

**Abstract Type : Poster**  
**Presentation No. : PDL 054**

**A randomized, open-label study to evaluate the efficacy and safety of plastic cannula compared with metal needle in incident hemodialysis patients.**

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**Objectives:** Successful cannulation of arteriovenous fistula (AVF) is an important issue especially in patients who start hemodialysis. Metal needles have been used for decades, but more recently, the usefulness of plastic cannula has been introduced. In this study, a comparison of metal needles and plastic cannula for early successful cannulation was done.

**Methods:** This was a single-center, prospective, randomized, open-label study with incident hemodialysis patients. Eligible patients were randomized into 2 groups in a 1:1 ratio (n=18 in each group) (metal needle: JMS, 16G, Singapore, plastic cannula: Supercath Clampcath®, 17G, Japan). Maturation of AVF was confirmed using Doppler US, and well-trained two nursing staffs implemented AVF cannulation. Primary endpoint was the rate of early successful cannulation, defined as the successful completion of three consecutive dialysis sessions with adequate blood flow rates. Also, data were collected on incidence of vessel injuries (bruising, swelling, erythema, and hematoma), degree of pain, and difficulties during cannulation.

**Results:** Among the 36 patients, radiocephalic AVFs were 41.7% and mean duration from AVF creation to first cannulation was  $53.6 \pm 27.3$  days. No significant difference was found between groups with respect to age, sex, diabetes, or AVFs types. Failure of early successful cannulation was observed in 8 patients, and the risks tended to be higher in metal group (2 in plastic group, but 6 in metal group,  $p=0.084$ ). In addition, the risk of vessel injury was significantly higher in metal group than in plastic group (44.4% vs 11.1%,  $p=0.030$ ). However, the degrees of pain that patients feel was slightly higher in plastic group (4.5 vs. 2.9,  $p=0.066$ ). The cannulation difficulties felt by nursing staffs were similar in both groups.

**Conclusions:** Use of plastic cannulas provided less vascular injury and may increase the rate of successful cannulation especially in early period of dialysis. It could be a new and innovative tool for improve dialysis quality.