“We evaluated the infusion accuracy and device-related safety of implantable drug infusion pumps in subjects with chronic pain or severe spasticity.” Wesemann et al (2014).

Reference:


Abstract:

BACKGROUND AND OBJECTIVES: We evaluated the infusion accuracy and device-related safety of implantable drug infusion pumps in subjects with chronic pain or severe spasticity.

METHODS: Nine centers in the United States enrolled patients receiving intrathecal drug delivery systems to manage chronic pain and/or severe spasticity. Infusion accuracy was assessed at 6 and 12 months by comparing syringe-measured delivered volumes to programmer-predicted volumes. Safety was evaluated through analysis of adverse events. Separate laboratory testing conducted by the manufacturer also evaluated infusion accuracy.

RESULTS: Eighty of 82 enrolled subjects were implanted. Sixty-five and 54 subjects, respectively, were analyzable for accuracy at 6 and 12 months. On average at 6 months, the pumps were measured to have delivered 1% more than the programmed delivery volume. Analyzed on a per-refill basis, the pumps delivered, on average, 2.5% more than the programmed delivery volume. Differences between per-refill means versus per-subject cumulative means were due to limitations in clinicians’ ability to precisely visualize single small syringe-volume differences, or possibly incomplete withdrawal of fluid from the pump. Laboratory testing demonstrated a per-refill mean accuracy error of minus 2.4%. Because average observed flow-rate error at 6 and 12 months (1% overinfusion) was derived from pump residual volume measurements by syringe and carried out in a clinical setting, clinical...
volume ratios were larger than direct volume measurements by weight observed in the laboratory. No deaths, permanent injuries, or unanticipated adverse device effects occurred.

CONCLUSIONS: The pump accurately delivered intrathecal medication in the clinical setting of this study. Adverse events were similar in nature and severity to those described in the product labeling and literature.

Other intravenous and vascular access resources that may be of interest (External links – IVTEAM has no responsibility for content).