



UTILITY OF “A SYSTEMATIC ALPHABETICAL REPERTORY OF HOMOEOPATHIC REMEDIES BY DR. C. VON BOENNINGHAUSEN IN THE CASES OF ACNE VULGARIS” - A RANDOMIZED SINGLE BLIND CONTROL TRIAL

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Keywords □ DLQI : Dermatological Life Quality Index □ GAGS : Global Acne Grading System
□ RCT : Randomised Control Trial □ IBM SPSS : International Business Machine
Statistical Package for the Social Sciences □ IPD : Indoor Patient Department □ OPD : Outdoor
Patient Department □ SRA : A Systematic Repertory of Homoeopathic Remedies □ *t* calc.: *t*
calculated; □ *t* tab.: *t* tabulated.



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Introduction: Acne vulgaris is a chronic inflammatory disease of the pilosebaceous unit characterized by seborrhoea, open and closed comedones, papules, pustules, and in more severe cases, nodules and pseudocysts.^[1] It commonly affects the face, upper chest, and upper back. More than 85% of adolescents suffer from acne.^[2] The major complications of acne are scarring and psychosocial distress which persists long after active lesions have disappeared.^[3]

The most common type of acne is the acne vulgaris that develops during the teenage year. due to rise in hormone levels especially aldosterone which causes sebaceous glands to start making more (sebum) oil. Acne begins when oil mixes with dead cell and clogs the skin pores. Bacteria can grow in this mixture and if this mixture leaks into nearby tissue; it causes swelling, redness, pus and nodules.^[4]

This is hospital based study where patients were 100 randomly selected from the outpatient department. It is a single-blinded RCT in which 50 patients were taken in control arm & 50 patients in intervention arm and treatment was provided following principles of homoeopathy using “A Systematic Alphabetical Repertory of Homoeopathic Remedies” by Dr. C. Von. Boenninghausen, translated by C.M. Boger. This repertory contain purely

Antipsoric remedies, acne are also due to functional change in the body (Hormonal change) and functional changes in body are psoric in nature, this work of Boger and this related concepts had arouses interest in our mind that how effective this repertory could be to manage the cases of Acne Vulgaris.

Homoeopathy takes into account the root cause of disease i.e., an imbalance of vital force and the underlying miasmatic influence esp. in resistant cases. It restores this balance by gently stimulating the vital force, strengthening it naturally and completes the healing process with the help of indicated remedy, viz. similimum.

Assessment of the participants was done by using Global Acne Grading System (GAGS), Dermatological Life Quality Index (DLQI) to assess not only the clinical symptoms but also its psychologically as according to Homoeopathy, it is important to treat the patient as a whole.

Study was conducted at O.P.D./I.P.D. of Dr. Madan Pratap Khunteta Homoeopathic Medical College, Hospital & Research Centre, Station Road, Jaipur & O.P.D. at Homeopathy University, Saipura, Sanganer, Jaipur for one year duration with effect from 04/07/2015 to 03/07/2016.

Aims and Objectives:

AIMS: 1. To ascertain the efficacy of homoeopathic medicines by comparing the effects of homoeopathic medicinal intervention with placebo in treatment of Acne Vulgaris.

2. To assess the utility of A Systematic Alphabetical Repertory of Homoeopathic Remedies by Dr. C. Von Boenninghausen in the cases of Acne Vulgaris.

OBJECTIVES: To assess the effects of homoeopathic medicines by using:-

- Global Acne Grading System(GAGS).
- Dermatological life Quality Index (DLQI).

Materials and Methods:

Tools:

*Case Taking Proforma was especially designed for the study

*Patient Information Sheet & Patient Consent Form

*A Systematic Alphabetical Repertory of Homoeopathic Remedies by C. Von. Boenninghausen, translated by C.M.Boger

*Global Acne Grading System (GAGS) & Dermatological Life Quality Index (DLQI)

Detailed case taking & clinical examination was carried out to clinch the diagnosis. Effectiveness of the Homoeopathic treatment was assessed according to statistical principles

on the basis of change in the score taken before and after treatment with Homoeopathic medicines as well as subjective feeling of improvement.

Inclusion Criteria

- * Diagnosed and undiagnosed cases of Acne Vulgaris of 12-35 years age group were included in the study irrespective of their sex, caste, religion & duration of illness.
- * Patient who consented to participate in the study
- * Follow-up of the cases were done at an interval of 7-15 days, as per gravity of the case upto 6 visits.

Exclusion Criteria

- * Cases not fulfilling the inclusion criteria.
- * The cases requiring emergency treatment involving any other system of body.
- * The cases that did not gave their consent for research.
- * The cases without proper follow-up.
- * The cases that showed poor compliance.

Study design

- * Allocation- Patient fulfilling the eligibility criteria were enrolled and randomized systematically to receive either the homoeopathic intervention or identical placebo.
- * Selection between interventional and control was done by systemized control study - alternate cases were taken under control group.
- * Type of study – Perspective, Experimental, Randomized Placebo Control
- * End point classification – Efficacy study
- * Masking – Single blind
- * Primary purpose – Treatment
- * Study was pursued under Systematic Randomized Control Study – from the study population and every alternate subject was under placebo control.
- * The patient was kept blinded to the identity of the treatment group.
- * Any sort of other medicinal intervention was not allowed, not even in patient's diet or environment.
- * The study was approved by the Institutional Ethics Committee

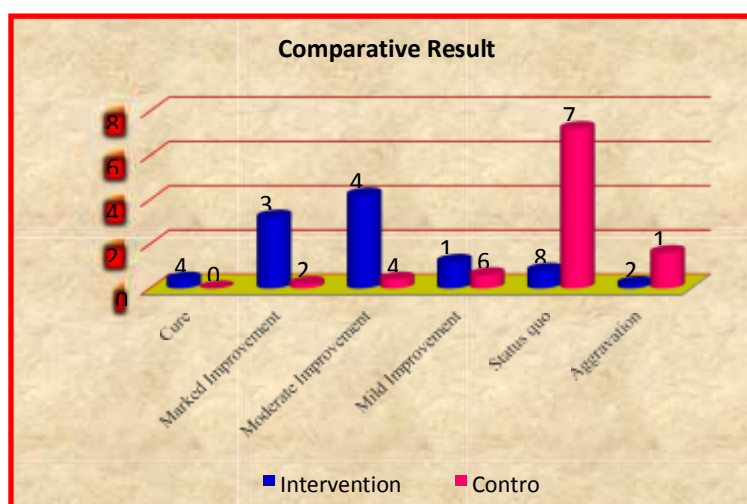
Result Criteria: Following parameters would be fixed according to the type of the response obtained after the treatment –

- Cure - > 90% improvement in GAGS and DLQI score for a period of 3 months along with feeling of mental & physical well-being & no relapse of symptoms upto 6 months or more.
- Improved – * Mild improvement: 0 - 30% improvement in GAGS & DLQI scores.
* Moderate improvement: 30 - <60% improvement in GAGS & DLQI scores.
* Marked improvement: 60 - <90% improvement in GAGS & DLQI scores.
- Status quo - When there was no change in the condition of the patient.
- Worse - When there was no improvement in condition of the patient and instead his/her condition got worse in respect to GAGS & DLQI scores. This was assessed in view of homoeopathic aggravation, disease and medicinal aggravation. Counseling of patient was done accordingly; if aggravation was continued for more than 30 days, was considered as “Worse”.
- Dropped out – When patient discontinued the treatment during the course of study or showed poor compliance. Patient could willfully withdraw from the study anytime; was considered as dropped out.

Benefits of the Study:

- Complete disappearance of Acne Vulgaris with betterment in general health. Study will provide strong evidence of efficacy of Homoeopathic interventions.
- Allows standardization of study maneuver and outcome assessment.

Observations and Results



As shown in above bar chart, in interventional arm, 2 (4%) cases got cured, 21 (42%) cases showed moderate improvement, 16 (32%) patients showed marked improvement, 04

(08%) were status quo, 6 (12%) patients showed mild improvement and 1 (2%) case got worse; Whereas in control arm, no case was cured, 3 (6%) cases showed mild improvement, 2 (4%) cases showed moderate improvement, 1 (2%) case showed marked improvement, 36 (72%) cases were status quo, and 8 cases (16%) got worse.

Test Statistic and data analysis

*Student t- test was applied to ascertain the statistical results of the study before and after the completion of study.

*Difference of Means was applied to ascertain the difference in results obtained of both Interventional and Control arm statistically. Statistical perspective is to see Global Acne grading System (GAGS) & Dermatological Life Quality Index (DLQI) before and after the treatment.

*Data analysed using Statistical Package for the Social Sciences (SPSS) version 20.0 and Microsoft Excel P< 0.05 was considered significant.

Student t- test

$$t_{cal} = \frac{\bar{d}}{s_d/\sqrt{n}} \sim t_{(n-1)}$$

$$\bar{d} = \frac{1}{n} \sum_{i=1}^n d_i \text{ and } s_d = \sqrt{\frac{1}{n-1} \sum_{i=1}^n (d_i - \bar{d})^2}$$

Where, d_i is the difference of DLQI and GAGS scores of first and final follow-up of i^{th} patient and n is the sample size.

We reject the null hypothesis at $\alpha\%$ level of significance if calculated value of t is greater than tabulated value of t with $(n-1)$ degrees of freedom (d. f.) at the same level of significance or the p-value corresponding to the test is less than $\alpha=0.05$, $p < 0.05$.

Table 1: Mean score data

Scales		Interventional Arm			Control Arm		
		Pre	Post	Change	Pre	Post	Change
Mean	Score	29.8	10.74	19.06	28.14	27.46	0.68
Mean							
DLQI	Score	9.66	3.76	5.9	8.7	8.2	0.5

Table 2: Paired sample t-test of Interventional Arm

S. No.	Assessment Scales (Pre & Post Scores)	Mean	Standard Deviation	$t_{(cal)}$	d. f.	p-value
1	GAGS	19.060	10.987	12.267	49	0.000*
2	DLQI	5.900	2.720	15.338	49	0.000*

* Significant at 5% level of significance.

Table 3: Paired sample t-test of Control Arm

S. No.	Assessment Scales & (Pre Post Scores)	Mean	Standard Deviation	$t_{(cal)}$	d. f.	p-value
1	GAGS	.680	5.909	.814	49	0.420 ^{NS}
2	DLQI	.4800	1.7171	1.977	49	0.054 ^{NS}

^{NS} Not significant at 5% level of significance.

Explanation of above tables:-

From Table 1, the p-values for both assessment scores GAGS and DLQI are less than 0.01, indicating a significant positive difference in the pre & post treatment scores in the intervention arm. DLQI & GAGS score were significantly ($p = .000$) & ($p = .000$) improved after the medication was done.

From Tables 2 & 3, it can be seen that the p-values corresponding to both assessment of Intervention and Control groups suggest no difference in the pre & post scores of assessment scales in control arm i.e., DLQI & GAGS were not improved in control arm. ($p = 0.420$) & ($p = 0.054$) whereas scores of GAGS and DLQI are significantly greater in the intervention group than in the control group.

Discussions and Summary:

In this study, out of 100 patients 62 cases (62%) had family history of acne vulgaris that means acne show heritability in first-degree relatives, observation similar to the study done by Shadi Zari et al^[33] undergraduate students to have acne by 78% heritability in first-degree relative.

In this study, Out of 100 patients grade II acne was the most prevalent one (44%) followed by grade III (25%), grade I (16%), and grade IV (15%). In the study by Adityan et al,^[34] grade I acne was the most prevalent (60.2%), grade II (27.5%), grade III (2.6%), grade IV (9.7%). In the study by Supreethi Biswas et al,^[35] grade II acne was the most prevalent one (45%), grade III (16%) and grade IV (7%). In the study by Pandey P. at el,^[12] grade II acne was the most prevalent one (36%), grade III (27%), grade I (25.7%), and grade IV (11.3 %).

The present study is almost in concurrence with the study by Cunliffe and Cotterill and Pandey Patel^[22] in which face was the most common site involved followed by face, back and chest, then face and back.

In this study, Natrum muriaticum was prescribed in 14 cases (28%) followed by Sulphur in 12 cases (24), Natrum carbonicum in 5 cases (10%), Mercurius Sol. was prescribed in 4 cases (8%), Hepar sulphuris in 3 cases (6%), whereas Belladonna, Lycopodium, Mag. Carb., Sepia in 2 cases (4%) each and Bovista, Calc. Carb., Kali. Carb., Silicea in 1 case (2%) each. The variability of selection of medicine is according to individuality of the patient, medicines were rich in symptoms related to mind & personality which we term as constitutional medicines in field of homoeopathy.

According to the study 30C was more common indicated potency based on totality of the patient and considering patient as a whole, as Acne vulgaris is problem situated on most superficial layer of body, i.e. skin, lower potency has quite a good role to play.

In this study, According to statistical analysis, in Intervention arm $t(\text{tab}) = 2.00$ and $t(\text{cal}) = 12.267$ (of GAGS score) and $t(\text{cal}) = 15.338$ (of DLQI score) i.e. $t(\text{cal}) > t(\text{tab})$, whereas in Control arm $t(\text{cal}) = 0.814$ (of GAGS score) and $t(\text{cal}) = 1.977$ (of DLQI score) i.e. $t(\text{cal}) < t(\text{tab})$ at 5% level of significance. Thus patients had significant improvement after receiving homoeopathic medicines. In testing of difference of means, in GAGS and DLQI of Interventional arm $t(\text{cal}) > t(\text{tab})$ whereas in GAGS and DLQI of Control arm $t(\text{cal}) < t(\text{tab})$ at 5% level of significance. Thus Patients of Interventional arm had significant improvement than in patients of Control arm.

Conclusion: The inference drawn from the study is as follows:

- According to the result obtained, Interventional arm showed significant improvement than control arm. Thus the aim of the study is fulfilled.
- A Systematic Alphabetical Repertory of Homoeopathic Remedies by Dr. C. Von Boenninghausen proved to be a useful aid in the selection of the similimum in working out the cases of Acne Vulgaris. In the study, 90% cases were benefitted by homoeopathic medicines selected with the aid of above repertory. It was also found that cases with history of suppression through external application were more difficult and reluctant to treatment and had shown either no or little improvement unless antimiasmatic intermittent dose of indicated medicine in appropriate potency and dose was administered as per analysis of related repertorial result. This proved benefit of above repertory to select anti miasmatic remedies in such complex cases of Acne Vulgaris equally. This substantiates the mileage of homoeopathy following holistic and miasmatic approach.

- GAGS and DLQI, proved to be significant assessment tool in this study. These scales showed significant difference before and after treatment. During study in addition to assessing objective change in cases of Acne Vulgaris, Dermatological Life Quality Index (DLQI) and Global Acne Grading System (GAGS) scales were used.
- It can be clearly concluded with the aid of statistical test viz. paired t-test and difference of means that homoeopathic medicinal intervention is effective over placebo in treatment of Acne vulgaris and it is not merely a self limiting disease and it surely calls for medicinal intervention.

Limitations of study

The study period was short and for conforming the conclusions using centesimal scale potency, long term studies will be required. We suggest that future studies using 50 millimal scale potencies should be conducted to prospect the effect of higher potencies on Acne vulgaris and as those medicines can be repeated in short time intervals, thus effects can be assessed in short term studies. More modern and advanced repertories like Synthesis, Complete Repertory can be assessed in cases of Acne vulgaris. Further study over Psychotherapy and Homoeopathic intervention is recommended to understand the action of individualized homoeopathic medicines in comparison with psychotherapy in cases of Acne vulgaris as it is considered as psychosomatic disease.

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