

Impact of a Specialty Pharmacy-Prepared Infused Prostacyclin Admixture Program on Central Venous Catheter Infections in Patients with Pulmonary Arterial Hypertension

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ABSTRACT

OBJECTIVE: Evaluate the impact of pharmacy-prepared admixture thermostable epoprostenol sodium and treprostinil on the rate of patient-reported central venous catheter (CVC) infections in patients with pulmonary arterial hypertension (PAH).

DESIGN: Retrospective, crossover comparison of patients on continuous intravenous epoprostenol or treprostinil who transitioned from self-admixture to pharmacy-prepared admixture of product.

METHODS: A preliminary review of the electronic medical records of patients receiving prostacyclin for a minimum of 36 months was conducted [minimum of 24 months on self-mix and minimum of 12 months on pharmacy-prepared]. Data was collected for self-mix patients 12 months prior to the conversion date to pharmacy-prepared medication. The collection of data for patients receiving pharmacy-prepared medication was collected for 12 months starting after the first ship date of prepared cassettes. Patients were included in the sample if they carried a diagnosis of PAH, were between the ages of 29 and 84, and had a CVC with point of access in the chest.

Exclusion criteria included, but was not limited to, any patient with less than 24 months of self-admixture or less than 12 months of pharmacy-prepared admixture, patients who started infused prostacyclin therapy prior to January 1, 2016, patients using a double lumen catheter, or utilization of a neutral pH diluent at any point during the review period.

Records were reviewed for patient-reported problems including: redness, swelling or soreness at the catheter site, CVC infection, and all-cause ER visits or hospitalizations. Pharmacy-prepared prostacyclin was admixed by specially-trained pharmacy technicians under the direct supervision of a pharmacist in a clean room compliant with United States Pharmacopeia <797> guidelines. The primary outcome was the patient-reported rate of CVC infection, defined as the number of CVC infections per 1000 patient catheter days.

RESULTS: The preliminary sample size of 25 patients reviewed encompassed 18,250 patient catheter days. The CVC infection rate trended lower in the pharmacy-prepared admixture group (0.38 vs 0.55 per 1000 patient catheter days).

CONCLUSIONS: Compared with the self-admixed infused prostacyclins observed, pharmacy-prepared admixture may be associated with a lower rate of CVC infections.

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METHODS

A review of electronic medical records for 25 patients receiving continuous infusions of thermostable epoprostenol sodium or treprostinil in high pH diluent to explore potential differences in the incidence of central venous catheter (CVC) infections [single lumen only] when reservoirs are patient versus pharmacy-prepared was performed.

Patient-prepared prostacyclin is admixed by the patient in their home following training to full independence with clean technique by a PAH specialist nurse (image 1). Pharmacy-prepared prostacyclin is admixed by specially-trained pharmacy technicians under the direct supervision of a pharmacist in a clean room compliant with United States Pharmacopeia <797> guidelines. The ASHP Guidelines on Compounding Sterile Preparations considers this type of compound medium-risk¹: more than three sterile products per cassette (image 2).



As part of the standard monthly reorder process at the Specialty Pharmacy, patients are asked a series of non-interpretive questions to assess for complications related to therapy. Affirmative answers are triaged to a clinician for follow-up.

- How often do you change your central line dressing?
- Have you had any catheter related problems in the last month, including any signs of redness, swelling, or soreness at your catheter site?
- Have you had any infection since the last order?
 - If yes, what was the site of infection?
 - Have you used any antibiotics to treat this infection?
- Since the last refill, have you spent time in the ER or hospital?

Data for this analysis was taken directly from notes documenting these patient interactions. One pharmacist reviewer collected the data and a second pharmacist was used to adjudicate the finding of CVC infection.

Figure 1 is a summary of the patient review period for both the self-mix and Pharmacy prepared cohorts.

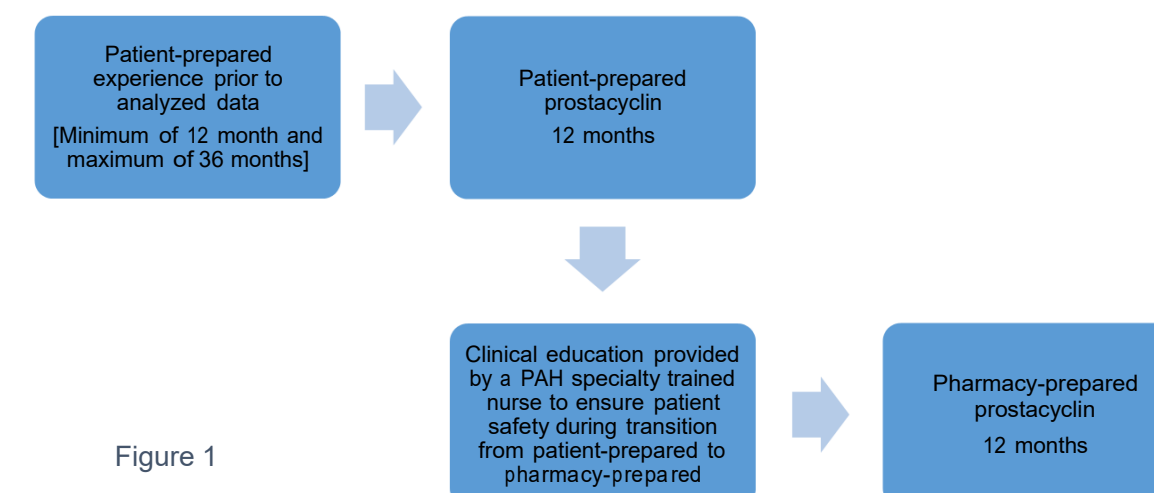
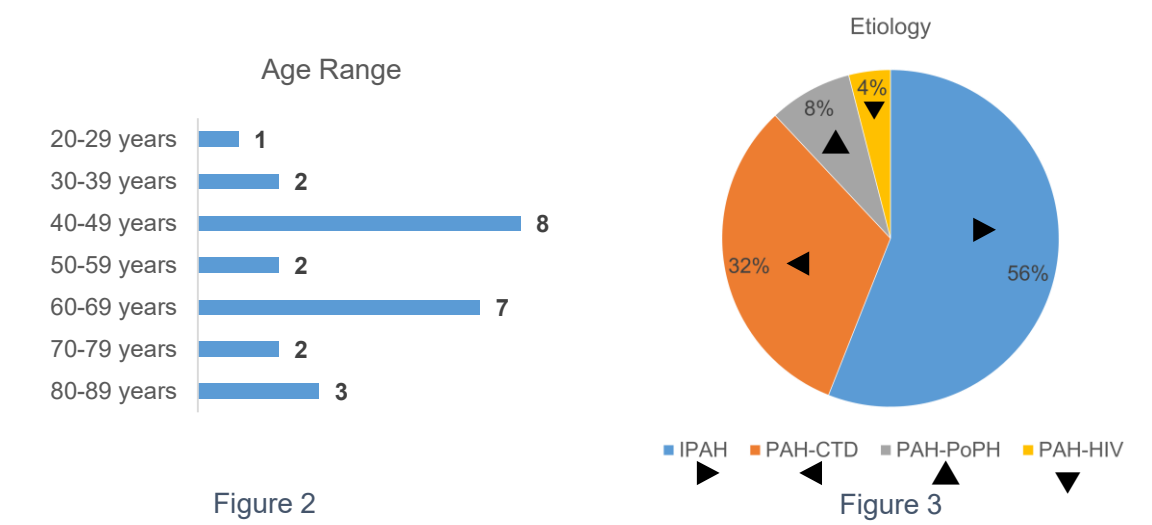


Figure 1

RESULTS

52% of patients in the final sample (13/25) were infusing treprostinil while 48% (12/25) were infusing thermostable epoprostenol sodium. Patient age distribution and etiology of PAH for the full sample is described in figures 2 and 3.



Infections per 1,000 calendar days

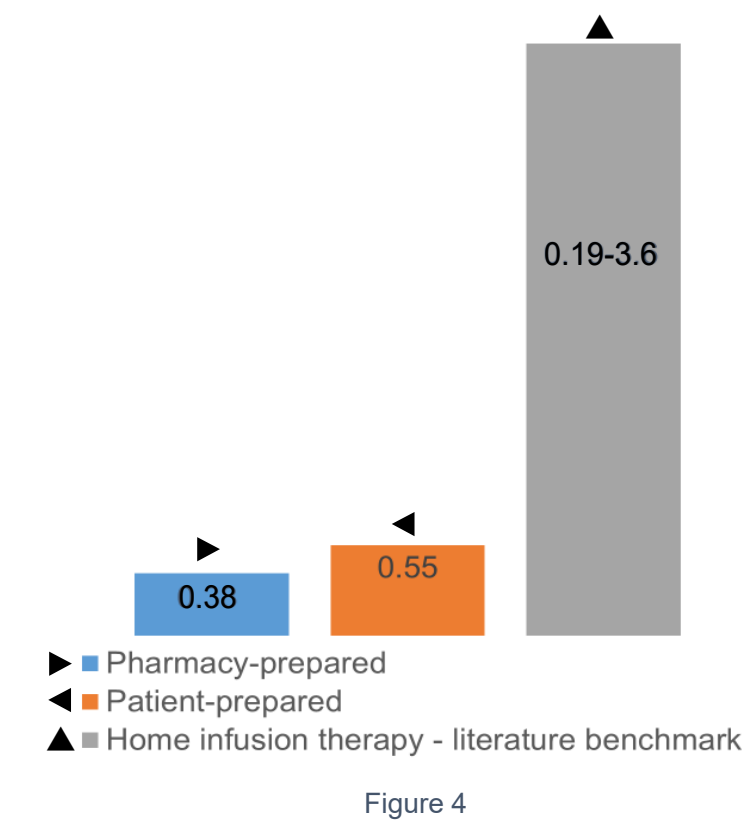


Figure 4

The rate of CVC infection trended lower in the pharmacy-prepared admixture group than the patient-prepared admixture group: 0.38 vs. 0.55 per 1,000 patient catheter days (figure 4).

The patient-prepared CVC infection incidence of 0.55 per 1,000 is significantly below the high end of the literature benchmark of 3.6.²

Figures 5, 6, and 7 illustrate the results of post-hoc analysis of hospitalizations and emergency department visits which suggest the absence of clinical worsening in patients receiving pharmacy-prepared prostanoids when compared to patient-prepared. Thirty-nine events [hospitalization or emergency department visit] occurred in each cohort. Further subanalysis by diagnosis and age (figures 2 and 3) illustrate specific patient sub-sets where pharmacy-prepared infused prostanoids may result in decreased hospitalizations or ER visits. While a pharmacy-prepared admixture program may not be as beneficial to patients with secondary PAH, the data indicates positive absolute change for patients with an idiopathic PAH diagnosis (24%): patients who are both 65 years of age or older and diagnosed with idiopathic PAH (100%).

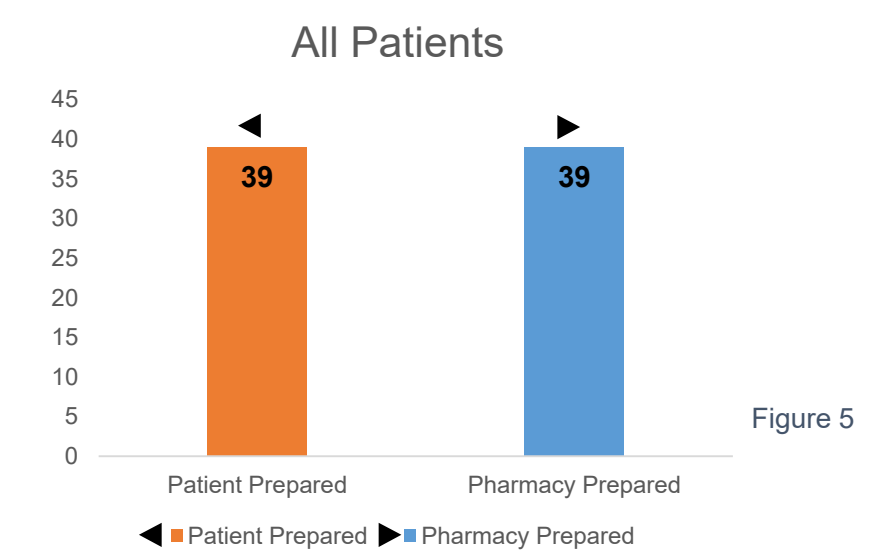


Figure 5

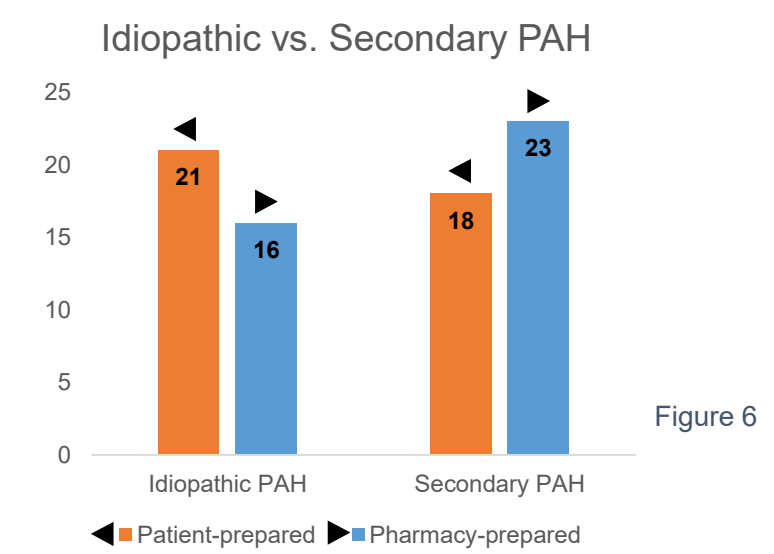


Figure 6

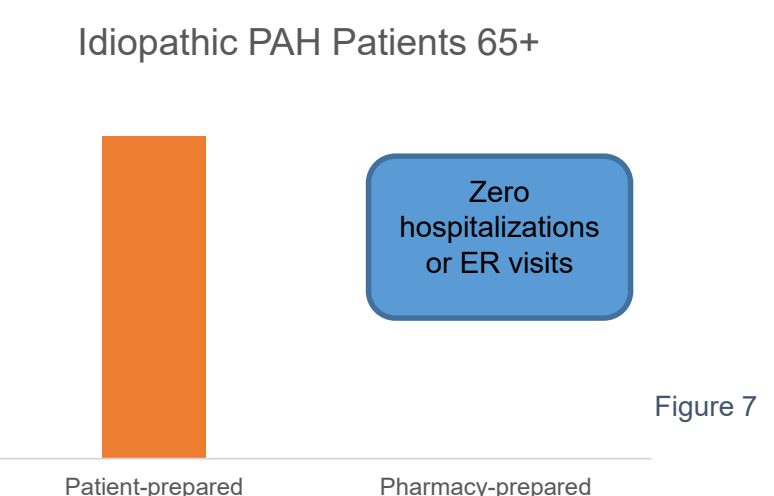


Figure 7

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- Keller SC, Williams D, Rock C, et al. A new frontier: Central line-associated bloodstream infection surveillance I home infusion therapy. Am J Infect Control. 2018;46(12):1419-1421

CONCLUSIONS

For infused prostanoid patients experienced with utilizing both patient-prepared and pharmacy-prepared cassettes, a trend existed which may lead to decreased infection rates, as well as hospitalizations and ER visits, for particular patient sub-sets while receiving cassettes prepared in a specialty pharmacy setting. Limitations to the study include, but are not limited to, overall number of patients analyzed, potential CVL infections not reported by the patient population, and lack of data surrounding patients and antibiotic use due to patient reported medication profiles.