Is Radial Shock Wave Therapy effective for subjects with subacute or chronic tendinopathy?

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Summary

This study investigates the effect of Radial Shock Wave Therapy (RSWT) on 38 subjects suffering subacute and chronic tendinopathy. All subjects are treated once a week for four weeks with high energy shock wave (> 20 mJ/mm²). The effect was measured by the use of the Likert Scale. Outcomes on pain were measured by Visual Analogue Scale (VAS) and by the Numerous Rating Scale (NRS). The results of this study show that RSWT might be an effective treatment on chronic tendinopathy (N=19) and on subacute tendinopathy (n=14). Significance is not found in both groups (P<0.05). This study also describes parameters for dosage, prognostic factors and practical implementation for the use of RSWT in (sports) physiotherapy.

Samenvatting

In deze studie is het effect van Radial Shock Wave Therapy (RSWT) onderzocht bij 38 proefpersonen met subacute en chronische tendinopathie klachten. Alle proefpersonen zijn een keer per week behandeld gedurende 4 weken met high energy shock wave (> 20 mJ/mm²) doseringen. Uitkomsten ten aanzien van het behandelresultaat zijn gemeten door gebruik te maken va de Likert-scale. Om de Uitkomsten met betrekking tot pijnafname te meten is gebruik gemaakt van de VAS. De resultaten van deze studie tonen aan dat RSWT een effectieve behandelmethode kan zijn bij chronische tendinopathie (N=19) en bij subacute tendinopathie klachten (N=14). In beide groepen is geen statistische significantie gevonden (P<0.05). Deze studie geeft daarnaast een aantal aanbevelingen inzake de behandelparameters zoals dosering, prognostische factoren en praktische implementatie van RSWT in de (sport) fysiotherapie setting.

Introduction

Since the introduction of Extracorporal Shock Wave Therapy (ESWT) many studies describe the efficacy of this "new" treatment in physiotherapy. Several authors conclude that the effect of ESWT is contradictory (Rompe et. al., 2007, Thomson et. al., 2005). Randomised Clinical Trials (RCT's) from 1999 to 2008 were included and tested on methodological quality. To verify the internal validity and the statistical data the Physiotherapy Evidence Database (PEDro)-guidelines are used (http://www.pedro.org.au/). The Pedro guidelines are based on the Delphi-guidelines and exist of 10 items tot verify the methodological quality of an RCT. The outcome of the score on the PEDro guidelines were classified as bad (n=1), moderate (n=2), fair (n=6) and high (n=4). The four studies that were classified as "good" showed no effect in favour of ESWT compared to stretching exercises[1], to eccentric training[2], to radiotherapy[3] nor to conservative treatment[4]. Furthermore literature showed no consensus of useful guidelines for the use of ESWT such as frequency of treatment, the dosage, the duration of the complaints (subacute; 6-12 weeks or chronic; more than 12 weeks[5] nor the number of treatment sessions. This study tries to test the effect of RSWT on several locations diagnosed with chronic or subacute tendinopathy (achilles, patellar, supraspinatus, lateral elbow and plantar fasciitis). For physiotherapy applications the use of RSWT and ESWT is introduced. ESWT devices contain converging focussed shockwaves. Maximum energy is reached at a specific focal point in the body. These devices produce a medium to high energy level. RSWT devices contain radial diverging shockwaves. The energy is spread over a large surface area. These devices produce a low to medium energy level.[6] In this study the use of RSWT is applied.

Materials and methods

Thirty-eight subjects are included for this pilot study in the period of January 1st 2008 to July 15th. The subjects are included by direct access physiotherapy in the Netherlands by referral from a general practitioner, they are at least 18 years old, suffer for more than 6 weeks of tendinopathy complaints, have aggravation of pain by movement and did not underwent surgery the last 12 months. Subjects

are excluded if they received corticosteroid injections the last 6 months. Informed consent was obtained. The subjects were divided in two groups. Group one consists of subjects suffering 6-12 weeks (subacute pain) and group two consists of subjects suffering more than 12 weeks (chronic pain). The outcomes on pain are measured by NRS scores before and after each treatment session. VAS scores are used before and after the treatment period of four weeks. General assessment is scored by the subject on a 6-point Likert scale, which measures the extent to which a person agrees or disagrees with a statement. The scale used is 1 to 6, with 1 being completely recovered; 2, much improved; 3, little improved; 4, unchanged; 5, a little worse; 6, much worse compared with baseline. For the computation of success rates, subjects who rate themselves 1 (completely recovered) or 2 (much improved) were counted as success.[7] The Likert scale is a valid scale to measure the effect of an intervention.[8] All subjects suffer from a tendinopathy at the achilles, patella, lateral elbow, shoulder or due to plantar fasciitis. Diagnosis is made by a general practitioner or physiotherapist on palpation and by the duration of the complaints.

The definition of tendon complaints that exist for several weeks is not common. Subjects suffering with tendon problems longer than 6 weeks are defined as tendinopathy.[9] Most tendon injuries take place in sports and there has been a general increase in the popularity of sporting activities, the number and incidence of tendon overuse injuries have increased in the industrialized countries during the last few decades. The term "paratendinopathy" is also used in clinical practice to describe activity-related pain combined with tenderness on palpation, providing that there is no suspicion of intratendinous pathology on the basis of patient history, clinical examination, or imaging examinations.[10] In this study the definition of tendinopathy is used. Subjects were excluded from this study if they had received corticosteroid injections during the last 6 months. The subjects nor the assessors or therapists were blinded. Subjects were allowed to participate in sports and in daily life activities. Thirty-eight subjects passed the inclusion and exclusion criteria and were enrolled in this trial. Eighteen men and twenty women are included in this trial, with a mean subject age of 42 (range, 18-61 years; SD 11,9). Sixteen subjects had complaints for 6-12 weeks and twentytwo for 12 weeks or more. Both groups were treated by the use of a masterpuls MP 100 from Gymna Uniphy, which is often used by physiotherapists in the Netherlands and Belgium. Conducting gel was applied to the site of pain, and the treatment head of the machine was placed in the point of maximum pain as identified by the subject. Localisation by clinical focussing, in which the shock waves are directed to the most painful area with the aid of subject feedback, seem the most reliable.[14]

Shockwave protocol

Each subject is treated by a protocol from Gymna Uniphy with 2800 shocks per session. 150 shocks are given at 1,5 bar power level, 150 shocks at 2 bar power level, 500 shocks at 2,5 bar power level at slow speed and 2000 shocks at 2,5 bar power level at high speed. Loew et al,[11] show in their study that it is useful to differentiate low-energy shock waves of less than 0.1 mJ/mm² from high-energy shock waves of 0.2 to 0.4 mJ/mm². The dosage used in this pilot-study corresponds to high-energy shock wave because of the maximum energy density of 0,22 mJ/mm². Each subject is treated once a week with RSWT only.

Table 1. Classification on result by outcome on the Likert scale

Score:	description Likert scale	Classification on result
1	Complaints disappeared completely	Good
2	Strongly reduced complaints	Good
3	Reduced complaints	Bad
4	Complaints did not change	Bad
5	Increased complaints	Bad
6	Complaints increased a lot	Bad

The treatment period is divided in four treatment sessions that take place during four continues weeks. After the treatment sessions the subjects had two weeks of non-treatment. After 6 weeks the subjects are asked to fill out the VAS score and the Likert scale. The Likert scale is allocated to 6 scores (table 1). The treatment was stopped for the subjects who scored 1 or 2 on the Likert scale. Scores of 3 or more led to 4 extra treatments with RSWT with the same dosage. After those treatments the subjects were asked to fill out the VAS score and the Likert scale again. If subjects still have complaints after 8 treatments the RSWT application stopped.

Results

Thirty-eight subjects are enrolled, sixteen in the subacute group and twenty-two in the chronic group. Two subjects are excluded due to missing rates. The included thirty-six subjects had a mean age of 42 (range, 18-61 years; SD 11,9). Thirty subjects are treated for four sessions with RSWT and six subjects are treated for eight sessions with RSWT. Two subjects are excluded by SPSS due to missing rates. They were treated 8 times and were included in the subacute tendinopathy group.

General outcomes

Thirty subjects report a Likert scale of 1 or 2 points after the first treatment period (84,2%). The subjects (n=6) without positive effect on the first treatment period are given a second treatment period of 6 weeks. One of these subjects scores 2 points on the Likert scale

after 4 more treatment sessions. This subject is enrolled in the patellar tendon group. The other subjects (n=5) scored 3 or 4 points and are divided over chronic achilles tendinopathy (n=1), chronic supraspinatus tendinopathy (n=1) subacute lateral elbow tendinopathy (n=2) and chronic lateral elbow tendinopathy (n=1).

Subacute outcomes

Sixteen subjects (42,1%) are enrolled with subacute tendinopathy. Two subjects are lost due to missing ranks. Eleven subjects score 1 (n=1) or 2 (n=9) points on the Likert scale after the first treatment period (78,5%). Three subjects score 3 (n=1) or four points (n=2). After 4 more sessions with RSWT one more subject score 2 points. Twelve subjects score 1 or 2 points after RSWT treatment (87,6%). The general outcomes are shown in table 2.

Chronic outcomes

Twenty-two subjects (57,9%) are enrolled with chronic tendinopathy. Nineteen subjects score 1 (n=4) or 2 (n=15) points on the Likert scale after the first treatment period (86,4%). Three subjects score 3 (n=1) or 4 (n=2) points. After 4 more treatment sessions no improvement occurrs for those subjects. The general outcomes are shown in table 2.

Table 2: General outcomes on chronic and subacute complaints after treatment with RSWT

Region_Complaints * Effectivity_of_treatment * Complaints Crosstabulation

Complaints				Effectivity_of_treatment				Total
				complaints completely disappeared	complaints strongly reduced	complaints reduced	complaints did not change	
Subacute	Region_Complaints	Lateral elbow	Count	0	3	1	1	5
			% within Region_Complaints	.0%	60.0%	20.0%	20.0%	100.0%
			% of Total	.0%	21.4%	7.1%	7.1%	35.7%
		Supraspinatus	Count	1	1	0	0	2
			% within Region_Complaints	50.0%	50.0%	.0%	.0%	100.0%
			% of Total	7.1%	7.1%	.0%	.0%	14.3%
		Fasciitis plantaris	Count	0	5	0	0	5
			% within Region_Complaints	.0%	100.0%	.0%	.0%	100.0%
			% of Total	.0%	35.7%	.0%	.0%	35.7%
		Patellar tendon	Count	0	1	0	1	2
			% within Region_Complaints	.0%	50.0%	.0%	50.0%	100.0%
			% of Total	.0%	7.1%	.0%	7.1%	14.3%
	Total		Count	1	10	1	2	14
			% within Region_Complaints	7.1%	71.4%	7.1%	14.3%	100.0%
			% of Total	7.1%	71.4%	7.1%	14.3%	100.0%
Chronic	Region_Complaints	Lateral elbow	Count	0	3	1	0	4
			% within Region_Complaints	.0%	75.0%	25.0%	.0%	100.0%
			% of Total	.0%	13.6%	4.5%	.0%	18.2%
		Supraspinatus	Count	0	4	0	1	5
			% within Region_Complaints	.0%	80.0%	.0%	20.0%	100.0%
			% of Total	.0%	18.2%	.0%	4.5%	22.7%
		Fasciitis plantaris	Count	1	3	0	0	4
			% within Region_Complaints	25.0%	75.0%	.0%	.0%	100.0%
			% of Total	4.5%	13.6%	.0%	.0%	18.2%
		Achilles tendon	Count	2	4	0	1	7
			% within Region_Complaints	28.6%	57.1%	.0%	14.3%	100.0%
			% of Total	9.1%	18.2%	.0%	4.5%	31.8%
		Patellar tendon	Count	1	1	0	0	2
			% within Region_Complaints	50.0%	50.0%	.0%	.0%	100.0%
			% of Total	4.5%	4.5%	.0%	.0%	9.1%
	Total		Count	4	15	1	2	22
			% within Region_Complaints	18.2%	68.2%	4.5%	9.1%	100.0%
			% of Total	18.2%	68.2%	4.5%	9.1%	100.0%

Table 5: Outcomes on statistical analysis by t-test for equality of means

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
subacute	Equal variances assumed	.129	.722	-1.698	34	.099	-13.753	8.099	-30.213	2.706
	Equal variances not assumed			-1.713	28.626	.098	-13.753	8.029	-30.184	2.678
chronic	Equal variances assumed	1.014	.321	.999	34	.325	6.409	6.417	-6.632	19.451
	Equal variances not assumed			.996	27.567	.328	6.409	6.436	-6.784	19.602

This RCT scored 8/10 points on the PEDro item-list on methodological quality. Another recent RCT of Rompe et al.[2] showed that heavy load training is as effective as the treatment with ESWT on achilles tendinopathy. This RCT scored 8/10 points on the PEDro item-list. Gross et al.[3] showed that there is no statistically significant difference between ESWT and radiotherapy in calcifying tendinopathy of the shoulder. This RCT scored 7/10 on the PEDro item-list. Malay et al.[4] showed that ESWT is both efficacious and safe for patients with chronic proximal plantar fasciitis. This RCT scored 7/10 points on the PEDro item-list. A review from Thomson et al.[13] including high quality trials on plantar heel pain showed no statistically significant effect. Rompe[14] identified conflicting results in a review including 17 studies. A pilot-study by Dekker et al.[15] showed positive effects on pain and function on recreational sportsmen with chronic fasciitis plantaris. Other recent studies from Furia et al.[16], Consentoni et al.[17] and Wang et al.[18] showed that ESWT is an effective treatment for achilles tendinopathy, calcifying tendinitis of the shoulder and for plantar fasciitis. Those studies unfortunately lack methodological quality. Furthermore it shows that parameters as frequency of treatment, dosage, duration of complaints and number of treatment sessions are poorly described in literature. In this study a useful frame was set by introducing a protocol that might be used in physiotherapy practices in Holland and Belgium. This trial has some limitations. In the current pilot study, both RSWT on subacute and on chronic tendinopathy led to successful outcomes in 78,5% of subacute subjects and 86,4% of chronic subjects. A slight better level of significance was found on Likert scale outcomes at subacute tendinopathy complaints (p=0.236) over chronic tendinopathy complaints (p=0.623). On Vas scores subjects with chronic tendinopathy complaints scored slightly better (p=0.312) than subjects with subacute tendinopathy complaints (p=0.722). Statistical significance was nevertheless not found for Likert Scale outcomes nor for VAS and NRS scores. Having been designed pragmatically in a physiotherapy practice in Holland, blinding of subjects, therapists and assessors was not possible due to ethic reasons. Another weakness is the small number of patients included. This can be one of the reasons that no statistic significance was found. Moreover the study protocol lacks a control group. It is recommended to include more subjects and blinding of therapists, assessors and subjects. The use of a sham group (placebo), intention to treat analysis and a follow-up might be useful to obtain a higher outcome on methodological quality. Nevertheless it seems that RSWT could be an effective treatment for both subacute and chronic tendinopathy complaints. Practically, improvements in technology have helped make RSWT a less expensive and quicker procedure than in the past. RSWT generating devices, in particular, are now much less expensive to purchase and to operate. A single RSWT session takes only 10 minutes and is now affordable for most practices and may be used more often in (sports) physiotherapy.

Conclusion

RSWT is not statistically significant in our study. Moreover it is not clear if the effect on subacute and chronic outcomes in patients with tendinopathy for more than 6 weeks is due to the RSWT as no control group is available. Although 87,6% of the subacute subjects and 86,%

Table 3: Statistical outcomes on Likert Scale

Chi-Square Tests

Complaints		Value	df	Asymp. Sig. (2-sided)
Subacute	Pearson Chi-Square	11.620[a]	9	.236
	Likelihood Ratio	10.021	9	.349
	Linear-by-Linear Association	.095	1	.757
	N of Valid Cases	14		
Chronic	Pearson Chi-Square	9.918[b]	12	.623
	Likelihood Ratio	10.748	12	.551
	Linear-by-Linear Association	1.580	1	.209
	N of Valid Cases	22		

a. 16 cells (100.0%) have expected count less than 5. The minimum expected count is .14.

b. 20 cells (100.0%) have expected count less than 5. The minimum expected count is .09.

In this study scores of 1 or 2 points on the Likert scale match with a positive effect of RSWT (Rompe, 2007). A statistical analysis is done by the use of crosstabs and a chi-square test. Values are considered to reach statistical significance at P< 0.05. Results are shown in table 3. After treatment, however, no statistically significance was observed on the outcomes of the Likert scale for nor the subacute group, nor the chronic group (P=0.236 on subacute subjects and p=0.623 on chronic subjects).

NRS and VAS scores

The outcomes on mean VAS scores show that pain reduces due to RSWT application. Mean, median, mode and standard deviation are shown in table 4. A statistical analysis is done by the use of an independent t-test for equality of means. SPSS software is used. Values are considered to reach statistical significance at P< 0.05. This study shows that there is no statistically significance found on reduction of pain by the use of a VAS scale. The level of significance for subacute tendinopathy is found p=0.722 and for chronic tendinopathy p=0.321. Results are shown in table 5. An overview of the spreading of VAS scores is shown in figure 1 and figure 2.

Table 4: Main outcomes on VAS scores

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Soort_Klacht * Effectiviteit_behandeling * Duur_klachten	36	94.7%	2	5.3%	38	100.0%

The main outcomes on NRS show that only slight improvements are made within one treatment session. Mean scores of the NRS varify from 5,0 at baseline to 1,9 after 4 treatment sessions. Since mean VAS scores improve from 50 to 12 and no significance was found, the conclusion was made that NRS scores could never be statistically significant for the same population.

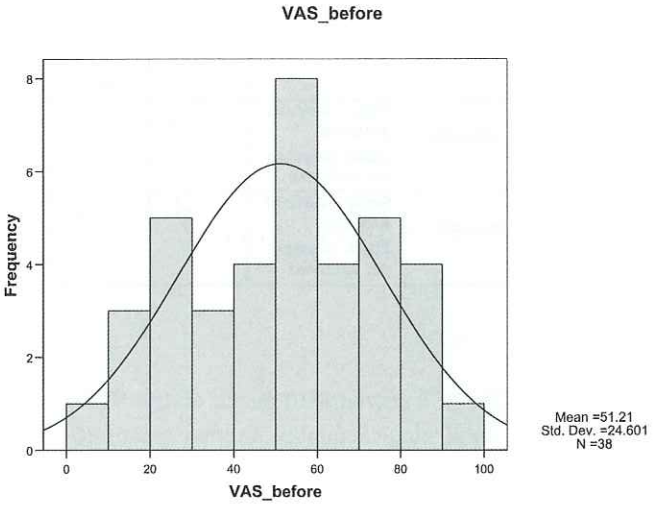

Figure1: Spreading of VAS scores before treatment with RSWT

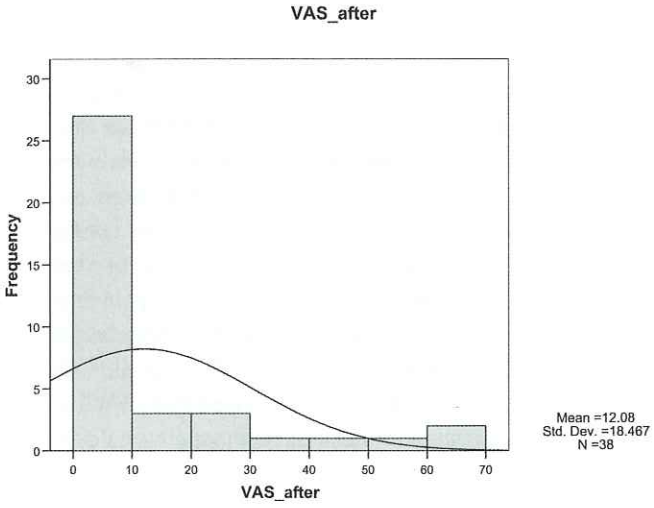

Figure2: Spreading of VAS scores before treatment with RSWT

Discussion

Causes and pathogenesis of tendon pain are unknown and management remains difficult.[7] Several studies on eccentric training show excellent short-term results in patients with tendinopathy.[14] There is contradictory evidence on the effect of ESWT on tendinopathy in literature. A few studies of high methodological quality, scored on the Pedro item-list, show conflicting evidence. Chung et al.[12] show that the use of ESWT in combination with stretch exercises is not effective on lateral elbow tendinopathy.

of the chronic subjects scored 1 or 2 points on the Likert scale. Mean VAS scores improved from 50 to 12 mm, statistical significance is not found (P<0.05). VAS scores of (p=0.312) are found in subjects with chronic complaints and VAS scores of (p=0.722) are found in subjects with subacute tendinopathy complaints. On Likert scale outcomes also statistical significance was not found at subjects with chronic complaints (p=0.623) nor on subjects with subacute complaints (p=0.236). Because of the small number of patients in this pilot study probably statistical significance is not found. Solid statements on outcomes cannot be made. Further studies, with the use a sham group, and a larger population are needed to prove the effect of RSWT as a treatment in (sports) physiotherapy.

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