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Title: Retrospective observational study of pulmonary hypertension patients dosed with greater than 9 breaths qid of inhaled treprostinil

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Body: Purpose: The objective of this retrospective cohort study was to determine the tolerability and safety of inhaled treprostinil (iTRE) dosed at a higher target maintenance dosage than previously studied in pulmonary hypertension (PH). Methods: World Health Organization (WHO) Group I-V PH patients treated at Duke prior to 8/2012 that have been prescribed iTRE at higher than target maintenance dose of 9 breaths qid (54mcg) were included in this analysis. Tolerability and safety parameters were assessed. Data were collected by chart abstraction and verified against source documents. Baseline data were collected at least 3 months prior to the increased dose. Follow up data were collected 3 to 6 months after the elevated dose. Results: 75 patients were analyzed; 67% female, 67% Caucasian, 51% WHO Group I and 35% Group III. Of the 75 patients, 73 received 12 breaths qid (72 mcg) while 2 only reached 10-11 breaths. Cough (41%) was the most common side effect at baseline decreasing to 18% at follow-up. Headache was present in 28% patients and decreased over time. Throat irritation was present in 8% patients and disappeared subsequently. One patient was hypotensive but did not discontinue. Another had a syncopal episode at baseline and later discontinued. Overall 20 of 75 (25%) patients discontinued iTRE; 9 transitioned to parenteral therapy, 4 stopped due to side effects, 3 died (worsening PH, post-op complications), and 4 had other reasons. Conclusions: Overall, inhaled iTRE dosed at a higher target maintenance dose than previously studied appeared safe and well-tolerated. These results warrant further investigation into the risk/benefit of elevated dosages.