Surgical interventions for the early management of Bell's palsy

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TABLE OF CONTENTS

[Intervention Review]

Surgical interventions for the early management of Bell's palsy

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ABSTRACT

Background

Bell's palsy is an acute paralysis of one side of the face of unknown aetiology. Bell's palsy should only be used as a diagnosis in the absence of all other pathology. As the proposed pathophysiology is swelling and entrapment of the nerve, some surgeons suggest surgical decompression of the nerve as a possible management option.

Objectives

The objective of this review was to assess the effectiveness of surgery in the management of Bell's palsy and to compare this to outcomes of medical management.

Search methods

We searched the Cochrane Neuromuscular Disease Group Specialized Register (23 November 2010). We also searched the Cochrane Central Register of Controlled Trials (CENTRAL) (23 November in *The Cochrane Library*, Issue 4 2010). We adapted this strategy to search MEDLINE (January 1966 to November 2010) and EMBASE (January 1980 to November 2010).

Selection criteria

We included all randomised or quasi-randomised controlled trials involving any surgical intervention for Bell's palsy.

Data collection and analysis

Two review authors independently assessed whether trials identified from the search strategy were eligible for inclusion. Two review authors assessed trial quality and extracted data independently.

Main results

Two trials with a total of 69 participants met the inclusion criteria. The first study considered the treatment of 403 patients but only included 44 in their surgical study. These were randomised into a surgical and non surgical group. The second study had 25 participants which they randomly allocated into surgical or control groups.

The nerves of all the surgical group participants in both studies were decompressed using a retroauricular approach. The primary outcome was recovery of facial palsy at 12 months. The first study showed that both the operated and non operated groups had comparable facial nerve recovery at nine months. This study did not statistically compare the groups but the scores and size of the

groups suggested that statistically significant differences are unlikely. The second study reported no statistically significant differences between their operated and control groups. One operated patient in the first study had 20 dB sensorineural hearing loss and persistent vertigo.

Authors' conclusions

There is only very low quality evidence from randomised controlled trials and this is insufficient to decide whether surgical intervention is beneficial or harmful in the management of Bell's palsy.

Further research into the role of surgical intervention is unlikely to be performed because spontaneous recovery occurs in most cases.

PLAIN LANGUAGE SUMMARY

Surgical operation for idiopathic facial paralysis

There is insufficient evidence to support surgical operation for the management of Bell's palsy.

Bell's palsy is a paralysis of the muscles of the face, usually on one side, that has no known cause. People generally recover but there is a small group who do not recover. It is thought to be caused by swelling and entrapment of the nerve. Some surgeons thought that an operation to release the nerve may improve recovery.

Two studies were included in our review. They compared surgery with non-surgical management of 69 participants with Bell's palsy in total. The first study did not state how the participants were randomly allocated into surgical and non-surgical groups. The second study allocated their participants randomly using statistical charts into surgical and control groups (no treatment). There was no attempt in either study to hide which groups patients were being allocated into and both patients and assessors were aware of the management plan proposed. The first study lost seven participants to follow-up and there were no losses to follow-up in the second study.

The most important outcome was recovery of facial palsy at 12 months. The first study showed that the operated and non operated groups both had comparable facial nerve recovery at nine months. The second study reported no differences in recovery of the facial palsy between their operated and control groups at one year. One patient operated on in the first study had mild hearing loss and vertigo after the surgery.

The review found that there was only very low quality evidence and that this was insufficient to decide whether an operation would be beneficial or harmful in the management of Bell's palsy.

Further research into the role of an operation is unlikely to be performed because spontaneous recovery occurs in most cases.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Surgery for Bell's palsy

Patient or population: Bell's palsy
Settings: Hospital attendance with idiopathic facial paralysis
Intervention: Surgery

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Control	Corresponding risk Surgery				
Recovery of facial nerve function at 12 months Follow-up: 12 months	See comment	See comment	Not estimable	69 (2 studies)	⊕◯◯◯ **very low**[1,2]	One study did not perform statistical analysis, one did not state the method used. Different outcome measures in each study made combining results impractical
Side effects and complications of treatment clinical assessment Follow-up: 12 months	See comment	See comment	Not estimable	69 (2 studies)	⊕◯◯◯ **very low**[1]	The numbers involved in the included studies were small and statistical analysis was not possible

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Limitations in study design: in one study the method of randomisation was not described. There were small numbers in both studies and large numbers were not followed up in one study. One study followed patients up to 9 months not 12 months. In both studies there was unclear allocation concealment and outcome assessors were not blinded.

[2] No evidence of publication bias for this outcome.

BACKGROUND

Bell's palsy is an acute paralysis of one side of the face due to a lesion of the facial nerve first described by Sir Charles Bell, a Scottish surgeon (1774 to 1842). Its cause is not known and it should only be used as a diagnosis in the absence of any other pathology. It was proposed in 1919 (Antoni 1919) that the underlying pathology was that of a viral neuropathy. Herpes simplex virus has been suggested as the likely pathogen (McCormick 1972) and animal studies have suggested that reactivation of the virus may lead to demyelination of the nerve leading to reduced function (Adour 1975, Stjernquist 2006).

The condition affects 25 to 35 people per 100,000 of the population per year and is most common in the 30 to 45 year age group. It is also more common in pregnant women, people with diabetes or people with a respiratory tract infection (Theil 2001). Recovery in most patients can be expected to be good. It has been shown in a large review (Peitersen 2002) that over 70% of patients will have normal function restored and of the remainder 25% will have slight or mild sequelae and only 4% will have severe sequelae. Contractures, facial disfigurement, with associated psychological difficulties, and facial pain (Morgenlander 1990) remain the most common long-term problems.

A number of studies have looked into identifying which population might benefit most from surgery. In addition to simple clinical assessment of disease using the House-Brackmann scale or similar, many studies have tried to assess the electrical function of the facial nerve. Electroneurography (ENOG) has been the most popular technique employed (Esslen 1977; Fisch 1984). In this the degree of muscle response to an electrically evoked stimulus is assessed. It was shown (Esslen 1977; Fisch 1984) that when 95% of the nerve had degenerated the patient had a 50% chance of a poor outcome (less than 50% chance of recovery to House-Brackmann grade 1 or 2) and would potentially benefit from surgical intervention (Sillman 1992).

Although it is a common condition, in the absence of an established aetiology, treatment continues to be based upon the presumed pathophysiology of swelling and entrapment of the nerve. Recent double blind randomised controlled studies have shown that early treatment with prednisolone but not aciclovir significantly improves the chances of complete recovery to 94% at 9 months (Sullivan 2007; Engstrom 2008). Recent Cochrane reviews on the use of corticosteroids (Salinas 2010) and antivirals (Lockhart 2009) in Bell's palsy are consistent with these findings.

As the proposed pathophysiology involves entrapment of the nerve, this has led some surgeons to suggest that surgical decompression of the nerve is a suitable management option. The first recorded attempt at surgical decompression of the facial nerve for Bell's palsy was in 1932 (Ballance 1932). Ballance 1932 recommended slitting the sheath in the distal descending segment of the nerve. This was consistent with theories of the site of the lesion at that time. Over the next few decades the proposed site for operation has migrated from the distal 1 cm at the stylomastoid foramen (Ballance 1932) to the entrance of the fallopian canal medially (Fisch 1972). The timing also varied from three months to immediately on onset (May 1972). In the early 1970s it was proposed that the most likely site of compression was at the entrance to the fallopian canal (Fisch 1972). Intraoperative evoked electromyography (EMG) and an oedematous swelling at this point proximal to the geniculate ganglion was noted in up to 94% of their patients. In this study transmastoid/middle cranial fossa approaches were used to allow decompression of the nerve and geniculate ganglion. Other studies (May 1984) suggested that a transmastoid approach to decompression of the labyrinthine segment was of benefit. Two further studies published around the same time gave evidence both for (Giancarlo 1970) and against (McNeill 1974) operation. Because of the good outcome of the condition without treatment and with medical management and also the potential for damage to the facial nerve and other ear structures during surgery, there has been a continued debate as to whether surgery has a role in the management of Bell's palsy (Adour 2002; Friedman 2000).

Despite the debate on different surgical approaches there is a paucity of high quality evidence regarding facial nerve decompression surgery for acute Bell's palsy. Few large studies have been carried out. Of these one study (May 1985) convinced many surgeons that surgery did not have a place in the management of Bell's palsy. More recently (Gantz 1999) found that when selected using ENOG, those patients who would have had a bad outcome as predicted by ENOG had a better outcome if surgically managed compared with those who were not. Currently most patients are managed medically with corticosteroids with or without aciclovir as discussed above. Surgery, certainly in the UK, is rarely undertaken (Sullivan 2007).

OBJECTIVES

This review aims to determine the evidence for surgery in the management of Bell's palsy and the effectiveness of surgery compared with outcomes of medical management.

METHODS

Criteria for considering studies for this review

Types of studies

We assessed randomised and quasi-randomised controlled trials in the main review. Other studies, including observational studies are included in the Discussion section of the final review.

Types of participants

We included any participant (adult or child) who presented with an idiopathic facial palsy which was diagnosed as Bell's palsy. Those who were diagnosed as having herpes zoster, who had a traumatic aetiology or other identified aetiology were excluded from the review. This included any cases of recurrent and familial Bell's palsy or Melkerson-Rosenthal syndrome.

Types of interventions

We included any surgical intervention carried out for Bell's palsy. The outcomes and evidence for different surgical interventions were considered. Any concurrent medical management was assessed.

Types of outcome measures

Primary outcomes

The primary outcome measure was the degree of recovery of facial nerve function and resolution of symptoms at 12 months as measured using the House-Brackmann scale, the Sunnybrook scale, the Yanigahara scale or other similar scale.

Secondary outcomes

Secondary outcome measures were:
1. Complete recovery at three and six months.
2. Synkinesis and contracture at 12 months.
3. Psychosocial outcomes at 12 months.
4. Side effects and complications of treatment.

We selected recovery of facial nerve function at 12 months and side effects and complications of treatment for inclusion in a 'Summary of findings for the main comparison' table.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Neuromuscular Disease Group Specialized Register (23 November 2010) using the following search terms 'Bell's palsy' 'facial palsy' or 'idiopathic facial paralysis'. We also searched the Cochrane Central Register of Controlled Trials (CENTRAL) (23 November 2010 in *The Cochrane Library*, Issue 4 2010). We adapted this strategy to search MEDLINE (January 1966 to November 2010) and EMBASE (January 1980 to November 2010).

The following phrases, adapted to each database as appropriate, were used:

#1 (Bell's palsy) OR (Bell palsy) OR (idiopathic facial paralysis) OR (facial paralysis) OR (facial palsy) OR (facial nerve)

AND

#2 (surgery) OR (surg*) OR (operative) OR (operat*) OR (decompression) OR (decompres*).

See Appendix 1, Appendix 2 and Appendix 3 for the search strategies.

Searching other resources

1. We reviewed the bibliographies of all trials identified.
2. We performed a search for conferences regarding latest research in this area.

Data collection and analysis

Selection of studies

Two review authors (Walker, McAllister) reviewed titles and abstracts identified by the search strategy. The review authors obtained full text for all relevant studies and assessed them independently. Two review authors (Walker, McAllister) assessed whether each trial met the inclusion criteria. Disagreement between the review authors was resolved by discussion with the lead author (Swan) where required.

Data extraction and management

The data extracted included study participants, methods, interventions used, outcomes along with 95% confidence intervals and results. The main outcome measure was degree of recovery of facial function and residual disability. Two authors extracted the data independently and entered them onto a specifically designed form.

Risk of bias

Two review authors independently assessed risk of bias using the Cochrane Collaboration's risk of bias tool, described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2008). Six risk of bias domains were addressed: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and 'other sources of bias'. We judged the adequacy of each study in relation to each domain, where 'Yes' indicated a low risk of bias, 'No' a high risk of bias and 'Unclear' an unclear or unknown risk of bias. Disagreement between the review authors was resolved by discussion with the lead author (Swan) where required.

Measures of treatment effect

There were insufficient studies to enable any statistical analysis. If in future updates statistical analysis is possible we will enter data into the Review Manager (RevMan 2008) software and analyse it using the standard statistical methods. For continuously measured

outcomes we will use means to obtain mean differences (MDs) with 95% confidence intervals (CI), for dichotomous outcome data we will estimate the pooled relative risk with 95 % CI from study log relative risks. We will calculate the number needed to treat (NNT) if possible. We will combine observational relative risks if little trial evidence is found.

Assessment of heterogeneity

There were insufficient studies to enable any statistical analysis. Had there been sufficient studies, we would have performed a Chi^2 test for homogeneity. If significant heterogeneity had been found, we would have tried to find the cause of this based on the characteristics of the studies included.

Assessment of reporting biases

There were insufficient studies to enable any statistical analysis. Had trials been available we would have assessed publication bias using a funnel plot.

Data synthesis

There were insufficient studies to enable any statistical analysis. If studies become available, initially, we will use a fixed-effect model and carry out the test for heterogeneity. Random-effects models such as DerSimonian and Laird account for more uncertainty and we will also utilise these, especially if there is heterogeneity (DerSimonian 1986).

Subgroup analysis and investigation of heterogeneity

There were insufficient studies and small data sets to enable statistical analysis. If it becomes possible in the future, we will perform a sensitivity analysis omitting studies of lower methodological quality. In addition, quality could be incorporated into mixed models simultaneously allowing for differences in quality using Bayesian methods, utilised in WinBUGS (Spiegelhalter 2000).

Economic issues

There was insufficient information in the included studies to discuss economic issues.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

The numbers of papers found by the current strategies were MEDLINE = 416, EMBASE = 308, NMD REGISTER = 5, CENTRAL = 45.

After screening of the results by two authors 67 papers were declared potentially eligible. 11 papers were then shortlisted but nine were subsequently excluded. Two trials met the inclusion criteria (Adour 1971; Mechelse 1971).

Adour 1971 considered the treatment of 403 patients but only included 44 in their surgical study. These were randomised into a surgical and non-surgical group. However, the non-surgical control group also contained those who refused surgery. Inclusion in the Adour 1971 study was based upon an extensive clinical examination which they report took around two hours for the initial assessment. Clinically this involved a neurological examination, an ear, nose and throat (ENT) examination, X-rays of the mastoid and chest, audiogram and a group of blood tests including full blood count, erythrocyte sedimentation rate (ESR) and glucose. More specifically for the facial nerve function they carried out serial 4 point nerve excitability tests and electromyography and nerve conduction studies. Patients were included in the study if they fitted all of the following criteria: a clinically complete facial nerve palsy, no contraindication to general anaesthesia and an increasing nerve excitability shown by a difference between the affected and unaffected sides. They excluded any participant that did not fit all three inclusion criteria. In addition, participants with facial paralysis thought to be of any cause other than Bell's palsy were excluded. The mechanism of randomisation was not stated. Three groups were selected: no surgery, surgery within 48 hours of onset of denervation, surgery 8 to 12 weeks after onset of denervation. Some patients declined surgery and were added to the non-surgical group. Other than the numbers no differences between the groups were stated.

In Mechelse 1971 25 participants were randomly allocated into surgical or control groups. Mechelse 1971 used similar initial assessments. Participants were selected on the basis of a complete facial palsy and electromyography showing no voluntary control of motor unit or a minimal applied current evoking a motor response on the affected side being 2.5 times that on the unaffected side. These responses needed to be confirmed on two occasions a few days apart. They excluded participants with signs or symptoms suggestive of another cause for their facial paralysis other than Bell's palsy, those with incomplete facial paralysis, those with an abnormality on ENT examination, skull X-ray or blood and urine tests. They randomised their patients using statistical charts prepared by a local statistics department. One participant declined surgery and was removed from the study. This study reports the age and sex of the participant and side affected but did not report if there were statistically significant differences between the two groups. See Characteristics of included studies.

Outcome Criteria

Adour 1971 used the Facial Paralysis Recovery Profile (FPRP)

and the Facial Paralysis Recovery Index (FPRI) to measure their outcomes. This was developed by the authors for this study and used by them for other subsequent studies. The FPRP score ranges from +2 for no recovery +10 for complete recovery. The FPRI score ranges from -12 to +10 (FPRI is the FPRP score minus points for complications, +10 represents complete recovery without any complications). This study did not stipulate what score on their clinical scale constituted a satisfactory recovery.
Mechelse 1971 used a scale of 0 to 5 to assess outcome (0 no function, 5 complete function). They did not stipulate what value on their clinical scale would represent a satisfactory recovery.
Both studies predate the House-Brackmann scale and it was not used in either study.

Operative Procedure

The participants in the surgical groups of both studies had facial nerve decompression using a retroauricular approach.

Excluded studies

Several studies were excluded on the basis of the selection of their control groups. Giancarlo 1970; Fisch 1981; Brown 1982; May 1984; Aoyagi 1988; Gantz 1999; McNeill 1974 and Yanagihara 2001 all had control groups which were self selected in that they were offered surgery and refused. By virtue of this they became the control groups for these studies. These studies did not therefore meet our inclusion criterion of a randomly selected control group. We did not feel therefore that comparisons made between the operated group of patients and the controls were valid as the reasons the patients refused surgery may have been relevant to their outcomes. For example in Yanagihara 2001 younger patients opted for surgery whereas older patients declined. See Characteristics of excluded studies.

Risk of bias in included studies

Allocation

In the Adour 1971 study the method of randomisation used was not described. Some patients who declined surgery were added to the non surgical group. Quote: "the attempt at randomisation into equal groups was made. Completely random distribution could not be effected because some patients and some patients' physicians, refused surgical intervention."
In the Mechelse 1971 study 25 participants were randomly allocated into surgical or control groups. It was stated that one more participant was allocated to the control group and one participant declined surgery and was removed from the study. Quote: "in both hospitals these patients were entered on a list, previously prepared by the statistical department, University of Leiden (head, Mr H. De Jonge), which randomly allocated them to surgical treatment or to a control group"

Allocation concealment

In both studies there was no mention of any attempted method of allocation concealment.

Blinding

In both studies blinding of the patient to either a surgical and non-surgical intervention was not possible. Also blinding of the investigator or outcome assessor was not commented on in either study and would have been difficult to perform because of the surgical intervention involved.

Incomplete outcome data

Adour 1971 lost six out of their control group to follow-up (from 21) and one from their operated group (from 23). No comment was made on reasons for loss to follow-up prior to the nine months aimed for.
Mechelse 1971 claim to have followed all their patients for one year with no losses. Quote: "All patients were followed clinically and electromyographically for a least a year"

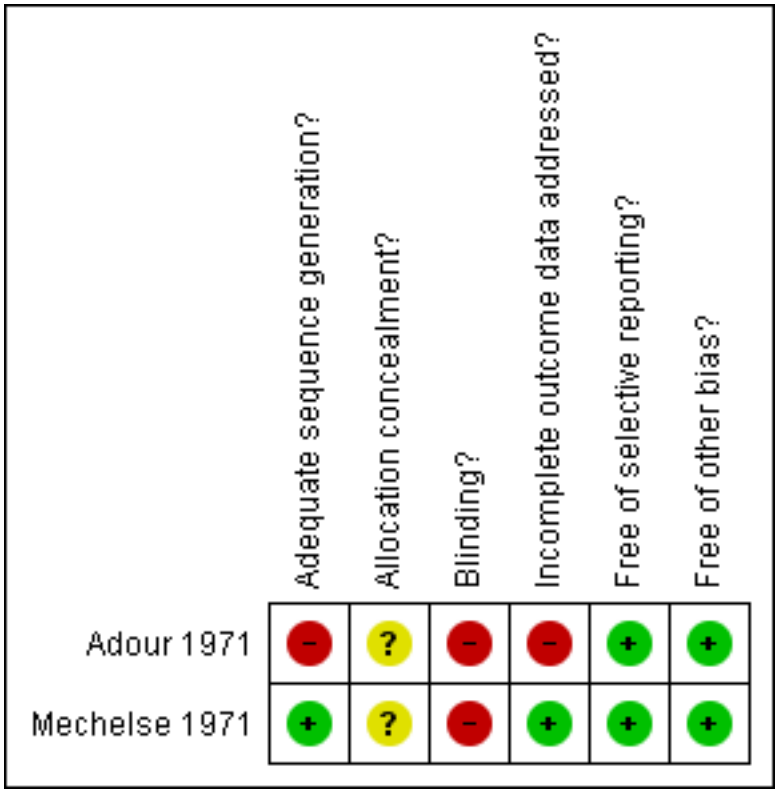
Selective reporting

No statistical analysis was reported by Adour 1971 for their data but all pre-specified outcomes were reported on.
Mechelse 1971 did report statistical comparison between the groups but did not report the statistical methods used. All pre-specified outcomes were reported on in this study.

Other potential sources of bias

Both studies appears to be free of other sources of bias.
Review authors' judgements about each risk of bias item for each included study are summarised in Figure 1.

Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Effects of interventions

See: **Summary of findings for the main comparison** Surgery for Bell's palsy

Primary outcome measure

Adour 1971 concluded that early or late surgical decompression of the facial nerve was not of benefit to patients with Bell's palsy who have evidence of impending or actual denervation. They used the FPRP and FPRI scores to assess degree of recovery of facial nerve function and resolution of symptoms at 9 months. They reported that the 21 patients not operated on had average outcome scores of +6 FPRP and +4 FPRI at nine months. The 10 participants operated on within 48 hours had average scores of +5 FPRP and +3 FPRI and the 13 operated on longer than eight weeks post onset of denervation had average scores of +5 FPRP and +2 FPRI. They do not statistically compare the groups but the scores given and size of the groups suggest statistically significant differences are unlikely.

Mechelse 1971 concluded that facial nerve decompression in the second or third week after the onset of paralysis did not increase the degree of recovery in participants with Bell's palsy. They reported that 11 patients were randomised to the operated group and 13 to the control group. They used a scale of 0 to 5 to assess outcome (0 no function, 5 complete function). Participants ranged in recovery from 2 to 5 on their scale and they reported no statistically significant differences between the surgical and non-surgical groups (P = 0.9).

Both studies predate the House-Brackmann scale and it was not used in either study.

Secondary outcome measures

1.Complete recovery at three and six months

Adour 1971 documents levels of recovery at three and six months but no statistical comparison was made.

In the Mechelse 1971 study EMG follow-up showed that onset of recovery did not occur before the third month in both the surgical and non-surgical group. Facial nerve outcome scores were not documented for three and six months.

2. Synkinesis and contracture at 12 months.

Adour 1971 lists individually the synkinesis and other clinical features but do not compare the different study groups. They found that almost all participants with evidence of denervation on nerve excitability testing had contracture and synkinesis by nine months.
In the Mechelse 1971 study synkinesis and contractures were seen equally in the control and operated groups.

3. Psychosocial outcomes at 12 months.

There was no mention of psychosocial outcomes in either study.

4. Side effects and complications of treatment

One patient in the Adour 1971 study had 20 dB sensorineural hearing loss and persistent vertigo. Tympanotomy showed injury to footplate and fibrous overgrowth. Removal of the overgrowth resulted in normal hearing and no further vertigo.
In the Mechelse 1971 study no complications of surgery, such as wound dehiscence, infection, bleeding and numbness were reported.

DISCUSSION

The evidence from the randomised controlled trials included in our study does not support surgical intervention for Bell's palsy. The two trials included had relatively small numbers, 44 in the Adour 1971 and 25 in the Mechelse 1971 trial. Considered individually the trials have too few participants to give sufficient statistical power to detect the magnitude of effect that might plausibly be expected. Both stated that the patients were randomised into surgical and non-surgical (control) groups. However, the methods of randomisation were not clearly stated in either. Therefore we cannot exclude the possibility of bias. In both studies there was unclear allocation concealment and outcome assessors were not blinded. Each study had similar inclusion criteria and only included patients with complete facial paralysis. The systems used in both studies to assess facial nerve function are less widely used in the assessment of Bell's palsy than the House-Brackmann facial nerve grading system. There were different assessment systems used in each trial with no stipulated score that constituted recovery. These factors made combining the results for statistical analysis impractical (see Summary of findings for the main comparison).

The results from the Mechelse trial did not show any statistically significant difference between the surgical intervention and control groups. No statistical analysis was conducted in the Adour trial but the scores given and size of the groups suggest statistically significant differences were unlikely. Observational studies have shown contrasting results after surgical decompression of the facial nerve for Bell's palsy. Some studies showed statistically significant improvement in facial nerve function in the surgical groups compared to control groups (Giancarlo 1970; Fisch 1981 and Gantz 1999). The studies mentioned all involved surgery on patients with complete facial paralysis and indicators of poor prognostic outcome but the numbers involved in each study were low. In contrast, other studies were unable to show any statistically significant differences between surgical and control groups (McNeill 1974; May 1984; Aoyagi 1988).

With regard to complications of surgery, one of the included studies reported that one patient developed 20 dB sensorineural hearing loss and persistent vertigo. The included studies did not report any other complications of surgery. Only a few observational studies have commented on postoperative complications after decompression of the facial nerve. In one study, one of 13 operated cases developed a 40dB hearing loss at 8 KHz (Fisch 1981). In another, six out of 19 participants who had surgical decompression had significant hearing losses postoperatively (McNeill 1974).

The natural history of Bell's palsy is spontaneous recovery in the majority of cases and this review did not find any evidence to support surgical intervention in this condition.

AUTHORS' CONCLUSIONS

Implications for practice

There is only very low quality evidence from randomised controlled trials and this is insufficient to decide whether surgical intervention is beneficial or harmful in the management of Bell's palsy.

Implications for research

Further research into the role of surgical intervention is unlikely to be performed because spontaneous recovery occurs in most cases.

ACKNOWLEDGEMENTS

None

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Adour 1971

Methods	Considered the treatment of 403 patients but only included 44 in their surgical study. Inclusion was based upon an extensive clinical examination. They were randomised into a surgical and non-surgical group The method of randomisation was not stated. Three groups were selected: no surgery, surgery within 48 hours of onset of denervation, surgery 8 to 12 weeks after onset of denervation. Some patients declined surgery and were added to the nonsurgical group
Participants	Patients had to fit three criteria: a clinically complete nerve palsy, no contraindication to general anaesthesia and an increased nerve excitability shown by a difference between the affected and unaffected sides
Interventions	All the patients in the operative group were decompressed using a retro-auricular approach. The non-surgical group were treated with prednisolone beginning with a dose of 40 mg and tapering to 5 mg at the end of eight days
Outcomes	Adour and Swanson used the Facial Paralysis Recovery Profile (FPRP) and the Facial Paralysis Recovery Index (FPRI) to measure their outcomes. The scales were developed by the authors for this study and used for their subsequent studies.The FPRP score ranges from +2 for no recovery to +10 for complete recovery. The FPRI score ranges from -12 to +10 (the FPRP score minus points for complications) The21 participants not operated on had average scores of +6 FPRP and +4 FPRI at 9 months. The 10 participants operated on within 48 hours of the onset of denervation had average scores of +5 FPRP and +3 FPRI and the 13 operated on >8 weeks post onset of denervation had average scores of +5 FPRP and +2 FPRI at 9 months. They do not statistically compare the groups but the scores given and size of the groups suggest statistically significant differences are unlikely Adour and Swanson list individually synkinesis and other clinical features but do not compare the different study groups
Notes	One patient had 20 dB sensorineural hearing loss and persistent vertigo. Tympanotomy showed injury to footplate and fibrous overgrowth. Removal of the overgrowth resulted in normal hearing and no further vertigo. No other complications of surgery, such as wound dehiscence, infection, bleeding and numbness were reported Follow-up: lost six out of their control group to follow-up (from 21) and 1 from their operated group (from 23). No comment was made on reasons for loss to follow-up prior to the nine months aimed for

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	High risk	Quote: "the attempt at randomisation into equal groups was made. Completely random distribution could not be effected

Adour 1971 (*Continued*)

		because some patients and some patients' physicians, refused surgical intervention." Comment: The method of randomisation used was not described. Some patients who declined surgery were added to the non surgical group
Allocation concealment?	Unclear risk	There was no mention of any attempted method of allocation concealment
Blinding? All outcomes	High risk	Blinding of the patient to either a surgical and non-surgical intervention was not possible. Blinding of the investigator/outcome assessor was not commented on and would have been difficult to perform in this study because of the surgical intervention involved
Incomplete outcome data addressed? All outcomes	High risk	Quote: "one patient was lost to follow-up" Comment: one patient in the operated group was lost to follow-up and was commented on. However, six patients out of the control group (from 21) were lost to follow-up at the 9 month assessment and other omissions in data are not mentioned in the text
Free of selective reporting?	Low risk	All pre-specified outcomes were reported on
Free of other bias?	Low risk	Appears to be free of other sources of bias

Mechelse 1971

Methods	25 patients were randomly allocated into surgical or control groups. Mechelse et al randomised their patients using statistical charts prepared by a local statistics department. One participant declined surgery and was removed from the study. Mechelse et al reported that the 11 patients were randomised to the operated group and 13 to the control group
Participants	Patients were selected on the basis of a complete facial palsy and electromyography showing no voluntary control of motor unit or a minimal applied current evoking a motor response on the affected side 2.5 times that of the unaffected side. These responses needed to be confirmed on two occasions a few days apart This study reports the age and sex of the participants and side affected but did not report if there were statistically significant differences between the two groups
Interventions	All the participants in the surgical group were decompressed using a retro-auricular approach

Mechelse 1971 (*Continued*)

Outcomes	Mechelse et al used a scale of 0 to 5 to assess outcome (0 no function, 5 complete function) Patients ranged in recovery from 2 to 5 on their scale and they report no statistically significant differences between the groups (P = 0.9) Mechelse et al did not report the statistical methods used
Notes	No general complications of surgery, such as wound dehiscence, infection, bleeding, numbness, were reported Follow up: Mechelse et al claim to have followed all their patients for one year with no participants lost to follow-up

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Low risk	Quote: "in both hospitals these patients were entered on a list, previously prepared by the statistical department, University of Leiden (head, Mr H. De Jonge), which randomly allocated them to surgical treatment or to a control group" Comment: 25 patients were randomly allocated into surgical or control groups as stated above. It is stated that one patient declined surgery and was removed from the study
Allocation concealment?	Unclear risk	There is no comment on any attempted method of allocation concealment
Blinding? All outcomes	High risk	Blinding of the patient to either a surgical and non-surgical intervention was not possible. Blinding of the investigator/outcome assessor was not commented on and would have been difficult to perform in this study because of the surgical intervention involved
Incomplete outcome data addressed? All outcomes	Low risk	Quote: "All patients were followed clinically and electromyographically for a least a year" Comment: complete follow-up with no losses
Free of selective reporting?	Low risk	All pre-specified outcomes were reported on
Free of other bias?	Low risk	Appears to be free of other sources of bias

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

Study	Reason for exclusion
Aoyagi 1988	No randomisation of the included participants into surgical or non-surgical groups
Brown 1982	Retrospective audit. Does not compare outcomes between the groups and does not describe how surgery or not surgery groups were selected
Fisch 1981	Retrospective study. No description is given as to how the surgically treated or not surgically treated groups were arrived at. No discussion about the group not operated on. Only 14 patients operated on
Gantz 1999	No randomisation. Participants self selected to have surgery or not. 11 out of 30 patients offered surgery declined therefore only 19 out of 169 evaluated had surgery
Giancarlo 1970	No randomisation. Participants self selected to have surgery or not. Also did not describe the degree of palsy clinically at the beginning, merely that nerve was degenerating
May 1984	Prospective audit. No attempt at randomisation. Control group either self selected, considered poor surgical risk or had already had corticosteroids. 50 participants were operated on with a control group of 35. However statistical comparison was performed on only the poorest prognostic groups of 25 surgical and 13 non-surgical participants which showed no statistically significant difference
McNeill 1974	Retrospective audit. Participants self selected to have surgery or not. Control group either declined surgery or were considered poor surgical risk
Yanagihara 2001	Participants had trial of corticosteroids initially before being considered for surgery. There was no randomisation. Participants self selected whether to have surgery or not. It notes that younger patients went for surgery and older patients refused surgery

DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix 1. MEDLINE (OvidSP) search strategy

1 randomized controlled trial.pt.
2 controlled clinical trial.pt.
3 randomized.ab.
4 placebo.ab.
5 drug therapy.fs.
6 randomly.ab.
7 trial.ab.
8 groups.ab.
9 or/1-8
10 exp animals/ not humans.sh.
11 9 not 10
12 bell palsy/ or facial paralysis/ or hemifacial spasm/
13 ((bell$ or facial or hemifacial$) adj3 (pals$ or paralys$ or paresi$ or spasm$)).mp.
14 12 or 13
15 surgery/ or (surg$ or operat$ or decompres$).mp.
16 14 and 15
17 bell palsy/su or facial paralysis/su or hemifacial spasm/su
18 16 or 17
19 11 and 18

Appendix 2. EMBASE (OvidSP) search strategy

1 crossover-procedure/
2 double-blind procedure/
3 randomized controlled trial/
4 single-blind procedure/
5 (random$ or factorial$ or crossover$ or cross over$ or cross-over$ or placebo$ or (doubl$ adj blind$) or (singl$ adj blind$) or assign$ or allocat$ or volunteer$).tw.
6 clinical trial/
7 or/1-6
8 animal/ not human/
9 7 not 8
10 Bell Palsy/
11 Facial Nerve Paralysis/
12 HEMIFACIAL SPASM/
13 ((bell$ or facial or hemifacial$) adj3 (pals$ or paralys$ or paresi$ or spasm$)).mp.
14 or/10-13
15 surgery/ or (surg$ or operat$ or decompres$).mp.
16 14 and 15
17 Bell Palsy/su or Facial Nerve Paralysis/su or HEMIFACIAL SPASM/su
18 16 or 17 (6044)

19 9 and 18

Appendix 3. CENTRAL search strategy

#1MeSH descriptor Bell Palsy, this term only with qualifier: SU
#2MeSH descriptor Facial Paralysis, this term only with qualifier: SU
#3MeSH descriptor Hemifacial Spasm, this term only with qualifier: SU
#4(bell NEAR/2 palsy or facial NEAR/2 palsy or facial NEAR/2 paralysis or facial NEAR/2 paresis)
#5hemifacial NEAR/2 palsy OR hemifacial NEAR/2 paralysis OR hemifacial NEAR/2 paresis
#6facial NEAR/2 palsy or facial NEAR/2 paralysis or facial NEAR/2 paresis
#7(#4 OR #5 OR #6)
#8surg* or operati* or decompressi*
#9(#7 AND #8)
#10(#1 OR #2 OR #3 OR #9)

HISTORY

Protocol first published: Issue 4, 2008

Review first published: Issue 2, 2011

CONTRIBUTIONS OF AUTHORS

Miss K McAllister devised the search strategy, designed the protocol, assessed study quality, undertook data collection and analysis and wrote the review.

Mr D Walker devised the search strategy, designed the protocol, assessed study quality, undertook data collection and analysis and wrote the review.

Mr P Donnan provided statistical knowledge and expertise required for the protocol and review.

Mr I Swan suggested the review and supervised the writing of the protocol and the review.

DECLARATIONS OF INTEREST

None

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- None, Not specified.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The risk of bias methodology has been updated since the protocol was published in order to conform to the 2008 Cochrane methodology and a Summary of findings table added.

INDEX TERMS

Medical Subject Headings (MeSH)

Bell Palsy [*surgery]; Decompression, Surgical [*methods]; Facial Nerve [surgery]; Randomized Controlled Trials as Topic

MeSH check words

Humans