A Contrast Frugal Approach to Transcatheter Aortic Valve Replacement in Chronic Kidney Disease: A Pilot Study

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Abstract

Background: Transcatheter aortic valve replacement (TAVR) is now regarded as a viable treatment option for all cases of severe aortic stenosis (AS). Acute kidney injury (AKI) is common and lowers the survival of patients after TAVR and iodine-based contrast-induced nephropathy (CIN) plays a significant adverse role in AKI. Therefore, in chronic kidney disease (CKD) patients requiring pre-operative evaluation for TAVR, the risk of CIN is of particular concern.

Methods: It was a single-center study including eight CKD patients who underwent pre-operative evaluation for TAVR with minimized contrast exposure by means of pre-operative contrast-sparing evaluation and intra-operative contrast minimization. All patients had glomerular filtration rate (eGFR) calculated before TAVR protocol and on a follow-up about one month and one year post-operatively to document the impact of this TAVR protocol on prognosis of kidney function in patients with advanced CKD.

Results: New York Heart Association (NYHA) functional classification demonstrated significant improvement of symptomatology (p = 0.0001) by one-year post-TAVR. Patients’ mean AS gradient was significantly improved (p = 0.0004) after the TAVR procedure. No significant post-operative paravalvular aortic regurgitation was noted on follow up echocardiogram. eGFR data showed mean eGFR for the group was slightly better (27.38 ml/min/1.73 m² BSA vs. 30.38 ml/min/1.73 m² BSA) after TAVR.

Conclusions: "Contrast frugal" approach is feasible and safe for pre-TAVR evaluation and the procedure itself. Our pilot study showed no significant paravalvular leak of the prosthetic valve following this proposed protocol. No statistically significant decrease in eGFR was noted on one-year follow-up.

Categories: Cardiology, Internal Medicine, Nephrology

Keywords: aortic stenosis, transcatheter aortic valve replacement, acute kidney injury, contrast induced nephropathy, chronic kidney disease

Introduction

Transcatheter aortic valve replacement (TAVR) has now emerged as a viable treatment option for all cases of severe aortic stenosis (AS), including patients who are considered otherwise low risk for surgical aortic valve replacement (SAVR) [1]. Despite encouraging published outcomes, acute kidney injury (AKI) is common and lowers the survival of patients after TAVR [2,3]. The pathogenesis of AKI after TAVR is multifactorial including TAVR-specific factors such as the use of iodine-based intravenous contrast dye agents, hypotension during rapid pacing, and embolization; preventive measures may include pre-procedural hydration, limitation of contrast dye exposure, and avoidance of intraprocedural hypotension. In recent years, the number of TAVRs performed worldwide has been increasing, as well as published data on renal perspectives of TAVR. TAVR is a complex procedure, and its timely planning is crucial. If not planned appropriately there are major complications which can occur, even mortality, e.g., significant paravalvular leak, valve embolization, annular rupture, coronary occlusion, conduction disturbance, etc. Even rare complications like strut inversion in the background of calcium spur have been reported [4]. The purpose of this paper is to establish the concept of contrast frugal technique that can be done safely without any significant complication.
Coronary angiography is recommended due to the high incidence of coronary artery disease in patients. Tomography (CT) of the aortic root and annulus, and a non-gated CT of the chest, abdomen and pelvis modalities for patients preoperatively: coronary angiography, electrocardiogram-gated computed TAVR procedure.

The current guidelines, provided by the 2017 Expert Consensus for TAVR, recommend three primary imaging modalities for patients who underwent TAVR between November 2011 and September 2015. The study evaluated the role of TAVR as a promising option for high-risk surgical patients requiring SAVR. This trial demonstrated non-inferiority to SAVR and a 2% decrease in all-cause mortality in TAVR patients at one year compared to SAVR. An additional trial named "PARTNER 2", published in 2016, further supported the non-inferiority of TAVR to SAVR in intermediate surgical risk patients.

TAVR, as a procedure has been evolving to become the alternative standard of care for patients with severe AS. However, the CKD patients remain a challenge in the context of work-up and perioperative risks. The PARTNER cohorts A and B excluded patients with a creatinine >3.0 or those with renal replacement therapy (RRT) [17,18]. Similarly, the CoreValve Trial excluded patients with end-stage renal disease or a creatinine clearance of <20 cc/minute [20], due to the need for contrast administration. However, it is well recognized that TAVR outcomes are significantly related to pre-procedural kidney function and changes in kidney function after TAVR have a significant impact on mortality. AKI after TAVR is associated with increased morbidity and mortality [21].

**Background**

**TAVR trials**

The most commonly discussed TAVR trials were conducted by the PARTNER (Placement of Aortic Transcatheter Valves) investigators. In 2010, data from this multicenter, randomized clinical trial showed the significance of transcatheter aortic-valve implantation (TAVI) for aortic stenosis in patients who cannot undergo surgery [17]. This study demonstrated decreased mortality and repeat hospitalization at one year in patients undergoing TAVR, compared to patients undergoing medical therapy alone. The PARTNER investigators in subsequent publication investigated the role of TAVR as a promising option for high-risk surgical patients requiring SAVR. This trial demonstrated non-inferiority to SAVR and a 2% decrease in all-cause mortality in TAVR patients at one year compared to SAVR [18]. An additional trial named "PARTNER 2", published in 2016, further supported the non-inferiority of TAVR to SAVR in intermediate surgical risk patients [19].

TAVR, as a procedure has been evolving to become the alternative standard of care for patients with severe AS. However, the CKD patients remain a challenge in the context of work-up and perioperative risks. The PARTNER cohorts A and B excluded patients with a creatinine >3.0 or those with renal replacement therapy (RRT) [17,18]. Similarly, the CoreValve Trial excluded patients with end-stage renal disease or a creatinine clearance of <20 cc/minute [20], due to the need for contrast administration. However, it is well recognized that TAVR outcomes are significantly related to pre-procedural kidney function and changes in kidney function after TAVR have a significant impact on mortality. AKI after TAVR is associated with increased morbidity and mortality [21].

**TAVR in patients with CKD**

There have been studies focused on the incidence of RRT following TAVR and the association of CKD on TAVR outcomes. One retrospective study utilized the Centers for Medicare and Medicaid database to identify patients who underwent TAVR between November 2011 and September 2015. The study evaluated the incidence of RRT following TAVR, in this population. A significant association of increased mortality was found in patients with low pre-procedural GFR (<60 ml/min) and in patients requiring new RRT following TAVR [22]. Another study demonstrated that increased mortality was associated with new dialysis following TAVR, but it also reported a decreasing proportion of TAVR patients requiring dialysis post-procedure. This proportion decreased from 6.1% in 2007-2008 to 2.3% in 2013-2014. Additionally, the study reported that the risk of new dialysis was found to be independently associated with moderate-to-severe aortic regurgitation post-procedure, the year of procedure, lower baseline renal function, and diabetes [23].

Overall, patients undergoing TAVR procedure have higher risk of post-procedural complications, morbidity (AKI and need of RRT) and mortality in cases of advanced pre-procedural CKD. Unfortunately, there has been no noteworthy research about how to minimize decline of renal function in CKD patients requiring TAVR procedure.

**Current Standard Pre-procedural Work-Up Guidelines for TAVR**

The current guidelines, provided by the 2017 Expert Consensus for TAVR, recommend three primary imaging modalities for patients preoperatively: coronary angiography, electrocardiogram-gated computed tomography (CT) of the aortic root and annulus, and a non-gated CT of the chest, abdomen and pelvis [24]. Coronary angiography is recommended due to the high incidence of coronary artery disease in patients.
undergoing TAVR (40-75%). The long-term clinical benefits of elective revascularization prior to TAVR are unclear at this time and not routinely performed [25]. A multidetector CT (MDCT) is the current standard for aortic valve evaluation, providing information concerning annular sizing, aortic root sizing, and procedure planning. For sufficient visualization using this method, 80-120 mL of low-osmolar iodinated contrast is typically utilized, carrying a significant risk for nephrotoxicity. In patients in whom iodinated contrast is absolutely contraindicated, alternative imaging includes transesophageal echocardiogram (TEE) for valve sizing and magnetic resonance imaging for vascular access, are recommended, but these modalities are highly dependent on local expertise and more often require multimodality integration.

Lastly, another CT imaging involving major thoracic arterial system, carotids, thoracoabdominal aorta, and iliofemoral vasculature, is recommended for the planning of vascular access. [24]

**High risk of AKI with standard pre-TAVR work-up**

Conventionally, contrast-induced nephropathy (CIN) is defined as a serum creatinine increase of >25% from baseline (>0.5 mg/dL) in the 48-72 hours following the procedure with additional sources of renal dysfunction having been ruled out. The exact mechanism of CIN is unclear; although, it is thought to be a combination of direct renal tubular toxicity and renal medullary hypoxia due to increased perivascular hydrostatic pressure along with direct tubular obstruction [26]. CIN is known to be associated with contrast CT imaging and coronary angiography independently, and the need for multiple contrast-exposure events to evaluate the peripheral vasculature, coronary structure, and replacement valve apparatus sizing inevitably increases that risk. Diabetes mellitus or atrial fibrillation, both common comorbidity in older patients with cardiovascular issues, can also increase risk of CIN in such patients [27]. The risk of renal function impairment associated with any iodinated contrast using radiological procedures in the general population is relatively low at 0.6-2.3 %. However, it can be significantly high in selected patient subsets (up to 20%), mainly in patients with underlying cardiovascular disease and chronic kidney disease [28]. Some studies have even claimed that it can be as high as 50% in high-risk patients with co-morbidities as mentioned above [29]. Therefore, in CKD patients requiring pre-operative evaluation for TAVR, the risk of CIN is of particular concern due to the increased risk of CIN in patients with pre-existing CKD, advanced age and other relevant comorbidities.

**Materials And Methods**

**A proposed protocol for CKD patients requiring evaluation for TAVR**

We utilized, in our single-center study, a new protocol for patients undergoing pre-operative evaluation for TAVR. This protocol minimizes contrast exposure in CKD patients requiring TAVR by means of two contrast-sparing steps: pre-operative contrast-sparing evaluation and intra-operative contrast minimization.

1. The pre-operative step included limited coronary angiography, a non-contrast gated CT/MRI of the thoracic aorta, and a carbon dioxide (CO₂) angiogram of the iliac vessels and abdominal aorta (below the level of the diaphragm) [Figure 1] with three-dimensional (3-D) trans-esophageal echocardiogram (TEE) for valve sizing [Figure 2].
FIGURE 1: Arrows showing patent blood circulation through aortic branches
In several cases, the peripheral vascular access exam was supplemented with intravascular ultrasound (IVUS). The recommended standard evaluation was followed and included the following: pulmonary function testing, carotid doppler, and pre-operative dental examination.

2. The intra-operative step utilized a two pigtail method with placement in the non-coronary and left coronary cusps. This was used to obtain the coplanar angle and determine valve positioning. A recapturable Medtronic Evolut R valve was then deployed under TEE guidance with minimal use of fluoroscopy.

The other standard protocol, which was followed included holding metformin, angiotensin converting enzyme, angiotensin receptor blocker on day of procedure and the next day. Unless the patient had very low ejection fraction, like our patient number 1, as per American Heart Association recommendations, pre-hydration with isotonic normal saline at 1 ml/kg/hr was done for three hours before and for six hours after the procedure [30].

The following eight cases include patients with symptomatic, severe aortic stenosis. These patients required transcatheter aortic valve replacement while having chronic kidney disease stage III (GFR 30-60) or IV (GFR 15-30). The cut off for GFR was 15. The post-procedural outcomes of renal function and aortic valve hemodynamics are discussed. Albeit the number of cases being low for any type of study, well researched study has demonstrated that the number needed to treat (NNT) in TAVR literature is five only as per the landmark PARTNER trial [17]. Therefore, our cohort is of reasonable size as proof of concept to evaluate the idea of contrast frugal approach in CKD patients to minimize kidney injury for TAVR. As a reminder, this a proof of concept only and we also suggest that randomized controlled trials would be needed with larger cohorts in future.

In order to measure clinical improvement or compare pre-TAVR versus post-TAVR status, we decided to look into validated clinical parameters. We checked New York Heart Association (NYHA) functional classification for symptom improvement and Kansas City Cardiomyopathy Questionnaire (KCCQ) for assessment of quality of life. Mean aortic stenosis gradient pre- and post-TAVR by means of transthoracic echocardiogram (TTE) demonstrated objective evidence of the degree of transvalvular flow improvement. Paravalvular aortic regurgitation was measured with TTE post-operatively to ascertain the valvular integrity and optimum placement. Left ventricular ejection fraction (LVEF) was measured pre- and post-TAVR as a marker of overall or global cardiac function. When mentioned as a range (eg, 50%-60%), the middle point of the range was taken as the LVEF (eg, 55%). All patients had eGFR calculated based on their age, ethnicity, and serum creatinine before TAVR and on follow up about one month and one year post-operatively in order to document baseline renal function and short-term or long-term impact of this TAVR protocol on prognosis of kidney function in patients with advanced CKD. In our cohort, there was zero contrast intraoperatively, CO₂ angiography was performed for the iliofemoral system and IVUS was used for trans-axillary access (when needed). Pre-operatively, non-contrast planning CT, TEE and CO₂ angiography of the iliofemoral system were used. Coronary angiography was performed using less than 20 cc of contrast in every case.

The study was approved by the institution IRB. The approval number is CHIRB0415.
Results

Our pilot study enrolled total of eight patients. Basic demographic and clinical information about the participants are presented in Table 1.

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TABLE 1: Patient characteristics

eGFR- estimated glomerular filtration rate; ml/min/m²- milliliters per minute per meter square; BSA: body surface area; CABG: coronary artery bypass grafting

All except one patient were >65 years old and the mean age of the group was about 74. The participants were predominantly male (75%) and Caucasian (87.5%) with significant prevalence of diabetes mellitus (62.5%) and hypertension (100%). None of the patients were active current smoker. There were two patients with previous permanent pacemaker and one with history of coronary artery bypass graft (CABG) surgery. Half of the patients had atrial fibrillation. Majority of our participants (75%) had advanced chronic kidney disease (CKD) stage 4 with eGFR between 15 and 29 ml/min/per 1.73 m² body surface area (BSA) and two participants were CKD stage 3B or close (eGFR 30-45 ml/min/per 1.73 m² BSA). The eGFR was calculated based on modification of diet in renal disease (MDRD) calculation used to measure renal function.

New York Heart Association (NYHA) functional classification demonstrated statistically significant improvement of symptomatology (p = 0.0001) by the one year mark post-TAVR. Although the KCCQ scores were noted to be overall improved pre to post TAVR, the numerical improvement did not reach statistical significance to suggest definite improvement of quality of life. As would be expected, patients’ mean aortic stenosis gradient was significantly improved (p ~0.00004) after TAVR procedure. No significant post-operative paravalvular aortic regurgitation noted on follow up TTE. There was no statistically significant difference noted in LVEF when compared pre-and post-operative TTE data. eGFR data showed no clear pattern in relation to the TAVR procedure, however, mean eGFR for the group was slightly better (27.38 ml/min/per 1.73 m² BSA Vs 30.38 ml/min/per 1.73 m² BSA) after TAVR. This observation was not statistically significant. The cardiovascular and renal outcomes pre-and post-TAVR are outlined in Table 2.
Participants’ parameters

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**TABLE 2: Cardiovascular and renal parameters pre and post TAVR procedure**

NYHA: New York Heart Association; TAVR: transcatheter aortic valve replacement; yr: year; mo: month; LVEF: left ventricular ejection fraction; KCCQ: Kansas City Cardiomyopathy Questionnaire; eGFR: estimated glomerular filtration rate; n/a: not applicable

**Discussion**

Our goal is to show that our “minimal-IV dye” protocol yields same expected cardiac outcome (LVEF, paravalvular leak, KCCQ) but preserved or better renal outcome (no statistically significant decline in eGFR and rather better eGFR post-TAVR due to postulated better cardiac output after valve surgery).

The results of our pilot study could be summarized in Table 3.

**Salient Findings**

1. “Contrast frugal” approach is feasible and safe. There was no significant paravalvular leak or misplacement of the prosthetic valve following this proposed protocol of pre-procedure evaluation.

2. There was statistically significant improvement of symptoms by one year post TAVR (as per the NYHA classification)

3. Slightly better mean eGFR in post TAVR period on one year follow up (though not statistically significant)

4. No statistical improvement in LVEF in pre and post TAVR group

5. Mean aortic stenosis gradient improved significantly after the procedure

**TABLE 3: Study Highlights**

LVEF: Left Ventricular Ejection Fraction; TAVR: Transcatheter aortic valve replacement; TAVT: Transcatheter aortic valve replacement ‘ eGFR: estimated glomerular filtration rate; NYHA: New York Heart Association

As we have described earlier, TAVR is expected to be more prevalent in coming days and it is being considered now the standard of care for more and more patient, including those with CKD. This approach will help preserve renal function, especially for those with advanced CKD (Stages 3b, 4 and 5), at the same time allow the very essential heart saving surgery for better patient outcome. Although iso-osmolar or low osmolar dye is postulated to be better choices for renal protection, it still carries significant risk of CIN [31].
It is known that mortality rates are higher in patients requiring new dialysis after TAVR [23]. In our pilot study, we have demonstrated that by lowering the contrast exposure, we would not compromise the cardiovascular outcome of the patients while maintaining the integrity of renal function, one year after the procedure. Our minimal dye exposure technique could be applied to a larger population of CKD patients in an attempt to prevent CKD progression and ESRD. The medicare expenses of USA for renal failure patient is significantly high [32] already and by mitigating the risk factors of CIN for TAVR, we could lower the cost burden of dialysis patients and attempt to reduce the huge financial expenses incurred from premature need for dialysis.

Study limitations

Our patient population was very small and included only eight patients which is not an ideal representation of CKD population. The improvement in eGFR cannot be concluded for certain in general population unless much bigger study is conducted. The age of the patients was older and does not represent younger population. Due to decreased sample size, we could not gather enough female patients or other racial background population hence this study outcomes are needed to be tested in a more diverse population setting through larger multi-center study. The follow up period was limited to only one year and longer follow up is needed to assess long-term renal outcomes.

Conclusions

"Contrast frugal" approach is feasible and safe for pre-TAVR evaluation and the procedure itself. Our pilot study showed no significant paravalvular leak of the prosthetic valve following this proposed protocol. No statistically significant decrease in eGFR was noted on one year follow-up. This could be a safer option in moderate to severe aortic stenosis patients at risk of worsening renal function. More studies need to be done on this approach to preserve kidney function in long run.

Additional Information

Disclosures

Human subjects: Consent was obtained or waived by all participants in this study. Centra Health Institute Review Board issued approval CHIRB0415. Animal subjects: All authors have confirmed that this study did not involve animal subjects or tissue. Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following: Payment/services info: All authors declare that no financial support was received from any organization for the submitted work. Financial relationships: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. Other relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

References


