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**Randomized Control Trial Article**

**Methylprednisolone acetate injection with casting versus casting alone for the treatment of De-Quervain’s Tenosynovitis: a randomized controlled trial**

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**Abstract**

**Objective:** To compare the success of treatment between thumb spica cast with “methylprednisolone acetate injection” versus thumb spica cast alone for the treatment of de Quervain’s disease as functional outcomes, complications and patient compliance.

**Methods:** A single blinded randomized controlled trial using a probability sampling technique was conducted from January 2014 to February 2017 at the Orthopaedic Unit II, King Edward Medical University / Mayo Hospital, Lahore. A total of 134 patients of both genders, between 30-60 years of age presented with wrist pain and diagnosed de Quervain’s disease, were included in the study. Patients were randomly divided into two group by the computer allocation method. Patients in Group-A received thumb spica cast with methylprednisolone acetate and xylocaine injection while patients in Group-B were treated with thumb spica cast alone. The outcome variable was frequency of successful treatment which was noted and compared among the groups.
Results: Amongst the total 134 patients, the age of the patients ranged from 30 to 60 years with a mean of 37.16±5.15 years. Most of the patients were aged between 30-40 years (78.8%) followed by 41-50 years (21.2%). There were 38 (28.4%) male and 96 (71.6%) female patients in the study group with a male to female ratio of 1:2.5. In group-A mean VAS and Quick DASH score before treatment and after the treatment was statistically significant (p-value <0.001). In group-B mean VAS and Quick-DASH score before and after the treatment was also significant (p-value <0.001) (Table 02).

Conclusion: The effectiveness of treatment was significantly higher in patients treated with thumb spica cast with methylprednisolone acetate injection as compared to thumb spica cast alone.

Keywords: “de Quervain’s Disease”, “Methylprednisolone Acetate”, “Thumb Spica Cast”

Introduction

De Quervain’s disease is a common cause of wrist pain that leads to dysfunction of the affected hand. It typically occurs in adults between 31 to 50 years. This condition is around 0.5% in men and 1.3% in women as reported in the United Kingdom. [1, 2] The tendons of abductor policis longus and extensor policis brevis muscles are involved. Impaired gliding within tendon sheath of these muscles can cause the disease. Most likely it is caused by the thick structures of ligaments that cover the tendons of the first dorsal compartment. [3, 4] The commonly used term for the condition is stenosing tenosynovitis but microscopically the appearance is consistent with degeneration, supplemented by myeloid, fibro-cartilaginous and mucopolysaccharides deposition.. [5]

A good history and clinical examination are considered enough for the diagnosis. The patient reports pain at the radial styloid process with radiation to the thumb and forearm. Clinical examination reveals local tenderness, with possible swelling in some cases along with crepitation on palpation. In typical cases, Finkelstein’s test is done [6] and the patient
is asked to clench the fist, keeping thumb inside and similarly examiner deviates the hand towards the ulnar side. In de Quervain disease the affected side of the patient is painful.\[7\]

No consensus is made on the best protocols of immobilization. Conservative management including rest, massage, cold and heat applications with a splint in this condition has shown no effect. Non-surgical treatment such as injection of locally administered corticosteroid, thumb spica cast, bracing and physical therapy has been most widely used. These methods of treatment are effective for De Quervain’s tenosynovitis and have an advantage over surgical intervention.\[8-10\]

Surgery is performed to release the 1st dorsal compartment of wrist. Surgical treatment (dividing or excision of strip covering tendon) has been reported cure rate of 90%, but it is associated with the risk of a surgical complication, hospital stay, and high cost.\[11\]

There is no clear-cut treatment for the deQuervain’s tenosynovitis and no consensus exists between conservative, intra-lesional steroid and surgical management for better outcomes. We wanted to carry out this treatment to find the outcome of one method over the other so in future treatment with better outcome can be selected as a preferred method of choice.

**Methodology**

It was a single- blinded randomized controlled trial using a probability sampling random technique. This study was conducted from January 2014 to February 2017 at the Orthopaedic Unit II, King Edward Medical University / Mayo Hospital, Lahore. A total of 134 patients were randomly divided into two groups A and B by the computer allocation method with 67 participants in each group. Our inclusion criteria were all adult patients between age 30 to 60 years & above with either gender, pain present at the radial side of the wrist with thumb restricted extension or abduction. Tenderness over the styloid process in the first dorsal extensor compartment with positive Finkelstein test.
Participants already taking treatment of minimum of six weeks (range 4-6 weeks) with oral and local NSAIDs and who did not respond to treatment and/or not satisfied with treatment confirmed on history and examination were also included. Exclusion criteria were all patients with acute trauma and neoplasm involving wrist joint, previous treatment in the form of steroid injection, surgery in the past six months for distal radius and presence of absolute contraindication for steroid confirmed on history, examination and conventional radiographs.

Study participants were recruited after the approval from the Ethical research committee from KEMU Registered participants who presented in the outpatients and fulfilled the above criteria were counseled and explained the details of the study. Informed written consent was obtained from all the patients. Data was recorded on a pre-tested questionnaire. Group A: Thumb Spica cast with Methylprednisolone acetate injection. Group-B: Thumb spica cast alone was given. The routine hospital purchased medicine from hospital supply were used. Patients’ pain at presentation was measured by applying a visual analogue scale (VAS) from 0 (no pain) to 10 (severe pain) and function outcome with Quick disabilities of arm shoulder hand (DASH) score before and after the treatment till the last follow up. Patients of both the groups received treatment as per group protocol. After two weeks of injection with thumb cast and thumb cast alone, each patient was examined clinically to find early clinical response after removal of thumb cast at two weeks intervals and followed fortnightly for six weeks. Successful treatment in two groups was documented by a reduction in the severity of pain on VAS and the absence of tenderness on the radial side of the wrist and negative Finkelstein test on every follow up till the last follow up. These were the primary outcomes that were measured in this study. All patients from both the groups in whom the primary outcome was not achieved, were probed about the presence of a continuous pain, pigmentation of the skin, tenderness test positive as secondary outcome. Failure was defined with the absence of any of the three findings or pain score improvement of less than 90%.
The Quick DASH is an 11-items questionnaire. It was used to assess the outcomes of function and patient’s symptoms having disorders of the upper limb.\textsuperscript{[12]} Participants were inquired to grade the capability to carry out eight routine activities of physical nature. Three-items, were related to the symptoms of a patient. According to literature the minimum change of 27.7 points in the Quick DASH score is statistically significant at the 95% confidence interval. Recently it is recommended that Minimum clinically important difference (MCID) with a Quick DASH score of 15, can be accepted for clinical significance, when each item is scored from scale one to five\textsuperscript{[13]}. The net raw score standardized to global score ranging from 0 to 100.

The data was entered into the software SPSS 21.0 for analysis, Numerical variables i-e age, pain score at presentation have been presented by mean ±SD. Categorical variables i-e gender and successful treatment was presented as frequency and percentage. The paired t-test was applied to compare the effects of successful treatment between the two groups taking \( p \leq 0.05 \) as significant.

**Injection Technique:** For group A, one ml (10mg) of triamcinolone acetonide and one ml of 1% lidocaine hydrochloride mixed in 5 ml syringe with 24- or 26-gauge needle was administered and thumb spica cast was applied. The area of tenderness was confirmed in the first extensor compartment of the wrist, directing proximally towards styloid process of radius and parallel to the abductor policis longus and extensor policis brevis tendon. Presumably no medicine, even a pain killer was allowed, with no absolute contraindication.\textsuperscript{[10]} In Group-B patients received casting alone.

**Results**

The age of the patients ranged from 30 years to 60 years with a mean of 40.73±9.20 years in group-A and 41.44±8.5 in group-B. Most of the patients were aged between 30-40 years (78.8%) followed by 41-50 years (21.2%). The demographic details are given in
Table 1. There were majority 41 (30.6%) who didn’t receive a formal education, while 32 (23.8%) had primary education, 24 (17.9%) middle, 25 (18.6%) had intermediate, 8 (5.9%) graduate and only 4 (2.9%) had master’s degree. In group-A mean VAS and Quick DASH score before treatment and after the treatment was statistically significant (p-value <0.001) (Table 2). In group-B mean VAS and Quick DASH score before and after the treatment was also significant (p-value <0.001) (Table 02). The secondary treatment outcomes were measured and in group-A and only 08 (11.9%) patients had skin pigmentation and 59 (88.1%) didn’t have skin pigmentation. In group-A, 57 (85.1%) had primary outcome while 10 (14.9%) were asked about secondary outcome. Out of 10 patients 07 (70%) didn’t have continuous pain wrist and 03 (30%) had continuous pain. In group-B, out of 42 patients who didn’t respond to treatment, majority 27 (64.3%) had continuous pain and most 15 (35.7%) didn’t have continuous wrist pain.

**Discussion**

De Quervain’s tenosynovitis present with pain at the radial styloid is disabling and require treatment. Non-surgical treatment is preferred over surgical management. Non-operative treatment consists of rest, physiotherapy, thumb casting, topical and intralesional corticosteroid \[14\]. The corticosteroid treatment is given due to its anti-inflammatory effect, however, the exact mechanism of action is not yet fully elucidated. \[15\].

An earlier study from Pakistan evaluated the outcome of methylprednisolone treatment in 80 patients of de Quervain16 where the mean age of patients was 29.32±6.09 years with a male to female ratio of 1:2.3. The mean baseline VAS score for pain was 6.2±1.7. They observed successful resolution of disease in 80% of patients \[16\]. Another study conducted on a smaller sample size of 50 patients with a male to female ratio of 1:5.25 achieved a little higher, i.e. 84% success rate17. The frequency of successful treatment with steroid injection in their series was 84% \[17\]. A study from Thailand has reported...
67% successful treatment rate with injection alone,\textsuperscript{15} while we had 85.1% successful
treatment with combined effects of two treatments and the age of the patients ranged
from 30 to 60 years with a mean of 40.73±9.20 years in group-A. Thus our results of the
combined treatment are a shade better, 85% in comparison to 83% reported in a recently
published systemic review and meta-analysis \textsuperscript{[18]} The primary outcome was taken
reduction in severity of pain on VAS and tenderness on the radial side of wrist and
negative Finkelstein test with minimally important clinical difference of Quick DASH
score was taken 15 score, The frequency of successful treatment was significantly higher
in patients treated with thumb spica cast with methylprednisolone acetate injection
(85.1% vs. 37.4%; p<0.001) as compared to thumb spica cast alone. Hadianfard et al.
(2013) studied 15 patients of de Quervain tenosynovitis with mean baseline pain score of
6.67±1.75. The mean age of the patients was 39.47±12.10 years with male to female ratio
of 1:2.7. They reported successful treatment in 87% of patients with local steroid
injection \textsuperscript{[19]} Peters-Veluthamaningal et al. (2009) studied Nine patients with de
Quervain’s disease undergoing triamcinolone injection with a mean age of 51.2±20.2
years and male to female ratio of 1:3. The mean baseline pain score in their series was
7±4.1. They observed the frequency of successful treatment to be 78% with steroid
injection alone \textsuperscript{[20]}.

It may worth reemphasizing that our rate of 85 % success stays in good agreement with
another randomized controlled trial conducted in Iran on 73 participants with a “mean
age” of 32.83±8.9 years and male to female ratio of 1:6.4. \textsuperscript{[21]} Rowland et al. (2015) \textsuperscript{[22]}
in his meta-analysis assessed the resolution of symptoms [RR 2.59, 95% CI:1.25 to 5.37,
p=0.05]and pain reduction on VAS after injection alone [mean difference -2.51, 95% CI:
-3.11 to -1.90, p=0.0003].

The present study was first of its kind from Pakistan, which adds valuable information to
the limited evidence available on the efficacy of thumb spica cast with
methylprednisolone acetate injection as compared to conventional treatment of thumb
spica cast alone. In the present study, the percentage of successful treatment was noticeably high amongst patients treated with thumb spica cast with methylprednisolone acetate injection (85.1% vs. 37.5%; p<0.001) as compared to the thumb spica cast alone regardless of patient’s age, gender and baseline pain severity. The results of the present study thus advocate the use of this combination therapy in future practice. Our study has revealed good results of combined effects of treatment with methylprednisolone injection plus casting.

In our study, we didn’t consider important limitation that was adverse effect other than corticosteroid treatment which are also equally important. We observed stiffness wrist in both patients and there required physiotherapy for rehabilitation in both groups and should be considered in future studies before adopting this treatment in routine practice.

**Conclusion**

We concluded that patients treated with methylprednisolone injection with casting showed the good results in pain relief, and negative Finkle-stein test and minimum to no complications. The patients also showed good compliance with corticosteroid injection with casting. The casting alone also showed reasonably good outcomes, but the success rate is lower in comparison to injection with casting.

**Disclaimer:** This study was part of thesis for Master of Surgery in Orthopedic Surgery (MS Orthopedic Surgery).

**Conflict of Interest:** None to declare.

**Funding Sources:** None to declare.

**References**


Table 1; Demographic Characteristics of Age, Marital Status, Gender, Financial Status, Income Group and Cigarette Smoker.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Injection with Thumb Cast (n=67) (%)</th>
<th>Thumb Cast Alone (n=67) (%)</th>
<th>N=134 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Male</td>
<td>20 (29.9%)</td>
<td>18 (26.1%)</td>
<td>38 (28.4%)</td>
</tr>
<tr>
<td>• Female</td>
<td>47 (70.1%)</td>
<td>49 (73.1%)</td>
<td>96 (71.6%)</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Married</td>
<td>61 (91%)</td>
<td>58 (86.6%)</td>
<td>119 (88.8%)</td>
</tr>
<tr>
<td>• Unmarried</td>
<td>06 (9%)</td>
<td>09 (13.4%)</td>
<td>15 (11.2%)</td>
</tr>
<tr>
<td>Mean Age±SD (years)</td>
<td>(40.73±9.20)</td>
<td>(41.44±8.5)</td>
<td>59 (44.02%)</td>
</tr>
<tr>
<td>Financial Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Self-earning</td>
<td>28 (41.8%)</td>
<td>31 (46.2%)</td>
<td>58 (43.28%)</td>
</tr>
<tr>
<td>• Dependent</td>
<td>31 (46.2%)</td>
<td>27 (40.3%)</td>
<td></td>
</tr>
<tr>
<td>• Un-employed</td>
<td>8 (11.9%)</td>
<td>9 (13.4%)</td>
<td>17 (12.7%)</td>
</tr>
<tr>
<td>Income Group</td>
<td></td>
<td></td>
<td>35 (16.14%)</td>
</tr>
<tr>
<td>• Low</td>
<td>16 (23.9%)</td>
<td>19 (28.3%)</td>
<td>99 (51.36%)</td>
</tr>
<tr>
<td>• Middle</td>
<td>51 (76.1%)</td>
<td>48 (71.7%)</td>
<td></td>
</tr>
<tr>
<td>Cigarette Smoker</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Yes</td>
<td>26 (38.8%)</td>
<td>15 (22.4%)</td>
<td>41 (30.6%)</td>
</tr>
<tr>
<td>• No</td>
<td>41 (61.2%)</td>
<td>52 (77.6%)</td>
<td>93 (69.4%)</td>
</tr>
</tbody>
</table>
Table 2: Paired t Test of both Group A (Methylprednisolone acetate injection with thumb cast) & Group B (thumb cast alone) Visual Analogue Score & Quick DASH Score Before and After the Treatment.

<table>
<thead>
<tr>
<th>Variables</th>
<th>n</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>t</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quick DASH Score before</td>
<td>67</td>
<td>46.75</td>
<td>14.84</td>
<td>18.39</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quick DASH Score after</td>
<td>67</td>
<td>11.7</td>
<td>9.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group B</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quick DASH Score before</td>
<td>67</td>
<td>42.01</td>
<td>13.8</td>
<td>8.137</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quick DASH Score after</td>
<td>67</td>
<td>28.25</td>
<td>18.71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS before Treatment</td>
<td>67</td>
<td>4.55</td>
<td>1.71</td>
<td>19.762</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>VAS Score after Treatment</td>
<td>67</td>
<td>0.791</td>
<td>1.17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group B</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS before Treatment</td>
<td>67</td>
<td>4.45</td>
<td>1.01</td>
<td>8.906</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>VAS Score after Treatment</td>
<td>67</td>
<td>2.53</td>
<td>1.67</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 01: Consort Flow Diagram: A randomized comparison of Methylprednisolone acetate injection with casting versus casting alone for the treatment of De Quervain's Tenosynovitis.

Enrollment

Assessed for eligibility (n=217)

Excluded (n=43)
  - Not meeting inclusion criteria (n=21)
  - Declined to participate (n=10)
  - Other reasons (n=2)

Randomized (n=174)

Allocation

Allocated to intervention (n=87)
  - Received Methylprednisolone injection with casting

Allocated to intervention (n=87)
  - Casting alone

Follow-Up

Lost to follow-up (n=20)

Lost to follow-up (n=18)
  - Did not continue the treatment (n=2)

Analysis

Effectiveness of the treatment: 57 (85.1%) (n=67)

Effectiveness of the treatment: 57 (37.4%) (n=67)