Journal Pre-proof

Questionable long-term results of the E-Petticoat technique in the Management of chronic type B Aortic Dissection

Michał Żołnierczuk, Marek Miśkiewicz, Jarosław Paduch, Anita Rybicka, Paweł Rynio, Tomasz Jędrzejczak, Jerzy Pacholewicz, Piotr Gutowski, Agata Krajewska, Arkadiusz Kazimierczak

PII: S0890-5096(22)00519-2

DOI: https://doi.org/10.1016/j.avsg.2022.08.012

Reference: AVSG 6471

To appear in: *Annals of Vascular Surgery*

Received Date: 30 May 2022

Revised Date: 4 August 2022

Accepted Date: 25 August 2022

Please cite this article as: Żołnierczuk M, Miśkiewicz M, Paduch J, Rybicka A, Rynio P, Jędrzejczak T, Pacholewicz J, Gutowski P, Krajewska A, Kazimierczak A, Questionable long-term results of the E-Petticoat technique in the Management of chronic type B Aortic Dissection, *Annals of Vascular Surgery* (2022), doi: https://doi.org/10.1016/j.avsg.2022.08.012.

Questionable long-term results of the E-Petticoat technique in the Management of chronic type B Aortic Dissection

Short title: Long-term results of E-Petticoat in cTBAD

Michał Żołnierczuk (1), Marek Miśkiewicz (1), Jarosław Paduch (1), Anita Rybicka (2), Paweł Rynio (1), Tomasz Jędrzejczak (3), Jerzy Pacholewicz (3), Piotr Gutowski (1), Agata Krajewska (4), Arkadiusz Kazimierczak (1)

1. Department of Vascular Surgery. Pomeranian Medical University. Szczecin, Poland.
2. Department of Nursing. Pomeranian Medical University. Szczecin, Poland.
3. Department of Cardiac Surgery. Pomeranian Medical University. Szczecin, Poland.
4. Department of Neurology. Pomeranian Medical University. Szczecin, Poland.

Corresponding author: Michał Żołnierczuk, Powstancow Wielkopolskich 72, 72 111 Szczecin, Poland; E-mail: mzolnierczuk98@gmail.com

Key words: Extended Petticoat, Chronic aortic dissection, TBAD, TEVAR, Remodeling

mzolnierczuk98@gmail.com
miskiewiczkeram@gmail.com
jaroslawpaduch@hotmail.com
anitarybicka@onet.eu
ryniopawel@gmail.com
tom.jedrzejczak@gmail.com
j.pacholewcz@spsk1-szczecin.pl
piotr_gutowski@poczta.onet.pl
biker2000@icloud.com
agattw@gmail.com

Abstract

Introduction: Published interim results of the e-Petticoat technique suggested favorable remodeling in chronic type B Aortic Dissection (cTABD). This report presents long-term results of the e-Petticoat technique for the management of chronic TBAD (without aneurysmal dilatation). **Material and Methods:** Patients with cTBAD below the 55mm mm aortic size were eligible for management using the e-Petticoat technique. Follow-up was conducted at 1, 2 and 5 years based on the angio-CT scan. All the pre-surgery risk factors (entry>1cm, inner curve entry, fusi-form index>0.65, FL>22mm, aortic size >40mm, recurrent pain or hypertension and Stanford Dissection Risk Calculation) and post-surgery complications were examined in the study. **Results**: 20 patients underwent the e-Petticoat surgery. The survival rate at 1, 2 and 5 years was 75%, 70% and 64%, respectively and the percentage of patients without any re-interventions was 100%, 93% and 18%. Aortic degeneration was recognized in 30%, 55% and 85% of the patients. Only 3 out of the 20 patients were alive and without any re-intervention after 5 years. The ROC analysis does not indicate any factor that would predict the remodeling result in the long-term follow-up. **Conclusion:** The use of E-Petticoat technique in cTABD might not have a beneficial influence on the long-term results.

Introduction.

Currently there is no consensus or specific guidelines on the surgical management of chronic type B aortic dissection (cTBAD) before the aortic degeneration leads to an enlargement of the aortic diameter exceeding 55 mm[12]. Commonly used Thoracic Endovascular Aortic Repair (TEVAR) does not always provide satisfying long-term effects and often results in reinterventions[3]. Irrespective of the chosen initial approach to managing cTBAD (repair or

best medical treatment only), at the point that the aortic diameter is greater than 55mm, surgical intervention, such as Fenestrated or Branched Endovascular Aortic Repair (F/BEAVR) or open repair [4] is recommended[45]. An interim report of a new technique called the e-Petticoat suggested favorable remodeling of cTBAD [6]. In this paper, we present the results of a long-term observation of patients treated with the e-Petticoat technique, who were diagnosed with cTBAD, but were not eligible for F/BEVAR (had not reached the size threshold).

Material

Patients that were included in this trial were initially diagnosed with a non-complicated chronic TBAD, which according to the current guidelines would be treated conservatively, however showing signs of rapid degeneration of the aorta: presenting a growth rate of the aortic diameter of over 5 mm/6 months or 10 mm/1 year. The main exclusion criterion was the diameter of the aorta greater than 55mm, at which point the patients would become eligible for FEVAR/BEVAR[7]. The patients of unknown disease onset or insufficient quality of the CTA were also excluded from the trial.

Methods

A retrospective observational cohort study was carried out between 2014 and 2022 at one institution. There was no control group or head-to-head comparison. We studied all of the patients that were eligible for the e-Petticoat technique (which is a combination of Stabilize and parallel iliac Stent-grafts placed into infrarenal aorto-iliac segment). Follow-up was evaluated prospectively at 1, 2 and 5 years after the surgery and was based on an angio-CT scan (triphasic CT scanning with 0,5mm slice thickness). All pre-surgery risk factors (summarized in table 1 and 2) and post-surgery complications were analyzed in the study. Computed angio-tomography was used for sizing and volumetric measurement of a True and False lumen (TL and FL) by means of region of interest (ROI) options of Osirix software (Pixmeo SARL, Bernex, Switzerland). Favorable remodeling was recognized as aortic

diameter size below 55mm in follow-up. Predicted risk of degeneration based on the Stanford Aortic Degeneration Risk was calculated in the acute phase of the disease and compared with the observed degeneration rate after treatment[8].

Statistics

All values are expressed as mean, range, and standard deviation. Shapiro-Wilk test was used to assess the normality of distributions. Comparisons of continuous variables were performed using the Wilcoxon test for dependent variables because of non-normal data distribution. The enumerable variables were compared by Fisher exact test. The Kaplan Meier estimator was used to calculate the survival function. Receiver Operating Curve (ROC) analysis was used to assess the accuracy of the possible threshold for unfavorable remodeling predictors. Statistical significance was set at p value less than 0.05. All statistical analyses were conducted using Statistica software (version 13, StatSoft; Dell, Round Rock, Tex).

Results

Study group and risk factors

Of the 20 patients, who underwent e-Petticoat, the median age was 64 years (range 37-76) 17 were male and 3 female. The median time from the first symptoms to the surgery was 18 months (range 12-47).

Tab 1. Common radiological risk factors

Tab 2. Factors assessed in the Stanford Aortic Dissection Risk Calculation, which is calculated in the acute phase, for patients eligible for best medical therapy.

LSA – left subclavian artery, RRA – right renal artery, LRA – left renal artery, SMA – superior mesenteric artery, CT- celiac trunk, IMA – inferior mesenteric artery, LICA – left common iliac artery, RICA – right common iliac artery.

Patient clinics

All the patients were asymptomatic. However, in four cases (20%) there were radiological findings of stenosis (>70%) of iliac arteries caused by FL thrombosis and TL collapse, three patients (15%) presented with similar findings in SMA (asymptomatic) and six had impaired patency of the renal arteries (one patient on permanent dialysis prior to the onset of TBAD).

Procedure

All the patients had signed a written consent form before the surgery approved by the Institutional Review Board. The E-Petticoat technique requires the implantation of a nitinol self-expandable Bare Metal Stent (Medicut, Pforzheim, Germany) into the visceral and infrarenal aorta (to re-expand TL). Then the thoracic stent graft (Valiant Captivia, Medtronic, USA) is deployed proximally with overlap (to cover proximal entry tear), followed by inserting two covered stent grafts (Endurant II, Iliac Extension; Medtronic, USA) below renal arteries as parallel kissing iliac stent grafts (to cover iliac re-entries). TEVAR proximal oversizing was usually 5% (range 2-10%) and visceral BMS-XL usually 8% (range 5-15%). The oversizing was based on the biggest diameter of the TL. The Stabilize technique supported the procedure by ballooning of all the implants with the Reliant balloon (Medtronic, USA).

Early results

The technical success (entry coverage and TL re-expansion) rate was 100%. Three patients died during the first year (non-aorta related). The rest of the patients went into a long-term surveillance program. The volumetric and linear changes after surgery were monitored and analyzed during follow-up (tab 3).

Tab 3. Radiological changes after surgery.

CT – celiac trunk, RA – renal arteries, FL – false lumen, TL – true lumen

True lumen re-expansion was achieved in all the patients after surgery. On-table diagnosis of the leak to the FL was made in 9 cases originating from: the right renal artery n-5 (25%), the left renal artery n-5 (25%), the superior mesenteric artery n-2 (10%) and the n-2 celiac trunk (10%).

Follow-up

Seven patients (35%) died during the 5 years of follow-up. Total survival rate was 75%, 70% and 63%, survival without re-interventions was 100%, 93% and 18% after 1, 2 and 5 years respectively (figure 1). Aneurysmatic degeneration was diagnosed in 30%, 55% and 85% of the patients after 1, 2 and 5 years respectively.

Figure 1.

A Long-term survival after e-Petticoat.

B Survival rate without reintervention

After five years only three patients had an aortic diameter size below 55mm (Table 4.)

Tab. 4. Degenerative changes in the aorta in a long-term follow-up.

Re-interventions

Eight patients needed a re-intervention (BEVAR procedure) in the follow-up. They received a BEVAR procedure, which required either a Custom Made five-branch stent-graft T-

Branch (COOK Medical, Bloomington, USA; n-7) or an Inner-Branch with a combined aortic bifurcation from Jotec (Hechingen, Germany; n-1). Custom-Made Devices had to be used because the parallel aorto-iliac stent-grafts were positioned just below the renal arteries. It was not possible to use FEVAR devices, as proper positioning of the stent-graft and attaching it to the aortic wall at the visceral level was unfeasible because of the inserted BMS-XL (Medicut). In five cases the BMS collapsed, which resulted in additional technical problems.

Fig 2. Stent collapse in the visceral segment

A- a-Celiac trunk; b-Contrast Enhanced False Lumen

B- a-Celiac trunk; b-Contrast Enhanced False Lumen; c- Medicut BMS-XL Stent collapse.

Furthermore, two patients had asymptomatic new occlusions of the renal arteries and the celiac trunk. One patient required the implementation of renal replacement therapy despite the patency of the renal arteries.

The difference between the observed and predicted degeneration rates appears insignificant 85% vs 66% ($p = 0.378$, Fisher exact test).

In the ROC analysis, no factor was found that would predict remodeling in the long-term follow-up.

Discussion

The Extended Petticoat is based on the concept of covering the distal re-entry tear and reducing the volume of the false lumen and was first published in 2018[97]. The interim results (1 to 3 years) were promising in both chronic and acute TBAD. However, its implementation

raised a significant issue regarding long-term results, whether this technique could protect against aneurysmal degeneration[10]. The advantages were the feasibility and safety of the technique (it does protect the branches to the spine). One of the biggest disadvantages was however the fact that the technique comes with the risk of a leak into the FL along the Visceral BMS .

The volumetric assessment and efficacy of preventive surgery.

After five years, favorable remodeling was maintained in only 3 patients, despite of the fact that the interim results (after the first 2 years) suggested favorable remodeling in all the patients. The treated patients were diagnosed with a leak to the FL, but the contrast enhanced FL volume did not change significantly. We observed a decrease in the contrast enhanced FL volume from 21 ml after one year to 15 ml after 2 years, only to see it increase to 39 ml after 5 years. In patients who did not receive any surgical treatment (Best Medical Therapy only) the degeneration rate might be lower (66%) (based on Stanford calculation) than in the patients receiving our treatment (85%). Although this difference is not statistically significant, we feel it might be important. This potential bias might be related to the small number of patients or the unexpected impact the devices themselves have on remodeling. Whether the e-Petticoat technique has the potential to reduce the FL inflow remains unestablished. This technique allows a leak to the FL in the area covered by Bare Metal Stent, which during the first two years of follow-up seemed insignificant, however in the longer follow-up the volume of contrast enhanced false lumen volume increased, which corresponded with an increased degeneration rate. Some of the patients eventually needed complex endovascular procedures with the use of Custom-Made Devices. Therefore, the patients still need to remain in close surveillance programmes. None of the patients could be considered “cured” or well protected.

Stent collapse.

This phenomenon was probably caused by the low radial force of the Medicut BMS-XL and severe pressure caused by the perfused FL. However, using the Medicut BMS has the advantage that it would not impede the BEVAR procedure (if it was needed in the future), because the small radial force of the stent would not compress the bridging stent.

None of the independent factors were found to influence the late remodeling rate, including the common risk factors (table 1) and the Stanford calculation (table 2). However, these factors refer to patients with an unknown outcome and the patients that were included in the study were known to have a bad outcome, as they had already been diagnosed with rapid degeneration. This could be the reason why the well-known predictors of aneurysmal degeneration failed to show any predictive value in our study.

Limitation.

The obvious limitation is the small number of patients in our study and the lack of head-to-head comparison to other strategies like TEVAR alone, Best Medical Treatment alone or initial BEVAR or FEVAR procedure.

The relatively high death rate raises concern. Even though the reported deaths have not been linked to the aortic dissection, the lack of post-mortem examination might cast doubts whether some of the deaths could be related to the aortic disease.

Summary

Extensive coverage of the dissection without complete exclusion of the FL from the circulation might not protect the TL efficiently. Instead, it might even impair the outflow from the FL, which could be harmful for the aorta and have a negative effect on the long-term results. Based on our data we cannot recommend the e-Petticoat technique for the management of chronic asymptomatic type B aortic dissection in patients who are not yet eligible for a F/BEVAR procedure.

Conclusion

The use of E-Petticoat technique in cTABD might not have a beneficial influence on long-term results.

Conflict of interest:

The authors declare no conflicts of interest.

Institutional Review Board Statement:

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Institutional Ethics Committee of the Pomeranian Medical University (protocol code KB-0012/15/18, date of approval 05.02.2018).

Bibliography

1. Scali ST, Feezor RJ, Chang CK, et al. Efficacy of thoracic endovascular stent repair for chronic type B aortic dissection with aneurysmal degeneration. *J Vasc Surg*. 2013;58(1):10-18. doi:10.1016/j.jvs.2012.12.071
2. Lombardi J V., Hughes GC, Appoo JJ, et al. Society for Vascular Surgery (SVS) and Society of Thoracic Surgeons (STS) reporting standards for type B aortic dissections. *J Vasc Surg*. 2020. doi:10.1016/j.jvs.2019.11.013
3. Fanelli F, Cannavale A, O'Sullivan GJ, et al. Endovascular Repair of Acute and Chronic Aortic Type B Dissections Main Factors Affecting Aortic Remodeling and Clinical Outcome. *JACC Cardiovasc Interv*. 2016;9(2):183-191. doi:10.1016/j.jcin.2015.10.027
4. Durham CA, Aranson NJ, Ergul EA, et al. Aneurysmal degeneration of the

thoracoabdominal aorta after medical management of type B aortic dissections. *J Vasc Surg*. 2015;62(4):900-906. doi:10.1016/j.jvs.2015.04.423

5. Czerny M, Schmidli J, Adler S, et al. Current options and recommendations for the treatment of thoracic aortic pathologies involving the aortic arch: An expert consensus document of the European Association for Cardio-Thoracic surgery (EACTS) and the European Society for Vascular Surgery (ESV. *Eur J Cardio-thoracic Surg*. 2019;55(1):133-162. doi:10.1093/ejcts/ezy313

6. Arkadiusz Kazimierczak, MD, PhD, a Pawe1 Rynio, MD, PhD, a Tomasz Jędrzejczak, MD, PhD, b Krzysztof Mokrzycki, DM, PhD, b Rabih Samad, MD, PhD, a Miros1aw Brykczy?nski, MD, Prof, b Anita Rybicka, PhD, c Labib Zair, MD, PhD d and PG. Expanded Petticoat technique to promote the reduction of contrasted false lumen volume in patients with chronic type B aortic dissection. *J Vasc Surg*. 2019;70(6):1782-1791. doi:http://dx.doi.org/10.1016

7. Kazimierczak A, Rynio P. Extended Petticoat Strategy in Type B Aortic Dissection. *Eur J Vasc Endovasc Surg*. 2019;57(2):302. doi:10.1016/j.ejvs.2018.07.038

8. Sailer AM, Van Kuijk SMJ, Nelemans PJ, et al. Computed Tomography Imaging Features in Acute Uncomplicated Stanford Type-B Aortic Dissection Predict Late Adverse Events. *Circ Cardiovasc Imaging*. 2017;10(4):1-10. doi:10.1161/CIRCIMAGING.116.005709

9. Jędrzejczak T, Rynio P, Samad R, et al. Complete Entry and Re-entry Neutralization protocol in endovascular treatment of aortic dissection. *Rev Cardiovasc Med*. 2020;21(1):129-137. doi:10.31083/j.rcm.2020.01.5105

10. Verhoeven ELG. Extended Petticoat Strategy in Aortic Dissection: when Is It Too Much, or Not Enough? *Eur J Vasc Endovasc Surg*. 2018;53(2):303. doi:10.1016/j.ejvs.2018.08.035

Tab 1. Common radiological risk factors

Risk Factor	n (%)
Entry size >1cm	14 (70)
Entry Inner Curve entry	7 (35)
Fusiform index>0,65	10 (50)
Partial FL thrombosis	17 (85)
Maximum Aortic Size >4cm	14 (70)
False Lumen >22mm	18 (90)

Tab 2. Factors assessed in the Stanford Aortic Dissection Risk Calculation, which is calculated in the acute phase, for patients eligible for best medical therapy.

		n (%) / median (range)
Connective tissue disease		0 (0)
Dissection angle		273 (79-360)
Perfused intercostal arteries		16 (10-22)
Maximum aortic size		45 (33-54)
Branches dissection:		
	LSA	0 (0)
	RRA	14 (70)
	LRA	8 (40)
	SMA	3 (15)
	CT	7 (35)
	IMA	5 (25)
	LICA	11 (55)
	RICA	9 (45)
Stanford 1 year (%)		27 (3.5-66.6)
Stanford 2 years (%)		43 (6.6-87.5)
Stanford 5 years (%)		66 (14.1-99)

Tab 3. Radiological changes after surgery.

	Median	Range
Maximal initial thoracic aorta diameter (mm)	46	30 - 54
Maximal thoracic aorta diameter after surgery (mm)	43	30 - 49
Initial aorta diameter at the level of CT (mm)	36	22 - 53
Diameter of the aorta at the level of CT after surgery (mm)	38	22 - 55
Initial aorta diameter at the level of RA (mm)	31	22 - 43
Aorta diameter at the level of RA after surgery (mm)	33	24 - 45
FL perfusion volume before surgery (ml)	210	35 - 506
FL Perfusion volume after surgery (ml)	22	0 - 94
TL perfusion volume before surgery (ml)	117	22- 268
TL Perfusion volume after surgery (ml)	290	133- 501

Tab. 4. Degenerative changes in the aorta in a long-term follow-up.

	Initially	1 year	2 years	5 years	p-value
Maximum aortic size >55mm; n (%)	0 (0%)	6 (30%)	11 (55%)	17 (85%)	ns
Number of occluded visceral branches; n (%)	6 (30%)	2 (10%)	2 (10%)	2 (10%)	ns
Volume of Contrasted FL (median in ml)	210	22	15	39	ns
TL volume (median in ml)	118	290	268	302	ns