A Non- Randomised Single-Blind Clinical Study to Observe the Effects of Homoeopathic Medicine in Patients with Adhesive Capsulitis

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Abstract-

Background:

"Adhesive Capsulitis" is commonly known as "Frozen Shoulder", it is a very common suffering among the joint disorder. Adhesive capsulitis is a poorly understood musculoskeletal condition related with the glenohumeral articulation that has a disabling capability. Homoeopathy today remains one of the most sought after therapies on account of pain and disability of the shoulder joints, and troublesome side-effects and dissatisfaction with the mainstream therapies; however, remained under-researched systematically. We evaluated whether individualized homoeopathy could produce a significant treatment effect in the patients suffering from adhesive capsulitis.

Method: It is a non-randomized, single blind clinical study conducted at the outpatient department of Bharati Vidyapeeth (Deemed to be University) Homoeopathic College & Research Centre, Pune. Total 35 patients (Male & Female) belonging to the age group of 30-70 years were enrolled in this study. Adhesive Capsulistis was checked according to the

Shoulder Pain and Disability scale (SPADI) for pain intensity and disability of shoulder and Outcome In Relation To Impact On Daily Living (ORIDL) for quality of life.

Result: 5 patients dropped out, 30 completed the trail. Protocol complaint sample (n=30). Analysis was done using Student paired "t" test. Mean reduction in intensity of symptoms in adhesive capsulitis before intervention **SPADI** score was **41.18 ± 3.45**, after intervention **26.10± 4.60**. In **ORIDL** the components are **Main Complaint** before intervention **-3.00± 0.64**, after intervention **3.17± 0.53**, **Overall coping** before intervention **-2.30± 0.54**, after intervention **2.57± 0.50**, **Overall Well-being** -**1.50 ± 0.57**, after intervention **2.03± 0.56** after completion of study.

Conclusion:

The study shows that homoeopathic medicines are quite efficacious in the management of Adhesive capsulitis. We may conclude that Adhesive capsulitis, which is the expression of internal sickness of man, has to be treated holistically and with appropriate homoeopathic drugs. Randomized trials are warranted.

Keywords- Adhesive Capsulitis, Homoeopathy, Frozen Shoulder, SPADI, ORIDL

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INTRODUCTION

Adhesive Capsulitis is a common but poorly implied disorder of gleno-humeral joint. It is characterised by pain and uniform limitation of all the movements, capsular inflammation, fibrous synovial adhesions and reduction of joint activity. It is a condition of ambiguous aetiology. Shoulder joint has the greatest range of motion. This allows complex movements and functions to be carried out and is of vital importance to the activities of daily living and work. Any restriction or pain involving the joint puts a huge amount of strain on patients, especially those who are in their most productive years of life. Adhesive capsulitis, a frequently come into contact disorder of the shoulder, has been recognised since early 1900s. Although nonthreatening, it has great impact on the quality of life of patients. Frozen shoulder, a term coined by Codman inn 1934, is an orthopaedic condition that is commonly encountered in general practice. Codman used this term to describe a condition with symptoms of shoulder pain and discomfort that is slow in onset and located around the deltoid insertion [1]. Adhesive capsulitis also known as peri-arthritis or frozen shoulder is the painful condition of the shoulder joint where the gleno-humeral joint becomes painful and stiff because of the resilience of the joint capsule, possibly with adhesions between its folds. It produces pain and stiffness of the shoulder. In early stages, pain is worst at night, and stiffness limited to abduction and internal rotation of the shoulder. Later, the pain is present at all times and all movements of the shoulder are severely limited. Often, there is a history of preceding trauma. The disease is commoner in diabetics [2]. It mainly

affects individuals 30-70 years of age. The exact incidence and prevalence of adhesive capsulitis are unknown, but various authors have quoted figures of 2-5% in the general population. Nevertheless, those with diabetes, prolonged shoulder immobility (trauma, overuse, injuries or surgery) or systemic diseases (hypothyroidism, hyperthyroidism, cardiovascular disease or Parkinson's disease) are at a higher risk. In addition, there is evidence that protease inhibitors used for antiretroviral therapy have been associated with the development of adhesive capsulitis [1].

Even though over a hundred years of treating adhesive capsulitis, the definition, diagnosis, pathology and most efficacious treatments are still unclear. Systemic reviews of current treatments for adhesive capsulitis examine the evidence base behind physiotherapy, both oral and intra-articular steroid, hydro-dilatation, manipulation under anaesthesia and arthroscopic capsular release. Adhesive capsulitis is a self-limiting condition, lasting on average 2-3 years, and some studies show that 20-50% of sufferers continue to have pain and restricted movement beyond 3 years [3]. Homoeopathic medicines are claimed to be effective in treating adhesive capsulitis; however, has remained mostly anecdotal and systematic research evidence remained sparse. Even after a careful and extensive search into different electronic and bibliographic database, no relevant research papers could be identified. So this study was undertaken to explore the possible effects of individualised homoeopathic medicines in relieving pain, stiffness and other symptoms, and reduction inn limitation, and disability in activities of daily life in the patients suffering from adhesive capsulitis.

METHODS

Trial Design: This is observational, non-randomised, non-controlled clinical trial of pro-post comparison design was conducted at the Homoeopathic Materia Medica outpatient department of Bharati Vidyapeeth Homoeopathic Medical College, Pune, India. The study protocol was approved by the Institutional Ethical Committee (ICE) [Ref. No. BVDUHMC/PG/2019/09]. The trial protocol (unpublished) and full dissertation was submitted as postgraduate thesis of the corresponding author to the Bharati Vidyapeeth University.

Participants: Inclusion criteria were the patients who have been radiologically diagnosed with adhesive capsulitis (ICD-10-CM diagnosis code M 75.02), both sexes, aged between 30 and 70 years, and the patients willing to give written consent to participate in the trial. Exclusion criteria were the patients suffering from any life threatening illness or other systemic disease affecting quality of life or any vital organ failure, cases willing for or requiring immediate surgical intervention or already underwent any major shoulder surgery in last 6 months, undergoing homoeopathic treatment for chronic disease within last 6 months, diagnosed cases of unstable psychiatric illness, pregnant and lactating women, self-reported immune-compromised

state, substance abuse and/or dependence, and the patients not willing to participate. Patients already taking any standard or other alternative therapy for adhesive capsulitis were included if agreed to discontinue for at least 1 month.

Intervention: Intervention was planned as administration of indicated homoeopathic medicines in centesimal or 50 millesimal potencies and in individualized dosage, as decided appropriate to the case or condition. In centesimal potencies, each dose consisted of a 4 cane sugar globules medicated with a single drop of the indicated medicine, preserved in 90% v/v ethanol. In 50 millesimal potencies, a single medicated cane sugar globule of poppy seed size (no. 10) was dissolved in 15 ml distilled water with addition of 2 drops 90% v//v ethanol, 10 doses were marked on the vial, each dose of 5 ml was instructed to be taken after 10 uniformly forceful downward strokes to the vial then pour it in 45 ml of this liquid orally, and to discard rest of the liquid in the cup. Each dose was directed to be taken orally on clean tongue with empty stomach. Duration of such therapy was 3 months. Medicines were obtained from- Good Manufacturing Practice certified firms. Single individualised medicine was prescribed on each occasion taking into account presenting symptoms totality, clinical history details, constitutional features, miasmatic expressions, repertorization using RADAR® software when required with due consultation with Materia Medica. Subsequent prescriptions were generated as per Kent's observations and Hering's law. Participants were assessed by three homoeopaths at a time. Medicine was selected on each occasion by homoeopathic doctor and in case of any differences in opinion, it was resolved by involvement of another homoeopath. All the homoeopaths involved were affiliated with respective state councils.

General Management: All the participants were given general guidelines to remain active within limits of pain, avoid activities which would make the pains worse (e.g. lifting heavy weights), consider alternate positions or ways to minimize pain, rest when needed, joint mobilization exercises and reassurance. They were advised to be present for monthly follow-ups.

Outcomes:

- Primary outcome measure: Translated Marathi version of the ORIDL questionnaire.
- Secondary outcome measure: Translated Marathi version of the Shoulder Pain and Disability Index (SPADI) questionnaire.

Before the trial was initiated, the questionnaires underwent standardized forward-backward translation into local vernacular Marathi, was checked for face and content validity, and subjected to pilot testing and thereafter formal psychometric validity and reliability testing, but will be reported elsewhere and beyond the scope of this paper.

Sample size: No relevant data was available on reduction of ORIDL or SPADI scores by individualized homoeopathic treatment using an

open observational study design over 12 months of intervention. Thus assuming a medium effect size (*d*) of 0.5, alpha = 0.05 and power of 85%, to detect a significant difference between two dependent means of ORIDL and SPADI scores by paired *t* test, we would have required a sample size of 30, keeping a provision for 5% dropout.

Statistical methods: The analysis was carried out with per protocol approach; i.e. only the protocol-complaint sample entered into the final analysis. Data distribution was examined by histograms, pie charts. The baseline descriptive data (categorical and continuous) were presented in terms of absolute values, percentages, means, and standard deviations. Parametric tests (Student's *t* test) were planned to be used as inferential statistics as per normality of data distribution comparing dependent observation of continuous outcomes at baseline and after 6 months. P values less than 0.01 were considered as statistically significant. No interim and subgroup analyses were planned.

RESULTS

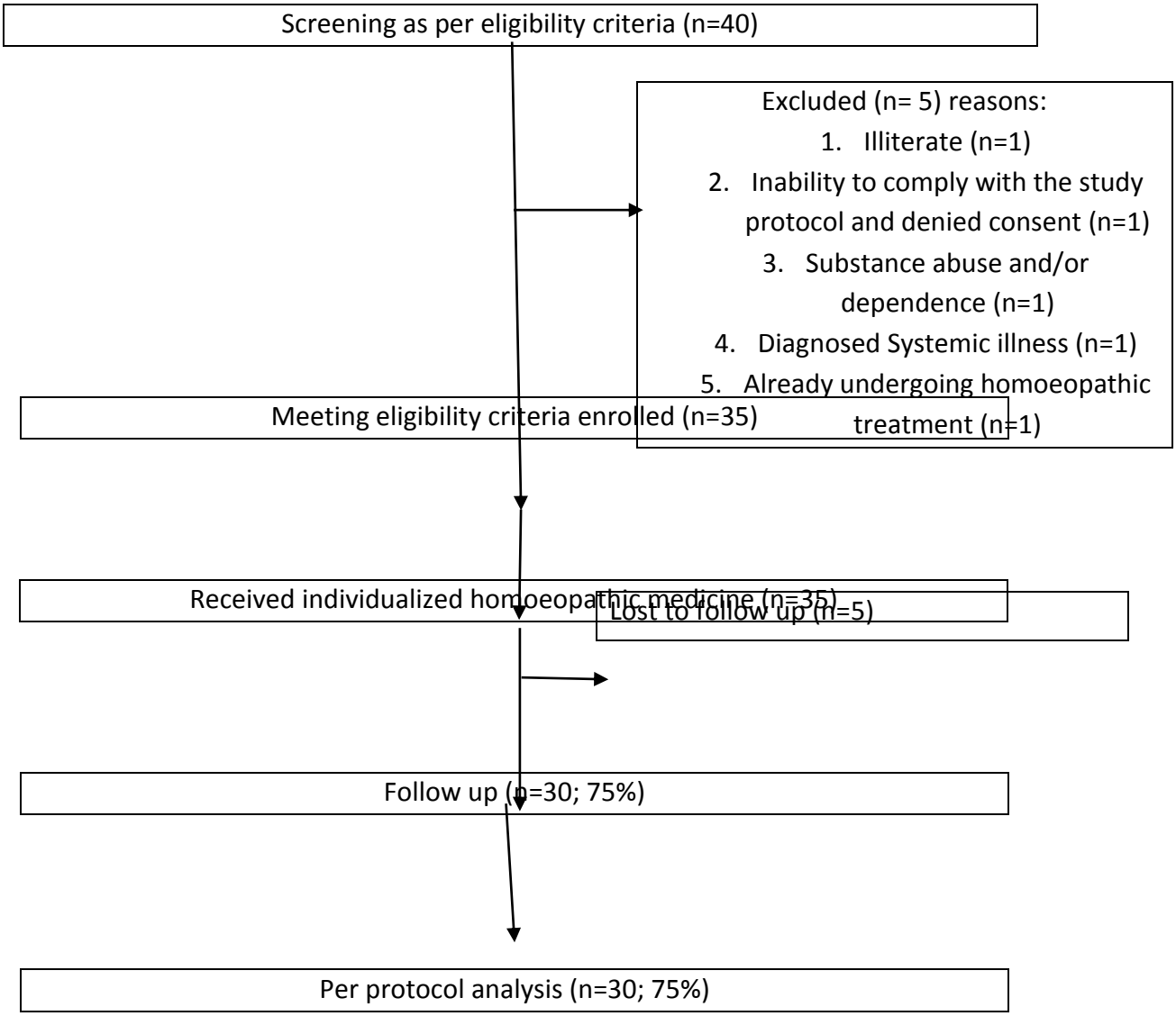
Participant flow: As per the pre-specified inclusion and exclusion criteria, 40 subjects suffering from adhesive capsulitis were screened; 35 met the eligibility criteria and were enrolled into the trail. Following that, baseline socio-demographic and outcome data was recorded again. During intervention, 5 dropped out; 30 completed the trail.

Recruitment: Starting from 2021 follow up of the last enrolled patient was completed by the end of 2022.

Baseline data: Many variables were studied for the baseline socio-demographic features of the subjects – age, gender, residence, religion, duration of suffering, food habit, risk factors, treatment taken, co-morbidities, body mass index (BMI), marital status, educational status, employment status, and family income status.

Numbers analysed: Outcomes from 30 out of 40 subjects were complete and only those entered into final analysis.

Data distribution: Data distribution seemed to be inconclusive from the histograms and Q-Q plots; however, the paired *t* test revealed P values much less than α (=0.05) indicating stronger evidences against normal distribution. Thus, first non-parametric Wilcoxon signed rank test was planned to be performed; and if significance was detected, then post hoc parametric ***t*** test.



Outcomes and estimation: Reductions in SPADI pain score and ORIDL score, SPADI disability score and SPADI total score were significant, both by paired *t* test. The histograms and chart plots revealed the changes in SPADI and ORIDL scores over 6 months (Fig.). The correlation between the changes in ORIDL scores and SPADI scores over 6 months of treatment suggested a strong positive correlation.

Table 1: Baseline socio-demographic features (n=30)

Features	N(%)
Age* (yrs; mean ± sd)	47.7 ± 7.8
Age groups* (yrs) ▪ Below 40 years ▪ 40-50 ▪ 50 years and above	 15 (50.0) 09 (30.0) 06 (20.0)
Gender* ▪ Male : Female	 24(80.0) : 6 (20.0)
Residence* ▪ Urban : Rural	 10 (33.0) : 20 (67.0)
Religion* ▪ Hinduism : Islam Duration of suffering* (yrs; mean ± sd)	 5.6 ± 6.8
Food habit* ▪ Veg : Non-veg	 04(13) : 26 (87)
Risk factor* ▪ Smoking	 07 (20.0)
Treatment taken* ▪ Allopathy ▪ Homoeopathy ▪ Both	 14(47.0) 03(10.0) 07 (23.0)
Co-morbidities* ▪ Diabetes mellitus ▪ Rheumatologic ▪ Miscellaneous	 05 (17.0) 03 (10.0) 02 (06.0)
Body Mass Index* (mean ± sd)	24.1 ± 1.7
Body Mass Index classes* ▪ Normal ▪ Overweight	 21 (70.0) 09 (30.0)
Marital status* ▪ Single ▪ Married	 01 (03.0) 29 (27.0)
Educational Status* ▪ 10th std or below ▪ 12th std	 10 (33.0) 09 (30.0)

▪ Graduate or above	11 (37.0)
Employment status*	
▪ Self-employed	13(43.0)
▪ Service	05(17.0)
▪ Unemployed	12 (40.0)
Family income status*	
▪ Low (less than Rs. 10,000)	19 (63.0)
▪ Medium (Rs. 10,000- 30,000)	08 (27.0)
▪ High (more than Rs. 30,000)	03(10.0)

Continuous data presented as mean ± standard deviation; *Categorical data presented as absolute values (percentages)

Table 2. Changes in outcomes over months. SPADI (Shoulder pain and disability scale) Test used: Paired t-test

Variable	Score	Mean ± SD	T-value	p-value	Decision
Pain Score	**Before treatment**	42.87± 4.35	15.19	0.000**	Reject H_0
	After treatment	27.13± 6.14			
	Difference	15.73 ± 5.67	**Difference is Highly Significant**		
Disability Score	**Before treatment**	40.13 ± 3.78	22.44	0.000**	Reject H_0
	After treatment	25.46± 4.83			
	Difference	14.67 ± 3.58	**Difference is Highly Significant**		
SPADI Score	**Before treatment**	41.18 ± 3.45	23.62	0.000**	Reject H_0
	After treatment	26.10± 4.60			
	Difference	15.08 ± 3.50	**Difference is Highly Significant**		

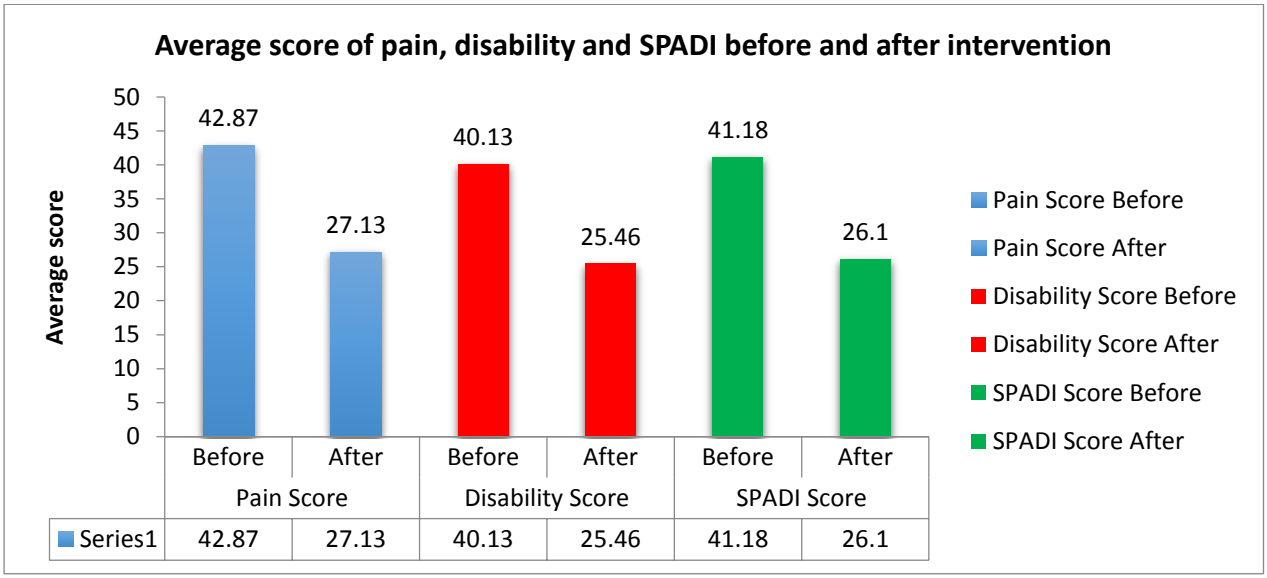


Fig. 1. Shows the descriptive statistics of pain, disability and SPADI score before and after intervention.

Table 3: Distribution of patients according to the improvement in the Adhesive Capsulitis after treatment

Domain		Improvement in the patients			
		Not expected improvement	Mild improvement	Moderate improvement	Marked improvement
Pain	*f*	0	0	22	8
	%	0.00%	0.00%	73.33%	26.67%
Disability	*f*	0	1	17	12
	%	0.00%	3.33%	56.67%	40.00%
Adhesive Capsulitis	*f*	0	0	20	10
	%	0.00%	0.00%	66.67%	33.33%

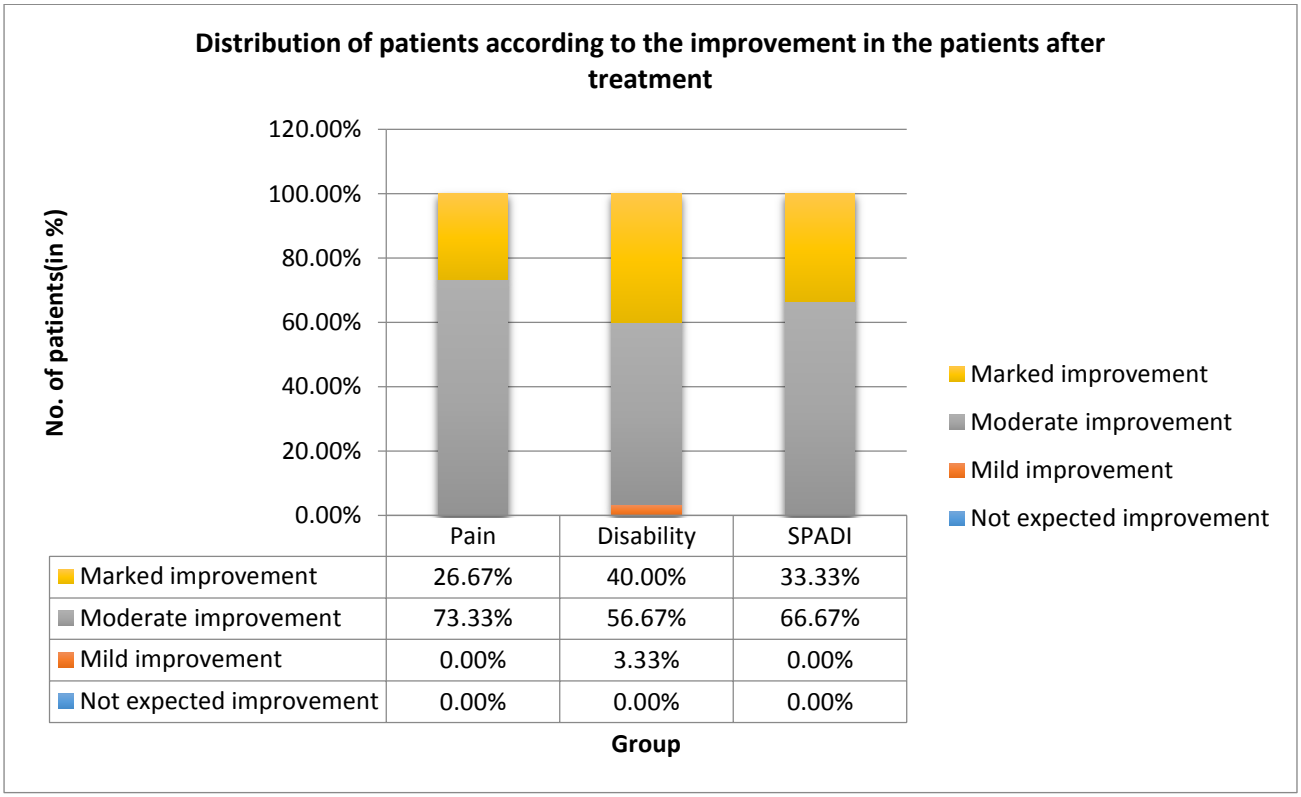


Fig. 2 Shows the distribution of patients according to the improvement in the patients after treatment

Table 4: Descriptive statistics of complaint rating, coping score and well-being score before and after intervention. Test used: Paired t-test.

Variable	Score	Mean ± SD	T-value	p-value	Decision
Main Complaint	**Before treatment**	-3.00± 0.64	-38.63	0.000**	Reject H_0
	After treatment	3.17± 0.53			
	Difference	-6.17 ± 0.87	**Difference is Highly Significant**		
Overall Coping	**Before treatment**	-2.30 ± 0.54	-34.35	0.000**	Reject H_0
	After treatment	2.57± 0.50			
	Difference	-4.87 ± 0.78	**Difference is Highly Significant**		
Overall Well-being	**Before treatment**	-1.50 ± 0.57	-22.49	0.000**	Reject H_0
	After treatment	2.03± 0.56			
	Difference	-3.53 ± 0.86	**Difference is Highly Significant**		

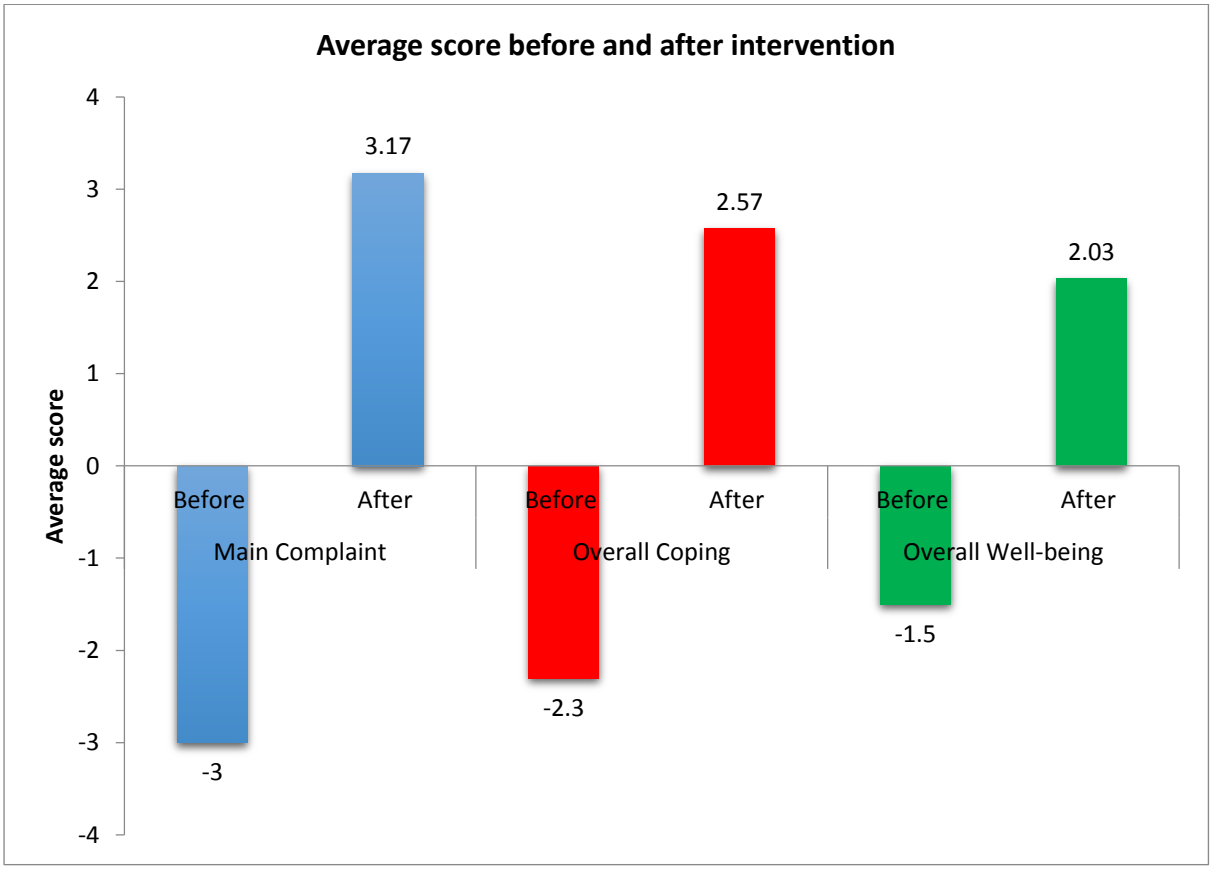


Fig 3. Shows the descriptive statistics of complaint rating, coping score and well-being score and after intervention.

Medicine used: The following medicines were indicated *Rhus toxicodendron* (n=9, 30%), *Ferrum metallicum (n=6, 20%), Arnica montana (n=3, 10%), Ruta Graveolens (n=3, 10.0%), Actea Racemosa (n=2, 6.67%), Belladonna (n=1, 3.33%), Causticum (n=2, 6.67%), Lycopodium (n=2, 6.67%).* Percentages were calculated by dividing the number of prescription of each medicine by total number of prescriptions (i.e. 30) multiplied by 100. Out of 30, 5 (17%) medicines were prescribed in 50 millesimal potencies.

Adverse events: Patients were instructed to report any harms, unintended effects, serious adverse events directly in the outpatient or over phone, but not a single incidence was reported from either group.

DISCUSSION

Principal findings: An open observational clinical trial was carried out at Bharati Vidyapeeth (Deemed to be University) Homoeopathic medical college on 40 subjects suffering from Adhesive Capsulitis and was treated with indicated homoeopathic medicines following homoeopathic principles. The SPADI and ORIDL scores were taken as the primary and secondary outcomes measures respectively, measured at baseline and after 6 months of treatment. Statistically significant improvement was achieved in both the outcomes after homoeopathic treatment suggesting homoeopathy as a promising treatment option for adhesive capsulitis and suggesting further substantiation using methodologically sound trial.

Strengths of the study: The possible effects of homoeopathic treatment in individuals suffering from adhesive capsulitis was estimated systematically for the first time by using the Marathi translated version of SPADI and OSS scores, a multidimensional measure of perceived discomfort and disability. Changes in the outcome over time correlated significantly, this validating the study findings further. Homoeopathic treatment was based on the principles of individualization. Formal validity and reliability of the scales has also been addressed prior to enrolment in this study, but will be reported elsewhere and beyond the scope of this paper. Another important strength was the participation of qualified and experienced homoeopaths schooled in and practicing “classical” homoeopathy. Our study was representative of individualized(“classical”) homoeopathy only. In a broader interpretation of the law of similar, medicines were selected for symptoms both typical of the diagnoses and outside the predominating pathologies (“constitutional”).

Weakness of the study: Though the trial was adequately powered to detect significant change in the specified outcome measures over 6 months, still the sample size was inadequate to make a definite conclusion regarding the effectiveness of homoeopathic treatment in adhesive capsulitis. The time period for the study was of short duration. The study was non-randomised and observational in design; hence did not involve any blinding, randomization or control. Thus efficacy data could not be generated and the effect sizes might have been

overestimated. This might be partly explained by placebo and/or regression to the mean effects that our study was not designed to control. We also could not rule out the undisclosed use of concurrent therapeutic modalities, if any.

Unanswered questions and future research: The role of homeopathic treatment on the radiological changes including bony and soft tissue changes could not be studied. The assessment for the same can be done in future. The trail would have been methodologically better if randomization and blinding techniques could have been included, thus warranting further efficacy or effectiveness trials comparing centesimal and 50 millesimal potencies.

CONCLUSION

In this non-randomized, prospective, observational, clinical trial of per-post comparison design conducted on 30 subjects suffering from adhesive capsulitis revealed statistically significant improvement in both SPADI and ORIDL questionnaire scores after 6 months of individualized homoeopathic treatment. Further exploration by randomized trails are warranted.

Conflict of interest statement: The authors declare that they have no competing interest. The trial was carried out as the postgraduate thesis of the corresponding author under the guidance of Prof. (Dr.) Vaishali V Dolas, was a permanent teaching faculty of the institute.

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Authors' contribution: Dr.Aninda Sarkar conceived and designed the study, collected data, then ran the statistical analyses and interpreted the data, and prepared the manuscript. All the authors reviewed and approved the final manuscript.

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REFERENCES

1. Wong PLK, Tan HCA. A review on frozen shoulder. Singapore Med J. 2010;51(9):694-697.
2. Maheshwari. J. Essential Orthopaedics. 3rd ed. New Delhi: Mehta Publishers; 2003, p. 258.
3. van Kampen DA, Willems WJ, van Beers LWAH, Castelein RM, Scholtes VAB, Terwee CB. Determination and comparison of the smallest detectable change (SDC) and the minimal important change (MIC) of four-shoulder patient reported outcome measures (PROMs). J OrthopSurg Res. 2013;8:40.
4. Dawson J, Fitzpatrick R, Carr A. Questionnaire on the perceptions of patients about shoulder surgery. J Bone Joint Surg Br. 1996;78:593-600.
5. Desai AS, Dramis A, Hearnden AJ. Critical appraisal of subjective outcome measures used in the

assessment of shoulder disability. Ann R Coll Surg Engl. 2010;92:9-13.
6. Schulz KF, Altman DG, Moher D, for the CONSORT group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c332.
7. Dean ME, Coulter MK, Fisher P, Jobst K, Walach H. Reporting data on homeopathic treatments (RedHot): a supplement to CONSORT. Homeopathy 2007;96(1):42-45.
8. Mathie RT, Van Wassenhoven M, Jacobs J, Oberbaum M, Roniger H, Frye J, et al. Model validity of randomised placebo-controlled trials of individualised homeopathic treatment. Homeopathy 2017;106(4):194-202.
9. Mathie RT, Van Wassenhoven M, Jacobs J, Oberbaum M, Frye J, Manchanda RK, et al. Model validity and risk of bias in randomised placebo controlled trials of individualised homeopathic treatment. Complement Ther Med. 2016;25:120-125.
10. Saha S, Koley M, Ganguly S, Rath P, Roy Chowdhury P, Hossain SI. Developing the criteria for evaluating quality of individualization in homeopathic clinical trial reporting: a preliminary study. J Integr Med. 2014;12(1):13-19.