

'HSS' – A NOVEL HYBRID SYSTEM FOR CONSCIOUS SEDATION

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Introduction: The aim of this project was to determine the performance of an hybrid closed loop sedation system ('HSS') which integrates a decision support system (DSS) for controlled sedation of patients undergoing knee or hip arthroplasty with spinal anesthesia and conscious sedation.

Methods: After Ethics approval and written consent, 120 patients undergoing knee or hip arthroplasty with spinal anesthesia and propofol sedation were randomized to receive either automatic sedation ('HSS'-group, Fig 1) or manually administered propofol (Control-group). Bispectral index monitoring (BIS) was used to guide sedation in all patients with a target of 65. The clinical performance of the sedation was defined as "Excellent", "Good", "Poor" or "Inadequate", when the BIS was within 10%, between 10 and 20%, between 20 and 30% or outside 30% of a target BIS of 65, respectively. In addition, a Decision Support System (DSS) which indicated critical events of respiration and hemodynamics via audio-visual alarms and offered decisional aid was evaluated (Fig 2). Critical respiratory events were defined as SpO₂ <92% and respiratory rate < 8/min. Critical hemodynamic event was defined as MAP < 60 mmHg and heart rate <40 bpm. The incidence of critical events detected by the DSS system was compared with the incidence of events in the control group as well as the time needed to detect those events and patients' awake time during surgery. Data were analyzed using XLstat 2010 software (data presented as mean, ±SD, p<0.05).

Results: Demographic data and surgery duration were similar in both groups. HSS-group: age, 63 (14) years; weight, 81 (16) kg; male/female, 27/33; anesthesia duration, 117 (42) min. Control group: age, 70 (12) years; weight, 80 (16) kg; male/female 23/37; anesthesia duration, 125 (37) min. The number of modifications of propofol doses per hour was significantly higher in the 'HSS'-group at 22 (5) than in the Control group at 5 (2), with no significant difference of propofol dose at 82 (39) $\mu\text{g kg}^{-1} \text{min}^{-1}$ in 'HSS'- group versus 69 (27) $\mu\text{g kg}^{-1} \text{min}^{-1}$ in the Control group. The control of the sedation was better in the 'HSS'-group (Fig 3). In the HSS-group, the patients' awake time during surgery was significantly shorter, 5min (8) than in the Control group at 14min (14) (Fig 4). All the respiratory and hemodynamic critical events were detected in the 'HSS'-group, while in the control group 26% of them were not detected. The delay for the detection of the critical events was significantly shorter in the 'HSS'-group at 8sec (4) than in the control group, at 29sec (21). There were no significant differences in physiological parameters in the two groups during surgery.

Discussion: 'HSS', a hybrid closed loop sedation system can control sedation better than manually delivered propofol sedation and detects all respiratory and hemodynamic critical events and in a shorter time frame.



Figure 1: HSS interface



Figure 2: Pop-up menu for Critical events

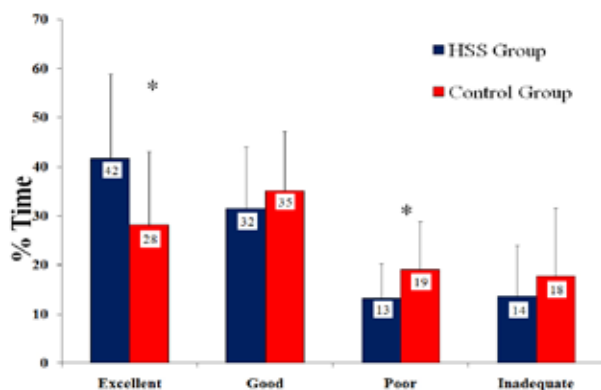


Figure 3: Clinical performance

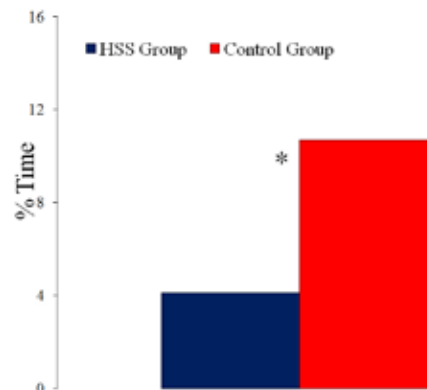


Figure 4: Awake time throughout surgery