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Might simplification of transcatheter aortic valve implantation reduce the burden on hospital resources?

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Transcatheter aortic valve implantation (TAVI) varies considerably in terms of the procedural approach taken and the hospital length of stay (LoS); both directly affect the cost of care. Our coronary and standard cardiology unit aimed to simplify TAVI (and thus shorten the LoS) while maintaining safety. A shorter LoS would also reduce the burden on hospital resources and free up beds for other patients. Data on 214 consecutive patients undergoing TAVI at a single centre between April 2018 and March 2021 were retrospectively collected. A simplified protocol was implemented in January 2020; patients were stratified by whether they underwent TAVI before or after simplification. All procedural phases were simplified. For cost comparison purposes, the LoS was defined as the number of hospitalization days from admission to discharge. The total hospitalization cost was the sum of the direct and indirect (including reallocated overhead) costs. The LoS fell significantly (by 36%) after TAVI simplification. The times in the coronary care unit (CCU) and standard cardiac unit (SCU) also fell significantly (by 33% and 37% respectively). Patients in the simplified TAVI group were discharged, on average, 6 days after admission. The CCU costs decreased by 31% and the SCU costs by 39%. Transcatheter aortic valve implantation simplification did not compromise safety. Indeed, patients who underwent the simplified procedure seemed to develop fewer complications, especially bleeding. Transcatheter aortic valve implantation simplification significantly reduced the LoS and other costs without compromising patient safety.

Introduction

Transcatheter aortic valve implantation (TAVI) is effective and safe for patients with severe aortic stenosis.[1] Transcatheter aortic valve implantation is the preferred treatment option in high-risk patients but is also useful in intermediate-risk patients[2] and possibly also in low-risk patients.[3] The need for simplified ('fast-track') TAVI is increasing as the indications expand and populations age. To treat more patients efficaciously and safely, it is essential to reduce costs.[4] Over 350 000 TAVI procedures have been performed in more than 70 countries; TAVI has progressed remarkably in recent years, accompanied by simplification and standardization using modern transcatheter heart valves and novel procedures.[5] Transcatheter aortic valve implantation simplification shortens the hospital stay and reduces procedural costs.[6] Several studies have shown

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that early discharge is both feasible and safe.[7-9] A retrospective analysis conducted in Vancouver found that 38.2% of patients were discharged within 48 h of the procedure. The median length of stay (LoS) of such patients was 1 and 3 days for other patients.[10] A report from Copenhagen stated that 57.8% of patients were discharged within 48 h of the procedure and only 7.9% were hospitalized for more than 5 days.[4] Reducing the LoS lowers costs. However, patient safety remains imperative. Here, we aimed to describe the impacts of TAVI simplification on the LoS, care costs, and patient safety in a Czech environment for which no data are yet available.

Methods

Patient population and study design

This retrospective single-centre study was performed at the Faculty Hospital Královské Vinohrady as a component of the Intercardis project involving the Third Internal Cardiology Clinic of FNKV and Medtronic Czechia Ltd. The outcomes and results of the project will optimize the treatment of patients with cardiovascular disease. The study was approved by our local ethics committee and adhered to all relevant tenets of the Declaration of Helsinki. All consecutive patients (214) who underwent TAVI between 2018 and 2021 were included and were stratified by the period when TAVI was performed. A total of 115 patients underwent non-simplified TAVI between 1 April 2018 and 31 December 2019. A total of 99 patients underwent simplified TAVI between 1 January 2020 and 31 March 2021. We retrieved clinical data and costs from our patient registry and the 30-day mortality were from the Institute of Health Information and Statistics. Simplified TAVI was implemented from January 2020. Simplification featured a reduction in thrombotic medication, no routine urinary bladder catheterization in either males or females, and no repeat echocardiography (ECG) if ECG had been performed within the last 2 months and there was no change in the clinical condition. During the procedures, the anaesthesiologist was in the hall and the clinic for about half (each) of all cases. The site was chosen in advance by the invasive cardiologist. The right radial route was preferred for second arterial access and over-the-wire pacing was preferred to right ventricular pacing. Immediately after the procedure, the invasive cardiologist stratified the risk of TAVI complications:

(1) Low-risk (left ventricular ejection fraction >40%, no inotropic support, use of the femoral implantation route, good cooperation, and low risk of conduction abnormality) patients were observed in the coronary care unit (CCU) for 1 day only and discharge was planned for Day 4;

(2) Medium-risk (does not meet the low-risk criteria but TAVI was performed without any complication) patients were observed in the CCU for 1–2 days and discharge was planned for Day 4;

(3) High-risk (failed the low-risk criteria and suffered a periprocedural complication) patients required individualized (usually longer) intensive care and rehabilitation prior to discharge.

After TAVI, each patient was given a card with information on the type of prosthesis placed, the date and place of implantation, and the contact number of our Cardiology Clinic. Further monitoring (at the clinic) featured clinical examination by a valve defect specialist and transthoracic ECG at 6 weeks, 1, 5 years, and then every 5 years.

Cost accounting model

We used a micro-costing method that calculates the cost of individual health service components (e.g. catheterization, laboratory tests, computed tomography, and intensive care). The total cost of hospitalization was the sum of these costs. Three steps followed:

- overhead cost allocation;
- direct cost allocation; and
- indirect cost allocation.

Overhead costs

The overhead costs included those of centres that provided auxiliary services to other centres and were difficult to associate with specific health services (e.g. The IT department, accounting, human resources, and sterilization). These costs were reallocated to medical departments by the demands made by those departments (e.g. Number of requests for sterilization, and number of health professionals).

Direct costs

The direct costs covered all medications and materials consumed by specific patients (e.g. catheters, introducers, and or valve implantation sets). Direct costs were calculated by identifying the medications and materials each patient consumed.

Indirect costs

Departmental indirect costs were those not directly related to patients, such as the emoluments of medical staff, the amortization of devices, and materials. Indirect costs were allocated to patients using the cost drivers that best expressed the relationships between costs and the health services provided. The following cost drivers were defined:

- Number of days for standard units (wards);
- Length of stay (min) for CCUs;
- Length of stay (min) in the catheterization laboratory or operating room;
- Point values of health services provided by other medical departments.

The total cost of hospitalization amounted to the sum of the direct and indirect costs (including the reallocated overhead).

Statistical analysis

Continuous variables are presented (in graphs and tables) as means with standard deviations. The significance of between-group differences was explored using the

Student's *t*-test or the Mann-Whitney U-test. Categorical variables are presented as frequencies with percentages and were compared with the aid of the χ^2 or Fisher's exact test. Normality was tested using the Kolmogorov-Smirnov test. A *P*-value of <0.05 was considered significant. All analyses were performed with the aid of IBM SPSS Statistics ver. 26. Graphical analyses were conducted using Sigmaplot ver. 14.

Results

Patient population
A total of 214 patients who underwent TAVI were enrolled, of whom 99 underwent simplified TAVI and 115 non-simplified TAVI. Both groups exhibited similar baseline characteristics (*Table 1*). Patients in both groups were at intermediate surgical risk (mean logistic EuroScore I 11.4 vs. 10.6, respectively; *P* < 0.918). Most patients had native aortic valve stenosis (95.7% vs. 94.0%, respectively; *P* < 0.358). Previous TAVI had been performed on only one patient (in the simplification group); more patients in the simplification group had undergone previous aortic valve surgery (5.0% vs. 3.5%, respectively; *P* < 0.413).

Length of stay and cost of care
The total LoS, and the LoSs in the CCU and standard cardiac unit (SCU), was significantly shorter in the simplified group. The mean total LoS decreased by 36% (9.7 vs. 6.25 days, respectively; *P* < 0.001); the mean time in the CCU by 29% (3.7 vs. 2.51 days, respectively; *P* < 0.001), and the mean time in the SCU by 37% (5.9 vs. 3.75 days, respectively; *P* < 0.001). *Figure 1* compares the LoSs of patients who underwent non-simplified (red) and simplified (green) TAVI. The figure shows the mean LoS decreases in the simplified group.

All costs were divided into material and non-material costs. Non-material costs included those of preparation for intervention, interventions per se, the CCU and SCU stays, and other (operations, other procedures). A significant decrease (20%) in non-material costs was evident in the simplified group (181 161 vs. 144 963 CZK, respectively; *P* < 0.001) but the between-group difference in material costs was not high, as shown in *Figure 2*.

Length of stay reduction was associated with a significant decrease in the cost of hospitalization in the simplified group. Coronary care unit costs decreased by 31% (63 250 vs. 43 747 CZK, respectively; *P* < 0.001) and SCU costs by 39% (31 222 vs. 19 045 CZK, respectively; *P* < 0.001). The mean total cost decreased by almost 5% (752 017 vs. 712 933 CZK, respectively; *P* < 0.001). The time and cost of preparation before intervention decreased significantly in the simplified group, but the cost of intervention was less in the group lacking simplification. *Figure 3* shows the non-material expenses of both groups; the most significant non-material cost savings were those of the CCU and SCU costs.

Thus, TAVI simplification significantly reduced costs, principally by shortening the LoS. The highest savings were achieved by reducing CCU and SCU costs.

Procedural details, complications, and mortality
The Medtronic CoreValve Evolut R System was used to treat almost all of the patients. Only six (5.2%) patients in the non-simplified group received St. Jude Medical Portico valves. In almost all cases, TAVI was not urgent but, rather, optional (92.2% vs. 93.9% in the non-simplified and simplified groups, respectively; *P* < 0.515). The femoral artery was used for access in almost all patients (97.4% vs. 99.0% in the non-simplified and simplified groups, respectively; *P* < 0.153). The procedural details did not differ between the groups, with the exception of balloon pre-dilatation; TAVI simplification significantly reduced the need for this procedure. The incidence of complications did not differ significantly between the groups. Bleeding, the need for a new pacemaker, stroke, myocardial infarction, heart failure, *de novo* atrial fibrillation, *de novo* dialysis, and red blood cell transfusion were rare; no difference in 30-day mortality was observed. Indeed, post-TAVI complications were less common in the simplified group. The procedural details, complications, and 30-day mortalities are summarized in *Table 2*.

Transcatheter aortic valve implantation simplification did not exacerbate complications or increase 30-day mortality. Indeed, there seemed to be fewer complications after simplification, but the difference was not statistically significant.

Discussion

Our single-centre study evaluated the impact of TAVI simplification on the cost of care. Our major findings are:

(1) Transcatheter aortic valve implantation simplification significantly reduced the LoS and the cost of care. As TAVI simplification improves over time, even greater savings can be expected.
(2) Transcatheter aortic valve implantation without pre-dilatation was not associated with more complications than TAVI with pre-dilatation; the post-dilatation rates were similar in both groups. Safety was not adversely affected; indeed, there were fewer post-TAVI complications in the simplified group.

The LoS is a surrogate indicator of the cumulative effects of several factors including patient characteristics and risk profile, complications during the procedure, post-procedural care, the established procedures and protocols, the hospital culture, and technological advances.[11] One report concluded that a reduced LoS not only lowered costs but also increased hospital capacity and improved access to care.[12] We came to a similar view. Reducing the LoS lowered costs. Our simplified process was aimed not only at shortening the overall hospital stay but also the LoS in the CCU. We sought to discharge patients as early as possible without compromising safety. We believe that shorter periods in the CCU and a general ward make it easier for patients to return to full mobility and reduce the incidence of care complications. In terms of follow-up, we recorded only 30-day mortality, thus not the quality of life. Therefore, the optimal LoS after TAVI requires further attention.
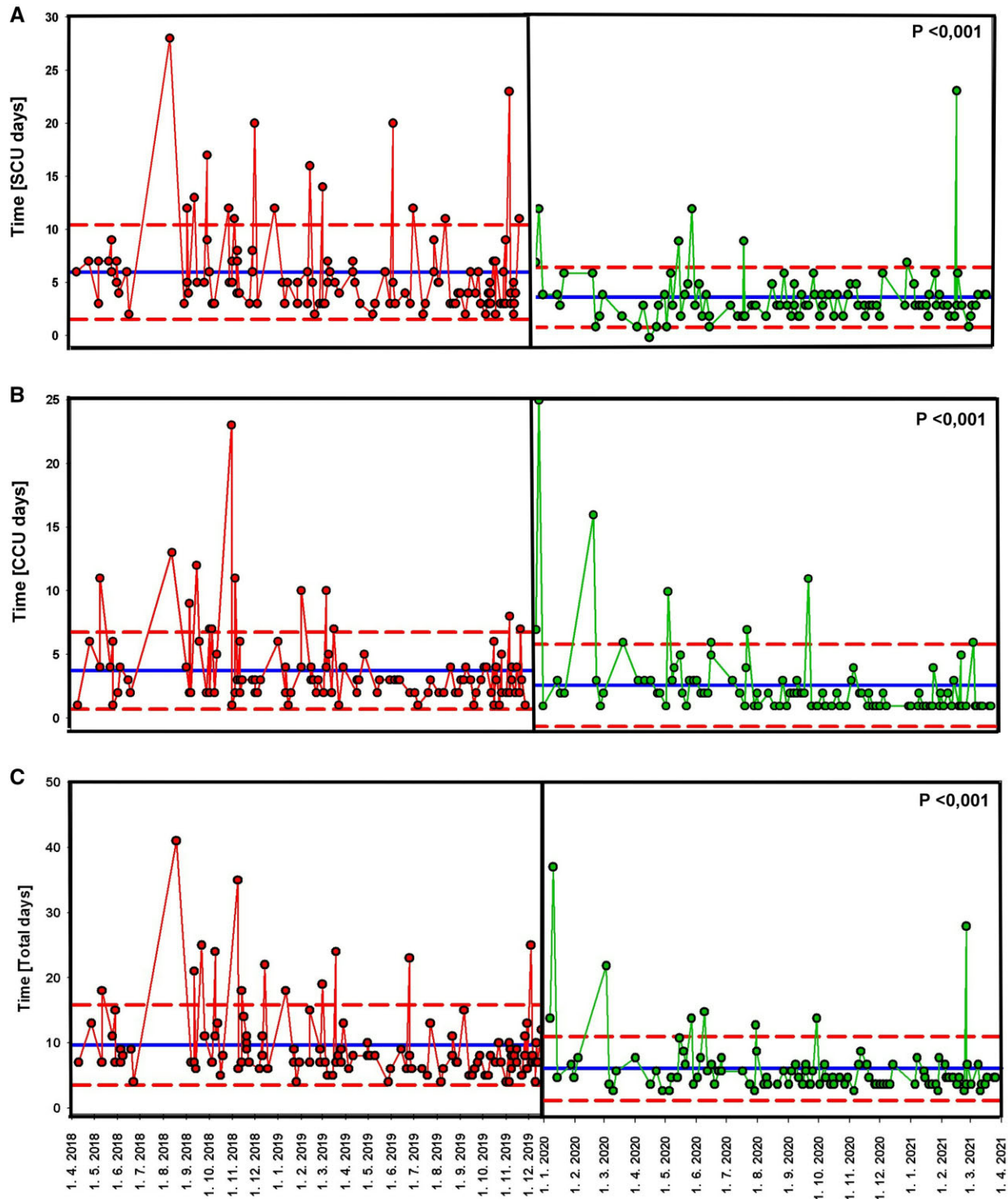
Figure 1 Comparison of hospital length of stays.

In our study, the mean total LoS in patients before TAVI simplification was 9.7 days and the CCU LoS 3.7 days, comparable to those of several earlier European registries. Most of our patients were implanted with the Medtronic CoreValve Evolut R. Data from the Italian CoreValve registry (June 2007 to December 2012) reveal that the median LoS was 8 days for patients treated under general anaesthesia and 7 days for those treated via local anaesthesia.[13] For TAVI patients treated between 2011 and 2015 in Switzerland, the mean LoS was 10.1 days.[14] Data on patients who underwent TAVI at a single centre from August 2008 and December 2017 in Geneva were prospectively collected. The mean LoS was 10.4 days, with a minimum of 2 and a maximum of 39 days. The median LoS was
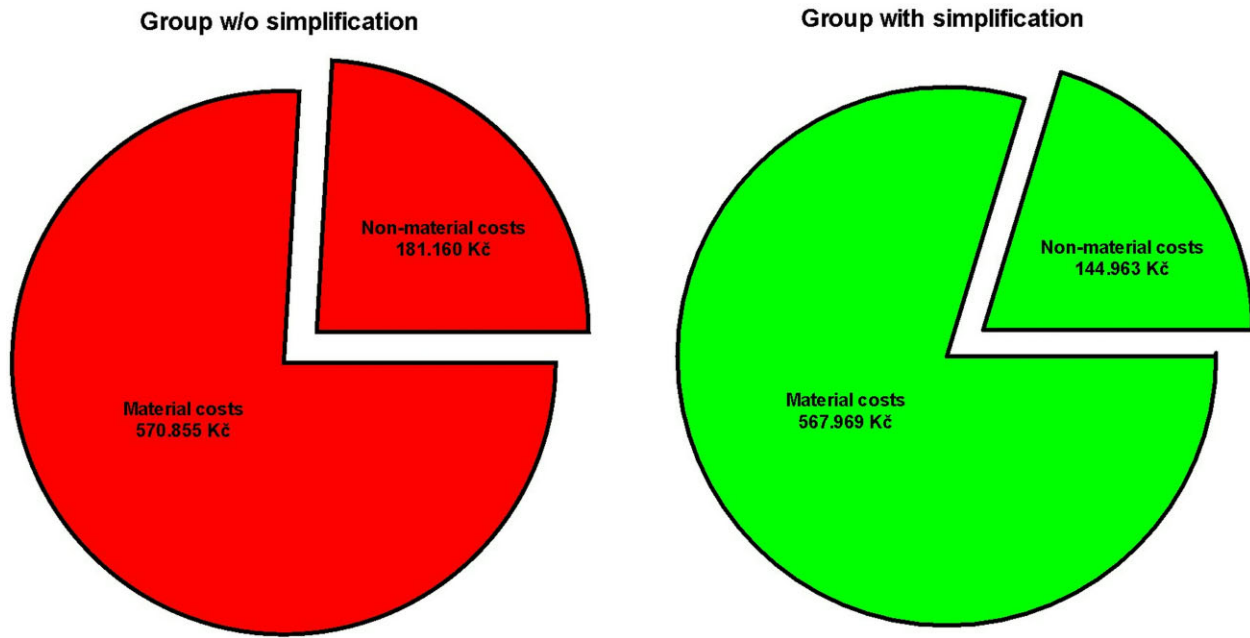
Group w/o simplification

Non-material costs
181.160 Kč

Material costs
570.855 Kč

Group with simplification

Non-material costs
144.963 Kč

Material costs
567.969 Kč

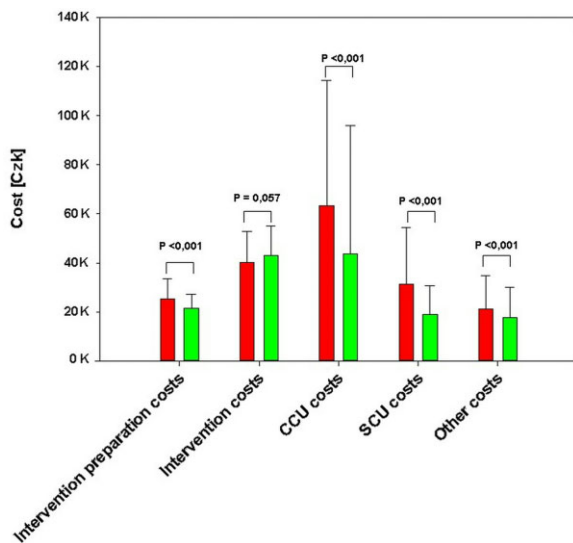**Figure 2** Comparison of material and non-material costs.

Figure 3 Distribution of non-material costs.

8 days.[15] These findings are supported by a prospective study conducted in Rotterdam between 2006 and 2010, where the mean total LoS after TAVI was 11.3 days.[16] However, different results were observed in the Pilot European Sentinel TAVI Registry. Patients from nine European countries and Israel implanted with Sapiens XT and CoreValves between January 2011 and May 2012 were included in the registry. Individual countries reported large LoS differences after TAVI; the mean LoS was 5.8 days in Israel but 12.6 days in Poland.[17] In contrast, some North American studies reported much shorter LoSs than European studies. In a study conducted in Vancouver between 2012 and 2014, 38.2% of patients were discharged within 48 h.[10] In a more recent study (March 2015 to April

2017), 80.1% of patients receiving Sapien XT (58.2%) or Sapien 3 (41.8%) valves were discharged the next day. The Vancouver 3M (Multidisciplinary, Multimodality, but Minimalist) Clinical Pathway features next-day discharge, aided by simplified and standardized guidelines for peri- and post-procedural care.[18] Although the LoS has steadily decreased since the time of TAVI introduction, a 2016 study reported that the median LoS in the USA remained between 3 and 5 days.[11] The European registries and North American studies thus suggest that the LoS is affected not only by the implantation time and the geographic region but also by the prosthesis used, the position of the surgeon on the learning curve and the type of anaesthesia induced (general or local). Although the marked differences in the LoSs may reflect local practice mores, they indicate that TAVI can be streamlined. We sought to reduce the total and CCU LoSs. The Czech Republic lacks LoS data; we cannot compare our LoSs to those of other centres. When we analysed only patients who underwent TAVI in 2021, we found a further significant decrease (compared with that from 2020 to 2021) in the CCU LoS (to 1.6 days), close to that of other centres that simplified TAVI and monitored patients for at least 12–24 h.[6]

The number of TAVIs will increase with time given population ageing and the expansion of the TAVI indications to younger and lower-risk patients. It is essential to prioritize cost-effectiveness. Many studies have already explored this topic in high-risk patients; current works evaluate intermediate- and low-risk patients. We achieved significant savings; the total LoS cost fell by 36%. However, comparisons with other centres are difficult; the reimbursement issues vary. Across US systems, the total savings in 2016 ranged from $6 500 000 to $16 300 000.[12]

In a prospective study in the Netherlands, the in-hospital and 1-year follow-up costs of patients at intermediate operative risk undergoing TAVI and surgical aortic valve

Table 1 The baseline characteristics of the patients

Characteristics	Non-simplification group (n = 115)	Simplification group (n = 99)	P-value
Sex (male/female)	53 (46.1%)/62 (53.9%)	53 (53.5%)/46 (46.5%)	0.154
Height (cm)	166.8 ± 9.4	168.2 ± 9.1	0.180
Weight (kg)	77.8 ± 15.9	82.8 ± 17.6	0.028
EuroScore I, logistic	11.8 ± 10.3	10.6 ± 7.9	0.918
EuroScore II	6.0 ± 7.3	4.7 ± 4.2	0.397
Smoker (current, former)	45 (39.1%)	45 (45.5%)	0.294
Dyspnoea status (NYHA I, II/III, IV)	50 (43.5%)/65 (56.5%)	34 (34.3%) 65 (65.7%)	0.613
Angina status (Class I, II/III, IV)	103 (89.6%)/12 (10.4%)	93 (93.9%)/ 6 (6.1%)	0.582
Diabetes mellitus	39 (33.9%)	44 (44.4%)	0.085
Hypertension	92 (80.0%)	86 (86.9%)	0.163
COPD	15 (13.0%)	11 (11.1%)	0.403
Previous dialysis	4 (3.5%)	3 (3.0%)	0.577
Previous stroke/TIA	18 (15.7%)	12 (12.1%)	0.284
Aortic valve area pre-TAVI (cm^2)	0.87 ± 0.26	0.89 ± 0.25	0.523
LVEF pre-TAVI	55.65 ± 12.20	53.85 ± 13.57	0.258
Previous myocardial infarction	24 (20.9%)	13 (13.1%)	0.089
Previous CABG	17 (14.8%)	14 (14.1%)	0.514
Previous PCI	38 (33%)	35 (35.4%)	0.437
Previous atrial fibrillation	49 (42.6%)	41 (41.4%)	0.460
Extracardiac arteriopathy	20 (17.4%)	14 (14.1%)	0.312
Syncope	30 (26.1%)	18 (18.2%)	0.104
Pacemaker	21 (18.3%)	14 (14.1%)	0.256

Values are n (%) or means ± SDs.

CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association Functional Classification; PCI, percutaneous coronary intervention; SD, standard deviation; TAVI, transcatheter aortic valve implantation; TIA, transient ischaemic attack.

replacement (SAVR) were calculated. The in-hospital costs for TAVI were EUR 40 802. Of this sum, the total cost of stay was EUR 8545 and the CCU cost EUR 2458. It was concluded that, for intermediate-risk patients with severe aortic stenosis, the 1-year cost was higher for TAVI than SAVR, attributable principally to the high cost of the transcatheter valve. This was not compensated for by the lower costs of blood products or the shorter LoS of TAVI patients.[16] However, costs will differ across the Czech Republic and other countries of the European Union. We believe that, without TAVI simplification, it will be difficult to treat more patients in future. Therefore, we are the first group in the Czech Republic to compare the LoSs and the costs of traditional and simplified TAVI. Simplification significantly reduced the LoS and the total cost. However, simplification must not compromise safety. We thus assessed 30-day mortality and the incidence of peri- and post-procedural complications.

In the early days of TAVI, balloon aortic valvuloplasty (BAV) was considered mandatory. However, BAV is associated with a risk of cerebral embolization, and severe acute aortic regurgitation may occur after pre-dilatation in up to 3% of cases. Currently, improvements in new-generation devices including paravalvular skirts, valve repositioning methods, lower-profile delivery systems, and prostheses have improved the outcomes.[6] Therefore, BAV seems to be no longer essential during TAVI; many centres no longer engage in pre-dilatation. We agree; balloon pre-dilatation was performed in only 11% of patients in the simplifed group; we found no adverse effects on clinical outcomes.

One of the most common complications after TAVI is a conduction system disturbance, i.e. an arm blockage or a complete heart block triggering a need for permanent pacemaker implantation. Such a disorder can greatly impact the patient's condition and long-term survival but is not usually fatal. Some researchers thus recommend that patients be monitored (via ECG) for at least 7 days, as most disturbances occur within the 1st week after the procedure.[19] The recent SWEDEHEART Observational Study reported that 14.1% of patients underwent permanent pacemaker implantation within 30 days of TAVI.[20] In our study, no difference was observed between the two groups; new pacemakers were implanted in 10% of patients. We expected that this figure would be lower. Thus, the fact that the two groups did not differ does not mean that there is no scope for further improvement.

Bleeding immediately after TAVI (or later) is usually associated with a poor outcome.[21] A recent meta-analysis reported that post-TAVI bleeding was associated with a 323% increase in 30-day postoperative mortality.[22] The POPular TAVI trial conducted at 17 European sites reported bleeding in 21.7% of patients receiving oral anticoagulants alone and in 34.6% of those on oral anticoagulants plus clopidogrel.[23] In our study, bleeding occurred in 9.6% of

Table 2 Procedural details and complications

	Non-simplification group (n = 115)	Simplification group (n = 99)	*P*-value
Procedural details			
TAVI valve size (mm)			0.202
23-27	45 (39.1%)	33 (33.3%)	
29-34	70 (60.9%)	66 (66.7%)	
Aortic regurgitation (final) (angiographically revealed)			0.334
None	34 (29.6%)	30 (30.3%)	
Mild	68 (59.1%)	61 (61.6%)	
Moderate to severe	13 (11.3%)	9 (9.1%)	
Aortic valve balloon pre-dilatation	26 (22.6%)	11 (11.1%)	0.020
Aortic valve balloon post-dilatation	10 (8.7%)	8 (8.1%)	0.536
Procedural complications			
Peri-TAVI			
Bleeding	7 (6.1%)	3 (3.0%)	0.358
All	10 (8.7%)	12 (12.1%)	0.478
Post-TAVI			
Bleeding	11 (9.6%)	4 (4.0%)	0.090
New pacemaker	12 (10.4%)	10 (10.1%)	0.559
All	35 (30.4%)	23 (23.2%)	0.142
30-day mortality	3 (2.6 %)	2 (2.0%)	0.570

Values are *n* (%).
TAVI, transcatheter aortic valve implantation.

patients in the non-simplified and in 4% of those in the simplified group. As the simplified protocol includes a reduction in thrombotic medication, these results are encouraging.

Follow-up studies are needed to demonstrate cost-effectiveness in low- and medium-risk patients and to confirm safety. However, our initial data suggest that simplification reduces costs while maintaining safety; the saved peri- and post-procedural care costs can be used to treat more patients.

Limitations

Our results should be interpreted with the following limitations in mind. This was a single-centre retrospective analysis that enrolled a small number of patients; the statistical power may thus be limited. We did not perform propensity score-matching, but the baseline characteristics of both groups were very similar. All data were self-reported; there was no central adjudication of clinical events. However, the definitions were those of VARC3 and 30-day mortality was derived from the national health information database.

Conclusions

We found that simplification of TAVI significantly reduced the LoS and thus care costs. We believe that TAVI simplification is a step in the right direction in terms of peri- and post-procedural care cost savings; we will be able to treat more patients. Despite the reduction in LoS (thus the earlier discharge of patients in the simplified group), safety was not compromised. We found no significant difference

in the incidence of complications between the two groups; indeed, post-TAVI complications seemed to be fewer in number in the simplified group.

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Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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