Comparison of safety according to the timing of flumazenil administration in sedative endoscopy with midazolam: A single center, prospective, randomized and double-blinded study

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Flumazenil is a benzodiazepine antagonist that blocks the central effects of benzodiazepines. Previous studies suggest that routine use of flumazenil after midazolam sedation for endoscopy shorten the recovery time, but there is no data on timing of flumazenil administration. In this study we assessed the timing of flumazenil in outpatients receiving intravenous sedation with midazolam. From 2012 August to 2015 July, 74 participants undergoing sedative diagnostic endoscopy with midazolam were prospectively included. They were randomized in a double-blind to receive either flumazenil immediately (immediately group) or 30 minutes later after the procedure (delayed group). Four hours after the sedative endoscopy each patient was interviewed by telephone to assess the primary end point, sleepiness and dizziness. 74 participants were analyzed, 37 with immediate administration of flumazenil and 37 with delayed administration. There were no significant differences between the two groups in age, sex, blood pressure, pulse rate, the average dose of midazolam, procedure duration, recovery time, previous history of endoscopy and satisfaction score from the patients. Also, there was no significant difference in sleepiness and dizziness between immediately group and delayed group. Sleepiness (immediately injected group=56.8%, delayed injected group=45.9%) and dizziness (immediately injected group=24.3% and delayed injected group=40.5%) was observed in almost half of the participants, in particular within two hours. In this prospective, randomized, double-blinded clinical trial showed that there is no significant difference in safety between two groups. Patient who received flumazenil should be monitored for 2 hours after its administration because of the potential for re-sedation.

Biography

Hong Soon Jung has completed his MD from Catholic University of Korea and Post-doctoral studies from Catholic University Korea, College of Medicine. He is now working in the Division of Gastroenterology of Seoul St. Mary’s Hospital and Fellowship training.

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