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## A systematic review and meta-analysis of randomized, controlled trials of moderate sedation for routine endoscopic procedures

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### **CRD summary**

This review concluded that moderate sedation provided high levels of satisfaction and low risk of serious adverse events in patients undergoing esophagogastroduodenoscopy or colonoscopy. Midazolam-based regimens had longer sedation and recovery times than propofol. The search was limited, studies were generally poor quality and the appropriateness of the synthesis was unclear. Thus, the reliability of the conclusions was unclear.

### **Authors' objectives**

To compare the efficacy, safety and efficiency of agents used for moderate sedation in esophagogastroduodenoscopy (EGD) or colonoscopy.

### **Searching**

EMBASE (from 1980) and MEDLINE (from 1950) were searched up to to January 2007. Search terms were reported. Only fully published studies reported in English were eligible for inclusion in the review.

### **Study selection**

Randomised controlled trials (RCTs) that compared two active interventions for moderate sedation or one sedation method with placebo or no sedation in unselected adults undergoing esophagogastroduodenoscopy or colonoscopy were eligible for inclusion. Only studies of intravenously administered agents (or combinations) administered by a healthcare professional with the goal of moderate sedation were eligible. Studies that compared different modes of administration of one agent were excluded from the review. Also excluded were studies that did not allow for dose adjustment of at least one component to achieve moderate sedation and studies of only antispasmodic or anticholinergic medications. Also excluded were studies in selected populations, including volunteers, studies of rigid or flexible sigmoidoscopy and studies of endoscopic retrograde cholangiopancreatography, endoscopic ultrasound and enteroscopy. Outcomes from the following classes were considered: patient monitoring or complications; procedural and efficiency; patient assessment; and physician assessment.

Included studies assessed the following interventions: diazepam, midazolam, propofol or narcotic; and combinations of these agents with each other or with diphenhydramine or droperidol. Doses and dosage schedule varied between the studies.

Two reviewers independently selected the studies for the review.

### **Assessment of study quality**

Studies were independently assessed for validity by two reviewers using the Jadad scale, which awards up to 5 points for the criteria of blinding, randomisation and treatment of withdrawals and dropouts. Disagreements were resolved through consensus.

### **Data extraction**

Two reviewers independently extracted data on a wide range of outcomes. Disagreements were resolved through consensus.

### **Methods of synthesis**

The studies were combined in a meta-analysis. A relative risk (RR) with 95% confidence interval (CI) was calculated where at least two studies assessed the same comparison. Statistical heterogeneity between studies was assessed using the  $X^2$  test. The presence of statistically significant heterogeneity determined the use of a random- as opposed to a fixed-effect model.

### Results of the review

Thirty-six studies (n=3,918) with 75 treatment arms were included in the review. Of these, 23 studies scored 3 or less on the Jadad scale, which was taken to indicate lower quality.

Sedation improved patient satisfaction (RR 2.29, 95% CI: 1.16, 4.53) and willingness to repeat esophagogastroduodenoscopy (RR 1.25, 95% CI: 1.13, 1.38) compared with no sedation. Midazolam had higher patient satisfaction (RR 1.18, 95% CI: 1.07, 1.29) and willingness to repeat procedure (RR 1.08, 95% CI: 1.04, 1.13), and less memory of the examination (RR 0.57, 95% CI: 0.50, 0.60) than diazepam. Midazolam plus narcotic had lower patient satisfaction than propofol (RR 0.90, 95% CI: 0.83, 0.97). There were no other significant differences in efficacy. Recovery times were statistically significantly shorter in groups treated with propofol containing regimes in five of the six RCTs that reported this outcome. Results of the assessments of heterogeneity were not fully reported.

### Authors' conclusions

Moderate sedation provided a high level of physician and patient satisfaction and a low risk of serious adverse events. Midazolam-based regimens had longer sedation and recovery times than propofol.

### CRD commentary

The review question and the inclusion criteria were clear and specific. The authors searched two relevant databases, but the decision to limit the review to published studies reported in English may have increased the risk of language and publication biases and may have excluded some relevant studies. Rigorous methodology was used at all stages of the review process. An appropriate validity assessment was conducted and used to inform the synthesis. It was unclear how appropriate the use of meta-analysis was as although heterogeneity was apparently assessed, the results of the assessment were not reported fully. The authors' conclusions reflected the results of the review accurately, but the reliability of the conclusions was unclear, given the limitations of clinical and (potentially) statistical heterogeneity, the quality of included studies (noted by the authors) and the limited search.

### Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that controlled trials were needed to assess the role of lower doses of propofol combined with midazolam or narcotics compared with propofol alone or with benzodiazepines plus narcotics.

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### Bibliographic details

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