Interim Analysis of the INTERPRET Patient Registry Program of Advanced Heart Failure Patients Treated with Intravenous Inotropes in the Ambulatory Setting

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Introduction

Inotropic therapy has been associated with increased risk of arrhythmic events and reduced survival. Yet inotropes continue to be prescribed for palliative care, or as a bridge to cardiac transplantation or a ventricular assist device (VAD). We conducted an interim analysis of the Inotrope, Evaluation and Research (INTERPRET) Patient Registry Program, a contemporary registry of advanced heart failure patients receiving continuous inotropic therapy in the ambulatory setting.

Methods

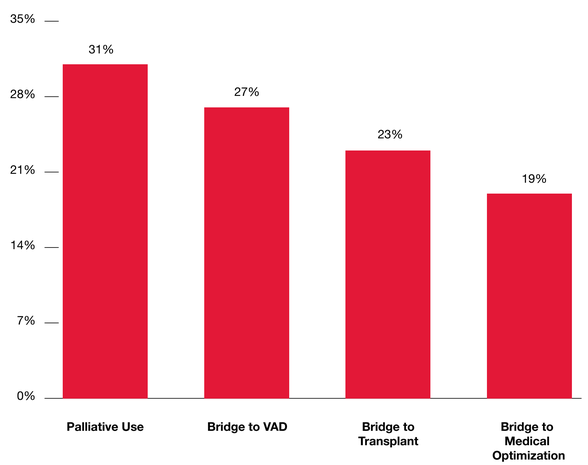
This is a multi-center, prospective, observational registry study. All patients prescribed intravenous dobutamine, dopamine, or milrinone for continuous home use, and who utilized the Coram CVS Specialty vendor, were eligible to participate. Outcome measures included mean time of survival on inotropes, frequency and cause of hospital readmissions, arrhythmia burden including ICD shocks, patient symptoms on a 10-point scale, and quality-of-life scores using the Kansas City Cardiomyopathy-12 (KCCQ-12) questionnaire.

Results

Twenty-six patients have been enrolled in the study. The average age of the patients was 61 yrs (range 18-94) and the majority of patients were male (81%).

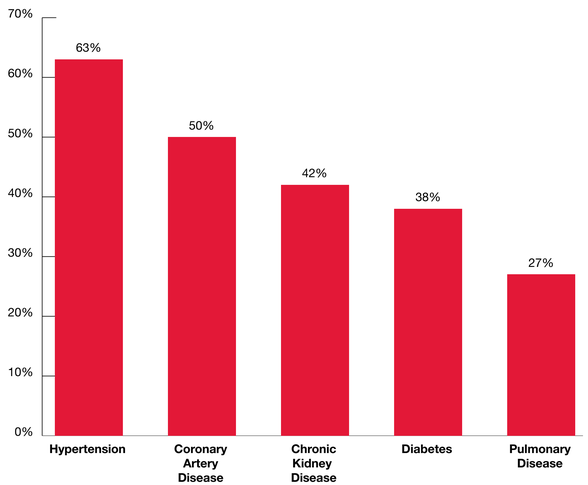
Reason for inotrope use was as a bridge to transplant (23%) or VAD (27%), as palliative care (31%), or as a temporary bridge to optimizing medical therapy (19%). See Figure 1.

Figure 1. Home Inotrope Patient Indication



In terms of associated comorbidities, we noted that 63% of patients (n=15) had hypertension, 50% (n=12) had coronary artery disease, 42% (n=10) had kidney disease and 38% suffered from diabetes (n=9). Two patients had congenital abnormalities leading to their heart failure diagnosis. See Figure 2.

Figure 2. Co-Morbidity Incidence in Home inotropic Registry Population



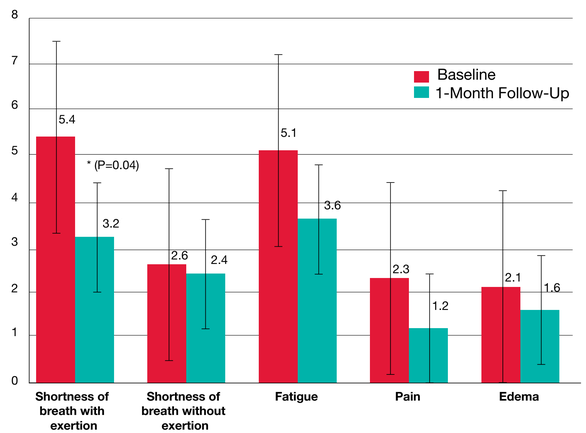
Ten patients (38%) have died, or moved to hospice care and off of inotropic therapy. Of these 10, 5 were on palliative inotropes, 2 were waiting for transplant, 2 were waiting for a LVAD insertion, and 1 was bridging to optimized medical therapy. Across this population, the average survival time on therapy thus far has been 93 days (range 33-188).

Six out of 26 patients (23%) were re-hospitalized within 30 days of discharge, none due to arrhythmias. Two patients reported altered mental status or confusion (hepatic encephalopathy), and two reported worsening heart failure symptoms. One patient was hospitalized for pre-transplant testing, and one for VAD insertion. Two patients with ICD devices reported palpitations or syncope, but only one indicated that the device fired.

At discharge from hospital to start of home therapy, patients were asked to rate their symptoms, including shortness of breath, with and without exertion, fatigue, bodily pain, and edema severity. Overall, patients reported more severe shortness of breath with exertion (5.4/10), fatigue (5.1/10), and edema (2.1/4) compared to less-severe shortness of breath without exertion (2.6/10) and pain (2.3/10).

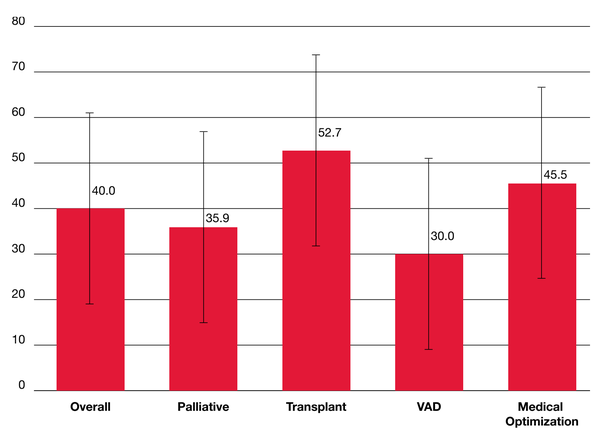
After one month of home inotropic therapy, the overall averages showed a significant improvement in shortness of breath with exertion, improving from 5.4/10 to 3.2/10 (p=0.04). The other symptoms showed non-significant improvements: shortness of breath without exertion (2.6/10 to 2.4/10); (fatigue 5.1/10 to 3.6/10); and pain (2.3/10 1.2/10. See Figure 3.

Figure 3. Patient-Reported Symptom Severity



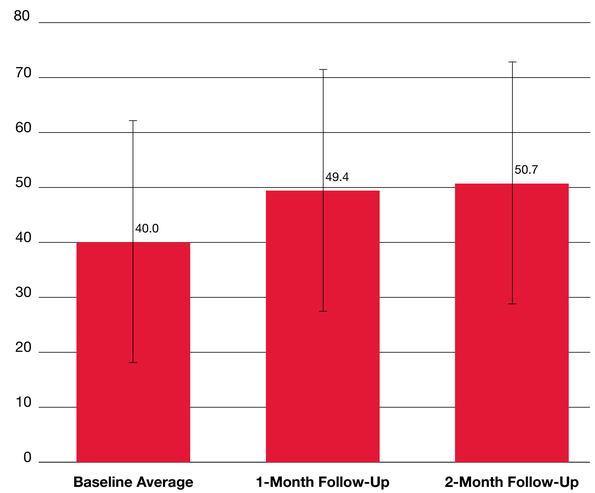
Baseline KCCQ-12 summary scores averaged 40.0 (range 0.0-82.6, n=24). Palliative care and VAD patients trended below the average (35.9 and 30.0 respectively), while transplant and bridge to medical optimization patients trended above the average (52.7 and 45.5 respectively). See Figure 4.

Figure 4. Baseline KCCQ-12 Quality-of-Life Scores



Follow-up KCCQ-12 surveys revealed an overall trend, but no significant difference from baseline, toward improved quality-of-life scores. The overall average after 1 month on therapy was 49.4 (range 0-68.8, n=10, P=0.27), while the overall average at 2 months was 50.7 (range 9.7-77.8, n=6, P=0.3). See Figure 5.

Figure 5. KCCQ-12 Quality-of-Life Follow-Up



Conclusions

An interim analysis of the INTERPRET Patient Registry revealed a number of trends for patients referred for home inotropic therapy.

- The majority of patients enrolled were male, with an average age of 61.
- More than half (63%) of patients had hypertension, half had coronary artery disease, and more than a third (38%) also had diabetes.
- Reason for inotrope prescription varied, including palliative care (31%), bridge to VAD (27%), bridge to transplant (23%) and bridge to optimized medical therapy (19%) .
- Overall, patients report an improvement in shortness of breath with exertion with non-significant trends toward improvements in other symptoms within the first month of home inotropic therapy.
- Patient-reported quality-of-life scores showed a non-significant trends toward improvement over the course of the first two months of home inotropic therapy.
- While encouraging trends towards improvements in symptoms have been observed, we are limited in our ability to firmly confirm the benefits of short-term inotrope use until adequate enrollment and follow-up time has been achieved.