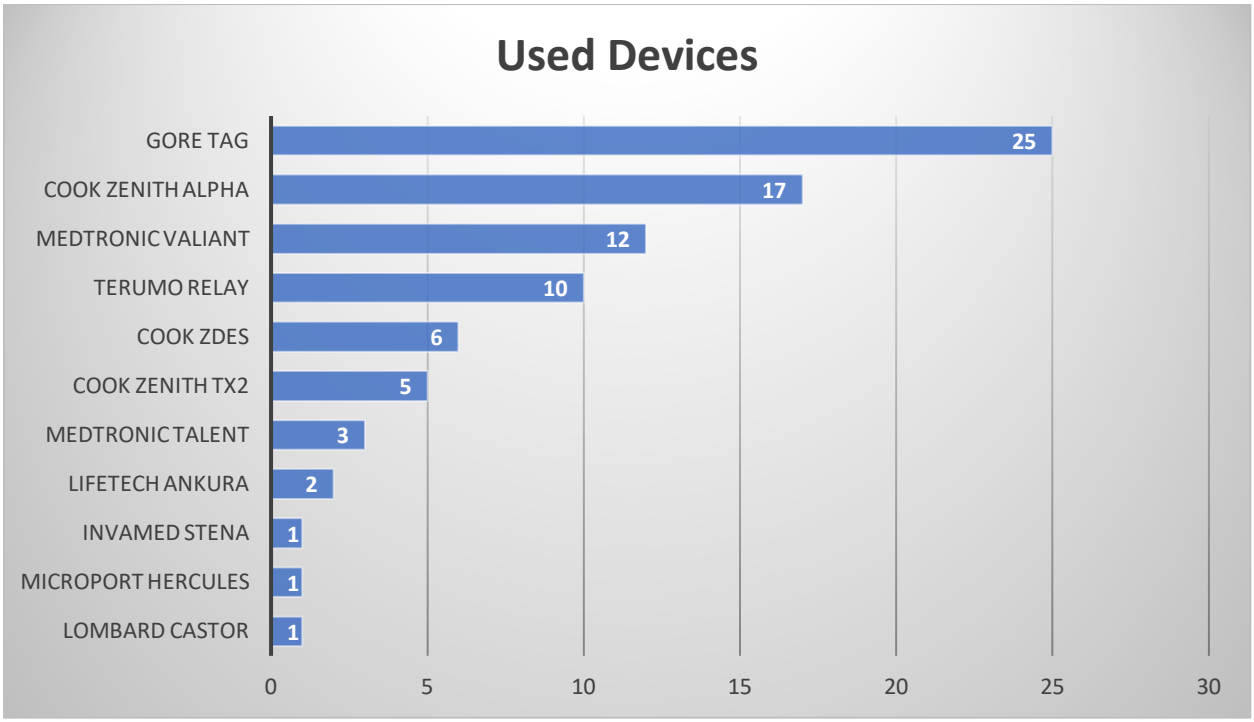

Figure 3: Reported Devices Used for Uncomplicated TBAD

Table 4: Custom Made Devices		N (%)
1. **Custom Made Device Availability**		27 (73%)
2. Device Manufacturer	Terumo Relay	15 (55.5%)
	Cook Zenith	14 (51.8%)
	Artivion (Jotec)	6 (22.2%)
	Kawasumi Najuta	3 (11.1%)
	Lombard Castor	2 (7.4%)
	Gore TAG	1 (3.7%)
3. Median Number of Stents Used		2

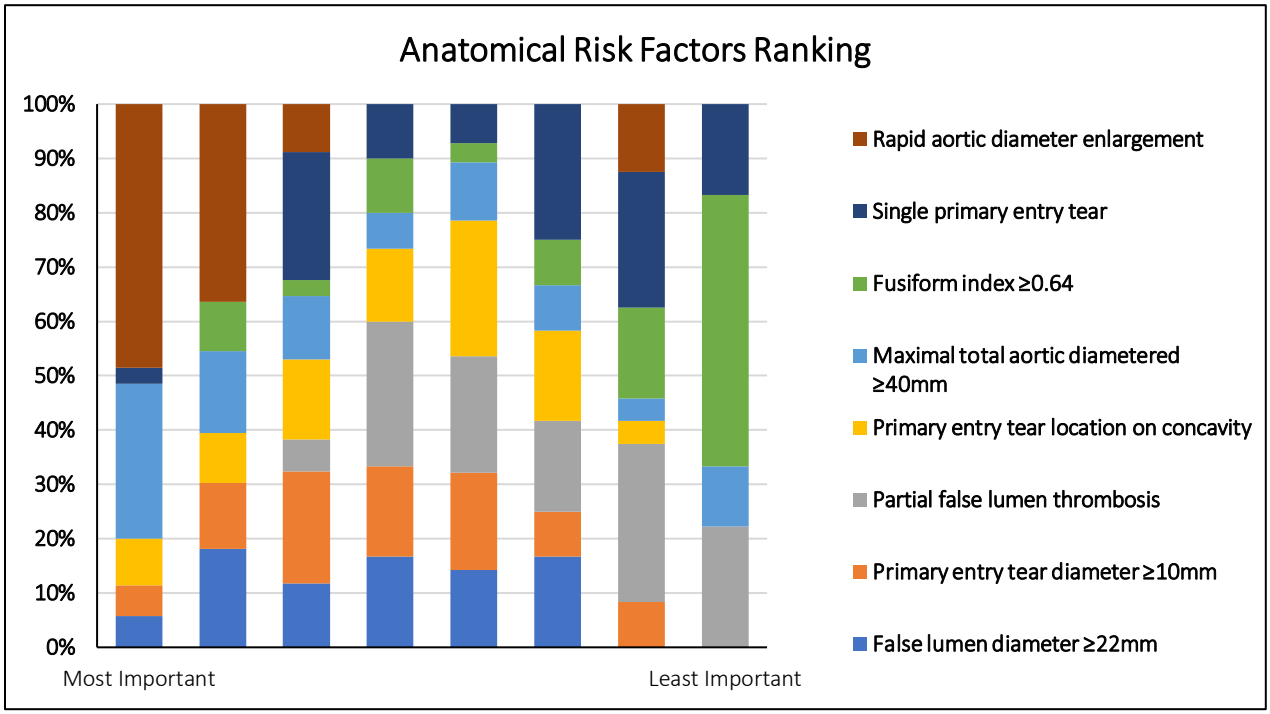

Figure 4: Anatomical Risk Factors Ranking

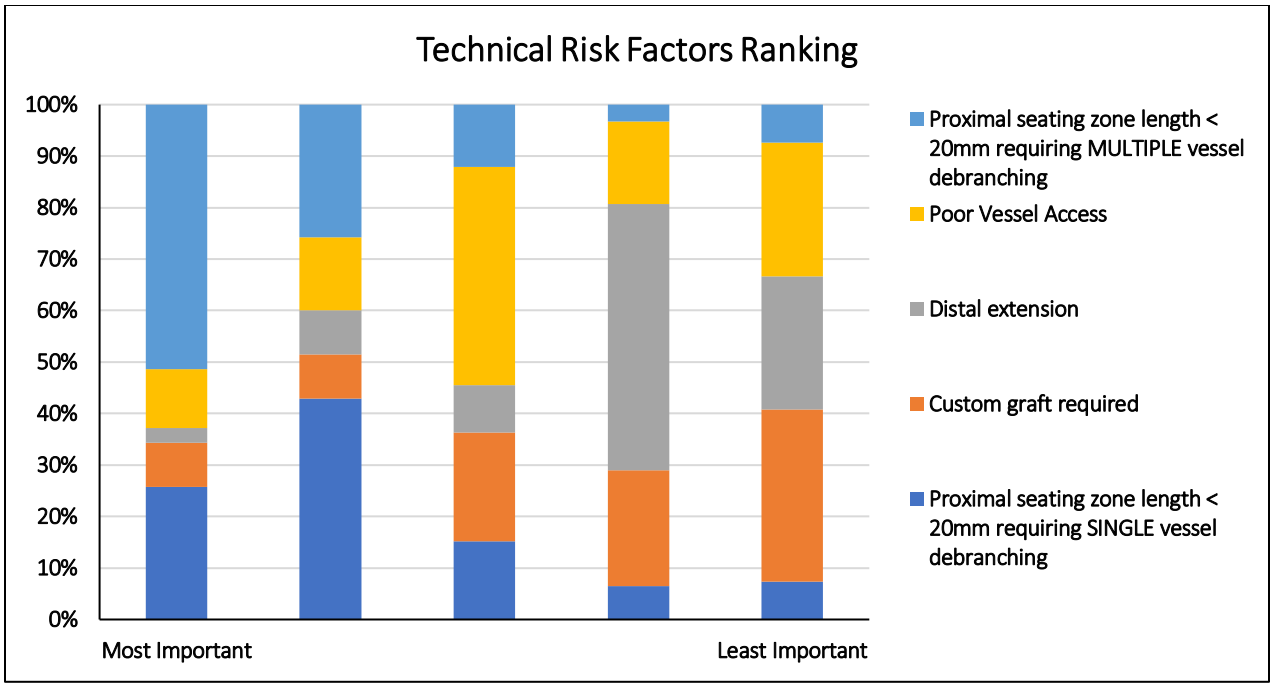

Figure 5: Technical Risk Factors Ranking

Table 5: Multidisciplinary Team (MDT)		**N (%)**
1. **Availability of MDT**		29 (78.4%)
2. MDT Component	Cardiac Surgeon	28 (96.5%)
	Vascular Surgeon	28 (96.5%)
	Interventional Radiologist	17 (58.6%)
	Other	8 (27.5%)
3. Protocols in Place for Treatment		29 (78.4%)

Table 6: Governance		N(%)
1. **Appointed Dissection Team/Rota**	Team	21 (56.7%)
	Rota	1 (2.7%)
	Both	5 (13.5%)
2. Available Standard Operative Protocol (SOP)		17 (45.9%)
SOP Covering:	Patient Hospital Journey	10 (58.8%)
	Treatment Pathway	14 (82.3%)
	Emergency Referral	10 (58.8%)
	Medical Management	16 (94.1%)
	Surgical Management	15 (88.2%)
	Transfer	4 (23.5%)
	Other	1 (5.8%)
3. Radiology Service Availability	On-site	35 (94.6%)
	Tertiary Centre	1 (2.7%)
4. Radiology Availability Times	24 Hours	34 (91.9%)
	7 Days	32 (86.5%)
5. Single Point of Contact for Emergency (SPC)		33 (89.2%)
SPC Available for Research		28 (75.6%)
SPC Backup/Rota Availability	Backup Available	27 (81.8%)
	Rota System	2 (6%)

Table 7: Transfer Service		N(%)
Transfer Service Availability		17 (45.9%)
Transfer Distance	0-25km	7 (41.2%)
	25-50km	4 (23.5%)
	>50km	6 (35.3%)
Patient Management During Transfer		14 (82.4%)
The same Transfer for Uncomplicated & Complicated Cases		17 (100%)

Table 8: Documentation & Performance		**N(%)**
1. **Type of Patient Documentation**	Paper	2 (5.4%)
	Electronic	16 (43.2%)
	Mix of Paper & Electronic	18 (48.6%)
2. Review of Performance Conducted		25 (67.5%)
Performance Review Interval	0-3 Months	6 (24%)
	3-6 Months	5 (20%)
	6-12 Months	14 (56%)
3. National Annual Governance Review		4 (10.8%)
4. Research Data Collection Support		27 (72.9%)

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