Efficacy of Tafamidis in Transthyretin Amyloid Cardiomyopathy in the ATTR-ACT Trial

Background: Transthyretin cardiomyopathy (ATTR-CM) is an underdiagnosed, fatal disease caused by the deposition of transthyretin amyloid fibrils in the heart leading to heart failure (HF). It can be hereditary due to mutations in the TTR gene (ATTRm) or acquired (wild-type [ATTRwt]). Tafamidis is a selective transthyretin stabilizer which prevents tetramer dissociation and amyloidogenesis. The Tafamidis in Transthyretin Cardiomyopathy Clinical Trial (ATTR-ACT) was an international, multicenter, double-blind, placebo-controlled, randomized trial of Tafamidis in patients with ATTR-CM.
Objectives: Given the limited number of patients with ATTR-CM, a novel study design was utilized to enable rigorous testing of the efficacy of tafamidis on hard cardiovascular (CV) endpoints in a study of relatively modest size compared with traditional CV trials. The primary results of this trial were further supported through the application of pre-specified sensitivity analyses.
Methods: Patients with ATTR-CM were randomized (2:1:2) to tafamidis (80 mg or 20 mg of tafamidis meglumine), or placebo (orally, once daily), for 30 months. Enrollment was stratified by NYHA class and genotype. The primary efficacy analysis was a hierarchical combination of all-cause mortality and frequency of CV-related hospitalizations comparing the pooled tafamidis groups (20 mg and 80 mg) vs. the placebo group using the Finkelstein-Schoenfeld (F-S) method. The primary efficacy analysis result was examined using a series of sensitivity analyses. Key secondary endpoints were change from baseline to Month 30 in the six-minute walk test distance and the Kansas City Cardiomyopathy Questionnaire (KCCQ) overall score. Safety assessments included adverse events, vital signs, and clinical laboratory tests.
Results: A total of 441 patients were randomized (tafamidis=264, placebo=177). Tafamidis was associated with a significant reduction in the hierarchical combination of all-cause mortality and CVrelated hospitalizations ($P<0.001$). Tafamidis also significantly reduced the decline in both the six-minute walk distance (by 75.68 m [standard error, 9.24]; $P<0.001$]),and KCCQ overall score (by 13.65 [2.13]; $P<0.001$) as compared with placebo. Sensitivity analyses consistently confirmed the efficacy of tafamidis in patients with ATTR-CM: there was a 30% reduction in risk of all-cause mortality (heart transplant and implantation of a cardiac mechanical assist device treated as death) with tafamidis compared with placebo (P=0.0259); and when heart transplant and implantation of a cardiac mechanical assist device were not treated as death, there was a 33% reduction in risk of all-cause mortality with tafamidis compared with placebo (P=0.018). Tafamidis was safe and well tolerated in this population.
Conclusions: ATTR-ACT, the largest randomized controlled trial in ATTR-CM, showed that tafamidis is the first treatment to improve survival and quality of life in ATTR-CM. Significant and clinically meaningful improvements were observed in functional capacity as measured by the six-minute walk distance and quality of life by KCCQ overall score. Sensitivity analyses confirmed the robustness of these results. Tafamidis was safe and well tolerated. The primary trial results, along with the sensitivity analyses described here, provide strong rationale for the use of tafamidis as first-line therapy in ATTR-CM.

The Effect of a Nurse-Driven Program Utilizing Implantable Pulmonary Artery Pressure Monitoring to Reduce Hospitalizations in Low-Socioeconomic Urban Patients with Heart Failure

Background: Hospitalizations in patients with heart failure (HF) remain high despite advances in treatment. While implantable pulmonary artery pressure monitors (Abbott CardioMEMS) reduce readmissions in largely white and male cohorts, their efficacy in poor, minority populations are not known. We hypothesized that a nurse-driven program using the CardioMEMS device could reduce HF hospitalizations in such patients.
Methods: 22 high-utilizing patients (86% non-white, 55% female) with NYHA Class III HF were implanted with a CardioMEMS following a hospital admission for HF. Data from the CardioMEMS guided a speciallytrained nurse in adjusting medications. Enrolled patients were matched using 30 clinical and demographic variables with contemporaneous control HF patients who received usual care. Each patient's hospitalizations were recorded for 6 months and compared using Fisher's exact test.
Results: Patients who received a CardioMEMS experienced a 61% decrease in HF-related readmission and a 70% reduction in HF-related ED visits ($p<0.01$ for both). Additionally, 19 out of the 22 CardioMEMS patients did not have any HF-related admissions after device implant. Time to first HF-related readmission (Figure) and first HF-related ED visit were both longer in CardioMEMS patients ($p<0.01$ for both) and cumulative rehospitalized days were significantly lower in the CardioMEMS patients.
Conclusion: A nurse-driven CardioMEMS program reduces HF-related hospitalization and ED visits among high-risk, low-socioeconomic, urban patients.

Heart Failure Nurse Navigator Program Interventions Based on LACE Scores Reduces Inpatient Heart Failure Readmission Rates

Objective: This presentation will identify top causes for Heart Failure (HF) patient readmissions and strategies for HF readmission prevention. The HF Nurse Navigator's role in preventing readmissions will be described. The implementation of the HF standard work discharge tool with seven interventions based on LACE scores used in the HF Nurse Navigator program will also be defined.
Background: Heart Failure continues to be one of the leading causes for hospitalization (national 30-day All-Cause HF readmission rates average: 22%). The goal of this community hospital is to decrease their average 30-day All-Cause HF patients' readmission rates from 21% to <17% post-intervention of the HF Nurse Navigator program.
Problem Statement: Increasing Heart Failure readmission rates due to avoidable readmission causes are unfavorable for our cardiac patients' quality of life and contribute to payment penalties.
Methods: The Heart Failure Nurse Navigator (HF NN) role was created at this hospital with the goal of decreasing readmissions and improving patient outcomes for the HF patient across the continuum of care. The HF NN is an expert clinician leader and a resource to the healthcare team in Progressive Care and other inpatient units through one-on-one HF education with the patient or significant other, and assists in identification of services unique to each patient's needs for a smooth transition from hospital to home. New Nurse Leader roles such as an Advanced Practice Nurse Navigator equipped with EvidenceBased knowledge and training is vital to oversee a specialized patient population in Acute Care; to design and implement interventions that can improve patient outcomes and decrease the patient's risk for readmission within 30 days. The HF NN in collaboration with the HF Team designed a Quality Improvement project implementing a HF Standard Work Discharge Checklist with seven patient interventions for the Acute Heart Failure patient. These interventions include: HF Teach-Back education; HF clinic referral; Outpatient pharmacy prescription delivery to bedside; Discharge Medication list education by the Pharmacist; Follow-up appointments made prior to discharge; Transitional Medical Clinic appointment within 5 days of discharge; and Home Health RN HF Medical Management. LACE (Lengthof-Stay, Acuity, Co-Morbidities and ED visits) scoring developed by Van Walvaren et al. (2010) was used to assess for readmission risk and to implement interventions specific for each HF patient based on their LACE score.
Results: This hospital's average 6-month All-Cause HF readmission rate decreased to 12.94% after the pilot of the HF Nurse Navigator program, vs. 21.1% pre-intervention. After the HF NN role was

implemented, the average 6-month HF 30-day All-Cause readmission rate decreased by 39% postintervention over the 6-month pilot period.
Conclusions: The team-based HF Nurse Navigator interventions described when implemented for every Acute HF patient admission decreased HF readmission rates. There is a need to have 7-day a week coverage by a HF NN in an institution to ensure identification of services unique to each HF patient's complex needs. The HF NN can ensure that the HF patient has a smooth transition from hospital to home with these interventions, resulting in a decreased readmission risk.

Case Study: Daily review of telemonitoring data by a critical care nurse improves outcomes in a patient with Class IV, Stage D heart failure with reduced ejection fraction receiving home intravenous dobutamine for palliation.

Purpose: The purpose of this case study is to demonstrate how a robust telemonitoring program, which includes daily critical care nurse review of heart failure symptoms, vital signs, oxygen saturation, weight, and blood glucose levels, prompts clinical interventions that result in overall improved symptom management and decreased hospital readmissions for a patient requiring home inotrope infusion.
Objectives: 1. To summarize particular telemonitoring data that triggered nursing telephonic outreach for further patient evaluation
2. To summarize clinical interventions resulting from data and nursing telephonic outreach
3. To report patient outcomes (symptom improvement and avoidance of hospitalizations)
Methods: A retrospective review of this patient's medical record was performed, which consisted of telemonitoring data, physician order changes, and clinical assessments performed by critical care nurses.
Results: This 50 year old male with Class IV, Stage D heart failure with reduced ejection fraction was admitted to this home infusion provider on 03/26/2015 to receive palliative treatment with continuous intravenous dobutamine 2.5 mcg/kg/min and daily telemonitoring. He was not a candidate for advanced heart failure therapies, such as left ventricular assist device or heart transplant, due to prior noncompliance with his treatment plan. The first telemonitoring data was transmitted on 03/28/2015. The patient was largely compliant with daily data transmissions throughout the course of care, which ended 06/03/2015 when the patient's insurance changed and the payor mandated transfer of care to another home infusion provider. A telephonic assessment performed by a critical care nurse occurred each day the transmitted data triggered an alert. A total of 25 alerts were received and are summarized as follows: 1 increased lower extremity edema, 5 weight increased more than 2 pounds in 24 hours, 7 heart rate and blood pressure elevations, 2 blood glucose elevations, 1 increased orthopnea, 1 significant weight loss in 24 hours, and 8 missing daily data transmissions. These alerts and resulting telephonic assessments prompted 61 clinical interventions, which included: 32 nursing visits for IV furosemide administration, 7 patient education sessions, 1 additional dose of oral furosemide, 7 rechecks of blood pressure and heart rate, 6 physician contacts, and 8 patient contacts requesting health check/data transmission.
Conclusions: Daily critical care nurse telemonitoring resulted in nearly daily interventions with gradual stabilization of weight and vital signs, no decline in respiratory status, and no hospitalizations throughout 69 days of service. Of particular significance is the fact that telemonitoring improved the patient's compliance to his treatment plan, which resulted in an evaluation for a left ventricular assist device placement.

It takes a Village to Care for the Mechanical Circulatory Support Device Patient throughout the Care Environment

Purpose: Over 23,000 mechanical circulatory support (MCS) devices have been implanted since 2006. Survival for patients with MCS at 3 years is approximately 60%. In the hospital environment, there are an increasing number of patients with devices from both index admissions, readmissions and non-device related admissions. Frequently patients in the Progressive and Acute Care settings are required to travel off the unit requiring nurses to leave their other patients while accompanying the MCS patient. Our urban, academic medical center needed a way to support these patients and the team members caring for them.
Objectives: Creating a safe environment for patients to receive care is of utmost importance in a complex patient population with essential life sustaining equipment. Empowering knowledge to our team members allows for smoother transitions throughout the practice areas and a shared ownership for their safety.
Methods: A class was developed for support team members and taught by CT Surgery Clinical Nurse Specialists and VAD Coordinators. Transporters, care partners, occupational therapists, physical therapists, speech therapists, nurses in procedural/ambulatory areas, and others attended the educational class. The 2 hour class consisted of introduction to MCD devices - Heart Mate II, III / HeartWare and Total Artificial Hearts devices. Opportunities for hands on learning allowed for greater comfort with handling the equipment during everyday care or an emergency. This annual required education was offered monthly.
Results: Stable ventricular assist device patients are able to travel off the Progressive and Acute care units without a nurse or VAD coordinator due to this collaborative effort. There has not been any serious safety events related to VADs being transported off the units since this practice was implemented in 2013.
Conclusions: It takes a village to care for patients with Mechanical Circulatory Support and this organization welcomes them throughout the care environment. Non-licensed team members in additional to nurses in ambulatory areas can safely care for patients when leaving their primary inpatient units, allowing for greater awareness of the special needs of this complex population.