Treatment for thoracic outlet syndrome (Review)

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[Intervention Review]

Treatment for thoracic outlet syndrome

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ABSTRACT

Background

Thoracic outlet syndrome (TOS) is one of the most controversial clinical entities in medicine. Despite many reports of operative and non-operative interventions, rigorous scientific investigation of this syndrome leading to evidence based management is lacking.

Objectives

To evaluate the beneficial and adverse effects of the available operative and non-operative interventions for the treatment of thoracic outlet syndrome.

Search methods

We searched the Cochrane Neuromuscular Disease Group Trials Specialized Register (July 2009), The Cochrane Central Register of Controlled Trials (The Cochrane Library Issue 2, 2009), MEDLINE (January 1966 to June 2009), EMBASE (January 1980 to June 2009), CINAHL (January 1981 to June 2009), AMED (January 1985 to June 2009) and reference lists of articles.

Selection criteria

We selected randomized or quasi-randomized studies in any language of participants with the diagnosis of any type of thoracic outlet syndrome (neurogenic, vascular, and 'disputed'). The primary outcome measure was change in pain rating on a validated visual analog or similar scale at least six months after the intervention. The secondary outcomes were change in muscle strength and adverse effects of the interventions.

Data collection and analysis

Four authors independently selected the trials to be included and extracted data. The one included study was rated for risk of bias according to the methods recommended in the *Cochrane Handbook for Systematic Reviews of Interventions*.

Main results

This review was complicated by a lack of generally accepted criteria for the diagnosis of TOS and had to rely exclusively on the diagnosis of TOS by the investigators in the reviewed studies. There were no studies comparing natural progression with any active intervention. In one trial with a high risk of bias involving 55 participants transaxillary first rib resection decreased pain more than supraclavicular neuroplasty of the brachial plexus. There were no adverse effects in either group.

Authors' conclusions

This review was complicated by a lack of generally accepted diagnostic criteria for the diagnosis of TOS. There was very low quality evidence that transaxillary first rib resection decreased pain more than supraclavicular neuroplasty but no randomized evidence that either is better than no treatment. There is no randomized evidence to support the use of other currently used treatments. There is a need for an agreed definition for the diagnosis of TOS, especially the disputed form, agreed outcome measures and high quality randomized trials that compare the outcome of interventions with no treatment and with each other.

PLAIN LANGUAGE SUMMARY

Treatment for thoracic outlet syndrome

Thoracic outlet syndrome (TOS) is one of the most controversial diagnoses in medicine. It is a spectrum of disorders that includes three related syndromes: a form where the brachial plexus, a collection of nerves in the neck and armpit, is compressed (the neurogenic form); a vascular form involving compression of the subclavian artery or vein, which are major blood vessels of the upper chest; and non-specific or disputed TOS. Clinical features may include pain in the shoulder and neck which spreads into the arm; weakness; decreased sensation; swelling; and a restricted blood supply to the affected arm.

TOS may result from a variety of abnormalities such as an extra rib in the neck (cervical rib syndrome), differences in the shape of the vertebrae, abnormal bands of tissue beneath the skin (fascial bands), and abnormalities of how muscles in the side of the neck attach to the bones. TOS is often associated with a history of trauma. There is a lack of widely accepted standards for making the diagnosis, so that for the purpose of this review we did not use objective criteria but relied exclusively on the diagnosis of TOS in participants by the investigators in the reviewed studies. The diagnosis of TOS is often made after other conditions that can cause one-sided symptoms of arm pain, weakness or sensory loss, or all three, have been excluded. Most people diagnosed with TOS have the disputed form.

This study demonstrated that there is not currently enough evidence that the established interventions for thoracic outlet syndrome are helpful in relieving pain. Until high quality, randomized clinical trials comparing the various interventions for TOS are performed, the decision whether to treat and the appropriate choice of treatment will have to be based on the preferences of the individual and health care provider.

BACKGROUND

Thoracic outlet syndrome (TOS) is one of the most controversial clinical entities in medicine. TOS represents a spectrum of disorders encompassing three related syndromes: compression of the brachial plexus (neurogenic TOS), compression of the subclavian artery or vein (vascular TOS), and a non-specific or disputed type of TOS. The differential diagnosis of unilateral arm pain, weakness, or sensory loss, individually or combined, includes all of these syndromes. The majority of people with TOS have the disputed form rather than neurogenic or vascular TOS. The objective diagnosis of (disputed) TOS is a challenge and generally accepted diagnostic criteria are lacking. TOS may result from a variety of anomalies such as a cervical rib (cervical rib syndrome), anomalous fascial bands, and abnormalities of the origin or insertion of the anterior or medial scalene muscles. Clinical features may include pain in the shoulder and neck region which radiates into the arm, paresis or paralysis of brachial plexus innervated muscles, loss of sensation, reduction of arterial pulses in the affected extremity, ischaemia, and oedema (Huang 2004; Wilbourn 1999). Despite many reports on conservative and surgical intervention, complications, outcomes and success rates, rigorous scientific investigation of this syndrome and its management is lacking. This review aimed to systematically examine the evidence for the effectiveness of established interventions for the treatment of TOS.

Epidemiology of TOS

Despite the fact that the term 'thoracic outlet syndrome' was coined in 1956 (Peet 1956) there are no good estimates of its prevalence (Wilbourn 1990). Cadaver dissection has suggested that only 10% of the population have what is considered 'normal' anatomy bilaterally of the thoracic outlet (Junoven 1995). The prevalence of symptomatic TOS has been estimated to be 10 per 100,000 people (Edwards 1999).

Aetiology of TOS

The aetiology and mechanisms underlying TOS are complex and not well understood. Vascular compromise is estimated to account for only 5% of all cases (Fechter 1993). Ninety-five per cent have only neurological symptoms. Neurogenic TOS exists in two variations. 'True neurogenic TOS' with characteristic clinical findings in the C8/T1 nerve root distribution is rare, and accounts for only about one to three per cent of all cases of TOS. The other variation has been designated 'disputed neurogenic TOS' and accounts for at least 90% of all operations for TOS in the United States (Wilbourn 1990). Factors considered influential in the development of TOS include trauma and the presence of a cervical rib (Sheth 2001).

Symptoms of TOS

Individuals with TOS frequently report pain, which can lead to significant disability. The range of complaints reported in the literature includes pain affecting the neck, shoulder, upper extremity or hand. Weakness is another common symptom (Huang 2004; Wilbourn 1999).

Interventions for TOS

Successful prevention and treatment of pain, muscular weakness and disability related to TOS are clinically challenging and heavily dependent on which of the three types of TOS the person is suffering from. While non-operative and operative approaches have been described in the literature, no firm evidence exists for any approach, in any of the three types of TOS. Non-operative management typically involves strategies to reduce and redistribute pressure and traction through the use of physiotherapy (Lindgren 1997) or orthoses (Nakatsuchi 1995). There are also several surgical approaches described in the literature. Surgical procedures fall into three main groups: (1) soft-tissue procedures (scaleneus release, neurolysis); (2) cervical rib excision; and (3) excision of the first thoracic rib (Sheth 2001). The outcome of treatment is said to be influenced by a number of factors such as gender, worker's compensation scheme, the position of the arm during work and fixed joint abnormalities (Green 1991).

OBJECTIVES

The objectives were to review systematically the evidence from randomized or quasi-randomized controlled trials of the effect of interventions for the treatment of each of the three (neurogenic, vascular and 'disputed') types of thoracic outlet syndrome.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomized controlled trials (RCTs) and quasi-randomized controlled trials of non-operative and operative interventions for the treatment of TOS. Evidence from high quality observational studies is reported in the Discussion.

Types of participants

We included participants receiving any non-operative or operative interventions for TOS of any aetiology and type. There was no restriction for age, sex, socioeconomic status, method of diagnosis, or duration of symptoms.

Types of interventions

Any intervention aimed at treating TOS. These included but were not limited to the following:

1. appliances, for example orthoses and neck collar;

2. physical therapies, for example, joint range of motion exercises, muscle stretching and strengthening;

3. medications, for example, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections and muscle relaxants;

4. operation, both soft-tissue and bony procedures.

Types of outcome measures

Primary outcomes

The primary outcome was change in pain at least six months after the intervention preferably measured as change on a validated visual analogue or similar scale.

Secondary outcomes

The secondary outcome measures were:

1. change in strength of potentially affected muscle groups at least six months after the intervention measured with Medical Research Council scale which ranges from 0 = complete paralysis to 5 = normal;

2. adverse effects of any treatment regimen.

Studies with different follow-up periods were combined with appropriate adjustments if the assumption of steady rates of change could be justified.

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Search methods for identification of studies

The Cochrane Neuromuscular Disease Group Trials Specialized Register was searched (13 July 2009) using the following search terms: 'Costoclavicular syndrome', 'Neurovascular syndrome, thoracic outlet syndrome', 'Scaleneus anticus syndrome', 'Thoracic outlet nerve compression syndrome', 'Aperture syndrome', 'thoracic outlet Nerve compression syndrome', 'horacic outlet, Neurogenic thoracic outlet syndrome', 'Neurologic syndrome, thoracic outlet, 'Superior thoracic aperture syndrome', 'Thoracic outlet neurologic syndrome', 'Thoracic outlet neurologic syndrome', 'Thoracic outlet syndrome

The above strategy was adapted to search the following: the Cochrane Central Register of Controlled Trials (The Cochrane Library issue 2, 2009), MEDLINE (January 1966 to June 2009); EMBASE (January 1980 to June 2009); CINAHL (January 1982 to June 2009); Allied and Complementary Medicine (AMED) (January 1985 to June 2009).

Electronic searches

See Appendix 1, Appendix 2, Appendix 3, Appendix 4, Appendix 5

Searching other resources

The databases were searched to include non-English reports, but none of these studies required translation. The bibliographies of the identified trials were reviewed for the identification of additional trials.

Data collection and analysis

Selection of studies

Four review authors independently and in duplicate, in a nonblind fashion, examined the title, keywords and abstract of reports identified from electronic searching for evidence of three criteria:

- Is it a randomized or quasi-randomized clinical trial?
- Does it involve an intervention for the treatment of TOS?

If the report fulfilled these criteria or if the authors were not able to assess this from the title, keywords or abstract then the full article was obtained. The authors then assessed the methodological quality of the selected articles using a standardized grading system, and independently decided upon inclusion. There were no disagreements amongst authors regarding the inclusion or exclusion of any of the papers.

Data extraction and management

Two review authors extracted data from the included trial onto a data extraction form independently. The trial authors were contacted for further information when appropriate. Data were entered into Review Manager by one author and checked by a second author.

Assessment of risk of bias in included studies

For each study included we completed a data extraction form to asses the risk of bias. This took into account: secure method of randomization, concealment of allocation, explicit inclusion/exclusion criteria, blinding (including blinding of participants, blinding of investigators, blinding of outcome assessors), how studies deal with baseline differences of the experimental groups, attrition bias, and completeness of follow-up. The trial was graded using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2008). We obtained missing information from the authors whenever possible.

Measures of treatment effect

Since we identified only one randomized trial for inclusion, we have included in the Discussion some prospective trials reporting consecutive series of patients that were assessed by someone other than the person providing the intervention.

Data synthesis

Since only one trial was included, this was not possible.

If more than one trial with a specific treatment or prevention approach had been identified, we would have calculated a pooled estimate of the treatment effect across the trials using the Cochrane statistical package Review Manager. The initial analysis would have been performed with a fixed-effect analysis. We would also have assessed if genuine heterogeneity might occur in advance in the methods section of the protocol and would also have ensured that the reasons for any such factors having the potential to cause heterogeneity were made clear in the background section of the protocol. To identify heterogeneity we would have examined the forest plots. If the confidence intervals of two studies had not overlapped or the I² statistic exceeded 50%, heterogeneity would have been suspected.

Subgroup analysis and investigation of heterogeneity

Since only one trial was included, this was not possible. For future updates of this review, if the data are available, we will compare the effect of interventions in the following subgroups of participants:

1. presence or absence of cervical rib or elongated C7 transverse process;

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2. acute (symptoms less than six months) or chronic (symptoms for six months or more);

3. male or female.

RESULTS

Description of studies

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

The following databases were searched and potential studies were found:

- MEDLINE (from January 1966 to 18th June 2009) = 81;
- EMBASE (from January 1980 to 18th June 2009) = 226;
- CINAHL (from January 1982 to 18th June 2009) = 4;
- Allied and Complementary Medicine (AMED) (from
- January 1985 to 18th June 2009) = 5;

• Evidence based medicine (EBM) reviews: (from 1991 to 18th June 2009) = 0;

Cochrane Central Register of Controlled Trials

(CENTRAL) on 18th June 2009 = 13;

• NMD (from January 1966 to 18th June 2009) = 12.

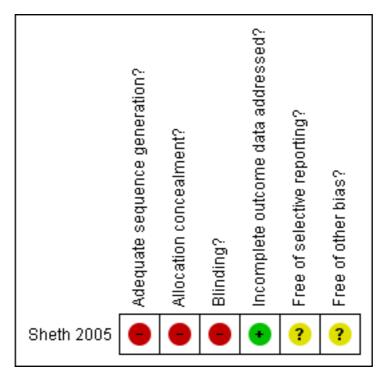
The total number of studies were 328 in total but there was overlap between the databases of 21 studies, so the net total was 301 articles. Based on review of the abstracts, full articles were obtained and reviewed for 33 studies. Of the 33 studies two RCTs were identified, one RCT was excluded due to insufficient duration of follow-up after the intervention but the other RCT was included in this review.

Risk of bias in included studies

This review was complicated by a lack of generally accepted diagnostic criteria for the diagnosis of TOS. We had to rely exclusively on the diagnosis of TOS in participants by researchers in the reviewed studies. This in itself creates a high risk of bias in all the identified studies.

The review authors' judgements about each methodological quality item for the included study are presented in Figure 1.

Figure 1. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.



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Effects of interventions

Transaxillary first rib resection (TFRR) versus supraclavicular neuroplasty of the brachial plexus (SNBP)

One trial (Sheth 2005) was identified. It evaluated the effects of TFRR (n = 25) versus SNBP (n = 24) on patient reported pain and numbness in 55 participants with the disputed type of TOS. Participants with anomalous elongated C7 transverse processes (cervical ribs), intrinsic weakness (characteristic of neurogenic TOS), and vascular TOS were excluded. Both interventions resulted in significantly decreased pain and numbness after surgery. The TFRR conferred superior results with respect to pain rating on 0 to 100 range VAS scale (39 + 7 versus 61 + 7) with an estimated difference in the treatment effects of -22.0 (95% CLs -41.9 to -2.1; P = 0.03), pain relief (52 + 8% versus 30 + 78%) estimated difference of 22.0 (95% CLs -0.8 to 44.8, P < 0.05), pain rating on an affective scale (3.7 + 0.4 versus 5.1 + 0.5) estimated difference of -1.4 (95% Cls -2.7 to -0.1, P < 0.03). Motor strength was not formally reported and none of the participants experienced adverse effects of the interventions.

DISCUSSION

This review was complicated by a lack of generally accepted diagnostic criteria for the diagnosis of TOS. We had to rely exclusively on the diagnosis of TOS in patients by researchers in the reviewed studies. We aimed to evaluate the effectiveness of various established interventions for TOS. An extensive search of the literature identified only one study that met our inclusion criteria. Most studies were retrospective; the few prospective studies that were identified lacked randomization or adequate follow-up. It was not possible to include a disability score as a second outcome measure in this version of the review but it will be included in future updates.

Sheth 2005 is the only prospective randomized trial for any established intervention for TOS with a follow-up of at least six months. This study provides limited support for the effectiveness of both TFRR and SNBP for relieving pain in people with the disputed type of TOS. In this group of patients TFRR provided significantly superior results compared to SNBP for all outcome measures. A limitation of this study is that it excluded people with an elongated C7 transverse processes (anomalous cervical rib) or signs and symptoms of neurogenic or vascular TOS. Thus, the diagnosis of disputed TOS was based solely on the subjective criteria set forth by the senior author. There is no report of the socioeconomic status of the participants or whether they were involved in ongoing litigation. In addition, the participants and assessors were not blinded to the specific intervention and there was no control group.

Other evidence (from excluded studies)

Interventions for TOS may be divided into non-operative and operative. Most patients are prescribed several types of non-operative interventions before surgery becomes an option. Non-operative interventions for TOS aim to decrease the compression on the brachial plexus, restore neural mobility, and correct muscle imbalance in the cervicoscapular region (Lindgren 1997; Novak 1995). Our search identified numerous retrospective studies, a few prospective studies, and one randomized clinical trial of nonoperative interventions for TOS. Taskaynatan 2004 performed a randomized prospective trial to investigate the effects of cervical traction added to exercise and heat pack therapy in 40 people with TOS of non-defined type. The participants were randomly divided into two groups. The control group received heat pack therapy and an exercise program; the experimental group received heat pack therapy, an exercise program, and cervical traction. The final outcome was assessed three weeks after the intervention. Outcome measures included response to provocative manoeuvres and a Likert Scale rating of improvement in pain and numbness. Both interventions produced improvement in some of the provocative manoeuvres and pain in most patients (75% control group versus 90% experimental group, P > 0.05). The difference in numbress scores between the groups was statistically significant in favour of adding cervical traction (80% versus 20%, P < 0.001). Although this study was a randomized controlled trial, it was excluded from our review because it did not meet the criteria for follow-up of at least six months. The authors did not describe the method used for sequence generation or allocation concealment. In addition, neither the participants nor the investigators were blinded to the interventions. Thus, the risk of selection and assessment bias was high.

Lindgren 1997 published a prospective descriptive study of 119 people with possible TOS who were treated with a non-operative inpatient rehabilitation program and instructions for home exercises to restore the normal function of their cervical spine and upper thoracic aperture. Patient satisfaction with the intervention at the end of the 11.4 (4 to 24) days inpatient period was 88%. The authors reported following the patients for a mean of 24.6 months, but do not provide standardized data at the long-term follow-up timepoint. Further, 30 of the 119 patients included in the study were found to have pathology other than TOS accounting for their symptoms. There was no assessment of compliance with the home exercises. Additional risk of bias was introduced by the lack of comparison groups, blinding, standardization of patient diagnosis, and use of validated outcome measures.

Gülbahar 2005 reported a prospective series of 34 patients with a subtype of disputed TOS, known as droopy shoulder syndrome, who were prescribed postural correction and shoulder girdle strengthening exercises. Compliance and symptom outcome were assessed at a mean (SD) follow-up of 13.7 (5.0) months, and the patients were divided into two groups with regard to their adherence to exercise programs as regular or irregular. Patients that

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completed the exercise program had significantly better results in pain on a VAS scale, satisfaction with the treatment, and radiographic assessment. Pretreatment equivalence was not established between the two groups and there was no randomization, therefore the risk of selection bias was high.

Jordan 2000 conducted a prospective single-blind trial of people with TOS of probable neurogenic type who received intrascalene injections of either botulinum toxin or lidocaine and steroids. One month after injection, 14 of 22 patients (64%) in the botulinum group reported greater than 50% reduction in symptoms compared to 4 of 22 patients in the lidocaine and steroid group. There are no data available regarding the method used to allocate the patients to a specific group, nor any information about the characteristics of the patients in each group. Thus, there was a high risk of selection bias.

There are numerous retrospective case series supporting the various established surgical interventions for TOS including scalenectomy, scalenotomy, division of fibrous bands, first rib resection, cervical rib resection or a combination of two or more of these procedures from either a supraclavicular or transaxillary approach. However, these retrospective studies lack randomization, blinding, and standardized outcome assessment and therefore have a high risk for selection, allocation, and assessment bias.

There are a few prospective series of consecutive patients that underwent surgical intervention for TOS. Martens 1980 reported on a consecutive series of 67 patients with various types of TOS who had undergone surgical intervention after failing non-operative therapy. The patients were contacted by telephone or letter and their long-term outcomes were categorized as excellent, satisfactory or poor. Surgical approaches included supraclavicular, posterior thoracoplasty and transaxillary. Satisfactory results were reported for 75% of posterior thoracoplasty, 64% of supraclavicular, and 100% of transaxillary approaches. Statistical analysis to compare the outcomes between the surgical groups was not reported. There was no attempt to randomize patients to the various surgical interventions, blind the patients or assessors, or attempt to account for unbalanced attrition rates across the surgical groups and therefore the risk of selection and assessment bias was high.

Sällström 1983 reported on a consecutive series of 63 patients with TOS of whom three had venous thrombosis and the others were not defined to a specific sub-group, who underwent transaxillary first rib resection. The patients were evaluated at regular intervals after surgery with a final evaluation at a mean of 2.5 years. At least marked improvement of symptoms was reported by 81% of patients. However, the lack of comparison groups, blinding, and validated outcome measures introduce significant risk of assessment bias. Balci 2003 prospectively studied 47 people with TOS. They subdivided the patients into four TOS subtypes: neurogenic upper plexus, neurogenic lower plexus, arterial, and venous. Nineteen patients had an anomalous cervical rib. Forty-nine surgical procedures were performed including first rib resection (n = 28), cervical rib resection (n = 10), first and cervical rib resection (n = 9), and

thrombectomy (n = 2). Follow-up, consisting of clinic visit, phone conversation, or mailed questionnaire, was conducted at one and two months postoperatively and with a long-term follow-up at an average of 4.6 years. At long-term follow-up, 75% of upper plexus and 50% of lower plexus patients remained asymptomatic. There was no difference in success when the various surgical groups were compared. The overall morbidity rate was 17% and included incisional pain, pneumothorax, intercostobrachial neuralgia, wound infection, and wound hematoma. The patients were not randomized to undergo the various surgical interventions, and the outcome measurement was not standardized, therefore the risk of selection and assessment bias was high.

Landry 2001 reported a prospective observational cohort study of people with disputed TOS who were evaluated by an independent medical examiner over an eight year period. The authors performed the initial examination, but were not involved with any interventions. At a mean follow-up of 4.2 years, the study participants completed a standardized telephone interview or a mailed questionnaire. Of the 79 survey respondents, 15 had undergone surgical intervention. Most patients reported improved symptoms and were able to return to work. Surgical intervention did result in additional relief of symptoms compared to nonoperative therapy. The lack of randomization, high attrition rate (42%), and inadequate patient allocation conferred a high risk of selection and assessment bias.

Bhattacharya 2003 reported an observational study of a consecutive series of 60 patients who had undergone supraclavicular neurolysis or transaxillary first rib resection for TOS of various types. Study participants were identified from a prospective patient database and evaluated using a standardized questionnaire that was mailed or completed over the telephone. The median follow-up was 43 months (range 4 to 102 months). At least fair improvement of symptoms was reported in 90% of the cases. There was no difference in outcome with regards to type of TOS or type of surgical intervention. There was no attempt to randomize patients to various surgical interventions, and the assessors were not blind to which intervention had been performed and therefore the risk of selection and assessment bias was high.

AUTHORS' CONCLUSIONS

Implications for practice

This review was complicated by a lack of generally accepted diagnostic criteria for the diagnosis of TOS. There is currently no evidence demonstrating the beneficial effects of established operative or non-operative interventions compared with natural progression for pain relief in TOS. There is very low quality evidence that transaxillary first rib resection is superior to supraclavicular neurolysis of the brachial plexus for pain relief in selected people with the disputed type of TOS that have failed non-operative interventions. standardized methods of outcome assessment and reporting.

Implications for research

There is a need for high quality randomized trials that compare the outcome of no intervention with the outcome of commonly used active interventions. In addition, research is needed to establish objective diagnostic criteria for the disputed type of TOS and

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Sheth 2005

Methods	Randomized clinical trial Sequence generation: odd or even hospital record number (not described in text; personal communication from authors) Allocation concealment: surgeon aware of hospital record number Blinding: no Incomplete data: four participants from each group lost to follow-up. Unclear how VAS was performed over the phone or if any of the included questionnaires were incomplete Selective outcome reporting: no description of differences between participants inter- viewed in clinic versus via telephone Other sources of bias: no description of how ongoing legal claims or dominant extremity were spread between groups. Both participants with bilateral symptoms were in the same group Mean duration of follow-up: 37 months
Participants	Number: 55 randomized, 47 evaluated Inclusion criteria: Aged 18 years or older with pain as predominant symptom and diag- nosed with TOS by senior author. No improvement with previous physical therapy Exclusion criteria: neurologic deficits, symptoms of vascular occlusion, prior TOS surgery, cervical spondylosis, cervical rib. If patients selected on procedure they were excluded
Interventions	Supraclavicular neuroplasty of the brachial plexus Transaxillary first rib resection
Outcomes	 Pain a. score (100 mm VAS) b. relief (Likert scale) c. average, best, worst level d. location location Numbness Tingling Symptom severity with arm raised Adverse events
Notes	Location: USA Socio-economic status: not reported
Risk of bias	

Adequate sequence generation? No Sequence generation: odd or even record number (not described in to	
sonal communication from author	xt; per-

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Sheth 2005 (Continued)

Allocation concealment?	No	Sequence generation: odd or even hospital record number (not described in text; per- sonal communication from authors)
Blinding? All outcomes	No	Surgeon knew about hospital number and was therefore not blinded
Incomplete outcome data addressed? All outcomes	Yes	Four participants in each group lost to fol- low-up
Free of selective reporting?	Unclear	No description of which patients were in- terviewed in person and who by phone
Free of other bias?	Unclear	Unclear which of the participants had on- going legal claims

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Abe 1997	Not a randomized clinical trial. Retrospective series
Balci 2003	Prospective operative series, not randomized
Bhattacharya 2003	Prospective operative series, not randomized
Chang 2009	Prospective operative series, not randomized
Derkash 1981	Not a randomized clinical trial. Retrospective series
Devin 1984	Not a randomized clinical trial. Retrospective series
Divi 2003	Not a randomized clinical trial. Retrospective series
Gockel 1994	Not a randomized clinical trial. Retrospective series
Goff 1998	Not a randomized clinical trial. Retrospective series
Gülbahar 2005	Prospective non-operative series, not randomized
Hanif 2007	Prospective non-operative series, not randomized
Johnson 1974	Not a randomized clinical trial. Retrospective series

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(Continued)

Jordan 2000	Prospective non-operative series, not randomized
Khalil 1975	Not a randomized clinical trial. Retrospective series
Krishnan 2005	Not a randomized clinical trial. Retrospective series
Landry 2001	Prospective operative series, not randomized
Leffert 1999	Not a randomized clinical trial. Retrospective series
Lindgren 1997	Prospective non-operative series, not randomized
Martens 1980	Prospective operative series, not randomized
Martinez 1982	Not a randomized clinical trial. Retrospective series
McGough 1979	Not a randomized clinical trial. Retrospective series
Nakatsuchi 1995	Not a randomized clinical trial. Retrospective series
Nannapeneni 2003	Not a randomized clinical trial. Retrospective series
Norgren 1984	Not a randomized clinical trial. Retrospective series
Qvarfordt 1984	Not a randomized clinical trial. Retrospective series
Roos 1982	Not a randomized clinical trial. Retrospective series
Sanders 1979	Not a randomized clinical trial. Retrospective series
Schneider 2004	Prospective operative series, not randomized
Sällström 1983	Prospective operative series, not randomized
Taskaynatan 2004	Randomized clinical trial; Follow-up period < 6 months
Terao 2008	Not a randomized clinical trial. Retrospective series
Urschel 1976	Not a randomized clinical trial. Retrospective series

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DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix I. MEDLINE (OvidSP) search strategy

1. randomized controlled trial.pt. 2. controlled clinical trial.pt. 3. randomized controlled trials/ 4. random allocation/ 5. double-blind method/ 6. single-blind method/ 7. or/1-6 8. animals/ not humans/ 9.7 not 8 10. clinical trial.pt. 11. exp clinical trials/ 12. (clin\$ adj25 trial\$).ti,ab. 13. ((singl\$ or doubl\$ or tripl\$ or trebl\$) adj25 (blind\$ or mask\$)).ti,ab. 14. placebos/ 15. placebo\$.ti,ab. 16. random\$.ti,ab. 17. research design/ 18. or/10-17 19. 18 not 8 20. 19 not 9 21. comparative study/ 22. exp evaluation studies/ 23. follow up studies/ 24. prospective studies/ 25. (control\$ or prospectiv\$ or volunteer\$).ti,ab. 26. or/21-25 27. 26 not 8 28. 27 not (9 or 20) 29. 9 or 20 or 28 30. Thoracic Outlet Syndrome/ or Thoracic Outlet Syndrome.mp. or TOS.mp. 31. nerve compression syndrome.mp. 32. Aperture syndrome.mp. 33. Superior thoracic aperture syndrome.mp. 34. neurologic.mp. 35. neurovascular.mp. 36. neurogenic.mp. 37. vascular.mp. 38. or/31-37 39. 30 and 38 40. Costoclavicular syndrome.mp. 41. Scalenus anticus syndrome.mp. 42. Superior thoracic aperture syndrome.mp.

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43. cervical rib syndrome/ or cervical rib syndrome.mp.
44. or/40-43
45. 30 or 39 or 44
46. exp Therapeutics/

47. 29 and 45 and 46

Appendix 2. EMBASE (OvidSP) search strategy

- 1. Randomized Controlled Trial/
- 2. Clinical Trial/
- 3. Multicenter Study/
- 4. Controlled Study/
- 5. Crossover Procedure/
- 6. Double Blind Procedure/
- 7. Single Blind Procedure/
- 8. exp RANDOMIZATION/
- 9. Major Clinical Study/
- 10. PLACEBO/
- 11. Meta Analysis/
- 12. phase 2 clinical trial/ or phase 3 clinical trial/ or phase 4 clinical trial/
- 13. (clin\$ adj25 trial\$).tw.
- 14. ((singl\$ or doubl\$ or tripl\$ or trebl\$) adj25 (blind\$ or mask\$)).tw.
- 15. placebo\$.tw.
- 16. random\$.tw.
- 17. control\$.tw.
- 18. (meta?analys\$ or systematic review\$).tw.
- 19. (cross?over or factorial or sham? or dummy).tw.
- 20. ABAB design\$.tw.
- 21. or/1-20
- 22. human/
- 23. nonhuman/
- 24. 22 or 23
- 25. 21 not 24
- 26. 21 and 22
- 27. 25 or 26
- 28. Thoracic Outlet Syndrome/ or Thoracic Outlet Syndrome.mp. or TOS.mp.
- 29. nerve compression syndrome.mp.
- 30. Aperture syndrome.mp.
- 31. Superior thoracic aperture syndrome.mp.
- 32. neurologic.mp.
- 33. neurovascular.mp.
- 34. neurogenic.mp.
- 35. vascular.mp.
- 36. or/29-35
- 37. 28 and 36
- 38. Costoclavicular syndrome.mp.
- 39. Scalenus anticus syndrome.mp.
- 40. Superior thoracic aperture syndrome.mp.
- 41. cervical rib syndrome/ or cervical rib syndrome.mp.
- 42. or/38-41
- 43. 28 or 37 or 42
- 44. exp therapy/
- 45. 27 and 42 and 44

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Appendix 3. CINAHL (EBSCOhost) search strategy

S1 (MH "Thoracic Outlet Syndrome") S2 thoracic outlet syndrome* or TOS S3 (MH "Nerve Compression Syndromes") or nerve compression syndrome* S4 aperture syndrome* S5 superior thoracic aperture syndrome* S6 neurologic* S7 neurovascular* S8 neurogenic* S9 vascular* S10 S9 or S8 or S7 or S6 or S5 or S4 or S3 $\,$ S11 S2 or S1 S12 S11 and S10 S13 costoclavicular syndrome* S14 scalenus anticus syndrome* S15 cervical rib syndrome* S16 S15 or S14 or S13 S17 S16 or S12 or S11 S18 (MH "Therapeutics+") S19 (MH "Random Assignment") or (MH "Random Sample") or (MH "Simple Random Sample") or (MH "Stratified Random Sample") or (MH "Systematic Random Sample") S20 (MH "Crossover Design") S21 (MH "Clinical Trials+") S22 (MH "Double-Blind Studies") or (MH "Triple-Blind Studies") S23 (MH "Placebos") S24 (MH "Quasi-Experimental Studies") S25 (MH "Solomon Four-Group Design") or (MH "Static Group Comparison") S26 (MH "Meta Analysis") S27 (MH "Concurrent Prospective Studies") or (MH "Prospective Studies") S28 (MH "Factorial Design") S29 PT clinical trial or PT systematic review S30 ARAB design* S31 (TI (single* or doubl* or tripl* or trebl*) or AB (single* or doubl* or tripl* or trebl*)) and (TI (blind* or mask*) or AB (blind* or mask*)) S32 (TI (meta?analys* or systematic review*)) or (AB (meta?analys* or systematic review*)) S33 (TI (clin* or intervention* or compar* or experiment* or preventive or therapeutic) or AB (clin* or intervention* or compar* or experiment* or preventive or therapeutic)) and (TI (trial*) or AB (trial*)) S34 (TI (cross?over or placebo* or control* or factorial or sham? or dummy)) or (AB (cross?over or placebo* or control* or factorial or sham? or dummy)) S35 TI random* or AB random* \$36 \$35 or \$34 or \$33 or \$32 or \$31 or \$30 or \$29 or \$28 or \$27 or \$26 or \$25 or \$24 or \$23 or \$22 or \$21 or \$20 or \$19 S37 S36 and S18 and S17

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Appendix 4. AMED (OvidSP) search strategy

1. Thoracic Outlet Syndrome/ or Thoracic Outlet Syndrome.mp. or TOS.mp.

- 2. nerve compression syndrome.mp.
- 3. Aperture syndrome.mp.
- 4. Superior thoracic aperture syndrome.mp.
- 5. neurologic.mp.
- 6. neurovascular.mp.
- 7. neurogenic.mp.
- 8. vascular.mp.

9. or/2-8

- 10. 1 and 9
- 11. Costoclavicular syndrome.mp.
- 12. Scalenus anticus syndrome.mp.
- 13. Superior thoracic aperture syndrome.mp.
- 14. cervical rib syndrome.mp.
- 15. or/11-14
- 16. 1 or 10 or 15
- 17. Randomized controlled trials/
- 18. Random allocation/
- 19. Double blind method/
- 20. Single-Blind Method/
- 21. exp Clinical Trials/
- 22. (clin\$ adj25 trial\$).tw.
- 23. ((singl\$ or doubl\$ or treb\$ or trip\$) adj25 (blind\$ or mask\$ or dummy)).tw.
- 24. placebos/
- 25. placebo\$.tw.
- 26. random\$.tw.
- 27. research design/
- 28. Prospective Studies/
- 29.. meta analysis/
- 30.. (meta?analys\$ or systematic review\$).tw.
- 31. control\$.tw.
- 32.. (multicenter or multicentre).tw.
- 33. ((study or studies or design\$) adj25 (factorial or prospective or intervention or crossover or cross-over or quasi-experiment\$)).tw.
- 34. or/17-33
- 35. exp Therapy/
- 36. 16 and 34 and 35

Appendix 5. Cochrane Library CENTRAL search strategy

#1 MeSH descriptor Thoracic Outlet Syndrome explode all trees
#2 "Thoracic Outlet Syndrome" or TOS
#3 nerve compression syndrome
#4 Aperture syndrome
#5 "Superior thoracic aperture syndrome"
#6 neurologic
#7 neurovascular
#8 neurogenic
#9 vascular
#10 (#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9)
#11 (#1 AND #10)
#12 Costoclavicular syndrome

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#13 Scalenus anticus syndrome
#14 Superior thoracic aperture syndrome
#15 MeSH descriptor Cervical Rib Syndrome, this term only
#16 cervical rib syndrome
#17 (#12 OR #13 OR #14 OR #15 OR #16)
#18 (#1 OR #11 OR #17)
#19 (#18)
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HISTORY

Protocol first published: Issue 3, 2008

Review first published: Issue 1, 2010

Date	Event	Description
20 April 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

B Povlsen wrote the first draft of the protocol. M Dorsi wrote the first draft of the review and B Povlsen coordinated the subsequent comments into the final review. A Belzberg and T Hansson made valuable comments to the subsequent drafts and all participated in assessing the selected papers.

DECLARATIONS OF INTEREST

None of the members of the review team have conflicts of interest.

SOURCES OF SUPPORT

Internal sources

• Department of Orthopaedics, Guy's & St Thomas Hospitals NHS Foundation Trust, UK.

External sources

• No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We did not search evidence based medicine reviews: ACP Journal Club, the Cochrane Database of Systematic Reviews (CDSR) or the Database of Abstracts of Reviews of Effects (DARE) in *The Cochrane Library*.

INDEX TERMS

Medical Subject Headings (MeSH)

Brachial Plexus [surgery]; Cervical Rib [surgery]; Randomized Controlled Trials as Topic; Thoracic Outlet Syndrome [diagnosis; etiology; *therapy]

MeSH check words

Humans