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Role of Homoeopathic Medicines in Cases of Acne Vulgaris in Young Adults Using Acne-QOL

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Abstract

Context: An experimental, open-label, non-randomized and non-comparative study was carried out at Homoeopathy University, India, to assess the possible effects of individualised Homoeopathy in young adults suffering from acne vulgaris. **Aim:** The aim of the study was to find the role of homoeopathic treatment in young adults suffering from acne vulgaris. **Methods:** Forty subjects were enrolled. The Global Acne Grading Scale (GAGS) and Acne Quality of Life (Acne-QoL) Questionnaire were used as the outcome measures, assessed at baseline and after 3 months of treatment. Medicines prescribed followed homoeopathic principles. Paired t test was applied to compare the dependent observations. **Results:** Four subjects dropped out and 36 completed the trial. Maximum participants had significant improvement (mean difference = 19.778, t (35) = 17.616, $p < .001$) with 24 (66.7%) cases showed more than 75 percent improvement in GAGS score. Maximum participants responded significant ($p < .001$) improvement in all the four domains of ACNE-QoL; domain of self-perception (mean difference = 10.917, t (35) = 13.798, $p < .001$; domain of role-social (mean difference = 8.444, t (35) = 14.085, $p < .001$); domain of role-emotional (mean difference = 10.556, t (35) = 12.77, $p < .001$); and domain of acne symptoms (mean difference = 9.917, t (35) = 12.830, $p < .001$). Medicines prescribed in maximum number of cases were Natrium muriaticum (17, 47.2%) and Calcarea carbonica (5, 13.8%). Psora was found as the predominant underlying miasm. **Conclusion:** Indicated homoeopathic medicines reduced GAGS and Acne-QoL scores markedly. Further randomised trials are warranted with enhanced methodological rigor.

Key word- Acne vulgaris, Homoeopathy, ACNE-QoL, GAGS

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INTRODUCTION

Acne vulgaris is a chronic multi-factorial inflammatory skin disorder affecting the pilosebaceous follicles. An alteration in the pattern of keratinization results in comedone formation, an increase in sebum production, proliferation of the bacterium Propionibacterium acnes, and the production of perifollicular inflammation.[1]

Acne is estimated to affect 9.4% of the global population, making it the eighth most prevalent disease worldwide.2 It affects 85% of adolescents and young adults. In late adolescents, above the age of 16 years, as they move towards young adult roles and appearance is given more importance than at an earlier age.[3] It is suggested that 90% of individuals, male and female, between puberty and age of 30 years, experience some degree of acne. There are estimated 200-300 million acne sufferers in the country[4] with approximately 38% prevalence of acne vulgaris in Rajasthan. Prevalence of acne is more in males as compared to females in rural western Rajasthan.[5]

Acne is associated with greater psychological burden.[6] Patients with acne have been reported to have functional and emotional effects comparable to those in patients having eczema or psoriasis and equivalent or greater levels of social, psychological and emotional problems are seen in patients with chronic disabling medical or surgical diseases (asthma, epilepsy, diabetes, back pain or arthritis). Better understanding of factors affecting acne vulgaris may, therefore, serve to identify patients needing special attention.[7,8] Several studies worldwide have reported that acne has major effects on patients' quality of life (QoL).[9-16]

Acne tends to be chronic, and is obstinately resistant to treatment. Moreover, it is subjected to periods of aggravation without treatment of any kind. Available management in Allopathy includes topical agents; benzoyl peroxide, antibiotics, retinoids, etc. as the mainstay of treatment; these can be given in combinations. While systemic therapy includes oral antibiotics, hormonal therapy, and isotretinoin.

The treatment comes with known side effects such as, irritant dermatitis, development of bacterial resistance and cross resistance, incidence of upper respiratory tract infection, affect musculoskeletal, mucocutaneous, and ophthalmic systems, as well as headache, and central nervous system effects.[17]

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Homoeopathy treats the patient as a whole not the specific disease. Individualised Homoeopathic remedy can permanently eradicate the symptoms and helps the organism to regain its healthy state. Literature review shows homoeopathic medicines are effective in acne vulgaris.[18-22]

Deep acting constitutional remedies based on totality of symptoms may provide a safer, more effective treatment in cases of Acne Vulgaris. This study was conducted to assess the effectiveness of Homoeopathic medicines prescribed on the basis of totality of symptoms in cases of Acne Vulgaris when. In addition, the study assessed the effect on Acne related Quality Of Life (QoL) and the miasmatic predominance in cases of Acne Vulgaris.

MATERIALS AND METHODS

Study Design- This open-label, prospective, experimental, non-controlled clinical trial of pre–post comparison

Study Setting- Participants were selected from the Outpatient departments of the Dr. Madan Pratap Khunteta Homoeopathic Medical College, Hospital & Research Centre, Saipura, Sanganer, Jaipur, Rajasthan, and, Collaborated Outpatient Department of Dermatology, CCRH, RRI, Sindhi Camp, Jaipur.

Participants- Inclusion criteria were male and female subjects suffering from acne vulgaris, aged between 18 and 35 years and willing to participate in the study by giving written consent.

Exclusion criteria were the cases of secondary acne (drug induced), diagnosed cases of hormonal imbalances like polycystic ovarian disorder, thyroid disorders, pregnant and lactating women. Patient on steroid treatment (including topical applications) and cases who refused to give their consent for the study.

Intervention - Intervention was planned as the administration of indicated homoeopathic medicines in 6C to CM potencies and in individualised dosage, as decided appropriate to the case and condition as per the guidelines mentioned in the 5th edition of Organon of Medicine. Patients were instructed to take doses orally on clean tongue. Duration of such therapy was 3 months. Medicines were obtained from good manufacturing practice-certified firms of India. Single individualised medicine was prescribed on each occasion taking into account presenting symptom totality of symptoms, clinical history details, constitutional features, miasmatic expressions, repertorisation using RADAR® software (version 10.0.028 (ck), Archibel 2007, Belgium) when required with due

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consultation with Materia Medica. Subsequent prescriptions were generated as per Kent's observations and Hering's law.

Sample Size- To see the effect of Homoeopathic medicines on Quality of Life in cases of Acne Vulgaris in young adults, considering standardized effect size 0.7 at 90% power(using Table III), 40 patients were included in the study (including dropped out).[23]

General Management - All the participants were given general guidelines for proper cleansing-wash the affected part with clean water, to avoid use of cosmetics, picking of pimples to avoid scarring, to avoid constipation-take diet rich in salads and fruits and plenty of water. To practice relaxation. . They were advised to be present for regular follow-ups.

Outcomes- The outcomes were assessed as the percentage change in Global Acne Grading System (GAGS) score from baseline in 3 months and change in Acne specific Quality of Life questionnaire (Acne QoL) score at the end of 3 months.

Global Acne Grading System: In brief, intensity of acne was graded using validated GAGS. This system divides the face, chest and back into six areas and assigns an area factor of 1, 2 or 3 (Forehead ,Right cheek & Left cheek 2; Nose & Chin-1;Chest and upper back-3). Each type of lesion is given a value from 0–4 (no lesions = 0, comedones = 1, papules = 2, pustules = 3 and nodules = 4). Area score/Local score is the product of the most severe lesion in that area multiplied by the area factor [Local score = (Factor)(Grade 0-4)]. The area scores were added to give the total GAGS score [Global Score= ∑(Local score)].

A Global score of 1-18 is considered mild; 19-30, moderate; 31-38, severe; and >39, very severe.24

Acne QOL questionnaire: The Acne-QOL is a patient completed questionnaire with a 1-week recall period composed of 19 items in four subscales: Self-Perception, Role-Emotional, Role-Social, and Acne Symptoms.

Instrument scoring is accomplished by summing the responses within the subscales to yield four overall domain scores, where higher scores indicate more favourable quality of life.

Responses are numbered starting with '0' in ascending order up to '6'. Coding begins on the left with 0, and that 'not at all' is actually coded as a 6;The response options for all but three domains (Self-Perception, Role-Emotional, Role-Social) include: extremely, very much, quite a bit, a good bit, somewhat, a little bit, and not at all. For acne symptoms

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responses include: extensive, a whole lot, a lot, a moderate amount, some, very few, and none.[25-27]

Statistical Methods - Paired sample t-test was conducted to compare pre and post GAGS score and domain scores of Acne-QOL questionnaire of Acne vulgaris treated with Homoeopathic medicines. SPSS®-IBM® version 20 (IBM Corp., IBM SPSS Statistics for Windows, Armonk, NY: USA) for Windows was used for the analysis of data.

RESULTS

Participant flow-chart- As per the pre-specified inclusion and exclusion criteria, 50 female subjects suffering from acne vulgaris were screened; 10 were excluded on account of various reasons; 40 met the eligibility criteria and were enrolled into the trial. Following that, baseline socio-demographic and outcome data were obtained. After 3 months of intervention, outcome data were recorded again. During the course of treatment, four dropped out; 36 completed the trial [Figure 1].

Recruitment- The total period of interventional treatment was of one year duration starting from July 2017 up to June 2018, out of which cases was registered in first 9 months and each case was followed up for a period of minimum 3 months.

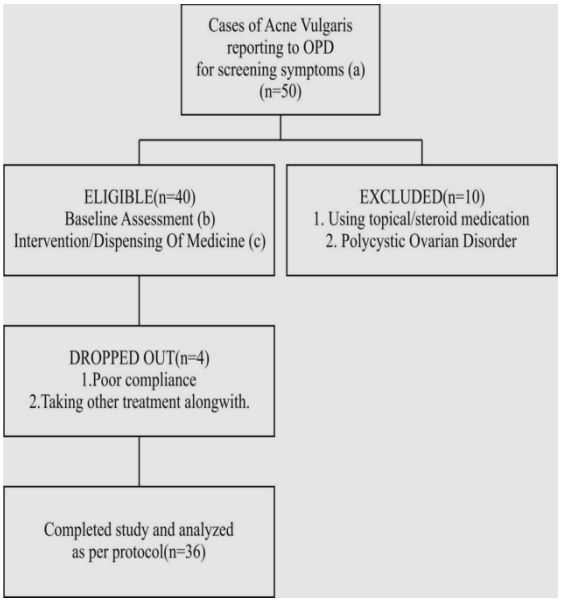

Fig.1. Study flow diagram

Baseline Data

Seven variables were studied for the baseline socio-demographic features of the subjects – age, gender, residence, socioeconomic status, family history of acne vulgaris, location of acne lesions and acne grading [Table 1].

Table 1. Baseline Characteristics

Characteristics	Number(n=36)	%
Age		
18-23	28	77.78
24-29	6	16.67
30-35	2	5.56
Sex		
Male	15	41.67
Female	21	58.33
Area of Residence		
Urban	24	66.67

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Rural	12	33.33
Socioeconomic Status		
Upper class	0	0
Middle class	33	91.67
Lower class	3	8.33
Family history of acne vulgaris		
Present	6	16.66
Absent	30	83.33
Location of Lesions		
Face	35	97.22
Chest + Face	2	5.55
Back + Face	1	2.7
Acne Grading		
Mild	4	11.1
Moderate	20	55.5
Severe	11	30.5
Very severe	1	2.9

Numbers analysed - Outcomes from 36 subjects were complete and therefore all these subjects (n=36) entered into the final analyses.

Outcomes and Estimation - Statistically significant reductions were achieved on GAGS score (P< 0.001) and improvement on four individual domains of Acne-QOL questionnaire score (P< 0.001).Maximum number of cases i.e. 24(66.7%) showed more than 75% improvement in GAGS score after treatment. (Fig.2)

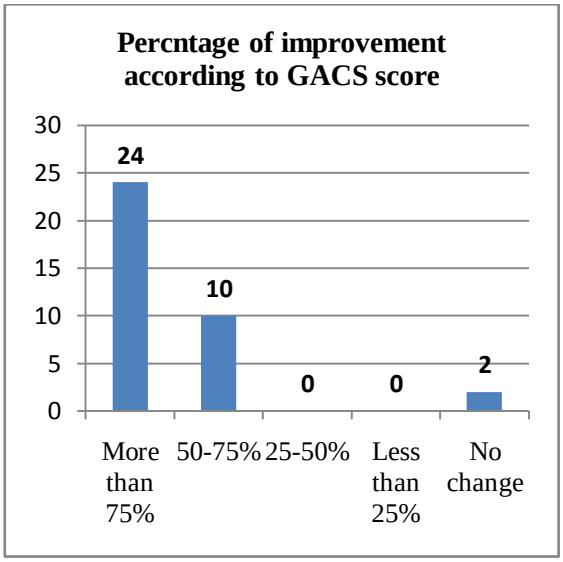

Fig 2 Improvement in GAGS score after treatment

Medicines Used

Twelve different individualised medicines were prescribed in the study – Natrium muriaticum (n=17, 47.2%), Calcarea carbonica (n=5, 13.8%), Pulsatilla and Sulphur (n=4,11.1%), Silicea (n=3,8.3%) , Belladonna and Hepar sulphuricum (n=2 each, 5.5%), Lycopodium Clavatum, Kalium Bromatum ,Nux Vomica, Sepia officinalis and Staphysagria (n=1,2.7%).

DISCUSSION & CONCLUSION

This is an open experimental clinical trial found statistically significant improvement in both the outcomes after homoeopathic treatment, suggesting Homoeopathy as a promising treatment option for young adults suffering from acne vulgaris and suggesting further

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studies to investigate the role of Homoeopathic medicines using Randomized controlled trials with longer duration to further enhance the impact of study in scientific medicinal field.

Strengths of the study

This study reiterate that patients of acne suffer from significant impairment in quality of life and Homoeopathic medicines along with assurance can help in alleviating symptoms of the diseases as well as improve the quality of life of the patients. These findings confirm the utility of the Acne-QOL for demonstrating the role of Homoeopathic medications in the treatment of acne. Psora was found as the predominant miasm lying in the background in the patients suffering from acne vulgaris.

Maximum number of cases i.e. 24(66.7%) showed more than 75% improvement in GAGS score after treatment. Statistically significant difference ($P<0.001$) has been seen in pre and post treatment scores of GAGS and Acne-QOL questionnaire domains scores with Homoeopathic medicines. The most indicated medicine was Natrium muriaticum followed by Calcarea carbonica.

Our study used individualized medicines (‘classical homoeopathy’) based on “law of similia” broadly covering the totality of symptoms from homoeopathic point of view.

Weaknesses of the Study

The first limitation of the study was that there was no control group so there was no randomization in the study which increases the impact of the study results. Second limitation was that sample size being too small. A larger sample size could have affected the conclusions derived from this study considerably. As acne vulgaris is a common condition and affects a wide variety of people, with a large sample size a greater perspective of the disease, its control, treatment and prognosis would be obtained. Third limitation was time constraint being short to confirm the changes in quality of life and to assure its improvement. Fourth limitation was multiple associated dermatological disorders with acne vulgaris such as alopecia, melasma etc. Fifth limitation was decimal and 50-millesimal potencies were not used in the present study so the role of different scales of potentisation was not explored.

Further studies should investigate the role of Homoeopathic medicines using Randomized controlled trials with longer duration to further enhance the impact of study in scientific medicinal field.

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