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Role of CTA Surveillance for Management of Endovascular Repair of Aortic Dissection

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ABSTRACT

Objectives: The aim of this study was to evaluate the effect of timing for post-interventional CT imaging on the rate of re-intervention and all-cause mortality in patients with endovascular treatment of type B aortic dissections (TBAD).

Material and methods: Data on 70 patients with endovascular repair of aortic dissection during a three-year period from a single institution retrospectively were collected. Study participants were stratified based on those who had a postoperative CTA in the first 30 days after index intervention (early) vs. those who did not (late). The re-intervention and all-cause mortality rates between the two groups were investigated using Kaplan-Meier and Cox regression analysis.

Results: During a median follow-up time of 230 days, the primary endpoint (additional operation) was reached in 24/70 patients (34.3%) with no statistically significant difference between the early and late CTA group (log-rank-test: $P = 0.886$). All-cause mortality was present in 14/70 (20%) patients, with no statistically significant difference between both groups (log-rank-test: $P = 0.440$). Additionally, both groups had no significant differences in time to additional operation and death. Cox regression analysis revealed the presence of a chronic TBAD and underlying connective tissue disease as relevant risk factors for the need for an additional operation and obesity as a protective and renal failure as a negative factor for all-cause mortality.

Conclusion: CTA surveillance within 30 days of the index operation did not significantly modify mortality or rate of re-intervention after endovascular treatment for TBAD. Surveillance recommendations should be tailored to individualized factors.

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INTRODUCTION

Aortic dissection is a rare but life-threatening disease in which the layers of the tunica media of the aorta separate due to a tear in the intima and create a false lumen due to the force of the blood flow [Lombardi 2020]. This separation and the resultant malperfusion may present with burning or tearing thoracic pain, along with myriad signs of malperfusion that are well known and described. Repeat operations and interventions after treatment of aortic dissection can be related to aortic degeneration, complications related to repair, and end-organ ischemia [Pape 2015]. Clinically, aortic dissections can be divided into Stanford Type A and Stanford Type B dissections, based on the involvement of the ascending aorta [Daily 1970]. There are, however, multiple classification systems in use, including the DeBakey system and recently proposed STS/SVS reporting system, both of which incorporate more precise anatomic landmarks [Lombardi 2020]. Furthermore, the onset and quality of symptoms are essential to classify the dissection (e.g., into acute and chronic dissection). Typically, an open surgical repair is recommended to treat Type A dissections. For type B dissections (TBAD), there are several treatment strategies: open-surgical, endovascular, and conservative management [Morello 2020]. The existence or persistence of symptoms is important for choosing the appropriate treatment strategy in TBAD [Booher 2013].

During the last two decades, endovascular repair of aortic dissection has become more established in the treatment of aortic diseases [Lombardi 2020; Sobocinski 2013]. Currently, thoracic endovascular aortic repair (TEVAR) is considered the preferred modality to treat acute, complicated TBAD based on its safety relative to open repair and its improved short- and long-term mortality versus medical management. TBAD also is used frequently in subacute and chronic TBAD with aneurysmal degeneration or chronic malperfusion to improve true lumen flow and promote favorable aortic remodeling [Lombardi 2020; Huptas 2009].

After treatment with TEVAR, computed tomography angiography (CTA) typically is performed to assess stent position and configuration, evaluate the presence of endoleaks, and detect potential perioperative complications [Flors 2014].

Albeit possessing useful features, CTA utilizes radiation and iodinated contrast and generates costs for healthcare systems [Walsh 2008; Brenner 2007]. European societies generally recommend the use of CTA for imaging before discharge, while American societies recently have changed their timeline to include a CTA follow up within 30 days of the index operation [Lombardi 2020; Grabenwöger 2012]. Of note, none of the recommendations are based on robust clinical data, but instead reflect the recommendations of stent-graft vendors from an era of construction and early clinical implementation, as well as extrapolation from the clinical experience of radiologists and vascular surgeons. This retrospective single-center study aims to investigate the role of timing for postoperative CTA following TEVAR for TBAD, defined as CTA performed within or after 30 days of the index operation. Relevant endpoints include all-cause mortality as well as freedom from additional interventions.

PATIENTS AND METHODS

Study design and population: There were 252 consecutive patients admitted to the hospital with an aortic dissection between July 2014 and October 2017. Patients with endovascular treatment of an acute or chronic TBAD were included in the study. Patients operated < 6 weeks after onset of pain were defined as acute dissection, including subacute TBAD; those patients with primary events > 6 weeks prior to intervention were deemed chronic, according to recent guidelines [Lombardi 2020]. The level of dissection and treatment was defined as a) distal arch, b) mid descending aorta, and distal descending aorta. Patients who received an index operation or imaging from an outside institution or those treated with an open surgical approach were excluded from the study. The final study cohort consisted of 70 patients. Existing clinical workflow patterns of attending endovascular surgeons resulted in 45 patients receiving a follow-up CTA within 30 days of the index operation (early CTA group), while 25 patients did not receive CTA imaging within 30 days (late CTA group). (Figure 1) All patients received a CTA examination at a certain timepoint for routine follow up or based on symptoms, according to the clinical evaluation of the attending endovascular surgeon. Demographic, operative, postoperative, and imaging data were extracted from the medical records and medical reports. Investigational Review Board approval was obtained for this study, and the need for individual patient consent was waived.

Study endpoints and statistical analysis: The need and time for an additional interventional or surgical procedure was defined as the primary endpoint. The secondary endpoint was defined as presence and time to all-cause mortality. Additional operations were categorized as complex or non-complex reinterventions by an experienced cardiothoracic surgeon. Statistical analyses were performed using SPSS software (release 22.0 for Windows; IBM, Chicago, IL, USA). Continuous data are expressed as the mean ± standard deviation when following a normal distribution, and as the median and interquartile range for non-normal distribution. Categorical data are displayed as an absolute value (percentage). Group comparisons were performed using the Mann-Whitney-U test and Fisher's exact test/chi-square tests for continuous and categorical variables, respectively. Kaplan-Meier curves were used to analyze survival, and log-rank tests were performed to investigate differences between groups. Hazard ratios were calculated by the Cox proportional hazards regression model, using a univariate approach.

RESULTS

Seventy patients were eligible for follow up, including 46 males and 24 females, with a mean age of 58.0 ± 14.6 years. Forty-five out of 70 patients (64.3%) received a follow-up CTA within 30 days of the index operation, while the remaining 25 patients (35.7%) did not receive CTA imaging within 30 days. The median time between index operation and first CT examination was three (2.0/7.0) and 57 (45.0/142.5) days for the early and late CT groups, respectively. Overall, six patients suffered from connective tissue disease, including three with Ehlers-Danlos (50.0%), two with Marfan (33.3%), and one with Loeys-Dietz syndrome (16.7%).

Table 1 lists the baseline characteristics of the study cohort divided by the early and late CTA groups. (Table 1) No significant differences in baseline characteristics existed between the groups.

Follow up and endpoints: During a median follow-up time of 230 (46.3/712.3) days, the primary endpoint (additional operation) was reached in 24/70 patients (34.3%) with no statistically significant difference between the early and late CTA groups (early CTA group: 15/45 (33.3%) vs. late CTA group 9/25 (36.0%), $P = 1.0$). Secondary endpoint (all-cause mortality) was reached in 14/70 (20.0%) patients, again without a statistically significant difference between the groups (early CTA group: 8/45 (17.8%) vs. late CTA group 6/25 (24.0%), $P = 0.548$). Time to re-intervention in the early CTA group had a median of 34.0 days (3.0/98.0), while in the late CTA group a mean of 100.1 days (± 88.0) elapsed until an additional operation was needed ($P = 0.558$). Regarding the secondary endpoint of time to reintervention, the late group had a Gaussian distribution, and the early CTA group had a non-Gaussian distribution. For this reason, mean and median are reported, respectively. The rate of complex interventions was not different between the groups. Endpoint data is summarized in Table 2. (Table 2)

Further statistical analysis, including Kaplan-Meier analysis, revealed no statistical differences regarding primary (additional operation) and secondary (all-cause mortality) endpoints (log rank test: $P = 0.886$ and $P = 0.440$, respectively). (Figure 2) (Figure 3)

Predictors of endpoints: To analyze risk factors beyond timing of CTA itself, we performed survival analysis on relevant clinical parameters using Cox-regression models. Regarding the primary endpoint (additional operation), only the presence of an acute vs. chronic dissection as well the presence of an underlying connective tissue disease revealed a relevant influence (Figure 4) (Figure 5) (Table 3) Concerning the secondary endpoint (death), only obesity showed a relevant (but protective) influence on the overall survival in this cohort. (Table 4)

Findings in the CT Group: The presence of relevant imaging findings was further evaluated. Out of the study population, 16 patients had symptoms that led to a dedicated indication for further imaging (other than post-interventional control). Altogether, CTA revealed 15 imaging findings (eight symptomatic patients), of which seven findings (in five symptomatic patients) were judged as acute actionable findings. Four symptomatic patients who exhibited acute actionable findings on imaging did not receive treatment due to death, inappropriate surgical candidacy, or refusal of further therapy. These findings are listed in the supplementary files. (Table 5)

DISCUSSION

The main findings from this study can be summarized as:

1. Implementation of an early imaging strategy with CTA pre-discharge/within 30 days did not provide any beneficial effect regarding the need for an additional intervention/ operation or all-cause mortality.
2. Factors that significantly influenced the need for an additional operation were the differentiation between acute or chronic dissection and the presence of underlying CTD.
3. All-cause mortality was positively influenced by obesity (obesity paradox) and negatively influenced by renal insufficiency. No other clinical parameter or imaging finding predicted all-cause mortality in this population

Table 1. Baseline characteristics of the study population

	All	Early CTA Group	Late CTA Group	*P*-value*
Number	70	45 (64.3%)	25 (35.7%)	N/A
Gender				
Male	46 (65.7%)	31 (68.9%)	15 (60%)	0.600
Female	24 (34.3%)	14 (31.1%)	10 (40%)	
Age (years)	57.95 ±14.6	57.91 ±14.58	58.04 ±14.96	0.792
Race				
Caucasian	33 (47.1%)	22 (48.9%)	11 (44%)	0.481
African American	35 (50%)	22 (48.9%)	13 (52%)	
Risk factors				
Hypertension	64 (91.4%)	41 (91.1%)	23 (92%)	1.00
Hyperlipidemia	34 (48.6%)	22 (48.9%)	12 (48%)	1.00
Diabetes mellitus	14 (20%)	11 (24.4%)	3 (12%)	0.350
Smoking history	50 (71.4%)	33 (73.3%)	17 (68%)	0.783
Current smoker	19 (27.1 %)	12 (26.7%)	7 (28%)	1.00
Pack years	10.00 (0.00-30.00)	7.50 (0.00-27.50)	14.00 (0.00- 30.00)	0.655
Duration of dissection				
Acute	34 (48.6%)	23 (51.1%)	11 (44%)	0.624
Chronic	36 (51.4%)	22 (48.9%)	14 (56%)	
Connective tissue disease				
Any	6 (8.6%)	4 (8.9%)	2 (8%)	1.00
Marfan syndrome	2 (2.9%)	2 (4.4%)	0 (0%)	0.534
Weight				
BMI (kg/m^2)	28.9 (23.73-33.78)	28.9 (23.55-33.90)	28.9 (24.25-32.80)	0.956
Underweight	3 (4.3%)	1 (2.2%)	2 (8.0%)	0.289
Normal	16 (22.9%)	12 (26.7%)	4 (16%)	0.383
Overweight	20 (28.6%)	12 (26.7%)	8 (32%)	0.783
Obesity	31 (44.3%)	20 (44.4%)	11 (44.0%)	1.00

*Comparison between CTA follow up within 30d and no CTA follow up within 30d; N/A, not available; CTD, connective tissue disease; BMI, body mass index

Table 2. Primary and secondary endpoints

	All	Early CTA Group	Late CTA Group	*P*-value*
PE				
Add. Operation	24 (34.3%)	15 (33.3%)	9 (36%)	1.00
Number of PE	1.50 (1.00-2.00)	1.00 (1.00-3.00)	2.00 (1.00-2.00)	0.726
Time to PE (days)	64.5 (5.75-124.5)	34.00 (3.00-98.00)	100.01(88.0)	0.558
SE				
Death	14 (20%)	8 (17.8%)	6 (24%)	0.548
Time to SE (days)	56.0 (16.5-637.3)	60.0 (13.5-1884.5)	40.5 (15.8-250)	0.662

PE, primary endpoint (additional operation); SE, secondary endpoint (death); No., number; *Comparison between CTA follow up within 30d and no CTA follow up within 30d

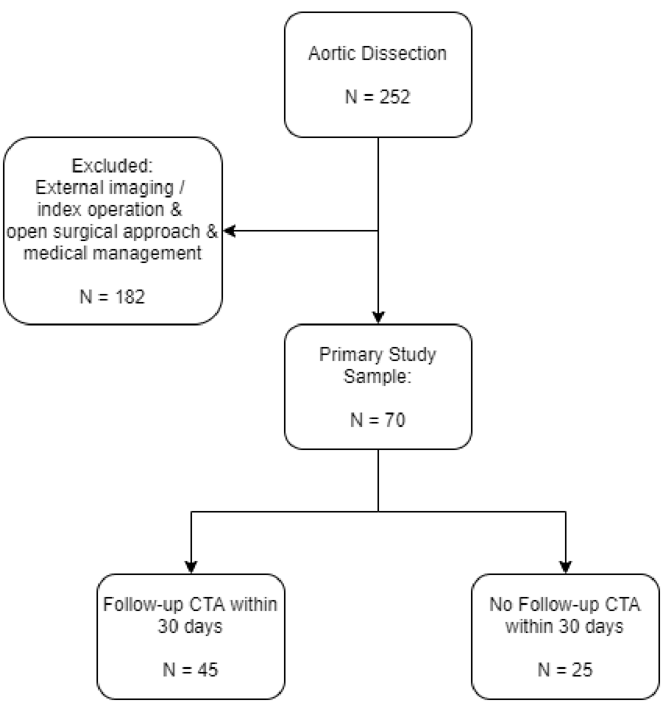

Figure 1. Study flowchart

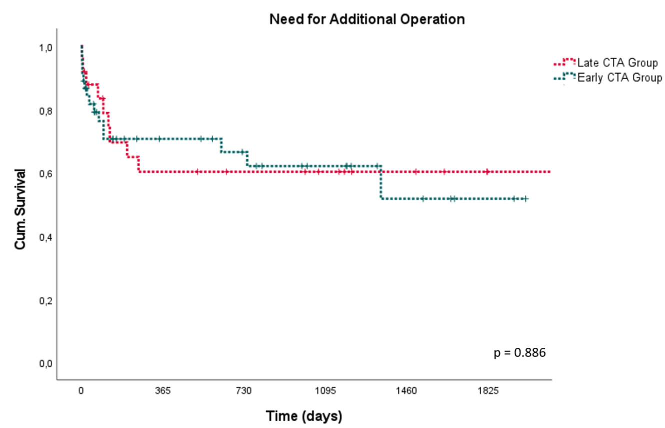

Figure 2. Kaplan-Meier curve for additional operation and early vs. late CTA

of endovascular treated TBAD.

The treatment of TBAD has changed significantly in the last two decades [Fattori 2013; Meena 2019]. During the early phase of implementing new techniques in the treatment of TBAD, several precautions had to be considered [Conrad 2009]. In consideration of these precautions, European guidelines from 2012 recommended a pre-discharge CTA after TEVAR and several CTA follow ups within a dedicated timeframes [Grabenwöger 2012]. Katsargyris et al. stated in 2014 that there seems to be overconsumption and too many follow-up CTAs and suggested a patient-tailored follow up, including primary TEVAR indication, underlying pathology, and treatment successful [Katsargyris 2012]. Our results support this thesis and provide insights into future patient-tailored follow-up imaging strategies. These findings are relevant to/for the interdisciplinary approach in the treatment of TBAD and can help to guide radiologists and vascular surgeons to choose the appropriate clinical imaging surveillance for patients after TEVAR.

Moreover, this is in line with current guidelines for EVAR surveillance [Moll 2011]. These guidelines propose a de-escalation in needed follow-up examinations and changed the method of follow-up imaging, recommending yearly duplex ultrasonography (DU) for patients without endoleaks and a stable or a shrinking abdominal aortic aneurysm after 12 months.

While CTA will likely remain the gold standard for imaging of TEVAR follow-up examinations due to the complexity and non-accessibility of the thoracic aorta with DU, the frequency of these follow ups in TEVAR patients needs to be reconsidered [Katsargyris 2012]. The SVS and STS recently published a new approach recommending only a CTA within 30 days of the index operation and "skipping" the previously mandated pre-discharge CTA [Lombardi 2020]. In addition, the two societies advise extending the timeframe for follow-up

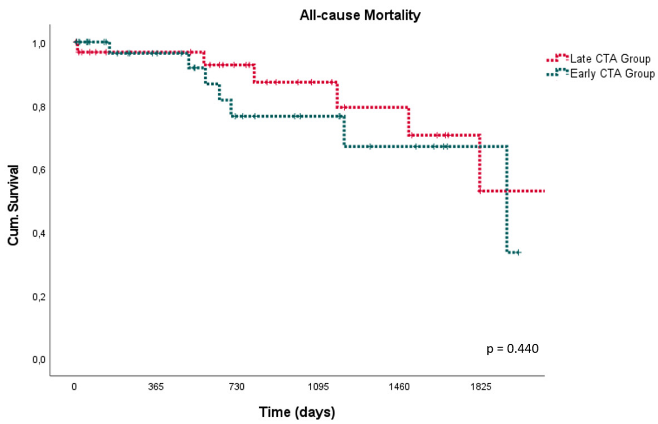

Figure 3. Kaplan-Meier curve for death and early vs. late CTA

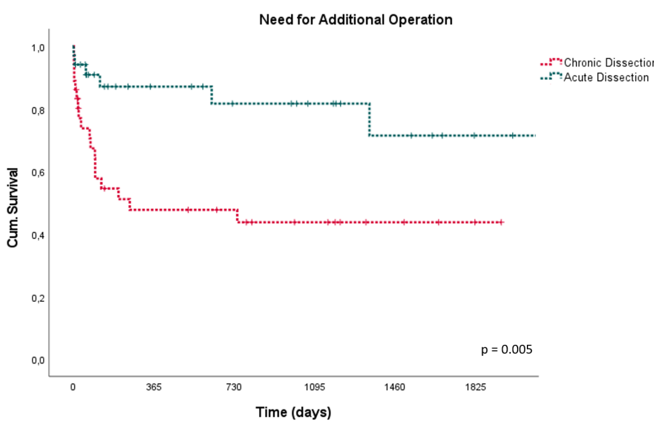

Figure 4. Kaplan-Meier curve for additional operation and acute vs. chronic dissection

CTA to 18-24-month intervals in some patients with stable findings greater than five years from the index repair or event. After two decades of safe treatment of aortic disease with EVAR and TEVAR, the early guideline of CTA surveillance as frequently as every other month in the first year after the index operation no longer is recommended. While these developments are all heading in the same direction, hard evidence on outcomes is still missing. To our knowledge, this study is the first to report evidence on the timing of imaging in a clinical real-life scenario.

In our cohort, we did not find differences in the amount and complexity of additional operations between patients with early and late CTA surveillance. Technically, interventions involving the distal aortic arch are more complex due to the need for debranching, chimney procedures, or subclavian occlusion and may have higher risks for Type I endoleaks, while interventions involving the distal descending aorta could increase the risk of paraplegia and celiac/mesenteric malperfusion. However, the level of the TEVAR implantation did not reveal any influence on the need for an additional operation or all-cause mortality in our analysis. These relationships should be studied further in larger-scale studies.

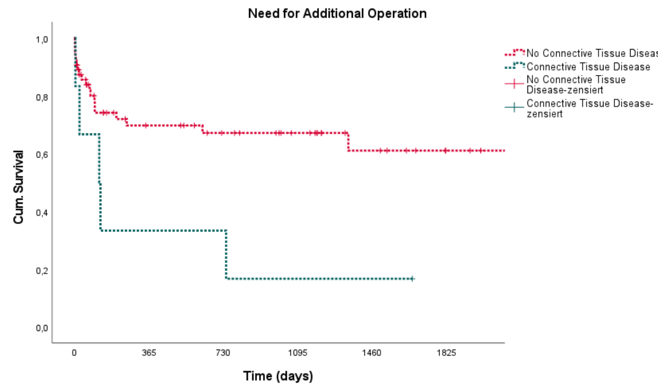

Figure 5. Kaplan-Meier curve for additional operation and CTD vs. no CTD

Excessive follow-up requirements have not been shown to positively influence follow-up or all-cause mortality. For example, Schanzer et al. reported that half of the 20000 Medicare beneficiaries treated by EVAR were lost to imaging follow up [Schanzer 2016]. Moreover, data from the EUROSTAR registry demonstrates higher mortality in the group with more imaging as compared with the group of patients with incomplete surveillance [Leurs 2005]. One factor to consider is that patients who already suffered from complications or struggled with symptoms are more likely to be compliant in surveillance than those who did not, this, however, could not be proven [Meena 2019] . The ESVS Guidelines stated that the true value of prophylactic regular imaging after EVAR is uncertain, they also argued that routine surveillance seldom identifies significant findings requiring reintervention [Moll 2011]. This is concordant with our findings, that regardless of the timing of the postoperative surveillance, the complexity of the additional operation did not differ between both groups.

Most patients who required reintervention after EVAR presented with symptoms. Although the literature on the subject of post-TEVAR is limited, numerous studies post-endovascular repair (EVAR) of abdominal aortic aneurysms have explored the beforementioned compliance with surveillance on outcomes [Meena 2019]. Meena et al. further recommended a surveillance strategy based on the initial indication for repair [Meena 2019]. While the study group of Meena et al. examined only 18 patients being treated with TEVAR for TBAD, our study included 70 patients. Furthermore, these 70 patients were subdivided into chronic and acute dissections to be treated with TEVAR to specify the importance of individualized surveillance follow ups.

Our study analyzed the implications of an early CTA strategy within pre-discharge and 30 days. Similarly, pre-discharge CTA had no influence on death or the need for additional operations in our cohort. While neither a positive impact of a pre-discharge nor a follow-up CTA within 30 days was proven, two important influencing parameters were revealed. First, the differentiation of acute versus chronic dissection showed a significant impact on the demand for an additional operation within the group with an underlying chronic dissection (HR for acute dissection: 0.288). These findings are

Table 3. Univariate Cox-regression analysis for primary endpoint (PE)

PE: Additional operations	HR	*P*-value
Age	1.001	0.958
Gender	1.293	0.554
Race	0.927	0.824
Hispanic	2.130	0.461
HTN	0.694	0.555
HLD	0.890	0.777
DM2	2.304	0.055
Smoking history	0.938	0.884
Current smoker	0.784	0.630
Pack years	1.010	0.213
BMI	0.974	0.390
Underweight	2.250	0.274
Normal weight	1.695	0.243
Overweight	0.401	0.096
Obesity	1.107	0.804
CTD	2.975	0.030
CTA	0.824	0.637
No CTA within 30 days	1.062	0.886
Finding on CTA	0.783	0.698
Acute actionable finding	0.938	0.935
Clinical indication for CTA	1.138	0.831
Acute dissection	0.288	0.008
CTA (days from operation)	1.077	0.551

PE, primary Endpoint (additional operation)

Table 4. Univariate Cox-regression analysis for secondary endpoint (SE)

SE: Death	HR	*P*-value
Age	1.024	0.145
Gender	0.576	0.323
Race	1.336	0.421
Hispanic	7.287	0.067
HTN	31.276	0.290
HLD	1.093	0.875
DM2	1.578	0.492
Ever smoked	3.218	0.128
Current smoker	2.176	0.204
Pack years	1.016	0.151
BMI	0.909	0.061
Underweight	2.987	0.167
Normal weight	3.233	0.062
Overweight	1.132	0.824
Obesity	0.221	0.049
CTD	0.983	0.987
CTA	1.428	0.524
No CTA within 30 days	1.557	0.444
Finding on CTA	1.485	0.608
Acute actionable finding	3.742	0.093
Clinical indication for CTA	1.695	0.491
Acute dissection	0.541	0.291
CTA days from operation	1.027	0.871

SE, secondary endpoint (death)

Table 5. Acute Actionable Findings

Case	Acute actionable finding	Treatment
1	Stent stenosis	No surgical treatment
2	RP bleed, SMA occlusion, renal artery occlusion	No surgical treatment
3	Ischemic bowel, SMA dissection	Exploratory laparotomy
4	Vascular injury, pelvic hematoma, aortoilliac damage	No surgical treatment
5	Celiac malperfusion	Thrombectomy
6	Renal malperfusion, Type 1 endoleak	Renal stent
7	Rapid FL growth, stent graft-induced new entry	No surgical treatment

RP, retroperitoneal; SMA, superior mesentic artery; FL, false lumen supported by the Meena group, who experienced a higher need for additional operations in patients who underwent TEVAR for TBAD [Meena 2019]. The frequent occurrence of additional reinterventions in the chronic dissection group led to the need for more frequent CTA surveillance in these patients. Secondly, patients with a connective tissue disease (CTD) required significantly more additional operations than those without CTD (HR: 2.975). Our study demonstrates that patients suffering from a chronic dissection and those with underlying tissue disease necessitate a short follow-up CTA. This information also can be used to target and educate patients who are predisposed to the need for an additional operation, or those at high risk for mortality.

Moreover, the indication for TEVAR needs to be taken into consideration. Regardless of their initial treatment modality, 60% of the patients with aortic dissection will develop aneurysmal growth during the next five years [Lombardi 2020]. An expert consensus reported a 5-year survival rate of a patient treated with TEVAR for TBAD to range from 56.3% to 87% [Fattori 2013]. With a mean age of 58.0 years in our study population, the importance of surveillance in this population cannot be overstated. A personalized approach based on underlying conditions, pathology, and aneurysmal growth are more favorable compared with a solely timeframe-guided CTA strategy. In 2007, approximately 29000 malignancies were estimated to be linked to CT radiation exposure [Berrington de Gonzalez 2009], and one study estimated that roughly 2% of all future malignancies in the U.S. will be attributed to CT use [Brenner 2007]. Therefore, the risk of yearly CTA follow ups in a middle-aged population should not be taken lightly. In addition to the potential harm of radiation, the potentially nephrotoxic usage of contrast agents could be reduced [Walsh 2008].

There were no significant differences in all-cause mortality between the group who received a CTA within 30 days of index operation and the group who did not. Patients with acute actionable findings showed a trend to die more frequently, although this did not reach statistical significance. Only obesity and renal insufficiency could be shown as conditions that influence survival. The protective relation between obesity and survival previously has been described as the obesity paradox [Oreopoulos 2008; Romero-Corral 2006]. Patients with normal or less-than-normal BMI tended to be at a higher risk of mortality. Patients suffering from severe impairment of renal function (GFR<30 ml/min) showed significantly higher rates of all-cause mortality compared with patients with preserved kidney function. The relationship between increased mortality and severity of renal impairment is widely established and has been proven in several studies [Grundmann 2021; Blumenfeld 2022; D'Oria 2021]. The link between renal impairment and survival also underlines the importance of reducing the amount of potentially nephrotoxic contrast agent applications by e.g., avoiding less relevant CTA examinations. These findings could additionally be integrated into a disease-guided, patient-tailored, personalized surveillance program.

Limitations of the study include study design, location deficiencies, and sample size. Our study was single-centered and conducted in a retrospective fashion, which represents our most prominent limitation. Patients who were transferred after initial imaging were excluded, as the referring institutions' imaging was not readily available for retrospective comparison. In addition, our final sample size was limited, consisting of only 70 patients, reducing the possibility to create general recommendations. Therefore, we opted not to perform a post-hoc power calculation as non-significant effects (*P*-values >> 0.05) are per definition linked to low observed post-hoc power [Laakens 2014]. The small sample size could introduce a selection bias. However, by including consecutive patients according to the in- and exclusion criteria, we tried to reduce this potential bias and present the largest cohort investigating the role of timing of CTA surveillance in TEVAR treatment for chronic and acute TBAD. This primary observation should be followed by prospective evaluations of the patient cohort. In addition, the group receiving a CTA within 30 days incorporated patients with symptoms after the index operation that could lead to a relevant bias for a higher need for re-intervention and mortality. Nevertheless, when excluding those patients from analysis, the results between the CTA within 30 days and the no-CTA within 30 days group did not significantly differ.

CONCLUSION

Patients who received a CTA within 30 days of index operation demonstrated no difference in needing an additional intervention or a difference in all-cause mortality compared with patients who did not receive CTA imaging within 30 days. An individualized surveillance program based on clinical factors such as the postoperative onset of symptoms, chronicity of dissection, or underlying CTD is promising and relevant for planning adequate imaging surveillance by radiologists and vascular surgeons. However, further prospective studies are needed to generate general recommendations.

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