Comparison of sedation and general anaesthesia for transcatheter aortic valve implantation on cerebral oxygen saturation and neurocognitive outcome.

Transcatheter aortic valve implantation (TAVI) is a treatment strategy for patients with severe aortic stenosis. Although general anaesthesia (TAVI-GA) and sedation (TAVI-S) have previously been described for TAVI, the difference in safety and efficacy of both methods has not been studied in a randomized trial. The INSERT trial was a single centre, controlled parallel-group trial with balanced randomization. Sixty-six patients (68-94 yr) with acquired aortic stenosis undergoing transfemoral CoreValve(TM) were assigned to TAVI-GA or TAVI-S. Comparable operative risk was determined from risk-scores (EUROscore, STS-Score). Monitoring and anaesthetic drugs were standardized. Near-Infrared-Spectroscopy was used to monitor cerebral-oxymetry blinded. Primary outcome was the perioperative cumulative cerebral desaturation. As secondary outcomes, changes in neurocognitive function and respiratory and haemodynamic adverse events were evaluated. Of 66 included patients, 62 (TAVI-GA: n=31, TAVI-S: n=31) were finally analysed. Baseline characteristics were comparable. In 24 patients (39%) cerebral desaturation was observed. Cumulative cerebral desaturation was comparable (TAVI-GA: (median [IQR]) (0[0/1308] s%) vs. TAVI-S: (0[0/276] s%); P=0.505) between the groups.
Neurocognitive function did not change within and between groups. Adverse events were more frequently observed in TAVI-S patients (P<0.001). Bradypnoea (n=16, 52%) and the need for airway manoeuvres (n=11, 36%) or bag-mask-ventilation (n=6, 19%) were the most common respiratory adverse events. Cerebral desaturation occurred in both patient groups, but there was no significant difference between the two groups. Based on primary outcome, both methods were shown to be comparable. Neurocognitive outcome was similar. The higher incidence of adverse events in the sedation group suggests a potential advantage of general anaesthesia. NCT 01251328.