

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Treating lateral epicondylitis with corticosteroid injections or non-electrotherapeutical physiotherapy: a systematic review
AUTHORS	Olaussen, Morten; Holmedal, Oeystein; Lindbaek, Morten; Brage, Soeren; Solvang, Hiroko

VERSION 1 - REVIEW

REVIEWER	Leanne Bisset PhD Research Fellow Griffith University Australia No competing interests.
REVIEW RETURNED	13-Nov-2012

THE STUDY	The statistical analyses in this paper are absent and/or inadequate and further work needs to be done to provide a summary of the effect size within and between interventions.
RESULTS & CONCLUSIONS	There is a mismatch between the aims and the methods, see comments to authors.
GENERAL COMMENTS	<p>The aims of this systematic review are to assess the current evidence for the effects of corticosteroid injection and non-electrotherapeutic physiotherapy in tennis elbow (page 5, lines 39-42).</p> <p>However, in its current form, the methods do not align well with this broad aim.</p> <p>If I have interpreted the methods correctly, it appears that the aim of this review was to assess the efficacy of corticosteroid injection and non-electrotherapeutic physiotherapy, compared to a control (no treatment), in tennis elbow. The inclusion criteria for studies appears to exclude papers that have compared either of these interventions with other active interventions, such as exercise, electrotherapy, braces, or each other. As such, the broad aim of assessing the effectiveness of these interventions (CI and physio) is not valid, unless all comparisons, are included.</p> <p>So, within the confines of this current paper, all comparisons between CI and physio should be excluded.</p> <p>My following comments are based on the current methods: Page 5, Objective: please change this statement to more accurately reflect the methods, e.g. ...'to assess the current evidence for the efficacy of corticosteroid injection and non-electrotherapeutic physiotherapy, compared with control (no-treatment), in people with tennis elbow'.</p> <p>I suggest a change in the term 'effectiveness' to 'efficacy', mainly because your current aim is to see if the interventions of interest (CI and physio) have the capacity to produce an effect over and above a control condition, using RCT methodology. I refer you to J Orthop</p>

Sports Phys Ther 2003. 33(4):163-65

Methods:

Were the dates that were searched within each database restricted or unrestricted? Please explicitly state in the text.

Page 7: there is mention that no assistance was provided by a librarian. This is unnecessary and could be removed.

Page 8, lines 25,26: You exclude study reference #41 (Vicenzino et al. 2001) on the basis that it was not a RCT. In fact, this study was a randomised, double-blind, placebo-controlled trial, with a repeated measures within-group design. This meant that participants acted as their own controls, they only received a single session of each intervention, and outcomes were only measured immediately post-intervention. Therefore, it is not valid to exclude this paper on the basis of randomisation. The same goes for a paper by Paungmali et al. (2003), which appears to be missing from your search. However, if the authors were seeking a longer follow up period, or a minimum number of treatment sessions as part of their inclusion/exclusion criteria, then this needs to be clearly stated in the inclusion/exclusion criteria.

Can the authors explain why the following study was excluded from this review, given that the compactor group (oral NSAID) appears to meet the inclusion criteria:

- Saartok T, Eriksson E. Randomized trial of oral naproxen or local injection of betamethasone in lateral epicondylitis of the humerus. Orthopedics 1986; 9: 191–94.

There is no mention of data analyses. A systematic review should attempt to report relative effects between groups, using e.g. relative risk (95% CI) for dichotomous variables and standardised mean difference (95%CI) for continuous variables.

Where outcomes could not be pooled, the strength of evidence should be reported as either strong, moderate, conflicting, or no evidence (van Tulder M, Furlan A, Bombardier C, Bouter L. Updated method guidelines for systematic reviews in the cochrane collaboration back review group. Spine 2003; 28: 1290–99).

Results.

What was the reliability between the two raters for quality assessment scores using the PEDro scale?

The results are reported in terms of timing of follow up – please define what you consider ‘short’ or ‘long’ term within the methods. Given that the outcomes for corticosteroid vary significantly between 3 and 12 months, I would recommend the authors include an ‘intermediate’ follow up period, in order to capture the true pattern of effect of this intervention.

Page 9, lines 34-33: please include references for 6 studies that measured pain free grip, and the 7 studies that used questionnaires, etc.

Page 11, Physiotherapy: It is not correct to say that ‘At one-year follow-up, there was no significant effect of manipulation and exercise on pain free grip strength and assessor severity rating.’, as this implies no within-group effect. The authors need to carefully differentiate within-group and between-group effects. It is more

	<p>correct to say 'At one-year follow-up, there was no significant difference between manipulation and exercise treatment and wait and see on pain free grip strength and assessor severity rating.'</p> <p>As the methods have excluded papers that compare CI or physiotherapy with other active treatments, you should not make these comparisons within your results or discussion.</p> <p>Table 2: Please include the excluded studies that did not meet the 50% cut-off.</p> <p>Discussion. Page 12 first paragraph, the authors cite that no comparisons could be made between studies on corticosteroid injections, due to differences in injection substance, dosages and injection techniques. Please include references to support this claim that these differences may influence outcomes. I would question the validity of this assumption, particularly when several studies have reported similar pattern of effect over time. Consistent findings across studies suggest that the substance, dose and technique may have little or no impact on the effect over time.</p> <p>Page 13, lines 5-10: The authors claim to use 'stricter quality criteria' than those used in previous systematic reviews. Please describe in more detail which criteria were more strict in this current review, as that is currently not clear. I think the authors are referring to the restriction of included studies to efficacy studies for CI and physiotherapy. It should also be acknowledged that this restriction also restricts the conclusions that can be drawn. From this review, we do not know which treatment is better than another, only which treatment is better than control, or which treatment has an additive effect to an underlying treatment that is common to both intervention groups. This should be acknowledged as a limitation within the discussion.</p> <p>In keeping with this, the results and discussion explicitly state 'compared with no treatment' or 'compared with placebo', etc.</p>
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REVIEWER	Aamir Siddiqui MD, FACS Division Head, Plastic Surgery Henry Ford Hospital Detroit MI USA
REVIEW RETURNED	02-Dec-2012

GENERAL COMMENTS	<p>Page 2 of manuscript (5/31) line 38. 'For topical NSAIDs, the conclusion is that it has a short term effect, whereas NSAIDs taken orally probably have a short-term effect [8].' Please rewrite this.</p> <p>Page 13 15/30 line 16. 'Our review strengthens this conclusion with the inclusion of a recently published study.' Although they explain why they did the study in the introduction, the rationale is less interesting based on the results. This review's findings do not represent anything new. The last review was 2010. They added one study to this review. Was this research really necessary? If their criteria are that much different than previous reviews, they should make their case in the discussion. Why should I read this article?</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: Leanne Bisset PhD

Research Fellow

Griffith University

Australia

No competing interests.

The statistical analyses in this paper are absent and/or inadequate and further work needs to be done to provide a summary of the effect size within and between interventions.

We have included statistics with calculation of relative risk and standard mean difference for outcomes and pooled the results where possible. See further comments below.

There is a mismatch between the aims and the methods, see comments to authors.

The aims of this systematic review are to assess the current evidence for the effects of corticosteroid injection and non-electrotherapeutic physiotherapy in tennis elbow (page 5, lines 39-42).

However, in its current form, the methods do not align well with this broad aim.

If I have interpreted the methods correctly, it appears that the aim of this review was to assess the efficacy of corticosteroid injection and non-electrotherapeutic physiotherapy, compared to a control (no treatment), in tennis elbow. The inclusion criteria for studies appears to exclude papers that have compared either of these interventions with other active interventions, such as exercise, electrotherapy, braces, or each other. As such, the broad aim of assessing the effectiveness of these interventions (CI and physio) is not valid, unless all comparisons, are included.

So, within the confines of this current paper, all comparisons between CI and physio should be excluded.

This has been clarified and changed – see ‘Introduction’

My following comments are based on the current methods:

Page 5, Objective: please change this statement to more accurately reflect the methods, e.g. ...'to assess the current evidence for the efficacy of corticosteroid injection and nonelectrotherapeutic physiotherapy, compared with control (no-treatment), in people with tennis elbow'.

This has been changed.

I suggest a change in the term 'effectiveness' to 'efficacy', mainly because your current aim is to see if the interventions of interest (CI and physio) have the capacity to produce an effect over and above a control condition, using RCT methodology. I refer you to J Orthop Sports Phys Ther 2003. 33(4):163-65

This has been corrected.

Methods:

Were the dates that were searched within each database restricted or unrestricted? Please explicitly state in the text.

This has been clarified in “Methods”

Page 7: there is mention that no assistance was provided by a librarian. This is unnecessary and could be removed.

This has been corrected.

Page 8, lines 25,26: You exclude study reference #41 (Vicenzino et al. 2001) on the basis that it was not a RCT. In fact, this study was a randomised, double-blind, placebo-controlled trial, with a repeated measures within-group design. This meant that participants acted as their own controls, they only received a single session of each intervention, and outcomes were only measured immediately post-intervention. Therefore, it is not valid to exclude this paper on the basis of randomisation. The same goes for a paper by Paungmali et al. (2003), which appears to be missing from your search. However, if the authors were seeking a longer follow up period, or a minimum number of treatment sessions as part of their inclusion/exclusion criteria, then this needs to be clearly stated in the inclusion/exclusion criteria.

This has been clarified by adding a minimal follow-up in the inclusion criteriae. The text in ‘Methods’ and Figure 1 has been changed to reflect this.

Can the authors explain why the following study was excluded from this review, given that the compactor group (oral NSAID) appears to meet the inclusion criteria:

• Saartok T, Eriksson E. Randomized trial of oral naproxen or local injection of betamethasone in lateral epicondylitis of the humerus. *Orthopedics* 1986; 9: 191–94.

This is because the follow-up was short, same as above, and the text and Figure 1 have been changed to clarify this.

There is no mention of data analyses. A systematic review should attempt to report relative effects between groups, using e.g. relative risk (95% CI) for dichotomous variables and standardised mean difference (95%CI) for continuous variables.

Where outcomes could not be pooled, the strength of evidence should be reported as either strong, moderate, conflicting, or no evidence (van Tulder M, Furlan A, Bombardier C, Bouter L. Updated method guidelines for systematic reviews in the cochrane collaboration back review group. *Spine* 2003; 28: 1290–99).

We have included statistics with calculation of relative risk and standard mean difference for outcomes and pooled the results where possible. Table 3 and 4 have been changed to reflect this, and we have added Forest-plots (Figure 2 and 3) of the outcomes and pooling.

Results.

What was the reliability between the two raters for quality assessment scores using the PEDro scale?

This has been added in 'Methods'

The results are reported in terms of timing of follow up – please define what you consider 'short' or 'long' term within the methods. Given that the outcomes for corticosteroid vary significantly between 3 and 12 months, I would recommend the authors include an 'intermediate' follow up period, in order to capture the true pattern of effect of this intervention.

This has been addressed in 'Methods, Data extraction and statistical analysis' and the tables 3 and 4 have been changed to include intermediate follow-up where available.

Page 9, lines 34-33: please include references for 6 studies that measured pain free grip, and the 7 studies that used questionnaires, etc.

This has been added and corrected (one study was missing).

Page 11, Physiotherapy: It is not correct to say that 'At one-year follow-up, there was no significant effect of manipulation and exercise on pain free grip strength and assessor severity rating.', as this implies no within-group effect. The authors need to carefully differentiate within-group and between-group effects. It is more correct to say 'At one-year follow-up, there was no significant difference between manipulation and exercise treatment and wait and see on pain free grip strength and assessor severity rating.'

As the methods have excluded papers that compare CI or physiotherapy with other active treatments, you should not make these comparisons within your results or discussion.

This has been corrected.

Table 2: Please include the excluded studies that did not meet the 50% cut-off.

The studies have been added to the table (Table 2).

Discussion.

Page 12 first paragraph, the authors cite that no comparisons could be made between studies on corticosteroid injections, due to differences in injection substance, dosages and injection techniques. Please include references to support this claim that these differences may influence outcomes. I would question the validity of this assumption, particularly when several studies have reported similar pattern of effect over time. Consistent findings across studies suggest that the substance, dose and technique may have little or no impact on the effect over time.

Page 13, lines 5-10: The authors claim to use 'stricter quality criteria' than those used in previous systematic reviews. Please describe in more detail which criteria were more strict in this current review, as that is currently not clear. I think the authors are referring to the restriction of included studies to efficacy studies for CI and physiotherapy.

This has been addressed in 'Introduction'.

It should also be acknowledged that this restriction also restricts the conclusions that can be drawn. From this review, we do not know which treatment is better than another, only which treatment is better than control, or which treatment has an additive effect to an underlying treatment that is common to both intervention groups. This should be acknowledged as a limitation within the discussion.

This has been addressed under 'Discussion, Potential bias in the review process'

In keeping with this, the results and discussion explicitly state 'compared with no treatment' or 'compared with placebo', etc.

This has been corrected and changed.

Reviewer: Aamir Siddiqui MD, FACS

Division Head, Plastic Surgery

Henry Ford Hospital

Detroit MI USA

Page 2 of manuscript (5/31) line 38 . ' For topical NSAIDs, the conclusion is that it has a short term effect, whereas NSAIDs taken orally probably have a short-term effect [8].' Please rewrite this.

This has been rewritten.

Page 13 15/30 line 16. 'Our review strengthens this conclusion with the inclusion of a recently published study.' Although they explain why they did the study in the introduction, the rationale is less interesting based on the results. This review's findings do not represent anything new. The last review was 2010. They added one study to this review. Was this research really necessary? If their criteria are that much different than previous reviews, they should make their case in the discussion. Why should I read this article?

We have now added statistical comparison of outcomes and added a recently published, high quality study which has not earlier been included in a systematic review.

VERSION 2 – REVIEW

REVIEWER	Leanne Bisset PhD Senior Lecturer Centre for Musculoskeletal Research Griffith University Australia I have no competing interests to declare.
REVIEW RETURNED	15-Aug-2013

THE STUDY	References 8-13 for the Cochrane systematic reviews are out of date - there are recent updates for Orthotics (2009), SWT (2009), Acupuncture (2013), NSAIDS (2013), Surgery (2011) and massage (2009).
RESULTS & CONCLUSIONS	<p>The Abstract aim should be more explicit: The aim of this review was to assess the current evidence for the efficacy of corticosteroid injection and non-electrotherapeutical physiotherapy compared with control in patients with tennis elbow</p> <p>Authors conclusions are not fully supported by the findings of this review: CI short-term benefit, intermediate-term worse; Manipulation/exercise – short-term benefit with no difference in the intermediate or long-term; So, why would you choose CI over manipulation/exercise?? Given that there is a natural history of recovery, it seems evident that manipulation/exercise gets people better faster, and without the intermediate negative consequences of CI. This review did not compare CI with manipulation/exercise, so no conclusions can be made as to which of these active interventions is superior over the follow-up period.</p> <p>Implications for research – why are more controlled trials needed on CI? It appears that the effects are very well documented, and consistent across several studies. The authors were able to pool intermediate follow-up data for measures of overall improvement, pain and grip strength, with consistent findings of a strong negative</p>

	<p>effect in CI compared to no treatment. This means that people who receive an injection are worse off in the intermediate term, than people who have no treatment, and no different in the long-term. Whereas, people who receive manipulation/exercise get better faster (superior in the short-term) and maintain that improvement over the intermediate and long-term, which is the time it takes for the control group to catch up.</p>
GENERAL COMMENTS	<p>Figure 2 and 3 – remove authors of papers where there is no representative data, e.g. Lindehovius, price, newcomer from the GI RR data for CI.</p>

VERSION 2 – AUTHOR RESPONSE

References 8-13 for the Cochrane systematic reviews are out of date - there are recent updates for Orthotics (2009), SWT (2009), Acupuncture (2013), NSAIDS (2013), Surgery (2011) and massage (2009).

RESPONSE: This has been corrected and the references updated.

in terms of accuracy of abstract and key messages, see comments below.

The Abstract aim should be more explicit: The aim of this review was to assess the current evidence for the efficacy of corticosteroid injection and non-electrotherapeutical physiotherapy compared with control in patients with tennis elbow

RESPONSE: This has been changed and made more explicit.

Authors conclusions are not fully supported by the findings of this review:

CI short-term benefit, intermediate-term worse;

Manipulation/exercise – short-term benefit with no difference in the intermediate or long-term;

So, why would you choose CI over manipulation/exercise?? Given that there is a natural history of recovery, it seems evident that manipulation/exercise gets people better faster, and without the intermediate negative consequences of CI.

This review did not compare CI with manipulation/exercise, so no conclusions can be made as to which of these active interventions is superior over the follow-up period.

RESPONSE: The paragraph “Author’s conclusions, Implications for practice” has been changed to reflect this point, in which we agree with the reviewer.

Implications for research – why are more controlled trials needed on CI? It appears that the effects are very well documented, and consistent across several studies. The authors were able to pool intermediate follow-up data for measures of overall improvement, pain and grip strength, with consistent findings of a strong negative effect in CI compared to no treatment.

This means that people who receive an injection are worse off in the intermediate term, than people who have no treatment, and no different in the long-term.

Whereas, people who receive manipulation/exercise get better faster (superior in the short-term) and maintain that improvement over the intermediate and long-term, which is the time it takes for the control group to catch up.

RESPONSE: We find that the evidence on the long-term efficacy of corticosteroid injection is conflicting with few high-quality studies. We have changed the paragraph to clarify our point.

Figure 2 and 3 – remove authors of papers where there is no representative data, e.g. Lindehovius, price, newcomer from the GI RR data for CI.

RESPONSE: We have changed this, and also removed the corresponding empty cells in Table 3 and 4.