Interventions for iatrogenic inferior alveolar nerve injury (Protocol)

Renton T, Coulthard P, Esposito M

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:
To evaluate the efficacy of interventions for iatrogenic inferior alveolar nerve injury.
To assess if there is an optimum timing of intervention for iatrogenic inferior alveolar nerve injury.
To compare the relative efficacy of the interventions (surgical, medical and psychological) for iatrogenic inferior alveolar nerve injury.

BACKGROUND

The inferior alveolar nerve, is a branch of the third division of the trigeminal nerve which supplies sensation to the lower lip, mandibular buccal gingivae (gums on the cheek side of the jaw) and dentition. Injury to the inferior alveolar nerve, resulting from dental treatment, is a relatively common complication and a prevalent medico-legal issue in dentistry. Causes of inferior alveolar nerve injury include dental local anaesthetic injections, implants, endodontic therapy, trauma, ablative and orthognathic surgery. However, the most common cause of inferior alveolar nerve injury is third molar surgery, with a reported incidence of % to 20% temporary (Rood 1990) and 0% to 2% permanent (Black 1997). As a consequence of these injuries and the loss of sensation or pain of the lower lip and mandibular dentition patients commonly complain of functional problems with eating, speaking, pain, altered sensation (spontaneous or evoked (anaesthesia/paraesthesia/dysaesthesia/hyperalgesisa/allodynia)) with resultant reduced quality of life.

The difference with inferior alveolar nerve injuries, compared with other peripheral sensory nerve injuries, is they are predominantly iatrogenic and 90% resolve in the first 8 weeks after injury. They are also closed injuries which delays diagnosis and intervention (Pogrel 2001). The inferior alveolar nerve is contained within a bony canal which predisposes it to compression and as a result ischaemic type injury. Persistence of any peripheral sensory nerve injury depends on the severity of the injury, age of the patient, the time elapsed since the injury and the proximity of the injury to the cell body (the more proximal lesions have a worse prognosis). If the injury persists beyond 6 months it is deemed to be permanent (Rood 1990).

The aim of the assessment of nerve injuries is the diagnosis of sensory impairment and accurate monitoring of sensory and functional recovery. The assessment of the recovery after injury or repair is based on subjective quantitative tests (neuropathic area (area of changed sensation), light touch, two point discrimination, pin prick or noxious heat, brush stroke direction) (Howe 1960; Rood 1990). Many authors have highlighted the particular discrepancy between these subjective quantitative methods (what pressure? how many millimetres?) and the patient's subjective qualitative reports (pain, altered sensation or disability), particularly as the patient's complaints are the driving-force behind the patient seeking further advice or treatment for their injury (Gregg 1990). Although there have been numerous studies evaluating trigeminal neurosensory disturbance due to maxillofacial surgery, there seems to be no consensus as to the ideal choice of methods with which to measure such impairments. Predominantly, inferior alveolar nerve injury studies have concentrated on the evaluation of recovery subsequent to orthognathic surgery rather than the efficacy of nerve repair.

The various surgical techniques that have been used for inferior alveolar nerve repair include: exploration, decompression (or exter-

nal neurolysis), internal neurolysis, excision of neuroma with direct anastimosis, excision of neuroma with nerve grafting (hypoglossal, sural (Eppley 1991), great auricular, long thoracic (Schultes 2000) nerves) and autologous (vein (Pogrel 2001), muscle) or allograft (Gore-Tex (Pitta 2001; Pogrel 1998) or collagen) conduits. The reparative studies illustrate the mean delay from injury to reparative surgery is several months which does not comply with recommendations for other peripheral nerve injury repair (within hours or days) to obtain the optimum outcome measured this delay is high.

At present there are no reports on other interventions including counselling or medical intervention for these injuries.

There appears to be no consensus on the timing of intervention, the type of intervention (surgical, medical or psychological) or the outcome measures for these injuries. Other specialties have derived recommendations for timing of intervention and outcome measures for peripheral nerve repair using either Medical Research Council (MRC) nerve assessment outcomes (Mackinnon 1988) or specific outcome indices (facial nerve, disability arm shoulder hand (DASH)).

OBJECTIVES

To evaluate the efficacy of interventions for iatrogenic inferior alveolar nerve injury.
To assess if there is an optimum timing of intervention for iatrogenic inferior alveolar nerve injury.
To compare the relative efficacy of the interventions (surgical, medical and psychological) for iatrogenic inferior alveolar nerve injury.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

All randomised controlled trials comparing interventions for the repair of inferior alveolar nerve injuries.

Types of participants

Patients with inferior alveolar nerve injury subsequent to surgical intervention.

Types of intervention

Comparison of different interventions (surgical compared with medical or counselling compared with surgical or medical interventions) or an intervention compared with no intervention.

- Surgical - exploration, decompression, neurolysis, repair, anastimosis or grafting.
- Medical - drugs (analgesics, antidepressants, antiepileptic and others) or topical agents (analgesics, capsaicin).
- Psychological (counselling, cognitive behavioural therapy).

Comparison of timing of different interventions (surgical, medical, counselling).

Types of outcome measures

Primary outcome measures

- Pain (continuous and binary)
- Altered sensation (spontaneous or evoked (anaesthesia/paraesthesia/dysaesthesia/hyperalgesia/allodynia]) (continuous and binary)
- Difficulty eating (binary)
- Difficulty speaking (binary)
- Patient satisfaction (continuous)
- Quality of life (continuous).

Secondary outcome measure

- Mechanosensory (pin prick/two point/light touch/pressure thresholds/pain thresholds/thermal thresholds) (continuous and binary)
- Thermosensory (continuous)
- Somatosensory evoked potentials (continuous)
- Nerve conduction tests (continuous)
- Morbidity of donor nerve site, e.g. altered sensation (spontaneous or evoked (anaesthesia/paraesthesia/dysaesthesia/ hyperalgesia/allodynia)) (continuous and binary).

Outcomes will be stratified according to the extent of the neural deficit.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Oral Health Group methods used in reviews.

To identify studies for inclusion or consideration in this review a detailed search strategy will be developed for each database searched. These will be based on the search strategy developed for MEDLINE but revised appropriately for each database. The search strategy will combine a sensitive search strategy for randomised controlled trials (RCTs) revised from phases one and two of the Cochrane Sensitive Search Strategy for RCTs (as published in Appendix 5c in the Cochrane Reviewers' Handbook). The subject search will use a combination of controlled vocabulary and free text terms based on the following search strategy for searching MEDLINE and OVID.

- Inferior alveolar adj dental adj Trigeminal adj nerve$
- inferior alveolar nerve$
- INFERIOR ALVEOLAR NERVE nerve$ (single MeSH term)
- OR/1-3
- (sensory adj disturbance)
- SOMATO SENSORY DISORDERS (single MeSH term)
- HYPOAESTHESIA (single MeSH term)
- PARAESTHESIA (single MeSH term)
- ANAESTHESIA (single MeSH term)
- ALLODYNIA (single MeSH term)
- HYPERALGESIA (single MeSH term)
- OR/5-11
- 4 and 12
- repair$ or surg$ or anastimosis$ or graft$ or decompression$
- NEUROSURGICAL PROCEDURES (single MeSH term)
- neurolysis
- medical$ or analgesic$ or antidepressant$ or antiepileptic$
- OR/14-17
- 13 and 18

Databases searched
Cochrane Oral Health Group Trials Register (most recent)
The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library,* most recent issue)
MEDLINE (1966 to most recent)
EMBASE (1980 to most recent).
The bibliographies of papers and review articles will be checked for studies outside the handsearched journals. Personal references will also searched.

Language
There will be no language restrictions.

Unpublished studies
Authors of RCTs will be identified and personal contacts will be written to in order to obtain further information about the trial and to attempt to identify unpublished or ongoing studies.

Handsearching
Several journals relevant to this review are being handsearched as part of the Oral Health Group's ongoing journal handsearching programme. The list of the dental journals handsearched by the Cochrane Oral Health Group can be found on the following website (http:\\www.cochrane-oral.man.ac.uk). The following journals have been identified as being important to be handsearched for this review: *British Journal of Oral and Maxillofacial Surgery, International Journal of Oral and Maxillofacial Surgery, Journal of the American Dental Association, Journal of Dental Research, Journal of Oral and Maxillofacial Surgery, Oral Surgery Oral Medicine Oral Pathology Oral Radiology and Endondontics, Journal of the American Dental Association, Australian Dental Journal, British Dental Journal, Journal of Orofacial Pain, European Journal of Oral Sciences.*

METHODS OF THE REVIEW

Study selection
The titles and abstracts (when available) of all reports identified through the electronic searches will be scanned independently by two authors. For studies appearing to meet the inclusion criteria, or for which there are insufficient data in the title and abstract to make a clear decision, the full report will be obtained. The full reports obtained from all the electronic and other methods of searching will be assessed in duplicate by two of the three authors to establish whether the studies meet the inclusion criteria or not. Any disagreements will be resolved by discussion. A third author will be consulted if there is unresolved disagreement. All studies meeting the inclusion criteria will undergo a validity assessment and data extraction. Any studies rejected at this or subsequent stages will be recorded in the table of excluded studies, and the reason for exclusion recorded.

Quality assessment
The quality assessment of the included trials will be undertaken independently and in duplicate by the two authors as part of the data extraction process.
Three main quality criteria will be examined.
(1) Allocation concealment, recorded as:
(A) Adequate
(B) Unclear
(C) Inadequate.

(2) Blind outcome assessment, recorded as:
(A) Yes
(B) No
(C) Unclear.

(3) Clear explanation of completeness of follow up by group, recorded as:
(A) Yes, less than or equal to 20% drop out
(B) Yes but more than 21% drop out
(C) No explanation
as described in the Cochrane Reviewers' Handbook.

After taking into account the additional information provided by the authors of the trials, studies will be grouped into the following categories.

(A) Low risk of bias (plausible bias unlikely to seriously alter the results) if all criteria are met.

(B) Moderate risk of bias (plausible bias that raises some doubt about the results) if one or more criteria are partly met.
(C) High risk of bias (plausible bias that seriously weakens confidence in the results) if one or more criteria are not met as described in the Cochrane Reviewers' Handbook.

Further quality assessment will be carried out to assess the definition of exclusion/inclusion criteria, adequate definition of success criteria and comparability of control and treatment groups at entry. The quality assessment criteria will be pilot tested using several articles. The agreement between the quality assesments will be measured using the kappa statistic. We will also note whether or not a priori calculation was undertaken for sample size.

Data extraction
Data will be extracted by two authors in duplicate using specially designed data extraction forms. The data extraction forms will be piloted on several papers and modified as required before use. Any disagreement will be discussed and a third author consulted where necessary. Authors will be contacted for clarification or missing information whenever possible.

For each trial the following data will be recorded.

- Year of publication, country of origin and source of study funding.
- Details of the participants including demographic characteristics, source of recruitment and criteria for inclusion.
- Details on the type of intervention (surgical, medical or psychological)
- Details of the outcomes reported, including method of assessment, and time intervals.

Data synthesis
For dichotomous outcomes, the estimate of effect of an intervention will be expressed as relative risks together with 95% confidence intervals. For continuous outcomes, means and standard deviations will be used to summarise the data for each group using mean differences and 95% confidence intervals (CIs).

Clinical heterogeneity will be assessed by examining the types of participants, interventions for all outcomes in each study. Only if there are studies of similar comparisons reporting the same outcome measures will a meta-analysis be attempted. Relative risks for dichotomous data and mean differences for continuous data will be combined using a random-effects model. The significance of any discrepancies in the estimates of the treatment effects from the different trials will be assessed by means of Cochran's test for heterogeneity and any heterogeneity will be investigated.

Sensitivity analyses will be undertaken to examine the effect of randomisation, allocation concealment, drop outs and blind outcome assessment on the overall estimates of effect for each intervention (surgical, medical or psychological). In addition, the effect of including unpublished literature on the review's findings will be examined.

Where possible, subgroup analyses will be undertaken in respect of the different interventions, the timing of intervention (< 3 months, < = 6 months and > 6months) and experience of surgeon (junior/senior).

AUTHORS' CONCLUSIONS

Implications for practice

There is no evidence to support or refute the usefulness of intervention in treatment of inferior alveolar nerve injury. There is also no evidence to suggest that intervention for inferior alveolar nerve injury is beneficial or harmful. Despite the lack of evidence, we should not abandon the mission of development of early referral criteria from general practitioners to specialist centres. All front-line healthcare staff should be educated and trained in this area to increase awareness and to improve the response in the recognition and provision of support for people with iatrogenic inferiro alveolar nerve injuries.

Implications for research

There is a need for randomised controlled clinical trials to investigate the effectiveness of interventions for iatrogenic inferior alveolar nerve injuries. These trials should be conducted in specialist hospital centres seeing large numbers of patients presenting with inferior alveolar nerve injury. The primary outcome of intervention programs should be a cause of injury, delay to treatment and pre and post operative quantitative sensory testing, pain VAS scores, reported altered sensation and patient centred disability measures. Better partnership between local general practitioners in the primary care setting and secondary specialist health care organisations may be the first crucial step in the development of such trials in this area.

POTENTIAL CONFLICT OF INTEREST

None known.

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Contact address	Dr Tara Renton

Senior Lecturer and Honorary Consultant
Oral and Maxillofacial Surgery
Barts and The London
Queen Mary's School of Medicine and Dentistry
Turner Street
London
E1 2AD
UK
E-mail: rentont@bp.com
Tel: +44 20 377 7000

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