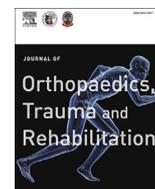




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## Orthopaedic Rehabilitation

### De Quervain's Tenosynovitis and Phonophoresis: A Randomised Controlled Trial in Pregnant Females

### De Quervain 腱鞘炎和超聲透入療法：一項在懷孕的女性的隨機對照試驗



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#### ABSTRACT

**Background:** De Quervain's tenosynovitis is a common cause of wrist pain in pregnant and postpartum females. This study provides objective evidence regarding the therapeutic efficacy of phonophoresis in treating de Quervain's disease during pregnancy.

**Methods:** In a single blind, randomised, controlled trial ( $n = 50$ ), ketoprofen phonophoresis was given to the intervention group and conventional ultrasound (US) was given to controls, coupled with thumb splint immobilisation, and supervised strengthening and stretching exercises for 1 month. Symptomatic and functional improvement was assessed by visual pain analogue, grip, tip, key, and palmer pinch scales.

**Results:** There was a statistically significant improvement in the intervention group compared to the control group in grip and pinch strength, and pain reduction.

**Conclusion:** Ketoprofen phonophoresis as an adjunct to supervised exercise and splint immobilisation is a safe and effective therapy for de Quervain's tenosynovitis during pregnancy. Phonophoresis augments the benefits of US in terms of reducing pain and inflammation, and improving functional strength.

#### 中文摘要

**背景：**De Quervain 腱鞘炎是在孕婦和產後婦女引起手腕疼痛的常見原因。這項研究提供了在懷孕期間利用透入療法醫治 de Quervain 腱鞘炎的客觀證據。

**方法：**單盲隨機對照試驗 ( $n = 50$ )。介入組病人接受酮洛芬 (ketoprofen) 透入療法，而對照組病人則接受普通超聲波。兩組均接受拇指夾板固定和受指導進行伸展運動一個月。症狀和功能改善評估依據視覺疼痛分數，握力，指尖夾力，鑰匙夾力和手掌捏尺度。

**結果：**介入組在握力，夾力和疼痛分數上，比對照組有統計學上顯著的改善。

**結論：**酮洛芬透入療法配合拇指夾板固定和受指導進行的伸展運動，是一種安全，有效治療懷孕期間 de Quervain 腱鞘炎的方法。酮洛芬透入療法在減少疼痛，消炎和改善功能方面，增強了超聲波的治療果效。

## Introduction

Phonophoresis is a method of driving topically applied substances across tissues using ultrasound (US) to enhance percutaneous absorption of selected drugs such as corticosteroids, local anaesthetics, and salicylates.<sup>1</sup> Despite prevalent applications in various musculoskeletal conditions including de Quervain's

disease, few modalities have been the target of as much controversy and speculation as phonophoresis.<sup>2,3</sup> Standardised research is needed to accurately determine the efficacy of phonophoresis in pregnant females suffering from de Quervain's disease; more so because this vulnerable group is generally excluded from routine clinical trials and prevailing knowledge about the same is scant. Our study provides objective evidence regarding the applicability of phonophoresis in treating de Quervain's disease in pregnant women. It describes appropriate drug concentration, vehicle type, US frequency, and the mode for bringing about maximal improvements in the condition.

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## Methods

A single blind (patients were blinded as to the type of therapy they were receiving), randomised, controlled trial enrolled 50 third-trimester pregnant females complaining of de Quervain's tenosynovitis, from the outpatient clinic of the obstetrics department at the Kasr-El-Aini University and Hospital, Cairo, Egypt during 2011 (Table 1). Patients with metabolic disorders, obesity, lymph oedema, hypertension, rheumatic disease, previous wrist operation or fracture, osteoarthritis, neurological disease, history of steroids injection, oral anti-inflammatory drugs, or analgesics intake were excluded from the study. The women were randomly divided into control and intervention ( $n = 25$  each) groups. The intervention group received 2.5% ketoprofen phonophoresis with Fastum gel whereas the control group received conventional US with inert K-Y gel as a coupling medium over the radial styloid process of the affected hand. In both groups, US device, mode, intensity, and frequency were kept identical (BTL-5000 series US device, National Ultrasound, Berkley road, Georgia, USA; pulsed mode, frequency 3 MHz, intensity 0.8 w/cm<sup>2</sup> for 10 minutes); applied for three sessions/week for 4 weeks. Here it is imperative to mention that the US operator in both groups was the same person to avoid applicator bias and confounding of outcomes. The two groups were prescribed thumb spica splint immobilisation during the day, and after the first six sessions they received supervised thumb strengthening and stretching exercises, repeated twice daily. The two groups were assessed before and after the therapy regime for pain (visual pain analogue scale: 0 = no pain, 1 = mild pain, 2 = moderate pain, 3 = severe pain, 4 = unbearable pain), grip strength (Jamar hand held dynamometer), and tip, key, and palmer pinch strength (B&L pinch gauge, National Ultrasound, Berkley road, Georgia, USA). Basic descriptive statistics were used to analyse the results, with the confidence interval set at 95% and  $p < 0.05$  considered as significant. Mean, standard deviations, percentages, frequency, Student *t* test, etc., were applied as required.

The study was approved by the institutional ethics committee and voluntary informed consent was obtained from participants before commencement of the study, as per guidelines of the Declaration of Helsinki.

## Results

The intervention group (A) showed remarkable improvement compared to the control group (B) in terms of reduction in pain intensity and enhancement of grip and pinch strength. The difference between the two groups was statistically significant on all three assessment scales.

### Pain perception intensity (PPI) scores

Pretreatment PPI scores of Group A ranged between 3 and 4 and post-treatment scores ranged between 0 and 1. The decrease in

**Table 1**

Randomised controlled trial on 50 third-trimester pregnant females with de Quervain's tenosynovitis; Kasr-El-Aini University and Hospital, Egypt during 2011

Demographics* ( $n = 50$ )	Value <sup>†</sup> , range (mean)
Age	25–35 y (29.16 ± 3.07)
Weight	66–95 kg (82.66 ± 6.07)
Height	150–170 cm (162.46 ± 5.59)
Body mass index	29–34 kg/m <sup>2</sup> (30.83 ± 1.11)

\* Physical demographic characteristics of patients.

<sup>†</sup> Difference between the control and intervention groups were statistically nonsignificant;  $p > 0.1$ .

pain was highly significant ( $p = 0.0001$ ) and the percentage of improvement was 92.5%. In Group B, pretreatment PPI scores ranged between 3 and 4, and at the end of the treatment program scores ranged between 0 and 4. Pre- and post-PPI scores showed no statistical difference ( $p > 0.05$ ). The percentage of improvement was a meagre 7.9% (Table 2; Figure 1).

### Grip strength

In Group A, pretreatment grip strength was 10.6 ± 2.22 kg, whereas the post-treatment value was 23.93 ± 2.6 kg. There was a highly significant increase in grip strength ( $p = 0.0001$ ) with 125.75% improvement. In Group B, before starting the treatment program, the grip strength was 11.66 ± 2.66 kg, whereas at the end of the treatment program, it was 10.8 ± 4.82 kg. There was no statistical difference between the two scores ( $p > 0.05$ ). The percentage of improvement was merely 7.37% (Table 3; Figure 2).

### Tip pinch

There was a highly significant increase in tip pinch strength of Group A; 126% improvement (pretreatment scores were 3.33 ± 0.85 kg whereas post-treatment scores were 7.53 ± 0.87 kg;  $p < 0.0001$ ). Conversely, Group B scores showed no similar improvement (pretreatment 3.73 ± 0.7 kg and post-treatment 3.43 ± 1.27 kg;  $p > 0.05$  and only 8.04% improvement) (Table 4; Figure 2).

### Key pinch

Key pinch strength in Group A showed a statistically significant improvement in post-treatment values;  $p < 0.0001$  and a progress of 110.17%. Corresponding scores of Group B showed minimal change between pretreatment and post-treatment values;  $p > 0.05$  and 11.9% improvement (Table 5; Figure 2).

### Palmer pinch

Palmer pinch strength showed an improvement of 106.99% between pretreatment and post-treatment values; (3.86 ± 0.91 vs. 8 ± 0.56;  $p < 0.0001$ ). By contrast, Group B scores improved only by 10.63% (3.76 ± 0.67 vs. 3.63 ± 1.23;  $p > 0.05$ ) (Table 6; Figure 2).

## Discussion

De Quervain's tenosynovitis is a frequently encountered pain of the hand and wrist. It results from compression and irritation of the extensor pollicis brevis and abductor pollicis longus tendons as

**Table 2**

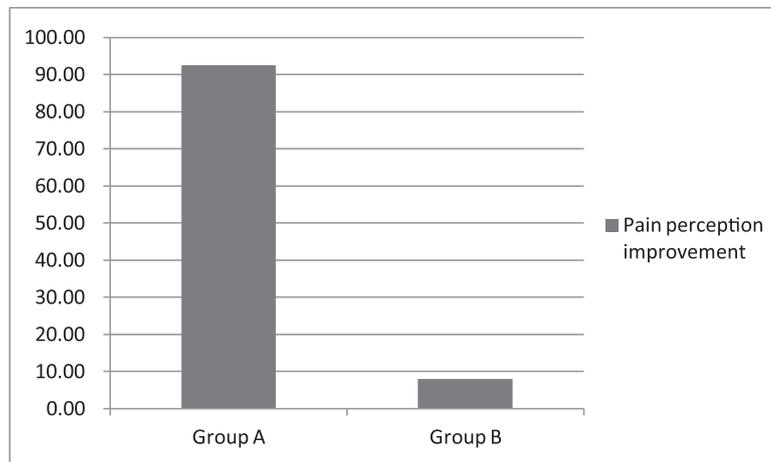
Percentage change in pain perception pretreatment and post-treatment (ketoprofen phonophoresis for intervention and inert gel for control)

Pain intensity	Group A (intervention; $n = 25$ )		Group B (control; $n = 25$ )	
	Pretreatment	Post-treatment	Pretreatment	Post-treatment
Mean ± SD	3.6 ± 0.5	0.26 ± 0.45	3.26 ± 0.45	3.0 ± 1.36
Mean difference	3.33		0.26	
<i>t</i> value	20.91		0.74	
<i>p</i>	0.0001*		0.46	
Percentage of change (%)	92.5		7.97	

\* *p* value significant.

Third trimester pregnant females ( $n = 50$ ) complaining of de Quervain's tenosynovitis of the dominant hand from the outpatient clinic of the obstetrics department, Kasr-El-Aini University and Hospital, Egypt during 2011; ketoprofen 2.5% phonophoresis proved highly effective.

SD = standard deviation.



Expressed as a percentage in Group A (intervention,  $n = 25$ ) and Group B (control,  $n = 25$ ); outpatient clinic obstetrics department Kasr-El-Aini University and Hospital, Egypt during 2011. Ketoprofen 2.5% phonophoresis proved highly effective in pregnant females ( $n = 50$ ) suffering from de Quervain's tenosynovitis.

**Figure 1.** Pain perception improvement pre- and post-treatment (ketoprofen phonophoresis for the intervention group and inert gel for the control group).

they pass through the first dorsal compartment of the wrist. Patients complain of tenderness and swelling proximal to the radial styloid process, as well as pain in the wrist and on the radial side of the hand. Owing to persistent pain and inflammation, the pinch and grasp strength of the hand is considerably compromised, coupled with tenderness over the anatomical snuff box. Although the condition occurs in both females and males, it is significantly more common in women, especially during pregnancy and postpartum. Some sources even quote a female:male ratio as high as 8:1.<sup>4,5</sup>

The allure of achieving outcomes “without the pill or needle” appeals to patients and practitioners alike and this has triggered the use of alternatives like physiotherapeutic regimes and penetration enhancing vehicles such as iontophoresis and phonophoresis in treating de Quervain's disease.<sup>3,6</sup> However, the actual efficacy of phonophoresis has not yet been conclusively established in medical literature.<sup>2,3</sup> Attending to this gap in evidence-based information, our study proves that ketoprofen phonophoresis coupled with short term thumb splintage and stretching exercise leads to considerable symptomatic and functional improvement in de Quervain's tenosynovitis.

Our results agree with numerous previous research which states that phonophoresis stimulates acceleration of tissue repair and

enhances transdermal delivery of drugs. Systemic absorption of drugs has been found to be as low as 1% after topical application<sup>17</sup> and this further supports employing phonophoresis as an absorption enhancer, which results in significantly high local tissue concentrations.<sup>9</sup> Further support comes from research by Mitragotri,<sup>1</sup> who reported that low-frequency US (20 kHz) enhanced transdermal transport of drugs, a phenomenon he referred to as sonophoresis. In spite of favourable outcomes in numerous trials, the efficacy of phonophoresis still remains a hotly debated topic. Clinical research reports equivocal results (Table 7).<sup>2,7–16</sup> Whereas some advocates suggest phonophoresis may be effective, critics are quick to point to the placebo effect and to the fact that positive outcomes are due to the thermal and tactile effects of US itself. In an interesting study, often cited by opponents of the technique, 16 asymptomatic men and women between the ages of 18 and 33 years were administered topical 10% hydrocortisone. US was delivered over a 50-cm<sup>2</sup> area for 5 minutes and subsequently, blood was drawn under control (US only) and experimental (hydrocortisone plus US) conditions. No rise in serum cortisol concentrations was detected, thereby questioning the very basis of the phonophoresis mechanism that states it as a “penetration enhancing vehicle”.<sup>18</sup> Despite ambiguous findings of other researchers, our study proves that ketoprofen phonophoresis has an excellent effect on relieving symptoms of de Quervain's tenosynovitis during pregnancy and that physiotherapists can safely and confidently use it.

Some strengths of this study were adequate blinding, appropriate randomisation, homogeneous selection of participants, and uniform measurement techniques which might have removed bias from the results. However, our study had certain drawbacks as well, including small sample size, short duration of therapy, and lack of long-term follow-up. Also, most measurements were done in relation to pain reduction and functional improvement in terms of grip and pinch strength, rather than assessment of the range of motion prior to and after treatment (considering that patients of de Quervain's disease often complain of limited thumb and wrist motion). Furthermore, estimation of the depths of muscle or tissue penetration was not done, but the researchers plan to tackle these “missed out” points as a future research task in a larger study group.

More investigation is needed to elucidate the underlying principles and therapeutic potential of phonophoresis. It could well be

**Table 3**

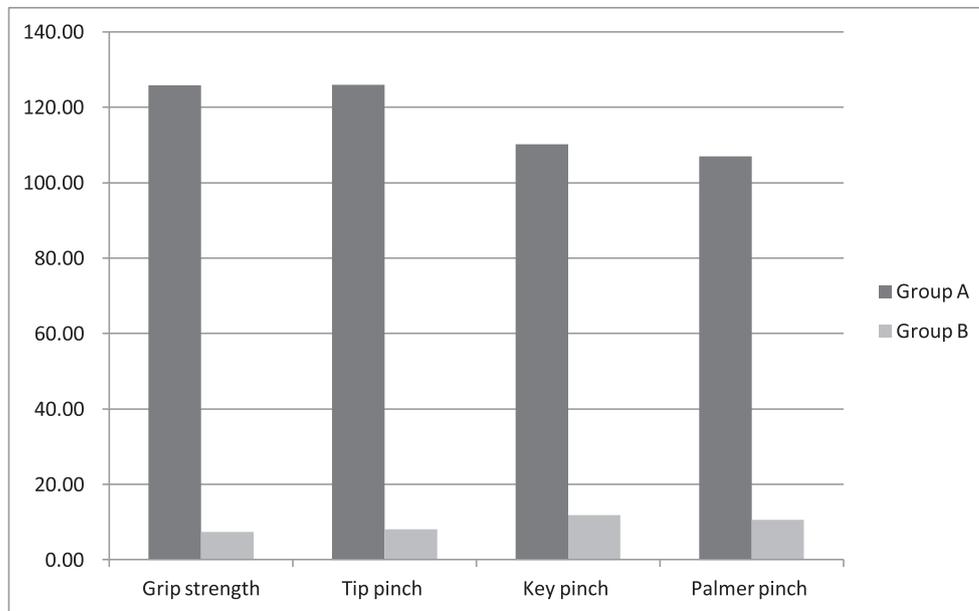
Mean grip strength pretreatment and post-treatment (ketoprofen phonophoresis for intervention and inert gel for control)

Grip strength	Group A (intervention; $n = 25$ )		Group B (control; $n = 25$ )	
	Pretreatment	Post-treatment	Pretreatment	Post-treatment
Mean $\pm$ SD	10.6 $\pm$ 2.22	23.93 $\pm$ 2.6	11.6 $\pm$ 2.66	10.8 $\pm$ 4.82
Mean difference	13.33		0.86	
<i>t</i> value	57.39		1.12	
<i>p</i>	0.0001*		0.28	
Percentage of change (%)	125.75		7.37	

\**p* value significant.

Third trimester pregnant females ( $n = 50$ ) complaining of de Quervain's tenosynovitis of the dominant hand from the outpatient clinic of the obstetrics department, Kasr-El-Aini University and Hospital, Egypt during 2011; ketoprofen 2.5% phonophoresis proved highly effective.

SD = standard deviation.



Expressed as a percentage in Group A (intervention,  $n = 25$ ) and Group B (control,  $n = 25$ ); outpatient clinic obstetrics department Kasr-El-Aini University and Hospital, Egypt during 2011. Ketoprofen 2.5% phonophoresis proved highly effective in pregnant females ( $n = 50$ ) suffering from de Quervain’s tenosynovitis.

**Figure 2.** Functional improvement pre- and post-treatment (ketoprofen phonophoresis for the intervention group and inert gel for control group).

**Table 4**

Tip pinch strength pre- and post-treatment (ketoprofen phonophoresis for intervention and inert gel for control)

Tip pinch strength	Group A (intervention; $n = 25$ )		Group B (control; $n = 25$ )	
	Pretreatment	Post-treatment	Pretreatment	Post-treatment
Mean $\pm$ SD	3.33 $\pm$ 0.85	7.53 $\pm$ 0.87	3.73 $\pm$ 0.7	3.43 $\pm$ 1.27
Mean difference	4.2		0.3	
<i>t</i> value	21.0		1.14	
<i>p</i>	0.0001*		0.27	
Percentage of change (%)	126.13		8.04	

\**p* value significant.

Third trimester pregnant females ( $n = 50$ ) complaining of de Quervain’s tenosynovitis of the dominant hand from the outpatient clinic of the obstetrics department, Kasr-El-Aini University and Hospital, Egypt during 2011; ketoprofen 2.5% phonophoresis proved highly effective. SD = standard deviation.

**Table 5**

Key pinch strength pretreatment and post-treatment (ketoprofen phonophoresis for intervention and inert gel for control)

Key pinch strength	Group A (intervention; $n = 25$ )		Group B (control; $n = 25$ )	
	Pretreatment	Post-treatment	Pretreatment	Post-treatment
Mean $\pm$ SD	3.93 $\pm$ 1.17	8.26 $\pm$ 0.77	3.36 $\pm$ 0.78	2.96 $\pm$ 1.31
Mean difference	4.33		0.4	
<i>t</i> value	20.02		1.6	
<i>p</i>	0.0001*		0.13	

\**p* value significant.

Third trimester pregnant females ( $n = 50$ ) complaining of de Quervain’s tenosynovitis of the dominant hand from the outpatient clinic of the obstetrics department, Kasr-El-Aini University and hospital, Egypt during 2011; ketoprofen 2.5% phonophoresis proved highly effective. SD = standard deviation.

possible that the outcomes of phonophoresis are “site” and “subject” dependent and that certain body regions or target populations respond better than others; hence, conclusions cannot be generalised and appropriate interventions for specific areas or groups need to be determined. Future studies should be designed to establish more concrete differences between outcomes of various treatment modalities for de Quervain’s tenosynovitis by using them in ways that simulate realistic clinical situations.

**Conclusion**

Ketoprofen phonophoresis as an adjunct to a supervised exercise regime and splint immobilisation is a promising therapy for de Quervain’s tenosynovitis during pregnancy. It is safe and provides symptomatic and functional relief of the condition, which makes it an ideal therapy for pregnant females. Technique is very important with any modality, but especially with phonophoresis; the angle of the sound-head and the speed of sound-head motion could affect

**Table 6**

Palmer pinch strength pretreatment and post-treatment (ketoprofen phonophoresis for intervention and inert gel for control)

Palmer pinch strength	Group A (intervention; $n = 25$ )		Group B (control; $n = 25$ )	
	Pretreatment	Post-treatment	Pretreatment	Post-treatment
Mean $\pm$ SD	3.86 $\pm$ 0.91	8.0 $\pm$ 0.56	3.76 $\pm$ 0.67	3.63 $\pm$ 1.23
Mean difference	4.13		0.4	
<i>t</i> value	20.87		1.27	
<i>p</i>	0.0001*		0.22	
Percentage of change (%)	106.99		10.63	

\**p* value significant.

Third trimester pregnant females ( $n = 50$ ) complaining of de Quervain’s tenosynovitis of the dominant hand from the outpatient clinic of the obstetrics department, Kasr-El-Aini University and hospital, Egypt during 2011; ketoprofen 2.5% phonophoresis proved highly effective. SD = standard deviation.

**Table 7**  
Therapeutic outcomes of phonophoresis in numerous clinical trials

Researchers	Year	Pharmacologic agent	Musculoskeletal condition	Therapeutic outcome of phonophoresis <sup>†</sup> (with comments)
Cabak et al <sup>7</sup>	2005	Ketoprofen gel	Epicondylitis of elbow	+++
Koeke et al <sup>8</sup>	2005	Hydrocortisone cream	Tendon injury and soft tissue damage	+
Cagnie et al <sup>9</sup>	2003	Ketoprofen gel	Knee disorders	+
White <sup>10</sup>	1991	Piroxicam gel, benzydamine HCl cream	Osteoarthritis of the knee and muscular pain	++
Airaksinen et al <sup>11</sup>	1993	Ketoprofen gel	Acute soft tissue injury	++
Gimblett et al <sup>12</sup>	1999	Movelet cream	Calcific tendinitis of the shoulder	+++ (complete resolution of the condition)
Ansari et al <sup>13</sup>	2013	Erythromycin	Chronic maxillary rhinosinusitis	+++ (complete resolution of the condition)
Klaiman et al <sup>2</sup>	1998	Fluocinonide cream	Epicondylitis, tendinitis, and tenosynovitis	+– (conventional ultrasound therapy was therapeutically equal)
Nagrle et al <sup>14</sup>	2009	Diclofenac gel	Lateral epicondylalgia	– (Mills physiotherapy was therapeutically superior)
Kozanoglu et al <sup>15</sup>	2003	Ibuprofen gel	Knee osteoarthritis	+– (conventional ultrasound therapy was therapeutically equal)
Jewell et al <sup>16</sup>	2009	NA*	Adhesive capsulitis	– – (joint mobilisation and exercise were therapeutically superior)
Hasan & Fauzi (present study)	2014	Ketoprofen gel	De Quervain's tenosynovitis	+++

+++ = excellent; ++ = very good; + = good; +- = nil; - = poor; - - = very poor.

\* Data not available.

† Range of therapeutic outcome.

treatment outcomes. Through experiential years of trial and error, physiotherapists can learn what actually works and what does not.

### Conflicts of interest

All contributing authors declare no conflicts of interest.

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