Extracorporeal Shock Wave Therapy in treating calcific supraspinatus tendinopathy

By

WorkSafeBC Evidence-Based Practice Group

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Clinical Services – Worker and Employer Services

About this report

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About the Evidence-Based Practice Group

The Evidence-Based Practice Group was established to address the many medical and policy issues that WorkSafeBC officers deal with on a regular basis. Members apply established techniques of critical appraisal and evidence-based review of topics solicited from both WorkSafeBC staff and other interested parties such as surgeons, medical specialists, and rehabilitation providers.

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Background

The issue on the provision of extracorporeal shock wave therapy (ESWT) to treat tendinopathies among injured workers has been reviewed a number of times at WorkSafeBC.

In December 2002, with the availability of Sonocur® (a low energy shock wave device (ESWT)) in British Columbia, the Evidence-Based Practice Group (EBPG) conducted a systematic review as well as a pilot study investigating the effectiveness of Sonocur® in treating injured workers with lateral epicondylitis. At that time, it was concluded that there were conflicting results within the literature regarding the effectiveness of ESWT in treating patients with lateral epicondylitis. Further, our pilot study showed disappointing return-to-work outcomes among injured workers treated with ESWT.[15]

In September 2004, the EBPG was asked to re-visit our previous systematic review investigating the efficacy/effectiveness of ESWT in treating lateral epicondylitis. Given the wide spread application of ESWT in treating different tendinopathies, the EBPG investigated the efficacy/effectiveness of ESWT (high or low energy shock wave) in treating tendinopathies in general. In that first update, we concluded that:

- The evidence was still inconclusive in regard to the effectiveness of ESWT in treating patients with lateral epicondylitis
- For plantar fasciitis, there was no evidence (or inconclusive at best) for low energy ESWT. However, there was some evidence suggesting high energy ESWT was effective in treating patients with this condition
- For shoulder tendinopathy (with or without calcification), there was moderate evidence that low energy ESWT did not have any effect, while there was moderate evidence that high energy ESWT was effective.

That updated systematic review is posted here:
http://www.worksafebc.com/health_care_providers/Assets/PDF/eswt_First_update.pdf

Question

Recently, the EBPG was asked to investigate the efficacy/effectiveness of low energy ESWT (Sonocur®) in treating patients diagnosed with calcific supraspinatus tendinopathy. Given the availability of the evidence that we already posses on this topic, we decided to investigate the efficacy/effectiveness of ESWT (low and high level energy shock wave) in treating calcific supraspinatus tendinitis or rotator cuff tendinopathy in general.

Methods

- Through the EBPG regular literature surveillance on clinical topics that are of interest to the work of the Board, we had identified two systematic reviews[5,12] investigating the efficacy/effectiveness of ESWT (low and high energy shock wave) in treating rotator cuff tendinopathy.
- We critically appraised these two systematic reviews[5,12] and, based on our assessment of the methodological quality of the reviews, decided to update the older systematic review published by the Canadian Agency for Drugs and Technologies in Health (CADTH).[5] To update this systematic review:
    - A systematic literature search was conducted on June 15, 2010.
    - The search was conducted on commercial medical databases including the Cochrane Library (together with Cochrane Controlled Trial Registry and Cochrane Database of Systematic Reviews); BIOSIS Previews; EMBASE; MEDLINE and MEDLINE Daily Update; which are available through the OvidSP Interface.
    - Combination keywords employed in this search included: ((extracorporeal shockwave therapy) OR (extracorporeal shock-wave therapy) OR eswt) AND ((supraspinatus OR (rotator cuff OR rotator-cuff)) AND ((calcific OR calcinosis) AND (tendinitis OR tendinosis OR tendinopathy))).
    - The search was first limited to studies in humans.
    - Since the CADTH[5] review included primary studies published up to 2006, we further limited our literature search to include only articles published from 2006 to June 15, 2010. This search identified 10 articles.[1-10](Appendix 1) It should be noted that the CADTH review[5] was also identified in this search since it was published in 2007. However, the systematic review by Saithna et al.,[12] which was published in the journal "Current Orthopaedic Practice", was not identified in this search. It may be due to the fact that the journal "Current Orthopaedic Practice" is not indexed in Medline or PubMed databases (journal database search date: June 16, 2010).
    - Upon examination of the titles and abstracts of these studies,[1-10] eight[1,2,4-8,10] articles were retrieved in full for further appraisal. Of these 8 articles,[1,2,4-8,10] four were excluded due to relevancy[6] and being expert review articles.[2,7,10]
    - Manual searching of references of the (expert or systematic) review articles fully retrieved [2,7,10,12] was also undertaken. One study[11] was identified and retrieved in full as the result of this manual searching.
- Overall, two systematic reviews[5,12] and four primary studies[1,4,8,11] were critically appraised and are presented below.

Results

1. As part of CADTH's *Issues in Emerging Health Technologies* series, Ho[5] conducted a health technology assessment investigating the efficacy/effectiveness of ESWT in treating chronic rotator cuff tendinitis (shoulder pain). This CADTH systematic review-based health technology assessment (level of evidence 1. Appendix 2), which was based on primary studies published in the years 2000 – 2006, concluded that there was some evidence to support the use of high energy ESWT to treat chronic calcific rotator cuff tendinitis but not for non-calcific rotator cuff tendinitis. Further, Ho concluded[5] that studies comparing low energy ESWT to placebo or radiotherapy for non-calcific tendinitis showed no significant differences in pain or function between the groups over time. *It should be noted that, even though for this particular paper the EBPG could not assess the quality of this technology assessment paper in full, in general CADTH has always produced high quality systematic reviews.*

2. Saithna et al.[12] conducted a limited, in terms of sources of evidence and dates of publication, systematic review (level of evidence 1. Appendix 2) investigating the effect of ESWT in treating calcific tendinitis of the rotator cuff compared to placebo at six months post treatment. This systematic review employed Constant-Murley scores, a validated measure of shoulder outcomes assessment, as the outcome of interest. The authors searched for published randomized controlled trials (RCTs) indexed in PubMed and systematic reviews published in the Cochrane Database of Systematic Reviews between January 2003 and May 2008. Three RCTs fulfilled the inclusion criteria and were appraised further. Based on these RCTs, Saithna et al. concluded that, compared to placebo, there was evidence on the effectiveness of *high energy* ESWT in improving the Constant-Murley score of patients diagnosed with calcific tendinitis of the rotator cuff. The mean difference in the improvement of the Constant-Murley scores at six months ranged from 24-37 points *(out of a maximum Constant-Murley score of 100 points)*. *Even though we consider this limited systematic review to be of good quality, it should be noted that it is not clearly described how the authors chose the three primary RCTs included in this review. Further, their application of the CONSORT statement as a tool to appraise the primary studies may not be appropriate. The CONSORT statement is intended to provide standard guidelines for the reporting of RCTs. It is not intended to provide guidance in appraising RCTs. As such, even though Saithna et al.[12] provided a "CONSORT score" for each of the three primary studies, it is not clear if these scores provided an appropriate means to judge the quality of these RCTs.* Manual searching conducted on the references of this systematic review revealed an RCT by Hsu et al.[11] which was not covered by the CADTH technology assessment or found by our own systematic literature search. As such, this primary study by Hsu et al.[11] is appraised and discussed separately below.

3. Albert et al.[1] conducted an RCT (level of evidence 1. Appendix 2) investigating the efficacy of high energy ESWT *(energy flux density between 0.28 mJ/mm^2 to 0.60 mJ/mm^2)* compared to low energy ESWT *(energy flux density < 0.08 mJ/mm^2)* in treating calcific tendinitis of the rotator cuff. In this study, eighty patients were recruited and half were assigned to each of the treatment groups. At the end of a mean follow up of 110 days post treatment, the authors reported that the improvement from baseline of the Constant-Murley score (the primary end point) was significant in the high energy group with a mean gain of 12.5 points (range: -20.7 to 47.5 points). On the other hand, the improvement was not statistically significant in the low energy group, with a mean gain of 4.5 points (range: -24.4 to 39.3 points). *It should be noted that the Constant-Murley score range is up to 100 points*. The authors concluded that high energy ESWT significantly improved symptoms in patients with refractory calcifying tendinitis of the shoulder after three months follow up; however, the calcific deposits remained unchanged in size in the majority of patients. *Even though this RCT clearly described the randomization and blinding methods, in which sample size was also calculated and implemented properly, the statistical analysis employed in this study may not have been appropriate. The follow up time periods employed in this study varied between patients. These differences in the length of follow up may have influenced the primary outcome of interest in this study, the pain and functional levels. It should be noted that the authors did not take into account these differences in the statistical analysis, regardless of the fact that the statistical analysis, by default due to no loss in follow up, was done according to the intention to treat principle. Further, looking at the difference in the Constant-Murley scores (max score 100 points), within each group, at the end of follow up, these mean differences were 12.5 points and 4.5 points in the high energy and low energy ESWT groups, respectively. As such, the conclusions and outcomes provided in this good quality RCT need to be interpreted with caution.*

4. Hearnden et al.[4] conducted this small (n = 20) RCT (level of evidence 1. Appendix 2) investigating the efficacy of high energy ESWT vs. placebo in treating chronic calcific tendinitis of the supraspinatus tendon. They employed the Constant-Murley score and visual analog scale (VAS) of pain measurement at week one, six weeks and, presumably, six months post-intervention as the main outcomes of interest. The randomization process was appropriate and clearly described. *However, the authors did not provide any information on the balance in the baseline characteristics of the samples, which in all likelihood is very important since this is a very small study and a sample size calculation was not reported*. *Further, it is not clear whether blinding was achieved*. At six months post-intervention, the authors concluded that 45% of patients in the ESWT arm were satisfied with their outcome and had an increase in their Constant-Murley score of 11 points *(out of 100 points). Given the information available in this paper, it is difficult to assess this outcome since, regardless of the described randomization and given the size of*

the sample, it is not clear whether the intervention and control group had similar characteristics that would not necessitate statistical adjustment in investigating this outcome. As such, the conclusion of this study needs to be interpreted with caution.

5. This paper by Rebuzzi et al.[8] reported a "case-control" study (level of evidence 3. Appendix 2) comparing the efficacy of medium energy ESWT (energy density of 0.10 - 0.13 mj/mm^2) (24 cases. Group 2) against arthroscopic extirpation (22 cases. Group 1) in patients diagnosed with chronic homogenous calcific deposit in the supraspinatus tendon. *It should be noted that* p*atient allocation was done based on the willingness of a patient's insurance carrier to reimburse for ESWT.* The outcome of interest was measured by employing the UCLA rating for pain and function at 24 months. At 24 months, the mean score of the UCLA rating for pain and function improved in Group 1 from a mean of 9.4 to 30.3 and for Group 2 from a mean of 12.4 to 28.1. Comparison of the UCLA rating for pain and function at 24 months between these two groups was not statistically significant. Hence, the authors concluded that ESWT is equivalent to arthroscopy in reducing pain and improving function. *The conclusion of this study needs to be interpreted with caution due to potential biases (selection and measurement) and confounding unaccounted for in the design and analysis of this study. In this study, the authors did not clearly describe the underlying population from which this sample was drawn. Further, in this "case-control"-like study, the authors did not take into account other factors such as occupation, duration of illness or co-intervention, which may have affected the outcome of this study due to lack of randomization. Concerning the level of the ESWT energy, the authors classified it as low energy, however, due to the fact that there is still no consensus with regard to this level of energy classification,[5,13,14] we have considered it as medium level ESWT energy.*

6. Hsu et al.[11] conducted an RCT (level of evidence 1. Appendix 2) investigating the efficacy of high energy ESWT vs. placebo ESWT in treating patients diagnosed with calcific tendinitis of the shoulder. Thirty-three and thirteen consecutive patients diagnosed with chronic calcific tendinitis of the shoulder were "randomly" assigned to receive two sessions of high energy ESWT or sham ESWT, respectively. *The randomization conducted in this study should be considered as pseudo randomization since the systematic sampling of consecutive patients in blocks of three, without use of central randomization and blinding, might be known by the investigators. It is not clear whether the authors tried to mitigate or take this potential problem into account, especially in their outcome measurements.* Outcome, which was measured at baseline, six weeks, twelve weeks, six months, and one year post intervention, was measured by employing the Constant-Murley score. *It is not clear at which stage of measurement the designated primary outcome measurement was taken. This problem is confounded by the fact that there was no sample size calculation presented.* The authors presented

separately, in graphical format, the outcomes in pain and Constant-Murley scores, by comparing the ESWT and control groups at six weeks, twelve weeks, six months, and one year. The authors concluded that the ESWT results were good to excellent in 87.9% of the shoulders and fair in 12.1%; meanwhile the control results were fair in 69.2% and poor in 30.1%. *It is not clear, though presumably based on Constant-Murley score, how the authors categorized these outcomes. Further, it is not clear at what time frame these results were evaluated.*

Summary/Conclusion

- Calcific rotator cuff tendinopathy, which occurs in 7% to 17% of rotator cuff tendinopathies, is one cause of shoulder pain.
- Extracorporeal shock wave therapy (ESWT), which is an outpatient procedure, has been promoted as an alternative to surgical intervention in treating rotator cuff tendinopathy that does not respond to conventional conservative therapies.
- Even though the mechanism is still unclear, it is thought that ESWT provides long-lasting analgesia and stimulates the healing process in patients with rotator cuff tendinopathies.
- At present, there is some high level, low quality evidence on the efficacy/effectiveness of high energy ESWT in reducing pain and increasing function (as measured by Constant-Murley score) among patients diagnosed with calcific rotator cuff tendinopathy. At present, there is no evidence on the efficacy/effectiveness of ESWT in treating non-calcified rotator cuff tendinopathy.

References

1. Albert J.-D.; Meadeb, J.; Guggenbuhl, P.; Marin, F.; Benkalfate, T.; Thomazeau, H., and Chalcs, G. High-energy extracorporeal shock-wave therapy for calcifying tendinitis of the rotator cuff: A randomised trial. Journal of Bone and Joint Surgery - Series B. 89(3)(pp 335-341), 2007.

2. Casentino, R.; Pasquetti, P.; Galeazzi, M., and Marcolongo, R. Extracorporeal shock wave therapy for calcific tendonitis of the rotator cuff: A review. Current Rheumatology Reviews. 2(4)(pp 333-343), 2006.

3. Gosens, T. and Hofstee D.-J. Calcifying tendinitis of the shoulder: Advances in imaging and management. Current Rheumatology Reports. 11(2)(pp 129-134), 2009.

4. Hearnden, A. Desai A, Karmegam A, Flannery M. Extracorporeal shock wave therapy in chronic calcific tendonitis of the shoulder--is it effective? Acta Orthopaedica Belgica. 75(1):25-31, 2009 Feb.

5. Ho C. Extracorporeal shock wave treatment for chronic rotator cuff tendonitis (shoulder pain) [Issues in emerging health technologies issue 96 part 3]. Ottawa: Canadian Agency for Drugs and Technologies in Health:2007. Downloaded from http://www.cadth.ca/media/pdf/E0013_chronic-shoulder-pain-part3_cetap_e.pdf on June 15, 2010.

6. Lorbach, O.; Kusma, M.; Pape, D.; Kohn, D., and Dienst, M. Influence of deposit stage and failed ESWT on the surgical results of arthroscopic treatment of calcifying tendonitis of the shoulder. Knee Surgery, Sports Traumatology, Arthroscopy. 16(5):516-21, 2008 May.

7. Mouzopoulos, G.; Stamatakos, M.; Mouzopoulos, D., and Tzurbakis, M. Extracorporeal shock wave treatment for shoulder calcific tendonitis: a systematic review. Skeletal Radiology. 36(9):803-11, 2007 Sep.

8. Rebuzzi, E.; Coletti, N.; Schiavetti, S., and Giusto, F. Arthroscopy surgery versus shock wave therapy for chronic calcifying tendinitis of the shoulder. Journal of Orthopaedics and Traumatology. 9(4)(pp 179-185), 2008.

9. Seil, R.; Wilmes, P., and Nuhrenborger, C. Extracorporeal shock wave therapy for tendinopathies. Expert Review of Medical Devices. 3(4):463-70, 2006 Jul.

10. Sems, A.; Dimeff, R., and Iannotti, J. P. Extracorporeal shock wave therapy in the treatment of chronic tendinopathies. Journal of the American Academy of Orthopaedic Surgeons. 14(4):195-204, 2006 Apr.

11. Hsu CJ, Wang DY, Tseng KF et al. Extracorporeal shock wave therapy for calcifying tendinitis of the shoulder. Journal of Shoulder and Elbow Surgery. 2008;17:55-59.

12. Saithna A, Jenkinson E, Boer R et al. Is extracorporeal shockwave therapy for calcifying tendinitis of the rotator cuff associated with a significant improvement in the Constant-Murley score? A systematic review. Current Orthopaedic Practice. Sept-Oct 2009;20(5):566-571.

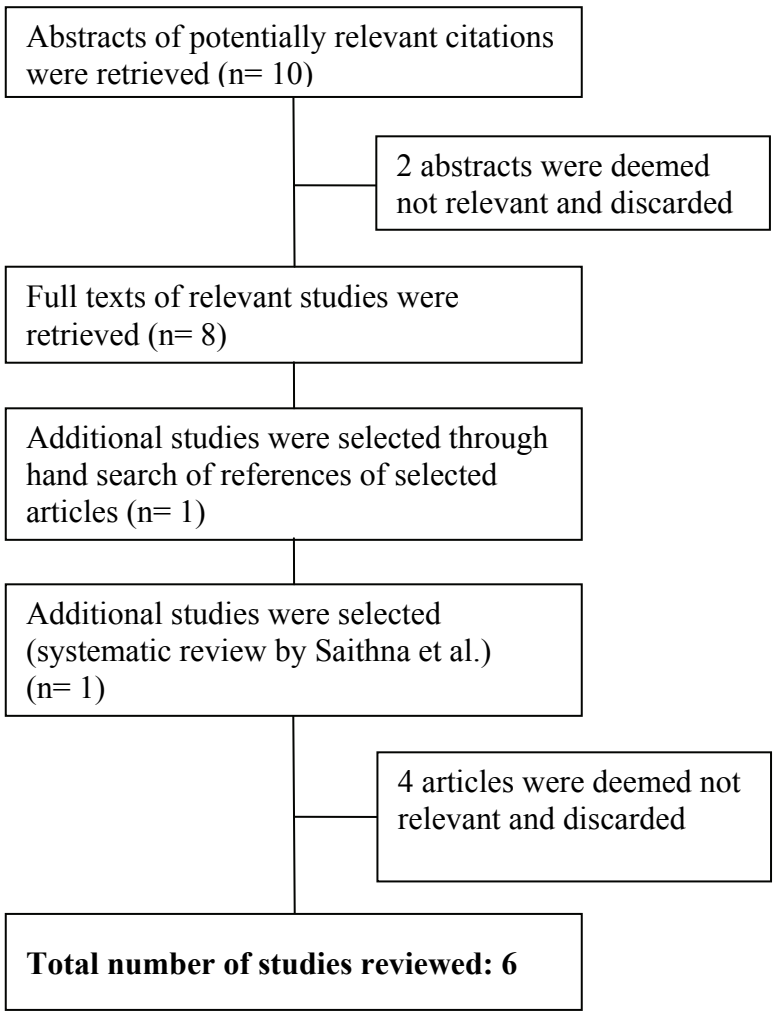
13. Chung B and Wiley JP. Extracorporeal shockwave therapy. A review. Sports Medicine. 2002;32(13):851-865.

14. Rompe JD, Kirkpatrick CJ, Mullmer K et al. Dose-related effects of shock waves on rabbit tendo Achillis. A sonographic and histological study. Journal of Bone and Joint Surgery. British edition. 1998;80-B:546-552.

15. WorkSafeBC Evidence-Based Practice Group. Extra Corporeal Shockwave Therapy (Sonocur®) in Workers with Lateral Epicondylitis. Richmond, BC; May 2003. Available at: http://www.worksafebc.com/health_care_providers/Assets/PDF/extracorporeal_shock_wave_therapy.pdf

Appendix 1

Flow diagram (Study selection)



Appendix 2

WorkSafeBC Evidence-Based Practice Group levels of evidence [adapted from 1,2,3,4]

1	Evidence from at least 1 properly randomized controlled trial (RCT) or systematic review of RCTs.
2	Evidence from well-designed controlled trials without randomization or systematic reviews of observational studies.
3	Evidence from well-designed cohort or case-control analytic studies, preferably from more than 1 centre or research group.
4	Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments could also be included here.
5	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

References

1. Canadian Task Force on the Periodic Health Examination: The periodic health examination. CMAJ. 1979;121:1193-1254.
2. Houston TP, Elster AB, Davis RM et al. The US Preventive Services Task Force Guide to Clinical Preventive Services, Second Edition. AMA Council on Scientific Affairs. American Journal of Preventive Medicine. May 1998;14(4):374-376.
3. Scottish Intercollegiate Guidelines Network (2001). SIGN 50: a guideline developers' handbook. SIGN. Edinburgh.
4. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. CMAJ. Aug 5, 2003;169(3):207-208.