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Legitimacy of Entry-Oriented Strategy in DeBakey I Dissection in the Era of Endovascular Therapy

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ABSTRACT

Background: Legitimacy of entry-oriented therapy for DeBakey I aortic dissection is of eminent importance in the era of emerging ascending aorta endovascular therapy. This study aims to evaluate early, midterm, and reintervention results of entry-oriented operative strategy compared to more aggressive strategies for treatment of DeBakey type I aortic dissection with an isolated intimal tear in the ascending aorta.

Methods: This study prospectively followed 98 consecutive patients who received an operation for DeBakey type I aortic dissection with the intimal tear in the ascending aorta between 2007 and 2013 for up to 6 years. Follow-up included survival, medical therapy, CT-imaging results, and reinterventions. Patients were grouped into entry-oriented (group I) receiving an isolated replacement of the ascending aorta and/or hemiarch (65 patients); and aggressive therapy (group II) receiving a replacement of the ascending aorta and complete aortic arch (33 patients).

Results: The in-hospital mortality was 19% and 23% respectively. The 3-year survival was 52% and 47% respectively (P = .193). Group II showed no advantage regarding persistence or progression of the dissection, thrombosis of false lumen, increase in aortic diameter, peripheral organ malperfusion (as assessed by follow-up computed tomography imaging) or freedom from reintervention.

Conclusion: In treating DeBakey I aortic dissection with an entry tear in the ascending aorta, it might be legitimate to adopt an entry-oriented operative strategy. Further research is also needed to clearly describe the indication of extending the operative strategy in such cases.

INTRODUCTION

With an incidence of approximately 2.9/100,000 per year [Isselbacher 2007] and a peak incidence at a mean age of 62 years [Nienaber 2004], acute aortic dissections are knowingly associated with high mortality [Tsai 2009; Hagan 2000]. DeBakey I and II dissections [Debakey 1965] reach 25% during the first 24 hours and up to 56% during the first 30 days if not surgically treated immediately [Daily 1970].

Data from the International Registry of Acute Aortic Dissection (IRAD) [Tsai 2009] showed that an emergency surgical approach could reduce 30-day mortality from more than 56% to 27%. Nevertheless, perioperative mortality is still high [Tsai 2009; Conzelmann 2011; Easo 2012].

There is no universal surgical strategy for approaching the DeBakey I dissection if the main entry is in the ascending aorta. Some experts believe that a curative therapy should be attempted with resection and grafting of all diseased aortic sections, as possible. Others suggest that surgery should be entry-oriented and tissue, other experts believe that the surgery should be limited to a life-saving procedure excluding the main entry lesion [Truls 2007]. Validating the legitimacy of entry-oriented strategy is getting more crucial in the era of endovascular therapies with the emerging interest in endovascular management of DeBakey type I and II aortic dissections with an endovascular stenting of the ascending aorta.

Several studies have examined perioperative and short-term outcome after DeBakey I aortic dissections with few follow-up studies [Haldenwang 2012; Legras 2012; Uchida 2013; Hata 2013; Uchida 2011]. However, most reports do not discuss the preferred surgical procedure according to the initial clinical findings. The present study was undertaken to analyze early results and midterm survival, perform a midterm follow-up and determine the need for reintervention after different surgical approaches for DeBakey type I aortic dissections with isolated entry tears in the ascending aorta.

PATIENTS AND METHODS

Patient Selection

Between July 2007 and December 2013, 137 consecutive patients underwent emergency surgery in our center for acute DeBakey I aortic dissection and were scanned for inclusion in the study. The inclusion criteria were a documented isolated entry tear in the ascending aorta with no reentries in the aortic arch or the thoracic descending aorta, and undergoing either a replacement of the ascending aorta (AAR) with/out hemiarch replacmement (HAR), or a complete aortic arch replacement (AR). The study was approved by the local ethics committee, and patients provided informed consent for follow-up. No other exclusion criteria applied.

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Study Groups

The patient population was divided into two groups according to the performed procedure. Patients in the entry-oriented group (group I) were defined as those who received an AAR or HAR, and patients in the aggressive therapy group (group II) were defined as those who received AR.

Baseline Characteristics

The baseline characteristics of the patient population were collected through history taking, preoperative reports, and clinical examination. Operative risk was estimated using the logarithmic EuroSCORE (log. EuroSCORE) [Nashef 1999].

Surgical Approach

The surgical procedures performed on the aorta included AAR, HAR, or AR (with or without aortic valve replacement or repair). The decision to either perform an entry-oriented or aggressive approach was at the surgeon's discretion. The replacement procedures were performed in a standard manner. The main surgical strategy included direct innominate artery cannulation, and open aortic repair under moderate hypothermic circulatory arrest with core temperature of 28°C with unilateral antegrade cerebral perfusion. In all cases, an aortic valve repair or replacement was performed if a moderate or severe aortic valve insufficiency was documented by echocardiography.

Survival Analysis

Early mortality was defined as death from any cause within 30 days of the procedure. Midterm survival data were calculated via direct contact with patients, clinic follow-up records, and information from families or referring physicians. All patients who were alive during the period of our study were invited to participate in the follow-up examinations. These included a medical history, assessment of cardiovascular risk factors and comorbidities, and documentation of current medications. A physical examination and imaging studies were performed. According to the follow-up protocol, CT angiography was performed at 3 and 12 months after the initial surgery, or when clinically indicated. Further follow-up imaging was performed between 2 and 3 years after the initial presentation. In case of contraindications to CT imaging, MRIs were performed.

Definitions

A persistent dissection on the follow-up CT scan was defined as any residual patent false lumen of the aorta. Thrombosis of the false lumen was defined as completely non-perfused and thrombosed false lumen. If the false lumen is not completely thrombosed in any segment, it was defined as partially thrombosed. A complete remodeling was defined as complete regression of the false lumen and regain of the single-lumen aorta. Progression of the dissection during follow-up was defined as a new dissection of a segment of the aorta or any of the aortic branches that was not present at the time of the primary procedure. A diameter increase at the follow-up was defined as an increase in the cross-sectional diameter of the whole aortic thickness, including the thrombosed or perfused false lumen. Freedom from reintervention was defined as freedom from any open surgical or endovascular therapy related to aortic pathology during follow-up.

Table 1. Preoperative Data

	Collective	Ascending	Asc. & Arch	*P*
Demographics and comorbidities				
No. of patients	98	65	33	
Age, y	63 ± 12	63 ± 13	65 ± 11	.433
Male sex, n (%)	57 (58)	35 (54)	22 (67)	.224
Diabetes mellitus, n (%)	12 (12)	8 (12)	4 (13)	.978
Coronary heart disease, n (%)	5 (8)	2 (5)	3 (12.5)	.253
Renal insufficiency, n (%)	66 (31)	41 (36)	25 (22)	.161
>COPD, n (%)	3 (5)	3 (7)	0 (0)	.296
Clinical presentation and operative risk, n (%)				
Aortic valve insufficiency (grade II or higher)	40 (41)	24 (37)	16 (48)	.449
Involvement of supraaortic branches	48 (49)	32 (49)	16 (48)	.780
Involvement of coronary ostea	18 (18)	11 (17)	7 (21)	.576
Involvement of visceral branches	11 (11)	9 (14)	2 (6)	.374
Involvement of renal branches	18 (18)	12 (18)	6 (18)	.661
Peripheral organ ischemia	18 (18)	12 (18)	6 (18)	.772
Cerebral	1 (1)	2 (1)	0	
Cardiac	2 (2)	2 (1)	1 (3)	
Renal	3 (3)	3 (5)	0	
Multiple splanchnic	1 (1)	1 (2)	0	
Lower extremities	5 (5)	4 (6)	1 (3)	
Multiple	6 (6)	2 (3)	4 (12)	
Neurological deficit	15 (15)	11 (17)	4 (12)	.805
Redo procedure	13 (13)	9 (14)	4 (12)	.812
Log. EuroSCORE	40 ± 22%	41 ± 21%	40 ± 24%	.921

Ascending indicates isolated replacement of the ascending aorta and/or hemiarch; Asc. & Arch, replacement of the ascending aorta and complete aortic arch; COPD, chronic obstructive pulmonary disease; Log. EuroSCORE, logarithmic European System for Cardiac Operative Risk Evaluation.

Statistical Analysis

Continuous variables are presented as mean ± standard deviation. In case of significant outliers, the continuous variables are presented with the median and the 25-75% interquartile region. Binary data are presented as the percentage of the total study population. Survival curves were

Table 2. Intraoperative and Postoperative Data

	Collective	Ascending	Asc. & Arch	*P*
Intraoperative				
Median operative time, min (25-75% quantiles)	234 (178-321)	227 (171-317)	240 (205-336)	.688
Median cross-clamp time, min (25-75% quantiles)	33 (0-68)	32 (0-64)	52 (0-85)	.247
SCP time, min	54 ± 31	48 ± 28	73 ± 8	.009
Lowest temp. on SCP	27.7 ± 1.6	27.6 ± 1.6	28.7 ± 1.2	.179
Cerebral flow on SCP, L/min	1.3 ± 0.6	1.3 ± 0.7	1.3 ± 0.4	.952
Concomitant CABG	18 (18)	8 (12)	10 (30)	.0528
David Procedure	5 (5)	4 (6)	1 (3)	.418
AVR	42 (43)	29 (45)	13 (39)	.285
Bentall / Cabrol Procedure	26 (26) / 2 (2)	16 (25) / 2 (3)	10 (30) / 0 (0)	.521
Mechanical AVR (% of total AVR)	23 (55)	14 (48)	9 (69)	.207
IABP	4 (4)	2 (3)	2 (6)	.264
Postoperative				
Bleeding (>1 L/24h)	14 (15)	10 (16)	4 (13)	.171
Rethoracotomy	7 (7)	6 (9)	1 (3)	.108
Postop. new neuro. deficit	7 (7)	6 (9)	1 (3)	.298
Postop. Dialysis	21 (21)	13 (20)	8 (26)	.545
Reintubation	5 (5)	3 (5)	3 (6)	.745
In-hospital mortality	22 (23)	12 (19)	10 (30)	.198
30-day mortality	29 (30)	17 (26)	12 (36)	.403
30-day mortality causes				.182
Intractable bleeding	9 (9)	5 (8)	4 (13)	
Aortic rupture	1 (1)	1 (2)	0 (0)	
Cardiac failure	8 (8)	2 (3)	6 (18)	
Cerebral malperf.	7 (7)	6 (9)	1 (3)	
Renal malperf.	1 (1)	1 (2)	0 (0)	
Splachnic malperf.	1 (1)	1 (2)	0 (0)	
Sepsis	1 (1)	0 (0)	1 (3)	
Respiratory failure	1 (1)	1 (2)	0 (0)	

Ascending indicates isolated replacement of the ascending aorta and/or hemiarch; Asc. & Arch, replacement of the ascending aorta and complete aortic arch; SCP, selective cerebral perfusion; CABG, coronary artery bypass grafting; AVR, aortic valve replacement; IABP, intraaortic balloon pump.

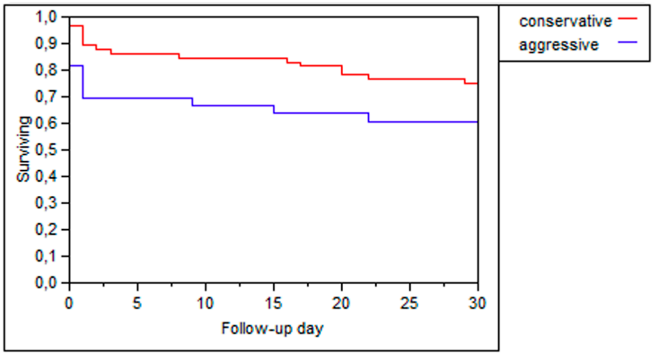
constructed using the Kaplan-Meier method, and the relationships of different surgical procedures to the survival rate were analyzed using the log-rank test. Statistical significance was defined as $P < .05$ (two-sided). All statistical analyses were carried out using JMP (version 6.0.0) software (SAS Institute, Cary, NC, USA).

RESULTS

In-Hospital Data

98 patients were included in the study. Baseline characteristics of the patients are presented in Table 1. The patient population consisted of typical patients at high cardiovascular risk: 19% presented with peripheral organ ischemia, and 15% suffered from neurological deficits at the time of surgery. The spectrum of neurological deficits ranged from disorientation to deep coma and from single limb paresis to hemi- or paraplegia. 65 patients received AAR or HR and were classified as group I, 33 patients received AR and were classified as group II. There were no differences in baseline characteristics or operative risk between the groups (Table 1).

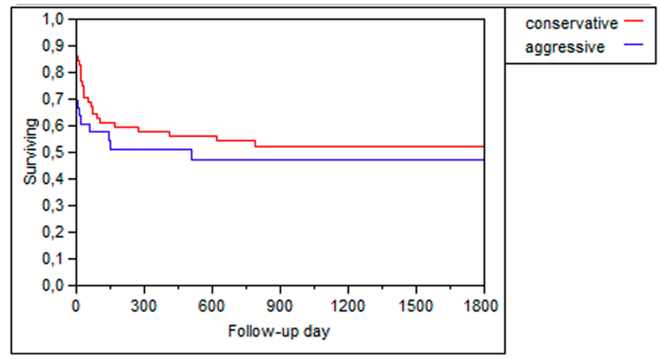
The analysis of intraoperative data (Table 2) showed a median operative time of 234 (178-321), with a significantly shorter selective cerebral perfusion time for group I patients



Patients at risk:

Day	0	1	5	10	15	20	25	30
Collective	98	90	80	77	76	73	71	69
Conservative	65	63	57	55	53	52	50	49
Aggressive	33	27	23	23	22	22	21	21

Figure 1. The 30-day survival. Kaplan-Meier survival curves were calculated according to the surgical procedure performed for each group. There were no statistically significant differences.



Patients at risk:

Day	0	300	600	900	1200	1500	1800
Collective	98	51	42	37	32	26	24
Conservative	65	37	30	25	22	16	16
Aggressive	33	15	13	13	11	11	9

Figure 2. Midterm survival. Kaplan-Meier survival curves were calculated according to the surgical procedure performed for each group. Aggressive surgical strategy continued to show lower survival rates at the midterm, yet the difference stayed statistically nonsignificant.

(48 ± 28 versus 73 ± 8, P = .0099). Other than that, there were no significant differences between the groups.

Postoperatively (Table 2), 7% of patients had to be reoperated for bleeding and/or tamponade, 7% had neurological deficit, 21% needed dialysis. Reintubation was necessary in 5% of patients. There were no statistical differences between the groups.

Early Survival

The overall in-hospital mortality was 23% (19% for group I, 30% for group II, P = .198). The 30-day survival was 70%, which concurs with published results from other registries [Uchida 2009; Nashef 1999; Omura 2016]. The 30-day survival rate was higher in group I (74%) than group II (60%), though the difference was not statistically significant (P = .182) (Figure 1). Causes of early deaths are listed in Table 2. 30% of early deaths were due to intractable bleeding or aortic rupture; 58% of deaths were due to organ malperfusion. There were no significant differences between the groups.

Midterm Results: Survival Data

Among the 69 30-day survivors, 4 patients were lost to follow-up. Survival data were compiled for 65 patients, comprising 94% of survivors. The overall 1,000-day survival was 50% of the total number of operated patients. 50 patients survived the follow-up period, with a mean follow-up of 1417 ± 816 days and a total follow-up of 235 patient years. The survival rate of group I patients was better than that of group II (52% and 47%, respectively), though this was not statistically significant (P = .193) (Figure 2).

Imaging Studies and Follow-up Results

Among the 50 surviving patients, follow-up imaging studies were performed in 41 patients (29 patients in group I, 12 patients in group II; 82% of survivors) after a mean follow-up period of 1492 ± 756 days and a total follow-up time of 167 patient years. The remaining patients declined the follow-up imaging studies.

Persistence of Dissection

As shown in Table 3, the total incidence of persistent dissection was 41%. The analysis did not show a statistical difference between the study groups (P = .158). Group I showed a higher rate of complete thrombosis of the false lumen than group II, which showed a higher rate of false lumen partial thrombosis, with no statistical significance (P = .679).

Dissection of the Aortic Branches

The statistical analysis showed no persistent dissection of the coronary arteries. Dissections of the supraaortic, renal, and visceral branches were detected in 35%, 40% and 10% of patients respectively, with no statistical differences between the groups (Table 3).

Progression of Dissection

As shown in Table 3, the total incidence of dissection progression during follow-up was 20%, with no statistical difference between the groups (P = .574).

Increase in Aortic Diameter

In group I patients, 18% showed an increase in the aortic diameter during follow-up (Table 3). In group II patients, the total incidence of further aortic distension was 17%, with no statistically significant difference (P = .288).

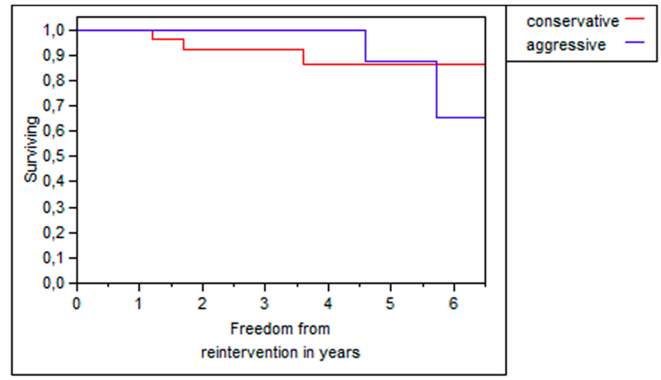
Peripheral Organ Malperfusion

Peripheral organ malperfusion was detected in 2 patients (5%). They were malperfusions of one of the kidneys. They were all in patients in group I, with no statistical significance (P = .412 (Table 3).

Table 3. Imaging Results

	Collective	Ascending	Asc. & Arch	*P*
Total number of patients	41	29	12	
Persistent dissection	17 (41)	10 (34)	7 (58)	.158
State of the false lumen				.679
Completely thrombosed	9 (30)	7 (33)	2 (22)	
Partially thrombosed	10 (33)	6 (29)	4 (44)	
Patent	11 (37)	8 (38)	33% (3)	
Dissection of aortic branches				
Coronary arteries	0	0	0	
Supraaortic branches	14 (35)	11 (39)	3 (25)	.385
Visceral branches	4 (10)	2 (7)	2 (16)	.183
Renal branches	16 (40)	12 (43)	4 (33)	.573
Renal malperfusion	2 (5)	2 (7)	0 (0)	.412
Progress of dissection	8 (20)	6 (21)	2 (17)	.574
Increase of aortic diameter	7 (17)	5 (17)	2 (17)	.641

Ascending indicates isolated replacement of the ascending aorta and/or hemiarch; Asc. & Arch, replacement of the ascending aorta and complete aortic arch.



Patients at risk:

Day	0	1	2	3	4	5	6
Collective	41	40	32	27	23	18	10
Conservative	29	29	21	18	14	11	8
Aggressive	12	12	12	12	9	7	3

Figure 3. Kaplan-Meier curves for freedom from reintervention during the follow-up period of up to 6 years. Aggressive surgical strategy failed to maintain its superiority and dropped below the conservative strategy after 5 years.

Freedom from Reintervention

The overall 3-year freedom from reintervention rate was 95% (Figure 3). This rate was 92% in group I and 100% in group II. The 6-year freedom from reintervention rate was 78% with no statistical significance between group I and group II (86% versus 65% respectively, $P = .626$). Table 4 lists the detailed reintervention data.

The univariate analysis of putative factors that increase the risk for reintervention showed a significant influence of presence of aortic valve insufficiency or aortic arch aneurysm at the time of the primary procedure (P = .032 and .042 respectively). The significant risk factors in the follow-up period were the presence of aortic arch aneurysm and the increase in the aortic arch diameter over the follow-up period (P = .022 and .008 respectively). However, multivariate analysis did not reveal any independent risk factor associated with higher reintervention rates.

DISCUSSION

Analysis of the results revealed that irrespective of the operative strategy, the acute dissection still carries a high early mortality risk, which concurs with published data [Tsai 2009; Conzelmann 2011; Easo 2012].

Our follow-up results showed that patients who underwent a more extended operation compared to excision and grafting of the ascending aorta alone did not show a significant lower rate of persistent or progression of the dissection, diameter increase, or reintervention, which is the main objective of the aggressive strategy. These data suggest that an entry-oriented approach in patients with isolated entry tear in the ascending aorta might be sufficient in the acute setting.

The debate on the optimal extent of the surgery in DeBakey type I aortic dissection is an ongoing process. Estrera and his colleagues [Rice 2015], Okita and the Kobe group [Omura 2016] and Dr. Di Eusanio and the Bologna group [Di Eusanio 2015] published different data supporting an entry-oriented approach. The above-mentioned data concurs with our results.

In the era of emerging endovascular therapy for the ascending aorta, validating an entry-oriented approach for the treatment of DeBakey I is of eminent importance. Based on the results of this study, we believe that an entry-oriented endovascular stenting of the aorta for DeBakey type I dissection could be a legitimate option to be developed. Although this therapeutic option is still in the early phase, promising initial results are emerging [Nienaber 2017].

Study Limitations

The study was based on a single institution's data. The study was based on a prospective registry with no randomization of the cases. Procedure selection bias may have existed according to the performing surgeon. Four frozen elephant trunk patients were excluded due to low statistical power of that group. The causes of late deaths could not be acquired. The long-term outcome data are yet to be obtained.

Conclusion

In treating DeBakey I aortic dissection with the entry tear in the ascending aorta, it might be legitimate to adopt an entry-oriented operative strategy. Extending the surgical therapy in such cases might not provide a clear short or midterm survival benefit, improve the midterm imaging findings, or significantly reduce the reintervention rates in midterm.

Table 4. Reintervention

Patient No.	Primary Preoperative Pathology besides DeBakey I Dissection	Primary Performed Procedure	Indication for Reintervention in Follow-up	Performed Reintervention	Time to Reintervention (days)
1	Dissected supraaortic vessels	Bentall-procedure	Increased aortic diameter	Frozen elephant trunk	1196
2	Dissected supraaortic, visceral, renal branches, AI II	AAR	Pseudoaneurysm	Bentall-procedure	1221
3	Dissected renal branches, renal malperfusion, AI II	AAR	Increased descending aortic diameter despite thrombosed false lumen	TEVAR	266
4	Dissected supraaortic vessels, AI II	AR	Infrarenal increase aortic diameter	Infrarenal aortic replacement	713
5	AI III	Bentall & AR	Pseudoaneurysm	Operative exclusion of the pseudoaneurysm	856
6	Coronary malperfusion	AAR, CABG	Increase of aortic arch diameter	AR	229
7	Coronary malperfusion	Bentall-procedure, CABG	Dissected subclavian artery, persistent dissection	TEVAR	219

AI indicates aortic valve insufficiency; AAR, replacement of the ascending aorta; TEVAR, thoracic endovascular aortic repair; AR, complete aortic arch replacement; CABG, coronary artery bypass grafting.

Further research is needed to clearly describe the indication of extending the operative strategy in such cases.

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