Kardiologia Polska 2018; 76, 1: 202–208; DOI: 10.5603/KP.a2017.0205

ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

Complete percutaneous approach versus surgical access in transfemoral transcatheter aortic valve implantation: results from a multicentre registry

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Abstract

Background: Although the femoral approach is the most common route utilised in transcatheter aortic valve implantation (TAVI), it still carries a substantial risk of severe bleeding and vascular complications.

Aim: The aim of our study was to compare the safety and efficacy of the complete percutaneous (CPC) approach with surgical cut-down and closure (SCC) in TAVI patients.

Methods: The study population comprised 683 patients with severe aortic stenosis, who underwent transfemoral TAVI. Bleeding and vascular complications were defined according to the Valve Academic Research Consortium (VARC-2) criteria. Propensity-matched cohorts were created to reduce the potential bias of non-random assignment to the type of vascular access technique (SSC, n = 203 vs. CPC, n = 203).

Results: The rate of minor vascular complications was higher in the CPC cohort (18.2% vs. 9.9%, p = 0.02). There were no differences in major vascular complications or in any type of bleedings between the two groups. Age (odds ratio [OR] 1.044; 95% confidence interval [CI] 1.003–1.09, p = 0.046), preprocedural haemoglobin (OR 0.849; 95% CI 0.760–0.944, p = 0.03), and baseline estimated glomerular filtration rate < 30 mL/min (OR 3.216; 95% CI 1.176–8.741, p = 0.021) were independent predictors of life-threatening/disabling and major bleedings. Diabetes remained the only independent predictor of major vascular complications (OR 1.695; 95% CI 1.014–3.156, p = 0.046).

Conclusions: In this retrospective analysis both vascular access and closure techniques were associated with a similar risk of severe bleeding and major vascular events. However, these findings should be further confirmed in a multicentre, randomised study.

Key words: bleeding complications, TAVI, vascular access, closure device

Kardiol Pol 2018; 76, 1: 202–208

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Received: 24.12.2016 **Accepted:** 22.06.2017 **Available as AoP:** 23.10.2017

INTRODUCTION

Over the last few years, transcatheter aortic valve implantation (TAVI) has become an important alternative to surgical aortic valve replacement (SAVR) in high-risk patients with severe aortic stenosis. Furthermore, TAVI has improved the survival compared to medical therapy in those unsuitable for surgery [1–3]. Although perceived as less invasive than SAVR, TAVI still carries a substantial risk of severe complications [4]. Vascular access site complications occur most frequently and are still considered a significant limitation to the femoral approach, the most common route for prosthesis delivery and implantation. In early experience with TAVI, a surgical arteriotomy was regarded as one that could ensure appropriate access and haemostasis. Despite technological advancement resulting in reduction of the sheath sizes and delivery system profiles, still a number of experienced centres use surgical cut-down and closure (SCC) as the default approach. However, some authors have raised the issues of the need for general anaesthesia, prolonged procedure duration, delayed patient mobilisation, and discharge from hospital [5, 6]. The less invasive technique to SCC is a complete percutaneous (CPC) approach utilising one of the two currently available vascular closure devices: the Prostar XL® 10 F and Perclose® ProGlide™, (both manufactured by the Abbott Vascular, Santa Clara, California). Recently, a few retrospective surveys and one small, randomised study suggested that CPC is as safe and feasible as SCC [7–9]. Nevertheless, the reported risk of vascular and bleeding complications related to CPC differs substantially between studies, ranging from several to 30%, which could potentially be attributed to differences in the sheath sizes and lack of standardised reporting of TAVI outcomes [10–13]. To address the issue of limited data regarding the impact of each vascular access technique on the risk of periprocedural complications, we set up a multicentre study. Our aim was to analyse and compare the surgical and complete percutaneous access with the contemporary used delivery systems, based on the unified criteria for endpoint assessment and reporting in TAVI trials developed by the Valve Academic Research Consortium (VARC-2) [14].

METHODS

Study population and data collection

The study group comprised patients who underwent TAVI in six experienced academic centres in Poland. The data of patients treated with the transfemoral (TF) approach (n = 745) were prospectively collected in local databases. For the purpose of this study, data were retrospectively recoded according to the VARC-2 criteria and pooled into the dedicated multicentre database.

High-risk patients with symptomatic severe aortic stenosis (valve area < 0.8 cm^2 or indexed valve area < 0.6 cm^2/m^2) were qualified for TAVI by the local, interdisciplinary Heart Teams comprising a general cardiologist, an interventional cardiologist, and a cardiac surgeon, based on clinical symptoms, echocardiography findings, and available multi-slice computed tomography imaging.

By default, the choice of access site, type of approach (percutaneous or surgical), and type and size of prosthesis were based on anatomical characteristics including peripheral vascular diameter, vascular tortuosity, annular and vessel calcification, annulus dimension, and the distance from coronary ostia to valvular plane. The procedures were performed by TAVI teams consisting of interventional cardiologists and cardiosurgeons according to local protocols, there were no predefined criteria for the particular vascular access type, and the choice between the surgical and the percutaneous access was left to the discretion of the Heart Team.

TAVI procedure

In all centres, the complete percutaneous approach was performed using the Prostar XL 10 F vascular closure system, which is approved for the treatment of artery puncture sites using large-bore sheaths ranging from 8.5 up to 24 French. This device contains four nitinol needles that are deployed from inside the artery and are connected to two braided polyester sutures used to make a knot that secures the vascular haemostasis. The percutaneous technique with pre-closure of the femoral artery access site using the Prostar XL device has been previously described [15]. The surgical access and closure were performed in a standard fashion, which included a transverse incision made above the inguinal ligament and exposure of the common femoral artery and superficial femoral artery. The running polypropylene suture was used or vessel closure and a limited endarterectomy was done if necessary. To confirm appropriate haemostasis and to exclude any immediate vascular complications a final angiography was performed from the contralateral site.

Procedural and clinical endpoints

The primary endpoints of this study were the incidence of minor and major vascular complications, as well as minor, major, and life-threatening/disabling bleedings (LTDB) at 30 days, as defined by the VARC-2 criteria [14] (**Supplemental Table 1 — see journal website**). Secondary endpoints included the incidence of death, myocardial infraction, and stroke, analysed both separately and as a combined major adverse cardiovascular events (MACE) endpoint. Selected peri-procedural and in-hospital parameters were also analysed.

Statistical analysis

The statistical analyses were performed using the statistical suite STATISTICA (data analysis software system) version 12.0 (StatSoft Inc.) and Excel (Microsoft). The quantitive variables were characterised by mean standard deviation, median or maximum/minimum (range), and 95% confidence interval (CI), as appropriate. The qualitative variables were presented

as counts and percentages. To check for normal distribution the W Shapiro-Wilk test was used. The statistical significance of differences was tested with the t-Student test (or Welch test in the case of lack of homogeneity) or U Mann-Whitney test. Chi-squared tests for independence were used for qualitative variables. Propensity-matched cohorts were created to reduce the potential bias of non-random assignment. Nearest neighbour 1:1 matching with similar propensity scores was applied as the most popular method. The propensity scores were estimated using non-parsimonious logistic regression models incorporating various patient characteristics including sex, age, logEuroSCORE, estimated glomerular filtration rate (eGFR), haemoglobin level (Hb) preTAVI, body mass index (BMI), peripheral artery disease (PAD), and sheath size, which resulted in 203 matched pairs. To determine the predictors of the major vascular and LTDB and major bleeding complications, we used univariate analysis and multiple regression analysis using a stepwise backward regression model. The following variables were taken into consideration: female gender, age, BMI, hypertension, diabetes mellitus, eGFR < 30 mL/min, atrial fibrillation, coronary artery disease (CAD), previous percutaneous coronary intervention (PCI), coronary artery bypass grafting, history of PAD, logistic EuroSCORE, Hb level before procedure, type of vascular access (SCC vs. CPC), and sheath size (< 18 French vs. ≥ 18 French). A statistical significance level of $p = 0.05$ was used in all the calculations.

RESULTS

Baseline clinical and procedural characteristics

Of the 1007 TAVI procedures performed in six academic centres in Poland between January the 1, 2009 and June 30, 2015, 745 (74.0%) were identified as TF cases. The final study group consisted of 683 patients; 62 cases were excluded due to missing data. The CPC technique with Prostar XL device was utilised in 445 (65.2%) patients, and in 238 (34.8%) patients a surgical cut-down was used. The comparison of baseline clinical characteristics revealed a significantly higher risk profile in the surgical group, which was expressed by greater logistic EuroSCORE and BMI, higher rate of hypertension, CAD, previous PCI, and PAD (Tables 1 and 2).

The procedural characteristics showed high variability of the type and size of the implanted valves, which was probably due to the anatomical differences of the treated patients as well as the local availability of the devices. Most patients received self-expanding valves. The latest generations of balloon expandable valves, i.e. the SAPIEN3, were more commonly implanted in the SCC cohort as compared to the CPC group. This had an impact on sheath sizes used; in the SCC group the rate of the lowest diameter profile (14 French) was significantly higher. There were also differences in terms of the procedure duration and the volume of contrast media; both parameters were greater in the CPC cohort (**Supplemental Table 2 — see journal website**).

Primary endpoints

Vascular complications in the whole study cohort were observed in 20.8% (n = 142) of patients. Of those events, 6.4% (n = 44) were classified as major and 14.3% (n = 98) as minor. Before propensity matching, there were no differences in the rate of major vascular complications. However, in the CPC cohort the rate of minor vascular complications was significantly higher (16.8% vs. 9.7%, $p < 0.01$), which remained unchanged after the propensity-matched analysis (18.2% vs. 9.9%, $p = 0.02$; Fig. 1).

The rate of all bleeding complications in the whole study cohort was 27.5% (n = 188). The rates of LTDB, and major and minor bleedings were 6.1%, 10.1%, and 11.3%, respectively. There were no differences in LTDB and minor bleedings. The initially observed significantly higher rate of major bleedings in the CPC group (11.6% vs. 7.1, $p < 0.01$) was no longer observed after propensity matching (9.9% vs. 8.4%, $p = 0.73$; Fig. 2).

Secondary endpoints

The length of hospital stay was shorter and the volume of contrast was lower in the SCC group. The initially observed shorter procedural time in the SCC did not differ after propensity matching. Other procedural parameters, including the radiation exposure dose and fluoroscopy time, were comparable. The rates of the combined MACE were similar in the CPC and SCC groups (9.9% vs. 10.1%, $p = 0.89$; Table 3).

DISCUSSION

To the best of our knowledge, this is one of the largest registries assessing the safety and feasibility of the complete percutaneous approach versus surgical access in patients undergoing TF-TAVI. The advantage of this study is the fact that it reflects contemporary clinical practice and that all complications were assessed according to the VARC-2 criteria. It should also be noted that the analysis employed the propensity-matching methodology to partially compensate for significant differences in risk profiles between the groups.

The main results of the study can be summarised as follows: 1) the rates of VARC-2 major vascular and LTDB/major bleeding complications did not differ between the groups; however, 2) the CPC approach was associated with more minor vascular complications and longer hospital stay.

Our results are consistent with the previous studies that compared the two different vascular access techniques. In the only randomised trial published so far, acceptable immediate safety and feasibility of the percutaneous approach were demonstrated. However due to the low number of subjects (n = 30), it was severely underpowered to detect any significant differences in vascular and bleeding complications between the two strategies [8].

In a single-centre retrospective registry (n = 274) the rates of vascular and bleeding complications were similar in the CPC

Table 1. Baseline clinical characteristics

	CPC (n = 445)	SCC (n = 238)	p
Gender (female)	56.2% (n = 250)	54.2% (n = 129)	0.62
Age [years]	79.7 ± 7.1	78.5 ± 8.6	0.14
Body mass index [kg/m^2]	27.0 ± 4.1	28.0 ± 4.9	**0.02**
Hypertension	64.2% (n = 286)	83.3% (n = 198)	**0.01**
Type 2 diabetes	33.8% (n = 150)	39.1% (n = 93)	0.18
Chronic kidney injury (eGFR < 60 mL/min)	53.8% (n = 239)	52.2% (n = 124)	0.75
Chronic kidney injury (eGFR < 30 mL/min)	7.6% (n = 34)	5.1% (n = 12)	0.32
eGFR [mL/min]	55.7 ± 17.2	56.6 ± 20.5	0.053
Atrial fibrillation	29% (n = 129)	30.1% (n = 72)	0.81
COPD/asthma	18.7% (n = 83)	20.3% (n = 48)	0.64
Pulmonary hypertension	25.5% (n = 113)	22.9% (n = 55)	0.49
Heart failure (NYHA III/IV)	76.9% (n = 342)	80.9% (n = 193)	0.34
Coronary artery disease	65.4% (n = 291)	75.1% (n = 179)	**0.01**
Myocardial infarction	19.4% (n = 86)	25.9% (n = 62)	0.11
Stroke	17% (n = 76)	14.7% (n = 35)	0.44
Percutaneous coronary intervention	35.8% (n = 159)	44.7% (n = 106)	**0.03**
Coronary artery bypass grafting	16.8% (n = 75)	15.6% (n = 37)	0.68
Peripheral artery disease	25.1% (n = 112)	38.1% (n = 91)	**0.01**
logEuroSCORE [%]	20.9 ± 13.1	24.0 ± 17.2	**0.04**
Hb level before TAVI [mg/dL]	10.6 ± 2.7	11.2 ± 2.2	**0.01**
Aortic valve area [mm^2]	0.7 ± 0.4	0.7 ± 5	0.63
Ejection fraction [%]	51.9 ± 15.4	50.6 ± 14.7	0.13
Peak AV gradient [mm Hg]	86.3 ± 31.4	84.5 ± 29.7	0.27
Mean AV gradient [mm Hg]	51.0 ± 22.4	49.4 ± 19.7	0.30

Data are given as mean ± standard deviation or percentage (number). AV — aortic valve; COPD — chronic obstructive pulmonary disease; CPC — complete percutaneous; eGFR — estimated glomerular filtration rate; Hb — haemoglobin; NYHA — New York Heart Association classification; SCC — surgical access and closure; TAVI — transcatheter aortic valve implantation

Table 2. Baseline characteristics pre and post matching

	Before matching			After matching		
	CPC (n = 445)	SCC (n = 238)	p	CPC (n = 203)	SCC (n = 203)	p
Gender (female)	56.2% (n = 250)	54.2% (n = 129)	0.62	53% (n = 108)	58% (n = 117)	0.37
Age [years]	79.7 ± 7.1	78.5 ± 8.6	0.14	79.1 ± 7.2	78.8 ± 8.5	0.87
Body mass index [kg/m^2]	27.0 ± 4.1	28.0 ± 4.9	**0.02**	27.4 ± 4.3	28.0 ± 4.9	0.61
Hb level before TAVI [mg/dL]	10.6 ± 2.7	11.2 ± 2.2	**0.01**	11.0 ± 2.2	11.3 ± 1.9	0.23
eGFR [mL/min]	55.7 ± 17.2	56.6 ± 20.5	0.053	55.8 ± 16.8	57.7 ± 19.1	0.37
logEuroSCORE [%]	20.9 ± 13.1	24.0 ± 17.2	**0.04**	22.4 ± 14.5%	24.3 ± 17.9%	0.78
Peripheral artery disease	25.1% (n = 112)	38.1% (n = 91)	**0.01**	32.3% (n = 66)	38.8% (n = 79)	0.08
Sheath size:						
14 French	0.6% (n = 3)	9.5% (n = 23)	**0.01**	1.0% (n = 2)	3.4% (n = 7)	0.17
16 French	4.8% (n = 22)	7.7% (n = 18)	0.23	5.9% (n = 12)	3.9% (n = 8)	0.49
18 French	89% (n = 405)	78.6% (n = 187)	0.56	88.2% (n = 179)	90.1% (n = 183)	0.63
20 French	5.6% (n = 25)	4.2% (n = 10)	0.43	4.9% (n = 10)	2.5% (n = 5)	0.29

Data are given as mean ± standard deviation or percentage (number). CPC — complete percutaneous; eGFR — estimated glomerular filtration rate; Hb — haemoglobin; SCC — surgical access and closure; TAVI — transcatheter aortic valve implantation

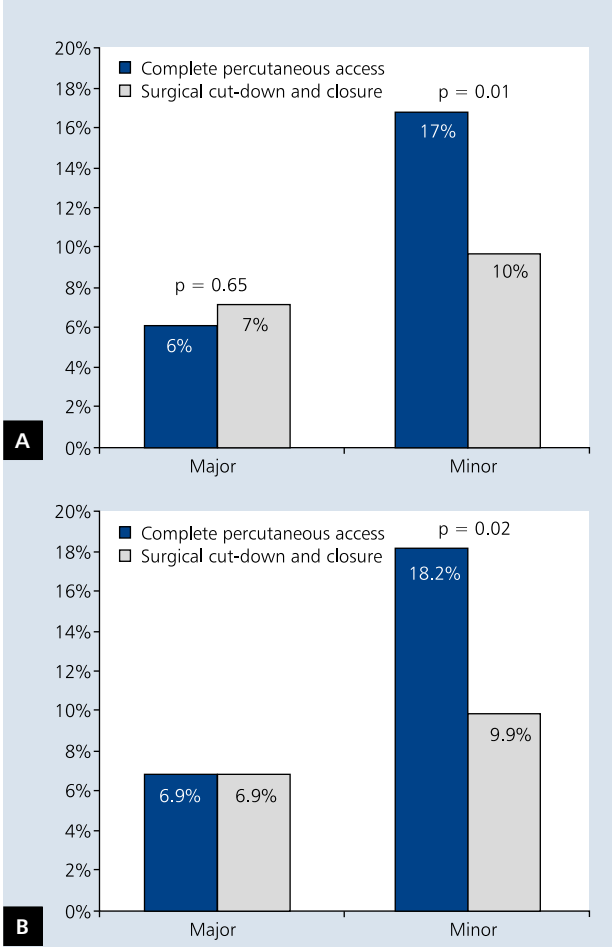

Figure 1. Vascular complications (Valve Academic Research Consortium-2); **A**. Before matching; **B**. After matching

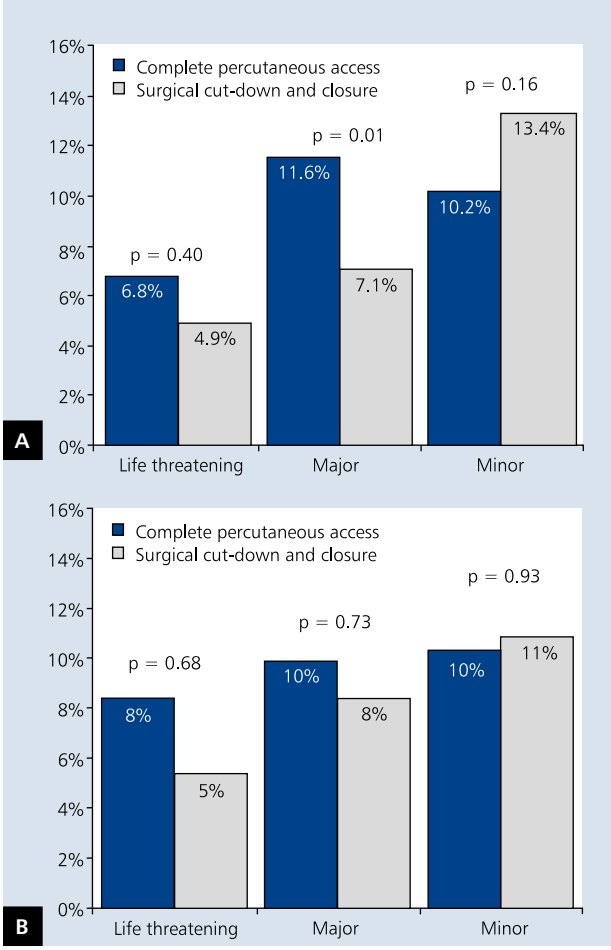

Figure 2. Bleeding complications (Valve Academic Research Consortium-2); **A**. Before matching; **B**. After matching

Table 3. Procedural and clinical outcomes (secondary endpoints)

	Before matching			After matching		
	CPC (n = 445)	SCC (n = 238)	p	CPC (n = 203)	SCC (n=203)	p
Stroke @30days	1.2% (n = 5)	1.6% (n = 4)	0.68	1.0% (n = 2)	1.0% (n = 2)	1.00
Myocardial infarction @30days	1.4% (n = 6)	0.8% (n = 2)	0.07	2.5% (n = 5)	1.0% (n = 2)	0.44
Death @30days	7.5% (n = 33)	7.4% (n = 18)	0.96	7.4% (n = 15)	7.9% (n = 16)	1.00
Hospital stay [days]	9.9 ± 5.7	8.1 ± 5.1	**0.01**	10.2 ± 6.2	8.3 ± 5.4	**0.01**
Ejection fraction after TAVI [%]	54.1 ± 10.9	52.1 ± 11.1	0.34	53.1 ± 9.9	52.5 ± 10.3	0.54
Mean AV gradient after TAVI [mm Hg]	10.5 ± 5.1	10.3 ± 4.8	0.69	10.5 ± 7.4	11.3 ± 8.4	0.48
Need for blood transfusion	26.6% (n = 118)	32.5% (n = 77)	0.15	29.5% (n = 60)	32.5% (n = 66)	0.56
Blood transfusion [Units]	1.1 ± 2.7	0.9 ± 1.6	0.67	1.1 ± 0.6	0.9 ± 0.7	0.27
Procedural time [min]	147.6 ± 59.1	135.7 ± 73.4	0.04	142.7 ± 53.8	139.6 ± 67.2	0.34
Radiation exposure dose [mGy]	1113 ± 865	1245 ± 969	0.39	1213 ± 925	1253 ± 782	0.65
Fluoroscopy time [min]	33.8 ± 12.6	34.0 ± 27.5	0.93	33.7 ± 14,5	34.2 ± 21.4	0.43
Contrast volume [mL]	221.5 ± 79.5	163.4 ± 77.5	0.01	238.6 ± 90.4	169.8 ± 75.2	0.01

Data are given as mean ± standard deviation or percentage (number). AV — aortic valve; CPC — complete percutaneous; SCC — surgical access and closure; TAVI — transcatheter aortic valve implantation

and surgical groups [6]. These results were further confirmed in the largest, so far, registry containing 986 TAVI patients who underwent TF-TAVI with both techniques. However, detailed comparison between the strategies was precluded; because of unmatched cohorts, a lack of important clinical information such as the length of stay, the small proportion of surgical access patients, and the lack of individuals with the second-generation sheath sizes [16].

The published rates of major vascular complications ranged from 13% to 20% in the percutaneous cohorts and from 11.2% to 16% in the surgical approach groups [7–9, 16–18]. These were higher than those obtained in our study (6.9% and 6.9%, respectively). We also observed lower frequencies of LTDB/major bleeding complications than in the above-mentioned reports. These differences may possibly be attributed to the smaller sheath sizes used in our study (96% of patients treated with sheath sizes ≤ 18 French). The trials quoted above included patients in whom access was obtained with larger sheath sizes, which seem to be associated with higher risk of vascular and bleeding complications [17, 19].

In our study, the unmatched major bleeding complications in the CPC were higher than the SCC approach. This was probably caused by baseline clinical and procedural discrepancies between the groups. In particular, it could be attributed to a lower preprocedural Hb level, which is a known predictor of LTDB/major bleeding, and only occasional usage of low profile vascular sheaths (14 French) in the CPC patients [13, 20, 21]. These differences in the bleeding complications were no longer detected after the propensity matching, which confirms the value of robust statistical methodology used in the retrospective assessment of non-randomised groups.

Authors of the above-mentioned largest study reported an increased risk of bleeding complications in the percutaneous cohort. The interpretation of these results remains unclear, as the detailed characteristics of the two studied populations were not disclosed. Thus, it is unknown if the incidences of bleeding were impacted solely by the type of access or modified by the differences in the baseline and procedural risk factors [16]. Furthermore, the only analysis comparing the two access strategies that utilised the propensity matching methodology unfortunately did not evaluate bleeding complications [17].

In regard to vascular complications, there were no significant differences in the rate of major events between both groups, and this is consistent with other reports [7, 8, 16, 17]. However, we found a higher rate of minor vascular complications in the CPC cohort, which remained significant after matching. This was not previously reported and we speculate that it might result from the relatively low number of TAVI cases per centre (approximately 40 per year), which in our view makes it difficult to fully overcome the learning curve related to percutaneous closure devices.

Contrary to previous findings, the CPC approach was unexpectedly associated with a longer hospital stay. In the paper by Kadakia et al. [17] the duration of hospital stay was shorter in the CPC group and might have been attributed to quicker recovery and ambulation time. In our study, all procedures were performed with general anaesthesia, which probably precluded early mobilisation and shortening of recovery time. Additionally, the increased duration of hospital stay might have resulted from the higher rate of minor vascular complications in the CPC cohort.

Limitations of the study

Our study, being one of the largest registries published so far and using the propensity score matching analysis, still has some limitations. The methodology of data collection precluded external verification of vascular and bleeding events because the participating centres were entering the individual medical records using the VARC-2 coding system, without detailed description of each complication. The collected data did not include specific computed tomography findings such as the vessel calcification, tortuosity, and diameter, which did not allow evaluation of their impact on the outcome in both subgroups. Patient selection, access strategy, and management of complications were left to Heart Team discretion, which led to considerable heterogeneity across participating centres. The information regarding antiplatelet/anticoagulation therapy was not collected, which might have influenced the results.

Another limitation of the current analysis is exclusion of patients in whom a Proglide device was used; this was driven by the fact that the Proglide system was utilised in < 3% of all study population and was used only by one centre. In the recent publication by Barbash et al. [22] the use of Proglide device was associated with improved outcomes as compared with Prostar. Additionally, the initial learning curve cases were not excluded from the analysis; however, all procedures were performed under direct proctor supervision.

Last but not least, the influence of unmeasured confounders on our analysis cannot be ruled out. The propensity score matching methodology adjusts for but does not control for non-random assignments to treatment. In particular, the important aspect of assignment to the type of vascular access was based upon local experience and potential technical issues compromising the safety of one or other approach. Furthermore, one cannot exclude the impact of the change in clinical practice, especially an increase in utilisation of CPC technique over time. These features are not easy to quantify, so randomisation remains the most appropriate and scientifically correct way to account for potential bias. That is why the presented results suggesting similar safety and efficacy of both approaches should be read with caution, and these techniques should rather be regarded as complimentary than competitive to each other.

CONCLUSIONS

The femoral access in TAVI can be obtained either with CPC or SCC, which both seem to provide similar safety and efficacy; therefore, there is no grounds to justify switching either from CPC to SCC or from SCC to CPC because it would probably not influence the outcomes. The experience of the operator seems to play the main role in the overall safety and efficacy of the procedure, so the choice between CPC and SCC should closely follow the local skills and practice. However, it should be underlined that our results are based on a retrospective analysis, and even the application of advanced statistical modelling does not control for non-random assignments to treatment. Therefore, a multicentre, randomised study is essential to provide the final and reliable assessment of these two methods.

Conflict of interest: *Zenon Huczek: proctor for Medtronic; Adam Witkowski: proctor for Medtronic; Marek Grygier: proctor for Medtronic and Boston Scientific, Advisory Board Member of Boston Scientific; Dariusz Jagielak: proctor for Edwards Lifesciences; Eberhard Grube: proctor for Medtronic and Boston Scienntific.*

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Cite this article as: Kochman J, Kołtowski Ł, Huczek Z, et al. Complete percutaneous approach versus surgical access in transfemoral transcatheter aortic valve implantation: results from a multicentre registry. Kardiol Pol. 2018; 76(1): 202–208, doi: 10.5603/KP.a2017.0205.