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COMPARISON OF ASTYM THERAPY AND KINESIOTAPING FOR ROTATOR CUFF TENDINOPATHY IN DIABETIC PATIENTS: RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Rotator cuff tendinopathy is a significant problem among diabetics that frequently restricts patient's activity in terms of pain and disability. The purpose of this study was to compare between the effect of Astym therapy and kinesiotaping in treating diabetic patients with chronic rotator cuff tendinopathy.

Methods: 56 diabetic patients diagnosed with chronic rotator cuff tendinopathy were randomly assigned into Astym therapy group (n=28) or kinesiotaping group (n= 28). All patients received conventional program in addition to Astym treatment or Kinesiotaping for 24 sessions (2times/week). Patients were assessed at baseline and at the end of corresponding intervention with visual analogy scale (VAS) for pain intensity, shoulder disability questioner (SDQ) for shoulder disability, and electrogoniometer for shoulder range of motion.

Results: For the 56 study participants (21 males and 35 females; mean age=41.9±6.9) years there were significant differences in all measuring outcomes in both group when compared to baseline measurements (p<0.05). Post treatment comparison showed a significant reduction in pain score in favour of kinesio taping group with no significant differences in SDQ score or active shoulder range of motion between the two groups (p > 0.05).

Conclusion: kinesiotaping appears to be more effective than Astym therapy in reducing pain for diabetic patients with chronic rotator cuff tendinopathy.

Keywords: Diabetes, Rotator cuff tendinopathy, Astym Therapy, Kinesiotaping.

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INTRODUCTION

Diabetes mellitus is one of the of metabolic diseases portrayed by hyperglycemia due to insufficient secretion of insulin and/or impaired insulin activity [1]. It has been postulated that up to 50% of diabetics drop out of lifestyle interventions because of their diabetes-related health complications [2]. Rotator cuff (RC) tendinopathy is a frequent musculoskeletal consequence of long lasting diabetes. However the obvious relation between diabetes and prevalence of tendinopathies still remain unclear, nevertheless, two systematic reviews emphasize the possible connection between diabetes and tendon degeneration in various parts of the body [3, 4].

Pain and functional disability associated with RC tendinopathy have an impact on patient's functional activities and performance; posing a major social and economic burden [5]. The main objective of conservative rehabilitation of RC tendinopathy is to gain a coordinated shoulder joint function with a pain free range of motion .Whereas several treatments have been employed in the management RC tendinopathy, the optimal treatment has not been conclusively approved [6]. Astym therapy is non-invasive emerging therapeutic techniques that modulate soft tissue dysfunction aiming to repair the pathologic structural changes of the tendon and encompassing tissues. This type of treatment includes specific protocols and instrumentation that was designed to provide appropriate tactile pressures and shear forces to the affected soft tissue structures to stimulate tissue healing at cellular level [7]. Hypothetically, Astym therapy induces leakage from dysfunctional capillaries that ends up with increased fibroblast activity, macrophage phagocytosis, and local growth factors released that enhanced more fibroblast recruitment [8].

The primary evidence from in vivo study in 1999 believed that Astym therapy is engage the body regenerative mechanisms in order to release scar tissue, improve tissue turnover, and remodeling of soft tissue[8]. It has also been proposed to reduce pain and restore function in people with musculoskeletal pathologies including epicondylitis [9]. The limited information on Astym application recommends improved joint range of motion, soft tissue integrity, and functional activities in patients with stiff total knee arthroplasty[10], hamstring muscle tendinopathy [11], and rehabilitation following mastectomy[12] respectively. This information supported by limited case studies so they have lower levels of significant clinical evidence.

Recently, the utilization of Kinesiotaping (KT) has become progressively prominent as a sort of cure and prevention of different types of sports injuries. KT has been intended to impersonate the qualities of human skin. KT has an indistinguishable thickness from the epidermis layers of the skin and can be stretched somewhere around 30% and 40% of its original length longitudinally without losing its properties [13]. Several effects of kinesiotaping have been proposed based on the degree of stretch applied through application that include : (1) providing a positional awareness through the skin (2) creating extra space by raising

soft tissue over area of tenderness and/or inflammation, (3) releasing facial tissues adhesions,(4) enhancing sensory stimulation that facilitate or restrict motion (5) Directing exudates toward a lymphatic circulation [14].However, a negligible evidence exists to bolster the utilization of kinesiotaping for musculoskeletal dysfunction [15, 16].

As the reduction of pain and restore upper extremity functions remain the major clinical aims of RC tendinopathy management, it is critical to identify which approach offers the best treatment. While Astym therapy and Kinesiotaping should theoretically revealed acceptable results, there is a dearth of literature that comparing effects of these two techniques for patients with tendinopathy. Therefore, the purpose of this study was to compare the effects of Astym therapy and kinesiotaping in diabetic patients with chronic RC tendinopathy.

MATERIALS AND METHODS

This study is a single blind randomized controlled trial to evaluate the effectiveness of Astym therapy versus Kinesiotaping for diabetic patients with chronic RC tendinopathy (AEARCTR-0001506). The study was approved and conducted between 2014 and 2015 in accordance to the guidelines of the local ethics committee of the Physical Medicine and Rehabilitation center for armed forces, Giza, Egypt.

Sample size

The sample size was calculated prior study providing 80% power and differences of 15mm on visual analogue scale with 20mm SD at 95% CI. Sample size calculation was based on previous studies [16, 17]

A sample of 60 diabetic patients were diagnosed with chronic RC tendinopathy by referring physician, were selected from outpatient clinic of the military hospital. Eligibility criteria were: age between 30-55 years, diagnosis of type II diabetes more than 2 years ago, all patients had <12% on their most recent (HbA1c) test (through last 3 months) and the blood glucose level ranges between 100 - 250 mg/dL at the time of study engagement [18], minimum six-month period of painful shoulder, tenderness over the glenohumeral joint region , +ve empty can test, pain with one of the resistance tests: abduction, external rotation, internal rotation or flexion, painful arc with active abduction or flexion. Exclusion criteria include: history of frozen shoulder, shoulder instability, calcified tendonitis, shoulder surgery and/or radiated cervical pain. also patients who received physical therapy program within last 3 month were not allowed to participate in this study.



Figure 1: Astym therapy application



Figure 2: kinesiotaping application

After informed consent and base line assessment, patients were assigned by a random-number generator to one of two intervention groups through concealed allocation : Astym therapy group (n=28) and Kinesiotaping group (n=28) fig 3. Patients were asked to decline any additional form of treatment for their shoulder during the course of the study .Also they were instructed to maintain current levels of medication and not to begin any new medications. All participants received conventional physical therapy program for shoulder pain, that include: hot packs for 20 mint/session and exercises in the form of strengthening exercises for the trapezius, serratus anterior and shoulder external rotation in addition to stretching for pectoralis muscles two times a week for 12 weeks.

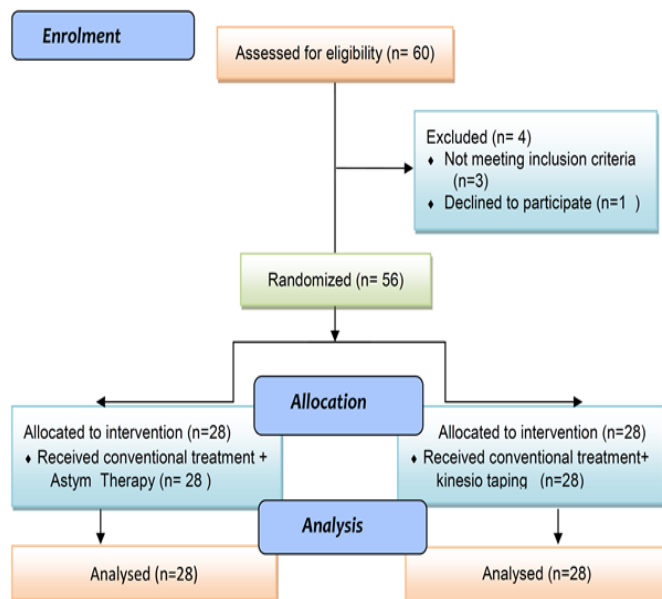


Figure 3 Flow chart of the 60 patients through the study

Patients enrolled to the Astym treatment group were seen two times per week for twelve weeks, two days were allowed between sessions for adequate response to Astym therapy regenerative stimulation. Each session followed the protocol described in the Astym clinical manual and lasted approximately 15–20 minutes. During Astym session ,the therapist applied a gentile gliding strokes over the skin while utilizing a lubricant (cocoa butter) to decrease the friction coefficient [19]. Therapist primarily moved the used instrument through a process of systematic strokes along the involved area in the direction of the underlying soft tissues for detection of rough or improperly organized

area. Once a potential area is identified, appropriate shear force and pressure was applied to stimulate a reparative cellular reaction in dysfunctional tissue[11]. The applied storks should be progressed with decreasing areas of surface contact during successive sessions. Astym therapy was conducted while patient in comfortable sitting position without back support with the involved limb supported over the treatment table to provide access for the proximal muscles insertion. Astym treatment application can be uncomfortable for some patients but is generally well tolerated.

Patients in kinesiotaping group received standardized protocol suggested by Kase et al 2002 for rotator cuff tendonitis/impingement. Standard Kinesiotaping with five cm width was used for all participants in this group. The skin was first cleaned with alcohol to aid adherence of the tape. KT application included deltoid and supraspinatus muscles inhibition techniques and glenohumeral joint mechanical correction technique. KT application for muscle inhibition were conducted with 10–15 % tension from the insertion to the origin for affected muscles. For glenohumeral mechanical correction technique, KT was applied from anterior aspect of the glenohumeral joint to the posterior part with 50–75 % tension of the tape to correct the joint alignment. The adhesion of the tape to the skin was achieved by rubbing the surface of the tape three times in an anterior to posterior direction. patients were instructed to take the tap off before the subsequent session [20]. KT was applied two times for a period of three consecutive days with two-day interval for tissue recovery.

Patients assessment were conducted at baseline and immediately after the end of 12 weeks of corresponding intervention by the principle investigator who has all information about the patients allocation. The main outcome assessment including: resting pain, functional disability of the shoulder and pain free active ROM of the shoulder joint.

Pain during rest was assessed by visual analogue scale (VAS). It is 10-cm horizontal line with two anchors. Each anchor represents level of pain. The left anchor indicates no pain at all, whereas the right anchor indicates severe pain. VAS score has a very good test-retest reliability (intra-class correlation coefficient ICC) 0.97- 0.99 [21].

Shoulder disability was measured by Shoulder Disability Questionnaire (SDQ). It consists of a 16-items assessing functional limitation in patients with shoulder dysfunction. With three answering options include yes, no, or not applicable. Score calculation was calculated by multiplying the yes/no ratio by 100. SDQ score ranges from 0 to 100 points. The validity of SDQ has been established alongside those of other shoulder questionnaires[22].

Pain free active range of motion of the shoulder was measured with electro goniometer according to the American Academy of Orthopaedic Surgeons guidelines, while the patients in a comfortable sitting position pre- and post-treatment. Shoulder flexion was measured in the sagittal plane while patient in the sitting position with the arm

at the side and hand pronated. shoulder abduction was assessed in the frontal plane with the arm at the side and shoulder externally rotated to obtain maximum abduction. Shoulder external rotation were measured in the transverse plane while patient in prone lying position with the arm abducted to 90°, the elbow flexed to 90° with the hand pronated and forearm perpendicular to the ground. Each measurement were rounded off to the nearest 5 degree as is common in research practice. Each motion range was measured 3 times and the average was calculated.[23].

Data Analysis

Data were analysed using SPSS for Windows software, version 24 (SPSS, Inc., Chicago, IL).. Patients' demographic characteristics were analysed with unpaired *t*-test and Mann-Whitney *u* test. Normal data distribution was tested using Kolmogorov-Smirnov test. Separated 2x2 mixed model analysis of variance (ANOVA) were performed to analyse intra group difference (Astym and kinesio taping), within group difference (pre-treatment and post-treatment) and the interaction. The effect size and 95% confidence interval (CI) were calculated between groups pre and post treatment for VAS score, shoulder disability score and shoulder pain free active ROM. Statistical significance was set at $P < 0.05$

RESULTS

Sixty diabetic patients aged from (30 to 55) years were referred by orthopaedist as chronic RC tendinopathy. Three patients were excluded because they did not fulfilled the inclusion criteria and one participant disagreed to participate in the study. Patients were randomly assigned to either the Astym therapy group (n=28) or kinesiotaping group (n=28).patients characteristics and baseline outcome measurements of the two groups are shown in (Table 1). The results showed that there was no significant difference between the two groups regarding patients demographic data and the baseline measurements ($P>0.05$).

Table 1: Patients characteristics and baseline assessment .

Characteristics	Astym therapy group Mean±SD	Kinesiotaping group mean±SD	P
Age (year)	43.28 ±8.2	40.57 ±5.3	0.14
Weight (kg)	82.46 ±8.4	79.78±5.9	0.17
Sex n (%)	Males	18(64.3%)	0.59
	females	10(35.7%)	
Symptom duration (month)	11.39±2.9	11.85±2.8	0.55
medication	Insulin n (%)	11(39.3%)	0.6
	Other n (%)	17(29.8%)	
Duration of diabetes (years)	7.1(2.4)	8.5(3.9)	0.11
VAS	8.03±1	7.6±1.3	0.23
SDQ	69.5±7.9	70.5±7	0.6
Shoulder Flexion	118.78 ±12.9	116.32±12.96	0.16
Shoulder Abduction	124.71 ± 15.5	121.35± 15.8	0.1
Shoulder External rotation	55.83±6.2	56.1±6.7	0.75

VAS: visual analogue scale SDQ: Functional disability questioner P: Probability

Pain intensity

Comparison of the pre- and post-treatment measure of the VAS score revealed a significant pain changes in the two groups over time ($p<0.05$). Post-treatment values comparison showed significant difference between groups in favour of kinesiotaping group (Cohen's $d =0.2$, mean differences (MD) =1.41 points with 95%CI= 1.11-1.71 points) fig 4.

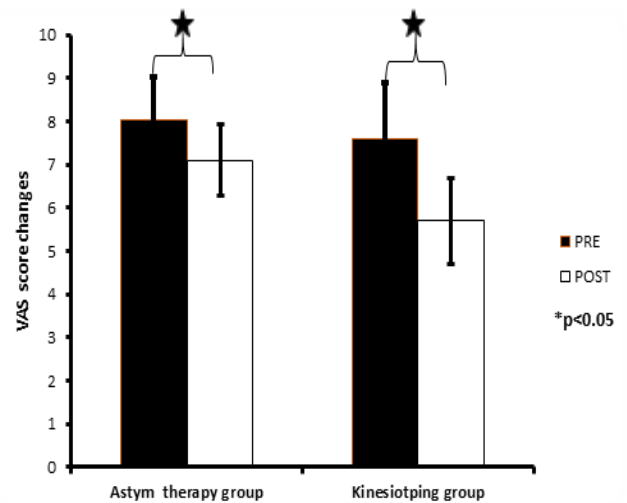


Figure 4. Comparison of pain intensity between groups pre and post treatment

Functional disability

Results of shoulder disability revealed that There was no significance difference ($p > 0.05$) in pre intervention disability score between the groups .Subjects in both groups (Astym and Kinesiotaping) experienced significant changes in shoulder disability score over time($p=0.001$,effect size=0.6), but there was no significant difference between both group post-treatment ($p=0.66$, Cohen's $d =0.004$, MD = 0.84 points with 95% CI= 4.6-3 points) Table 2.

Table 2. Pre and post values of SDQ between groups.

SDQ	Astym therapy group Mean±SD	Kinesio taping group mean±SD	P- value (time effect)
Pre	69.5±7.9	70.5±7	0.6
Post	66.4±7.5	67.07±7.1	0.74
P- Value (group effect)	0.001*	0.001*	

SDQ: shoulder disability questionnaire

SD: Standard Deviation

P: Probability

Active shoulder ROM

Analysis of active shoulder range of motion results revealed that there were no significance differences between the two groups at the base line assessment. However there were significant changes of shoulder flexion, abduction and external rotation over time ($p<0.5$). Between groups analysis revealed that, there was no significant difference in the active shoulder ROM post intervention. Table 3.

Table 3: P-Value of shoulder ROM pre and post treatment between groups

Variables	Astym therapy group Mean±SD	Kinesiotaping group mean±SD	Mean differences	95%CI	P-Value
Pre Shoulder flexion	118.78 ±12.9	116.32±12.96	4.9	2-11.8	0.16
Post	130.75±10.95	128.4±12.08	2.3	3.8-8.5	0.45
P- value	0.001*	0.0001*			
Pre Shoulder abduction	124.71 ± 15.5	121.35± 15.8	6.7	1.4-14.8	0.1
Post	134.03 ± 19.16	129.35± 24.05	4.6	6.9-16.3	0.42
P- Value	0.043*	0.048*			
Pre Shoulder Ext. Rot.	55.83±6.2	56.1±6.7	0.53	3.9-2.8	0.75
Post	59.14±8.33	60.53±8.64	1.3	5.9-3.1	0.54
P- Value	0.028*	0.005*			

SD: Standard Deviation, P: Probability
Ext. Rot.: External Rotation *significant

DISCUSSION

Rotator cuff has a primary role for the shoulder joint activities and its tendinopathy may cause major restrictions of the patient functional capabilities [24]. This study was designed to compare the effects of Astym therapy and kinesiotaping in diabetic patients with chronic RC tendinopathy. The results demonstrated that, kinesiotaping treatment had a more pronounced effect on pain reduction than Astym therapy. However, there were no significant difference in functional disability or shoulder ROM between both groups post- intervention. To the best of our knowledge, this study is the first comparative study between Astym therapy and kinesiotaping in this patient population. Although some studies showing positive outcome with kinesiotaping application[25, 26], the exact mechanism for this improvement has not been elucidated. It has been postulated that pain modulation via the gate control theory is one explanatory mechanism of kinesiotaping techniques via increased afferent feedback from cutaneous receptors of the affected structure [27].

Furthermore Alexander et al 2008 hypothesizes that kinesiotaping could shorten the targeted muscle fibres causing reduction in the afferent(Ia) discharge from the neuro-muscle spindle, inhibition of muscle reflex excitability , lowering muscular tone which might explain pain control and functional disability improvement following kinesiotaping application [28]. Another possible mechanical effect by which taping may improve joint function may be related to re-location of the joint in such a way to provide a splint or alter the periarticular structures length-tension relationships to create the required musculo-skeletal posture for proper motor pattern [29, 30].

In agreement of our findings Shakeri et al 2013 reported that kinesiotaping produces short term control of pain intensity at movement and nocturnal pain in patients

with subacromial impingement [31]. Also the results of the current study are in general concurrence with the study of SubaşI et al 2016 who suggested that both kinesiotaping and steroid injection were found to be effective in reducing pain in patients with subacromial impingement syndrome [32]. Moreover Öztürk et al 2016 found a statistically significant improvement in pain and trapezius muscle strength in individuals with myofascial pain syndrome [33]. Garcia-Muro et al 2010 observed a case of myofascial pain and tenderness of the deltoid muscle that exhibited improvement in pain level after kinesiotaping application[34]. Frazier et al 2006 reported significant improvements in disability of hand and shoulder scores and pain in five patients with various shoulder disorder by kinesiotaping in addition to physical therapy program[35]. Similarly, Kaya et al 2011 proposed that kinesiotaping help to reduce the mechanical irritation of the involved soft tissue and direct joint activities through the proper arc of motion[36].

However, the results of the present study are contradicted with Kocyigit et al 2016 who concluded that KT and sham taping generated similar results regarding pain and shoulder ROM. subacromial impingement syndrome [37]. Also Pekyavas et al 2016 reported that kinesiotaping application has no effect on tissue mobilization and shoulder ROM in subacromial impingement compare with laser and manual therapy approaches [16]. Alam et al 2015 stated that kinesiotaping has no significant effect on shoulder maximum torque, shoulder internal and external range of motion in healthy individuals [38]. Thelen et al 2008 did not find a significant difference between kinesiotaping and sham kinesiotaping regarding pain or disability level for patients with rotator cuff tendinitis and impingement syndrome [39]. The results of Thelen may be related to some potential limitation regarding the age and underlying pathology of the subject group recruited. The plausible explanation for kinesiotaping discrepancy results in our study could be related to the selectivity of kinesiotaping application to specific muscles (supraspinatus and deltoid muscles) and difference in taping technique application.

The results of the current study add support to Astym therapy which is a promising component of rehabilitation for patients with tendinopathies. It was designed targeting cellular mediators and growth factors for improving soft tissue healing and regeneration. So it could improve healing in patients who were resistant to conservative physical therapy [9]. Many clinical studies have demonstrated positive effects of Astym therapy on connective tissue lesions [40-42]. Some potential mechanisms may explain our results. The first is that Astym therapy administered to connective tissue tendinopathy resulted in fibroblast proliferation and activation, which may be associated with acceleration of tissue healing. Second possible mechanism by which Astym therapy improve joint pain and ROM may be related its effect on the biomechanical properties of the injured tissues with enhancement of blood flow and possible angiogenesis in the vicinity of the these tissues [43].

Our results are consistent with the conclusion of Scheer et al 2016 who find that Astym therapy improve hamstring flexibility and Achilles tendinopathy in a children with cerebral palsy [7]. Also McCormack 2012 results revealed significant pain reduction with improvement of the lower limb function in patient with high hamstring tendinopathy [11]. The finding of Chughtai et al 2016 proved a significant gain in knee joint ROM in patient undergo Astym therapy compared with standard physical therapy program following total knee arthroplasty [44].

One of the plausible explanation for the superior effect of kinesiotaping compared with Astym therapy in reducing pain Perhaps the taping gave the participants a greater awareness of the affected structure while moving, thus improve their ability to reduce the mechanical irritation of soft tissues when performing activities and preventing movements that were detrimental to the healing of the affected tissues. In addition, the potential economic consequences of kinesiotaping approach due to various factors such as shorter duration of application and less frequent visits should be considered as an important practical difference between the two treatments.

There are number of limitations of the current study that should be recognized. The main limitation of our study was the fact that the conventional program, which was prescribed for the two groups, is already effective by itself. Therefore, the results of this study failed to prove the independent effects of kinesiotaping and Astym therapy alone. In addition, this study only reported the short-term effects of Kinesiotaping, so we cannot generalize about long-term effects. Another limitation is that the investigators who performed the two applications and assess the main outcome measurements were not blinded to the treatment allocation. Thus, the beliefs and expectations of the investigators may have affected the measurements unknowingly.

CONCLUSION

Kinesiotaping has been shown to produce greater gains in pain reduction compared with Astym therapy in diabetic patients with chronic RC tendinopathy. It should be considered as an optional clinical adjunct in the treatment of RC tendinopathy as part of a comprehensive physical therapy regimen especially when pain is the major patient complains. Further research is warranted to explain the physiological mechanisms through which kinesiotaping and Astym therapy may address soft tissue disorders and long lasting effect of these teachings of treatment.

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