The First Human Trial of a Novel Threaded Epidural Access Device to Determine Initial Safety and Technical Feasibility

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Introduction: For decades, clinicians have accessed the epidural space by advancing cutting needles with a forward force and using “loss of resistance” techniques. The Epiphany™ epidural access system (Figure) is a new, blunt tipped, threaded needle system. Rotation of the needle offers more controlled advancement of the device toward and into the epidural space, in contrast to traditional “pushing” force used with standard epidural needles. The purpose of this study was to evaluate the safety and technical feasibility of using the Epiphany™ epidural access system in human subjects undergoing elective surgery.

Design: Prospective, single-arm, single-center, safety and technical feasibility study.

Methods: After receiving local ethics committee approval, seven patients were enrolled at a single center in Asunción, Paraguay. Baseline, procedural and post-procedural clinical data as well as 2-week follow-up telephone data were collected from all patients. The primary safety endpoint for this trial was the rate of major adverse events (MAE) defined as mortality, failed analgesia, dural puncture, postdural puncture headache and epidural vein puncture. The secondary feasibility endpoint for this trial was the success rate of the Epiphany™ epidural access system for epidural space access.

Results: The epidural space was accessed using the using the Epiphany™ system based on definitive loss of resistance in 6 of 7 patients. The procedure was aborted in one patient due to a vaso-vagal reaction during initial percutaneous puncture. Of the 6 patients in whom the epidural space was accessed, 3 had an epidural catheter successfully placed in the epidural space with subsequent excellent regional analgesia. One epidural vein puncture was suspected among 16 distinct placement attempts. No other adverse events occurred during the trial of follow-up period.

Conclusions: This study proved initial safety and technical feasibility of the Epiphany™ epidural access system in the first-ever human cases. The combination of a threaded shaft and blunt-tip provide a mechanism of controlled entry into the epidural space. The device is undergoing regulatory review in the United States and Europe. Further clinical trials are needed to determine if the theoretical benefits of the system will translate into outcome benefits for patients undergoing epidural access procedures.

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