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Recommended Citation

Myszenski A, Michon B, Lupcke D, Melican C, Pedawi N, Ahmed N, Wyman JF. Acute Care Physical and Occupational Therapy Early Intervention Pathway After Transcatheter Aortic Valve Replacement: A Retrospective Study. *Journal of Acute Care Physical Therapy* 2021; 12(2):65-71.

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Acute Care Physical and Occupational Therapy Early Intervention Pathway After Transcatheter Aortic Valve Replacement: A Retrospective Study

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ABSTRACT

Purpose: Transcatheter aortic valve replacement (tAVR) has emerged as a less-invasive alternative to traditional surgical aortic valve replacement. The purpose of this study was to examine the effect of a novel clinical pathway with an emphasis on early physical therapy and occupational therapy on patients undergoing tAVR in the acute care setting.

Methods: A retrospective study was conducted involving 189 patients who underwent tAVR. The control group (n = 74) included patients who underwent tAVR prior to the implementation of the pathway. The intervention group (n = 115) included patients who underwent tAVR following the implementation of the pathway. Inpatient length of stay and discharge disposition were measured.

Results: No differences in demographics or clinical variables were found; for example, mean age was 79.5 ± 11.2 years, with 57% male in the control group versus 81.6 ± 8.4 years and 59% male in the intervention group. Length of stay was significantly lower in the intervention group (control 6.9 ± 5.4 days, intervention 4.8 ± 5.4 days, $P = .009$) and significantly shorter length of stay postprocedure (control 4.8 ± 2.9 days, intervention 3.5 ± 4.0 , $P = .015$). The incidence of the patient's discharge disposition to home increased from 77% of patients in the control group to 86% of patients in the intervention group but was not statistically significant ($P = .118$).

Conclusions: A clinical pathway specific to patients post-tAVR provided early mobility, targeted education, individualized functional goals, and discharge disposition recommendations. Patients in the intervention group experienced reduced hospital length of stay.

Transcatheter aortic valve replacement (tAVR) has emerged as an effective alternative medical treatment in place of traditional surgical procedures for patients with severe, symptomatic aortic valve disease.¹⁻⁷ The procedure replaces the diseased valve with a self-expanding prosthetic valve via catheter either

through a femoral access site or through a small incision in the chest and was initially approved for use by the US Food and Drug Administration in 2011 for individuals at high to prohibitive risk for traditional open-heart surgery via a sternotomy, or surgical aortic valve replacement (sAVR).⁸ According to internal records, the first tAVR procedures at Henry Ford Hospital (HFH), Detroit, Michigan, were completed in 2012 for a total of 46. From 2012 to 2014, volumes tripled to 153 tAVR procedures, and the rehabilitation (rehab) team identified that these patients were not receiving physical therapy (PT) and occupational therapy (OT) consults as routinely as those following sAVR. Patients post-sAVR at HFH followed a postsurgical pathway, including phase I cardiac rehabilitation (see Figure 1). This pathway was established for patients undergoing sternotomy, general anesthesia, and cardiopulmonary bypass and anticipated longer periods of bed rest, hospital stay, and recovery.⁹⁻¹¹ The Rehabilitation Services department proposed that, due to the less-invasive nature of the tAVR procedure, patients likely would not require the same intensity nor duration of PT or OT intervention as those on the postsurgical sAVR pathway.

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A.M., B.M., N.P., N.A., D.L., and J.W. contributed to the conception and design of this study. A.M. and J.W. contributed to the analysis and interpretation of data. A.M., B.M., J.W., and C.M. drafted the manuscript. A.M. critically revised the manuscript. All authors gave final approval and agreed to be accountable for all aspects of the work, ensuring integrity and accuracy.

The authors have no conflicts of interest and no source of funding to declare.

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DOI: 10.1097/JAT.000000000000147



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Inpatient Cardiac Rehabilitation Stages after Cardiac Surgery

STAGE I:	Bedrest – Usually in the ICU; Post Operative day (POD) #1. Nursing responsibility.	(1.0 – 1.5 METS)
STAGE II:	Room ACTIVITY – Usually in the ICU; POD #2. Nursing responsibility.	(1.0 – 1.5 METS)
STAGE III:	Begin Therapy Intervention Usually POD #3: Usually on P5 GPU, however, may start in ICU, depending on patient’s condition	(2.0 METS)
	<ul style="list-style-type: none"> a. Introduce role of therapy in Cardiac Rehabilitation b. Issue and review packet: <ul style="list-style-type: none"> • Warning signs and symptoms • Overview of Phase II • Overview of Activity Limitations • Instruct in self pulse taking or dyspnea monitoring d. Ambulate patient 200 feet <ul style="list-style-type: none"> • Monitor HR: Pre Mid Post 3 – 5 minute Post* • Monitor BP: Pre Mid Post 3 – 5 minute Post* * 3 - 5 minute Post check is completed if post reading is not within expected physiological response. • Patient fails to pass stage if any of the following occur: <ul style="list-style-type: none"> • HR increase greater than 30 bpm from rest • Diastolic BP increase or decrease greater than 10 mm Hg from rest • Activity elicits warning signs or symptoms • Irregular pulse e. Thoracic Surgery patients require chest assessment, training for splinted cough and deep breathing 	
STAGE IV:	Intermediate Activity	(2.5 METS)
	<ul style="list-style-type: none"> a. Review pulse taking or dyspnea monitoring b. Ambulate patient 400 feet <ul style="list-style-type: none"> • Monitor as in Stage III 	
STAGE V:	Prepare for Discharge	(3.0 – 3.5 METS)
	<ul style="list-style-type: none"> a. Review pulse taking or dyspnea monitoring b. Ambulate patient up and down 10 - 14 stairs <ul style="list-style-type: none"> • Monitor as in Stage III • Patient should not ambulate significant distance prior to stairs c. Review Activity Limitations <ul style="list-style-type: none"> • Limit stairs, lifting, and driving as discussed on Activity Restriction HO d. Issue and discuss Home Walking Program e. Complete Phase II form if/when appropriate 	

FIGURE 1. Henry Ford Hospital Inpatient Cardiac Rehabilitation Stages After Cardiac Surgery.

Those who did receive consults following tAVR often did not receive those consults until several days into hospitalization. Delayed time to PT and OT consults has the potential to impact outcomes and delay discharge planning, especially for patients with functional deficits.^{12,13}

In 2014, the authors completed a thorough review of the available literature, which provided no published protocols or guidelines related to the rehabilitation after tAVR in the inpatient setting. To address this, a multidisciplinary team composed of an advanced practice nurse, PTs, and OTs was formed and consulted with the primary interventional cardiologist on staff at HFH. The team

developed an early intervention PT and OT clinical pathway specific to patients post-tAVR that included targeted education for patients and families (see Figure 2). The team implemented that pathway on December 2, 2014. The purpose of this study was to evaluate patient outcomes before, and after the early intervention, PT and OT clinical tAVR pathway (tAVR pathway) was implemented.

METHODS

Ethical Considerations and Consent

The hospital’s Institutional Review Board approved the study design and data collection methods. Informed



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Inpatient PT and OT Early Intervention Pathway after Transcatheter Aortic Valve Replacement

- Day of Procedure: Bedrest for 6 hours. Up to chair with Nursing. (1.0 – 1.5 METS)
- Post Procedure Day 1: Physical and Occupational Therapy Evaluations. (2.0-3.5 METS)
- a. Functional Evaluations; Goals set based on patient presentation and home situation
 - b. Monitor physiologic response to activity
 - Monitor HR: Pre Mid Post 3 – 5 minute Post*
 - Monitor BP: Pre Mid Post 3 – 5 minute Post*
 * 3 - 5 minute Post check is completed if post reading is not within expected physiological response.
 - Treatment will be terminated if any of the following symptoms occur:
 - HR increase greater than 30 bpm from rest
 - Diastolic BP increase or decrease greater than 10 mm Hg from rest
 - Activity elicits warning signs or symptoms
 - Irregular pulse
 - c. Issue and review handouts in “Structural Heart” patient education packet:
 - Overview of outpatient Cardiac Rehabilitation Program
 - Instruct in self pulse taking or dyspnea monitoring
 - Energy Conservation Techniques
 - Activity Progression handout with exercise log
 - Warning signs of activity intolerance
 - d. If patient meets goals: Complete referral to outpatient Cardiac Rehab.
 - e. If patient requires discharge destination other than Home, treatment frequency may be reduced as needed.
- Post Procedure Day 2 and daily through discharge or achievement of goals: (2.0-3.5 METS)
- a. Functional treatment interventions; Goals set based on patient presentation and home situation
 - b. Monitor physiologic response to activity
 - Monitor HR: Pre Mid Post 3 – 5 minute Post*
 - Monitor BP: Pre Mid Post 3 – 5 minute Post*
 * 3 - 5 minute Post check is completed if post reading is not within expected physiological response.
 - Treatment will be terminated if any of the following symptoms occur:
 - HR increase greater than 30 bpm from rest
 - Diastolic BP increase or decrease greater than 10 mm Hg from rest
 - Activity elicits warning signs or symptoms
 - Irregular pulse
 - c. If patient meets goals: Complete referral to outpatient Cardiac Rehab.

FIGURE 2. Henry Ford Hospital Inpatient Clinical Pathway After Transcatheter Aortic Valve Replacement Procedure.

consent was waived due to the retrospective nature of the study.

Study Design

This was a retrospective study involving 189 patients who received a tAVR procedure via transfemoral catheter percutaneous access site in the catheterization laboratory at HFH from March 1, 2012, through December 31, 2015. Exclusion criteria included access sites other than femoral, the occurrence of major events including death, stroke, myocardial infarction (MI), additional cardiac or vascular surgery, electrophysiological monitoring, pacemaker placement, atrial fibrillation, other car-

diovascular repair or surgery required, gastrointestinal bleeds, hematoma or access bleeds, or complications. The control group included patients who underwent tAVR prior to the implementation of the pathway from March 1, 2012, through November 1, 2014. The intervention group included patients who underwent tAVR following the implementation of the pathway from November 2, 2014, through December 31, 2015. Data collected included age, gender, body mass index (BMI), STS Risk Score,¹⁴ medical history, 5-m walk test time, and catheter valve sheath size (French, mm). Outcomes measured included total hospital length of stay (LOS), postprocedure LOS, and discharge destination. All data

were collected from the Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC) STS/ACC TVT Registry, which uses standard definitions to collection information from participating centers on consecutive tAVR cases.¹⁵

PT/OT Implementation Pathway

The pathway was implemented by a physician-driven order set in the electronic medical record (EMR), which included activity orders for “out of bed with nursing staff” 6 hours post-tAVR and automatic PT and OT consults for postprocedure day 1. Nurses were trained by a PT to conduct Dionne’s Egress test to assess the patient’s ability to safely participate in activities out of bed, including sitting in a chair.¹⁶ PT and OT completed separate evaluations on postprocedure day 1. These evaluations included functional evaluations, activity monitoring, patient education, recommendation for a discharge destination, and goal setting based on the patient’s functional level and home situation (see Figure 2). Patients were seen daily until goals were met or the patient was discharged. Patients were required to have heart rate and blood pressure monitored pre-, mid- and posttreatment and documented in the daily therapy notes.^{17,18} Intervention was terminated with onset or increase in any of the following: neurologic/visual/orthostatic symptoms within 60 seconds of upright positioning; heart rate increase more than 30 beats per minute above resting heart rate; change in systolic blood pressure of 30 mm Hg or change in diastolic blood pressure of 10 mm Hg; angina, or shortness of breath. The guidelines for termination of treatment were based on recommendations by physicians in the cardiology and nephrology departments for the safe treatment of patients by Physical and Occupational Therapists at HFH.¹⁹ PT goals were individualized to each patient, focusing on the progression of aerobic capacity for functional transfers, ambulation, and stair climbing for safe return to the home environment. Activity was titrated per required metabolic equivalent of task (MET levels) for phase I cardiac rehab²⁰ and in response to changes in the patient’s physiological status. OT goals were also individualized for returning to independence in basic activities of daily living, including education and training in energy conservation, task simplification, and adaptive techniques to improve quality of life upon returning home. Patient education handouts were developed that included self-monitoring activity progression, a pedal bike program with an exercise log, energy conservation techniques, and warning signs of activity intolerance. PT and OT were directly involved in recommending discharge plans for a safe transition to the next level of care.²¹ Patients who were expected to return home at discharge were referred to phase II cardiac rehab rehabilitation (2 weeks postdischarge). Those unable to return home due to functional limitations and lack of home support were referred to a postacute rehabilitation facility.

Statistical Analysis

All continuous data were tested for normality and are described using means and standard deviations, while categorical data are described using counts and column percentages. Univariate 2-group comparisons were performed using χ^2 and Fisher’s exact tests (when expected cell counts are <5) for categorical variables, using 2-group *t* tests and Wilcoxon rank-sum tests (when normality distributions were violated) for continuous variables. Statistical significance was set at $P < .05$. All analyses were performed using SAS 9.4 (SAS Institute, Cary, North Carolina).

RESULTS

Patient demographics and medical history were compared for all patients in the study, as detailed in Table 1. No significant differences in age, gender, BMI, or STS risk factor were found between the 2 groups. The incidence of other comorbidities or prior surgical procedures was comparable between the 2 groups, with 3 exceptions:

1. Patients in the control group had a higher rate of recent heart failure than their counterparts (intervention 42%, control 27%, $P = .03$).
2. Conversely, patients in the control group had a lower rate of prior MI than those in the control group (intervention 33%, control 20%, $P = .06$).
3. The 5-m walk test scores were collected for more patients in the intervention group than in the control group (intervention 74%, control 50%, $P < .001$).

For those who participated in the 5-m walk test, 22% of patients in the control group were unable to walk, compared with 7% in the intervention group. In addition, more patients in the intervention group (45%) required greater than 6 seconds to walk 5 m than those in the control group (9%).

Catheter valve sheath delivery size was larger in the intervention group (control 18.1 ± 4.2 mm, intervention 19.3 ± 3.8 mm, $P = .04$). The average total hospital LOS for patients in the intervention group was 2.1 days shorter in the intervention group (control 6.9 ± 5.4 days, intervention 4.8 ± 5.4 days, $P = .009$). The average postprocedure LOS was also significantly shorter in the intervention group (control 4.8 ± 2.9 days, intervention 3.5 ± 4.0 days, difference 1.3 days, $P = .015$). The percentage of patients discharged to home rather than to a rehab facility was 13 percentage points higher in the intervention group but did not meet criteria for statistical significance. All data are reported in Tables 1 and 2.

DISCUSSION

This study aimed to determine whether an early PT and OT intervention pathway in the tAVR population would improve patient outcomes. Our retrospective study demonstrates shorter hospital lengths of stay overall and postprocedure LOS for those who participated in

TABLE 1. Descriptive Statistics and 2-Group Comparisons

Variable (Count)	Control Group (n = 74)	Intervention Group (n = 115)	Test Statistic (df)	P Value
Age, mean \pm SD, y	79.5 \pm 11.2	81.6 \pm 8.4	-1.37 (125)	.17
Gender: male	42 (57%)	68 (59%)	0.10 (1)	.75
BMI, mean \pm SD	28.4 \pm 6.2	28.4 \pm 6.1	-0.02 (154)	.99
STS Risk Score, mean \pm SD	8.5 \pm 8.5	7.0 \pm 4.6	1.35 (102)	.18
Hypertension	66 (89%)	108 (94%)	1.38 (1)	.24
Afib/aflutter	29 (40%)	48 (42%)	0.07 (1)	.78
Prior MI	15 (20%)	38 (33%)	3.64 (1)	.06
Prior CABG	17 (23%)	26 (23%)	0.003 (1)	.95
Prior stroke	12 (16%)	9 (8%)	3.21 (1)	.07
Previous AV balloon	30 (41%)	36 (31%)	1.69 (1)	.19
Previous AV repair	2 (3%)	0 (0%)	3.14 (1)	.08
Chronic lung disease	28 (38%)	37 (32%)	0.64 (1)	.42
Heart failure prior 2 wk	31 (42%)	31 (27%)	4.56 (1)	.03
Diabetes	27 (36%)	49 (43%)	0.70 (1)	.40
5-m walk test prior			33.71 (4)	<.001
Not performed	37 (50%)	30 (26%)		
Unable to walk	16 (22%)	8 (7%)		
\leq 6 s	14 (19%)	26 (23%)		
>6 but \leq 10 s	3 (4%)	34 (30%)		
>11 s	4 (5%)	17 (15%)		
Valve sheath delivery, mean \pm SD, French, mm	18.1 \pm 4.2	19.3 \pm 3.8	-2.07 (187)	.04

Afib, atrial fibrillation; AV, aortic valve; BMI, body mass index; CABG, coronary arterial bypass graph; MI, myocardial infarction; N/A, unable to complete statistical test due to low incidence; STS Risk Score, Society of Thoracic Surgery Risk Score.

the pathway compared with historical controls. Although the percentage of patients returning home at discharge was not statistically significant, the incidence did slightly increase after the pathway was implemented. While the benefits of early intervention by PT and OT in the acute care setting are well established in the literature,²²⁻²⁴ studies specific to patients' status post-tAVR have not been published previously. Daily PT and OT interventions were likely contributors to patients meeting functional

goals in a shorter timeframe for discharge home. The authors hypothesize that several additional factors contributed to the success and of the tAVR pathway, including the multidisciplinary collaboration in the design and implementation of the program. Other factors included having an automatic order set for PT and OT consults in the EMR that were placed immediately postprocedure and streamlined the process of evaluation, treatment, and monitoring of all patients undergoing tAVR.

TABLE 2. Patient Outcomes: Descriptive Statistics and 2-Group Comparison

Variable	Control Group (n = 74)	Intervention Group (n = 115)	Test Statistic (df)	P Value
Postprocedure LOS, mean \pm SD, d	4.8 \pm 2.9	3.5 \pm 4.0	2.46 (184)	.015
Total LOS, mean \pm SD, d	6.9 \pm 5.4	4.8 \pm 5.4	2.64 (187)	.009
Home discharge disposition (count, % of total)	57 (77%)	99 (86%)	4.28 (2)	.118
Rehab facility discharge disposition (count, % of total)	17 (23%)	16 (14%)		

LOS, length of stay.

Additionally, mobility training encouraged nursing staff to adhere to the expected mobilization of patients 6 hours postprocedure. The development of tAVR-specific educational materials provided written documentation of verbal instruction to reinforce training provided during PT and OT evaluation and intervention. Consistent and timely documentation in the EMR promoted clear communication among service providers throughout patients' continuum of care. Finally, early recommendations for discharge destination from PT and OT helped coordinate discharge planning.

PT's and OT's early intervention on day 1 post-tAVR likely provided the patient and medical team with defined therapeutic goals, as well as accurate and appropriate discharge recommendations, as Smith et al²¹ found in a 2010 study. Daily PT and OT interventions were also likely contributors to patients meeting functional goals in a shorter timeframe for discharge home. The authors hypothesize that several additional factors contributed to the success of the tAVR pathway, including the multidisciplinary collaboration in the design and implementation of the program. Other factors included having an automatic order set for PT and OT consults in the EMR that were placed immediately postprocedure and streamlined the process of evaluation, treatment, and monitoring of all patients undergoing tAVR. Additionally, mobility training encouraged nursing staff to adhere to the expected mobilization of patients 6 hours postprocedure. The development of tAVR-specific educational materials provided written documentation of verbal instruction to reinforce training provided during PT and OT evaluation and intervention. Consistent and timely documentation in the EMR promoted clear communication among service providers throughout patients' continuum of care. Finally, early recommendations for discharge destination from PT and OT helped coordinate discharge planning.

The authors acknowledge several limitations in this study. The retrospective study design introduces selection bias and limits study results and generalizability. Data on frequency and timing of PT and OT could not be captured, as all documentation was recorded on paper to November 2014. Additionally, the patient's level of function prior to cardiac surgery was not accounted for, which may have impacted the results. The patient's level of social support was not taken into consideration, which could have affected discharge recommendations. Discharge disposition recommendations are made at the discretion of the PT or OT assessing the patient, which involves clinical judgment. Objective measurements guided this clinical decision-making (ie, levels of assistance required, vital sign response to activity, etc); however, all clinical decision-making involves a degree of subjective judgment, which is difficult to measure and may have impacted this study in ways the authors

could not control. Finally, the STS Risk Score, which is a common indicator used by interventional cardiologists prior to tAVR, was developed for patients undergoing traditional cardiac surgery,¹⁴ thus limiting its applicability to the tAVR population.

Overall, the authors were encouraged to continue the use of the tAVR pathway in this surgical population due to the potential effect on patient outcomes. Early PT and OT intervention following tAVR appears to promote statistically significant shorter inpatient LOS, and possibly increased discharge home versus to a rehab facility. Further research is needed to determine the effect of patients' preoperative level of function, level of social support, and clinician judgment on discharge recommendations. Future studies should include the use of standardized functional tests post-tAVR, STS Risk scores calculated specifically for patients who undergo a tAVR procedure, assessment of a patient's prior level of function, and comorbid conditions pre-tAVR procedure and long-term outcomes. Supplementary research may consider more detailed records of PT and OT interventions to determine whether specific treatments have improved efficacy or altered patient outcomes. The authors intend to assess results of the implementation of the tAVR pathway for intermediate and/or lower-risk patient populations, as transcatheter procedures have become the recommended alternative to sAVR for high-risk patients, and studies continue to investigate the efficacy of tAVR for patients in lower risk populations.^{6,25,26} Additionally, the authors recommend expanding the pathway program to include patients post-tAVR regardless of catheter access site, transcatheter mitral valve replacement (tMVR), and other minimally invasive catheter-based procedures.^{26,27}

CONCLUSION

This early intervention PT and OT clinical pathway specific to patients post-tAVR provided early mobility, targeted education, individualized functional goals, and discharge disposition recommendations. Upon implementation of this tAVR pathway, patients experienced reduced hospital LOS, reduced postprocedure LOS, and a trend toward a higher incidence of discharge home versus a rehabilitation facility. Upon implementation of this tAVR pathway, patients experienced reduced hospital LOS and postprocedure LOS and a trend toward a slightly higher incidence of discharge home versus rehabilitation facility. Further research is needed to determine optimal parameters within the pathway protocol and expand the pathway to more inclusive populations as advancements in transcatheter procedures, and standardized care continues. This study suggests that an acute care PT and OT early intervention clinical pathway is feasible and can impact hospital and postprocedure LOS.

ACKNOWLEDGMENTS

The authors wish to acknowledge the Departments of Rehabilitation Services and Structural Heart at Henry Ford Hospital, particularly Drs William O'Neill and Adam Greenbaum and Nanette Hannum for research support. This study is registered with ClinicalTrials.gov NCT03117296.

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