BPS vs. Propofol Monosedation in Therapeutic ERCP/EUS: A Prospective, Randomized, Double-blind Study

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Backgrounds/Aims: Balanced propofol sedation (BPS) may cause synergism between propofol and midazolam and reduce dose of propofol. However, there are few proven benefit between propofol alone titrated to moderate level of sedation and BPS in ERCP. We evaluated the safety and efficacy between propofol alone and BPS in therapeutic ERCP.

Materials and Methods: As a prospective randomized controlled study, consecutive 218 patients who were scheduled for therapeutic ERCP or interventional EUS were recruited from March 2011 to August 2011. For the propofol group, an intravenous bolus injection of propofol 0.5 mg/kg was given, and then followed by 10-20 mg as needed for induction. For the BPS group, both midazolam 0.05 mg/kg and fentanyl 25-50 mg were given intravenously at the initiation of sedation. Thereafter, repeated doses of 10 to 20 mg propofol were administered to maintain an adequate level of sedation in both groups. The target level of sedation was moderate sedation based on the ASA levels. The primary objectives were to compare the rates of recovery time and cost-effectiveness. Secondary outcomes included sedation efficacy, procedure outcomes, and complications.

Results: Compared with BPS, propofol sedation alone had a rapid recovery time, mean (SD) [18.37 (7.86) vs. 13.4 (6.24) min, p<0.001], and cost-effectiveness for sedatives [8142.09 (2639.16) vs. 5505.84 (2550.39) Korea Won, p<0.001]. There were no significant differences in the rates of cardiopulmonary complications [7.8% (8/102) vs. 9.6% (10/104), p=0.652]. No patient required assisted ventilation or permanent termination of procedures. Health care providers’ satisfaction with overall sedation, procedures, or patient cooperation, and patient intolerance were not different between two groups.

Conclusions: Compared with BPS, propofol alone sedation had a rapid recovery time and cost-effectiveness without differences of quality of sedation, patient satisfaction, and adverse events in therapeutic ERCP.

Key Words: Balanced propofol sedation; Propofol; Sedation; ERCP