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Converting From Brand to Generic Treprostinil (Intravenous): Aggregate Cohort Data From One Specialty Pharmacy

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Background: Intravenous infusion of branded treprostinil (Remodulin®) has been standard therapy for the treatment of advanced pulmonary arterial hypertension (PAH) for over a decade. A lower cost generic equivalent has recently been brought to market. Given the narrow therapeutic index and delicate pharmacokinetics associated with intravenous treprostinil, conversion from brand to generic has been met with some reluctance.

Methods: A retrospective cohort analysis of patients converting from branded Remodulin to the generic equivalent (treprostinil) between 04/07/2019 and 05/07/2019 was conducted using the specialty pharmacy electronic medical record. Records were included in the analysis if the primary diagnosis of record was PAH, the patient age fell between 18 and 89 years, and generic treprostinil was interchanged for established therapy with the brand. Data collected at the time of conversion from brand to generic included the following: dose and concentration, the presence of medication side effects and patient reported symptoms of PAH. A pharmacist called patients who converted from brand to generic at 24-72 hours to assess for changes in clinical status. If the patient was unavailable, a request for a return call to report any problems post conversion was made. For those patients who placed a refill of generic treprostinil, similar data was collected and compared to baseline.

Results: Forty-nine patients converted from brand to generic treprostinil during the study period, with doses ranging from 12-220ng/kg/min. All patients transitioned in the home setting with a 1:1 dose conversion. One patient transitioned back to the brand, while 48 remained on the generic equivalent. Five (10%) patients reported side effects during the 24-72 hour follow-up call. Four patients described side effects experienced with the generic equivalent as typical (diarrhea, nausea, headache) and self-limiting. One patient was transitioned back to brand following generalized complaints of intolerance. Twenty-three patients (23/48, 47%) explicitly denied any side effects or changes in symptoms with brand to generic conversion, while twenty-one (21/48, 43%) did not return the call.

Forty patients were on the generic long enough to have placed a refill; one required transfer to an alternate specialty pharmacy. Analysis of the data for the 39 patients who refilled generic treprostinil revealed that 79% (31/39) did not require any dose adjustment on conversion from brand to generic. The remaining eight patients reported a dose increase of the generic equivalent with the first refill. Four patients increased doses by 2-3ng/kg/min, while four increased by 4-9ng/kg/min, over an up to 4-week period.

Eight calls from patients converting from brand to generic treprostinil were placed to the specialty pharmacy after-hours emergency helpline: three admixture/stability questions for a PAH specialist pharmacist, three reported hospitalizations (electrolyte imbalance, lung transplant, smoke inhalation), one reported ER visit (damaged Hickman catheter), and one ambulatory infusion pump alarm.

Conclusions: Conversion from branded Remodulin to the generic equivalent appears to be well tolerated in the home setting without significant adjustments to dose.

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