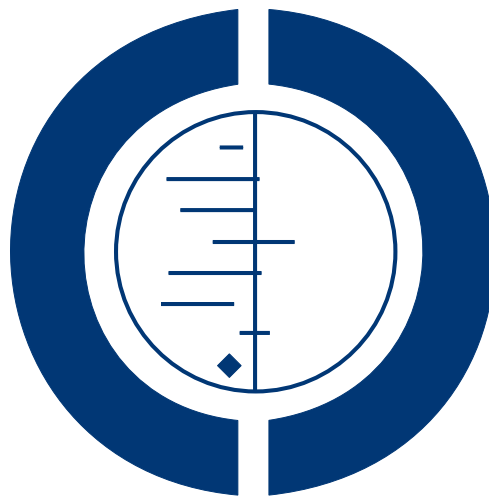


Analgesics for postoperative pain after tonsillectomy and adenoidectomy in children (Protocol)

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[Intervention Protocol]

Analgesics for postoperative pain after tonsillectomy and adenoidectomy in children

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effectiveness of analgesics for management of post-operative pain in children who have undergone a tonsillectomy or adenoidectomy, or both. The questions to be addressed are:

1. What analgesics (or combination of analgesics) are effective for the treatment of post-operative pain in children who have undergone a tonsillectomy or adenoidectomy, or both?
2. What adverse effects, if any, are associated with the use of individual or combined analgesics for treatment of post-operative pain in children who have undergone a tonsillectomy or adenoidectomy, or both?

BACKGROUND

This protocol has been updated from the previously published one (Francis-Baldesari 2007). The update reflects changes in methodology such as the inclusion of the Risk of Bias tool, changes in authorship and the tasks assigned to each author.

Tonsillectomy or adenoidectomy, or both (T&A), are the most common pediatric surgical procedures, with approximately 5,000,000 performed each year worldwide (AAO-HNS 2006). Definitive indications for T&A include swollen tonsils and adenoids accompanied by sleep apnea or failure to thrive, and hemorrhagic tonsillitis, while relative indications are swollen tonsils and adenoids with upper airway obstruction, swallowing difficulties, or speech impairment. Relative indications for adenoidectomy with-

out tonsillectomy include otitis media (earache), previous tonsillectomy without adenoidectomy, and recurrent streptococcal infections (Darrow 2002).

Children report severe pain after T&A - particularly in the first 24 hours post-operatively (Idvall 2005). They also show increased levels of fear and anxiety, avoidance behaviors related to further healthcare, and somatic (other physical) symptoms after an encounter with significant levels of pain (AAP 2001). Additionally, inadequate pain management has been found to increase morbidity and mortality rates in post-operative patients of all ages (EAU 2003).

Clinical practice has not changed significantly, despite the development of reliable pediatric pain measurement scales and the

demonstrated safety and efficacy of numerous analgesics in children (Liozzi 2006). Although morphine is most frequently used to treat post-operative pain in adults, it is less often prescribed for children recovering from surgery (US Dept of VA 2006). Notably, the US Food and Drug Administration has recently identified the use of morphine in the pediatric population as a research priority, highlighting the need for evidence that can guide clinical practice to achieve optimal pain control in children (NIH 2006).

There are a number of barriers, related both to the clinical case and to a lack of high quality evidence in this population, that conspire to prevent adequate pain management in children. Clinicians may lack confidence when it comes to selecting the most appropriate (of the many) pediatric pain measurement scales for their setting (Chambers 1999). Clinicians may also be unaware of evidence supporting the use of opioid and non-opioid analgesics, adjuvant medications, and non-pharmacological interventions (AAP 2001; Liozzi 2006). Research contributing to definitive guidelines on pediatric analgesia is limited (ASA 2004), and the risks of respiratory depression and addiction associated with the use of opioid analgesics have not been fully established in the pediatric population (AAP 2001; Bösenberg 1998). Pre-operative, prophylactic administration of non-steroidal anti-inflammatory drugs (NSAIDs) has been shown to be effective, though it may contribute to erroneous assumptions that standard assessment of post-operative pain, scheduled post-operative administration of analgesics, and monitoring for breakthrough pain after medications have been given are unnecessary (Kokki 2003). Finally, research has shown that pediatric pain measurement is most reliable when self-reported (Chambers 1999). Parents and clinicians consistently under-estimate children's pain levels compared to children's own rating, potentially leading to under-dosing of analgesia (Chambers 1998).

A systematic review of the effects of analgesics for post-operative pain in children who have undergone a T&A will increase awareness and understanding of the factors associated with pediatric pain management, supported by the most recent findings available, to improve pain management in this group of patients.

OBJECTIVES

To assess the effectiveness of analgesics for management of post-operative pain in children who have undergone a tonsillectomy or adenoidectomy, or both. The questions to be addressed are:

1. What analgesics (or combination of analgesics) are effective for the treatment of post-operative pain in children who have undergone a tonsillectomy or adenoidectomy, or both?
2. What adverse effects, if any, are associated with the use of individual or combined analgesics for treatment of post-

operative pain in children who have undergone a tonsillectomy or adenoidectomy, or both?

METHODS

Criteria for considering studies for this review

Types of studies

Double-blind, randomised controlled trials (RCTs) that have been published fully in a journal will be considered for inclusion, but not thus published only as abstracts.

Types of participants

Children aged one to 16 years (inclusive) who have undergone a tonsillectomy or adenoidectomy, or both, in an outpatient or inpatient setting.

Types of interventions

Interventions of interest include any type of analgesics, administered by any route, dosage, and schedule, pre-, peri- or post-operatively for tonsillectomy or adenoidectomy, or both. Specific analgesics, alone or in combination, administered for the control of post-operative pain management will be included. Steroids will not be included in this review as they have been reviewed for participants like these in another Cochrane Review (Steward 2003).

Types of outcome measures

Primary outcomes

Pain intensity and pain relief: as measured by validated paediatric pain scales that may include a Visual Analog Scale (VAS), Faces Pain Scale, Color Analog Scale (CAS), and categorical scales. Ideally, pain will be assessed by patients, but if no other outcome is available, observer assessed pain will be included.

Secondary outcomes

Any reported adverse events. Use of rescue analgesia will be taken as a secondary measure of pain relief.

Search methods for identification of studies

Electronic searches

A search strategy will be developed for use in MEDLINE, and revised appropriately for other databases, in cooperation with the Cochrane Pain, Palliative Care and Supportive Care Cochrane Review Group. The search strategy will combine the subject search with phases 1 and 2 of the Cochrane Sensitive Search Strategy for RCTs as published in Appendix 5c in the Cochrane Handbook (Higgins 2009). The subject search will use a combination of controlled vocabulary and free text terms based on the search strategy for MEDLINE via OVID which can be seen in Appendix 1.

Databases to be searched

- Cochrane Pain, Palliative & Support Care Register (current issue)
- The Cochrane Controlled Trials Register: *The Cochrane Library* (current issue)
 - MEDLINE (1966 to present)
 - EMBASE (1980 to present)
 - CINAHL (1982 to present)
 - BioMed Central Current Controlled Trials (1998 to present)
 - DARE (1994 to present)
 - MEDLINE In-process and other non-indexed citations
 - LILACS (1990 to present)
 - The National Research Register (2000 to present)

Searching other resources

The reference lists of eligible trials and previous systematic reviews generated by the searches outlined above will be reviewed. The search strategy will attempt to identify all relevant studies irrespective of language. Non-English papers will be assessed through selective translation by a native speaker where possible. Translations of full texts will be conducted if deemed necessary.

Data collection and analysis

Selection of studies

Two review authors (DOM, PW) will screen the titles and abstracts of retrieved records to identify records likely to meet the inclusion criteria. Full text copies of records initially deemed eligible for inclusion will be obtained for review. All review authors will assess full text reports and determine inclusion or exclusion of the trials, with group discussion for arbitration and resolution if there is uncertainty or disagreement.

Data extraction and management

Two review authors (of DOM, PW, JC) will independently conduct data extraction using a data extraction form. The third review author will be consulted for resolution if there is disagreement. RevMan will be used for statistical analysis. DOM will enter data into RevMan and this will be checked by the other authors.

Assessment of risk of bias in included studies

Two review authors (DOM, JC) will independently assess the methodological quality of included studies. Another review author (PW) will be consulted for arbitration and resolution if there is uncertainty or disagreement.

The risk of bias in included studies will be assessed as described in Chapter 8 of the Cochrane Handbook (Higgins 2009). The risk of bias data will be presented in tables and figures on the low to high scales as recommended in Cochrane Handbook. The methodology of each trial will be assessed for:

- sequence generation
- allocation concealment
- blinding (of participants and outcome assessors)
- incomplete outcome data (covering drop-outs and ITT analysis)
 - selective reporting of outcomes
 - other possible sources of bias (including baseline differences and trial funding)

Measures of treatment effect

Summary statistics for continuous data will be reported as weighted mean difference or standardized mean difference.

Summary statistics for dichotomous data will be reported as relative risk (RR).

Number needed to treat (NNT) or number needed to harm (NNH) will be calculated.

Dealing with missing data

If more than 20% of the data are data missing from a study, data from that study will be excluded from meta-analysis.

Assessment of heterogeneity

The presence of heterogeneity will be determined with visual examination of forest plot(s) generated from meta-analysis of studies initially considered appropriate for pooling. The degree of statistical heterogeneity will be assessed based on the value of I^2 from meta-analysis and, if present, explanations explored through subgroup or sensitivity analysis (or both), quality control checks of data extraction and data entry, and reviewing of the clinical and methodological aspects of the trials.

Data synthesis

A fixed-effect model will be used for dichotomous data with the assumption that between-trial variance will be minimal. If I^2 is greater than 50% a random-effects model will be used.

A fixed-effect model will also be used for continuous data.

If the studies are sufficiently homogeneous, meta-analysis will be carried out and statistical heterogeneity assessed based on intention to treat data where possible.

Subgroup analysis and investigation of heterogeneity

Sub-group analysis will be conducted if there are considerable differences in effects or class of analgesics, or both; different doses of analgesics; age-related variations of patients; type of surgical procedure (T&A, tonsillectomy, or adenoidectomy); and timing of

medication administration (pre-operative, peri-operative, or post-operatively).

Sensitivity analysis

Sensitivity analysis will only be conducted if appropriate to analyze those studies with adequate allocation concealment.

ACKNOWLEDGEMENTS

Catherine Francis-Baldesari drafted the original protocol and screened the titles and abstracts obtained from the first search. Lisa Horwill assisted with searching for trials .

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Idvall E, Holm C, Runeson I. Pain experiences and non-pharmacological strategies for pain management after tonsillectomy: A qualitative interview study of children and parents. *Journal of Child Health Care* 2005;**9**(3):196–207.

Kokki 2003

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Liossi 2006

Liossi C. Psychological interventions for acute and chronic pain in children. *Pain Clinical Updates* 2006;**14**(4):1–4.

NIH 2006

United States National Institutes of Health, Department of Health and Human Services. List of drugs for which pediatric studies are needed. Federal Register (accessed on 1 December 2006 from www.fda.gov/cder/pediatric/71FR23931.pdf) 2006; Vol. 71, issue 79.

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US Dept of VA 2006

Clinical practice guidelines: management of postoperative pain. United States Department of Veterans Affairs, Office of Quality and Performance (accessed on 11 Dec 2006 from http://www.oqp.med.va.gov/cpg/PAIN/pain_cpg/also1frameset.htm).

References to other published versions of this review

Francis-Baldesari 2007

Francis-Baldesari C, O'Mathúna DP, Horwill L, Wiffen PJ, Conlon JA. Analgesics for postoperative pain after tonsillectomy and adenoidectomy in children. *Cochrane Database of Systematic Reviews* 2007, Issue 3. *Cochrane Database of Systematic Reviews* 2007, Issue 3, Art. No.: CD006630. DOI: 10.1002/14651858.CD006630.

* Indicates the major publication for the study

APPENDICES

Appendix I. MEDLINE search strategy

1. Tonsil/
2. Adenoids/
3. (remov\$ or surg\$ or operat\$)
4. (1 or 2) and 3
5. (tonsillectom\$ or adenoidectom\$)
6. ((tonsil\$ or adenoid\$) adj4 (remov\$ or surg\$ or operat\$))
7. or/4-6
8. Pain, Postoperative/
9. ((postoperative or post-operative) adj3 pain\$)
10. post-operative-pain
11. ((post-surgical or "post surgical" or post-surgery) adj4 pain\$)
12. (((("pain relief after" or "pain following") adj surg\$) or "pain control after")
13. (((post and surg\$) or post-surg\$) and (pain or discomfort))
14. (pain adj4 ("after surg\$" or "after operat\$" or "follow\$ operat\$" or "follow\$ surg\$"))
15. or/8-14
16. 7 and 15

The subject search strategy above should be run with phases 1 and 2 of the Cochrane Sensitive Search Strategy for RCTs as below:

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized controlled trials.sh.
4. random allocation.sh.
5. double blind method.sh.
6. single blind method.sh.
7. or/1-6
8. (ANIMALS not HUMANS).sh.
9. 7 not 8
10. clinical trial.pt.
11. exp clinical trials/

12. (clin\$ adj25 trial\$).ti,ab.
13. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab.
14. placebos.sh.
15. placebo\$.ti,ab.
16. random\$.ti,ab.
17. research design.sh.
18. or/10-17
19. 18 not 8
20. 19 not 9
21. 9 or 19

WHAT'S NEW

Date	Event	Description
21 June 2010	Amended	Protocol amended and authors revised

HISTORY

Protocol first published: Issue 3, 2007

Date	Event	Description
8 September 2008	Amended	Revisions made to facilitate use of protocol in UKCC online training project
1 July 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

DOM: helped draft the original protocol and approved the final protocol; for the full review he will search for trials, screen titles and abstracts of retrieved records, enter citations into RevMan, select which trials to include, assess the risk of bias of included studies, extract data from trials, enter data into RevMan, decide which analyses to conduct, interpret the analysis, draft the final review, and coordinate future updates of the review.

PW: helped draft the original protocol and approved the final protocol; for the full review he will screen titles and abstracts of the retrieved records, extract data from trials, interpret the analysis, and edit the final review.

JC: approved the final protocol; for the full review s he will assess the risk of bias of included studies, extract data from trials, and edit the final review.

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- Dublin City University, Ireland.
- UK Cochrane Centre, UK.

External sources

- No sources of support supplied