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ORIGINAL ARTICLE

Comparison of Standard Incision and Deep Incision Approaches in Terms of Bleeding and Vascular Complications in Patients Undergoing Percutaneous Transcatheter Aortic Valve Implantation

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Abstract

Introduction: In this study, we aimed to compare bleeding and vascular complications associated with deep incision (with removal of perivascular adipose tissue) and standard incision (without removal of perivascular adipose tissue) approaches in patients who underwent transcatheter aortic valve implantation (TAVI).

Methods: We retrospectively included 80 adult patients who underwent elective percutaneous TAVI at a tertiary cardiac center between 2012 and 2018. The percutaneous TAVI procedure was performed in 41 patients using the deep incision approach and in 39 patients using the standard incision approach. The primary outcome was bleeding and vascular complications.

Results: The percutaneous TAVI procedure was performed in 41 patients using the deep incision approach and in 39 patients using the standard incision approach. In the deep incision and standard incision groups, respectively, the number of female patients was 27 (65.9%) and 21 (53.8%), while the mean age was 80.46±6.43 years and 78.79±7.87 years. Bleeding, according to the VARC-2 (The Valve Academic Research Consortium-2 Consensus Document) criteria, was lower in the deep incision group but did not reach statistical significance: 17 (41.5%) in the deep incision group vs. 19 (50%) in the standard incision group (p=0.447). Mean hemoglobin decline (g/dL) was significantly lower in the deep incision group (0.55±1.44) compared to the standard incision group (1.93±1.98) (p=0.001). The results for in-hospital mortality, hematoma, pseudoaneurysm, femoral artery dissection, and stenosis were similar between the two groups.

Discussion and Conclusion: In patients undergoing percutaneous TAVI, the mean hemoglobin decline was found to be lower in those who underwent the deep incision approach compared to the standard incision approach. No significant difference was found between the two methods in terms of vascular complications and other bleeding complications.

Keywords: Aortic valve stenosis; bleeding; transcatheter aortic valve implantation; transcatheter aortic valve replacement; vascular complication.

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Aortic stenosis is the predominant valvular pathology requiring intervention in North America and Europe. As the older population grows, its prevalence is concurrently increasing. The frequency of aortic valve sclerosis is around 4-5% in individuals under the age of 65, increasing to 25% above 65 and rising to 48% above 75.

Aortic stenosis has become the most common reason for transcatheter interventions, similar to valve surgery, among structural heart diseases[1]. TAVI has evolved over the last two decades from an experimental procedure to a well-established therapeutic alternative for patients with symptomatic aortic stenosis at elevated surgical risk[2,3].

The definitive intervention for aortic stenosis is surgical aortic valve replacement (SAVR). The mortality rate of SAVR performed under ideal conditions is 4%. However, the incidence of operative mortality and postoperative complications increases due to comorbid conditions such as coronary artery disease, age, chronic obstructive pulmonary disease, renal insufficiency, and low left ventricular ejection fraction. Due to these factors, surgery cannot be performed in one-third of patients. At this point, TAVI has emerged as a favorable option for these patients, who are considered more likely to be harmed than helped by surgery and would otherwise remain untreated[4].

Patients with severe aortic stenosis now have a less invasive alternative to surgical valve implantation, known as TAVI. This procedure provides faster recovery, a shorter stay in the critical care unit and hospital, and a reduced risk of bleeding[5]. Due to the minimally invasive nature of TAVI, blood loss is minimal, and the inflammatory response is also significantly lower[6,7].

In individuals undergoing TAVI, vascular complications and procedure-related bleeding are significant concerns in terms of mortality. The transfemoral (TF) TAVI procedure can be performed using either a percutaneous or surgical approach. In percutaneous procedures, the incision method at the entry site can be performed in two ways: deep incision (with the removal of subcutaneous fat tissue) and standard incision (without the removal of subcutaneous fat tissue). These methods have not been extensively compared in terms of complications and outcomes in previous studies. Determining whether one of these methods has an advantage over the other may help reduce complications and mortality associated with the percutaneous TF-TAVI procedure.

In this study, we examined the bleeding and vascular complications of patients who underwent percutaneous TAVI with either a deep or standard incision. In this regard, we aimed to determine whether one method offers an advantage over the other.

Materials and Methods

We retrospectively screened 90 patients who underwent percutaneous transcatheter aortic valve implantation at our hospital between August 2012 and July 2018 to compare the deep and standard incision entry methods. To avoid potential learning curve interactions, we excluded the first five patients who underwent percutaneous TF-TAVI using the deep incision method and the first five patients who underwent percutaneous TF-TAVI using the standard incision method. The study included the remaining 80 patients who underwent percutaneous TF-TAVI.

Percutaneous TAVI was performed in 41 patients using the deep incision approach and in 39 patients using the standard incision approach. The investigation was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of Haydarpaşa Numune Training and Research Hospital of the İstanbul Provincial Health Directorate (HNEAH-KAEK 2018/82). Due to the retrospective nature of the study, individual patient consent was not required.

Demographic characteristics and comorbidities were documented as baseline characteristics. Laboratory and echocardiographic parameters were recorded before and after the procedure. All patients who underwent TAVI via the percutaneous route were divided into two groups based on the incision method: deep incision and standard incision.

Outcomes

The primary endpoints of the study were determined according to the VARC-2 criteria[8] and included bleeding complications, hematoma, pseudoaneurysm, stenosis, and femoral dissection. This evaluation also included the length of hospitalization and in-hospital mortality.

Statistical Analysis

The NCCS (Number Cruncher Statistical System, Kaysville, USA) software was used for all statistical analyses. Categorical data are presented as percentages, while continuous variables are displayed as mean±standard deviation.

The distribution of continuous variables was assessed using the Kolmogorov-Smirnov test and histogram analysis for a single sample. In cases where the distribution was normal and variance was equal, differences between groups containing continuous variables were examined using Student's t-test. The equality of variances was assessed using Levene's test. In cases where the distribution was not normal or when one group contained fewer than 10 samples, the Mann-Whitney U test was used.

For categorical variables, the χ^2 or Fisher's exact test was applied according to the appropriateness of sample sizes in the compared groups. A p-value<0.05 was considered statistically significant in all analyses. All tests were conducted within a 95% confidence interval (95% CI).

Results

Between August 2012 and July 2018, 80 patients who underwent percutaneous TF-TAVI were included in the study. Of these, the deep incision approach was used in 41 patients (51.2%), while the standard incision approach was used in 39 patients (48.8%).

In the deep and standard incision groups, there were 27 female patients (65.9%) and 21 female patients (53.8%), respectively (p=0.273). The average age was 80.46±6.43 years in the deep incision group and 78.79±7.87 years in the standard incision group (p=0.301), with no statistically significant difference. The CT annulus diameter was 26.77±3.08 mm in the deep incision group and 27.03±3.31 mm in the standard incision group (p=0.736), showing no difference. The LV EF (%) was 47.68±12.25 in the deep incision group and 50.25±11.52 in the standard incision group (p=0.300), with no statistically significant difference.

In the deep and standard incision groups, respectively, hypertension (HT) was observed in 33 patients (80.5%) and 34 patients (87.2%) (p=0.417); chronic obstructive pulmonary disease (COPD) in 8 patients (19.5%) and 14 patients (35.9%) (p=0.101); and previous cardiac surgery in 10 patients (24.4%) and 16 patients (41%) (p=0.112). The patients' coronary artery disease (CAD), body mass index (BMI), creatinine level, femoral artery diameter, and other essential characteristics, primarily based on imaging methods, were similar between the deep and standard incision groups (Table 1).

Table 1. Demographic and Baseline Properties of Study Patients

	Standard Incision (n=39)	Deep Incision (n=41)	P
Age (year)	78.79±7.87 (80)	80.46±6.43 (81)	0.301
Female Gender, n (%)	21 (53.8)	27 (65.9)	0.273
BMI (Body Mass Index) (kg/m^2)	27.56±3.65 (26.6)	27.58±3.81 (27)	0.979
Hypertension, n (%)	34 (87.2)	33 (80.5)	0.417
Diabetes, n (%)	14 (35.9)	21 (51.2)	0.167
Smoker, n (%)	6 (15.4)	3 (7.3)	0.254
Coronary Artery Disease, n (%)	22 (56.4)	20 (48.8)	0.495
Chronic Obstructive Pulmonary Disease, n (%)	14 (35.9)	8 (19.5)	0.101
Previous Cardiac Surgery, n (%)	16 (41)	10 (24.4)	0.112
Creatinine (mg/dL)	0.97±0.25 (0.9)	1.19±0.91 (1)	[b]0.120
STS (Society of Thoracic Surgeons) Score	11.02±8.48 (9.2)	5.84±2.61 (5.6)	[b]0.026*
Logistic EuroSCORE	15.78±11.8 (13)	29.74±11.1 (27.7)	[b]0.001**
Echocardiographic Parameters			
LVEF (Left Ventricular Ejection Fraction) (%)	50.25±11.52 (55)	47.68±12.25 (50)	[b]0.300
AVA (Aortic Valve Area), cm^2	0.72±0.15 (0.7)	0.72±0.17 (0.7)	0.945
Mean aortic gradient (mmHg)	49.05±12.89 (49)	51.48±15.93 (48)	[b]0.780
Maximum aortic gradient (mmHg)	80.84±19.42 (80)	82.31±21.44 (78)	[b]0.900
Pulmonary Artery Pressure (mmHg)	46.35±15.25 (46)	46.02±15.65 (45)	0.926
Electrocardiography Findings			
Atrial fibrillation, n (%)	9 (25)	11 (26.8)	0.855
CT Findings			
Femoral artery diameter, (mm)	8.46±1.24 (8.5)	8.65±1.34 (8)	[b]0.767
Aortic annulus diameter, (mm)	27.03±3.31 (27.5)	26.77±3.08 (26)	0.736

Student t Test; [b]Mann Whitney U Test; Pearson Chi-Square Test Fisher's Exact Test; *p<0,05; **p<0,01.

Table 2. Valve Diameters and Types Used In The Process

	Standard Incision (n=39)	Deep Incision (n=41)	p
Valve Diameter (mm), n (%)			
20	2 (5.4)	0 (0)	
23	10 (27)	4 (9.8)	
25	1 (2.7)	2 (4.9)	
26	8 (21.6)	16 (39)	0.141
27	3 (8.1)	3 (7.3)	
29	13 (35.1)	14 (34.1)	
34	0 (0)	2 (4.9)	
Valve Types, n (%)			
Edwards Sapien XT/3	31 (83.8)	19 (46.3)	
Lotus	6 (16.2)	0 (0)	0.001**
Core-valve	0 (0)	17 (41.5)	
Evolut R	0 (0)	5 (12.2)	

Pearson Chi-Square Test; Fisher's Exact Test; **p<0,01.

All patients in the study underwent TAVI via the percutaneous TF approach. The distribution of valve diameter and brand used in patients is shown in Table 2. In patients who underwent percutaneous TF-TAVI, according to VARC-2 criteria, bleeding was observed in 17 cases (41.5%) in the deep incision group and in 19 cases (50%) in the standard incision group (p=0.447), showing a statistically non-significant increase in bleeding in the standard incision group.

When bleeding was classified according to VARC-2 as minor, major, or life-threatening:

- Minor bleeding was detected in 7 cases (17.1%) in the deep incision group and in 12 cases (31.6%) in the standard incision group (p=0.132), showing a statistically non-significant increase in the standard incision group.
- Major bleeding was observed in 5 patients (12.2%) in the deep incision group and in 6 patients (15.8%) in the standard incision group (p=0.645), with no significant difference between the two groups.
- Life-threatening bleeding was detected in 5 patients (12.2%) in the deep incision group and in 1 patient (2.6%) in the standard incision group. Considering the small number of patients and the lack of power analysis, a non-statistically significant increasing trend in life-threatening bleeding was observed in the deep incision group.

The average hemoglobin decrease (g/dL) was 0.55±1.44 (0.7) in the deep incision group and 1.93±1.98 (1.5) in the standard incision group (p=0.001), showing a statistically significant lesser decrease in hemoglobin in the deep incision group. Postoperative hemoglobin (g/dL) was 10.66±1.83 (10.4) in the deep incision group and 10.46±1.76 (10.1) in the standard incision group (p=0.634), with no statistically significant difference.

The length of hospital stay (days) was 6.77±4.78 (6) in the deep incision group and 5.78±4.83 (4) in the standard incision group (p=0.387), with no statistically significant difference. Similar results were found between the two groups in terms of in-hospital mortality, hematoma, pseudoaneurysm, femoral dissection, and stenosis (Table 3).

Table 3. In-Hospital Bleeding and Vascular Complications

	Standard Incision (n=39)	Deep Incision (n=41)	P
Bleeding n (%)	19 (50)	17 (41.5)	0.447
Minor bleeding n (%)	12 (31.6)	7 (17.1)	0.132
Major bleeding n (%)	6 (15.8)	5 (12.2)	0.645
Life-Threatening bleeding n (%)	1 (2.6)	5 (12.2)	0.203
Mean hemoglobin decline (g/dl)	1.93±1.98 (1.5)	0.55±1.44 (0.7)	[b]0.001**
Post-procedure hemoglobin (g/dl)	10.46±1.76 (10.1)	10.66±1.83 (10.4)	0.634
Hospital stay (day)	5.78±4.83 (4)	6.77±4.78 (6)	0.387
In-hospital mortality n (%)	2 (5.1)	6 (14.6)	0.265
Hematoma	4 (10.3)	3 (7.5)	0.712
Pseudoaneurysm	2 (5.1)	2 (5)	1.000
Femoral dissection	1 (2.6)	2 (5)	1.000
Stenosis	1 (2.6)	4 (10)	0.359

Student t Test; [b]Mann Whitney U Test; Pearson Chi-Square Test Fisher's Exact Test; **p<0,01

Discussion

In this retrospective, single-center study, the mean hemoglobin decline was lower in the deep incision group when comparing standard and deep incision approaches in patients undergoing percutaneous TAVI. When evaluated in terms of vascular and other bleeding complications, no significant difference was found between the two methods.

In our study, the baseline characteristics between the two groups were generally similar. While the STS score was higher in the standard incision group, the higher Logistic EuroSCORE in the deep incision group is thought to be due to the different parameters that make up these scoring systems. Piazza and colleagues determined that the STS score more effectively recognized the existing risk,[9] while Dewey and Anderson observed that the STS score underestimated the risk in high-risk patients[10,11].

In patients undergoing TAVI, vascular complications influence both mortality and morbidity, thereby determining prognosis[12]. In a study conducted by Holper and colleagues, TAVI patients who underwent surgical and percutaneous interventions were randomly compared, and no differences were found in terms of vascular and bleeding complications[13]. Similarly, a study involving 683 patients found that percutaneous and surgical methods yielded comparable results in terms of bleeding and vascular complications[14].

Proglide and Prostar XL percutaneous closure devices were evaluated in a study by Barbanti and colleagues, and Prostar XL was found to be safer in terms of vascular complications[15]. However, in a large multicenter study conducted by Barbash and colleagues, the Proglide vascular closure device was found to be safer than the Prostar XL[16]. The Proglide device is more widely used due to its simplicity and lower profile[17,18].

In this study, the deep incision group exhibited a significantly smaller hemoglobin decline. It is believed that Proglide provides improved bleeding management by enabling more secure femoral artery closure through the deep incision approach.

In our study, major bleeding and other vascular complications were observed at similar rates. Other in-hospital events also had comparable outcomes between the two groups.

The percutaneous approach has rapidly evolved in recent years and is increasingly preferred by experienced centers for TAVI. These techniques, which require a technical learning curve, continue to be refined over time. In a recently published study, Proglide and MANTA percutaneous closure methods were compared, and no differences were found in terms of major bleeding and other vascular complications[19].

Regarding hemoglobin decline, the deep incision approach appeared to be superior to the standard incision approach in our study. Similar results were obtained concerning vascular and other bleeding complications. However, the current literature has primarily focused on comparisons between surgical and percutaneous methods, with limited research on the superiority of deep incision versus standard incision approaches in terms of vascular and bleeding complications. Considering these factors, the deep incision approach, when performed by centers with sufficient experience in percutaneous TF-TAVI, may be a viable alternative to the standard incision approach in certain patient groups, particularly those with a high risk of bleeding.

Study Limitations

This study has several limitations. The primary limitation is the relatively small patient population, and an additional constraint is its single-center design. Due to these factors, the study's power is insufficient. Additionally, because of the retrospective nature of the study, certain parameters that could influence statistical outcomes—such as tortuosity, calcification, and procedure duration—could not be included in the analysis.

Conclusion

In patients undergoing percutaneous TAVI, when comparing deep and standard incision approaches, mean hemoglobin decline was found to be lower in the deep incision group. However, when evaluated in terms of vascular and other bleeding complications, no significant difference was observed between the two methods.

Ethics Committee Approval: The study was approved by Haydarpaşa Numune Training and Research Hospital Ethics Committee (No: HNEAH-KAEK 2018/82, Date: 03/12/2018).

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