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Remifentanil vs. propofol controlled infusion for sedation of patients undergoing gastrointestinal endoscopic procedures: A clinical randomized controlled clinical trial[☆]

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ABSTRACT

Background: Target controlled infusion (TCI) for the administration of anesthesia may provide a safe alternative for managing the discomfort of patients undergoing gastrointestinal endoscopic procedures. However, the most appropriate drug available for TCI is yet to be established. The objective of this trial was to compare remifentanil vs. propofol in TCI for sedating patients during GI endoscopy.

Materials and methods: Sixty-nine patients requiring GI endoscopies were randomly distributed to receive remifentanil ($n=30$) or propofol ($n=39$) TCI at the effect site (e). The primary outcome was patient's satisfaction. Secondary outcomes included the gastroenterologist satisfaction, comparison of the percentage of adverse events between the two groups (occurrence of arrhythmias, major respiratory depression, bradycardia, hypotension, pain, nausea or vomiting and absence of amnesia), and the level of awareness. Retrospective registration number is NCT01746641 at Clinicaltrials.gov.

Results: The mean (range) of patient satisfaction with remifentanil vs propofol was 1 (1–2) and 2 (1–4), respectively (χ^2 , $p<0.001$). Pain during the procedure was found to differ between remifentanil and propofol (mean 2 vs. 1, χ^2 , $p=0.042$), nausea or vomiting (4 vs. 0, χ^2 , $p=0.01$), and absence of amnesia (29 vs. 10, χ^2 , $p<0.001$), respectively. No statistically significant differences were found between the two groups.

Conclusion: Propofol in TCI seems to be an adequate agent for sedation of patients undergoing GI endoscopic procedures, with less adverse effects and higher patient satisfaction.

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Most likely, the combination of these two drugs may be synergistic and further reduce any adverse effects.

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Remifentanilo versus propofol con infusión controlada a objetivo en sitio efecto para la sedación de pacientes durante procedimientos endoscópicos gastrointestinales: ensayo clínico controlado aleatorizado

R E S U M E N

Palabras clave:

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Contexto: La administración de sedación con sistemas de infusión controlada a objetivo (TCI) podría ofrecer una alternativa segura para el manejo del malestar de los pacientes llevados a procedimientos endoscópicos gastrointestinales. Sin embargo, no se conoce qué medicamento de los disponibles para TCI es el más apropiado. El objetivo del estudio fue comparar remifentanilo y propofol en TCI para la sedación de pacientes durante procedimientos endoscópicos gastrointestinales.

Materiales y métodos: Sesenta y nueve pacientes que requerían un procedimiento endoscópico gastrointestinal fueron asignados aleatoriamente a recibir una TCI en sitio efecto (TCIe) de remifentanilo ($n = 30$) o propofol ($n = 39$). El desenlace primario fue la satisfacción del paciente. Los desenlaces secundarios incluyeron la satisfacción del gastroenterólogo, se compararon las proporciones de eventos adversos entre los 2 grupos (ocurrencia de arritmias cardíacas, depresión respiratoria leve, depresión respiratoria mayor, bradicardia, hipotensión, dolor, náuseas o vómitos, y ausencia de amnesia) y el nivel de consciencia. Número de registro retrospectivo: NCT01746641 en Clinicaltrials.gov.

Resultados: Las medianas (rango) de satisfacción del paciente entre remifentanilo y propofol fueron 1 (1-2) y 2 (1-4), respectivamente (2, $p < 0,001$). Se encontraron diferencias en la ocurrencia de dolor durante el procedimiento (mediana 2 vs. 1, 2, $p = 0,042$), náuseas o vómito (4 vs. 0, 2, $p = 0,01$), y ausencia de amnesia (29 vs. 10, 2, $p < 0,001$) entre remifentanilo y propofol, respectivamente. Para las otras variables estudiadas no se encontraron diferencias estadísticamente significativas entre los grupos.

Conclusión: El propofol en TCIe parece ser un medicamento adecuado para la sedación de pacientes durante procedimientos endoscópicos gastrointestinales, y presentó menores efectos adversos y mayor satisfacción del paciente. Es probable que con la sinergia de estos 2 medicamentos se pudiera lograr disminuir aún más los efectos adversos.

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Introduction

Target-controlled infusion (TCI) systems can control the concentration in the plasma or at the site of drug effect. Since their introduction into clinical practice in 1996¹ various pharmacokinetic models have been developed to simulate the expected concentration of these agents in humans.²⁻⁴ The starting point was programming of the Marsh & Schnider⁵⁻⁷ models for propofol, followed by the Shafer & Scott⁸ models for fentanyl, and lastly the Minto model for remifentanil.⁹ Several authors felt that the models should be adapted to a few sub-groups of patients, i.e. obese patients, with important differences in the distribution of body compartments.^{8,10}

Medical practice usually demands doing procedures that may cause pain or anxiety. Sedation for clinical procedures reduces any procedure-associated discomfort, fear and potential unpleasant memories, and facilitates the performance of the procedure.¹¹ In GI endoscopies some studies report using patient controlled sedation/analgesia (PCA) with midazolam, fentanyl, propofol and remifentanil that have evaluated

the patient's satisfaction, the level of sedation in accordance with scales like Ramsay's and frequency of adverse events.^{12,13} TCI models are often used for administering general anesthesia.¹⁴⁻¹⁷ However, only few cases have reported their use to provide analgesia and/or sedation for airway endoscopic procedures; as far as we know, there have been no reports on TCI used for GI endoscopic procedures.¹⁸⁻²² Of particular interest is the use of TCI models in situations in which spontaneous ventilation should be allowed and in patients with a critical health status. A study using remifentanil TCI for sedation during flexible fiberoptic bronchoscopy in critical patients suggests that this is a safe and effective sedation technique for this type of patients.²³ Another study compared bi-spectral index (BIS) monitor guided propofol TCI against manual infusion for dental procedures and found that the TCI infusion is useful and safe in patients with intellectual disability.²⁴ Furthermore, several studies have evaluated the use of TIC for awake fiberoptic intubation.^{22,25-27}

Target controlled infusion (TCI) systems may offer a safe approach for managing discomfort in patients undergoing GI endoscopic procedures. However, the most appropriate agent