

A Randomized Controlled Trial of Probability Ramp Control of Propofol for Esophagogastroduodenoscopy

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Background

Endoscopic sedation requires titration of propofol to an endpoint of deep sedation with minimum overshoot. This is typically accomplished by intermittent boluses of propofol followed by an infusion to maintain the desired state. Patients vary in pharmacokinetics and pharmacodynamics, and proper timing of incremental doses is required to assure a steady increase in drug concentration and observation is required to determine when an adequate dose has been given. Probability Ramp Control (PRC) is decision support software that simplifies and standardizes this approach by providing the clinician with a simple infusion sequence that gradually increases the propofol until the desired endpoint is achieved. Our hypothesis was that PRC could deliver sedation that was substantially equivalent to that delivered by experienced practitioners with a reduction in the need for intervention in the control process.

Methods

With IRB approval and informed consent, 40 patients scheduled for elective diagnostic esophagogastroduodenoscopy were enrolled in a randomized open label study. Depth of sedation was assessed by SEDLine PSI. Patients were judged adequately sedated when a Robertazzi nasopharyngeal airway could be passed without purposeful response. In the control arm, a CRNA titrated propofol to this endpoint then selected an infusion rate, providing additional propofol as deemed necessary; with propofol administration was logged by an investigator. In the experimental arm PRC was employed to achieve sedation and determine the maintenance infusion. Deviation from the initially specified infusion rate and time to target identification were assessed.

Results

The two groups were similar in age, weight, and procedure duration, as were total propofol dose, estimated effect site concentration at loss of responsiveness, estimate peak effect-site concentration, and average PSI score. Time to tolerance of airway placement was lower in control. Adjustments to control were required in 20/20 control and 2/20 experimental patients. In the experimental group, 5 patients achieved adequate sedation at target levels below 4 µg/ml, while in control; no patients were identified at this low a target.

Conclusions

Faced with an equivalent cohort of patients and procedure durations, PRC administered a similar dose of propofol to that of CRNAs, yielding similar effect-site concentrations and PSI values. It was able to do so with fewer alterations in propofol dosing during the procedure and was able to identify patients requiring lower maintenance doses.

References: Mandel JE, and Sarraf E. The variability of response to propofol is reduced when a clinical observation is incorporated in the control: a simulation study. *Anesth Analg.* 2012;114:1221S9.