

Reaching TAVR's Full Potential by Optimizing Postprocedure Care

Realizing the potential benefits that can be gained when clinical pathways are implemented post-TAVR.

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The advent of transcatheter aortic valve replacement (TAVR) has ushered in a new era of interdisciplinary collaboration in valve therapy and has transformed the fields of both cardiology and cardiac surgery. Studies have shown significant improvements in survival compared to conventional therapy in both extreme- and high-risk patients.^{1,2} Such patients now have an alternative to the deleterious effects of sternotomy, cardiopulmonary bypass, and, in some centers, intubation when aortic valve replacement is indicated. Given the rapid adoption of TAVR worldwide and promising early results, it may be easy to forget that TAVR is still a technology in its infancy—rapidly developing but nonetheless yet to realize its full potential.

Much of industry's attention to date has appropriately centered on optimizing valve and delivery system design to reduce procedural complications and rates of paravalvular leak. Certainly, we can look forward to other meaningful advancements from industry in the coming years. On the other hand, it behooves the medical community to ensure the optimization of all aspects of patient care and the seamless integration of these technological advances into robust and rigorous clinical pathways. Only with such attention will TAVR reach its full potential.

Postprocedure care in the United States is an excellent example of an aspect of TAVR management with ample room for improvement. The average hospital length of stay (LOS) for transfemoral TAVR is 7.8 days.³ Understandably, many institutions consider that acceptable, given that TAVR patients are typically frail and

elderly. However, the status quo may not be acceptable in the face of compelling evidence that prolonged hospital stays for elderly patients can lead to significant downstream consequences and that a shorter LOS is both safe and feasible in appropriately selected patients.⁴ We do not endorse reductions in LOS for their own sake, but rather propose that appropriate reductions are of benefit to the patients. Moreover, LOS may be an easily measured metric of the health and performance of a TAVR program.

There are a number of barriers to improving TAVR LOS in the United States, including inertia on the part of medical teams, misunderstandings regarding reimbursement and the financing of TAVR programs, and a lack of experience in many centers with the implementation of and adherence to well-designed, flexible clinical care pathways. Herein, we address all three of these barriers in turn and provide guidance for centers interested in optimizing postprocedure care.

HISTORICAL PERSPECTIVE

Conventional surgical aortic valve replacement (SAVR) requires general anesthesia, sternotomy, and cardiopulmonary bypass with a resultant prolonged postoperative course. Naturally, in the early United States experience with TAVR, postprocedure care was simply that of SAVR, despite distinct differences between the two procedures. Surgical care processes were both tested and imbued with an abundance of safety. As such, it was both prudent and appropriate to use such processes early on, as there was simply little experience with any alternative. Since that

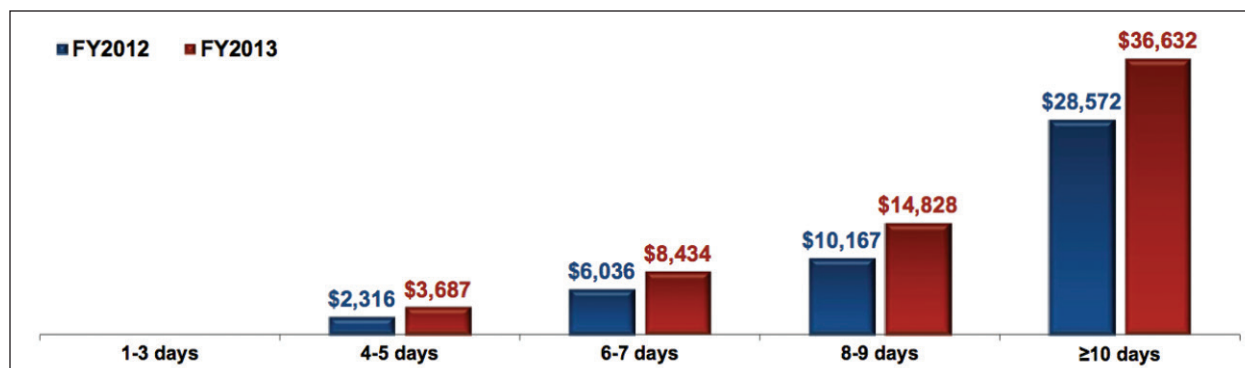


Figure 1. Incremental hospital cost by LOS (regression adjusted) compared to short-stay group (1–3 days). All differences were significant ($P < .05$).

time, however, post-TAVR care has considerably evolved around the world, and some leading United States centers have shown that such care pathways can easily be adapted to the United States context to improve patient care.

Yet, overall, there appears to be a general reluctance in the United States to change postprocedure care. Anecdotally, we have found that many TAVR programs believe that it is not worthwhile to risk changing programs that “work,” particularly as many appear unsure as to what steps to take to safely optimize postprocedure care for TAVR. Such inertia is reflected in the stagnant LOS data from MedPAR in 2012 and 2013.³ However, we did notice in our analysis of these data that there was a good deal of variability in LOS, with 19.3% of patients being discharged within 3 days in 2013. We believe that this demonstrates the potential for a natural evolution toward shorter LOS in the United States, as has been shown to be possible in Europe and Canada.^{4,5} As elsewhere in cardiology, our practices and care pathways must evolve to fully exploit technological advances. If a technology allows the safe and appropriate earlier discharge of patients, failing to realize that potential is a disservice to our patients.

COSTS AND REIMBURSEMENT

It is unfortunate that some of the resistance to LOS reduction initiatives has come from the institutions supporting TAVR programs. This resistance was born of negative financial implications resulting from a misunderstanding of Medicare’s Post-Acute Care Transfer (PACT) policy. Many centers saw their reimbursements hollowed out as a result of the arguably ill-advised early discharge of TAVR patients to skilled nursing facilities (we would call this practice “premature discharge,” as it runs contrary to the appropriate early discharge of home discharge-ready patients that we are advocating). As such, many institutions have become wary of any new initiatives with a goal or likely result of earlier discharge.

The PACT policy, conceived to ensure that Medicare does not “double pay” for care, financially penalizes centers that discharge earlier than the mean LOS for a given diagnosis-related group by transferring a patient to another acute care facility (ie, skilled nursing facility or inpatient rehab) or home with home health services within 3 days of discharge. In 2012, 35% of all TAVR cases triggered PACT, with an average penalty of \$7,491 per case.⁶ For many centers already struggling to finance expensive TAVR programs, such per-patient losses jeopardize the viability of the entire program. As such, some institutions became wary of discharging patients earlier than the reference mean LOS for that patient. However, this too is a nonviable solution in the long term. The reality is that the impact of LOS on a program’s contribution margin is somewhat nonlinear and strongly influenced by discharge disposition. Simply keeping patients longer will not ensure the financial health of TAVR programs, and neither will crudely reducing LOS at any cost.

The real answer, we believe, is that there is no penalty for programs that appropriately discharge patients home when they are ready. By appropriately reducing LOS for those who do well post-TAVR and by optimizing care so that more patients do well, there is the potential for both significant cost savings for the hospital and avoidance of PACT-related penalties. This idea has been validated by our evaluation of the impact of LOS on cost among transfemoral TAVR patients in 2012 and 2013.³ Using administrative data and adjusting for all known confounders, there was an average total hospitalization cost savings of \$7,235 in patients discharged 1 to 3 days after TAVR versus day 6 or 7 (Figure 1). Furthermore, patients discharged on days 1 to 3 were more than twice as likely to be discharged to home without assistance compared to those discharged on days 6 to 7. This analysis is therefore important for two reasons. First, it confirms that earlier discharge, when it happens, is being appropriately granted



Figure 2. Representative image of both the iOS and Android versions of the Post-TAVR Optimization mobile application, which is currently available free of charge. Available via www.post-tavr.com, the Apple App Store, and Google Play.

for patients who do well. Second, it confirms that targeting appropriate earlier discharge for patients is a viable endeavor for TAVR programs.

In 2014, we developed a free educational mobile application (Figure 2), which is available at www.post-tavr.com, that provides recommendations for the postprocedure management of TAVR patients.⁷ Recognizing that confusion regarding Medicare's reimbursement policies was an obstacle to the implementation of reasonable TAVR-specific care pathways, we also included educational material explaining TAVR reimbursement and an interactive tool designed to illustrate the impact of the PACT policy and patient care decisions on the viability of TAVR programs in the United States. The application has been downloaded by administrators and medical leadership in centers across the United States and continues to be updated annually to reflect changes in Medicare's policies.

In summary, despite criticisms that might be made about TAVR reimbursement in the United States, the current system is such that, just as inappropriately keeping patients hospitalized is bad for patients and costly to programs, so is discharging patients before it is appropriate to do so. In essence, contrary to what has been the prevailing impression among administrators in many centers, TAVR programs are financially rewarded for appropriately reducing LOS.

A good clinical pathway reduces unnecessary and potentially dangerous variations in care while allowing for the flexibility to address the complexities of today's patients and therapies.

THE CASE FOR CLINICAL PATHWAYS

The adoption of TAVR-specific postprocedure care that recognizes and reflects the unique aspects of transcatheter versus conventional SAVR can have positive effects for both patients and centers (both financial and reputational). However, even if these points are acknowledged, hurdles remain. Most centers have been performing TAVR for at least 3 years, and changing clinical practice and team attitudes can be challenging.

Robust, locally adapted, tested, and refined clinical pathways are the key to ensuring the safe and appropriate reduction of hospital LOS to the minimum necessary in all patients. Clinical pathways have been shown in many areas of medicine to be an effective tool for enacting change, engaging all team members, and ultimately optimizing patient care. A good clinical pathway reduces unnecessary and potentially dangerous variations in care while allowing for the flexibility to address the complexities of today's patients and therapies.

A number of clinical leaders in TAVR have taken an interest in optimizing all aspects of TAVR care, particularly postprocedure management, and regularly exchange ideas on how they have addressed hurdles to optimizing care at their institutions. One result of this collaborative approach is the clinical pathways that we include in the Post-TAVR Optimization application.

The postprocedure clinical pathways were initially developed as post-TAVR "best practice" milestones by a working group composed of TAVR leaders at four United States centers. These were intended to be clear, reasonable objectives in the first 24 hours postprocedure that would allow patients a quick recovery after a TAVR procedure. Each milestone represents a time-appropriate, achievable clinical target. Meeting these milestones provides positive feedback for both patients and the care team. Similarly, not meeting these targets by the suggested time allows for early recognition and action to correct problems with potentially simpler solutions than if the same problem were to be recognized later. The pathways provided in our application, as well as locally adapted versions, have

Piedmont Heart Clinical Pathway



Transcatheter Aortic Valve Replacement (TAVR): Transfemoral

Goals: 0-4 hours

Extubate within 1 hour, if not extubated in OR.

Wean off all drips within 1 hour of arrival. Saline lock all IVs except renal protection intravenous fluids. Continue 6 hours post op if ordered.

Remove pulmonary artery catheter within 1 hour, if present. Continue central line.

Remove arterial line.

Out of bed to chair after 4 hours of bed rest.

Discontinue foley catheter once patient has been out of bed.

Discontinue oxygen within 4 hours if oxygen saturation $\geq 90\%$.

Avoid all sedatives and narcotics.

Goals: 4-12 hours

Restart oral antihypertensive medications in 4 hours, if able to swallow. Hold if SBP <100 . Do not give beta blockers if heart rate is <60 .

Restart BPH medications in 4-6 hours. Double dose for first dose.

Begin incentive spirometry, cough and deep breathe every 2 hours.

RN bedside evaluation for dysphagia. Consult speech therapy on POD #1 if patient unable to swallow.

Begin ice chips, advance to clear liquids, and then advance to regular diet.

Walk within 6 hours.

Reinforce early ambulation with family. Educate family how to mobilize patient.

Goals: Post Op Day 1

Transfer to 3 North.

Aggressive blood sugar control.

Antiplatelets: Begin aspirin 325 mg/day. Begin Plavix 75 mg/day, unless contraindicated.

Anticoagulation: Begin Coumadin at 1700 if patient was taking preoperatively.

Insert peripheral IV and removed central line POD #1.

Ambulate 6 times a day. Encourage all meals out of bed.

Patient Care Coordination consult, if indicated.

Discharge if discharge criteria met on POD #1-3.

Discharge Criteria and Follow-up

1. Baseline neurological function.
2. Stable heart rhythm and has not required pacing within 24 hours.
3. Vital signs stable: HR 60-90, SBP 90-140 (or at baseline).
4. Voiding without difficulty, emptying bladder.
5. Blood sugar <150 .
6. Creatinine at or below baseline.
7. Oxygen weaned off with oxygen saturation $\geq 90\%$ with effective cough and airway clearance.
8. Effective pain control on oral medications.
9. Independent in ADLs and ambulation, or has appropriate assistance and equipment.
10. Able to ambulate 200 feet, or baseline.
11. Groins without bleeding or hematoma.
12. Patient and family voice appropriate understanding of post TAVR discharge instructions.
13. Discharge studies completed: TTE, CXR, EKG, BMP, PT, PTT.
14. Return to Marcus Heart Valve Clinic for appointment at 30 days.

Figure 3. TAVR clinical care pathways at Piedmont Heart. This pathway was adapted from a group originally assembled by Edwards Lifesciences (David Brown, MD; Michael Mack, MD; Steven Ramee, MD; Christian Spies, MD; and Brian Whisenant, MD, et al).

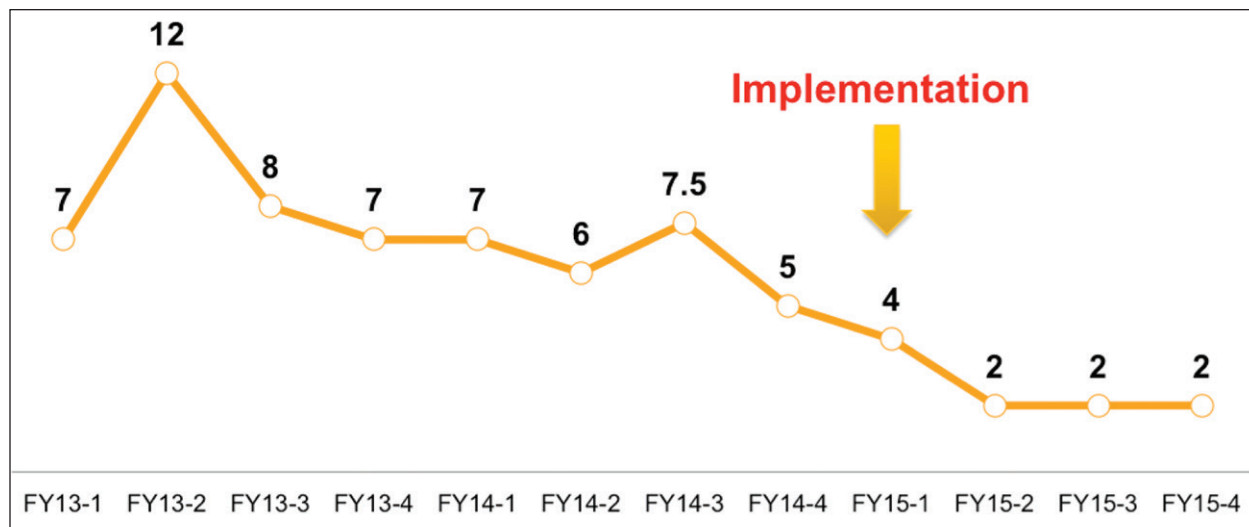


Figure 4. Trends in median LOS for transfemoral TAVR patients at Piedmont Atlanta Hospital by fiscal quarter. The arrow shows implementation of optimization strategies.

now been tested in a number of centers. Importantly, it is unlikely that one clinical care pathway will be the best pathway for every center, but the one that we provide in the application represents the most simple form of generally regarded important milestones that all programs interested in optimizing post-TAVR care should consider (Figure 3).

Currently, TAVR patients tend to be by and large the frail elderly who are at risk for delirium and rapid deconditioning, as well as procedure-specific complications. Up until now, most United States centers have kept patients in a critical care setting for the first 24 to 48 hours after TAVR, where they are frequently exposed to narcotics and sedatives and are on bed rest for most of this time. Although these patients are fragile, and the TAVR procedure is necessarily invasive, avoidance of these medications when possible, early extubation, central line removal, and ambulation are simple measures that can reduce the risk and consequences of delirium and deconditioning and shorten both intensive care unit and hospital LOS.

The clinical pathway that we propose recommends that patients be mobilized to a chair by 4 hours and ambulating by 6 hours. Although this may seem far from the reality in many centers today, it is certainly attainable in most patients. Mobilizing patients early minimizes muscle loss and decreases the risk of respiratory issues. Additionally, a program of early ambulation has the effect of being very motivating for patients' families and the care team. Obviously, such milestones may not be achievable in all patients, but it is reasonable to strive for them in almost all cases. In our institutions, early ambulation is the rule rather than the exception.

Importantly, post-TAVR optimization will be hampered without parallel optimization of preprocedure care pathways and optimization of the procedure itself. Preprocedure optimization includes the adequate preparation of patients and families for the possibility of early discharge and identification and discussion of any unique barriers for a given patient. Procedurally, most United States centers have transitioned away from surgical cut-downs to fully percutaneous access. Anecdotally, as well, there have been reports of the successful adoption of conscious sedation, which may have additional benefits. Together, proper patient selection, preparation, and education, along with streamlined TAVR procedures that exploit the technological advancements in transcatheter valve systems and tested, simple, and realistic clinical care pathways, are key to ensuring optimal patient outcomes and appropriate reductions in LOS.

THE PIEDMONT EXPERIENCE

Although these measures seem logical and even intuitive, they remain to be fully validated for TAVR in the United States setting. The Piedmont Heart Institute and Marcus Heart Valve Center chose to tackle these challenges early, and, herein, we relate our experience with optimizing post-TAVR care.

In August 2014, we began implementing a broad range of strategies designed to optimize every aspect of TAVR care to ensure the best possible outcomes for our patients, with a secondary goal of measuring the impact of these interventions on LOS and the average per-patient cost of TAVR. This type of transformational change would have been very difficult without the full

support of all members of the care team, the medical leadership, and our administrators.

Ours was a three-tiered approach, involving staff education initiatives, an explicit transition away from general anesthesia, and the implementation of postprocedure clinical pathways. Numerous sessions were held to explain both the rationale and the implementation of the proposed care changes to cardiologists, intensive care unit and floor nursing staff, anesthesiologists, physical therapists, and case managers. Such efforts paid off by fostering broad stakeholder buy-in for the program. We worked closely with a dedicated team of clinical and efficiency experts to develop concrete care pathways that were specifically tailored for our institution and patients.

Although there were challenges along the way, the results have been remarkable. After a run-in period where we field-tested and refined the pathways, we set an ambitious goal of a 2-day LOS for self-expanding valves and 1 to 2 days for balloon-expandable valves in transfemoral patients. Figure 4 shows our performance, with a median LOS of 2 days in transfemoral TAVR patients over the past 7 months compared to a median LOS of 6.5 days in the previous year. This remarkable reduction in LOS has been accomplished with mortality and stroke rates well below the national average. Additionally, the number of patients who are discharged with any increased level of assistance, including home health care, is under 10%, which is well below the national average of 32%. Most importantly, we have seen no adverse events related to early discharge, and the patients and families are grateful for the quick recovery.

To prevent readmissions and ensure optimal care for patients, we have them check their heart rate, blood pressure, and weight on a daily basis, and we make follow-up phone calls on postdischarge days 1, 5, 14, and 21. These precautionary steps have allowed us to identify any potential issues, which can frequently be addressed by phone. As a result, our 30-day readmission rate is < 5%.

Not only have the clinical outcomes been outstanding, with extremely high levels of patient satisfaction, but there has been a significant financial impact as well. On a per-patient level, there has been a reduction in cost of \$8,207 per hospital stay. Additionally, as a large quaternary medical center, Piedmont Atlanta Hospital, like others, frequently has bed shortage challenges. Our reductions in LOS have allowed us to free up an additional two hospital beds for the care of other patients.

CONCLUSION

Although TAVR appears destined to be a lasting technology, the field continues to evolve, and there are still significant opportunities for improving patient care, particularly in the postprocedure phase. Clinical path-

ways have been shown to foster greater engagement on the part of the medical team and administrators, improve patient outcomes and patient satisfaction, and have led, in our center at least, to an ancillary benefit of both improving the financial viability of our TAVR program and ensuring that we can further fulfill our mission of providing excellent care to the largest number of patients. Optimizing patient care after TAVR can therefore be to the benefit of patients, programs, and society as a whole. ■

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