# Treatment for thoracic outlet syndrome

# **Protocol information**

## **Authors**

Bo Povlsen<sup>1</sup>, Allan Belzberg<sup>2</sup>, Thomas Hansson<sup>3</sup>, Michael Dorsi<sup>2</sup>

<sup>1</sup>Department of Orthopaedics, Guy's and St Thomas' Hospitals NHS Trust, London, UK

<sup>2</sup>Department of Neurosurgery, The Johns Hopkins Hospital, Baltimore, USA

<sup>3</sup>Plastic Surgery, Hand Surgery and Burns, University Hospital, Linkoping, Sweden

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## **Contact person**

## **Bo Povlsen**

Consultant Orthopaedic Surgeon Department of Orthopaedics Guy's and St Thomas' Hospitals NHS Trust St Thomas Street London SE1 UK

E-mail: bo@manusmedical.com

### **Dates**

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Date of Search:	
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Last Citation Issue:	Not specified

## What's new

Date / Event	Description

## History

Date / Event	Description
21 April 2008 Amended	Substantive amendment
21 April 2008 Amended	Converted to new review format.

# 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, and/or sensory loss includes all of these problems. The majority of TOS patients do not have a neurogenic or vascular TOS but a disputed TOS. The objective diagnosis of (disputed) TOS is a challenge and generally accepted diagnostic criteria are lacking. Thoracic outlet syndrome 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 how best to manage it is lacking. This review will examine the evidence for the effectiveness of established interventions for the treatment of thoracic outlet syndrome.

## **Epidemiology of TOS**

Despite the fact that the term "thoracic outlet syndrome" was coined in 1956 (<u>Peet 1956</u>) there are no good estimates of its prevalence (<u>Wilbourn 1990</u>). Cadaver dissection has suggested that only 10% of the population have what is considered "normal" anatomy bilaterally of the thoracic outlet (<u>Junoven 1995</u>). Clinical figures of 10 TOS sufferers per 100,000 population have been published (<u>Edwards 1999</u>).

## Aetiology of TOS

The aetiology and mechanisms underlying TOS are complex and not well understood. Vascular compromise is estimated to only account for 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, about 1 to 3% 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 neck pain, shoulder, upper extremity and hand pain. Muscular weakness is another common symptom (Huang 2004; Wilbourn 1999).

## Interventions for TOS

Successful prevention and treatment of TOS regarding pain, muscular weakness and associated disability are clinically challenging and heavily dependent on which of the three types of TOS that the person is suffering from. While conservative and surgical approaches have been described in the literature, no firm evidence exists for any approach in any of the three types of TOS. Conservative management of people with TOS typically involves strategies to reduce and redistribute pressure and traction through the use of physiotherapy (Lindgren 1997) or orthoses (Nakatscuchi 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) excision of cervical rib; and (3) excision of 1st thoracic rib (Sheth 2001). The outcome following treatment is influenced by a number of factors such as gender, worker's compensation scheme, position of arm during work and fixed joint abnormalities (Green 1991). This review will be undertaken because of the complex nature, the apparently high incidence of pain and chronic morbidity in people with this condition, and the apparently limited scientific data on all aspects of its treatment. We will aim to investigate each of the three

types of TOS independently regarding intervention.

## **Objectives**

The objectives are to systematically review the evidence from randomised or quasi-randomised 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**

As we expect the number of prospective trials to be few, we will include all randomised and quasi-randomised controlled trials of interventions for the treatment of each of the types of thoracic outlet syndrome (neurogenic, vascular and "disputed"). We will in the first instance accept the author's diagnosis if attempts have been made to separate the three types on a clinical basis so that each type can be investigated individually. If there are no or inadequate randomised controlled trials, we will report in the discussion evidence from high quality observational studies. These must be prospective studies of consecutive case series with the outcomes preferably assessed by an individual who was not directly associated with delivering the intervention.

## **Types of participants**

We will include studies on participants of all ages who are described as having TOS of any aetiology and type.

## **Types of interventions**

Any intervention aimed at treating thoracic outlet syndrome. These may include but are not limited to:

- (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 (NSAID's), corticosteroid injections and muscle relaxants.

(4) Operation, both soft-tissue and bony procedures.

### Types of outcome measures

### **Primary outcomes**

The primary outcome will be 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 will be:

(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 will be combined with appropriate adjustments if the assumption of steady rates of change can be justified.

### Search methods for identification of studies

We will search the Cochrane Neuromuscular Disease Group Trials Register for randomised trials using the

**Review Manager 5** 

PDF created with pdfFactory trial version www.pdffactory.com

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following search terms: 'Costoclavicular syndrome', 'Neurovascular syndrome, thoracic outlet', 'Scaleneus anticus syndrome', 'Thoracic outlet nerve compression syndrome', 'Aperture syndrome', 'thoracic outlet Nerve compression syndrome', 'thoracic outlet, Neurogenic thoracic outlet syndrome', 'Neurologic syndrome, thoracic outlet', 'Superior thoracic aperture syndrome', 'Thoracic outlet neurologic syndrome', 'Thoracic outlet neurologic syndrome', 'Thoracic outlet', 'Superior thoracic outlet syndrome', 'Thoracic outlet syndrome', 'Thoracic outlet', 'Superior thoracic outlet', 'Superior thoracic outlet syndrome', 'Thoracic outlet', 'Superior thoracic outlet', 'Superior', 'Thoracic outlet', 'Superior', 'Superior',

We will adapt this strategy using an appropriate combination of MeSH and text word terms, combined with the strategy to identify randomised controlled trials (Cochrane Handbook for Systematic Reviews of Interventions and the Cochrane Neuromuscular Disease Group information for authors) to search the following: MEDLINE (from January 1966 to the present); EMBASE (from January 1980 to the present); CINAHL (from January 1982 to the present); Allied and Complementary Medicine (AMED) (from January 1985 to the present); Evidence based medicine (EBM) reviews: ACP Journal Club (ACP) from 1991, the Cochrane Central Register of Controlled Trials (CENTRAL), the Cochrane Database of Systematic Reviews (CDSR), and the Database of Abstracts of Reviews of Effects (DARE) in *The Cochrane Library*, Issue 2, 2008.

### **Electronic searches**

See Appendix 1, Appendix 2, Appendix 3, Appendix 4.

#### Searching other resources

Non-English reports will be included and we will review the bibliographies of the trials identified, contact the authors and known experts in the field and approach pharmaceutical companies to identify additional published or unpublished data.

### **Data collection and analysis**

#### Selection of studies

The authors will independently check the titles and abstracts of the articles identified by the search. The authors will assess the methodological quality of the selected articles using a standardised grading system, and independently decide upon inclusion. Disagreements about whether a study should be included will be resolved by e-mail discussion until consensus is reached.

#### Data extraction and management

Two review authors will extract data from the trials onto a data extraction form independently. They will write to trial authors for further information as necessary. Data will be entered into Review Manager by one author and checked by a second author.

### Assessment of risk of bias in included studies

A standardised grading system will be used to assess the risk of bias of the trials. This will take into account: secure method of randomisation, 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, and completeness of follow-up. These will be graded using the Cochrane approach: A, adequate; B, unclear; C, inadequate or not done. Missing information will be obtained from the authors whenever possible.

### Measures of treatment effect

The three (neurogenic, vascular and "disputed") types of thoracic outlet syndrome will be analysed individually. Where possible, weighted mean differences and 95% confidence intervals (CIs) will be calculated for all continuous outcomes, and relative risks and 95% CIs will be calculated for dichotomous outcomes.

If we were to find very few or no randomised trials for inclusion, we would include consecutive series of patients in the Discussion section. However, the assessment will have to have been made by someone other

than the person who gave the treatment and the number of patients assessed will have to have exceeded 80% of those that had been treated during a particular period.

## Dealing with missing data

If the data are not available we will try to retrieve them from the authors of the original trial and include the omitted data as if the participant had been treated within the randomly allocated treatment group. If that is not possible, the possibility of bias will be reported.

### Data synthesis

If there is more than one trial with a specific treatment or prevention approach, we will calculate a pooled estimate of the treatment effect across the trials using the Cochrane statistical package Review Manager. The initial analysis will be performed with a fixed-effect analysis.

## Subgroup analysis and investigation of heterogeneity

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.

- (2) Acute (less than six months) or chronic (six months or more).
- (3) Male or female.

Studies with different follow-up periods will be presented separately to assess the effect of follow-up period and also combined with appropriate adjustments if the assumption of steady rates of change can be justified.

We will test for heterogeneity across trials. If found, we will look for clinical differences between the trials. If none are found, we will perform sensitivity analyses by repeating the calculation after omitting trials with low scores on individual quality items and repeat the analysis using a random effects model.

## Economic issues

Costs and cost-effectiveness will be considered in the Discussion.

# Acknowledgements

The authors are grateful for the assistance of Professor Richard Hughes and Kate Jewitt of the Cochrane Neuromuscular Disease Group.

# **Contributions of authors**

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

## **Declarations of interest**

A Belzberg has been involved in publications that may be eligible for consideration in this review. Other members of the review team have no conflicts of interest.

# **Published notes**

# Additional tables

# **Other references**

### **Additional references**

### Edwards 1999

Edwards DP, Mulkern E, Raja AN, Barker P. Trans-axillary first rib excision for thoracic outlet syndrome. Journal of the Royal College of Surgeons of Edinburgh 1999;44(6):362-5.

### Fechter 1993

Fechter JD, Kuscher SH. The thoracic outlet syndrome. Orthopedics 1993;16(11):1243-51.

### Green 1991

Green RM, McNamara J, Ouriel K. Long term follow-up after thoracic outlet decompression. Journal of Vascular Surgery 1991;14(6):739-46.

## Huang 2004

Huang JH, Zager EL. Thoracic outlet syndrome. Neurosurgery 2004;55(4):897-2, discussion 902-3.

### Junoven 1995

Juvonen T, Satta J, Laitala P, Luukkonen K, Nissinen J. Anomalies at the thoracic outlet are frequently in the general population. American Journal of Surgery 1995;170(1):33-7.

### Lindgren 1997

Lindgren KA. Conservative treatment of thoracic outlet syndrome. Archives of Physical Medicine and Rehabilitation 1997;78(4):373-78.

### Nakatscuchi 1995

Nakatsuchi Y, Saitoh S, Hosaka M, Matuda S. Conservative treatment of thoracic outlet syndrome using an orthosis. Journal of Hand Surgery 1995;20(1):34-9.

### Peet 1956

Peet RM, Henriksen JD, Anderson TP, Martin GM. Thoracic outlet syndrome: evaluation of a therapeutic exercise program. Mayo Clinic Proceedings 1956;31(9):281-7.

### Sheth 2001

Sheth RN, Belzberg AJ. Diagnosis and treatment of thoracic outlet syndrome. Neurosurgery Clinics of North America 2001;12(2):295-309.

### Wilbourn 1990

Willbourn AJ. The thoracic outlet syndrome is overdiagnosed. Archives of Neurology 1990;47(3):328-30.

### Wilbourn 1999

Willbourn AJ. Thoracic outlet syndromes. Neurologic Clinics 1999;17(3):477-97.

### Other published versions of this review

## **Figures**

## Sources of support

### **Internal sources**

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

### **External sources**

• No sources of support provided

## Feedback

## **Appendices**

### **1 OVID MEDLINE 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.
- 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

### 2 OVID EMBASE 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

### **3 EBSCOhost CINAHL 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\* S36 S35 or S34 or S33 or S32 or S31 or S30 or S29 or S28 or S27 or S26 or S25 or S24 or S23 or S22 or S21 or S20 or S19 S37 S36 and S18 and S17

### **4 OVID AMED 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. cross over studies/
- 30. meta analysis/
- 31. (meta?analys\$ or systematic review\$).tw.
- 32. control\$.tw.
- 33. (multicenter or multicentre).tw.

34. ((study or studies or design\$) adj25 (factorial or prospective or intervention or crossover or cross-over or quasi-experiment\$)).tw.

- 35. or/17-34
- 36. exp Therapy/
- 37. 16 and 35 and 36