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Complications Related to Puncture Site in TAVI Procedures in Relation to 3 Different Closure Devices

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1. Abstract

1.1. Background: Vascular complications in TAVI are still considered as a limiting factor for outcome despite the major development of closure devices and sheath diameter. In our study we aim to compare the access site complications in 4 groups. Group I: One Proglide (Presuture) plus one Angioseal versus group II: One MANTA (Collagen Plug) versus Group III: 2 Proglides versus Group IV: one Prostar.

1.2. Methodology: Retrospective observational non-randomized study was implemented in 2 heart centers in Germany (Zentralklinik Bad Berka and Augsburg University Clinic). We analysed consequetive 496 patient's patients operated in 2 german heart centers (from March January 2020 until April 2021) through 2 TAVI teams following the same operative techniques. Our evaluation protocol entailed intraoperative iliofemoral angiography immediately after valve implantation and duplex before hospital discharge. We defined the endpoints as puncture site bleeding, dissection or stenosis and need for intervention or surgery.

1.3. Results: We analyzed consequetive 496 patient's patients operated in 2 german heart centers (from March January 2020 until April 2021) through 2 TAVI teams following the same operative techniques (one of the TAVI operators used to operate in both centers during the study phase). From 496 patients, we used Proglide (PG) + Angioseal in 288 patients (58.2%), 2X PG only in 18 patients (3.6%), Manta in 112 (22.6%) and PS in 74 patients (14.9%). The use of 18 and 20 F sheaths was more frequent in the Manta group (26.8% Manta vs 9.5% in PS and 5.2% in PG group). As regard other preoperative and operative characteristics there was no significant difference between the groups. The mean BMI was 28.6 (5.5) in Manta group vs 28.6 (5.6) in PG group and 28.6 (5.6) in PS group. Female gender was tending to be higher in other groups other than Manta group; 37.55 vs 45.1% in PG and 52.7% in PS group, p value 0.08. The mortality rate was significantly higher in Manta group 3.6% vs 0.7% in PG group and 0% in PS group. The rate of life threatening and major bleeding was also higher in Manta group 2.7% and 3.6%, respectively. While it was 0% in PS group and 0.7% for both life threatening and major bleeding in PG group. There was no further remarkable statistical significance concerning haemoglobin value decrease or length of operative time among the 2 groups. Shorter hospital stay after TAVR was favouring the non-Manta groups (3.1 vs. 6.4 days, p=0.02).

1.4. Conclusion: One ProGlide in addition to one Angioseal was statistically significantly lower in overall vascular complications requiring surgery or interventions when compared to the MANTA system. However, the role of PS is decreasing in the setting of TAVR. It showed a comparable result to PG in this study.

2. Background

Recently, Transcatheter Aortic Valve Implantation (TAVI) has advanced in the treatment of severe symptomatic aortic valve stenosis in not only high-risk, but also intermediate surgical risk patients

[1]. Fortunately, the incidence of TAVI-related complications has decreased significantly over recent years, mainly due to progressive improvements in interventional skills, additional experience with the heart team, and advancements in catheter-based equipment, sheath diameter and closure devices technologie. However, Vascular complications wether minor or major remains one of the most relevant complications and, despite being rare, is associated with increased postprocedural morbidity and mortality [2, 3].

However, vascular complications are likely a multifactorial event that is not only related to the use of specific closure device but also to the presence of pre-existing vascular pathology, calcification, aneurysm or massive kinking. The risk of vascular complications is inversely proportional to the level of experience of the team and depends on the vessel quality and morphology as well. The choice of closure device has been previously studied denoting non-statistical significance between various devices concerning minor or major complications [7].

Notably, there are numerous closure devices in market with different closure techniques as Prostar, Proglide, Angiosealss and Manta. Each of which needs a specific learning curve and the incidence of complications logically declines with the increased experience and the non pathologoical puncture site and iliofemoral tree. No data are published concerning the preferability of one closure device over the others in correlation to the vessel morphology and pathology [8]. Herein, we describe our comparative results between 4 different closure techniqes.

Historically, with the first generation of TAVI sheaths (18-22 fr), we went through the learning curve from femoral cut down passing by Prostar systems until the current generations of percutaneous pre-suture mediated closure device proglide and collagen plug based post procedure closure device MANTA systems. in the past 5 years, the drastic fruitful competition between TAVI companies lead to a dramatic positive development in the manufacture of small diameter sheath with hydrophilic smooth expandable outer sheath as for the Edwards, Gore, Lotus and Isleeve sheaths. ProGlide is a well-established in many centres, while the Manta device was introduced later on [9, 10].

3. Methods

We present a retrospective observational study including 496 consecutive patients who were scheduled for TF TAVI in 2 heart centers in Germany (Zentralklinik Bad Berka and Augsburg University Clinic). We collected the data of patients from January 2020 until April 2021. All patients were classified by the Societyof Thoracic Surgeons/American College of Cardiology transcatheter aortic valve replacement (STS/ACC TAVR) risk score. CT was routinely performed for all Patients for annular dimensions and for iliofemoral tree morphology. Our routine puncture site was located intraoperatively using road Mapping method then introducing the J tip wire in the Common femoral artery under fluoroscopy. Ultrasound guided puncture was done in cases of preterminal renal failure or known contrast solution allergy. All punctures were made by the same three experienced operatures (stated in the authors list) and all the procedures took place in hybrid room under general anesthesia [11].

All patients received intravenous Heparin and Activated Clotting Time (ACT) was targeted to 250–300 s. Vascular closing with both ProGlide and Manta were started after reversing the Heparin effect with intravenous Protamin. The Perclose ProGlide (Abbot Vascular, USA) is a 6 Fr suture mediated closure system developed for closure of femoral artery punctures up to 8 Fr. When using larger access site diameters, 14–24 Fr, 2 ProGlide can be used in the same puncture site. The 2 ProGlides are placed as presutures with an angle of 30–45 degrees to each side. After completion of the TF-TAVI procedure the large bore sheath is removed and the prelaid sutures are advanced and tightened to obtain hemostasis. The Manta (Essential Medical Inc., USA) is a collagen based vascular plug for post procedure closure of large bore access sites. Briefly, the Manta VCD consists of a resorbable intraarterial toggle and an extra-vascular hemostatic collagen plug and a suture and a stainless steel suture lock which keeps the toggle and the collagen plug together, on each side of the arterial wall. The Manta components resorb within 6 months but if earlier reintervention would be needed, the puncture is clearly indicated by the stainless steel suture lock and can thus be avoided. The Manta is delivered in two sizes, 14 and 18 Fr, for punctures of 10–22 Fr. Study endpoints this study focuses on ipsilateral large bore arterial access site complications during index hospitalization, which with a reasonable probability can be attributed to failure of the vascular closure device used. Bleedings included corresponded to Valve Academic Research Consortium(VARC)-2“Major bleeding”while other complications likepseudoaneurysm best correspond to VARC-2“Minor vas-cular complications”.

3.1. Study Design

All eligible patients from two TAVI center were included in a non-randomized registry and analysed retrospectively. All patients were treated using self-expanding bio-prostheses from Medtronic (Medtronic, USA); CoreValve, Evolut R or Evolut PRO or Ballon expandable valves (Edwards Sapien 3). Initially, all 14–20Fr closures were performed using the ProGlide. Sixty-nine consecutive patients were treated using theProGlide VCD. In May 2017 the first TAVI procedureusing Manta VCD was performed. Subsequently, all patients but seven have consecutively been treated using Manta. Of the seven later, non-consecutive ProGlide procedures four were performed due to availability and three due to operator preferences. The ProGlide and the Manta groups have been compared for endpoints in the total cohort of patients. Further, both groups were divided into the first 25 patients with the respective VCD to access the learning period complications and into the remaining in patients (51 for ProGlide and 50 for Manta) to assess the results

during established use of the device.

3.2. Vessel Characteristics

The diameter and calcification was evaluated from contrast enhanced multislice Computed Tomography (CT) images performed as pre-procedural planning for the TAVI procedure. Smallest lumen diameter was measured in two planes in the external iliac artery and in the Common Femoral Artery (CFA). The mean of these diametersis used as minimal diameter in the respective segment. Calcification was visually graded as none or mild or moderate or severe. Measurements of lumen diameter and calcium scoring were performed by an external observer not involved in the choice of VCD. Procedure planning and choice of introducers was based on CT angiography. Evolut TAVR Procedures were performed using tthe medtronic Sentrant sheath. The mean of the CFA inner diameter was also related to the sheath size to calculate a CFA/ sheath size ratio.

3.3. Statistical Considerations

Continuous variables were tested for normality of distribution by using the Shapiro-Wilk test. Normally distributed variables were expressed as mean ± standard deviation. For non-normally distributed variables, the median and Inter-Quartile Range (IQR) were calculated and tested for statistical significance with the Mann–Whitney U test. Categorical variables were compared by chi-square statistics. Statistical analyses were performed with SPSS (version 24.0; IBM Corporation, Armonk, NY). A two sided P < .05 was considered statistically significant (Table 1).

Table 1: preoperative patients` characteristics

	No MV Complication 487 (96.4%)	MV Complication 18 (3.6%)	Total 496	P Value
Female n (%)	215 (44.4%)	10 (55.6)	225 (45.3)	
Age median (IQR) BMI >30	41 (8.6%)	5 (27.8)	46 (9.3)	0.006
BMI	28.6 (5.5)	29.4 (7.3)	28.6 (5.6)	0.002
STS Score	7.7 (5.4)	11.1 (4.3)	11 (5.1)	
DM n (%)	228 (47.7)	12 (66.7)	240 (48.4)	
CLD n (%)	69 (14.4)	6 (32.3)	75 (15.1)	
CKD n (%)	128 (26.7)	3 (16.7)	131 (26.4)	
Stroke n (%)	31 (6.5)	1 (5.6)	32 (6.4)	
CAD n (%)	251 (52.6)	11 (61.1)	262 (52.9)	
Atrial fibrillation	151 (31.6)	5 (27.8)	156 (31.5)	
LVEF	52 (13)	47.6 (11.9)	52 (12.9)	
Pmax	68.5 (22.6)	66.2 (20)	62 (22)	
Pmean	43 (15.4)	42.2 (12.9)	43 (15)	
Aortic valve area	0.8 (0.1)	0,9 (0,1)	0,8 (0,1)	

BMI: Body Mass Index; HTN: hypertension; CLD: Chronic Lung Disease; CKD: chronic kidney disease; NYHA: New York Heart Association.

4. Results

A total of 496 continuous patients underwent TF-TAVI were included. Mean age was 81 ± 4 years and the STS/ACC TAVR score was 4.7 ± 1.6. Mean echocardiographic transaortic valve gradient was 43 ± 15 mmHg and aortic valve area was 0.8 ± 0.1 cm2. Baseline characteristics of the respective groups of all study patients with and without Major Vascular Complication (MVC) are presented in Table1. There were no significant differences between patients with and without MVC, except for obesity. (Table 2 and 3) showed the operative and postoperative data comparing between patients with and without MVC. The MVC was associated with more mortality, 5.6% vs 1.7%, p value 0.05. From 496 patients, we used Proglide (PG) ± Angioseal in 288 patients (58.2%), 2X PG in only 18 patients (3.6%), Manta in 112 (22.6%) and PS in 74 patients (14.9%). The use of 18 and 20 F sheaths was more frequent in the Manta group (26.8% Manta vs 9.5% in PS and 5.2% in PG group). As regard other preoperative and operative characteristics there was no significant difference between the VCD groups. The mean BMI was 28.6 (5.5) in Manta group vs 28.6 (5.6) in PG group and 28.6 (5.6) in PS group. Female gender was tending to be higher in other groups other than Manta group; 37.55 vs 45.1% in PG and 52.7% in PS group, p value 0.08. The mortality rate was significantly higher in Manta group 3.6% vs 0.7% in PG group and 0% in PS group. The rate of life threatening and major bleeding was also higher in Manta group 2.7% and 3.6%, respectively. While it was 0% in PS group and 0.7% for both life threatening and major bleeding in PG group [13].

In the multivariate analysis the two significant predictors of MVC were BMI > 35 (OR 4.1, 95% QI 1.3-12, p value 0.019) and CFA < 5.5mm (OR 3.3, 95% QI 1.1-9.9, p value 0.018). Other parameters as the type of used valve and VCD were not a significant predictor of MVC.

Table 2: Operative Data

	No MV Complication 487 (96.4%)	MV Complication 18 (3.6%)	Total 496	P Value
Transfemoral TAVR				
Type of THV				0.001
Edward Sapien	282 (59)	9 (50%)	291 (58.7)	
Evolut	114 (23.8)	53 (38.9)	121 (24.4)	
AccurateNeo	53 (11.1)	1 (5.6)	54(10.9)	
Lotus	29 (6.1)	0	29 (5.8)	
Sheath (F)				
14	281 (58.89)	10 (58.8)	291 (58.8)	NS
16	144 (30.1)	5 (29.4)	149 (30.1)	
18	37 (7.7)	2 (11.8)	39 (7.9)	
20	14 (2.9)	0	14 (2.8)	
SFR > 1	11 (3.1%)	1 (6.3)	12 (3.3)	
Closure device				
One Proglide + Angioseal	278 (58.2)	10 (58.8)	288 (58.2)	NS
Two Proglide	18 (3.8)	0	18 (3.6)	
Manta	107 (22.4)	5 (29.4)	112 (22.6)	
Prostar	72 (15.1)	2 (11.8)	74 (14.9%)	

Table 3: Postoperative Data

	No MV Complication 487 (96.4%)	MV Complication 18 (3.6%)	Total 496	P Value
30-days mortality	8 (1.7%)	1 (5.6%)	9 (1.8)	
VARC Major bleeding	5 (1%)	1 (5.6%)	6 (1.2%)	0.08
Life threatening bleeding	6 (1.3)	2 (11.1)	8 (1.6)	0.0001
Blood transfusion	64 (13.4%)	8 (44.4%)	72 (14.5%)	0.001
ICB	3 (0.6)	0	3 (0.6)	Ns
Non disabling stroke	10 (2.1)	1 (5.6%)	11 (2.2)	Ns
Delirium	73 (15.3%)	2 (11.1)	78 (15.7)	
AKI	64 (13.4)	5 (27.8)	69 (13.9)	0.04
PPMI	64 (13.4)	5 (27.8)	69 (13.9)	ns
PO Pmean	11 (5)	10(5)	11 (5)	
PO moderate AR	15 (3)	0	5 (3)	

THV: transcatheter heart valve, VARC: valve academic research consorium, PPMI permanent pacemaker implantation.

5. Discussion

The main finding of this study supports the findings of the recent studies comparing between Manta and PG VCD. In this study needle based VCD (both PG and PS) were associated with fewer bleeding complications and mortality than Manta.

In the multivariate analysis the two significant predictors of MVC were BMI > 35 and CFA < 5.5mm. However, MVCs could not be predicted based only on specific anatomical risk factors as it depends also on the puncture technique and the used material. In the previous studies, some other risk factors were supposed to be also associated with more MVC as off-target punctures [12], Femoral Artery Depth (FAD) and Sheath-To-Femoral-Artery-Ratio (SFAR) [3]. The use of low-profile sheaths (<19Fr), female gender and severe iliofemoral tortuosity patterns as well as operator experience were considered also as independent predictors of vascular complications [9].

The rate of MVC in this study was 3.8%. Comparing the high vascular complication rates in the early days of TAVR, a significant decrease could be observed in the recent literature. However, MVCs influence the outcomes after TAVR and they increased the hospitalization stay and the 30-day and 1-year mortality. Observed 30-day mortality was significantly higher in patients with major vascular complications (5.6%) in comparison with patients without vascular complications (1.7%).

In this study needle based VCD (both PG and PS) were associated with fewer bleeding complications and mortality than Manta (Table 4).

The most common used VCD are Prostar XL (PS), ProGlide (PG) (both by Abbott Vascular Inc., Santa Clara, CA) and MANTA device (Teleflex, PA, USA). PS and PG are needle based VCD and Manta is plug based VCD. The MANTA™ VCD (Essential Medical) is a collagen-based closure device, which resolves completely in 6 months. There are different technique to use the PG to close a large bore, firstly the use of two devices, secondly the use of angioseal as a second device. The use of 2 X PG techniques was associated with higher rate of vascular complications, especially residual bleeding and the combination of dissection and bleeding. However, the use of 1X PG technique was associated with lower vascular complication in sub analysis BRAVO 3 trial. Dobule Choice trial was a randomised head-to-head comparison, the MANTA device was associated with more vascular complications. In a post hoc analysis of the BRAVO 3 trial, Power et al (746 patients) showed

that PG was associated with lower inciedence of minor vascular complication and acute kidney injury after the correction of the other cofactors. In these study, patients with common femoral artery < 6.5 mm was excluded, which is a significant proportion of TAVR patients in the daily practice. Sheath size's <18 mm were more frequently used in patients treated with the PG devices. MANTA resulted in a significantly lower complication rate, especially for bleeding, than did ProGlide, despite the operators' inexperience in the use of MANTA. In a single retrospective study included 512 TAVR patients, VCD (Manta) related complications occurred in 8% of patients and were mainly due to percutaneous closure device failure. Multivariate logistic regression showed that smaller minimal diameter of the femoral artery, punctures on- or below the bifurcation and high punctures >2 cm above the bifurcation were independent predictors of accesssite related vascular complications [12]. According to our experience we prefer to use the MANTA VCD in obese patients with large CFA, at least 6 mm. It should be noticed that the puncture site and the technique of the use of VCD might affect the results. However, the learning curve needed to use the MANTA is significantly shorter than the other needle based VCD especially PS. Following tips should be considered while using MANTA, [1]. The measuring of vessel depth should be done without compression of the suuounding tissues, [2]. The release of the anchor in the vessel should not be too deep and the rule of depth plus one centimeter should be respected to avoid unneeded long journey of anchored inside the vesse [l, 3]. The initial reflex to applay a rapid excessive tension due to the first gush of the blood should be avoided, a slowly sustained tension with control of the red&green and yellow alarm is essential, [4]. Give the half dose of protamine before the sheath removal and then the other half after the control angiogram, [5]. The wire inside the plug should be removed after the inter arterial toggle touch the vessel wall and before the applying the extra vascular part, [6]. The use of cross over technique might be useful in Manta to avoid excessive bleeding in case of VCD failure due to the lack of bail ouit wire.

Table 4: Comparison Between the Different **VCDs**

	PG±Angio 288 (58.2)	2X PG 18 (3.6)	Manta 112 (22.6)	PS 74 (14.9)	P Value
Female	130 (45.1)	11 (61.1)	42 (37.5)	39 (52.7)	0.08
BMI > 35	25 (8.7)	2 (11.1)	13 (11.6)	5 (6.8)	NS
BMI	28.6 (5.6)	27.6 (4.4)	28.6 (5.5)	28.9 (5.5)	NS
CFA < 5.5mm	34 (11.8)	0	10 (8.9)	8 (10.8)	NS
CTA	8.4 (2.1)	8.6 (1.5)	8.7 (1.8)	7.9 (2)	NS
Sheath > 18	15 (5.2)	1 (5.6)	30 (26.8)	7 (9.5)	NS
SFR > 1	5 (2.4)	0	5 (4.9)	2 (4.4)	NS
30-days mortality	2 (0.7)	0	4 (3.6)	0	0.001
All VC	66 (22.9)	5 (27.8)	31 (27.7)	18 (24.3)	Ns
MVC	10 (3.5)	0	5 (4.5)	2 (2.7)	NS
Blood transfusion	38 (13.2)	0	19 (17)	12 (16.2)	Ns
Hematoma	59 (20.9)	4 (22.2)	30 (26.8)	17 (23)	Ns
Dissection	6 (2.1)	0	4 (3.6)	0	
Occlusion	2 (0.7)	0	2 (1.8)	1 (1.4)	Ns
Pseudo	2 (0.7)	0	0	1 (1.4)	Ns
Intervention	8 (2.8)	1 (5.6)	2 (1.8)	2 (2.7)	0.004
AKI	33 (11.5)	1 (5.6)	21 (18.8)	14 (18.9)	NS
Life threatening	1 (0,3)	0	4 (3.6)	0	0.001
VARC Major	1 (0.3)	0	3 (2.7)	0	0.002
VARC Minor	3 (1)	0	4 (3.6)	2 (2.7)	0.001

6. Conclusion

One ProGlide in addition to one Angioseal was statistically significantly lower in overall vascular complications requiring surgery or interventions when compared to the MANTA system. However, the role of PS is decreasing in the setting of TAVR. It showed a comparable result to PG in this study.

References

1. Abu Saleh WK, Tang GH. "Vascular complication can be minimized with a balloon-expandable, re-collapsible sheath in TAVR with a self-expanding bioprosthesis". Catheterization and Cardiovascular Interventions. 2016; 88: 135-43.
2. Burri M, H. Ruge H. "Surgical Cutdown Avoids Vascular Complications in Transcatheter Aortic Valve Replacement in Calcified and Small Femoral Arteries". The Thoracic and Cardiovascular Surgeon. 2021.
3. Durand E, Penso M. "Standardized Measurement of Femoral Artery Depth by Computed Tomography to Predict Vascular Complications After Transcatheter Aortic Valve Implantation". Am J Cardiol. 2021; 145: 119-27.

4. Glaser N, O'Sullivan CJ. "Transcatheter aortic valve replacement using the iSleeve expandable sheath in small femoral arteries". Open Heart. 2021; 8: 001703.
5. Goldsweig AM, Faheem O. "A balloon-expandable sheath facilitates transfemoral TAVR in patients with peripheral vascular disease and tortuosity". Therapeutic advances in cardiovascular disease. 2015; 9: 95-102.
6. Gonska B, Reuter C. "Vascular access site complications do not correlate with sheath diameter in TAVI procedures with new generation devices". Frontiers in cardiovascular medicine. 2021; 1805.
7. Kaneko U, Kobayashi K. "Successful use of an esheath for failed introduction of the Evolut R valve during transfemoral transcatheter aortic valve implantation". Korean circulation journal. 2020; 50: 372-3.
8. Kappetein AP, Head SJ. "Updated standardized endpoint definitions for transcatheter aortic valve implantation: The Valve Academic Research Consortium-2 consensus document". The Journal of thoracic and cardiovascular surgery. 2013; 145: 6-23.
9. Mach M, Okutucu S. "Vascular Complications in TAVR: Incidence, Clinical Impact, and Management". Journal of clinical medicine. 2021; 10: 5046.
10. Power D, Schäfer U. "Impact of percutaneous closure device type on vascular and bleeding complications after TAVR: a post hoc analysis from the BRAVO-3 randomized trial". Catheterization and Cardiovascular Interventions. 2019; 93: 1374-81.
11. Ristalli F, Dini CS. "Role of lithotripsy for small calcified iliacs in the era of big devices". Curr Cardiol Rep. 2019; 21: 1-8.
12. van Wiechen MP, Kroon H. "Vascular complications with a plug-based vascular closure device after transcatheter aortic valve replacement: Predictors and bail-outs". Catheterization and Cardiovascular Interventions. 2021; 98: 37-45.
13. Yashige M, Zen K. "Combining the CoreValve Evolut PRO and 14-French eSheath in transfemoral transcatheter aortic valve replacement". Cardiovascular intervention and therapeutics. 2021; 36: 266-7.