34 Is There Any Role for Open Surgery Via Thoracotomy in Acute Type B Dissection?

Thomas Lübke and Jan Brunkwall

Abstract

Acute complicated type B aortic dissection is a life-threatening condition. During the last decade, the endovascular reconstruction of the true lumen by the use of stent grafts has gained increasing attention as the first line therapy in this disease entity. We summarized all published studies for TEVAR among patients with acute complicated type B aortic dissection (TBAD) with respect to clinical success, complications, and outcomes. Furthermore, we determined whether TEVAR reduces death and morbidity compared with open repair for TBAD. Studies were identified from a literature search using various databases, and included studies when three or more patients were reported and at least in-hospital mortality was reported. Data from comparative studies of TEVAR versus open repair of the descending aorta in TBAD were combined through meta-analysis. Ninety-four observational studies involving 5,982 patients were included in the present meta-analysis. In-hospital mortality was 10.6 % and other major complications (i.e, stroke (5.9 %), paraplegia (5.1 %), occurred less frequently. Long-term follow- up was limited to a mean of 23.3 months. During this time late aortic rupture was calculated for 4.3 % of cases. A complete false lumen thrombosis was estimated to occur in 77.4 % of cases. Late mortality reached 10.2 %. In comparative studies, 30-day/ in-hospital mortality and paraplegia/ paraparesis were significantly reduced for TEVAR versus open repair. There was no significant difference between TEVAR and open repair in patients with acute complicated TBAD for the following outcomes: late mortality, and stroke rate. This summary analysis suggests that endovascular treatment of complicated acute type B aortic dissection produces favourable initial outcomes and would seem to be a great addition to the treatment options for this

T. Lübke, MD, PD (✉) • J. Brunkwall, MD, PhD
Department of Vascular and Endovascular Surgery,
University of Cologne, Kerpener Str. 62,
Cologne 50937, Germany
e-mail: thomas.luebke@uk-koeln.de

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condition. If the long term gains of TEVAR over open repair could be proven in the near future, unquestionable this technique will replace open surgery in the treatment of complicated type B aortic dissections.

Keywords
Aortic dissection • Endovascular repair • Stent-graft • Thoracic aorta • Thoracic aorta • Thoracotomy • Acute type b dissection • Meta-analysis

Introduction

Acute aortic dissection is the most common aortic emergency, and affects about three to four per 100,000 persons per year [1]. Approximately 30–42 % of the acute type B aortic dissections (TBAD) are complicated, and 20–30 % of patients die before hospital admission [2], underlining that immediate diagnosis and treatment are crucial to reduce morbidity and mortality.

Aortic dissection is characterized by a laceration of the aortic wall that allows blood flow to course through a false lumen within the aortic wall, mostly in the outer third of the media. This in turn may lead, via aortic wall destabilization, to aortic rupture. Furthermore, aortic branch compromise may cause loss of blood supply to vital organs (malperfusion syndrome), either via static or dynamic obstructions.

In most or all patients with uncomplicated acute type B dissection (stable hemodynamic status, no branch vessel involement, absence of periaortic hematoma or aortic dilation and controllable hypertension and aortic pain), to date, optimal medical treatment remains the treatment of choice, in adherence with currently available scientific evidence. Under modern anti-impulse and anti-hypertensive pharmacologic therapy, clinical outcomes and mortality rates for uncomplicated type B aortic dissections have improved significantly over the last decades with satisfactory results in the acute phase, with a 30-day mortality rate of 10 % or less at present [3–5]. However, as these patients are exposed to long-term, life threatening risks (including the formation of a dissecting thoracic aneurysm in 20–30 % of such patients) subsequent serial clinical and imaging follow-ups are essential.

Complicated type B aortic dissections are characterised by thoracic aortic rupture, shock, malperfusion (involving the viscera, kidneys, spinal cord, or the lower extremities), intractable hypertension and pain, or rapid expansion in the distal arch or proximal descending aorta with a total aortic diameter of 4.5 cm or greater. These complications constitute a clinical imperative for surgical intervention, because they instantly threaten life or limb.

In these patients, thoracic aortic stent-grafting or open surgical aortic graft replacement constitute the two main currently available therapeutic options. They both aim to seal (or to resect, respectively) the entry intimal tear, leading to depressurization and shrinkage of the false lumen and repressurizing the collapsed true lumen with subsequent remodelling and stabilization of the aortic wall. This may prevent aortic rupture and, by relining the true lumen in the proximal and mid descending aorta with the stent-graft, obliterate the entry site and redirect all blood flow to the true lumen, exclusively, and abolish any distal malperfusion, often without the need of any adjunctive treatment.

In some cases, surgical flap fenestration or percutaneous balloon fenestration can also be required in patients with acute type B dissections. The aim of these procedures is to create a wide orifice of communication between the false and the true lumina, and thus obtaining homogeneous pressures and flows across the dynamic obstructing intimal flap and into the aortic branch vessel ostia [6]. However, nowadays surgical fenestration is seldomly performed because of operative mortality rates as high as 50-88 % in patients with renal and mesenteric ischemia, respectively [6, 7]. Further complications of fenestration include the risk that the torn intimal flap may occlude the iliac arteries and the risk of future aneurysmal dilation of the thin-walled false lumina in long-term survivers [8].

Open repair using prosthetic graft interposition is the conventional treatment for acute type B aortic dissection. It is routinely performed through a left thoracotomy in conjunction with single-lung ventilation, full heparinization, cardiopulmonary bypass, profund hypothermia, cerebrospinal fluid drainage, and circulatory arrest, in order to minimize morbidity, especially stroke and paraplegia [9–11]. Despite remarkably improved operative techniques and improved perioperative care, suboptimal results of open surgical treatment of the acutely dissected descending aorta are reported with contemporary mortality rates ranging from 15 to 30 % and even exceed 50 % in complicated cases under emergency conditions [12, 13]. Another devastating complication of the open operative technique is the ischemic spinal cord injury with high paraplegia rates [14]. Current preventive strategies aim at the augmentation of the peri-operative spinal perfusion and include cerebrospinal fluid (CSF) drainage and maintaining distal body perfusion by bypass [15]. Coselli et al. [16] reported a significantly reduced incidence of postoperative paraplegia in the group treated prophylactically with CSF drainage (2.6 % versus 13 %). Furthermore, the afflicted population is usually older of age and present with various comorbidities, such as hypertension, obstructive pulmonary disease, and coronary heart disease, all of which have significant effects on the open surgical outcome.

TEVAR interventions have added a strong alternative and new dimension to the surgical management of aortic dissection and recently, the paradigm of treatment of acute complicated distal dissections has shifted in favour of thoracic endovascular aortic repair (TEVAR) over open surgical intervention (OR) [17]. However, TEVAR intervention for uncomplicated type B aortic dissection is currently not supported by scientific evidence. TEVAR has some potential advantages over open repair. These include avoidance of extracorporal circulation and aortic cross-clamping, reduced blood loss, and more rapid procedural and recovery times and are related to the decreased invasiveness of the procedure.

However, the safety, efficacy, and durability of TEVAR have been discussed controversely [18–20]. The currently available literature is sparse and complicated by heterogeneous clinical definitions and therapeutic treatments and information on late outcome is scant. To date, we still lack level-1 evidence in support of TEVAR for type B aortic dissections for no randomised trials of TEVAR versus OR for TBAD have been performed with substantial follow-up. Thus, management recommendations for TBAD are mostly derived from uncontrolled retrospective cohorts or case series, registry data or expert opinions, and are not firmly settled yet, and acute complicated type B aortic dissection is seldom referred [20–27].

The objective was to provide a contemporary review of the outcome of patients undergoing TEVAR for acute complicated TBAD and to perform a comprehensive meta-analysis of available comparative, non-randomized, controlled studies to determine whether TEVAR improves short- and long-term outcome compared with OR for adults presenting with acute complicated TBAD.

Methods

The current guidelines for performing comprehensive systematic reviews and meta-analysis, including the PRISMA (Preferred Reporting Items for Systematic reviews Meta-Analyses) [28] and MOOSE (Meta-analysis Of Observational Studies in Epidemiology) [29] guidelines for randomised and non-randomised studies, respectively, were applied in the present study.

Study Selection

To keep findings contemporary, only studies published between 1997 and 2012 were included. To restrict only to experienced centres regarding TEVAR or OR for acute complicated TBAD, we limited entry to studies including a minimum of three (predominantly ten) adults. The minimum outcome data required for the study was in-hospital mortality or 30-day mortality, respectively.

Regarding patient selection, all patients in whom complicated TBAD has been diagnosed by either computed tomography or magnetic resonance tomography or conventional angiography within 14 days from onset of symptoms were included. Patients with a traumatic dissection, type A aortic dissection or chronic, uncomplicated TBAD were excluded from the present analysis. For comparison with OR, all kinds of endovascular stent grafts were considered.

A comprehensive search was performed using the MEDLINE database, the Cochrane Central Register of Controlled Trials on the Cochrane Library, the International Association of Health Technology Assessment (INAHTA), EMBASE and Chinese Biomedicine Database, and surgical meeting abstracts from 1997 to 2012. The electronic database search strategy can be requested from the authors. Based on the entry and exclusion criteria, **94** articles were included.

Definitions

Acute type B aortic dissection denoted dissection confined to the descending aorta and presenting within 14 days from the onset of symptoms. Procedural success indicated successful stent-graft deployment at the intended target location without emergency conversion to open surgery to correct aortic complications. Death was defined as cumulative incidence of all-cause mortality. Incidence of paraplegia, paraparesis, or stroke, whether permanent or temporary, was reported as an aggregated outcome, and only post-operative incidence of new paraplegia, paraparesis or stroke was considered. Renal dysfunction was defined as per authors' definition (increase in serum creatinine over baseline by more than 50 % or need for renal replacement therapy). Endoleaks were classified according to the usual nomenclature [30].

Statistical Analysis

A number of studies presented combined data on a number of pathologies other than acute TBAD. In a few instances, the data presented in these articles was only available for the combined patient group. In these instances, weighted numbers were calculated for the variables in question. Variables with data only available in less than 30 % of the total number of studies were excluded from the final analysis and presentation. As a result, the number of patients (denominator) varies, with the specific variables reported in the analysis. For the other data, the extracted variables were used to derive pooled weighted event rates for the total series of patients. In evaluating multiple publications of overlapping patient populations, all studies were classified by the center(s) and dates of patient enrollement, and selected the most recent and/or most complete series from each center to extract as many relevant outcomes as possible.

Patient characteristics and outcomes were entered into a database, and analysed using Comprehensive Metaanalysis Software version 2 (Biostat, Littlewood, New Jersey). While performing meta-analysis, for dichotomous variables, individual and pooled statistics were calculated as weighted odds ratios (ORs) with 95 % confidence intervals (CIs). Since heterogeneity was anticipated across trials, the random effects model was used for all calculations to provide an overall conservative analysis [31]. For sensitivity analysis, all calculations were repeated by using the fixed effects model. We preferentially captured intention-to-treat data whenever available [32]. No adjustment for multiple testing was applied because the statistical analysis was performed in an explorative manner.

Heterogeneity across trials was explored for each outcome by calculating I^2, which indicates the percent of heterogeneity across trials that cannot be explained by chance variation alone [33]. $I^2 > 50$ % was considered to indicate high heterogeneity. Publication bias was assessed through funnel plots, and Egger's regression test was applied [34].

Results

A total of 94 studies involving 5,982 patients met the inclusion criteria for the present analysis and were selected for data extraction included [2, 7, 23, 30, 35–123] (Table 34.1). In all studies in which the

Table 34.1 Included studies, follow-up, and survival after endovascular repair of acute complicated type b aortic dissection

Author	Year	N	Follow-up (months)	Survival (%)
Dake et al. [35]	1999	19	12	80
Nienaber et al. [36]	1999	12	12	100
Czermak et al. [37]	2000	7	–	–
Hausegger et al. [38]	2001	5	–	–
Kang et al. [39]	2001	6	–	–
Sailer et al. [40]	2001	7	–	–
Taylor et al. [41]	2001	6	–	–
Tiesenhausen et al. [42]	2001	4	–	–
White et al. [30]	2001	9	–	–
Won et al. [43]	2001	12	–	–
Bortone et al. [44]	2002	12	–	–
Cambria [7]	2002	4	–	–
Duda et al. [45]	2002	5	–	–
Haulon et al. [46]	2002	4	–	–
Herold et al. [47]	2002	18	–	–
Hutschala et al. [48]	2002	9	–	–
Lepore et al. [49]	2002	11	19	91
Kato et al. [50]	2002	38	27	85
Nienaber et al. [51]	2002	127	28	97
Palma et al. [52]	2002	14	29	92
Buffolo et al. [53]	2002	120	15	92
Quinn et al. [54]	2002	15	–	–
Rousseau et al. [55]	2002	20	–	–
Saccani et al. [56]	2002	3	–	–
Gonzales-Fajardo et al. [57]	2002	12	12	80
Shim et al. [58]	2002	15	–	–
Totaro et al. [59]	2002	25	–	–
Herold et al. [47]	2002	12	8	–
Balzer et al. [60]	2003	8	–	–
Beregi et al. [61]	2003	46	8	83
Fattori et al. [62]	2003	22	–	–
Gerber et al. [63]	2003	3	–	–
Grabenwöger et al. [64]	2003	11	–	–
Krogh Sorensen et al. [65]	2003	3	–	–
Lambrechts et al. [66]	2003	11	–	–
Lonn et al. [67]	2003	20	13	85
Lopera et al. [68]	2003	10	–	–
Matravers et al. [69]	2003	9	–	–
Nienaber and Eagle [70]	2003	11	–	–
MacKenzie et al. [71]	2004	10	–	–
Iannelli et al. [72]	2004	8	–	–
Hansen et al. [73]	2004	16	24	81
Rocchi et al. [74]	2004	14	30	95
Duebener et al. [75]	2004	10	25	80
Bortone et al. [76]	2004	43	21	94
Leurs et al. [77]	2004	131	12	90 (1 year)
Grabenwoger et al. [78]	2004	20	–	–

(continued)

Table 34.1 (continued)

Author	Year	N	Follow-up (months)	Survival (%)
Eggebrecht et al. [79]	2005	10	18	56
Dialetto et al. [80]	2005	14	18	86
Nathanson et al. [81]	2005	23	20	85
Böckler et al. [82]	2006	15	24	62
Kaya et al. [83]	2006	12	11	83
Chen et al. [84]	2006	62	27	95
Xu et al. [85]	2006	63	48	89
Tsai et al. [2, 86]	2006	27	27.6	76.2 (3 years)
Resch et al. [87]	2006	79	14	–
Song et al. [88]	2006	17	11	–
Schoder et al. [89]	2007	28	36	89 (3 years)
Tespili et al. [90]	2007	17	29	83
Pitton et al. [91]	2008	13	13	77
Sandroussi et al. [92]	2007	12	23	58
Neuhauser et al. [93]	2008	28	48	68
Fattori et al. [23]	2008	66	1	–
Coselli and LeMaire [94]	2008	28	–	78 (5 years)
Szeto et al. [95]	2008	35	18	93.4 (1 year)
Verhoye et al. [96]	2008	16	36	73 (5 years)
Sayer et al. [97]	2008	38	30	93 (3 years)
Rodriguez et al. [98]	2008	59	–	–
Chang et al. [99]	2008	47	28.2	87.2
Jing et al. [100]	2008	35	17	96.2 (4 years)
Sayer et al. [97]	2008	40	30	66.5 (30 months)
Patel et al. [101]	2009	69	–	–
Feezor et al. [102]	2009	33	–	–
Cambria et al. [103]	2009	19	13.6	79 (1 year)
Khoynezhad et al. [104]	2009	28	36	78 (5 years)
Alves et al. [105]	2009	45	35.9	80 (2 years)
Kische et al. [106]	2009	37	22.3	81.8 (3 years)
Guangqi et al. [107]	2009	49	22.1	64.7 (3 years)
Kim et al. [108]	2009	72	64.4	98.3 (5 years)
Garbade et al. [109]	2010	46	37	80 (5 years)
Mastroroberto et al. [110]	2010	13	47.2	69 (8 years), 84 % (3 years)
Younes et al. [111]	2010	17	–	–
Parsa et al. [112]	2010	22	38	63 (3 years)
Steingruber et al. [113]	2010	35	9 [34]	78.4 (5 years)
Ehrlich et al. [114]	2010	32	26	76 (5 years)
Sachs et al. [115]	2010	764	1	90
Xu et al. [116]	2010	84	33.2	84 (5 years)
Ham [117]	2011	9	1	78
Hu et al. [118]	2011	73	34.1	97.3 (1 year)
O'Donnell et al. [119]	2011	28	21	85
Shu et al. [120]	2011	45	13	95.6 (1 year)
Steuer et al. [121]	2011	60	–	87 (5 years)
White et al. [122]	2011	96	12	84.2 (1 year)
Zeeshan et al. [123]	2011	45	37	79 (5 years)

indication for the intervention were clearly stated, only patients with complications such as aortic rupture, impending rupture, peripheral malperfusion, visceral malperfusion, uncontrollable hypertension, or refractory pain were present.

Besides the preferred random effects model, for sensitivity analysis, in the following section all results are presented by using the fixed effects model as well.

Initial Outcomes

The stent graft placement procedure was successful in 93.0 % (50 studies, 1,763 patients, $I^2=0$ %). Although most publications reported technical success rates of 100 %, a few large studies described lower success rates that had a significant impact on the overall technical success rate.

Three hundred and sixteen of 3,435 of patients with available data died during the in-hospital period. Within the 30-day interval, there were no additional deaths, yielding an overall in-hospital/30-day (operative) mortality rate of 10.6 % (93 studies, $I^2=1.201$ %).

Concerning neurologic complications, the overall risk for stroke was 5.9 % (53 studies, 1,909 patients, $I^2=0$ %) whereas paraplegia or paraparesis (permanent or temporary) occurred with an event rate of 5.1 % (52 studies, 1,829 patients, $I^2=0$ %).

Bowel infarction occurred with an event rate of 4.8 % (34 studies, × patients, $I^2=0$ %).

The event rate for vascular complications including major amputation was calculated to be 2.4 % (30 studies, 1,002 patients, $I^2=0$ %).

The event rate for renal impairment and/or renal failure requiring dialysis during hospital admission was 9.1 % (45 studies, 1,639 patients, $I^2=43.477$ %).

The event rate of endoleaks was 15.3 % (14 studies, 515 patients, $I^2=54.489$ %) when limited to studies in which endoleaks were definitely reported. However, this may be an underestimate, since many studies did not expressly report endoleaks and not presuming that the incidence was zero when endoleaks were not mentioned. Since most of the studies failed to provide sufficient data about the endoleaks, it was not possible to analyse the aggregate incidence of early versus late endoleak and the different subtypes of endoleaks. Stent fractures and migration were not reported.

The aggregated event rate for retrograde type A aortic dissection was computed to be 6.8 % (45 studies, 1,347 patients, $I^2=5.247$ %).

Late Postoperative Outcomes

The mean follow-up time was 23.3 months (median: 22.9 months).

During follow-up, late mortality was calculated to be 10.2 % (48 studies, 1,770 patients, $I^2=7.595$ %).

The event rate for late aortic rupture was 4.3 % (36 studies, 1,171 patients, $I^2=0$ %).

During follow-up, the event rate of false lumen thrombosis was calculated to be 77.4 % (30 studies, 858 patients, $I^2=16.994$ %).

Reintervention rates by adjunctive endovascular and surgical means over the follow-up period were reported separately in 44 and 33 studies, respectively. Endovascular reintervention was calculated to be more frequently required with an aggregated event rate of 16.2 % (1,492 patients, $I^2=71.381$), while surgical reintervention was calculated to be required in 14.5 % of patients (1,075 patients, $I^2=68.568$ %).

Meta-Analysis

Table 34.2 describes the included studies for meta-analysis of comparative studies for TEVAR versus open repair in case of acute complicated TBAD.

Cumulative 30-day all-cause mortality was significantly reduced for TEVAR versus open repair (seven studies, TEVAR: n=982, Surgery: n=2,680, OR=0.357, p=0.001; $I^2=0$ %) (Fig. 34.1).

In contrast to the operative mortality, for late mortality at the time point of last follow-up there was no significant difference between TEVAR and OR (five studies, TEVAR: n=143, surgery: n=82, OR=0.565, p=0.360; $I^2=0$ %) (Fig. 34.2).

Paraplegia or paraparesis (permanent or temporary) was significantly reduced for TEVAR versus

Table 34.2 Characteristics of included comparative studies for tevar versus open repair

Author, year, ref.	n	Pathology	Type of control	Location	Year	Stent name
Single center studies						
Zeeshan et al. (2010) [123]	77	TBAD	Consecutive	USA	2002–2010	Gore
Garbade et al. (2010) [109]	51	TBAD	Consecutive	Germany	2000–2008	Talent, Gore, Valiant
Mastroroberto et al. (2010) [110]	24	TBAD	Consecutive	Italy	2001–2008	Talent
Nienaber et al. (1999) [36]	24	TBAD	Concomitant	Europe	1997–1998	Talent
Multicenter studies						
Sachs et al. (2010) [115]	3284	TBAD	NIS database	USA	2005–2007	Mixed
Fattori et al. (2008) [23]	125	TBAD	Overlapping	Europe, Canada, U.S.	1996–2005	Mixed
Tsai et al. (2006) (IRAD) [2]	242	TBAD	Concomitant	Europe, U.S., Canada	1996–2003	Mixed

IRAD International Registry of Acute Aortic Dissection, *TEVAR* thoracic endovascular aortic repair

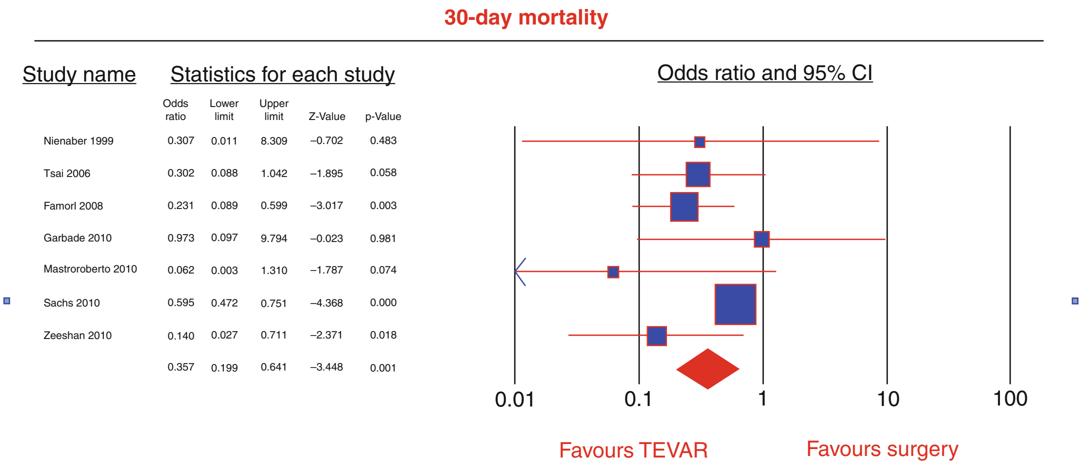

Fig. 34.1 Meta-analysis comparing death at 30 days for thoracic endovascular aortic repair (*TEVAR*) versus open surgery. The odds ratio (*OR*) for death for each included study is plotted. A pooled estimate of overall OR (*diamonds*) and 95 % confidence intervals (*CI*) summarize the effect size using the random effects model (and for sensitivity analysis the fixed effects model). Effects to the left of 1.0 favour TEVAR; effects to the right favor open surgery. When the horizontal bars of an individual study, or the pooled diamond width, cross 1.0, the effect is not significantly different. The I2 for heterogeneity was not significant, suggesting homogeneity in effect size across each study

open surgery (six studies, TEVAR: n=218, surgery: n=160, OR=0.408, p=0.045; I^2=0 %) (Fig. 34.3).

The overall risk of stroke was similar for TEVAR versus open repair (seven studies, TEVAR: n=1,590, surgery: n=3,764, OR=0.783, p=0.520; I^2=0 %) (Fig. 34.4).

Concerning the reintervention rate, there was no significant difference in the aggregated value between TEVAR and OR (four studies, TEVAR: n=152, surgery: n=101, OR=0.648, p=0.502; I^2=0 %).

The odds of renal impairment or renal failure requiring dialysis differed not significantly between TEVAR versus open repair, though indicating a trend towards TEVAR (five studies, TEVAR: n=1,517, surgery: n=3,737, OR=0.452, p=0; I^2=76.144 %).

Vascular problems (including major amputation) were significantly reduced for TEVAR compared to open repair (six studies, TEVAR: n=1,545, surgery: n=3,732, OR=2.038, p=0.043; I^2=87.265 %).

Late mortality at last follow-up

Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Nlenaber 1999	0.076	0.004	1.594	−1.660	0.097
Mastroroberto 2010	0.593	0.088	3.981	−0.538	0.590
Garbade 2010	3.077	0.319	29.709	0.971	0.331
Tsal 2006	1.571	0.388	6.368	0.633	0.527
Zeeshan 2010	0.194	0.071	0.534	−3.176	0.001
	0.565	0.166	1.919	−0.915	0.360

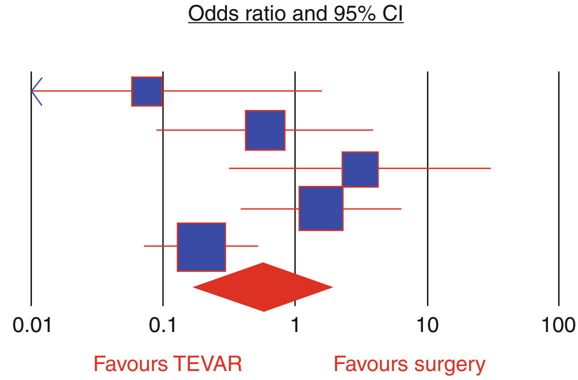

Fig. 34.2 Meta-analysis comparing death at last follow-up for thoracic endovascular aortic repair (*TEVAR*) versus open surgery. The odds ratio (*OR*) for late death for each included study is plotted. A pooled estimate of overall OR (*diamonds*) and 95 % confidence intervals (*CI*) summarize the effect size using the random effects model (and for sensitivity analysis the fixed effects model). Effects to the left of 1.0 favour TEVAR; effects to the right favor open surgery. When the horizontal bars of an individual study, or the pooled diamond width, cross 1.0, the effect is not significantly different. The I2 for heterogeneity was not significant, suggesting homogeneity in effect size across each study

Paraplegia / paraparesis (permanent / temporary)

Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Nlenaber 1999	0.307	0.011	8.309	−1.702	0.483
Tsal 2005	0.302	0.088	1.042	−0.895	0.058
Fattori 2008	0.231	0.089	0.599	−3.017	0.003
Garbade 2010	0.973	0.097	9.794	−0.023	0.981
Mastroroberto 2010	0.082	0.003	1.310	−1.787	0.074
Zeeshan 2010	2.308	0.435	12.254	0.982	0.326
	0.408	0.169	0.981	−2.003	0.045

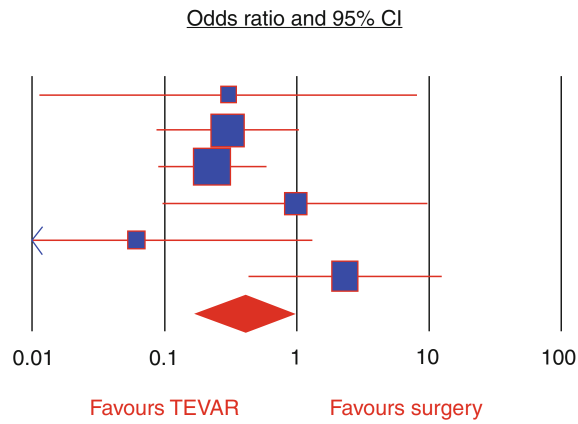

Fig. 34.3 Meta-analysis comparing paraplegia/ paraparesis for thoracic endovascular aortic repair (*TEVAR*) versus open surgery. The odds ratio (*OR*) for paraplegia/ paraparesis for each included study is plotted. A pooled estimate of overall OR (*diamonds*) and 95 % confidence intervals (*CI*) summarize the effect size using the random effects model (and for sensitivity analysis the fixed effects model). Effects to the left of 1.0 favour TEVAR; effects to the right favor open surgery. When the horizontal bars of an individual study, or the pooled diamond width, cross 1.0, the effect is not significantly different. The I2 for heterogeneity was not significant, suggesting homogeneity in effect size across each study

Stroke

Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Nlenaber 1999	0.168	0.007	3.902	–1.112	0.266
Tsal 2005	4.343	0.452	41.803	1.273	0.203
Famorl 2008	0.583	0.094	3.618	–0.579	0.563
Garbade 2010	1.257	0.127	12.460	0.196	0.845
Mastroroberto 2010	1.818	0.142	23.254	0.460	0.646
Sachs 2010	0.480	0.342	0.674	–4.239	0.000
Zeeshan 2010	5.353	0.267	107.321	1.097	0.273
	0.783	0.372	1.648	–0.644	0.520

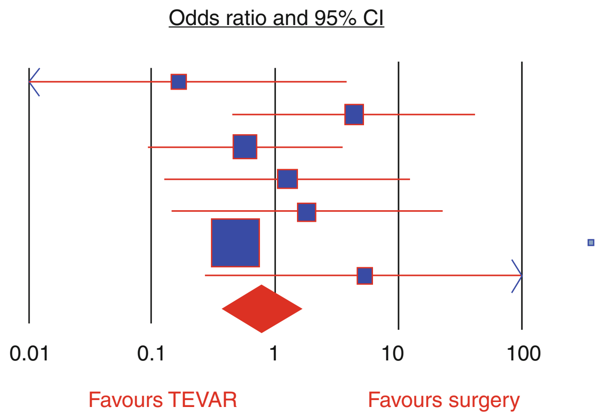

Fig. 34.4 Meta-analysis comparing stroke for thoracic endovascular aortic repair (*TEVAR*) versus open surgery. The odds ratio (*OR*) for stroke for each included study is plotted. A pooled estimate of overall OR (*diamonds*) and 95 % confidence intervals (*CI*) summarize the effect size using the random effects model (and for sensitivity analysis the fixed effects model). Effects to the left of 1.0 favour TEVAR; effects to the right favor open surgery. When the horizontal bars of an individual study, or the pooled diamond width, cross 1.0, the effect is not significantly different. The I2 for heterogeneity was not significant, suggesting homogeneity in effect size across each study

Discussion

The present study provides a current comprehensive aggregate analysis of the available evidence regarding endovascular stent-graft treatment of patients with acute, complicated type B aortic dissections and included only studies with larger number of patients and the latest publications in this field (predominantly $n \geq 10$).

Although the mainstay of treatment for acute, uncomplicated type B aortic dissections has been the intensive medical management by traditional antihypertensive therapy with beta blockers and nitrates and adequate pain relief while maintaining renal perfusion [124, 125], TEVAR is gaining more and more attention for patients with evidence of impending rupture or malperfusion associated with type B aortic dissection. However, although the medical management of acute uncomplicated dissection has a good survival outcome, 20–50 % of these patients will eventually develop late aortic complications by 4 years [126]. Predictors of late aortic complications include aortic diameter, persistent flow in the false lumen, and arterial hypertension [22].

The concept of TEVAR was brought forward by the fact, that the outcome of open surgery seems not to be favourable in this disease entity, as shown in the International Registry of Acute Aortic Dissections (IRAD), in which 82 of 476 (17 %) of patients with type B dissection were treated with open surgery [13]. In these patients in-hospital mortality was 29 %, and new neurologic deficits occurred in 23 % of patients (i e., stroke, 9 %; coma, 8 %; and paraplegia, 5 %, and unstated neurologic complications, 1 %). TEVAR instead, has been shown to have high technical success rates and improved morbidity and mortality (7 % in IRAD; $p < 0.001$), compared to its surgical counterpart [127, 128]. Predictors of follow-up mortality included age 70 year, female gender, hypertension, renal failure, atherosclerosis, previous aortic surgery, and patients who presented with signs of rupture or impending rupture.

The theoretical background for TEVAR is the coverage of the primary entry tear in the promise of obliterating flow in the false lumen and preferentially directing flow back into the true lumen and thus facilitating endorgan perfusion and control of hemorrhage [129]. In the middle to long term, TEVAR is anticipated to promote the induction of aortic remodeling by depressurizing the false lumen and induction of thrombosis of the false lumen which should reduce subsequent future false lumen aneurysmal dilation and rupture, and avoiding the risk associated with open surgical therapy. In cases of persisting malperfusion of a branch vessel or in type IIIb dissections with continued flow in and from the false lumen in the abdominal segment, vessel stenting or the technique of provisional extension with a series of uncovered metal stents to induce complete attachment and true lumen relining (PETTICOAT) may be used with open bare-metal stents to correct distal malperfusion [130]. In addition to that, TEVAR offers a number of potential attractive advantages in comparison to open repair because of the possibility to facilitate expedient control of life-threatening hemorrhage and provision of rapid restoration of end-organ perfusion, including avoidance of cross-clamping, reduced blood loss, avoidance of thoracotomy and single-lung ventilation, and a more rapid procedural time. However, patients presenting with aortic rupture and shock, regardless of treatment, have a very high mortality and open repair still presents the last therapeutic option after failure of both medical and endovascular management.

The present analysis reviews **3,462** patients with TBAD who underwent TEVAR between 1999 and 2010 in Europe and North America.

It demonstrated that TEVAR of TBAD was performed with a pooled primary technical success rate of 93.2 %.

Regarding the 30-day mortality or in-hospital mortality, a pooled event rate of 11.5 % was calculated. In contrast to TEVAR, the open emergency surgical procedure among the same category of patients carried a mortality of approximately 40 %, and was as high as 70 % for patients treated medically [35, 131, 132]. Additionally, Hagan et al. [22] reported a 31.4 and 10.7 % in-hospital mortality for acute complicated TBAD treated surgically and medically, respectively. The present results are favourable when compared with the surgical results reported in IRAD [23].

However, general comparisons with surgical or medical outcomes have some inherent problems, for in the absence of randomisation, patient selection might differ across the various studies. The preoperative condition is one of the most important determinators of the outcome of any surgical procedure. In case of patients with TBAD, the preoperative degree of shock has a very significant impact on the outcome of open surgical treatment [13]. Unfortunately, in many of the studies included in the present meta-analysis, the incidence and degree of shock was not mentioned. Thirty percent of the patients in IRAD who underwent open surgery had signs of shock prior to surgery. As a result, one should be careful in drawing any final conclusions without having randomised between medical or surgical treatment options, as patient characteristics and outcome determinators might otherwise be heterogenous in the two patient groups.

Early major complications of TEVAR in patients with acute complicated TBAD are stroke, paraplegia or paraparesis, bowel infarction, major amputation, and renal insufficiency requiring dialysis. Among these complications, stroke and paraplegia/paraparese constitute the most severe adverse outcomes of TEVAR, which also is the case for surgical repair of TBAD.

Stroke

Stroke may be secondary to embolic events from the passage of the guidewire or device around the aortic arch. Especially, larger and less conformable stent graft delivery systems and air entrapment within the constrained stent graft may be responsible for perioperative strokes [35, 133]. Strokes may also be related to covering the origin of the left subclavian artery. In the unlikely event of a posterior circulation stroke occurring as a consequence of covering the left subclavian artery, a chimney stent can be placed via access from the left brachial artery or a carotid—subclavian bypass procedure can be performed prior to TEVAR to restore perfusion to the left subclavian and vertebral arteries.

Paraplegia, Paraparesis

The occlusion of several intercostal arteries (especially the Adamkiewicz artery) is generally believed to be responsible for the increased risk of paraplegia [62]. In addition to that, previous or simultaneous abdominal and thoracic aortic repair with loss of lumbar and intercostal arteries seems to aggravate the risk of spinal cord damage because of insufficient collateral circulation [134].

If the proximal intimal tear is very close to the origin of the left subclavian artery, the stent graft may be placed in the distal aortic arch with coverage of the left subclavian artery. The clinical impact of covering the left subclavian artery is still discussed controversial. Low quality evidence from meta-analysis suggests that the intentional coverage of the left subclavian artery during stent graft placement in the descending thoracic aorta increases the risk of spinal cord ischemia and anterior circulation stroke. These data resulted in guidelines suggesting that left subclavian artery coverage can be managed expectantly unless anatomic conditions such as dominance of the left vertebral artery, significant stenosis of the carotids, brachiocephalic trunk, or vertebral arteries, and left internal thoracic artery to coronary bypass are identified [135].

Retrograde Aortic Dissection

Another devastating and potentially lethal complication of TEVAR is the retrograde type A aortic dissection (rATAD). The patient may develop a neurological deficit, myocardial ischemia, aortic regurgitation and finally cardiac tamponade. Urgent diagnosis using either transoesophageal ECHO or CT-scan is mandatory followed by urgent referral to the cardiothoracic surgeon. This complication occurs mostly after the use of endografts with proximal bare stents [136], but the same complication has reportedly occurred after the implantation of devices of all types- with and without a proximal bare stent. Preoperative planning and procedural technique might minimize the risk of retrograde type A aortic dissection: not excessively oversizing the stent-graft diameter (up to 2 mm only), avoiding post-ballooning to secure proximal fixation after endograft deployment, and targeting an aortic segment that is healthy and intact for proximal endograft fixation—well above the dissection process. Patients with Marfan syndrome and other connective tissue disorders may also be at increased risk of retrograde type A aortic dissection [137].

Eggebrecht et al. [136], analyzing EUReC data including a total of 4,750 cases, estimated the incidence of rATAD to 1.33 %. Recently, Dong et al. [137] reported the results of 443 patients treated by TEVAR for TBAD in a single center. In this setting, rATAD occurred with an incidence of 2.5 %. The calculated weighted event rate of 7 % for rATAD of the present analysis significantly exceeds the figure mentioned above, however, the present meta-analysis only included acute complicated TBADs, whereas the other authors presented mixed entities of TAD. Thus, regarding acute complicated TBAD, the incidences for rATAD mentioned in the literature seem to be underestimated. Possible complications of rATAD are aortic valve regurgitation, cerebrovascular ischemia, pericardial tamponade, and obstruction of the coronary arteries. The treatment of choice of rATAD is open surgery, though the open procedure is associated with mortality rates ranging between 20 and 57 % [93, 136–138]. rATAD may present acute or delayed, and in several cases it occurred even up to 36 months after TEVAR [73, 136–145]. Furthermore, EUReC data showed that patients with rATAD during the TEVAR procedure had the worst outcome compared to patients in whom rATAD occurred during the index hospitalization or after discharge, during the follow-up [136]. Furthermore, imperfect stent-graft position in the aortic arch can lead to aortic rupture by either erosion of the arterial wall or failure of the proximal seal provided by the stent-graft [133]. Moreover, the misalignment of stent-grafts in angulated aortic arches, together with the high hemodynamic forces, can cause stent-graft collapse [146].

The pooled incidence of endoleaks in the present meta-analysis was 23.1 %. However, this figure is of limited value, if any, for the true incidence of endoleaks was very low across the studies (n=44), and most studies reported only on type I and II endoleaks. This lack of information is probably caused by the insufficient longitudinal follow-up to adequately identify type III endoleaks. Compared with endoleaks after TEVAR for thoracic aortic aneurysms, endoleak physiology in aortic dissection is complex and incompletely understood and direction of blood flow may vary with different phases of the cardiac cycle. In general, the risk of type 1a endoleak development may be increased in patients with coverage of the left subclavian artery [133].

The present meta-analysis highlights one of the major concerns with TEVAR in TBAD, namely that TEVAR may only provide initial protection from aortic rupture [35]. In the present meta-analysis, TEVAR abolished the false lumen in 76.1 % of cases, suggesting that it might not be a definitive treatment of TBAD. Furthermore, during follow-up there might an enlargement of the distal thoracic and abdominal aorta even in cases of thrombosed false thoracic lumen. This might cause late aortic rupture, which has been calculated to occur with a pooled event rate of 3.2 %. In order to prevent this deleterious complication, there is a need for adjunctive stent graft placement or a need for open operation. In the present meta-analysis we calculated a pooled event rate for endovascular reinterventions of 11.3 % and for open surgical reinterventions of 7.7 % during follow-up. However, the long-term follow-up of most patients presented in the studies included in the present meta-analysis was limited with a mean value of 24 months. In order to assess the outcome of the TEVAR procedure more precisely, a longer follow-up would be desirable. On the other hand, the need for repeat endovascular and open surgical reintervention and the incidence of late aortic rupture might also be associated with the progression of the disease itself. Therefore, late aortic rupture and late mortality (in the present meta-analysis with a pooled event rate of 8.2 %) might not necessarily reflect treatment failure of the TEVAR procedure. When the same category of patients is treated medically or with open surgery, respectively, 11–20 % and 10–44 % of patients with TBAD require repeated operations [147, 148].

The present figures were derived not only by assessing the absolute event rates for the various outcomes, but by estimating the pooled weighted event rates by means of a meta-analytical technique by applying a random effects model. By doing so, we accounted for the possible uncertainty and risk of underestimation of the true effect which may be caused by pooling small volume studies. Thus, the present results provide a more robust and valid basis for evaluating the risk of complications and outcomes of TEVAR for acute complicated TBAD than the raw data.

Meta-Analysis

To date, no randomised trial has compared TEVAR to open surgery for complicated type B aortic dissections. In fact, most of the studies were retrospective, in which the indications were not defined so clearly, reflecting the fact that there are controversial understandings with respect to the correct treatment of acute complicated type B aortic dissection. Considering the emergency situation in which the patients present, and anatomical reasons (e.g, extent of the dissection and landing zone) making the patient only suitable for one of the two alternative approaches and the potential unwillingness of patients and specialists to consider both of very different procedures, it is very unlikely, that a prospective randomised trial will ever take place. In absence of such a trial, we intended to summarize the current efficacy and safety of TEVAR for acute complicated TBAD by means of a large scale meta-analysis.

Given the abovementioned lack of information, we performed a comprehensive meta-analysis of current aggregate data of comparative studies of TEVAR versus open repair in this cohort of patients. The present analysis provided increasing evidence for improved outcomes compared with open surgery.

Regarding 30-day/ in-hospital mortality, TEVAR seems to reduce this risk significantly compared to open repair (OR=0.256, p=0.001, $I^2=0$ %).

In contrast to this early outcome, late mortality did not show any significant reduction for TEVAR compared to the open surgical procedure (OR = 0.930, p = 0.908, $I^2 = 0$ %). However, one has to keep in mind that survival data after discharge from hospital were not reported in all publications, and as a result, heterogeneity across the trials for this outcome was higher ($I^2 = 31.64$ %). At least, the pooled and weighted data confirm that the mid-term results for TEVAR were not worse than that for open repair. To better specify this main outcome, further, preferably randomised studies will be needed with a sufficient number of patients to be powered adequately and with a complete follow-up.

Another main aspect provided by the present meta-analysis is the significantly reduced risk for (permanent and/or temporary) paraplegia/ paraparesis for TEVAR compared to the open procedure (OR = 0.256, p = 0.001, $I^2 = 0$ %). This may be related to the opening up of natural fenestrations to perfuse the intercostal arteries as the pressure in the true lumen increases following closure of the entry tear with the stent graft. The majority of procedures can be performed under regional or local anaesthesia so that it is possible to assess the neurological status of the patient under operation. Drainage of the CSF for scute paraplegia can be rapidly followed by return of function. However, excessive drainage of CSF fluid can result in intracerebral haemorrhage originating from the subdural veins and prolonged use of CSF drainage may result in dural fistulae which may be very difficult to treat and may increase the risk of infection. In general, patients with these neurological confinement after thoracic aortic repair are known to be significantly compromised concerning their long-term functionality and their quality of life [149]. For this outcome, there was no detectable statistical significant heterogeneity across the included trials, and thus confidence can be put in these results.

Anther benefits of TEVAR compared to open repair is the reduction of the odds of vascular complications including major amputation (OR = 0.373, p = 0.036, $I^2 = 0$ %). However, the present meta-analysis failed to show any significant difference between the two therapeutic options for acute complicated TBAD regarding the late mortality ($I^2 = 31.64$ %), reintervention rate ($I^2 = 0$ %), the odds of renal dysfunction and/or dialysis ($I^2 = 0$ %), and the stroke rate ($I^2 = 0$ %). The robustness and stability of the results presented in the meta-analysis is underlined by a generally low heterogeneity across the trials for the different outcomes.

Conclusions

The present study constitutes a comprehensive systematic review and meta-analysis of published data for TEVAR versus open surgery focused on the treatment of acute complicated TBAD performed in experienced centers.

Acute complicated TBAD is a very particular entity of aortic pathologies. To proper evaluate this technique, the results of TEVAR for this special disease should not be mixed with other aortic pathologies, in which TEVAR may be performed, as well (e.g., Marfan syndrome, thoracic aortic aneurysm).

The present meta-analysis from current observational studies provides nonrandomised evidence that in patients with acute complicated TBAD appropriate use of endovascular stent graft placement may reduce the early mortality, paraplegia, and vascular complications compared to the open surgical procedure, eventually similar to patients with an uncomplicated stable course requiring only medical management. Especially, as technologies continue to improve and indication specific endograft design will emerge, these benefits will assumingly aggravate. However, optimal outcomes of the TEVAR procedure can only be achieved by appropriate preoperative planning and technical expertise.

Mid-term or long-term benefits of TEVAR over the open repair has still to be assessed and lifelong clinical and imaging surveillance of patients is mandatory to exclude progression of the disease or stent failure. To underlie the need for lifelong surveillance one has to keep in mind, that the stent graft fails to obliterate the false lumen in up to 25 % of patients with potential need for late surgical conversion and occurrence of aortic rupture during follow-up.

Although the results are based on observational comparative studies, the results seem to be robust, for in most outcomes no significant heterogeneity was present across studies. In order to evaluate the benefit of TEVAR in this cohort of patients adequately, further well-powered randomised trials with sufficient follow-up intervals will be required. If the long term gains of TEVAR over open repair could be proven in the near future, unquestionable this technique will replace open surgery in the treatment of complicated type B aortic dissections [94, 119].

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