



## **Safety of Two Epidural Catheters in Thoracic Epidural Anaesthesia (TEA)**

B. Braun Melsungen AG, Hospital Care, Clinical Development

**Background:** Paresthesia with insertion of an epidural catheter is a common finding, which can be disturbing to the patient as well as the anesthesiologist. B. Braun Melsungen AG has developed a new generation of Perifix® epidural catheters. These new catheters are different in their composition compared to the current Perifix® Standard catheter with regard to the catheter material and tip configuration. To compare the recently introduced catheter with the standard catheter regarding occurrence of spontaneous paresthesia a randomized study, approved by the local ethics committee was conducted. Secondary endpoints were incidence of accidental dural and inadvertent vascular puncture and handling characteristics.

**Methods:** A prospective, single-blind, randomised controlled trial was conducted in 131 patients, ASA I-III, age 18-90 years, scheduled for elective surgery and epidural anesthesia puncture level T4-10. A 20 G polyamide (standard) catheter (Perifix® standard, B.Braun Melsungen AG, Germany) and a 20 G combined polyurethane-polyamide catheter (new) (Perifix® One, B.Braun Melsungen AG, Germany) were evaluated. Both catheters are CE-marked. Spontaneous reactions upon catheter-insertion were recorded. If the patient did not spontaneously report paraesthesia the observer systematically asked for it. Inadvertent dural or intravascular positioning of the catheter was recorded as well as handling features.

**Results:** Paresthesia was indicated spontaneously by 16% of patients. This is in concordance with previous studies. Looking at the total (paresthesia reported spontaneously or on questioning) an incidence of 48% was found. There were no significant differences between groups. No accidental dural punctures occurred and catheter insertion was possible in all patients. No differences between the two catheters regarding paresthesia, malpositioning or handling characteristics were detected.

**Principal investigator:** Dr. Marco Marcus, University Hospital Maastricht, The Netherlands

**Status:** Finalized as planned

**Sponsor:** B. Braun Melsungen AG

**Register:**

<http://www.clinicaltrials.gov/ct2/show/NCT00394459?term=NCT00394459&rank=1>