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ARTICLE

Bridging the gap between study outcomes and real-world results. Algorithm-driven management in a rural cardioMEMS population

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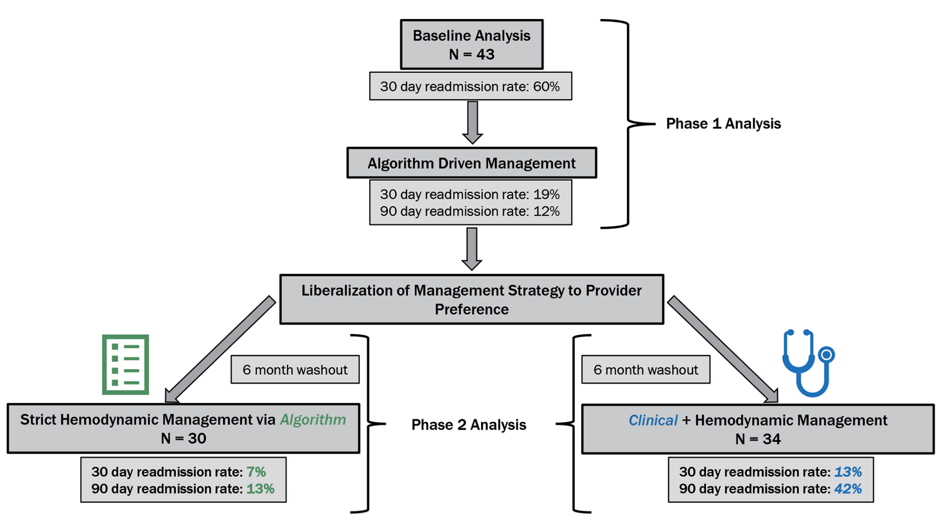
Abstract

Current therapeutic strategies are ineffective at keeping heart failure patients out of hospital. In 2017, all-cause readmission rates were 19.9% at thirty-days and 34.6% at ninety-days. Large scale studies have shown potential advantages with remote pulmonary artery pressure monitoring. We sought to refine the management of our remotely monitored cohort by introducing a hemodynamic treatment algorithm. A population of rural heart failure patients previously implanted and managed with remote pulmonary artery pressure sensors were studied (n=43). Algorithm based hemodynamic management began with prospective outcome monitoring for ninety days during which algorithm use was mandatory. Following the initial observation period, some physicians reverted to prior practice habit which included consideration of standard heart failure metrics into decision making. Following a six-month washout period, retrospective analysis was performed in evaluation of the intervention arm (n=34), patients managed by hemodynamic plus usual heart failure data, and the control group (n=30), those who remained strictly managed by algorithm. Pre-algorithm thirty-day heart failure specific hospitalization (HFH) rate was 60%. Algorithm-driven management decreased HFH rates to 19% at thirty-days and 12% at ninety-days. Incorporating standard heart failure metrics with remotely pulmonary artery (PA) pressure data markedly increased risk of readmission (7% *vs* 13% at thirty-days and 13% *vs* 42% at ninety-days). Heart failure patients managed *via* remote pulmonary artery pressures benefitted from algorithm-driven hemodynamic therapies. Utility and effectiveness of remote PA monitoring is stunted with consideration of traditional heart failure metrics (weights, symptoms, exam findings) in their management.

Graphical abstract

Heart failure patients transmitting remote pulmonary artery pressures fare better when strictly managed by hemodynamic algorithm. Routine care guided by algorithm ensures hemodynamic triggers for intervention while simultaneously curbing entrenched practice patterns. Beware usual heart failure metrics in this population. Incorporating weights, symptoms, and exam findings into decision making complicates management, increases hospitalizations, and blunts the advantages afforded by implantable pulmonary artery pressure sensors.



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Introduction

Estimation of central venous pressures *via* physical examination of the jugular veins was first described by Sir Thomas Lewis in 1930 and has since become a cornerstone in the volume examination of heart failure patients. Aided by the scale, made popular by the Babylonians more than 4,500 years ago, the assessment of heart failure patients in the 21st century remains similar to that of providers in the era of smallpox, polio, and scurvy. Unsurprisingly, mortality in this population remains poor with a 5-year survival of 25% regardless of left ventricular ejection fraction (LVEF).[1,2]

Modern day ingenuity has created the opportunity for medical providers to provide precision care from a distance. Wireless internet connectivity reaches across the globe, connecting us through our pockets. Rapid technologic advancement has supercharged the smartphone into a computer 100,000 times more powerful than that which landed mankind on the moon. Implantable hemodynamic cardiac monitoring leverages this marvelous electronic infrastructure to give providers the opportunity to deliver precise, patient specific, superior heart failure care. Pulmonary artery (PA) pressure monitoring has been shown to improve mortality, quality of life, and risk of hospitalization compared to standard of care (SOC).[3,4,5] Despite mounting evidence in favor of PA pressure monitoring, this strategy remains uncommon. At most, 3% of the 6.7 million Americans with heart failure have enjoyed the benefits of a hemodynamically guided management strategy.[6] The remaining 6.5 million patients and their providers are relegated to SOC management which is based off inherently unreliable data. Physical examination findings, subjective symptoms, and standing weights comprise the SOC and as a consequence successful heart failure management *via* usual methods is difficult. Heart failure readmission rates at thirty and ninety-days increased 8.1% and 18.3%, respectively, from 2010 to 2017.[6]

Literature on remote PA pressure management has sought to define patient outcomes. These trials provided a high-level overview of day-to-day management of PA pressure variations. We sought to develop a detailed workflow that would enable our resource-limited clinic to utilize remote PA pressures effectively. We hypothesized that implementation of a novel algorithm would standardize management and ensure treatment of hemodynamic derangements. The results of this single-center investigation evaluate the usability of a detailed algorithmic approach in management of this population and assesses preliminary effectiveness of this strategy.

Methods

A rural heart failure population managed *via* remote PA pressures PM (n=43) was retrospectively analyzed after approval was granted by our institutional review board. The study was conducted in accordance with the 1964 Helsinki Declaration ethical standards. Baseline demographics, comorbid conditions, prescription medication regimens (Table 1), and thirty-day heart failure specific hospitalization (HFH) rates were obtained.

A novel treatment algorithm (Figure 1) was developed loosely based on previously published supplementary materials.[2] On implant day, antiplatelet and/or anticoagulation therapy was prescribed per manufacturer recommendation(s). Patient(s) with implant PA diastolic pressures of 36 mmHg or greater were excluded from the study (n=1).

The "decongestion phase' immediately followed implantation where goal PA diastolic pressures were set and aggressively sought *via* guideline directed medical therapies (GDMT) titration, diuretic adjustment, and/or behavioral/dietary reinforcement. Diastolic PA pressures are thought to best reflect left ventricular filling pressures assuming no other significant co-existing pathology. As such, we relied on the diastolic PA pressure as our surrogate to volume status.

Goal PA diastolic pressures were set at 10 mmHg below implant value or 15 mmHg, whichever higher. Aggressive pharmacotherapy adjustments in the week following implantation were expected to reach the PA diastolic target. Patients with implant values of 30-35 mmHg would have an additional 5-10 mmHg reduction in target PA diastolic pressures at the end of the "decongestion phase" as renal function and blood pressures allowed. Following decongestion, patient specific PA diastolic targets were identified and marked the start of the "maintenance phase". Pharmacologic interventions during this phase were strictly triggered per our algorithm (Figure 1). Day to day variability in PA pressures was considered in our workflow by reviewing data every other workday. This strategy also reduced taxation upon limited clinical resources. No additional full time equivalent position was required to implement and sustain our algorithm despite program growth of 125%.

Three consecutive increases or decreases in PA pressures were considered an actionable trend and thereby met "trigger threshold" for intervention per algorithm. Trigger thresholds above target of 3-5 mmHg and 6-10 mmHg mandated diuretic bursts of either one or three-day durations, respectively. Pressures 5-7 mmHg below target were also a trigger threshold for algorithmic driven changes to diuretic regimen.

Particular attention to pharmacology was paid in the design of the algorithm and selection of interventions. Bumetanide and torsemide were favored over furosemide given their superior pharmacokinetics, better oral bioavailability, and predictable half-lives regardless of renal function.[7] The concept of diuretic threshold dosing was also considered. Physiological response to diuretics was assessed frequently during the initial decongestion phase. Once in the maintenance phase, diuretic effectiveness was reassessed if an algorithm-driven intervention threshold was met. An effective diuretic dose was defined by a void within 30-60 min of administration followed by additional voids every 30-60 min lasting a total of 6 h. If an above goal algorithm threshold were met, diuretic effectiveness would be confirmed prior to increasing diuretic frequency to twice daily. If the dose of loop diuretic was deemed ineffective by failing to meet the aforementioned criteria, the dose would be doubled without increase in administration frequency. A third and final treatment option was the addition of distally active thiazide-like diuretic. Metolazone was dosed according

Table 1. Baseline characteristics, comorbid conditions, and medications of study population.

Demographics	Age*	Female	BMI*	History of PCI	History of CABG	History of AFIB/AFL
	74	55% (24/44)	35	64% (28/44)	18% (8/44)	68% (30/44)
Chronic kidney disease stage	GFR >60	II	III	IV	V	
	11% (5/44)	25% (11/44)	50% (22/44)	23% (10/44)	3% (1/44)	
Guideline directed medical therapies	ACE/ARB	Sacubitril/valsartan	SGLT2i	ALD-A	Isosorbide dinitrate hydralazine	Betablocker[#]
Pre-algorithm	39% (17/44)	0%	0%	14% (6/44)	0%	59% (26/44)
90 days post-algorithm	43% (19/44)	0%	0%	23% (10/44)	0%	66% (29/44)

*on average; [#]guideline directed betablockers; BMI, body mass index; PCI, percutaneous intervention; AFIB, atrial fibrillation; AFL, atrial flutter; GFR, glomerular filtration rate; ACE, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; SGLT2i, sodium glucose cotransporter-2 inhibitor; ALD-A, aldosterone receptor antagonist.

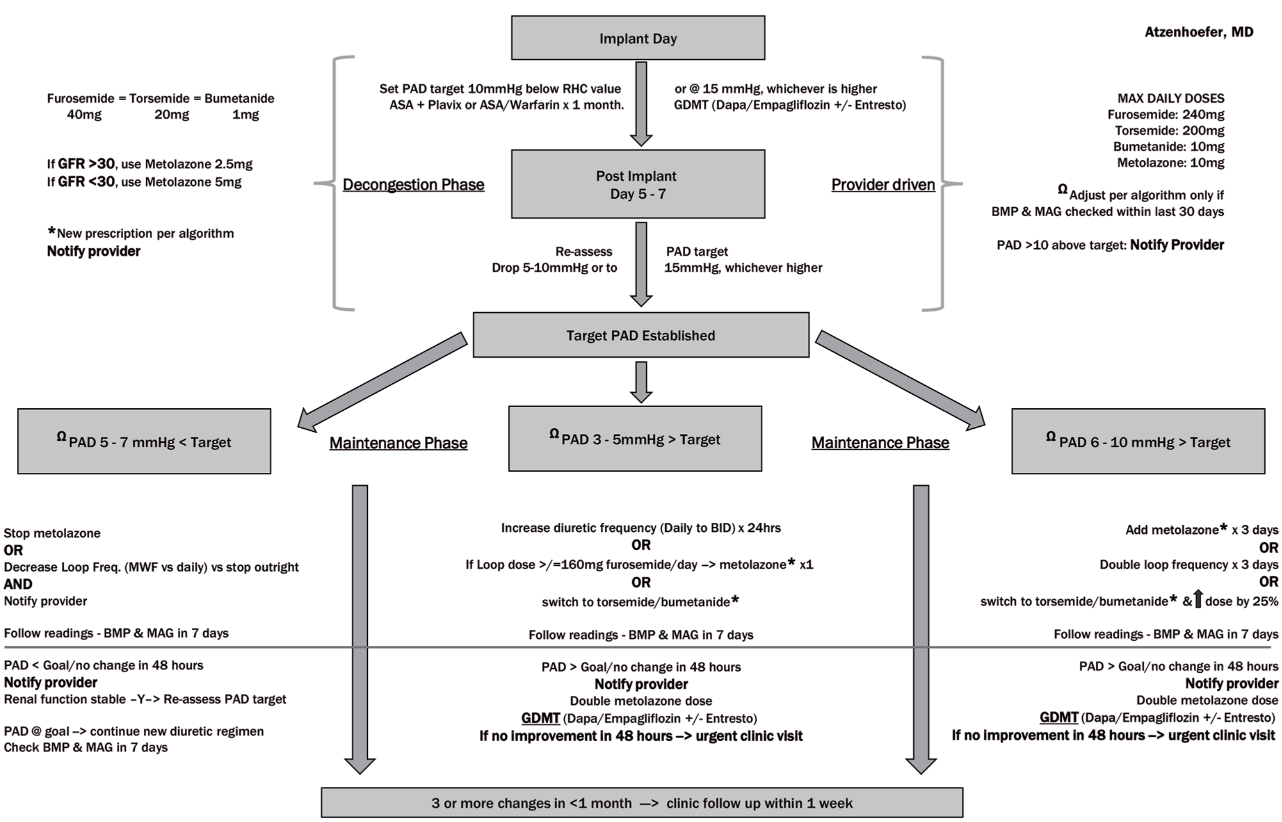

Figure 1. Novel algorithm guiding workflow and management of heart failure patients monitored via remote pulmonary artery pressure sensor. PAD, pulmonary artery diastolic pressure; RHC, right heart catheterization; ASA, aspirin; GDMT, guideline directed medical therapies; BMP, basic metabolic panel; MAG, magnesium; Freq., frequency; Y, yes; BID, twice daily; MWF, Monday; Wednesday; Friday.

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to baseline serum creatinine and administered thirty minutes prior to usual loop diuretic. If the patient was metolazone naïve a one-time dose would be given to evaluate duration of response. The algorithm was tolerant of up to 5 mmHg decreases in PA diastolic pressures below target but less lenient with pressure elevations. Transmitted measurements 3-5 mmHg above PA diastolic target in a trend warranted a 24-hour burst of diuretic therapy. As congestion burden increased, so did the duration of diuretic burst. PA diastolic pressures 6-10 mmHg above target in a trend were treated with three-day durations of decongestive measures.

Patient safety was paramount and built into our approach. Prerequisite to any algorithm triggered intervention were recent renal and electrolyte assessments defined as basic metabolic panel (BMP) and serum magnesium (MAG) levels drawn in the past thirty days. Additionally, interventions were followed by repeat BMP and MAG analyses within seven days. Successful interventions were characterized by return of PA diastolic pressures to target (±2 mmHg). Interventions were expected to improve pressures within 48 hours. If no improvement was observed or a patient required ≥3 interventions within 30 days, urgent office visits were scheduled for prompt evaluation within 7 days. All algorithm triggered interventions were accompanied by review of the patient's GDMT regimen.

After stakeholder approval, the algorithm was prospectively implemented in phase one of our study (Figure 2). All patients with a CardioMEMS™ device (n=33) and any subsequent implants between 1/1/2022 and 4/1/2022 (n=10) were exclusively managed *via* hemodynamic algorithm (Figure 1) for a minimum of three months. Care teams under the direction of a treating physician began Monday, Wednesday, Friday reviews of PA measurements upon initiation of an individual patient's maintenance phase. Using the manufacturers online interface, target pressures were set for each patient allowing quick identification of those that required review. Trend identification was streamlined by utilizing the graph display function available through the device's online utility. The primary endpoint of thirty-day all cause hospitalization was prospectively monitored along with secondary endpoint of ninety-day all cause hospitalization. Medication regimens were assessed before the start and at the completion of phase one during which all patients were exclusively managed *via* algorithm.

Phase two of the study began immediately following termination of the initial 90-day observation period (Figure 2). Control patients continued to be strictly managed by hemodynamic algorithm. The intervention arm represented patients managed with a hybrid approach. Clinical data from SOC, i.e. symptoms, daily weights, and physical exam findings, were considered in tandem with remote PA pressures in the routine management of the intervention group. Providers employing a hybrid management approach had continued access to the algorithm to be used at their discretion.

In order to mitigate potential confounding from lingering effects of phase one mandated algorithm use, retrospective chart review in phase two was performed after a 6-month washout period. Patients during the washout period were managed according to their group. Controls made up 47% (n=30/64) while patients managed *via* a hybrid clinical and hemodynamic approach comprised the remaining 53% (n=34/64) of phase two analysis. Inclusion/exclusion criteria were the same as previously mentioned. The same primary and secondary endpoints of phase two were the same as phase one, all cause hospitalization at thirty and ninety days. Admissions to hospital were subsequently adjudicated for a heart failure specific cause by three independent reviewers. Only hospitalizations that were unanimously identified as not due to heart failure were excluded from the HFH total. If one or more reviewers independently determined a hospitalization was due to heart failure, the admission was identified as HFH. Statistical analysis performed using the Z-Test with a *p*-value of <0.05 considered significant.

Hospitalizations due to hypervolemia as well as potential sequelae from heart failure therapy like hypovolemia, syncope, or electrolyte disturbance were included as heart failure specific etiologies for hospitalization. Additional attention was paid to admissions for new onset cardiac arrhythmias, acute on chronic renal dysfunction, orthostatic hypotension, dizziness, near syncope or other signs of possible dehydration from excessive diuresis.

Results

Baseline thirty-day HFH rate was 60% (26/43) in the phase one cohort. Five patients had >1 HFH. Strict algorithm-driven management immediately reduced thirty-day HFH rate by 68% *p*=0.00005 (post algorithm HFH 19% (8/43) *vs* pre algorithm HFH 60% (26/43). Admissions to hospital continued to decline with an observed 12% (5/43) ninety-day HFH rate (Figure 2). The cohort was 55% female with an average body mass index of 35. Nearly 66% (32/44) of patients had stage III or IV chronic kidney disease. Use of sacubitril/valsartan, sodium glucose cotransporter-2 inhibitors, and isosorbide dinitrate with hydralazine was not observed. Angiotensin converting enzyme inhibitors, angiotensin receptor blockers, cardio-specific beta-blockers, and aldosterone antagonists were prescribed more frequently at termination of phase one (Table 1).

Retrospective chart review in phase two revealed a variable hospitalization within the cohort. (n=64) Intervention arm patients managed via hybrid approach were at increased risk of all cause and HFH. Thirty-day all cause hospitalizations were 86% lower in controls *p*=0.16 (2/30 *vs* 5/34) At ninety days, hospitalizations were twice as frequent in the hybrid cohort compared to strict use of our hemodynamically-based treatment algorithm *p*=0.006 (14/34 *vs* 4/30) Adjudication for heart failure specific driver of hospitalizations similarly demonstrated a markedly higher rate of admission in patients managed via hybrid approach compared to strict hemodynamic algorithm (*p*=0.02 at 30 days 0/30 *vs* 4/34, *p*=0.003 at 90 days 1/30 *vs* 10/34) There were no hospitalizations due to consequences of algorithm guided management. Episodes of diuretic induced electrolyte disturbance were minor and managed outpatient. Patient reports of lightheadedness on standing were managed conservatively with patient education and did not result in syncope or falls.

Discussion

Implementation of our algorithm refined the effectiveness of therapeutic interventions based on remote PA pressure measurements. Standardization of therapy *via* algorithm ensured that treatments were decisively hemodynamically driven. Previously described by Adamson and colleagues,[5] clinical signs and symptoms of hypervolemia are appreciable weeks following changes in PA pressures. The design of our algorithm was therefore intentionally void of traditional heart failure metrics, discouraging SOC practices. A 68% reduction in thirty-day HFH rate immediately followed the implementation of our algorithm. Similar improvements were demonstrated in prior large studies.[8,9] Our research differs from other studies in that all subjects had PA implants with transmitted pressures available for review by their care teams at baseline. We conclude the observed decrease in hospitalizations was due to the refined utilization of hemodynamic data via standardized algorithmic treatment. Standardized management guided by our algorithm ensured treatments were driven by hemodynamics isolated from confounding data derived from usual heart failure care. Patients managed via a hybrid approach by incorporating standard heart failure assessment (physical examination, patient reported symptoms, standing weights) alongside remotely transmitted hemodynamic data were more likely to be hospitalized compared to those strictly managed by hemodynamic algorithm. Despite differences between providers' "style" and clinical gestalt, no signal was appreciated in the hybrid management group to suggest a particular provider or common practice habit biased Phase 2 results within the intervention arm. That said, deviation from hemodynamically-based management likely drove the observed increased hospitalization rate in the hybrid group.

The primary barrier we encountered during our investigation was variable physician willingness to adopt a new practice pattern. Physician preference influenced algorithm implementation and directly dictated its continued use beyond the initial ninety-day observation period of phase one. Physicians accustomed to detailed and direct involvement in routine decision making struggled the most in adapting to our nursing-driven workflow.[10] Our strategy was successful, at least in part, due to the willingness of nursing to follow an algorithm that dictated intervention(s). This ensured the algorithm was utilized as written and thus free of clinical confounders often included in the usual care provided by physicians.

The algorithm was designed to be primarily implemented by nurses with direct physician supervision. We found no evidence that this approach resulted in any patient harm. We adopted a Monday/Wednesday/Friday cadence in reviewing transmitted data and found that this could likely be further reduced to Monday/Thursday for most patients. A barrier we

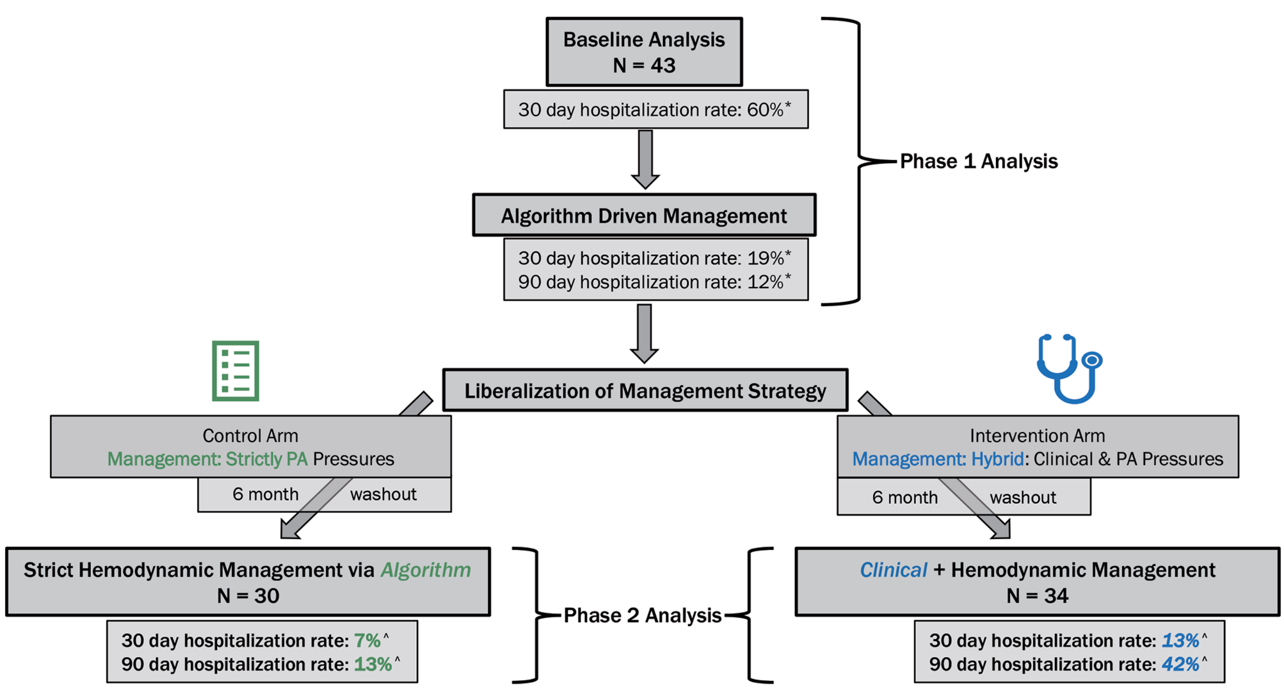

Figure 2. Study outline with results. Phase one demonstrates the impact of mandated hemodynamic management via strict use of our novel algorithm (Figure 1). Phase two analysis demonstrates how typical heart failure care stunts the benefit that remote pulmonary artery pressure monitoring has on outcomes. *Heart failure specific hospitalization; PA, pulmonary artery; ^all cause hospitalization.

encountered in optimizing our algorithm-driven workflow was the web site where PA pressures were securely stored. Additional training was needed to maximize the utility of web-based tools some of which were less than intuitive.

An interesting barrier uncovered during phase two of this study was physician resistance to augmenting practice habits. An inherent characteristic of human behavior is the general resistance to change, medical professionals are no exception. A 17-year lag between the clinical application of proven medical research in part because of this resistance.[11] We underestimated how difficult it might be for the average physician to relinquish a well-rehearsed pattern of practice. When mandatory use of the algorithm terminated, half of the providers (2/4) managing remotely monitored heart failure patients reincorporated usual heart failure care into their decision making. Phase two revealed if routine management of this patient population was not strictly guided by hemodynamics, hospitalizations increased.

Research focused on implementation of changes into medical practice have defined several key factors that can be a source of friction in growth. These same factors also serve as targets for specific interventions to mitigate resistance. Although normally associated with negative outcomes, the psychological phenomena known as groupthink can be leveraged *via* social influence to increase adoption of new practice methods particularly when framed in a manner consistent with medical providers' professional values.[12] Preventing defensive thoughts and behaviors rooted in egos greatly improves the uptake of new practices. An effective method to doing just this relies on fostering an environment of psychological safety. Early adopters are commonly found in practices where providers feel safe to express concerns, ask questions, and provide critical feedback without fear of judgement or retribution. These groups are led by humble leaders that are proponents of open dialogue and emphasize life-long learning as desirable character trait.[13]

Some prescribers considered the algorithm overly aggressive with a potential for harm. No hospitalizations occurred as a consequence of algorithm-driven management. Minor electrolyte and hemodynamic disturbances occurred all of which were managed in the outpatient setting. A particular point of contention was regarding changes to serum creatinine during decongestion *via* algorithm. Consequently, physicians in the intervention arm during phase two often set higher PA diastolic targets for their patients. Consequently, these patients were more likely to be hospitalized. Increase in creatinine in heart failure patients as a result of diuresis is, in fact, not a result of injury.[14] One might surmise the rise in serum creatinine is relative to the change in volume of distribution of total body water. Surprisingly, even in a hypothetical situation where 7.5 liters could be instantly removed from a congested patient, that would still be insufficient to increase their serum creatinine by >0.3 mg/dl as a result of decreased volume of distribution.[15] Changes in creatinine of >20% either above or below baseline are seen in more than half of heart failure patients being actively diuresed.[15] Additionally, increases of >0.3 mg/dl in serum creatinine were not associated with worse outcomes when accompanied by brisk diuresis.[16] Changes in serum creatinine therefore need be considered in context and not reflexively labeled as "worsening" or presumed harmful. Variability in surrogate markers for the glomerular filtration rate, i.e. serum creatinine, ought to be expected when decongesting heart failure patients and thoughtfully interpreted.

Medical centers, care teams, and payors have all put forth efforts to reduce heart failure hospitalizations over the past decade. The Centers for Medicare and Medicaid introduced the Hospital Readmissions Reduction Program the goal being to decrease thirty-day readmissions in the heart failure population, among other high re-admission risk diagnoses. With the threat of payment reductions for readmitted heart failure patients, hospital systems took note. Close outpatient follow-up was identified as an intervention that might reduce readmissions. A 2010 study evaluated the effectiveness of this strategy. They identified a 2.8% reduction in readmissions when comparing hospitals in the top *vs* lowest quartiles regarding their rates of seven-day post discharge follow up success.[17] The American Heart Association included this follow up time frame as a metric in their Get With the Guidelines-Heart Failure recognition criteria. Paradoxically, despite these initiatives, incentives, and metrics the following years would see an increase in all cause and HFH.[3] At best, there was about a 20% chance for a heart failure patient to be readmitted within thirty-days then. Now, over a decade later, thirty-day national HFH rates are no better.[18]

A fundamental shift in the management of heart failure patients is past due if we seek substantial improvements in this population's morbidity and mortality. Age-old dogmas need be set aside, new strategies embraced, and technology leveraged to our advantage if we are to effectively combat the growing burden of heart failure. Early adopters of hemodynamic management of heart failure patients have demonstrated excellent results[6] mirroring that of landmark trials like CHAMPION,[4] LAPTOP-HF,[19] MONITOR-HF[20] and GUIDE-HF.[21] No longer only a strategy to improve quality of life and reduce heart failure hospitalizations, hemodynamically guided heart failure management reduces mortality when used for over a year.[4]

Studies have shown that remote pulmonary artery pressure management is most effective in patients with NYHA class II heart failure and less so in the later stages of advanced heart failure. Once the circulatory system reaches its limit to compensate the heart begins its slide down the curve across Frank-Starling's x-axis. Patients with advanced heart failure are frequently difficult to decongest with blood pressure, renal function, electrolyte, and rhythm instability complicating management. However, pseudo-normalize these patients' physiologies with durable mechanical circulatory support (MCS) and hemodynamic monitoring returns center stage as an effective strategy in managing this group. Advanced heart failure patients supported by durable MCS with PA pressure sensors benefited hemodynamic management resulting in improved 6-minute walk times and reduced HFH.[22]

Limitations

Like most other small studies without funding ours is subject to the same limitations. Conclusions drawn from our non-randomized, single center study should be considered in context. Generalizability of our results is fundamentally limited. Regional and institutional practice patterns could have played a role in driving outcomes in the intervention arm. Standard of care heart failure therapy can vary significantly between physicians. Several providers managed the intervention arm which should mitigate the impact of any single provider's practice pattern. This does not preclude the possibility of an institutional or regional norm within usual heart failure care. Conversely, deleterious practices in delivery of usual heart failure care can be confidently excluded as the study site merited recognition by the American Heart Association Get With the Guidelines for heart failure campaign prior to algorithm introduction.

Conclusions

There is clear value in the standardization of care delivery when guided by evidenced based outcomes. That is not to say creativity need be stifled. Intuitive minds investigate hypotheses in hopes their critically appraised results might enhance our understanding and ultimately deliver the best care possible. It is the lexicon we use to describe the variability of heart failure management that requires some scrutiny. The colloquial use of "style" and "art" in describing variations of heart failure management is concerning. In our era of information technology, the wealth of data in support of evidence-based therapies must guide our management strategies.

During our investigation we observed how standardized interventions produced similar responses across the cohort. This allowed us to determine appropriate responses to algorithm-driven interventions. When PA pressure readings did not behave as expected or renal function declined excessively, additional pathologies were often playing a role. Incidental asymptomatic paroxysmal atrial fibrillation, progression to severe mitral insufficiency, acute gastrointestinal bleeding, and renal cell carcinoma are a few examples. Further investigation is needed to evaluate if this is, in fact, a reliable added value of algorithm-driven management.

Remote pulmonary artery pressure monitoring in heart failure patients is most effective when coupled with a hemodynamic management strategy. Inclusion of usual heart failure practices via weights, patient reported symptoms, or physical examination increases the rate of hospitalization. Nursing-driven routine management of remote PA pressures guided strictly by our novel hemodynamic algorithm reduced hospitalizations in a cohort previously managed by physicians with access to remotely transmitted PA pressures. These results detail potential barriers to establishing and growing successful remote PA programs and outline possible solutions which could benefit the broader community.

Contributions

All the authors made a substantive intellectual contribution, read and approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

Conflict of interest

ED, RS, NW, KS, KR declare no conflicts of interest. MA is a Key Opinion Leader for Abbott Heart Failure CardioMEMS which may be considered as a potential competing interest.

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