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RESEARCH ARTICLE

NON-ACCESS SITE COMPLICATIONS IN TRANSCUTANEOUS AORTIC VALVE REPLACEMENT

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ABSTRACT

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Background: Transcatheter aortic valve replacement for severe aortic stenosis patients became an acceptable non inferior alternative to routine surgical replacement with good outcomes in high-risk patients and inoperable patients. But a new group of complications start to be encountered after performing this procedure, one of these groups is non-access site complication. Objectives: in this study we try to find the incidence of post transcutaneous aortic valve replacement complications, especially non-access site complications, and try to find if there are any association between some risk factors and complications incidence. Methods: From 2015 to 2022, a total of 89 patients can be followed in transcutaneous aortic valve replacement clinic at queen alia heart institute. baseline patient characteristics, procedural details, and clinical outcomes retrospectively collected through reviewing their electronic medical files. We evaluated the total cohort for different types of complications, especially the following: post procedural acute kidney injury, post procedural high degree atrioventricular block mandating permanent pacemaker implantation, post procedural cerebrovascular accident, post procedural paravalvular leak and intraprocedural acute pulmonary edema. We try to find a relationship between. These major complications and certain risk factors as diabetes, hypertension, pre-existing chronic kidney disease, associated mitral valve dysfunction, preexisting conduction abnormalities and left ventricular dysfunction. Study population also divided into subgroups according to age and gender, and we try to find a difference between these subgroups regarding incidence of complication. *Results:* Mean patient age was 80 ± 7 years, 49.4% of the patients were women, 84.3% were hypertensive, 39.3% were diabetic, 7.9% were chronic kidney disease patients, 5.6% had a history of cerebrovascular accident. 3.4% had post procedural moderate paravalvular regurgitation, 15.4% developed high degree atrioventricular block mandating permanent pacemaker implantation, 7.9% developed intraprocedural acute pulmonary edema, 6.7% developed post implantation cerebrovascular accident and 4.5% developed post procedural acute kidney injury. *Conclusions:* various type of complication can be encountered and should be managed promptly after Transcatheter aortic valve replacement, addressing and studying these complication should be encouraged worldwide as this procedure became a novel strategy in managing severe aortic stenosis, right heart catheterization for filling pressure measurement and controlling co-morbidities as diabetes and hypertension may decrease the incidence of transcatheter aortic valve replacement periprocedural complications.

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INTRODUCTION

Aortic stenosis is associated with increased mortality rates after appearance of its related symptoms, knowing that many patients do not undergo surgical aortic valve replacement due to high operative risk associated with surgery which make them more vulnerable for devastating consequences related to morbidity and mortality.¹ Three decades before, the idea of Transcatheter intervention for aortic stenosis start to be investigated by cardiovascular professionals, and lastly in 2002 Cribier demonstrated for the first time the proof that transcatheter aortic valve intervention can be used instead of surgical option.² A lot of recent studies results have established a strong evidence that transcatheter aortic valve replacement can be considered a safe and effective alternative to surgical aortic valve replacement in high risk patients or patients with prohibitive operative risk.^{3,4,5} This new developing procedure (transcutaneous aortic valve replacement) is basically a left heart catheterization and depending on the delivery of the new prosthetic valve to the site of implantation through accessing a peripheral artery (femoral artery for example) as an entry point to the arterial circulation and advancing the new valve in a retrograde manner.⁶ As all other angiograms its mandatory to use a contrast agent during this procedure in addition to advancing a pacing wire during aortic valve ballooning and valve implantation.^{7,8} As this procedure start to be used in a wide range, a new emerging complication for aortic valve replacement start to be a great concern for the operating

physician and health care providers. Multiple trials investigate the outcome of this new procedure as well as the complication rate.^{9,10} the newly emerged complications for this new procedure are Acute aortic insufficiency, pericardial effusion (typically from right ventricular perforation by the pacing wire or aortic root trauma), coronary arteries occlusion, stroke, valve embolization, peripheral artery complications of the access site, conduction system complications and contrast use complication as cardiotoxicity, acute kidney injury and allergic reaction.^{9,10} a lot of recent studies concentrate on access site complications as they are more prevalent and lead to significant morbidity and mortality.¹¹ In this study we try to estimate the incidence of non-access site complications in patients underwent transcatheter aortic valve replacement in queen alia heart institute.

METHODS

From 2015 to 2022, 116 patients underwent TAVR in queen alia heart institute, 89 of them can be followed in this study through the transcutaneous aortic valve replacement follow up clinic. baseline patient characteristics, procedural details, and clinical outcomes data from a series of these patients who underwent TAVI were retrospectively collected using hospital electronic database. All patients had echocardiogram review by echocardiogram laboratory specialist. aortic valve, aorta and peripheral arteries computed tomography angiograms done and reviewed by radiology specialist for valve size, annular size, coronary ostia heights and patency of peripheral arteries that will be used as an access for valve delivery. Before valve replacement procedure all of them were screened for coronary artery diseases by invasive coronary angiography or coronary computed tomography angiogram, all obstructive coronary arteries diseases revascularized accordingly by percutaneous coronary artery intervention as they are already labelled high risk for surgery before the procedure. All candidates were approached with bilateral femoral artery access and one femoral vein access for temporary pacemaker lead and all implanted valves were Medtronic corevalve. Patients electronic files reviewed for age, sex, body mass index, comorbidities, left ventricular function, base line electrocardiogram, valve abnormalities, coronary artery angiogram findings, implanted valve size, in addition to intra and post procedural complication. Complication of transcutaneous aortic valve replacement then divided into multiple groups including valvular complication, coronary arteries complication, conduction complication, non-access site bleeding, blood transfusion, thrombocytopenia, acute kidney injury and vascular complication. Study population also subdivided into two groups according to age and gender, then the rate of complication compared between the groups. SPSS program was used for statistical analysis. Simple descriptive analysis and odd's ratio were used to estimate the incidence and differences of transcatheter aortic valve replacement complications.

RESULTS

Total number of 89 patients included in this study, all of them have symptomatic severe aortic stenosis and deemed high risk for surgical aortic valve replacement after cardiac surgery assessment the median age for the patients was (80 \pm 7) year, male to female ratio was nearly 1:1 (45:44), the median body mass index was 30 ± 5.3 with maximum body mass index 47.3 and minimum 19.9. 75 patients were hypertensive (84.3%), 35 patients were diabetic (39.3%), 5 patients had a history of cerebrovascular accident (5.6%), 7 patients were chronic kidney disease patients (7.9%), 4 patients had peripheral vascular disease (4.5%), 6 patients were chronic obstructive pulmonary disease patients (6%), 7 patients were hypothyroid (7.9%) and one patient was chronic liver disease patient. Regarding patient's baseline electrocardiogram findings, 13 of them have atrial fibrillation (14.6%), 78 of them have narrow QRS complex (87.6%), 8 patients have wide QRS complex (9%) and 3 of them already have implanted permanent pacemaker (3.4%). Regarding echocardiograms findings in addition to severe aortic valve stenosis, 70 patients have normal left ventricular function (78.7%), 11 patients have mild left ventricular function impairment (12.4%) and 8 patients have moderate left ventricular function impairment (9%). 6 of them also have moderate aortic regurgitation (6.7%), 50 patients have mild to moderate mitral regurgitation (56%), 4 patients have moderate mitral stenosis (4.4%), only one patient has mixed moderate mitral regurgitation and moderate mitral stenosis (1.1%). From coronary arteries angiography point of view, 40 patients (44.9%) didn't have obstructive coronary arteries disease, while 15 of them had single vessel disease (16.9%), 11 had two vessel disease (12.4%) and 3 of them had three vessel disease (3.4%), all of them were treated with percutaneous coronary artery intervention before valve implantation procedure. 20 of the study patients have already underwent aorto-coronaries bypass surgery (22.5%) and also screened and managed by native coronary artery or grafts percutaneous intervention.

All of the implanted valves were Medtronic corevalve, 45 of them were 29mm valves (50.5%), 28 of them were 26mm valves (31.4%), 10 of them were 34mm valves (11.4%). 40 transcutaneous aortic valve replacement procedures were uneventful (44.9%), while the other 49 procedures were complicated by various types of complication's ranging from minor access site bleeding up to death (55.1%). Post valve implantation 60 patients had no aortic regurgitation (67.4%), 26 patients had mild aortic regurgitation (29.2%), while only 3 patients had moderate aortic regurgitation despite post dilatation (3.4%). 52 patients had no change in QRS duration after valve implantation (58.4%), while 23 patients developed QRS prolongation but less than 50% of the baseline duration (25.8%) and 14 patients developed high degree atrioventricular block mandating permanent pacemaker implantation (15.4%). Pericardial effusion developed in 6 patients (6.7%), 2 of them lead to cardiac tamponade. Access site complication (hematoma & dissection) found in 6 patients (6.7%), intraprocedural acute pulmonary edema developed in 7 patients (7.9%), right ventricular perforation happened in 2 patients (2.2%), non-access site bleeding happened in 4 patients (4.5%); 2 abdominal wall hematoma's, 1 upper gastrointestinal bleeding and 1 hematuria. During hospital stay, Infection developed in 7 patients (7.9%), 4 of them diagnosed as chest infection, 1 urinary tract infection and 1 diagnosed as sepsis. Iliac and femoral arteries perforation happened in 7 patients (7.9%), thrombocytopenia developed in 4 patients (4.5%).

post implantation cerebrovascular accident developed in 6 patients (6.7%), all of them were hypertensive patients. 4 patients developed acute kidney injury (4.5%), 2 patients developed acute limb ischemia (2.2%) and only one patient had coronary artery occlusion after valve implantation. 32 patients need blood transfusion (36%) for procedural blood loss, access site complication and bleeding.

Intraprocedural acute pulmonary edema and mitral valve: Regarding the 7 patients who developed intraprocedural acute pulmonary edema, all of them have mild to moderate mitral regurgitation, 38 patients who had normal mitral valve none of them developed intraprocedural acute pulmonary edema (0.0%), while the 51 patients who had mild to moderate mitral regurgitation 7 of them developed intraprocedural acute pulmonary edema (13.7%). The odds ratio (OR) for developing intraprocedural acute pulmonary edema in patients with mild mitral regurgitation or more relative to patients with no mitral regurgitation was 12.9 [95% confidence interval (CI) = 0.71-234.7] p = 0.08.

Intraprocedural acute pulmonary edema and left ventricular function: Patients with normal left ventricular function who developed intraprocedural acute pulmonary edema were 4 out of 70 (5.7%), while those with mild left ventricular dysfunction were 1 out of 11 (9.0%) and those with moderate left ventricular dysfunction were 2 out of 8 (25.0%). The odds ratio (OR) for developing congestion in patients with mild left ventricular dysfunction relative to patients with normal left ventricular function was 1.65 [95% confidence interval (CI) = 0.16-16.3] p=0.66.

The odds ratio (OR) for developing congestion in patients with moderate left ventricular dysfunction relative to patients with normal left ventricular function was 5.5 [95% confidence interval (CI) = 0.83-36.5] p=0.07.

Pre procedural QRS complex and developed high degree block mandating atrioventricular permanent pacemaker implantation: The 78 patients with narrow QRS complex baseline electrocardiogram only 8 patients developed high degree atrioventricular block mandating permanent pacemaker implantation (10.3%), while the 8 patients with wide QRS complex baseline electrocardiogram, 6 of them developed high degree atrioventricular block and require permanent pacemaker implantation (75%). The odds ratio (OR) for developing complete heart block in patients with wide QRS complex base line ECG relative to patients with narrow QRS complex base line ECG was 26.25 [95% confidence interval (CI) = 4.5 - 152.5 p=0.0003.

Acute kidney injury in hypertensive or diabetic patient's: Regarding the 4 patients who developed acute kidney injury post procedure all of them were diabetic and hypertensive, while all non-diabetic & non-hypertensive patients showed normal postprocedural kidney function test. Regarding chronic kidney disease patients, 1 patient developed postprocedural acute kidney injury (14.3%), while 3 patients of the non-chronic kidney disease patients developed postprocedural acute kidney injury (3.6%). The odds ratio (OR) for developing acute kidney injury in patients with chronic kidney disease relative to patients without chronic kidney disease was 4.4 [95% confidence interval (CI) = 0.40-48.8] p=0.23.

Age groups analysis: Study population further divided into two groups, the first is 54 patients' group with age equal or more than 80 years (61.8%), the second is 35 patients' group with age below 80 years (38.2%). In overall complication, 29 patients of the First group have developed complication (52.7%) while 20 patients of the second group have complication (58.8%). The odds ratio (OR) for developing complications in patients of equal or more than 80 years age group relative to patients of less than 80 years age group was 0.781 [95% confidence interval (CI) = 0.33-1.85]. post implantation cerebrovascular accident developed more in above 80 years age group, 6 patients (11%), while none of the less than 80 years age group developed this complication. The odds ratio (OR) for developing post implantation cerebrovascular accident in patients with age equal or more than 80 years relative to patients with age less than 80 years was 9.51 [95% confidence interval (CI) = 0.52-174.5] p = 0.13.

Intraprocedural acute pulmonary edema developed in 2 of 54 patients in the equal or more than 80 years age group (3.7%) and in 5 of 35 patients in the less than 80 years age group (14.3%). The odds ratio (OR) for developing intraprocedural acute pulmonary edema in patients with age equal or more than 80 years relative to patients with age less than 80 years was 0.23 [95% confidence interval (CI) = 0.04-1.26] p= 0.09. Postprocedural acute kidney injury developed in 2 of 54 patients in the equal or more than 80 years age group (3.7%) and in 2 of 35 patients in the less than 80 years age group (5.7%). The odds ratio (OR) for developing Postprocedural acute kidney injury in patients with age equal or more than 80 years relative to patients with age less than 80 years was 0.63 [95% confidence interval (CI) = 0.08-4.72] p= 0.65. postprocedural paravalvular leak of more than moderate severity developed in 2 of 54 patients in the equal or more than 80 years age group (3.7%) and in 1 of 35 patients in the less than 80 years age group (2.8%). The odds ratio (OR) for developing postprocedural paravalvular leak of more than moderate severity in patients with age equal or more than 80 years relative to patients with age less than 80 years was 1.3 [95% confidence interval (CI) = 0.11-14.9] p= 0.82. high degree atrioventricular block mandating permanent pacemaker implantation developed in 6 of 54 in the equal or more than 80 years age group (11%) and 8 of 35 patients in the less than 80 years age group (23%).

The Odds ratio for developing high degree atrioventricular block mandating permanent pacemaker implantation in in patients with age equal or more than 80 years relative to patients with age less than 80 years was 0.42 [95% confidence interval (CI) = 0.13-1.3] p= 0.14. Acute limb ischemia developed in 2 patients of the equal or more than 80 years age group, while none of the less than 80 years age group developed this complication. The odds ratio (OR) for developing post implantation cerebrovascular accident in hypertensive patients group relative to non-hypertensive patients' group was 5.14 [95% confidence interval (CI) = 0.60-43.6]. Cardiac chamber perforation developed in 2 patients of above 80 years age group, while none of the less than 80 years age group developed this complication. The odds ratio (OR) for developing cardiac chamber perforation in patients with age equal or more than 80 years relative to patients with age less than 80 years was 3.38 [95% confidence interval (CI) = 0.16-72.5] p= 0.40.

Acute coronary occlusion developed in 1 patient of above 80 years age group, while none of the less than 80 years age group developed this complication. The odds ratio (OR) for developing acute coronary occlusion in patients with age equal or more than 80 years relative to patients with age less than 80 years was 2.0 [95% confidence interval (CI) = 0.08-50.25] p=0.41. Regarding mortality 2 patients of the first group have passed away (3.7%) while 3 patients of the second group have passed away (8.5%). The odds ratio (OR) for mortality in patients with age equal or more than 80 years relative to patients with age less than 80 years was 0.41 [95% confidence interval (CI) = 0.06-2.6] p=0.34.

Gender groups analysis: Study population also subdivided into two groups according to gender, 45 male patients & 44 female patients. post implantation cerebrovascular accident developed in 2 of 45 male patients (4.4%) and 4 of 44 female patients (9%). The Odds ratio for developing post implantation cerebrovascular accident in male relative to female was 0.46 [95% confidence interval (CI) = 0.08-2.67] p= 0.39 intraprocedural acute pulmonary edema developed in 5 of 45 male patients (11.1%) and 2 of 44 female patients (4.5%). The Odds ratio for developing intraprocedural acute pulmonary edema in male relative to female was 2.62 [95% confidence interval (CI) = 0.48-14.3] p= 0.26 high degree atrioventricular block mandating permanent pacemaker implantation developed in 10 of 45 male patients (22.2%) and 4 of 44 female patients (9%). The Odds ratio for developing high degree atrioventricular block mandating permanent pacemaker implantation in male relative to female was 2.85 [95% confidence interval (CI) = 0.83-9.92] p= 0.09 Postprocedural acute kidney injury developed in 3 of 45 male patients (6.6%) and 1 of 44 female patients (2.2%). The Odds ratio for developing postprocedural acute kidney injury in male relative to female was 3.0 [95% confidence interval (CI) = 0.31-30.7] p= 0.34 postprocedural paravalvular leak of more than moderate severity developed in 2 of 45 male patients (4.4%) and 1 of 44 female patients (2.2%). The Odds ratio for postprocedural paravalvular leak of more than moderate severity in male relative to female was 2.0 [95% confidence interval (CI) = 0.17-22.86] p= 0.57.

DISCUSSION

Aortic stenosis is the most common valvular disease mandating surgery in countries with advanced health care system, as the prevalence increase in aged population.¹² When the stenosis become severe and associated with depressed left ventricular function or stenosis related symptoms, its mandatory to treat this condition.¹³Two decades before, the definitive treatment for severe aortic stenosis was achieved only by surgical aortic valve replacement.² but increased mortality and morbidity in high risk patients, and non-promising benefits of medical conservative treatment, open the door into searching for another modality of treatment which can be tolerated by high risk patients with the same benefit regarding mortality and morbidity.^{14,15} this new modality is transcutaneous aortic valve replacement, and after being a worldwide procedure and labelled as definitive treatment for certain population, a new complication for aortic stenosis management start to be encountered and being an important risk factor for mortality and morbidity. As this new complication affect the survival rate and quality of life, a lot of centers worldwide start running a lot of studies and research's regarding these complications, in a way to find a relationship between certain parameters and these complications. ¹⁶⁻²⁰ this study is a retrospective monocenter study performed in queen alia heart institute which is a part of royal medical services in Jordan where transcutaneous aortic valve replacement start to be the modality of choice in managing high risk aortic stenosis patients. as most of the research's in the literature studied the vascular and access sites complication thoroughly and deeply, we try here to concentrate on the incidence of non-access site complication post transcutaneous aortic valve replacement and tries to find if the age or gender is a significant risk factor for developing certain complication type.

When comparing our study results with other large trials we have found that. In our study, Post valve implantation only 3 patients had moderate aortic regurgitation (3.4%), while in partner 1 trial the percentage was 11.8%, and in a pooled partner 2 study in 2022 was 6%.²¹ Regarding conduction complication, in our study 14 patients developed high degree atrioventricular block mandating permanent pacemaker implantation (15.4%), while in 2019, a part of reprise 3 trial showed that 18% of the patients who underwent transcutaneous aortic valve replacement using corevalve developed high degree permanent pacemaker atrioventricular block mandating implantation.²² And In Sweden 2021, using swedeheart database a large trial showed that 14.1% of the patients who underwent transcutaneous aortic valve replacement developed high degree atrioventricular block mandating permanent pacemaker implantation.²³ Regarding post procedural acute kidney injury, in our study 4 patients developed acute kidney injury (4.5%), while in 2021 Using data from the Society of Thoracic Surgeons/American College of Cardiology National Cardiovascular Data Registry Transcatheter Valve Therapy Registry, they found that acute kidney injury is common after transcatheter aortic valve replacement, with 10.7% of patients developed this complciation.²⁴ and In Italy 2022, Consecutive patients undergoing TAVR were prospectively enrolled at 5 high-volume centers and they found that 17.3% of the study population developed acute kidney injury.25

Regarding post implantation cerebrovascular accident, in our study 5 patients developed cerebrovascular accident (5.6%), while in partner 1 trial the percentage was (6.7%), In Germany 2021 a trial showed that incidence of periprocedural cerebrovascular accident was 3.6%, despite using embolic protection devices.²⁶ and in a review article 2018, the incidence of periprocedural cerebrovascular accident was ranging between (1%-11%).²⁷ In our study the incidence was 5.6% which nearly equal to the average of worldwide incidence of periprocedural cerebrovascular accident despite that our study group patients underwent the procedure without embolic protection devices. This study showed that there is a statistically significant difference between narrow QRS complex baseline electrocardiogram patients and wide QRS complex baseline electrocardiogram patients, as wide ORS group tend more to develop post procedural high degree atrioventricular block and require permanent pacemaker implantation, the odds ratio (OR) was 26.25 [95% confidence interval (CI) = 4.5-152.5] p=0.0003. Its worthy mentioned that our study also showed that aortic stenosis patients who had mild or moderate mitral valve regurgitation or depressed left ventricular function had observational tendency to develop intraprocedural acute pulmonary edema, and patients who had diabetes or hypertension also had a tendency toward developing postprocedural acute kidney injury and surprisingly there were no significant difference between chronic kidney disease patients and non-chronic kidney disease patients in developing post procedural acute kidney injury, but all these observational differences are not statistically significant. Also, in the subgroup's analysis, our study showed that patients who aged equal or more than 80 years are more prone observationally to develop postprocedural cerebrovascular accident and males are more prone observationally to develop postprocedural high degree atrioventricular block mandating permanent pacemaker implantation, but both observational differences are not statistically significant.

CONCLUSION

as transcutaneous aortic valve replacement starts to be a modality of choice in high risk patients or inoperable patients, its start to be performed in a wide range worldwide. Of course, this procedure as every medical intervention can not be performed uneventfully without any complication. So, a lot of preoperative risk assessment and intraoperative cautions should be considered before performing this procedure, trying to avoid devastating complications that can lead to a great morbidity and mortality. After reviewing our study results, we think that Right heart catheterization and filling pressure's measurement may be needed at time of transcutaneous aortic valve replacement in patients with valve abnormality other than aortic stenosis and patients with left ventricular dysfunction to decrease the risk for developing intraprocedural acute pulmonary edema. Also, controlling blood pressure and keep good glycemic control in hypertensive and diabetic patient may decrease the risk for developing postprocedural acute kidney injury.

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