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Therapeutic Potentials of Radial Shock Wave in Cubital Tunnel Syndrome

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ABSTRACT

Background Cubital tunnel syndrome is a common compressive neuropathy, its conservative and surgical treatments results are not satisfactory; the need for a novel, safe, and effective therapeutic modality is highly required.

Patients and methods 30 patients (30 elbows) in the intervention group received 3 sessions of rESWT (radial extracorporeal shock wave therapy) one session/week, and placebo control group (17 patients - 20 elbows) received sham treatment. Clinical, functional, electrophysiological and ultrasonography morphological assessment were done at baseline, 2 weeks after last session, and after 3 months of follow up.

Results Patients of intervention group showed significant improvement of clinical, functional, electrophysiological and ultrasonography morphological assessment parameters relative to control group either after treatment or at follow up period.

Conclusion rESWT is an effective and safe treatment for relieving symptoms of compressive ulnar neuropathy at the elbow.

Keywords: Neuropathy, Ulnar nerve entrapment, Shock wave therapy.

INTRODUCTION

Cubital tunnel syndrome is a form of compressive neuropathy that is caused by multiple minor traumas to the ulnar nerve during repetitive flexion [1,2].

It is presented clinically by gradual loss of intrinsic hand muscles power, pain and numbness in the medial one and half fingers [3]. Electro diagnostic studies confirm the diagnosis with a sensitivity of 37% to 86%[4]. High resolution neuromuscular ultrasonography (NMUS) is used for localization and confirmation of the diagnosis [5]. Conservative treatments include anti-inflammatory, neurotropic drugs, physical therapy and protective orthosis to prevent excessive elbow flexion [6]. While severe cases are indicated for surgery [7].

Extracorporeal shock waves therapy ESWT are indicated for a lot of musculoskeletal diseases. Its biological effects include angiogenesis, neurogenesis, increase levels of growth factors. Also, it has a role in regeneration of neural axons and Schwann cells activation which is responsible for nerve repair [8-11].

This study is aiming to evaluate rESWT as a treatment option for entrapment of ulnar nerve in the cubital tunnel.

PATIENTS AND METHODS

This prospective randomized controlled study was conducted on 47 patients (50 elbows) suffering from cubital tunnel syndrome.

Ethical approval

The study is in accordance with the ethical principles of Helsinki and was approved by the local Research Ethics Committee of Faculty of Medicine, Tanta University. Written informed consents were obtained from all patients after explanation of the therapeutic procedure.

Cubital tunnel syndrome was diagnosed clinically and electrophysiologically by a single doctor using a Nihon Kohden Neuropack 2 (Tokyo, Japan), four domains were measured: MCV across elbow, CMAP above and below elbow, SCV and SNAP amplitude.

Patients with McGowan grade 1 and grade 2 complaining more than 6 months were included. [12, 13].

Diagnosis was done according to The American Association of Neuromuscular and Electro diagnostic Medicine guidelines, also, drop rate of CMAP amplitude more than 20% was considered diagnostic for conduction block [14,15].

Neuromuscular ultrasonography (NMUS) was used to confirm the diagnosis using SAMSUNG (UGEO H60) by a single doctor; a) CSA was measured in mm^2 at three levels; 2 cm proximal to epicondyle, at epicondyle, and 2 cm distal to epicondyle [16]; b) Swelling ratio above elbow (MS/PROX), and below elbow (MS/DIST) were calculated. [17]; c) Nerve Echogenicity at epicondyle on longitudinal and transverse scans [18]; d) Nerve hypervascularization determined by power Doppler ultrasound (PDUS) for presence of intraneural vascular structure [19].

Exclusion criteria

1. Patients with brachial plexopathy.
2. C8-T1 radiculopathy, polyneuropathy.
3. Previous elbow fractures or operation.
4. Systemic diseases such as diabetes mellitus, malignancy, and active infection.
5. Patients with any contraindications to shock wave therapy.

Patients were assigned randomly into the treatment groups as follows:
(30 patients, 30 elbows) in the intervention group and (17 patients, 20 elbows) in the control group.

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The former received radial ESWT 2000 shots, by a single physician, one session/week for 3 weeks. The latter received sham rESWT treatment for the same interval using an air-chambered polyethylene foil placed without coupling gel.

Assessments

1-Clinically, by:

a) Visual Analog Scale (VAS) [20].

b) McGowan score [12].

c) (SQUNE) questionnaire [21].

2-Functionally, by (Quick DASH) questionnaire [22].

3-Electrophysiological assessment [13-15].

4-Ultrasonographic assessment [16-19].

Assessment was done at baseline, 2 weeks after treatment (last session), then after 3 months for follow up.

Statistical analysis

Data were analyzed using IBM SSPS software package version 20.0 (Armonk, NY: IBM Corp). Qualitative data were described using number and percent, quantitative data were described using range , mean, standard deviation . Significance of the obtained results was adjusted at the 5% level. Paired t- test was used for normally distributed quantitative variables, to compare the means between two periods, and Student t-test was used to compare the means of the studied groups, Chi square test to compare independent variables and the repeated measures ANOVA test was used to compare the same group at different times . [23].

RESULTS

No significant statistical difference of demographic data and all evaluation parameters (Clinical, functional, electrophsiological, and ultrasonographic) at baseline (Table 1).

Table (1): Demographic data of the studied groups

	Intervention group 30 patients		**Control group 17 patients**		**Test of sig.**	**P**
Age (years) Mean ±SD	**35.70± 6.30**		**33.85±9.25**		F=0.734	**0.471**
Sex	**No**	**%**	**No**	**%**		
Male	**24**	**80**	**13**	**76.47**	□□□□□□□	**^{MC}p=0.236**
Female	**6**	**20**	**4**	**23.53**	□	
Side affected	**No**	**%**	**No**	**%**		
Right	**19**	**63.3**	**15**	**75**	□□□□□□□	**^{MC}p=0.386**
Left	**11**	**36.7**	**5**	**25**	□	
Disease duration (months) Mean ±SD	**9.20±5.70**		**8.70±6.35**		0.269	**0.789**

χ^2: Chi square test MC: Monte Carlo F: F for ANOVA test

P: p value for comparing between the different studied groups

Tables 2, 3, and 4 illustrate the following data:

After 2 weeks significant improvements were noted relative to control subjects of VAS, SQUNE, above elbow CMAP amp, conduction block by drop rate, CSA and distal swelling ratio.

At 3 months follow up, significant improvements in comparison to control group regarding MGS, Q DASH, MCV across elbow and proximal swelling ratio were also noticed, whatever, the improvement of these parameters 2 weeks after treatment had no significant value.

No significant changes were noted between both groups at any point regarding below elbow CMAP amplitude, SNAP amplitude, SCV, nerve echogenicity, and Doppler activity ($p>0.05$).

Patients of intervention group showed significant improvement after treatment and at the follow up relative to baseline in all parameters except for below elbow CMAP amplitude and sensory conduction study.

Patients of control group showed significant improvement of VAS, MGS, SQUNE and Q DASH only 2 weeks after treatment comparative to base line, but not observed at 3 months follow up, with mild insignificant improvement in electrophysiological and morphological data during the two peroids.

Table (2): Comparison of clinical and functional data at baseline, 2 weeks after rESWT, and 3 months follow up between the two studied groups

	Intervention Group (30 elbows)	Control Group (20 elbows)	P	Intervention Group	Control Group
VAS					
Baseline	**5.83±0.87**	**6.21±0.67**	**0.105**	**P1 <0.001***	**P1 <0.001***
At 2 weeks	**4.22±0.64**	**5.34±0.47**	**<0.001***	**P2 <0.001***	**P2 0.194**
At 3 months	**3.81±0.52**	**6.43±.0.33**	**<0.001***	**P3 0.009***	**P3 <0.001***
MGS					
Baseline	**1.64±0.32**	**1.58±0.23**	**0.443**	**P1 0.003***	**P1 0.04***
At 2 weeks	**1.32±0.12**	**1.35±0.21**	**0.523**	**P2 <0.001***	**P2 0.563**
At 3 months	**1.13±0.22**	**1.52±.0.36**	**<0.001***	**P3 0.129**	**P3 0.378**
SQUNE					
Baseline	**19.87±2.75**	**18.83±2.10**	**0.134**	**P1 <0.001***	**P1 0.027***
At 2 weeks	**15.74±1.87**	**17.4±1.84**	**0.003***	**P2 <0.001***	**P2 0.161**
At 3 months	**13.23±2.04**	**18.04±.1.17**	**<0.001***	**P3 <0.001***	**P3 0.468**
Q DASH					
Baseline	**13.38±3.32**	**12.80±2.66**	**0.498**	**P1 0.0014***	**P1 0.013***
At 2 weeks	**11.27±2.34**	**10.93±1.68**	**0.170**	**P2 <0.001***	**P2 0.680**
At 3 months	**8.98±1.56**	**13.10±.1.78**	**<0.001***	**P3 <0.001***	**P3 0.0002***

P1= 2 weeks after rESWT versus baseline. P2= 3 months follow up versus baseline.
P3= 3 months follow up versus 2 weeks after rESWT. P: p value for comparing between the different studied groups

Table (3): Comparison of electrophysiological data at baseline, 2 weeks after rESWT, and 3 months follow up between the two studied groups

	Intervention Group (30 elbows)	Control Group (20 elbows)	P	Intervention Group	Control Group
Motor CMAP Amp (mv)					
Below elbow					
Baseline	**7.70±1.25**	**8.02±1.07**	**0.335**	**P1 0.427**	**P1 0.729**
At 2 weeks	**7.95±1.17**	**8.15±1.30**	**0.582**	**P2 0.109**	**P2 0.257**
At 3 months	**8.25±1.35**	**8.36±.0.76**	**0.716**	**P3 0.361**	**P3 0.533**
Above elbow					
Baseline	**5.30±1.75**	**5.43±1.86**	**0.804**	**P1 <0.001***	**P1 0.279**
At 2 weeks	**7.65±1.30**	**6.08±1.74**	**<0.001***	**P2 <0.001***	**P2 0.117**
At 3 months	**8.45±1.08**	**6.25±.1.25**	**<0.001***	**P3 <0.001***	**P3 0.682**
Drop rate					
Baseline	**26.64±5.70**	**27.43±5.66**	**0.629**	**P1 <0.001***	**P1 0.292**
At 2 weeks	**18.73±6.40**	**25.70±4.34**	**<0.001***	**P2 <0.001***	**P2 0.116**
At 3 months	**16.32±4.87**	**24.94±3.82**	**<0.001***	**P3 <0.001***	**P3 0.563**
Across elbow MCV (m/s)					
Baseline	**38.00±6.45**	**39.20±4.50**	**0.446**	**P1 0.011***	**P1 0.10**
At 2 weeks	**41.98±5.20**	**41.4±3.67**	**0.646**	**P2 <0.001***	**P2 0.220**
At 3 months	**44.85±6.38**	**40.7±.2.86**	**0.004***	**P3 0.06**	**P3 0.501**
SNAP					
Amp (µv)					
Baseline	**13.60±5.56**	**14.70±4.86**	**0.463**	**P1 0.533**	**P1 0.458**
At 2 weeks	**14.66±7.40**	**15.93±5.50**	**0.494**	**P2 0.240**	**P2 0.812**
At 3 months	**16.15±10.30**	**14.25±.6.76**	**0.432**	**P3 0.520**	**P3 0.395**
SCV (m/s)					
Baseline	**39.47±8.50**	**40.70±7.20**	**0.584**	**P1 0.469**	**P1 0.742**
At 2 weeks	**40.70±3.77**	**41.33±4.65**	**0.616**	**P2 0.225**	**P2 0.647**
At 3 months	**41.67±4.93**	**39.86±.3.33**	**0.126**	**P3 0.400**	**P3 0.263**

P1= 2 weeks after rESWT versus baseline.
P2= 3 months follow up versus baseline.
P3= 3 months follow up versus 2 weeks after rESWT
P: p value for comparing between the different studied groups

Table (4): Comparison of ultra-sonographic data at baseline, 2 weeks after rESWT, and 3 months follow up between the two studied groups

	Intervention Group (30 elbows)	Control Group (20 elbows)	P	Intervention Group	Control Group
CSA					
Baseline	**16.33±2.84**	**15.78±2.77**	**0.501**	**P1 <0.001***	**P1 0.064**
At 2 weeks	**12.80±1.65**	**14.43±1.35**	**<0.001***	**P2 <0.001***	**P2 0.530**
At 3 months	**11.60±1.10**	**14.30±.1.56**	**<0.001***	**P3 0.139**	**P3 0.777**
Swelling ratio MS/ DIST					
Baseline	**2.95±0.66**	**2.58±0.23**	**0.592**	**P1<0.001***	**P1 0.138**
At 2 weeks	**2.36±0.44**	**2.53±0.48**	**0.009***	**P2<0.001***	**P2 0.097**
At 3 months	**2.15±0.74**	**2.49±0.65**	**0.0016***	**P3 0.190**	**P3 0.664**
MS/PROX					
Baseline	**2.78±0.47**	**2.65±0.64**	**0.447**	**P1 <0.001***	**P1 0.646**
At 2 weeks	**2.38±0.83**	**2.55±0.73**	**0.397**	**P2 0.021***	**P2 0.950**
At 3 months	**2.10±0.87**	**2.64±.0.28**	**0.004***	**P3 <0.001***	**P3 0.610**
Loss of Echogenicity					
Baseline	**83.3%**	**85%**	**□□□□□□□**	**MCp=0.947**	
At 2 weeks	**76.7%**	**80%**			
At 3 months	**70.0%**	**80%**			
Absent power Doppler activity					
Baseline	**80.0%**	**85%**	**□□□□□□□**	**MCp=0.942**	
At 2 weeks	**73.3%**	**85%**			
At 3 months	**66.7%**	**80%**			

P1= 2 weeks after rESWT versus baseline.
P2= 3 months follow up versus baseline.
P3= 3 months follow up versus 2 weeks after rESWT
P: p value for comparing between the different studied groups

Figures 1 and 2 show the improvement by treatment as found in the nerve conduction study and ultrasound scan.

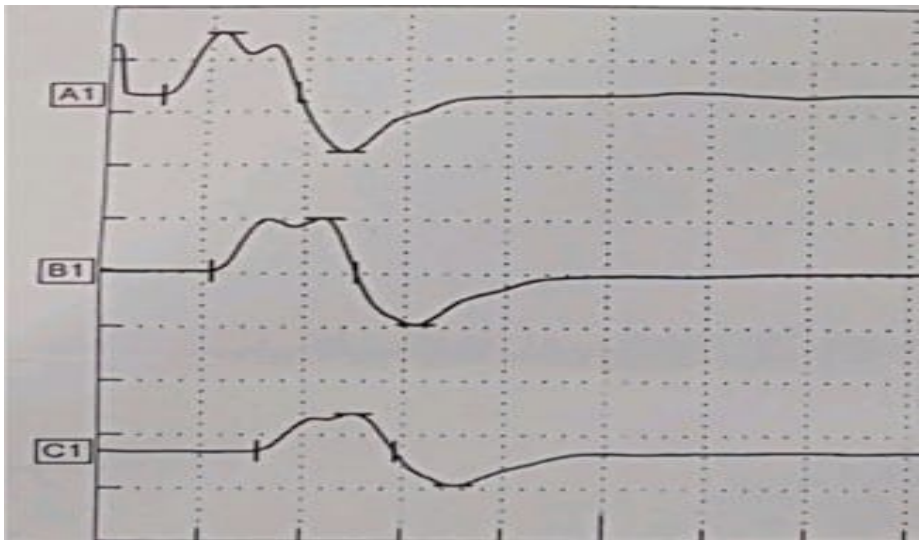

Fig 1 a) Nerve conduction study of right ulnar nerve showing decreased MCV across elbow (40.7 m/s) and above elbow CMAP amplitude (6.8 mv) at baseline before treatment

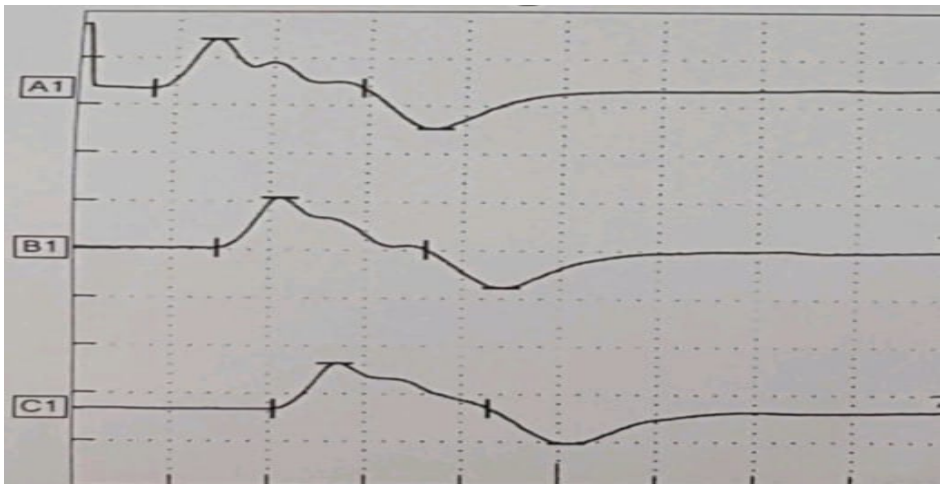

Fig 1 b) Nerve conduction study of right ulnar nerve showing improved MCV across elbow (43.3 m/s) and above elbow CMAP amplitude (8.2 mv) after 3 months of follow up

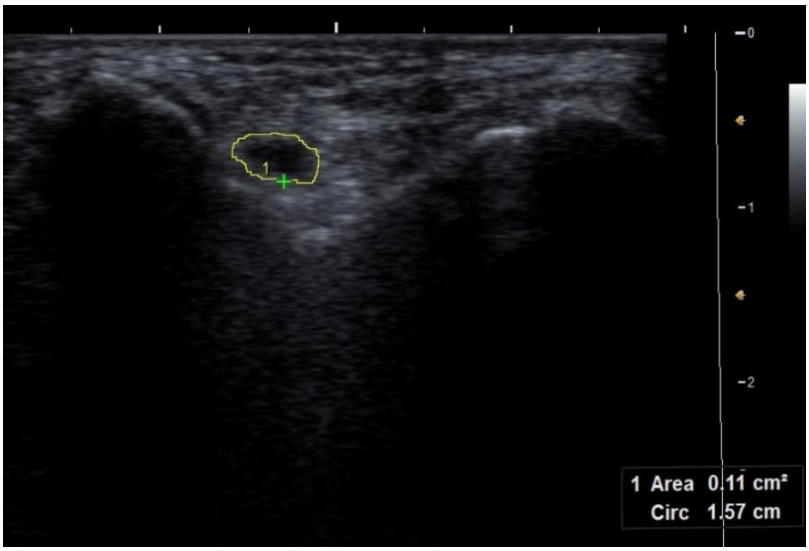

Fig. 2.a) Ultrasound scan before treatment. CSA = 11 mm^2 at baseline before treatment

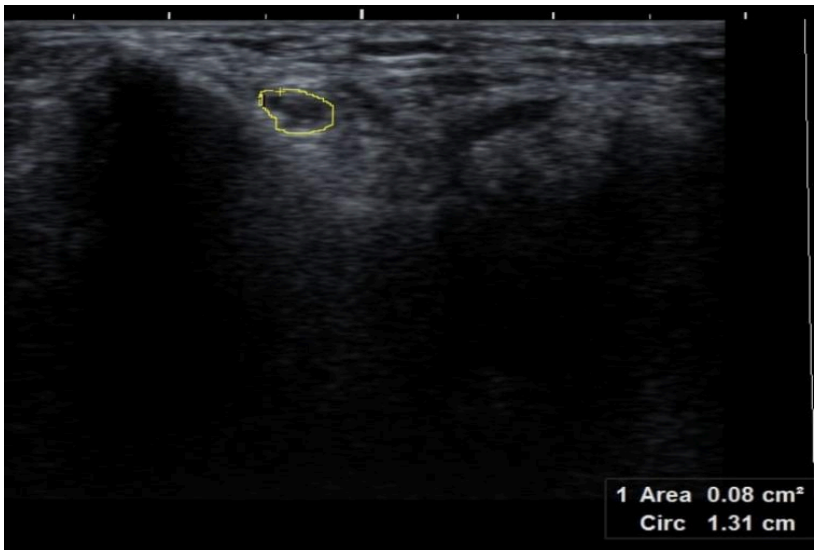

Fig 2. b) Ultrasound scan after treatment. CSA = 8 mm^2 after 3 months of follow up

DISCUSSION

Cubital tunnel is a fibroosseous tunnel; the arcuate ligament forming its roof, medially the humeral and ulnar heads of flexor carpi ulnaris (FCU), laterally the elbow joint, and anteriorly the medial epicondyle[24- 26].

All patients included in our study showed no significant difference regarding clinical and functional data of cubital tunnel syndrome (VAS, MGS, SQUNE and Q DASH), electrophysiological data (CMAP amplitude below and above elbow, drop rate, MCV across elbow, SNAP amplitude, and SCV), and ultrasonographic morphological data (CSA of ulnar nerve at epicondyle, swelling ratio, nerve echogenicity, and Doppler activity) at the start of the study. However, 2 weeks after last session and at 3 months follow up, neurological improvement was noticed in the intervention group relative to control with significant differences between them regarding VAS, SQUNE, above elbow CMAP amp, conduction block by drop rate, CSA and distal swelling ratio. While MGS, Q DASH, MCV across elbow and proximal swelling ratio showed significant improvement only 3 months after treatment. And below elbow CMAP amplitude, SNAP amplitude, SCV, nerve echogenicity, and Doppler activity showed no significant change between both groups.

In the intervention group significant improvement 2 weeks after treatment and at 3 months follow up in all parameters was recorded with exception of below elbow CMAP amplitude and sensory conduction study.

rESWT is relatively new, more affordable and more widely available now. It is relatively well tolerated without anesthesia [27].

In current study, patients of intervention group received 3 sessions of rESWT, one week apart, they showed improvement in clinical symptoms and signs assessed by VAS, MGS, and SQUNE and functional status assessed by Q DASH in both after treatment and follow up periods compared to patients of control group.

Pain reduction effect of ESWT is explained by production of nitric oxide (NO), which leaves the nerve in a hyperpolarized state through acting on potassium and calcium channels [9, 28]. Also, reducing swelling and the subsequent decrease of pressure inside the tunnel is one of the anti-inflammatory effects of ESWT[9]. Additionally, inactivation of C fibers and stimulation of descending inhibitory pathways from the brain stem [29].

Repetitive compression and stretching within the tunnel affect the small blood capillaries producing nerve ischemia. ESWT is known to stimulate angiogenesis through the upregulation of vascular endothelial growth factor and thus act through improving tissue perfusion and reduce the ischemic pain [30-34].

According to previously mentioned mechanisms, pain reduction, partial symptoms relief and subsequent functional improvement in patients of intervention group received rESWT is explained. **Lohse–Busch *et al*.** [31], found that pain intensity decreased significantly after six sessions of ESWT, but it then increased after 8 weeks in patients with distal symmetric polyneuropathy.

On electrophysiological aspect, we observed insignificant mild improvement of SCV and SNAP amplitude in intervention group, also the difference between the two groups regarding MCV across elbow was insignificant 2 weeks after treatment, but the difference was significant at follow up compared to after treatment. Patients of control group showed mild improvement of all parameters after treatment but with no significant difference relative to baseline (except for clinical and functional parameters that were significantly improved), however, this improvement was not maintained at the follow up period. Spontaneous remission and placebo effect could partially explain this limited improvement after sham treatment in the initial 2 weeks.

No previous controlled studies were conducted to discuss the efficacy of ESWT on cubital tunnel syndrome. To date, only one pilot study was conducted on 10 patients with cubital tunnel syndrome that were evaluated only clinically for symptoms improvement by VAS and Q DASH[11].

CONCLUSION

rESWT is an effective therapeutic modality to be implemented in the treatment regimen of mild and moderate cubital tunnel syndrome.

Recommendations: We recommend using rESWT as a treatment option for entrapment of the ulnar nerve at the cubital tunnel.

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