Prostacyclins improve symptoms and survival in pulmonary arterial hypertension (PAH). In response to risks associated with external delivery systems, an implantable intravenous infusion system was developed” Waxman et al (2017).

Abstract:

BACKGROUND: Prostacyclins improve symptoms and survival in pulmonary arterial hypertension (PAH). In response to risks associated with external delivery systems, an implantable intravenous infusion system was developed. A multicenter, prospective, single-arm, clinical trial (DelIVery for PAH) was conducted to evaluate this system for treprostinil in PAH. This analysis describes the findings related to the implant procedure.

METHODS: Patients (n=64) with PAH (WHO Group 1) receiving stable intravenous treprostinil were enrolled. Patients were transitioned to a temporary peripheral intravenous infusion catheter prior to the procedure. System implantation was performed at 10 centers under general anesthesia or deep intravenous sedation by clinicians from various specialties. Central venous access was via the cephalic, subclavian, jugular or axillary vein. Using an introducer and fluoroscopic guidance, the distal tip of the infusion catheter was placed at the
superior caval-atrial junction. The catheter was tunneled from the venous access site to an abdominal subcutaneous pocket where the pump was placed.

RESULTS: Of the 64 patients enrolled, four exited prior to implant. All 60 implant procedures were successful. At baseline, all patients were receiving treprostinil via an external pump at a mean dose of 71.4 ± 27.8 ng/kg/min (range 22 to 142 ng/kg/min). The implant averaged 102 ± 32 minutes (range 47 to 184 minutes). Clinically significant implant procedure-related complications included 1 pneumothorax, 2 infections and 1 episode of atrial fibrillation. There were 3 post-implant catheter dislocations in 2 patients. Common implant-related events that were not complications included implant site pain (83%) and bruising (17%).

CONCLUSION: The procedure for inserting a fully implantable system for treprostinil was successfully performed with few complications.

Reference: