CLINICAL PERFORMANCE OF ELECTRONIC CONTROL FOR AISYS™, TO AUTOMATICALLY ADJUST FRESH GAS, AGENT AND OXYGEN

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Traditionally, anesthesiologists administer oxygen and agent (AA) by manually adjusting vaporizer and FGF settings. However, it is technically possible to design a feedback system to automate manual adjustment. We did evaluate the end-tidal control (EtC) prototype designed for Aisys™ (GE Healthcare) on the human subjects. Our aim was to access clinical performance vs. expectations of anesthesiologist, plus to compare behavior of the control system vs. technical specs.

Methods: After approvals of ethical committee and authorities, and with written informed consent, we enrolled 20 ASA 1-3 patients undergoing standard gynecological procedures. Anesthesiologist responsible of patient care stayed in the O.R. observing the control system, and there was a technical observer to record time marked notes. At induction, anesthesiologist dialed targets for Et-AA and Et-O2 to the controller, enabling software algorithm to control FGF and vaporizer. Non-invasive monitoring included ECG, SpO2, NIBP, Entropy, NMT, spirometry, and airway gas concentrations of O2, N2O, CO2 and AA. Clinical data and control system's data flow were collected in real time. Clinical quality indicators (e.g. hemodynamic variability) had been defined a priori. After the case, anesthesiologist estimated whether any monitored variability was due to technical or clinical reasons.

Results: Enrolled 20 patients met all inclusions criteria; none had to exit during study. There were no adverse effects. HR and BP remained stable (±25% from control) in 16/20 patients, (clinical reason in 4 patients). In 18/20 cases SpO2 was above 90% all the time, (clinical reason in 2 patients).

Five anesthesiologists used the system in sevoflurane anesthesia: three were consultants and two were junior staff. Nobody stopped using controller during the cases. Neither did EtC system exit unexpectedly. Technical assessment of control performance parameters included response and setting times, command overshoot and steady state deviations of both Et-O2 and Et-AA.

Conclusion: This open observational study was the first systematic comparison on human subjects, with the prototype end-tidal control system designed for Aisys™ . Both clinical findings and technical data were according to pre-set specifications.