Review article: safety profile of propofol for paediatric procedural sedation in the emergency department
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CRD summary
This review concluded that use of propofol for paediatric procedural sedation was associated with a low rate of minor adverse events and major adverse events with propofol sedation were extremely rare. These conclusions should be interpreted cautiously given concerns about the review methods and the possibility of publication and language biases.

Authors' objectives
To assess the adverse events of propofol for paediatric procedural sedation in the emergency department.

Searching
MEDLINE, EMBASE and The Cochrane Library were searched from inception to December 2008 for studies in English. Search terms were reported. Reference lists of retrieved publications were screened.

Study selection
Studies that evaluated propofol for paediatric procedural sedation in the emergency department in patients aged between one day and 17 years were eligible for inclusion. Eligible studies had to use propofol as the primary sedation agent in at least one arm of the study and not perform the intervention in an operating theatre. Combined adult paediatric studies were included if there were age-specific groups for adverse event data. Studies of patients who received inhalational anaesthetics and studies in which sedation data were not collected specifically for propofol-related complications were excluded. The review outcomes were minor adverse events (oxygen desaturation, assisted ventilation, apnoea, hypotension, pain with injection and emesis without aspiration) and major adverse events (death, unplanned hospital admission, aspiration, laryngospasm and unplanned intubation).

Reported propofol loading doses varied between included studies and ranged from 0.5mg/kg to 5.4mg/kg. Propofol sedations in included studies were performed in various hospital settings that included emergency departments, radiology departments, gastroscopy units, intensive care units and oncology departments. Most of the included studies used supplemental oxygen; some studies used capnography. Reported age of patients ranged from 0.1 month to 21 years.

One reviewer assessed studies for inclusion.

Assessment of study quality
One reviewer assessed the study quality of randomised controlled trials (RCTs) using criteria for blinding, allocation concealment, clearly defining outcome measures and baseline comparability.

Data extraction
One reviewer extracted data on incidence of adverse events.

Methods of synthesis
Average rates of adverse events were calculated. A separate analysis was conducted for RCTs.

Results of the review
Sixty studies were included in the review (n=17,066 propofol sedations): 20 RCTs and the rest appeared to be case series. For RCTs, only 18% of studies had adequate blinding, 24% had adequate concealment of allocation and 47% had adequate baseline comparability. Outcome measures were clearly defined in 76% of studies.

Incidences of adverse events of propofol for procedural sedation were: desaturation 9.3%, apnoea 1.9%, assisted ventilation 1.4%, hypotension 15.4%, unplanned intubation 0.02%, emesis post procedure 0.14%, laryngospasm 0.2%,
bradycardia 0.1% and myoclonus 0.13%.

No incidents of aspiration or emesis during sedation were reported. There were no deaths associated with procedural propofol sedation.

The results of separate analyses of adverse events in RCTs were: desaturation 13.8%, apnoea 3.2% and assisted ventilation 1.4%.

Authors’ conclusions
Use of propofol for paediatric procedural sedation was associated with a low rate of minor adverse events that were reversible with minimal intervention. Major adverse events with propofol sedation were extremely rare.

CRD commentary
This review’s inclusion criteria were clear. Relevant databases were searched. Efforts were made to find published studies. Unpublished studies were not sought and this increased potential for publication bias. The search was limited to studies in English and this increased the risk of language bias. One reviewer performed study selection, data extraction and validity assessment; the author acknowledged that reviewer errors and biases could not be ruled out in the review process. Appropriate criteria were used to assess the quality of RCTs. No formal validity assessment was performed for non-RCTs. Deriving a single average rate of adverse events might not have been appropriate as it did not take into account the clinical heterogeneity between included studies.

The author’s conclusions should be interpreted with caution given concerns about the review methods and the possibility of publication and language biases.

Implications of the review for practice and research
Practice: The author stated that the ongoing use of propofol for paediatric procedural sedation in the emergency department was supported by the current evidence.

Research: The author did not state any implications for research.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.