Role of homoeopathy in the management of adhesive capsulitis: A pretest-posttest study

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Abstract
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Objectives: Primary objective was to evaluate change in shoulder pain after individualised homoeopathy treatment for over 2 months. Secondary objective was to assess the change in the QoL and outcome related to impact on daily living (ORIDL).

Methods: A single-arm, pretest-posttest, clinical study on AC was conducted on 40 participants recruited from the outpatient clinic of rheumatological disorders at Clinical Research Unit (Homoeopathy), Siliguri, West Bengal, India. Medicines were prescribed on the basis of the totality of symptoms. Changes in shoulder pain over 2 months were evaluated using the shoulder pain and disability index (SPADI). QoL was evaluated using SF-12v2 and ORIDL (participants and physician assessed), respectively.

Results: Thirty-six participants completed the study and four participants dropped out. A protocol compliant sample of n = 36 was analysed. There was a statistically significant reduction of SPADI score (91.92 ± 10.22 vs. 34.14 ± 24.43; mean reduction 57.78, 95% CI 49.41–66.14, P < 0.001) and statistically significant increase in SF-12 v2 score (44.39 ± 9.70 vs. 72.27 ± 10.97; mean increase 27.87, 95% CI 23.89–31.85, P < 0.001). The Spearman's correlation between the changes in physician assessment ORIDL scores and participants assessment ORIDL scores over 2 months suggested a statistically significant correlation (rs = 0.998, P < 0.01).

Conclusion: The findings showed symptom alleviation, and improvement in the QoL after homoeopathic treatment. Randomised controlled trials are further warranted.

Acknowledgments and Source of Funding
Role of homoeopathy in the management of adhesive capsulitis: A pretest-posttest study

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Abstract

Background: Adhesive capsulitis (AC) is an insidious and painful stiffening of the glenohumeral (shoulder) joint, resulting in compromised functional ability and quality of life (QoL). Objectives: Primary objective was to evaluate change in shoulder pain after individualised homoeopathy treatment for over 2 months. Secondary objective was to assess the change in the QoL and outcome related to impact on daily living (ORIDL). Methods: A single-arm, pretest-posttest, clinical study on AC was conducted on 40 participants recruited from the outpatient clinic of rheumatological disorders at Clinical Research Unit (Homoeopathy), Siliguri, West Bengal, India. Medicines were prescribed on the basis of the totality of symptoms. Changes in shoulder pain over 2 months were evaluated using the shoulder pain and disability index (SPADI). QoL was evaluated using SF-12v2 and ORIDL (participants and physician assessed), respectively. Results: Thirty-six participants completed the study and four participants dropped out. A protocol compliant sample of n = 36 was analysed. There was a statistically significant reduction of SPADI score (91.92 ± 10.22 vs. 34.14 ± 24.43; mean reduction 57.78, 95% CI 49.41–66.14, P < 0.001) and statistically significant increase in SF-12 v2 score (44.39 ± 9.70 vs. 72.27 ± 10.97; mean increase 27.87, 95% CI 23.89–31.85, P < 0.001). The Spearman’s correlation between the changes in physician assessment ORIDL scores and participants assessment ORIDL scores over 2 months suggested a statistically significant correlation (r = 0.998, P < 0.01). Conclusion: The findings showed symptom alleviation, and improvement in the QoL after homoeopathic treatment. Randomised controlled trials are further warranted.

Keywords: Adhesive capsulitis, Frozen shoulder, Homoeopathy, India, Inflammation, ORIDL, SF-12v2, SPADI

INTRODUCTION

Adhesive capsulitis (AC) (frozen shoulder) is a clinical condition characterised by spontaneous onset of shoulder pain and gradual loss of active and passive shoulder movements.[1] The prevalence is more in women aged 40–60 years, diabetic population with the occurrence rate of approximately 2–5% of the general population,[2] and up to 20% in diabetics.[3] 13.4% of participants with AC have thyroid dysfunction.[4] The incident of AC in one shoulder increases the risk of contralateral shoulder involvement by 5%–34%, and simultaneous bilateral shoulder involvement develops in approximately 14% of cases.[5] Zuckerman classified AC into primary and secondary and subdivided the latter into intrinsic, extrinsic and systemic ones.[6,7]

Participants presenting with AC often report an insidious onset with a progressive increase in pain and a gradual decrease in active and passive range of motion (ROM).[3] The subjects frequently have difficulty with dressing, grooming, performing overhead reaching activities and particularly fastening items behind the back for a period of several months to several years.[7]

The literature reports that AC progresses through three overlapping clinical phases that is, acute/freezing/painful phase, adhesive/frozen/stiffening phase and resolution/thawing phase.[6,8] The diagnosis of AC is usually based on clinical findings, medical history and physical examination.[7] The orthopaedic clinical examination for AC shows high sensitivity...
and specificity for the confident diagnosis of AC and is the reference standard for diagnosis.\(^{[10]}\) Despite the value of imaging techniques in recent advances, these are not initially indicated to diagnose AC but can be used to rule out other intra-articular pathology.\(^{[11]}\) There is currently no gold standard for diagnosis nor have validated diagnostic criteria been published in the literature.\(^{[12]}\)

Systemic reviews of the current therapies for AC such as physiotherapy, both oral and intra-articular steroid, and operative interventions do not provide significant long-term benefits.\(^{[11]}\) The Cochrane review also reports very inconclusive results or add little evidence in interventions such as manual therapy and acupuncture. Even though AC is a self-limiting condition, lasting on average for 2–3 years; few studies have shown that 20–50% of affected individuals do continue to have pain and restricted movement beyond 3 years.\(^{[7]}\) In spite of this, recent clinical evidence of persistent functional limitation, lasting for years, has challenged this theory.\(^{[13]}\) A 2017 systematic review of seven studies found low-quality evidence that no treatment yielded some, but not complete improvement in ROM after 1–4 years of follow-up. Moderate-quality evidence from three randomised controlled trials with longitudinal data demonstrated that most improvement in pain and ROM occurs early, not late.\(^{[14]}\) Homoeopathic medicines have been shown to provide relief and improve quality of life (QoL) in rheumatic disorders such as fibromyalgia and rheumatoid arthritis,\(^{[15–17]}\) and could be a valid alternative treatment for AC.\(^{[14]}\) Unfortunately, there is inadequate evidence to conclude the utility of individualised homoeopathic medicine (IHM) in the management of AC. An observational study of homoeopathy in AC by Magotra et al.\(^{[18]}\) illustrates an encouraging role with IHM having a positive treatment option for AC. To further extrapolate the role of IHM in managing AC, a study design incorporating an added outcome measurement of QoL (SF-12) along with different study setting was devised. Therefore, there was a need to explore the possible role of IHM in relieving pain and stiffness, reduction in limitation and disability in activities of daily life in the participants suffering from AC. To generate such evidence, a preliminary single-group, pre-test, a post-test clinical study has been undertaken by the investigators. The research question for this study was the generated clinical hypothesis that whether 2 months of IHM can significantly reduce pain, stiffness, limitation of movements and improve QoL when measured on standardised scales. The generated null hypothesis is that there is no statistical significant difference of the shoulder pain and disability index (SPADI) scores, SF-12v2 and outcome related to impact on daily living (ORIDL) score of the patients between baseline and after 2 months of homoeopathic treatment.

**Methods**

**Setting and design**

This was a prospective, single-group, pretest-posttest clinical study conducted in the out patient department of rheumatological disorders at Clinical Research Unit (Homoeopathy), Siliguri, West Bengal, India from July 2019 to March 2020. The study protocol was approved by the Institutional Ethics Committee, of Clinical Research Unit (Homoeopathy), Siliguri, and was registered with the Clinical Trials Registry – India (CTRI/2019/05/019121) before the enrolment of the first participant. The proposed plan of work adhered to the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th WMA general assembly, Helsinki, Finland, June 1964.\(^{[19]}\) Each participant was provided with a participant information sheet written in local vernacular Bengali language detailing the objectives, methods, risks and benefits of participating and confidentiality issues. Written informed consent was obtained from each participant before the study participation.

**Eligibility**

Participants suffering from AC (ICD10-75.02) of painful and stiffening phase of one or both shoulders were only included. AC was clinically diagnosed, by assessing the shoulder pain followed by gradual loss of both active and passive ROM of the shoulders. Participants accompanying pain at the extreme of motion observed mainly in the stiffness phase were also included. Impaired ROM with forward flexion, abduction and external and internal rotation was the prime clinical finding in diagnosing AC.

Participants aged between 30 and 70 years old and who had provided written informed consent were included in the study. Excluded participants were those with severe degeneration of the shoulder joint with marked joint narrowing with recent shoulder surgery within the past 6 months, deformity of the shoulder (≥12°); evidenced by imaging or other evidence and requiring surgical intervention, self-reported joint disorders (e.g., inflammatory joint diseases, specific arthropathy, severe axis deviations or instabilities, joint or skin infections and the joint prosthesis of the upper limbs) other than AC. Exclusion criteria also included those cases suffering from uncontrolled systemic illness or life-threatening infections, those already undergoing homoeopathic treatment for any chronic disease within past 3 months, who were compromised by substance abuse and/or dependence, were pregnant or puerperal or lactating women, patients with psychiatric diseases, and self-reported immune-compromised states.

**Study procedures**

As per the specified eligibility criteria, participants underwent preliminary screening. Following this, a thorough case taking was undertaken on a pre-designed case recording form. The overall process of the selection of individualised medicine was based on the presenting symptoms’ totality, repertoration and consultation with homoeopathic Materia Medica\(^{[20–24]}\) when required. On the whole, the decision-making was influenced by two experienced practitioners after mutual consensus. Successive prescriptions were generated following the homoeopathic principles.\(^{[25]}\) Symptoms considered for the homoeopathic prescription and, in the subsequent visits, the changes in these symptoms were mentioned clearly.
Homoeopathic medicines, dilution methods, potency, pharmaceutical form and dose were also recorded. All medicines were procured from a GMP-certified firm: SBL Pvt. Ltd. Each dose was directed to be taken orally on a clean tongue. It consisted of four medicated sugar globules of size 30. Each participant enrolled was treated for 2 months, and follow-up was done at every 2 weeks interval or earlier, as and when required by the participants. Repetition was done depending on the intensity of the complaints. The participants were free to report on follow-up days, as mentioned above, in person or by telephone as per convenience.

General management
All the participants were advised to maintain an ambulatory state, avoid actions that can aggravate the pain and perform joint mobility exercises.

Outcome assessment
Primary outcome
SPADI, a commonly used shoulder-specific health status questionnaire\textsuperscript{24,27} and described as the most responsive shoulder pain and disability tool for shoulder conditions,\textsuperscript{28} was used in this study. It is ranked as one of the most relevant questionnaires for shoulder pain for being easy to complete in the least time that is, 2–5 min.\textsuperscript{27,29} It consists of 13 items and is divided into two constructs: Pain (5 items) and functional disability (8 items). It is scored on an ordinal scale from 0 (no pain/no difficulty) to 10 (worst pain imaginable) with higher scores indicating greater pain and/or disability.\textsuperscript{27} SPADI was assessed at baseline and after 2 months of intervention.

Secondary outcomes
The Short Form12 version 2 health survey (SF-12\textsuperscript{v2}) estimates eight domains of functioning and well-being of respondents by considering their health status over the past 4 weeks.\textsuperscript{30} The SF-12 consists of 12 items and eight subdomains: Physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE) and mental health (MH). The subscales PF, RP, BP and GH form the physical component summary (PCS-12) scores, whereas the subscales VT, SF, RE and MH form the mental component summary (MCS-12) scores.\textsuperscript{31} Each item of the questionnaire has response categories which vary from 2- to 6-point scales and raw scores for items ranging from 1 to 6.\textsuperscript{31} The raw scores are summated and linearly transformed into 0–100 scale\textsuperscript{31,32} with a higher score indicating better health status.\textsuperscript{31,32}

The clinical improvement and outcome of signs and symptoms were assessed by ORIDL score\textsuperscript{33} at every follow-up visit. The ORIDL instrument records the assessment of response to the previous prescription on the main complaint as well as on general well-being on a numerical scale of −4 to +4.

Sample size
The sample size was calculated using the software G*Power software (latest ver. 3.1.9.7; Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany; http://www.gpower.hhu.de/).\textsuperscript{34} Considering a chance to drop out of 20%, the sample size was taken as 40. Therefore, we planned a sample size of 40 participants to be recruited for this clinical study. (The statistical analysis was performed by ‘t-test’ and ‘Difference between two dependent means (matched pairs)’ with ‘two tails test.’ The effect size was fixed at 0.5, alfa=0.05, power [1-beta] = 0.8, degree of freedom was 1).

Statistical analysis
All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS), version 20.0 (IBM Corp., IBM SPSS Statistics for Windows, Armonk, New York: USA). Per protocol (PP) analysis was performed meaning only the protocol-compliant sample was used in the final analysis. Data distribution for its normality was examined by histograms, Q-Q plots and the Shapiro–Wilk test. Descriptive data (categorical and continuous) were presented in terms of absolute values, percentages, means and standard deviations. Student’s t-test (parametric test) was used as inferential statistics as per normality of data distribution comparing dependent observation of continuous outcomes at baseline and after 2 months. Pearson correlation coefficient was measured to detect a correlation between physician assessment score and participants’ assessment score for ORIDL. P < 0.01 two tailed was considered as statistically significant.

Results
A total of 70 participants reporting for pain in the shoulder were preliminarily screened of which 30 (42.8%) were excluded; 40 met the eligibility criteria and were enrolled in the study. Among those four participants dropped out and 36 completed the study. The demographic details [Table 1] and the flow diagram of participants [Figure 1] are given in the table and figure, respectively.

Baseline features
The baseline sociodemographic features – age, gender, residence, duration of illness, treatment history comorbidities, marital status and educational status are shown in Table 1.

Test of normality of the data distribution
When histogram, Q-Q plot and Shapiro–Wilk test were carried out, there was no significant departure from normality both in terms of age and baseline data of SPADI and SF-12\textsuperscript{v2} data.

Pre-post comparison of outcome measures
The objective was to compare the mean scores of SPADI (pain, disability and total) and of SF-12\textsuperscript{v2} (PCS, MCS and total) at baseline and after 2 months of participants receiving IHT. The data were analysed with the help of a correlated t-test and the results are given in Table 2.

From Table 3, it can be seen that the t values of the primary outcome measure of SPADI (pain, disability and total) and SF-12\textsuperscript{v2} (PCS, MCS and total) are significant at 0.01 level with df = 35. It indicates that mean scores of SPADI and SF-12\textsuperscript{v2} at pre-
test and post-test stages after IHT differ significantly. Therefore, the null hypothesis that there is no significant difference in mean scores of pain, limitation of movement and QoL at pre-test and post-test stages after IHT is rejected. Further, the primary outcome measure reductions in SPADI pain score (38.31 ± 4.11 vs. 15.61 ± 10.75; mean reduction 22.7, 95% CI 19.10–26.29, \( P < 0.001 \)), SPADI disability score (53.61 ± 7.25 vs. 18.53 ± 13.88; mean reduction 35.08, 95% CI 30.19–39.98, \( P < 0.001 \)) and SPADI total score (91.92 ± 10.22 vs. 34.14 ± 24.43; mean reduction 57.78, 95% CI 49.41–66.14, \( P < 0.001 \)) were statistically significant by parametric paired t-test [Table 3].

Secondary outcome measures – in SF-12 v2 health survey increased in PCS score (41.43 ± 9.53 vs. 70.52 ± 12.58; mean value increased 29.08, 95% CI 25.12–33.05, \( P < 0.001 \)), MCS score (49.72 ± 12.76 vs. 75.42 ± 8.89; mean value increased 25.69, 95% CI 21.13–30.25, \( P < 0.001 \)) and overall score (44.39 ± 9.70 vs. 72.27 ± 10.97; mean value increased 27.87, 95% CI 23.89–31.85, \( P < 0.001 \)) were statistically significant by parametric paired t-test [Table 3].

Table 2 shows that Pearson’s correlation coefficient is 0.802 which is positive and nearer to 1 and significant at the 0.01 level. It reflects that the changes in SPADI scores and SF-12v2 overall scores over 2 months of IHT were positively and significantly correlated [Figure 2].

Further, Table 4 reflects that there is a significant positive correlation between ORIDL scores of the participants assessment and the physician assessment with a correlation coefficient of 0.998 significant at 0.01 level and df = 142. To see the clinical significance between the baseline and after 2 months of treatment, the effect size (Cohen’s-d) was calculated from this primary outcome (SPADI score). The obtained Cohen’s-d score (score ‘5.65’) [Table 3] indicates

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**Table 1: Sociodemographic information at baseline (n=40)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (in years)</td>
<td>*50.43 ± 12.10</td>
</tr>
<tr>
<td>Age group (in years)</td>
<td></td>
</tr>
<tr>
<td>30–40</td>
<td>10 (25.00)</td>
</tr>
<tr>
<td>41–50</td>
<td>13 (32.50)</td>
</tr>
<tr>
<td>Above 50</td>
<td>17 (42.50)</td>
</tr>
<tr>
<td>Duration of illness in months</td>
<td>3 (1–6)***</td>
</tr>
<tr>
<td>Duration of illness categorised</td>
<td></td>
</tr>
<tr>
<td>Up to 6 months</td>
<td>31 (77.50)</td>
</tr>
<tr>
<td>More than 6 months–1 year</td>
<td>6 (15.00)</td>
</tr>
<tr>
<td>More than 1 year–2 years</td>
<td>1 (2.50)</td>
</tr>
<tr>
<td>More than 2 years</td>
<td>2 (5.00)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>7 (17.50)</td>
</tr>
<tr>
<td>Female</td>
<td>33 (82.50)</td>
</tr>
<tr>
<td>Residence</td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>30 (75.00)</td>
</tr>
<tr>
<td>Urban</td>
<td>10 (25.00)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>30 (75.00)</td>
</tr>
<tr>
<td>Unmarried</td>
<td>1 (2.50)</td>
</tr>
<tr>
<td>Divorcee/widower</td>
<td>9 (22.50)</td>
</tr>
<tr>
<td>Comorbidity</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>12 (30.00)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>4 (10.00)</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>2 (5.00)</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>1 (2.50)</td>
</tr>
<tr>
<td>Others</td>
<td>4 (10.00)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>Up to class 10</td>
<td>20 (50.00)</td>
</tr>
<tr>
<td>Up to class 12</td>
<td>8 (20.00)</td>
</tr>
<tr>
<td>Graduation and above</td>
<td>12 (30.00)</td>
</tr>
</tbody>
</table>

Data are presented as *mean±standard deviation, ***median (IQR)

**Table 2: Correlations between the changes in SPADI total score and SF-12 v2 overall score after 2 months of treatment**

<table>
<thead>
<tr>
<th>Correlations</th>
<th>Changes in SPADI total score after 2 months of treatment</th>
<th>Changes in SF-12 v2 overall score after 2 months of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Changes in SPADI total score after 2 months of treatment</td>
<td>Changes in SF-12 v2 overall score after 2 months of treatment</td>
</tr>
<tr>
<td>Pearson correlation</td>
<td>1</td>
<td>0.802**</td>
</tr>
<tr>
<td>Sig. (two tailed)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>( n )</td>
<td>36</td>
<td>36</td>
</tr>
</tbody>
</table>

**Correlation is significant at the 0.01 level (two tailed)**

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**Figure 1: The participant flow diagram**

Excluded (n = 30); reasons:
- Age beyond range (n = 5)
- Illiterate (n = 9)
- Not willing to participate and denied consent (n = 3)
- Uncontrolled diabetes (n = 3)
- Uncontrolled hypertension (n = 4)
- Already undergoing medical treatment for AC (n = 4)
- Deformity of the shoulder joint (n = 2)

Eligible participants (n = 40)

Received individualized homeopathy (n = 40)

Drop out after baseline (n = 4)

Followed up (n = 36)

Per protocol analysis (n = 36)
the large effect size (above 0.8) and ascertains the clinically significant reduction of the SPADI score.

Medicines used
Overall in this study, 16 different medicines were prescribed in 30cH, 200cH and 1000cH potencies. The most frequently indicated medicines were *Rhus toxicodendron* (n=7; 17.5%), *Ferrum Metallicum* (n=5; 12.5%) and *Syphilinum* (n=5; 12.5%) [Figure 3].

Adverse or unanticipated events
Throughout the course of treatment, no unanticipated event in the form of aggravation or worsening of symptoms, that is, ‘adverse event’ [34,35] was reported by the participants either directly in the OPD or over the phone.

**DISCUSSION**
This study intended to explore the possible effects of IHM in relieving pain, stiffness, reduction in limitation of movement and disability in activities of daily life in the participants suffering from AC. Upon thorough search, we realised there is severe paucity of conclusive evidence-based homeopathy study in the mainstream database for AC. We, therefore, devised a study to come up with a single-arm clinical study to find some effects of IHM on AC. AC, though a self-limiting condition, its
suffering may stretch for more than 3 years, leading to a serious compromise along with the impaired psychosocial status among the working section of the society.\[8,37,38\] This study reflected a statistically significant result in the reduction of pain, stiffness and improvement in limitation of the movement of affected shoulder joints along with favourable improvement in the QoL of the individuals suffering from AC. IHM was able to reduce the pain, stiffness and limitation of movement within a plausible time frame of 2 months which was the objective of this study. The study also assessed the difference in response before and after the administration of IHM in a single arm of 36 participants suffering from AC. The validated outcome such as SPADI and SF-12 v2 was taken as the primary and ORIDL scores as secondary outcome measures, calculated, respectively, at baseline and after 2 months of treatment. To see the clinical significance between the baseline and after 2 months of treatment, the effect size (Cohen’s-d) was calculated from this primary outcome (SPADI score). The obtained Cohen’s-d score (score ‘5.65’) \[Table 3\] indicates the large effect size (above 0.8) and ascertains the clinically significant reduction of the SPADI score.

A study of Magotra et al.\[18\] on AC used the SPADI and Oxford Shoulder Score outcome measure to show the positive effect of homoeopathy in AC. This study utilised the QoL assessment scale measure like SF-12 v2 along with the AC-specific rating scale to evaluate the effects of IHM. The pre-post comparison study of SF-12 v2 a well-validated Bengali questionnaire showed changes in the outcomes over time significantly. The significant correlation between SPADI a disease-specific rating scale and SF12 v2 also showed that IHM when used in pursuance with homoeopathic principles gives an overall improvement. We used the ORIDL scale to detect the overall improvement of the participants in the realm of participants and physician observation both. The correlation between the changes in physician assessment ORIDL scores and participants’ assessment ORIDL scores over 2 months of treatment reflects that there is a significant correlation that supports the overall timely improvement of the pain, stiffness and QoL of the individual. However, AC participants suffering from comorbidities \[Table 1\] were reported to be low in terms of improvement in pain and stiffness. Altogether authors were able to find only one such study Magotra et al.\[18\]

Figure 3: Homoeopathic medicines used: Sixteen different individualised medicines were prescribed in the clinical study

Table 4: Non-parametric correlation between patient assessment and physician assessment of ORIDL score

<table>
<thead>
<tr>
<th>Correlations</th>
<th>ORIDL score physician assessment</th>
<th>ORIDL score patient assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spearman’s rho</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correlation coefficient</td>
<td>1.000</td>
<td>0.998**</td>
</tr>
<tr>
<td>Sig. (two tailed)</td>
<td>&lt;0.001</td>
<td>0.998**</td>
</tr>
<tr>
<td>n</td>
<td>144</td>
<td>144</td>
</tr>
<tr>
<td>ORIDL score patient assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correlation coefficient</td>
<td>0.998**</td>
<td>1.000</td>
</tr>
<tr>
<td>Sig. (two tailed)</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>144</td>
<td>144</td>
</tr>
</tbody>
</table>

**Correlation is significant at the 0.01 level (two tailed)
where IHM had a possible effect on the systematic estimation of results. Moreover, this study with a multidimensional approach to measure perceived pain, stiffness, discomfort and QoL along with the subjective measure of ORIDL has been well-documented for the readers. AC responding with IHM significantly within a reasonable time edge supported by Magotra et al.[18] along with this study demands more robust randomised controlled trials with a multicentre design in near future. The strength of the study was following the approach of model validity of homoeopathic treatment accompanying all the six domains such as the rationale of the intervention, principles of homoeopathy, practitioners experience, outcome measures and outcome sensitivity along with the follow-up of the condition treated.[39] The Bengali-translated version of the SPADI questionnaires was able to elicit the minute significant changes in the pain which was the primary outcome measure in the study. The follow-up to evaluate the effects of IHM which was for 2 months in this study was done to bring in comparison with the conventional system of medicines which can bring down the pain of AC within 3–4 weeks of administration. The AC participants have to continue long treatment along with supplements as in the conventional system, which automatically brings in a disinterest and accrues economic burden along with the chance of side effects during the discourse.[7] In this study, the results were not only statistically significant within the 2 months of follow-up but also clinically with a large effect size. However, the study missed the opportunity to find the role of IHT in radiological changes in the affected joint and its assessment. The study if conducted with control group and considering a large sample size along with longer follow-up could further explore the efficacy or effectiveness of the intervention which is warranted in the future. This exploratory approach of the study without incurring any major budgetary expenditure was a potential explanation and its worthiness for further controlled trials.

The limitation of the study is that it is of one-group pretest-posttest design, where measures such as blinding, randomisation or control are missing, offers disadvantages of ruling out any possible alternative explanations and poses a threat to their validity.

**Conclusion**

This open-label, prospective one group of pretest-posttest comparison design conducted on 40 subjects suffering from AC showed statistically significant improvement in the SPADI scale, SF-12 v2 health survey and ORIDL scores after 2 months of individualised homoeopathic treatment. Further experimentations by adequately powered randomised trials and independent replications with longer follow-ups are merited.

**Financial Support and Sponsorship**

The study was funded by the Central Council for Research in Homoeopathy, under the Ministry of AYUSH, Government of India.

**Conflicts of Interest**

None declared.

**References**

Choubey, et al.: Homoeopathy in the management of adhesive capsulitis


Rôle de l’homéopathie dans la prise en charge de la capsulite adhésive: Une étude basée sur un modèle pré-test-post-test

RÉSUMÉ Contexte: La capsulite adhésive (CA) est un raidissement insidieux et douloureux de l’articulation gléno-humérale (épaule), entraînant une diminution de la capacité fonctionnelle et de la qualité de vie (QOV). Objectifs: L’objectif principal était d’évaluer l’évolution de la douleur à l’épaule après un traitement homéopathique individualisé sur 2 mois. L’objectif secondaire était d’évaluer l’évolution de la qualité de vie et des résultats liés à l’impact sur la vie quotidienne (ORIDL). Méthodes: Une étude clinique à un seul bras, de type pré-test-post-test, a été menée sur 40 participants souffrant de CA et fréquentant la clinique externe des troubles rhumatologiques de l’unité de recherche clinique (homéopathie), à Siliguri, au Bengale occidental, en Inde. Les médicaments ont été prescrits sur la base de l’ensemble des symptômes. L’évolution de la douleur à l’épaule sur 2 mois a été évaluée à l’aide de l’indice de douleur et d’incapacité à l’épaule (SPADI). La qualité de vie a été évaluée à l’aide du SF-12v2 et de l’ORIDL (évalués par les participants et les médecins), respectivement. Résultats: 36 participants ont terminé l’étude et quatre participants ont abandonné. Un échantillon conforme au protocole de (n = 36) a été analysé. On a constaté une réduction statistiquement significative du score SPADI (91,92 ± 10,22 contre 34,14 ± 24,43 ; réduction moyenne de 57,78, IC 95 % 49,41-66,14, P < 0,001) et une augmentation statistiquement significative du score SF-12 v2 (44,39 ± 9,70 contre 72,27 ± 10,97 ; augmentation moyenne de 27,87, IC 95 % 23,89-31,85, P < 0,001). La corrélation de Spearman entre les changements dans les scores ORIDL évalués par les médecins et les scores ORIDL évalués par les participants sur une période de 2 mois a suggéré une corrélation statistiquement significative (rs = 0,998, P < 0,01). Conclusion: Les résultats ont montré une atténuation des symptômes et une amélioration de la qualité de vie après le traitement homéopathique. Des essais contrôlés randomisés sont encore nécessaires.

Die Rolle der Homöopathie bei der Behandlung der adhäsiven Kapsulitis: Eine Studie mit Prä-Test-Post-Test-Design

Abstrakt Hintergrund: Die adhäsive Kapsulitis (AC) ist eine schleichende und schmerzhafte Versteifung des Schultergelenks, die zu einer Beeinträchtigung der Funktionsfähigkeit und der Lebensqualität führt. Zielsetzungen: Primäres Ziel war die Bewertung der Veränderung der Schulterschmerzen nach einer individualisierten homöopathischen Behandlung über 2 Monate. Sekundäres Ziel war die Bewertung der Veränderung der Lebensqualität und des Ergebnisses in Bezug auf die Auswirkungen auf das tägliche Leben (ORIDL). Methoden: Eine einarmige klinische Prä-Test-Post-Test-Studie wurde mit 40 Teilnehmern durchgeführt, die an AC litten und die Ambulanz für rheumatologische Erkrankungen in der Clinical Research Unit (Homöopathie), Siliguri, Westbengalen, Indien, aufsuchten. Die Medikamente wurden auf der Grundlage der Gesamtheit der Symptome verschrieben. Die Veränderungen der Schulterschmerzen über 2 Monate wurden anhand des Schulterschmerz- und Behinderungsindex (SPADI) bewertet. Die Lebensqualität wurde anhand des SF-12v2 und des ORIDL (nach Einschätzung der Teilnehmer und des Arztes) bewertet. Ergebnisse: 36 Teilnehmer schlossen die Studie ab, vier Teilnehmer brachen sie ab. Es wurde eine protokollkonforme Stichprobe von (n = 36) analysiert. Es gab eine statistisch signifikante Verringerung des SPADI-Scores (91,92 ± 10,22 vs. 34,14 ± 24,43; mittlere Verringerung 57,78, 95% CI 49,41-66,14, P < 0,001) und eine statistisch signifikante Erhöhung des SF-12 v2-Scores (44,39 ± 9,70 vs. 72,27 ± 10,97; mittlere Erhöhung 27,87, 95% CI 23,89-31,85, P < 0,001). Die Spearman-Korrelation zwischen den Veränderungen der ORIDL-Scores nach ärztlicher Beurteilung und den ORIDL-Scores nach Einschätzung der Teilnehmer über einen Zeitraum von 2 Monaten deutete auf eine statistisch signifikante Korrelation hin (rs = 0,998, P < 0,01). Schlussfolgerung: Die Ergebnisse zeigen eine Linderung der Symptome und eine Verbesserung der Lebensqualität nach homöopathischer Behandlung. Randomisierte kontrollierte Studien sind weiterhin gerechtfertigt.
Abstract

Background: Adhesive capsulitis (AC) is a gradual and painful stiffening of the shoulder joint, leading to restricted function and quality of life (QoL).

Objectives: The main objective was to evaluate the change in shoulder pain after the individualized homoeopathic treatment during 2 months. The secondary objective was to evaluate the change in QoL and the result related to the impact in daily life (ORIDL).

Methods: A single-arm pre-test-post-test clinical study was conducted in 40 participants with AC who attended the ambulatory clinic for rheumatological disorders at the Research Unit (Homoeopathy), Siliguri, West Bengal, India. Medications were prescribed based on the totality of symptoms. The changes in shoulder pain during 2 months were assessed using the shoulder pain and disability index (SPADI). Quality of life was evaluated using SF-12v2 and ORIDL (participants and doctor assessed), respectively.

Results: Thirty-six participants completed the study and four participants dropped out. An analysis of the sample according to the protocol (n = 36) showed a statistically significant reduction in the SPADI score (91.92 ± 10.22 vs. 34.14 ± 24.43; mean reduction 57.78, 95% CI 49.41–66.14, P < 0.001) and a statistically significant increase in the SF-12v2 score (44.39 ± 9.70 vs. 72.27 ± 10.97; mean increase 27.87, 95% CI 23.89–31.85, P < 0.001). A statistically significant Spearman correlation (rs = 0.998, P < 0.01) between the changes in the ORIDL scores of the medical evaluation and the ORIDL scores of the participant evaluation over 2 months suggested a correlation.

Conclusion: The findings showed relief and improvement of symptoms in the QoL after homoeopathic treatment. Randomized controlled trials are additionally justified.