Comparison of Adequacy of Anaesthesia Monitoring with Standard Clinical Practice during routine general anaesthesia: An International, Multi-Centre, Single-blinded Randomized Controlled Trial.

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Background and Goal of Study:

The use of clinical signs such as hypertension or tachycardia for guidance of anaesthesia can be challenging. Previous studies have suggested that incidence of unwanted anaesthesia events could be reduced by measuring the components of anaesthesia i.e. hypnosis and analgesia (1,2). However, the evidence regarding the benefits for such monitoring is still limited (3).

Materials and Methods:

After approval of each ethics committee, a total of 494 patients were recruited in a multi-centre, single-blinded, randomized controlled trial (RCT). Patients were randomized into two groups and anaesthesia was guided with Entropy (hypnosis) and surgical pleth index SPI (analgesia) in (adequacy of anaesthesia group; AoA group) or standard monitoring alone (Control group). Anaesthesia was conducted with TCI of propofol and remifentanyl. The patients were followed for signs of inadequate anaesthesia (i.e. grimacing, hypertension or tachycardia) or signs of too deep anaesthesia (i.e. hypotension and bradycardia) namely unwanted anaesthesia events.

Conclusion:

In the present RCT, the guidance of TIVA by Entropy and SPI in comparison to standard monitoring alone was unable to reduce unwanted events. However, there was a slight reduction in the use of propofol and shorter times for emergence. The findings may have been influenced by low-risk profile of surgeries with low frequency of unwanted events.

References: 1) Chen et al.; Anesthesiology 2010 2) Martinez et al.; Anesthesia and Analgesia 2010 3) Gruenewald et al.; Minerva Anesthesiol 2017

Acknowledgements: The authors thank all patients, all sub-investigators for their countless effort, as well as GE Healthcare (sponsor of the study).

Table 1:

Event	Number of Event		p-value
	Control Group (N=248)	AoA Group (N=246)	
Inadequate Anaesthesia	175 (0.7)	183 (0.7)	0.519
Hypertension	98 (0.4)	119 (0.5)	0.316
Tachycardia	15 (0.1)	8 (0.0)	0.433
Movements	62 (0.3)	56 (0.2)	0.493
Somatic Arousal	48 (0.2)	39 (0.2)	0.652
Somatic Response	14 (0.1)	17 (0.1)	0.497
Hypotension	292 (1.2)	341 (1.4)	0.543
Bradycardia	190 (0.8)	229 (0.9)	0.675
Total Unwanted Events	657 (2.6)	753 (3.1)	0.392

Figure 1:

Results and Discussion:

Incidence of unwanted events was 0.7 events per subject in both groups ($p=0.519$; Table 1). In the AoA group, the overall consumption of propofol was significantly reduced with 6.88 vs. 7.53 mg/kg/h in Control group ($p<0.01$). Time of emergence was significantly shorter in AoA group with 8.0 vs. 9.6 min in Control group ($p<0.01$; Figure 1). With respect to post-anaesthesia care, we found a trend towards faster full recovery with AoA monitoring but no difference with respect to pain or pain medications.