Complete Entry and Re-entry Neutralization protocol in endovascular treatment of aortic dissection

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1. Introduction

There have been indisputable developments in techniques for stabilizing acute aortic syndromes. However, aneurysmal degeneration following aortic dissection remains a problem to be solved. The currently available treatment options for aortic dissection still fail to take into account the known risk factors for aneurysmal degeneration. This is why we introduced a new approach to treating patients with an aortic dissection, called Complete Entry and Re-entry Neutralization (CERN). This is our initial report on the promising interim results. Material and Methods: 68 patients qualified for endovascular treatment of an acute or chronic aortic dissection. Computed tomography was performed post-operatively to assess aortic remodeling after 1/6/12/24/36 months. Results: the 30-day mortality rate was 4.4%. In 29 cases (43%) unfavorable remodeling was noted in the follow-up. The most important factors leading to unfavorable remodeling were: uncovered entry tear including the infra-renal segment, no relining of dissection membranes and insufficient coverage of the descending aorta. We analyzed these factors to develop the CERN protocol. This concept consists of six basic rules: A. cover all entry tears, B. amplify the BMS radial force, C. use the STABILISE technique, D. consider using thrombus plugs, E. avoid stenting the visceral branches, F. spare the intercostal and lumbar side branches. CERN improves the rate of favorable remodeling from 25% to 85% (P = 0.0067). Conclusion: Introduction of the Complete Entry and Re-entry Neutralization protocol improves the rate of favorable remodeling following endovascular treatment of aortic dissection in mid-term follow-up in patients with diffused aortic dissection.

Keywords
E-Petticoat; petticoat; STABILISE; aortic dissection; TEVAR; aneurysmal degeneration

There have been indisputable developments in techniques for stabilizing acute aortic syndromes. The most commonly used techniques are: TEVAR (Thoracic Endovascular Aortic Repair), used to cover proximal entry tears; Petticoat (provisional extension to induce complete attachment), which uses an additional Bare Metal Stent (BMS) in the visceral aorta to improve distal perfusion; and STABILISE, which involves additional ballooning of TEVAR and BMS devices to create one luminal aorta and stop the flow into the false lumen (Brunkwall et al., 2012; Lombardi et al., 2014; Melissano et al., 2018; Mossop et al., 2005; Nienaber et al., 2013; Sailer et al., 2017; Sobocinski et al., 2016). The problem that we still need to tackle is aneurysmal degeneration following aortic dissection. The risk factors leading to aneurysmal degeneration following aortic dissection are well known (e.g.: aortic size > 40 mm, FL > 22 mm, entry > 10 mm, fusiform index > 0.65, partial FL thrombosis, dissection along the inner aortic curve) (Sailer et al., 2017). Nevertheless, these risk factors are not currently taken into account in the treatment options (there are no specific guidelines on how to initially treat patients in order to minimize the risk of further aneurysmal degeneration). New endovascular techniques, alongside several modifications to the old techniques, have given moderate results as far as improving the rate of favorable remodeling following endovascular treatment of aortic dissection (He et al., 2015; Molinari et al., 2019). The problem of aneurysmal degeneration remains unsolved. The unsatisfactory long-term results of previous strategies have led us towards a new concept: Complete Entry and Re-entry Neutralization (CERN).

2. Material

A number of patients were treated in 2013-2017 in Poland’s West Pomeranian Voivodship (population of 1.7 million). Some only qualified for conservative treatment (Best Medical Therapy) and a follow-up in our surveillance program. This group was excluded from our study. In our study, we included all the compli-
cated acute cases. Subacute or chronic cases were only included if there was fast progressing degeneration (increase of over 5 mm in aorta size over 6 months) or aneurysmal degeneration (maximum size > 5.5 cm). We excluded patients if the size of the aorta (TL + FL) at the level of the celiac trunk exceeded 40 mm. Those patients qualified for more complex procedures (branched or fenestrated stent-grafts) and are therefore not included in the study.

Type A AD patients underwent an initial cardiac surgery of the ascending aorta with the distal re-entry tear located either in infra-renal or iliac arteries. Initial cardiac surgery was supposed to create a suitable landing zone in the descending aorta for further interventions.

3. Methods

This is a single center, non-randomized study. The patients were divided into two groups: the control group and the examined group. The patients were assigned to the control group if currently available guidelines (cover only proximal entry tear but leave the distal re-entry tear uncovered) were followed, and to the examined group if our CERN protocol was followed. CERN consists of six basic rules: A: cover all entry tears; B: use an oversized bare metal stent (BMS) and amplify its radial force; C: use true lumen forced ballooning (the STABILISE technique); D: consider using thrombus plugs; E: avoid stenting the visceral branches; F: spare the lumbar and sacral branches. If we were able to stay in compliance with the CERN criteria (regardless of the type of endovascular intervention carried out), patients were assigned to the examined group. If the CERN criteria were not met, they were assigned to the control group (Fig. 1).

The V-POSSUM scoring system was used for all patients to assess the risk of death and/or complications during the procedure. V-POSSUM is a tool based on a logarithmic calculator that takes account of many clinical and biochemical factors. This calculator seems to be most suitable for our population. It is an on-line free access tool (http://wwwriskprediction.org.uk/vasc-index.php) (Kazimierczak et al., 2010).

Surgery: We performed classic TEVAR, Petticoat, STABILISE or E-Petticoat procedures. In all of the procedures we used TEVAR devices from Medtronic (Vaillant II, Santa Rosa, CA, USA), and the BMS from Medicut (Pforzheim, Germany).

Aortic remodeling was assessed 1, 6, 12, 24 and 36 months after surgery. Changes in the size of the aorta, false lumen thrombosis, and the volumes of the false and true lumens were assessed. Favorable remodeling was defined as a complete true lumen re-expansion, complete false lumen thrombosis and stable aorta size over at least two years. Lumen volumes were calculated using a ROI (region of interest) function of Osirix. Computed Angio- Tomography (CTA) was performed in arterial and venous phases in all patients. The total size of the aorta is the true lumen size plus the false lumen size (TL + FL).

4. Statistics

Data are expressed as mean, range and standard deviation. Comparisons of countable variables were performed using Fisher’s exact test. To compare the multifactorial influence of the suspected risk factors, discriminant analysis was performed using Wilks’ Lambda tests. Receiver Operating Curve analysis was used to calculate criterion (by Youden index) for continuous variables, by assessing model accuracy using Area Under Curve (AUC) calculation, and its sensitivity and specificity. Differences were considered significant if the P-value was less than 0.05. All statistical analysis was conducted using Statistical software (version 13, Stat Soft, Dell, USA).

5. Results

Out of 105 patients, 37 were excluded either due to BMT or Fenestrated/Branch Endovascular Aortic Repair (FEVAR/BEVAR) procedures.

The study group (n=68) consisted of 53 males and 15 females; aged 56 ± 13.2 (range 35-84). The initial size of the aorta in the arch, thoracic, abdominal and infra-renal aorta is respectively: 36 ± 2.3 mm (23-46 mm), 48 ± 8.9 mm (32-76 mm), 34 ± 5.3 mm (30-46 mm), 32 ± 4.3 mm (24-54 mm). Risk of death and complication (predicted by means of V-POSSUM calculator) is respectively 0.9 ± 0.6 (0.3-19) and 14.32 ± 13.1 (2.9-98) for control and examined groups (P = 0.045).

11 cases (type B AD) were treated due to acute complicated dissection (n=10 with acute limb ischemia, n=8 with bowel malperfusion, n=2 with aortic ruptures). 57 cases were treated due to fast progressing degeneration in the subacute or chronic phase.

There were 46 patients with type B aortic dissection (TBAD), and 22 with type A aortic dissection (TAAD). In TAAD all patients had previous open cardiac surgery: either arch debranching (n=5) or Bentall procedure (n=17).

In total, 34 cases were treated according to CERN rules (examined group), and 34 according to the current guidelines, thus becoming our control group. In the examined group e-Petticoat (n=32) and STABILISE (n=2) procedures were performed. In the control group e-Petticoat (n=2), classic Petticoat (n=30) and TEVAR (n=2) procedures were performed.

Procedures non-compliant with the CERN rules presented a number of suspected risk factors shown in Table 1.

In the end, only TEVAR (n=2/2), STABILISE (n=2/2), Petticoat (n=3/30), e-Petticoat (n=27/34) remain compliant with CERN rules.

Discriminant analysis (Wilks’ Lambda test: 0.47858; F (6.44) = 7.9897; P < 0.00001) shows no evidence of the type of dissection (A or B) or the stage of the disease (acute, subacute, chronic) having any effect on the results (Table 2). Even the type of procedure (e-Petticoat) has little effect on the results. However, a univariate analysis suggests the use of e-Petticoat technique is related to a higher rate of favorable remodeling (P = 0.00001).

Three early deaths were reported. Two patients from the examined group due to an acute complicated dissection. One patient from the control group - due to a technical error during surgery (during renal artery stenting the kidney was damaged, which resulted in a hemorrhagic shock). There were no statistical differences between the control and examined group.

We observed a re-opening of 40 visceral branches (previously with dynamic stenosis). There were 11 branches completely supplied from FL and 29 supplied from both TL and FL. Additionally, we noticed cases of re-opening of previously completely occluded renal arteries (in static mechanism without thrombosis of its FL in 8 cases). No new occlusions were detected in the follow-up. Only
three patients needed an additional visceral or renal artery stenting through the aorta (BMS-XL). (2 Renal and 1 Superior Mesenteric artery). No statistical differences were noticed between the control and examined group.

We have a 24-month period of follow-up for 53 cases and a 36-month period for 27 cases. In a long-term observation another 5 patients died (n-3 due to progressing aortic degeneration and rupture, n-2 due to unknown reason). One patient suffered from paraplegia two years after a classic Petticoat (control group: statistically insignificant difference). Total follow-up time summed up to 1564 patient years. Mean follow-up time was 23 months (SD ± 13.2; range 1-42 months). All late deaths were noticed in the control group. No late deaths were reported in the examined group ($P = 0.038$).

Favorable remodeling was observed in only 38 cases in follow-up. Unfavorable remodeling was reported in 30 cases. There were 13 stent collapses due to FL expansion. Contrast Enhanced FL Volume (CEFLV) was detected in 29 cases. Moreover, in 24 (83%) cases with unfavorable remodeling the CEFLV exceeded 20ml. Examples of unfavorable remodeling and its potential reasons are
Presented in Fig. 2. We performed a ROC analysis (AUC = 0.904; \( P = 0.0001 \)), where the criterion for unfavorable remodeling for CEFLV was defined as exceeding 20ml (Sensitivity 83%; Specificity 85%).

Factors observed in cases with an unfavorable remodeling are presented in Table 3.

Discriminant analysis confirmed an independent relation between some of the risk factors and unfavorable remodeling (Wilks’ Lambda test: 0.15713; \( F(10.45) = 24.139; P < 0.00001 \)). The results are shown in Table 4.

Finally, in the examined group (compliant with CERN rules) favorable remodeling was observed in 29 (85%) cases, whereas in the control group favorable remodeling was present in only 9 (25%) cases (\( P = 0.0067 \)).

6. Discussion

Unfavorable remodeling is a problem in chronic dissections (Hollier et al., 1988). Through observation of our patients we noticed which factors were associated with unfavorable remodeling. The breakthrough observation was the negative effect of distal re-entry tears left untreated following TEVAR or classic Petticoat (He et al., 2015; Sobocinski et al., 2014). Long term observation of unfavorable outcomes led us to create six rules to improve the prognosis. These are summarized in our CERN protocol.

6.1 Rule A. -- Cover all entry tears

In some cases ineffective coverage of proximal entry tear (only in type A AD) was the reason of FL extension and TL collapse. Undertaking the great effort to create a suitable landing zone during the initial cardiac surgery did not prevent some FL flow from the remaining arch. This resulted in a situation where there was no suitable landing zone in a few patients. We assumed that the retrograde perfusion came from the descending aorta, and performed a TEVAR in hope of closing the distal entry tear. However, this assumption turned out to be wrong, as it was the proximal entry tear that was left untreated. A similar situation, leading to a collapse of TL (even leading to BMS collapse) was observed, when the last re-entry tear was located in the iliac arteries (type IB endo-leak).

It has been proven that all entry tears must be closed completely (Akin et al., 2010; Fattori et al., 2013; Hughes et al., 2013; Jing-dong et al., 2011; Van Bogerijen et al., 2014). Therefore, a stent-graft should be used to cover the entry tears in proximal aorta, as well as in the iliac arteries covering the distal re-entry tears (Fig. 3A) (Kazimierczak and Rynio, 2019; Kazimierczak et al., 2019a,b).

6.2 Rule B. -- Oversize and amplify BMS radial force

Dissection membranes have to be attached firmly together to stop the flow into the FL. This is the basic concept of the STA-BILISE technique (Melissano et al., 2018; Mossop et al., 2005; Sobocinski et al., 2014). Therefore, because of the natural tapering of the aorta, 5-15% oversizing is required (VIRTUE Registry Investigators, 2014). In cases without oversizing we observed FL perfusion leading to TL collapse. Ineffective sealing of the dissection membranes effects in high contrast enhanced FL volume (CEFLV). This is because the radial force of Medicut (BMS) is usually not strong enough to overcome the high pressure inside the FL. Therefore, it is important to amplify its radial force by implementing a stent-graft inside (He et al., 2015). As shown of Fig. 3B, the bigger the overlap the better the BMS expansion, so it is important to terminate the covered stent-graft as close as possible to the celiac trunk. On the other hand, it is critical to avoid getting closer than 6 cm to the celiac trunk, to avoid the risk of spinal cord ischemia. That is because this is the level -at which the artery of Adamkiewicz typically arises from the left side of the aorta (between T8 and L2) (Kornafel et al., 2010). In most cases, if the BMS was not supported from the inside by a stent-graft, or the distal end of the stent-graft terminated more than 10 cm above the CT, there was a leak to the FL in the abdominal aorta. In conclusion, the distal end of the stent-graft should be implanted inside the BMS and should terminate between 6 and 10 cm above the CT. To overcome the problem of weak radial force of BMS other devices could be used (for example dissection devices from COOK). However, these devices are only available in two sizes and were not included in our study.

Table 1. Risk factors in various surgical interventions non-compliant with the CERN protocol

| Risk factors                      | TEVAR | PETTICOAT | STABILIZE | e-PETICOAT |
|----------------------------------|-------|-----------|-----------|------------|
| A Endo-leak type IA              | 0     | 0         | 0         | 2          |
| B BMS inside TEVAR              | 0     | 25        | 0         | 4          |
| C Iliac parallel grafts start > 2cm below the RA | NA    | NA        | 0         | 5          |
| D TEVAR terminating > 10cm above the CT | 0     | 0         | 0         | 4          |
| E Too little overlap             | 0     | 4         | 0         | 1          |
| F Oversizing < 5%                | 0     | 6         | 0         | 1          |
| G Distal re-entry tear left uncovered | NA    | 26        | 0         | 0          |
| H CEFLV > 20ml                   | 0     | 22        | 0         | 2          |
| I Insufficient TL expanding leading to BMS collapse | NA    | 7         | 0         | 0          |

Table 2. Discriminant analysis for group epidemiology and type of surgery.

| Procedures non-compliant with the CERN protocol | Wilks’ Lambda test | p-value |
|--------------------------------------------------|--------------------|---------|
| Stanford type of AD                              | 0.483496           | 0.505089|
| Stage of AD (acute/chronic)                      | 0.478731           | 0.907974|
| Age                                              | 0.478789           | 0.89148 |
| Gender                                           | 0.490004           | 0.311117|
| e-Petticoat                                      | 0.502822           | 0.142628|
Figure 2. Conditions potentially leading to a technical failure. The figure shows examples of all suspicious technical factors that were observed in cases ending in unfavorable remodeling. All presented factors were then subjected to single and multifactor statistical analysis to determine the need for their elimination during endovascular treatment of aortic dissection. These were the following factors. A: Endo-leak type IA (after Cardiac Surgery in type A aortic dissection); B: BMS inside TEVAR (classic deployment); C: Iliac parallel grafts starting > 2 cm below the Renal Arteries; D: TEVAR terminating 10-15 cm above the Celiac Trunk (the lower part of the BMS unsupported-compressed by the FL); E: Too little overlap between devices; F: Oversizing < 5%; G: Iliac re-entry tear left uncovered (lack of e-Petticoat technique in type IIb AD); H: Contrast Enhanced False Lumen Volume over 20ml; I: Collapsed BMS due to high pressure in FL and insufficient true lumen re-expansion during surgery.

Likewise, in the infra-renal aorta, if the parallel stent-grafts are positioned more than 2cm below the renal arteries, a collapse of the BMS in the renal and infra-renal region usually results. Therefore, the infra-renal aorta containing BMS-XL inside, should be supported by two parallel grafts deployed just below the renal arteries. Failure to obtain these distances accounts for around 80% of unsuccessful cases in our center.

6.3 Rule C. True lumen forced ballooning

Lack of effective re-expansion of the TL means lack of relining of the dissection membranes. Therefore, ballooning must be carried out from the top to the bottom of the device (STABILISE technique) to fully expand it and reduce the volume of FL (Melisano et al., 2018). As shown of Fig. 3C, this carries a certain risk of aortic rupture (Rynio et al., 2017). According to the STABILISE concept, if achieving full TL expansion and maintaining peripheral flow requires an intimal tear, then it is fully justified (Fanelli et al., 2016; Hofferberth et al., 2014; Köbel et al., 2013; Midulla et al., 2011). Ballooning is quite safe if carried out inside the stent-graft (Fanelli et al., 2016; Hofferberth et al., 2014). Moreover, the implantation of BMS followed by stent-graft deployment (with overlap) prevents stent-induced distal re-dissection (SIDR) and stent-induced new entry tears (SINE) (Canaud et al., 2014, 2019; He et al., 2015). Neither SIDR, nor SINE were observed if the procedure was performed in compliance with the CERN rules.

6.4 Rule D. Thrombus plug

This suggestion couldn’t be supported by our statistics so far. However, in practice it turned out to be beneficial. Therefore, we added it to the protocol as a factor which could be examined in the future. A thrombus plug is observed during forced ballooning of the endovascular devices (STABILISE technique) in the presence of partial False Lumen thrombosis. Pushing the thrombus whilst ballooning along the FL in the thoracic and infra-renal aorta, works as a plug for the small tear branches. This works as a plug and stops the flow into the false lumen (similar with type II endo-leak after TEVAR). As shown of Fig. 3D, this way it stops the leak into the FL and promotes favorable remodeling. However, shifting the thrombus along the abdominal aorta, may lead to occlusion of the visceral branches. Fortunately, partial thrombosis of this region is not observed as often as in the thoracic or infra-renal aorta. We did not observe visceral branch occlusion (in this mechanism). We reported one case of iliac artery occlusion (while pushing the thrombus form FL to TL). Using the thrombus as a plug for the FL is a similar concept to the Knickerbocker or Candy-plug techniques proposed by Tilo Kobel (Köbel et al., 2014, 2013).

6.5 Rule E. Avoid stenting the visceral branches.

We do not recommend initial stenting of the visceral branches if they are supplied by the FL or both the FL and the TL, even if they are dissected. This is because a re-expansion of the TL alone solves this problem (see the results section). A well extended BMS with the intima stretched over it works just as well as the best-fitting fenestrated stent-graft. As shown of Fig. 3E, the only situation when stenting the visceral branches could be beneficial is an occlusion of the vessels due to thrombosis (static occlusion of
the branch with thrombosis of the FL (Kazimierczak et al., 2018).

6.6 Rule F. Spare the small branches.

Covering the thoracic, abdominal and infra-renal aorta with stent-grafts (during BEVAR, FEVAR) is sometimes too extensive and could lead to paraplegia due to spinal cord ischemia (Scali et al., 2013; Spear et al., 2018). Therefore, staging and other less invasive options are advised (Geißbüsch et al., 2014). Leaving the distal re-entry tear uncovered seems to protect the spinal cord perfusion, however this may eventually lead to further aortic degeneration (25-40% during first 5 years) (Hollier et al., 1988; Sailer et al., 2017). However, there is room for compromise between effective coverage and sparing the flow to the branches. Combining the benefits of Covered Endovascular Reconstruction of Aortic Bifurcation (CERAB) (using amplification of the radial force of the infra-renal stent and lower radial mismatch) and Kissing Stents technique (sparring the branches) is called Extended Petticoat (e-Petticoat) and is compatible with the CERN protocol (Goverde et al., 2013; Groot Jebbink et al., 2017; Jebbink et al., 2015). Using BMS instead of covered stents in CERAB allows the flow to the branches along the gutters between the iliac parallel stent-grafts (Kazimierczak et al., 2018, 2019a,b). It spares the small branches along the abdominal and infra-renal aorta (Fig. 3F).

7. Clinical implication

The CERN protocol is our modification of the currently used surgical strategies. We currently use Extended Petticoat (e-Petticoat) technique in case of a distal re-entry tear located in the iliac artery (type III B aortic dissection which contributes for about 80% of all our cases) (Kazimierczak and Rynio, 2019; Kazimierczak et al., 2019a,b). CERN rules are applicable also in type A AD after surgical closure of the entry tear located in the ascending aorta (e.g.; debranching see Fig. 4) (Kazimierczak et al., 2018). So far, most cases performed according to the CERN protocol present a promising outcome in follow-up.

It seems that early application of CERN rules in the treatment of extensive aortic dissections may slow down or stop the aneurysmal degeneration and, as a result, minimize the need for difficult, expensive and risky procedures with the use of branched or fenestrated stent-grafts. The question is when to treat and how extensive should the treatment be (Verhoeven, 2019). In our experience in chronic and degenerated dissections, when the total size of the aorta at the level of Celiac Trunk exceeds 40mm, the CERN protocol is not appropriate. In this situation neither e-Petticoat, nor STABILISE could stop further degeneration.

Even though, the e-Petticoat technique is fully compliant with the CERN protocol, it does not always guarantee favorable remodeling in a long-term observation. In other words, every patient should be considered with a custom approach. Sometimes more advanced techniques (FEVAR/BEVAR) might be considered as more appropriate.

8. Limitations

The obvious limitation to our study was a small number of cases and the lack of randomization. A small number of cases is the reason why we included both patients with type A and type B dissections in our study. This does not interfere with our concept of CERN and was carefully considered in the process of statistical analysis (discriminant analysis shows no influence on the final results).

One should keep in mind, that the aim of this paper was to study the technical details of endovascular treatment, not the risk factors for unfavorable remodeling.
Figure 3. CERN rules. The figure summarizes all six conditions for compliance with CERN principles during endovascular treatment of aortic dissection. For an explanation of their significance, see the discussion chapter. A: Cover all entry tears; B: Oversize and amplify BMS radial force; C: Perform True lumen forced ballooning [STABILISE technique]; D: Use a thrombus plug; E: Avoid stenting the visceral branches; F: Spare the small branches; TL: true lumen; FL: false lumen.

Figure 4. Examples of favorable remodeling after treatment performed accordingly to the CERN rules [e-Petticoat technique] in type A and B aortic dissection. TAAD – Type A Aortic Dissection; TBAD: Type B Aortic Dissection; A: Initial CTA in TAAD; B: Frame of the Stent-grafts used for e-Petticoat technique (fully comply with CERN rules); C: Favorable remodeling after TAAD (Hybrid arch debranching and e-Petticoat as a Stage procedure); D: Initial CTA in TBAD; E: Frame of the Stent-grafts [e-Petticoat technique performed in compliance with CERN rules]; F: Favorable remodeling after TBAD.

Results coming from this study also have certain limitations, because applying CERN rules requires that the maximum size of the abdominal aorta must not exceed 40 mm. This is because the biggest available size of BMS-XL Medicut is 42 mm. This means
that patients with severe degeneration of the abdominal aorta (>40 mm) cannot be treated according to CERN rules.

Although COOK dissection devices are available in size 46mm, an aorta which size is between 40-46mm is definitely too degenerated to believe that STABILISE could work. Those patients remain candidates for more risky procedures (BEVAR, FEVAR) (Spear et al., 2018). Any previous endovascular interventions limit the effectiveness of the CERN concept. For example, it would be very hard to achieve proper relining of the membranes if small stents had been previously deployed.

Finally, we still have a relatively short follow-up to properly assess the results of our concept.

9. Conclusions

Introduction of the Complete Entry and Re-entry Neutralization protocol leads to improved rates of favorable remodeling following endovascular treatment of an aortic dissection at mid-term follow-up.

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Conflicts of Interest

The author declares that there is no conflict of interest regarding the publication of this study.

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