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Sedation versus general anaesthesia for provision of dental treatment to patients younger than 18 years (Review)

Ashley PF, Williams CECS, Moles DR, Parry J

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[Intervention Review]

Sedation versus general anaesthesia for provision of dental treatment to patients younger than 18 years

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ABSTRACT

Background

A significant proportion of children have caries requiring restorations or extractions, and some of these children will not accept this treatment under local anaesthetic. Historically this has been managed by the use of a general anaesthetic in children; however, use of sedation may lead to reduced morbidity and cost. The aim of this review was to compare the efficiency of sedation versus general anaesthesia (GA) for provision of dental treatment to children and adolescents younger than 18 years. This review was originally published in 2009 and was updated in 2012 and again in 2015.

Objectives

We will evaluate morbidity and effectiveness of sedation versus GA for provision of dental treatment to patients younger than 18 years. If data become available, we will analyse the cost-effectiveness of different interventions. If data are not available, we will obtain crude estimates of cost.

Morbidity can be defined as 'an undesired result or complication'. For the purposes of this review, 'postoperative morbidity' refers to undesired results or complications such as nausea following a procedure, once the patient had been restored to consciousness and could breathe unaided. 'Intraoperative morbidity' refers to any complications that occur during the procedure that may necessitate action by the anaesthetist or the sedationist, such as respiratory arrest.

Search methods

In this updated review, we searched the Cochrane Central Register of Controlled Trials (CENTRAL; 2015, Issue 7); MEDLINE Ovid SP (1950 to July 2015); EMBASE Ovid SP (1974 to July 2015); System for Information on Grey Literature in Europe (SIGLE) (1980 to October July 2012); Latin American & Caribbean Health Sciences Literature (LILACS) (1982 to July 2015); and Institute for Scientific Information (ISI) Web of Science (1945 to July 2015).

We also carried out handsearching of relevant journals to July 2015. We imposed no language restriction.

Selection criteria

We planned to include randomized controlled clinical trials that compared sedative agents versus general anaesthesia in children and adolescents up to 18 years of age undergoing dental treatment. We excluded complex surgical procedures and pseudo-randomized trials.

Data collection and analysis

Two review authors assessed titles and abstracts for inclusion in the review. We recorded information relevant to objectives and outcome measures by using a specially designed 'data extraction form'. We will employ the Grades of Recommendation, Assessment, Development and Evaluation Working Group (GRADE) approach to interpret findings.

Main results

In our original review, we identified 16 studies for potential inclusion after searching available databases and screening titles and abstracts. After retrieving full-text studies, we found none to be eligible. We identified no additional studies in the updated search of July 2012. We identified two studies for possible inclusion in the updated search of July 2015; again we found these to be ineligible.

Authors' conclusions

Randomized controlled studies comparing use of dental general anaesthesia versus sedation are needed to quantify differences such as morbidity and cost.

PLAIN LANGUAGE SUMMARY

Comparing sedation versus general anaesthesia for children who need to have dental treatment

Review question

This updated Cochrane systematic review aimed to look at evidence comparing use of sedation versus general anaesthesia to help children (up to 18 years of age) undergoing dental treatment. We wanted to see which (if any) approach allowed dental treatment to be carried out safely and effectively. We were also interested in the relative financial cost of each approach.

Background

At present, children unable to cope with dental care under local anaesthetic may be given general anaesthesia or sedation to help them. This choice is dependent on factors such as patient or dentist preference, the cost of the procedure or local regulations. Some people believe that sedation is better for this, as patients prefer it and it may be cheaper.

Methods

For our original review, we searched the databases until October 2008. For this updated review, we searched the following databases to July 2015: CENTRAL, MEDLINE, EMBASE, LILACS and ISI Web of Science.

Key results

Unfortunately, we could not identify any randomized controlled trials on this topic. These trials are required for comparison of dental general anaesthesia versus sedation, to quantify differences such as morbidity and cost.

BACKGROUND

Description of the condition

It is widely recognized that the level of caries in children of industrialized nations has dropped substantially over the past few

decades. Unfortunately, a significant proportion of these children still have caries, which often remain untreated. Untreated decay into dentine in primary teeth was found in 28% of five-year-olds and in 39% of eight-year-olds in England, Wales and Northern Ireland (Child Dental Health Survey 2013). Similar patterns of disease are seen in other developed countries. This represents a significant problem because if dentine caries are left untreated, they usually lead to pain and sepsis, which often can be managed only by extraction or extensive restoration of affected teeth.

The obvious alternative is to provide treatment under local anaesthesia; however, some children will not be able to accept this. Barriers to treatment may include dental fear or behaviour management problems. Dental fear and behaviour management problems are closely related phenomena; in one study, 61% of children with dental fear presented with behaviour management problems (Klingberg 1995). Estimates of the prevalence of dental fear are difficult to find; however, one Swedish study reported that 10.5% of children in a population of four- to 11-year-olds had behaviour management problems (Klingberg 1994). Dental fear or anxiety is associated with increased levels of caries (Julihn 2006).

Methods of managing anxiety and behaviour are required to meet this need. Whilst behavioural techniques that do not involve the use of drugs can play an important part in management of a child's treatment, many children find it difficult to tolerate dental treatment. In these cases, sedation or general anaesthesia could be considered as a method for reducing anxiety and facilitating provision of dental treatment.

Description of the intervention

Sedation or general anaesthesia (GA) is widely used to manage behaviour and to support provision of dental treatment across the world. However, it is unclear whether either technique offers advantages over the other. Both carry risks of mortality (albeit small) and postoperative morbidity (Atan 2004; Chicka 2012; Lee 2000). Finally, both procedures require use of additional facilities, including drugs, equipment and staff; therefore, both lead to additional costs for the service provider and the patient.

How the intervention might work

One of these interventions might be superior to the other in terms of cost, safety and patient acceptance.

Why it is important to do this review

We are conducting this systematic review in an attempt to determine which is the most safe, effective and cost-efficient method of providing dental care for children who cannot accept care under local anaesthetic without additional support.

Therefore, the aim of this review was to compare the efficiency of sedation versus GA for provision of dental treatment to children and adolescents younger than 18 years. Gaining an understanding of the costs involved in providing GA was another objective of this review (costs may be affected by how and where the anaesthetic or sedation is administered).

OBJECTIVES

We will evaluate the morbidity and effectiveness of sedation versus GA for provision of dental treatment to patients younger than 18 years. If data become available, we will analyse the cost-effectiveness of different interventions. If data are not available, we will obtain crude estimates of cost.

Morbidity can be defined as 'an undesired result or complication'. For the purposes of this review, 'postoperative morbidity' refers to undesired results or complications such as nausea following a procedure, once a patient had been restored to consciousness and could breathe unaided. 'Intraoperative morbidity' refers to any complications that occur during the procedure that may necessitate action by the anaesthetist or the sedationist, such as respiratory arrest.

METHODS

Criteria for considering studies for this review

Types of studies

We planned to include randomized controlled clinical trials (RCTs) (including cluster-randomized trials).

We planned to exclude pseudo-randomized trials.

Types of participants

We planned to include children and adolescents up to 18 years of age. We planned to include children and adolescents undergoing dental treatment including fillings, removal of the nerve from a tooth and extraction of a tooth.

We excluded from this study children and adolescents undergoing complex surgical procedures. For the purposes of this review, we defined complex surgical procedures as procedures during which bone was removed.

Types of interventions

Test group

Sedative agents administered via any route by an anaesthetist, a dentist or another healthcare professional in any setting.

Control group

General anaesthesia administered via any route by an anaesthetist, a dentist or another healthcare professional in any setting.

Types of outcome measures

We planned to measure the following outcomes.

Primary outcomes

- Mortality (if any).
- Completion of treatment: yes or no.
- Postoperative morbidity.

Secondary outcomes

- Cost to the participant.
- Cost of the procedure.
- Participant satisfaction.
- Parental satisfaction.
- Intraoperative morbidity.

Estimation of cost may not be recorded, or different methods may be used to calculate this. Therefore, in addition to cost data, we planned to record the following variables, when available.

- Length of participant stay.
- Length of the procedure.
- Facilities used.
- Materials used.
- Equipment used.
- Staff required.

We planned to perform the following subgroup analyses.

- Age.
- Dental procedure.
- Sedative agent.
- Operator providing sedation or anaesthetic (i.e. dentist or anaesthetist).

Search methods for identification of studies

Electronic searches

In this updated review, we searched the Cochrane Central Register of Controlled Trials (CENTRAL; 2015, Issue 7; see Appendix 1); MEDLINE Ovid SP (1950 to July 2015; see Appendix 2); EMBASE Ovid SP (1974 to July 2015; see Appendix 3); System for information on Grey Literature in Europe (SIGLE) (1980 to October July 2012); Latin American & Caribbean Health Sciences Literature (LILACS) (1982 to July 2015; see Appendix 4); and Institute for Scientific Information (ISI) Web of Science (1945 to July 2015; see Appendix 5).

We performed our original search in October 2008 (Ashley 2009). We developed detailed search strategies for each database. We based these on the search strategy developed for MEDLINE and revised them appropriately for each database.

Our search was combined with a subject search in phases one and two of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) and was also run separately.

We searched the following databases up to July 2015 (free text search for dent* and sed* and (anaesth* or anesth*)) for additional relevant trials and references.

- World Wide Web (Google).
- Community of Science Database.
- ClinicalTrials.gov (http://www.controlled-trials.com/).
- http://www.opengrey.eu/.

We cross-checked these with studies already identified.

We imposed no language restrictions.

Searching other resources

Handsearching

In our original review, we handsearched the following journals for the period 2000 to 2007 (Ashley 2009). In this updated review, we searched the journals to 3 August 2015.

- *American Academy of Pediatric Dentistry*.
- *Anaesthesia*.
- *British Dental Journal*.
- *British Journal of Anaesthesia*.
- *Dental Update*.
- *International Journal of Paediatric Dentistry*.
- *Journal of American Dental Association*.
- *Journal of Dentistry for Children*.
- *Pediatric Dentistry*.

We checked the reference lists of all eligible trials for additional studies.

Unpublished studies

We contacted specialists in the field known to us to ask for unpublished data.

Data collection and analysis

Selection of studies

Two review authors (CWI and PA) assessed titles and abstracts for inclusion in the review. We used our selection criteria to select papers suitable for inclusion.

Data extraction and management

We extracted information relevant to objectives and outcome measures onto a specially designed 'Data Extraction Form' (Appendix 6). We resolved disagreements between review authors by discussion. We were not blinded to the journal of publication nor to the authors' names on the papers.

We planned to collect descriptive data (when available), in addition to details already outlined. These data were to be used to provide contextual information for the main outcomes, thus aiding interpretation of results from this review. We have provided details in Appendix 6.

- Year study started (if not available, year it was published).
- Country in which study was carried out.
- Previous treatment of participant.
- Fasting before the procedure.
- Use of restraints during the procedure.
- Level of consciousness throughout the procedure.
- Monitoring used.
- Procedure and recovery times.
- Anxiety before and after treatment.
- Participant satisfaction/acceptance.
- Treatment carried out.

Assessment of risk of bias in included studies

We planned to assess risk of bias using the methods set out in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We planned to assess included trials according to the following criteria.

- Random sequence generation.
- Allocation concealment.
- Blinding, assessed in three groups: participant, operator or sedationist or anaesthetist and outcome assessor. If study authors state that a study is double blind, it is assumed that at least the participant and the outcome assessor are blinded.
- Incomplete outcome data.
- Selective reporting.
- Other bias.

We planned to prepare a description of what was reported to have happened in the study in sufficient detail to support a judgement about risk of bias for each included trial, along with a judgement of low, high or unclear risk of bias.

The criteria applied for risk of bias judgements regarding allocation concealment are given below, as described in the *Cochrane Handbook for Systematic Reviews of Interventions* 5.1.0 (Higgins 2011).

- Low risk of bias: adequate concealment of the allocation (e.g. sequentially numbered, sealed, opaque envelopes or centralised or pharmacy-controlled randomization).
- Unclear risk of bias: uncertainty about whether the allocation was adequately concealed (e.g. when the method of concealment is not described or is not described in sufficient detail to allow a definitive judgement).
- High risk of bias: inadequate allocation concealment (e.g. investigators knew in advance what the allocated assignment of the next participant would be).

We planned to undertake a summary assessment of risk of bias for the primary outcome (across domains) (Higgins 2011).

Within a study, a summary assessment of low risk of bias will be given when low risk of bias is noted for all key domains, unclear risk of bias when unclear risk of bias is seen for one or more key domains and high risk of bias when high risk of bias is observed for one or more key domains. Across studies, a summary assessment will be rated as having low risk of bias when most information is derived from studies at low risk of bias, unclear risk of bias when most information is derived from studies at low or unclear risk of bias, and high risk of bias when the proportion of information derived from studies at high risk of bias is sufficient to affect interpretation of results.

We plan to include in this review all studies meeting the selection criteria regardless of quality.

Measures of treatment effect

For dichotomous outcomes such as treatment completion, it was planned to calculate risk ratios (RRs) along with 95% confidence intervals (CIs); continuous outcomes would be reported in each group as means and standard deviations.

Unit of analysis issues

We planned that the approaches used would be outlined as described in the *Cochrane Handbook for Systematic Reviews of Interventions* 5.1.0 (Higgins 2011).

Dealing with missing data

We planned that the approaches used would be outlined as described in the *Cochrane Handbook for Systematic Reviews of Interventions* 5.1.0 (Higgins 2011).

Assessment of heterogeneity

We planned to assess heterogeneity in trial results, when appropriate, by inspecting a graphical display of the results and performing formal tests of heterogeneity.

Assessment of reporting biases

We planned that this would be assessed, when appropriate, by inspecting funnel plots of study results and performing formal tests if possible.

Data synthesis

We planned that when dichotomous outcome variables or continuous outcome variables with means and standard deviations were available, these data would be recorded.

A random-effects model was planned when more than four trials were included in an analysis. The outcome of standardized mean difference was planned to be used in situations in which different scales were used to measure the same outcome.

Subgroup analysis and investigation of heterogeneity

We proposed conducting subgroup analyses for the following groups, provided sufficient data were available.

- Age: this would be subdivided into three groups: birth to five, six to 11 and 12 to 17 years (as recommended by the British National Formulary (BNF) for use in prescribing drugs to children).
- Dental procedure.
- Sedative.
- Operator providing sedation or anaesthetic.

Sensitivity analysis

We planned to perform sensitivity analysis a priori to compare study results for risk of bias. We planned to undertake both fixed-effect model and random-effects model meta-analyses to assess the robustness of study results.

Summary of findings

We planned to employ the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) approach to interpret findings (Guyatt 2008) and the GRADE profiler (GRADEPRO) to import data from Review Manager to create 'Summary of findings' tables. We planned that these tables would provide outcome-specific information concerning the overall quality of evidence from studies included in the comparison, the magnitude of effect of the interventions examined and the sum of available data on outcomes considered. Outcomes to be considered included the following.

Primary outcomes

- Mortality (if any).
- Completion of treatment: yes or no.
- Postoperative morbidity.

Secondary outcomes

- Cost to the participant.
- Cost of the procedure.
- Participant satisfaction.
- Parental satisfaction.

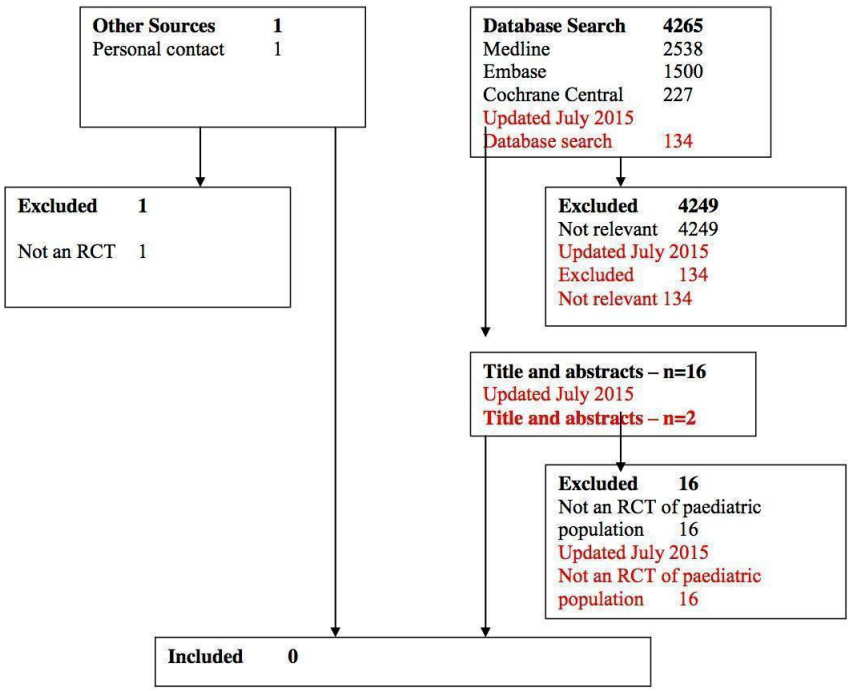
RESULTS

Description of studies

Results of the search

In Ashley 2009, we originally identified 16 studies for potential inclusion after searching available databases and screening titles and abstracts (search flow figure in Figure 1). Upon full-text retrieval of the studies, we found none to be eligible (see Characteristics of excluded studies). We identified no additional studies in the updated search of July 2012. We identified two possible studies in the updated search of July 2015; again we found these to be ineligible (see Characteristics of excluded studies).

Figure 1.



Included studies

We found no eligible studies (see Characteristics of excluded studies).

Excluded studies

We excluded studies that were not RCTs comparing sedation versus GA (see Characteristics of excluded studies).

Risk of bias in included studies

We found no eligible studies (see Characteristics of excluded studies).

Allocation

We found no eligible studies (see Characteristics of excluded studies).

Blinding

We found no eligible studies (see Characteristics of excluded studies).

Incomplete outcome data

We found no eligible studies (see Characteristics of excluded studies).

Selective reporting

We found no eligible studies (see Characteristics of excluded studies).

Other potential sources of bias

We found no eligible studies (see Characteristics of excluded studies).

Effects of interventions

We found no eligible studies (see Characteristics of excluded studies).

DISCUSSION

Summary of main results

We found no randomized controlled trials (RCTs) comparing general anaesthesia (GA) versus sedation for providing dental care to children. Some publications compared any form of sedation versus GA using methods such as case control studies (Averley 2004; Jameson 2007; Lyratzopoulos 2003; Rastogi 2013; Silay 2013). Comments related to these studies are provided below.

Overall completeness and applicability of evidence

If treatment with sedation is to be an effective alternative to GA, it needs to allow provision of similar levels of dental treatment and should be suitable for younger children, as they are more likely to require GA. Use of nitrous oxide and oxygen (IHS) was reviewed by Lyratzopoulos and Blain (Lyratzopoulos 2003), who noted that children selected for IHS treatment were non-representative of the population requiring GA treatment, and that IHS was unlikely to ever be suitable for young children requiring extractions of multiple diseased teeth. Intravenous midazolam was reviewed in the case series described by Silay 2013. Study authors concluded that IV midazolam sedation was not an alternative to GA when patients had 'multiple dental management issues', that is, when they needed more than just simple dental extractions.

Could other methods of sedation be appropriate? Averley et al (Averley 2004) demonstrated that sedation with inhaled sevoflurane and intravenous (IV) midazolam can be used to successfully provide dental treatment to a group of children and adolescents who otherwise might need GA. Again, though, investigators made no direct comparisons with GA. In a subsequent paper, this team looked at the cost of this alternative approach compared with the cost of GA (Jameson 2007) and concluded that GA was 46.6% more expensive than an 'advanced' conscious sedation approach; however, data were not based on direct comparisons. Whilst one episode of dental care under sedation might be cheaper than a similar episode under GA, it is not clear if a similar level of treatment can be delivered under sedation. Dental treatment provided under sedation may require several visits for treatment completion; this is not the case for dental treatment delivered under GA. In addition, sedation may be unsuccessful on some occasions, thereby necessitating subsequent GA.

So how should an RCT be designed to compare sedation versus GA? The first consideration clearly is the type of sedative technique to be used. This needs to allow provision of extractions and restorations for children and adolescents comparable with those

achievable under GA. It is important to note that it also needs to allow placement of restorations that will last. GA facilitates the 'ideal' placement of restorative materials, as the patient will not move throughout the procedure. This may not be the case in a sedated patient.

Outcome variables must be chosen carefully. Mortality and serious morbidity following sedation or GA are rare, and sample sizes required to objectively look at these probably would be too large to allow a study to be run. However, less serious measures of morbidity (such as nausea) are common and occur frequently enough to be used as sensible outcome variables. Patient satisfaction and quality of life are important considerations. Cost is another important outcome for consideration. Sedation may well be cheaper per visit than GA, but how many sedation visits will be required to complete the treatment that will almost certainly be completed in one GA visit? Treatment quality must be assessed. As described above, sedation may not provide the optimal situation for restoration placement. Rastogi 2013 measures some of these outcomes in adults; in this study, treatment under sedation was preferred by study participants and resulted in reduced postoperative morbidity.

Quality of the evidence

No RCTs were available for assessment.

Potential biases in the review process

No RCTs were available for assessment.

Agreements and disagreements with other studies or reviews

No RCTs were available for assessment.

AUTHORS' CONCLUSIONS

Implications for practice

We found no RCTs comparing general anaesthesia versus sedation for children and adolescents undergoing dental treatment. Therefore, we are not able to make recommendations about use of sedation or general anaesthesia for provision of dental treatment in patients younger than 18 years.

Implications for research

Carefully designed and well-run RCTs are required to compare sedation versus GA for provision of dental treatment to children and adolescents. At present, none have been conducted.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Arch 2001	Structured interview measuring anxiety in child at pretreatment and at 1 week follow-up set in a primary healthcare centre. Children 9 to15 years of age were provided information about IHS and GA and then were invited to choose which method they preferred. Children having IHS were less anxious postoperatively than children who had GA Reason for exclusion: not an RCT
Bettelli 1990	Review/opinion article Reason for exclusion: not an RCT
Blain 1998	Patients (mean age 7.6 years) referred for management of caries under GA were given IHS instead. Outcomes included treatment completion and relative cost. 83% of patients referred for GA were managed with IHS Reason for exclusion: not an RCT
Camm 1987	Case control study with 3 groups of children (age range 23 to 71 months). Children underwent dental treatment with GA, sedation or just LA, and postoperative behavioural change was assessed. Study authors reported that GA and sedation produced postoperative behavioural changes (both positive and negative). Children who received treatment under LA showed no change in behaviour after the procedure Reason for exclusion: not an RCT
Chalazonitis 1968	Review/opinion article Reason for exclusion: not an RCT
Crawford 1990	Patients referred for GA extractions were offered IHS instead. Of those who consented to take part, 87% completed treatment under IHS Reason for exclusion: not an RCT
Crock 2003	Retrospective analysis of experiences of children with cancer who received GA or sedation for bone marrow aspirates/lumbar punctures. Those given GA regimen showed much lower levels of pain and distress than those given sedation Reason for exclusion: not an RCT. No dental treatment
Fabre 2004	Reason for exclusion: letter. Not an RCT
Foley 2008	Prospective analysis of children attending for paediatric minor oral surgical procedures under sedation or GA. Most procedures were carried out under GA Reason for exclusion: not an RCT
Girdler 1997	Reason for exclusion: letter. Not an RCT
Lee 2000	Cost analysis looking at the cost of GA in a group of 22 children and estimating the cost of conscious sedation in the same group. GA was more cost-effective if it was likely that the conscious sedation group would require more than 3 visits to complete treatment Reason for exclusion: not an RCT

(*Continued*)

Loyola 2004	Case report describing use of sedation or GA to manage a group of children and young adults with cerebral palsy requiring dental treatment. Most children (77%) were treated with GA Reason for exclusion: not an RCT
Milnes 2003	Description of a "cost-effective" intravenous sedation programme used in a pediatric dental practice in Kelowna, British Columbia Reason for exclusion: not an RCT
Rastogi 2013	Clinical trial comparing GA vs sedation, but most participants were adults and investigators could not analyse data from younger participants (15 years old and older). In addition, complex surgical procedures were provided
Shaw 1996	Patients referred for extractions (n = 133, four to 17 years of age) were offered treatment under IHS rather than GA. 90% were successfully treated along with most of those who had had GA and previously expressed a preference for IHS Reason for exclusion: not an RCT
Shaw 1998	Reason for exclusion: letter. Not an RCT
Shepherd 2000	Paediatric patients referred for orthodontic extractions were offered IHS or GA (n = 101); 35 chose GA and the remainder chose IHS. Postoperative morbidity in the IHS group was significantly lower than in the GA group Reason for exclusion: not an RCT
Silay 2013	Study comparing GA vs sedation in children, but not an RCT - parents were allowed to choose their group

GA: general anaesthesia.
IHS: inhalation sedation with nitrous oxide and oxygen.
LA: local anaesthesia.
n: numbers.
RCT: randomized controlled trial.
vs: versus.

DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor Dentistry explode all trees
#2 MeSH descriptor Dentition explode all trees
#3 (((dent* or oral) near (surg* or operat*)) or orthodont* or endodont* or pulp* or carie* or carious) or ((dental or tooth or teeth) near (filling* or restor* or extract* or treat*))
#4 (#1 OR #2 OR #3)
#5 MeSH descriptor Conscious Sedation explode all trees
#6 MeSH descriptor Anti-Anxiety Agents explode all trees
#7 MeSH descriptor Hypnotics and Sedatives explode all trees
#8 MeSH descriptor Barbiturates explode all trees
#9 MeSH descriptor Benzodiazepines explode all trees
#10 sedat*:ti,ab or relative analgesia or (anti?anxiety near agent*) or barbiturate* or benzodiazepin* or nitrous oxide or midazolam or diazepam or chloral hydrate or hydroxyzin* or temazepam or ketamin* or meperidin* or promethazin* or triazolam or trimeprazin* or metaclopramid* or flunitrazepam or sevofluran*
#11 (#5 OR #6 OR #7 OR #8 OR #9 OR #10)
#12 MeSH descriptor Anesthesia, General explode all trees
#13 MeSH descriptor Anesthetics, General explode all trees
#14 general an?esth* or halothan* or sevofluran* or nitrous oxide or isofluran* or enfluran* or ketamin* or midazolam or lorazepam or xenon or sevofluran* or thiopenton* or methohexitol or diazepam or propofol
#15 (#12 OR #13 OR #14)
#16 p?ediatric* or child* or infant* or adolescent* or preschool
#17 (#4 AND #11 AND #15 AND #16)

Appendix 2. MEDLINE (Ovid SP) search strategy

1. exp Dentistry/ or exp Dentition/ or (((dent* or oral) adj4 (surg* or operat*)) or orthodont* or endodont* or pulp* or carie* or carious).mp. or ((dental or tooth or teeth) and (filling* or restor* or extract* or treat*)).mp.
2. Conscious Sedation/ or sedat*.mp. or exp Anti-Anxiety Agents/ or exp "Hypnotics and Sedatives"/ or exp Barbiturates/ or exp Benzodiazepines/ or (relative analgesia.mp. or (anti?anxiety adj4 agent*) or barbiturate* or benzodiazepin* or nitrous oxide or midazolam or diazepam or chloral hydrate or hydroxyzin* or temazepam or ketamin* or meperidin* or promethazin* or triazolam or trimeprazin* or metaclopramid* or flunitrazepam or sevofluran*).mp.
3. exp "Anesthesia, General"/ or exp "Anesthetics, General"/ or (general an?esth* or halothan* or sevofluran* or nitrous oxide or isofluran* or enfluran* or ketamin* or midazolam or lorazepam or xenon or sevofluran* or thiopenton* or methohexitol or diazepam or propofol).mp.
4. exp Child/ or exp Infant/ or exp Adolescent/ or (p?ediatric* or child* or infant* or adolescent* or preschool).mp.
5. 1 and 2 and 3 and 4
6. ((randomized controlled trial or controlled clinical trial).pt. or randomized.ab. or placebo.ab. or drug therapy.fs. or randomly.ab. or trial.ab. or groups.ab.) not (animals not (humans and animals)).sh.
7. 5 and 6

Appendix 3. EMBASE (Ovid SP) search strategy

1. exp dentistry/ or exp dentition/ or (((dent* or oral) adj4 (surg* or operat*)) or orthodont* or endodont* or pulp* or carie* or carious).mp. or ((dental or tooth or teeth) and (filling* or restor* or extract* or treat*)).mp.
2. exp dental anesthesia/ or conscious sedation/ or sedat*.mp. or exp anxiolytic agent/ or exp hypnotic agent/ or sedative agent/ or exp barbituric acid derivative/ or exp benzodiazepine derivative/ or (relative analgesia.mp. or (anti?anxiety adj4 agent*) or barbiturate* or benzodiazepin* or nitrous oxide or midazolam or diazepam or chloral hydrate or hydroxyzin* or temazepam or ketamin* or meperidin* or promethazin* or triazolam or trimeprazin* or metaclopramid* or flunitrazepam or sevofluran*).mp.
3. exp general anesthesia/ or exp anesthetic agent/ or (general an?esth* or halothan* or sevofluran* or nitrous oxide or isofluran* or enfluran* or ketamin* or midazolam or lorazepam or xenon or sevofluran* or thiopenton* or methohexitol or diazepam or propofol).mp.
4. exp child/ or exp infant/ or exp adolescent/ or (p?ediatric* or child* or infant* or adolescent* or preschool).mp.
5. 1 and 2 and 3 and 4
6. (randomized-controlled-trial/ or randomization/ or controlled-study/ or multicenter-study/ or phase-3-clinical-trial/ or phase-4-clinical-trial/ or double-blind-procedure/ or single-blind-procedure/ or (random* or cross?over* or multicenter* or factorial* or placebo* or volunteer*).mp. or ((singl* or doubl* or trebl* or tripl*) adj3 (blind* or mask*)).ti,ab. or (latin adj square).mp.) not (animals not (humans and animals)).sh.
7. 5 and 6

Appendix 4. LILACS (BIREME) search strategy

((dentistry or dentition or (((dent$ or oral) and (surg$ or operat$)) or orthodont$ or endodont$ or pulp$ or carie$ or carious) or ((dental or tooth or teeth) and (filling$ or restor$ or extract$ or treat$)))) and (sedat$ or barbiturate$ or benzodiazepine$ or relative analgesia or (anti?anxiety SAME agent$) or nitrous oxide or midazolam or diazepam or chloral hydrate or hydroxyzin$ or temazepam or ketamin$ or meperidin$ or promethazin$ or triazolam or trimeprazin$ or metaclopramid$ or flunitrazepam or sevofluran$) and (general an?esth$ or halothan$ or sevofluran$ or nitrous oxide or isofluran$ or enfluran$ or ketamin$ or midazolam or lorazepam or xenon or sevofluran$ or thiopenton$ or methohexitol or diazepam or propofol)

Appendix 5. ISI Web of Science search strategy

#1 TS=(dentistry or dentition or (((dent* or oral) SAME (surg* or operat*)) or orthodont* or endodont* or pulp* or carie* or carious) or ((dental or tooth or teeth) SAME (filling* or restor* or extract* or treat*)))
#2 TS=(sedat* or barbiturate* or benzodiazepine* or relative analgesia or (anti?anxiety SAME agent*) or nitrous oxide or midazolam or diazepam or chloral hydrate or hydroxyzin* or temazepam or ketamin* or meperidin* or promethazin* or triazolam or trimeprazin* or metaclopramid* or flunitrazepam or sevofluran*)
#3 TS=(general an?esth* or halothan* or sevofluran* or nitrous oxide or isofluran* or enfluran* or ketamin* or midazolam or lorazepam or xenon or sevofluran* or thiopenton* or methohexitol or diazepam or propofol)
#4 TS=(p?ediatric* or child* or infant* or adolescent* or preschool)
#5 #4 AND #3 AND #2 AND #1

Appendix 6. Data extraction form

Sedation versus general anaesthesia for provision of dental treatment in patients younger than 18 years

Data extraction form

Study ID	
First author	
Reviewer ID	
Year of publication	
Title (first 5 words)	
Country of study	

Please complete at end of data extraction:

Possible duplicate report: Yes No
Author contact recommended: Yes No

Verification of study eligibility/category

	Yes	No	Unclear
Children and adolescents up to 18 years old having dental treatment			
Comparison of sedation with GA			
Primary outcome(s) of interest reported			
Study designed as RCT			

Primary outcomes are

- mortality(if any);
- completion of treatment yes/no;
- intraoperative morbidity; and
- postoperative morbidity.

Study eligible? **Yes** **No**
(no to any of above renders study ineligible. Unclear renders study eligible until further clarified)

Comments:

QUALITY Assessment

	Yes	No	Unclear
Sample size calculation reported			
Was method of generation of randomized sequence adequate? (Adequate = generated by random number table, tossed coin and shuffled cards) (Inadequate = alternate assignment, hospital number and odd/even DOB) (Unclear = reference to randomization but method not reported or inadequately explained)			
Was allocation concealment adequate? (Adequate = central registrar, sequentially coded containers, sequentially coded opaque envelopes) (Inadequate = randomization not concealed, e.g. alternate assignment, hosp. no., odd/even DOB) (Unclear = reference to allocation concealment but method not reported or inadequately explained)			
Was the patient blind to the therapy?			
Was the operator blind to the therapy?			
Was the assessor blind to the therapy?			

(*Continued*)

Were Inclusion and exclusion criteria clearly defined in the text?			
Did the text state that no withdrawals occurred?			
Were outcomes of participants who withdrew or were excluded after allocation detailed separately?			
Were outcomes of participants who withdrew or were excluded after allocation included in an intention-to-treat analysis?			
Were treatment and control groups adequately described at entry?			
Treatment and control groups were adequately described at entry			
Use of intention-to-treat analysis stated			

Study characteristics

Country where trial was conducted: ·····

Source of funding: Academic Govt Non-govt Industry Unclear

Year trial conducted: ·····, Unclear

Number of centres in trial: ·····, Unclear

Ethical approval obtained: Yes No

Informed consent obtained Yes No

Population characteristics

Where were participants recruited?

Uni/Hosp GP Practice Paed Speciality Practice Unclear

Number of eligible participants	Number enrolled in study	
Number of males	Number of females	
Mean age (SD)	Age range	
No. of participants in sedation group at baseline	No. of participants in sedation group at trial completion	
No. of participants in GA group at baseline	No. of participants in GA group at trial completion	

Previous dental treatment of patient: Yes No Unclear

Interventions

Intervention	Drugs (specify)	Dose	Duration	Route	Delivered by (dentist/anaesthetist/other)
Sedation group					
GA group					

Sedation

Fasting before procedure: Yes (time)..... No Unclear

Use of restraints during procedure Yes No Unclear

Monitoring used Yes.....

No Unclear

Recovery time .....

Treatment carried out .....

.....

GA

Fasting before procedure: Yes (time)..... No Unclear

Monitoring used Yes.....

No Unclear

Recovery time .....

Treatment carried out .....

Outcomes
What was measured at baseline?

	Yes	No	Result reported	Index used
Anxiety				
Behaviour				

What was measured at final follow-up exam?

	Yes	No	Result reported	Index used
Anxiety				
Behaviour				
Intraoperative morbidity				
Postoperative morbidity				
Completion of treatment				
Satisfaction				
Cost to participant				
Cost of procedure;				
Participant satisfaction				
Parental satisfaction.				

Additional comments
Statistical analysis:
Was the analysis clearly inappropriate? Yes No Unclear

Analysis used

	N=	Outcome data please describe nature of data e. g. mean differences between groups etc. and any assessment of variability (e.g. SD, 95% CI)	P values
Behaviour			
Anxiety			
Treatment completion			
Intraoperative morbidity			
Postoperative morbidity			
Completion of treatment			
Cost to participant			
Cost of procedure			
Participant satisfaction			
Parental satisfaction			

Outcomes (other)

Outcome	N=	Describe results reported or article page on which description can be found for further reference
Length of participant stay		
Length of procedure		
Facilities used		
Materials used		
Equipment used (including monitoring)		
Staff required		

(*Continued*)

Treatment carried out		
Level of consciousness throughout procedure		
Quality of life		
Adverse events		

Additional items

Does anything about this study give the impression that it could be a duplicate report on the same trial? Yes
No

Additional comments about study:

Key to abbreviations
CI: confidence intervals.
DOB: date of birth.
GA: general anaesthetic.
GP: general practitioner.
RCT: randomized controlled trial.
SD: standard deviation.

WHAT'S NEW

Last assessed as up-to-date: 16 July 2015.

Date	Event	Description
28 August 2015	New search has been performed	Search updated to July 2015. No trials eligible for inclusion in this review
28 August 2015	New citation required but conclusions have not changed	No change to conclusions

HISTORY

Protocol first published: Issue 1, 2007

Review first published: Issue 1, 2009

Date	Event	Description
25 September 2012	New citation required but conclusions have not changed	No new or excluded studies. Methods updated to conform to Higgins 2011
25 September 2012	New search has been performed	In previous version of this review (Ashley 2009), databases searched until October 2008. In this updated version, databases searched to July 2012
8 January 2008	Feedback has been incorporated	Substantive amendments made

CONTRIBUTIONS OF AUTHORS

Paul F Ashley (PA), Catherine ECS Williams (CW), David R Moles (DM), Jennifer Parry (JP)

Conceiving the review: PA, CW, JP

Co-ordinating the review: CW

Undertaking manual searches: CW, PA

Screening search results: CW, JP

Organizing retrieval of papers: CW, PA

Screening retrieved papers against inclusion criteria: CW, PA

Appraising quality of papers: CW, PA

Extracting data from papers CW, JP

Writing to authors of papers for additional information: CW, PA

Providing additional data about papers: CW, PA

Obtaining and screening data on unpublished studies: CW

Managing data for the review: CW

Entering data into Review Manager (RevMan 5.3): CW

Analysing RevMan statistical data: CW, DM

Performing other statistical analysis not using RevMan: DM

Performing double entry of data: data entered by person one: CW; data entered by person two: PA

Interpreting data: CW, PA, JP

Making statistical inferences: DM

Writing the review: CW, PA

Securing funding for the review: N/A

Performing previous work that was the foundation of the present study: PA

Serving as guarantor for the review (one review author): CW

Taking responsibility for reading and checking the review before submission: JP

DECLARATIONS OF INTEREST

Paul F Ashley: none known.

Catherine ECS Williams: none known.

David R Moles: none known.

Jennifer Parry: none known.

SOURCES OF SUPPORT

Internal sources

- Eastman Dental Institute, UK.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We made the following changes to the protocol (Williams 2007).

- Added use of GRADE to 'Summary of findings' section in 'Data analysis'.
- Moved intraoperative morbidity from primary outcomes to secondary outcomes.

INDEX TERMS

Medical Subject Headings (MeSH)

Anesthesia, Dental [*methods]; Anesthesia, General [*methods]; Dental Care for Children [*methods]; Hypnotics and Sedatives [*therapeutic use]

MeSH check words

Adolescent; Child; Humans