EFFECTIVENESS OF HOMOEOPATHIC MEDICINES IN CASES OF ACNE VULGARIS IN ADOLESCENCE – A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Acne vulgaris is a disorder in which hair follicles develop obstructing horny plugs (comedones), as a result of which inflammation later develops around the obstructed follicles, causing tissue destruction and scar formation. Acne is estimated to affect 9.4% of the global population, making it the eighth most prevalent disease worldwide. The most common type of acne is the Acne vulgaris that develops during the teenage years. Epidemiological studies have demonstrated that acne is most common in adolescence, with boys most frequently affected, particularly with more severe forms of the disease. Patients with acne have social, psychological, and emotional impairment. These patients are more prone to embarrassment, social withdrawal, depression, anxiety and anger. **Objective:** To assess the effectiveness of Homoeopathic medicines as compared to Placebo in cases of Acne vulgaris in both groups by using Global Acne Grading System scale for acne as assessment criteria. **Study Design:** Randomized single blind, placebo controlled Study. **Methods:** 60 cases of Acne vulgaris were randomly allocated to the two treatment groups. In Group A (n = 30 cases) individualized Homoeopathic medicines selected on the basis of the totality of symptoms were prescribed and in Group B (n = 30 cases) placebo was prescribed. Potency selection, dosage and repetition of medicines were done according to the Hahnemannian guidelines in 5th edition of Organon of Medicine. Assessment and reassessment was done by Global Acne Grading System scale. **Results:** Observations and results shown that Acne vulgaris is more common in the age group of 18-20 years i.e. 37 cases (61.66%), more commonly affects males 37 cases (61.66%) in comparison to females i.e. 23 cases (38.33) and is reported more commonly in middle socioeconomic status. Maximum numbers of, 34 cases (56.67%) were

from urban area. Papulopustular eruptions were the commonest type of acne found i.e. in 16 cases (26.66%) followed by comedo-papular eruptions in 10 cases (16.66%), comedo-pustular and comedo-papulopustular in 9 cases (15%) each, only papules in 7 cases (11.66%), only pustules and only comedones in 3 cases (5%) each, comedo-cystic, pustule-cystic, papulopustular-cystic in 1 case (1.66%) each. Maximum patients had moderate form of acne i.e. 28 cases (46.67%), 19 cases (31.67%) had mild form of acne, 11 cases (18.33%) had severe form of acne and 2 cases (3.33%) had very severe form of acne on the basis of Global Acne Grading System scale. Psora was found as the predominant miasm in maximum number of cases i.e 56 cases (93.33%) In group A cases treated with Individualized Homoeopathic medicines 03 cases (10%) were markedly improved, 13 cases (43.33%) were moderately improved, 10 cases (30%) were mildly improved, 3 cases (10%) were improved but not significantly, while 03 cases (10%) remained status quo, so overall 27 out of 30 patients in medicine group were improved in the course of treatment. Paired t – test shows that Individualized Homoeopathic medicines are significantly effective in the cases of Acne vulgaris. Medicines prescribed in maximum number of cases were Natrum muriaticum, Calcarea sulphurica and Sulphur. Whereas in group B maximum no. of cases i.e. 14 cases (46.66%), in placebo group remained status quo, 6 cases (20%) were mildly improved, 05 cases (16%) got worse, 4 cases (13.33%) were improved but not significantly, 1 case (3.33%) was moderately improved. Comparison of both groups by independent t - test shows that both groups, group A (n = 30) and group B (n = 30) have significant difference in results. Hence, it can be concluded that indivizualised Homoeopathic medicines are more effective as compared to placebo in cases of Acne vulgaris.

KEYWORD: Acne vulgaris, Homoeopathy, Controlled trial.

INTRODUCTION

Acne vulgaris is a chronic inflammatory disease of the pilosebaceous unit that affects at least 85 percent of adolescents and young adults.[1] It is characterized by comedones, papules, pustules, cysts, nodules, and occasionally scars.[2] Severest form occurs in boys but it tends to persist longer in girls. The incidence peaks at teenage but also affects men and women between 20-40 years of age.[3] The most common type of acne is the Acne vulgaris that develops during the teenage years. Puberty causes hormone levels to rise especially aldosterone. These changing hormones cause skin glands to start making more (sebum) oil, this secretion releases from the pores to protect the skin and keep it moist. 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. Precipitating factors include genetics, exposure to industrial compounds, trauma, rubbing from tight clothing, cosmetics, emotional stress and unfavorable climate.[5] Severity of the disease varies markedly from one individual to the other depending upon the interplay of various factors involved in the development of Acne vulgaris. Grading systems based on the clinical appearance of lesions as well as lesion counting are useful in assessing the severity of Acne vulgaris.[6,7] Across the globe, acne affects 80% of individuals between pubescence and 30 years of age. Many research studies have reported acne in 79-95% in the age group of 16-18 years. In India, research studies have reported acne in 50.6% of boys and 38.13% of girls in the age group of 12-17 years.[6] Though, acne is not a life-threatening condition, the complications of acne such as permanent scarring effects the quality of life and emotional well-being of the person.[8,9] Recent study have noticed significant associations between acne & suicidal ideation, mental health problems and social impairment.[10] Acne is the most common problem that presents to dermatologists. Acne commonly involves face. Facial appearance represents an important aspect of one"s perception of body image. Therefore it is not surprising that a susceptible individual with facial acne may develop significant psychosocial disability. As a part of emotional impact increased level of anxiety, anger, depression and frustration are observed in patients with acne. The majority of studies on psychosocial impact of acne have been conducted among patients in US and Europe, but there is poor understanding of this among the Indian population.[11] In Allopathy, the mainstay for the treatment of acne is use of topical or systemic antibiotics and retinoids but the long term use of these drugs produce significant side effects like erythema, peeling, burning and drying of the skin. Moreover, the development of antibiotic resistance to *Propionibacterium acne* may limit the use of topical antibiotics.[12] Thus there is an obvious need for alternative modes of treatment to be investigated i.e. Homoeopathy. Although Homoeopathic medicines have been used for acne treatment prior to this, it has not been compared to placebo before. Govender N.[13] in his study investigated the effectiveness of Homoeopathic medicines in the treatment of Acne vulgaris and had found significant improvement in the clinical manifestations of Acne vulgaris. The prime objective of this study was to treat the patients suffering from Acne vulgaris and also to compare the effectiveness of individual Homoeopathic medicines to placebo. The study also attempted to find the predominant miasm in cases of Acne vulgaris. Patient"s response was evaluated on the basis of GAGS scale.

MATERIALS AND METHODOLOGY

Study setting: The study was conducted at the

☐ **Site 1:** O.P.D. of Dr. Madan Pratap Khunteta Homoeopathic Medical College, Hospital & Research Center, Station Road, Jaipur (Rajasthan).

☐ **Site 2:** O.P.D. Homoeopathy University Saipura, Sanganer, Jaipur, (Rajasthan).

Study duration:

☐ The study was undertaken for a period of 12 months. Out of which cases were registered in first 9 months so that minimum 6 visits, observation could be obtained.

Selection of samples

60 cases were included in the study randomly from college OPD/IPD

☐ Group A: Homoeopathic medicine treatment group -30 cases

☐ Group B: Placebo group -30 cases

Inclusion criteria: Following cases were included irrespective of their caste, religion & duration of illness.

☐ Adolescents of both sexes having signs and symptoms of acne vulgaris

☐ Age group of 11 to 20 years.

☐ Willing to give informed consent.

Exclusion criteria: Following cases were excluded.

☐ Secondary acne (drug induced).

☐ Subjects diagnosed of having hormonal imbalances like PCOD, thyroid disorders.

☐ Pregnant and lactating women.

☐ Patient on steroid treatment.

Study design

☐ Allocation- Patients fullfilling eligibility criteria were enrolled and randomized systematically (Lottery method) to receive either Homoeopathic interventions or placebo.

☐ Type of study- Randomised, single blind, placebo controlled trial.

Intervention

Homoeopathic medicine: Homoeopathic medicines were given from the hospital OPD to the patients on the basis of symptoms similarities.

☐ **Group A:** 30 Cases - Medicines prescribed on the basis of Totality of symptoms.

☐ Potency selection, Dosage and Repetition – As per the Hahnemannian guidelines in 5th edition of Organon of Medicine.

☐ **Group B:** 30 cases - Placebo was prescribed

Medicine dispensing

☐ Medicines were dispensed in globule form (size 60) from dispensing unit of Dr. Madan Pratap Khunteta Homoeopathic Medical College, Hospital and research centre, Jaipur (Rajasthan).

Auxillary Measures

☐ All the precipitating causes and aggravating factors were advised to avoid.

☐ Photographs were taken before and after treatment.

Statistical analysis

The GAGS score of each patient before the commencement of the treatment and after 6 follow-ups were assessed by the formula.

$$\frac{\text{Score at Baseline – Score at the end}}{\text{Pe Score at Baseline}} \times 100$$

The percentage was then alloted in one of the following criteria for improvement-

Marked Improvement= 75%-100%

Moderate Improvement= 50%-74%

Mild Improvement= 25%-49%

Non significant= <25%

Status Quo= 0%

SPSS software was used to analyze the study. Paired t-test was used to assess before and after scores in a group. Independent t-test was used to compare effect between medicine and placebo. Alpha of 0.05 was used to determine statistical significance.

RESULTS

Table1: Paired Samples Statistics.

		Mean	N	Std Deviation	Std. Error Mean
Group A	Before	23.87	30	8.901	1.625
	After	12.63	30	6.896	1.259

Table 2: Paired sample t-test of medicinal group(Group A).

Paired Differences					t	df	Sig. (2-tailed)
Mean	Std Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
			Lower	Upper			
11.233	6.263	1.143	8.895	13.572	9.825	29	.000

A paired sample t- test (Table 1 and 2) was conducted to compare the before and after scores of Group A i.e Individualised Homoeopathic medicines in cases of acne vulgaris. Before (M=23.87, SD=8.901) and after score (M=12.63. SD= 6.896) Conditions, t = (29) =9.825, p = 0.000. These results suggest that individualised Homoeopathic medicines had shown significant results in cases of acne vulgaris.

Table 3: Paired Samples Statistics.

		Mean	N	Std. Deviation	Std. Error Mean
Group B	Before	22.70	30	9.113	1.664
	After	20.97	30	9.364	1.710

Table 4: Paired sample t-test of control group (Group B).

	Paired Differences					t	df	Sig. (2- tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Group B Before - After	1.733	4.748	.867	-.040	3.506	1.999	29	.055

A paired sample t -test (Table 3 and 4) was conducted to compare the before and after scores of Group B i.e. Placebo in cases of acne vulgaris. Before (M=22.77, SD=9.113) and after score (M=20.96. SD=9.364) conditions t= (29) =1.999, p = 0.055. These results suggest that Placebo had not shown significant results in cases of acne vulgaris.

Table 5: Group Statistics of After -After score of both group.

Group	N	Mean	Std. Deviation	Std. Error Mean
A	30	12.63	6.896	1.259
Score				
B	30	20.97	9.364	1.710

Table 6: Independent Samples Test.

	Levene's Test for Equality of Variances		t-test for Equality of Means						
	F	Sig.	t	d.f	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
								Lower	Upper
Scor Equal Esvariances assumed	6.231	.015	-3.925	58	.000	-8.333	2.123	-12.583	-4.083
Equal variances not assumed			-3.925	53.305	.000	-8.333	2.123	-12.591	-4.075

Levene's test indicated equal variance (F = 6.231, P = .015) so d.f. = 58. There is significant (P < 0.005) improvement in acne vulgaris with individualized Homoeopathic medicines (M = 12.63,SD = 6.896) than placebo (M=20.97, SD = 9.364), t(58)= -3.925, P < 0.005, therefore rejecting null hypothesis (H$_0$) and accepting alternate hypothesis (H$_1$) that individualized Homeopathic medicines has a significant role in treating the cases of acne vulgaris. Taken together, these results suggest that intervention of individualized Homoeopathic medicines appears to be significantly effective in treating the cases of acne vulgaris as compared to placebo.

A discussion on various aspects observed in the study has been given below: **AGE GROUP***:* In this study it is found that more commonly affected age group is 18 to 20 years i.e. 37 cases (61.66%) which is similar to other study by Reddy N.et.al. where the peak prevalence age was 19.5 years.[14]

SEX RATIO: In present study it is indicated that out of the total number of 60 cases, 37 cases (61.66%) were males and 23 cases (38.33%) were females. Similar male preponderance has been reported by Adityan B. et. al.[6]

AREA OF RESIDENCE: In this study it is found that out of 60 cases maximum numbers of cases i.e. 34 cases (56.67%) were from urban area. This is supported by the data from Varanasi where 21.35% of boys (13–18 years) from rural areas had Acne vulgaris versus 37.5% from the urban areas.[15] The Western diet, including meats, dairy, and high glycemic index foods, can be the influencing factors in urban area.

SOCIOECONOMIC STATUS: maximum number of cases i.e. 37 cases (61.66%) were from middle socioeconomic status, whereas minimum 11 cases (20%) were observed from low socioeconomic status. This is supported by a cohort study by Haider A. et.al. In his study, he observed a significant association between socioeconomic status and visitation to a dermatologist for the treatment of acne. The fact that patients in lower socioeconomic groups are less likely to receive specialist consultation. A possible explanation is that individuals with a higher or middle socioeconomic status may have greater expectations about the level of care they receive.[16]

TYPES OF LESIONS: Commonest type of lesion found were *papulopustular i.e* in 16 cases (26.66%).

SEVERITY OF ACNE: Out of total 60 cases 28 cases (46.67%) had moderate form of acne, 19 cases (31.67%) had mild form of acne, 11 cases (18.33%) had severe type of acne and 2 cases (3.33%) had very severe type of acne partially similar to Reddy N.B et. al. study where mild facial acne vulgaris was seen in 43% of patients where as 57% patients were with moderate acne.[14]

FAMILY HISTORY: In present study it is found that 35 cases (58.33%) had family history of acne vulgaris that means acne are heritability in first-degree relatives similar to the study of Bhate et.al. where heritability of acne was found to be almost 80% in first-degree relatives.[17]

INDICATED MEDICINE IN GROUP A: *Natrum muriaticum* is prescribed in maximum number of cases i.e. in 6 cases (20%), followed by *Calcarea sulphurica* in 5 cases (16.66%), *Sulphur* in 3 cases (10%), *Antimonium Crudum, Belladonna*, *Hepar sulphuris, Kali bromatum, Lycopodium clavatum* and *Sepia officinalis* in 2 cases (6.66%) cases each; *Arsenicum album*, *Calcarea carbonica, Nux vomica, Phosphorus* in 1 case (3.33%) each.

GROUP B- Placebo was prescribed.

CONCLUSION

From this study, it has been observed that the Homoeopathic medicines prescribed on the basis of totality of symptoms to the patients suffering from acne vulgaris had shown beneficial results. In Group A cases treated with individualized Homoeopathic medicines on the basis of totality of symptoms, overall 27 out of 30 patients in this group were improved

out of which 3 cases (10%) were markedly improved. The most indicated medicines were *Natrum muriaticum*, *Calcarea Sulphurica*, and *Sulphur*. Whereas in group B (placebo group) maximum, 14 cases (46.66%) remained status quo while none of the case was markedly improved. Statistically significant difference has been seen in effects of individualized Homoeopathic medicines as compared to placebo in the treatment of acne vulgaris on the basis of GAGS score. It has been noticed that as far as the perceptions of the patients and the clinical manifestations are concerned, Homoeopathy play an observably notable and statistically significant role, as compared to placebo in the treatment and management of Acne vulgaris.

LIMITATIONS OF THE STUDY

The limitation of the study was the 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. It is advisable that further research should be done with large sample size.

REFERENCES

1. Robaee A. Assessment of general health and quality of life in patients with acne using a validated generic questionnaire. Acta dermatoven APA [Internet]. 2009 [cited 2017 Aug 7]; 18(4): 157-64. Available from: https://www. ncbi.nlm .nih.gov /pubmed.

2. Bagatin E, Timpano D, Guadanhim L. Acne vulgaris: prevalence and clinical forms in adolescents from São Paulo, Brazil. An Bras Dermatol [Internet]. 2014 [cited 2017 Aug 7]; 89(3): 428–43. Available from:https://es.scribd.com//333477791.

3. Nilfroushzadeh MA, Siadat AH, Baradaran EH et al. Clindamycin lotion alone versus combination lotion of clindamycin phosphate plus tretinoin versus combination lotion of clindamycin phosphate plus salicylic acid in the topical treatment of mild to moderate acne vulgaris: A randomized control trial. Indian J Dermatol Venerol Leprol [Internet]. 2009 [cited 2017 Aug 7]; 75(3): 279-282. Available from: https://www.ncbi.nlm.nih.gov/pubmed/19439881.

4. Acne Vulgaris, causes, WebMD [Internet]. [cited 2017 Aug 7]; Available from: www.webmd.com/skin-problems-and-treatments/acne/acnevulgaris-cause.

5. Patil M, Bendigeri J. Clinico-epidemiological study of Acne Vulgaris in Southern India. International Journal of Biomedical Research [Internet]. 2015 [cited 2017 Aug 8]; 6(07): 509-511. Available from: www.ssjournals.com.

6. Adityan B, Thappa DM. Profile of acne vulgaris –A hospital based study from south India. Indian J Dermatol Venereal Leprol [Internet], 2009 [cited 2017Aug 8]; 75: 272-8. Available from: http://www.ijdvl.com/ text.asp?2009/ 75/3/272/ 51 244.

7. Makrantonaki E, Ganceviciene R, Zouboulis C. An update on the role of the sebaceous gland in the pathogenesis of acne. Dermatoendocrinol [Internet]. 2011 [cited 2017 Aug 8]; 3(1): 419. Available from:https://www.ncbi.nlm.nih.gov/pmc.

8. Ray C, Trivedi P, Sharma V. Acne and its treatment lines. International Journal of Research in Pharmaceutical and Biosciences [Internet]. 2013 [cited 2017 Aug 8]; 3(1): 1-16. Available from: https://www.urpjournals.com/tocjnls/40_13v3i1_1.
    Mancini AJ. Incidence Prevalence and pathophysiology of acne. Advanced Studies in Medicine [Internet]. 2008 [cited 2017 Aug 8]; 8(4): 100-5. Available from: www.jhasim.com/files/articlefiles/pdf/ASM_8_4p100-105.pdf.

9. Halvorsen JA, Stern RS, Dalgard F et.al. Suicidal ideation, mental health problems and social impairment are increased in adolescents with acne: a population-based study. J Invest Dermatol [Internet], 2011 [cited 2017 Aug 9]; 131(2): 363-70. Available from:https://www.ncbi.nlm.nih.gov/pubmed.

10. Samanthula H, Kodali M. IOSR. Journal of Dental and Medical Sciences [Internet], 2013[cited 2017 Aug 9]; 6(3): 59-62. Available from:www.iosrjournals. org/ iosr-jdms/papers/.

11. Lone A.H, Habib S, Ahmad T et. al. Effect of a Polyherbal Unani formulation in acne vulgaris: A preliminary study. Journal of Ayurveda and Integrative Medicine [Internet], 2012 [cited 2017 Aug 12]; 3(4): 180–183. Available from: https: // www. ncbi. nlm.nih.gov/pmc/articles/PMC3545236/.

12. Govender N. A study comparing the effectiveness of a herbal-complex (Arctium lappa, Berberis aquifolium, Echinacea purpurea and Taraxacum officinale) as compared to homoeopathic simillimum in the treatment of Acne vulgaris. Durban University of technology; 2003. Available from: http://ir.dut.ac.za/bitstream/.

13. M.Jotish, Pranitha CN. et.al. Novel Drug Delivery System and Its Use In The Treatment Of Acne. Int. Journal of Pharmacy & Technology [Internet], 2010 [cited 2017 Aug 16]; 2(1): 41-53. Available from: http://www.ijptonline.com/wp-content /uploads /2009/10/41-53.

14. Pandey P. et al. a Cross Sectional Study on Quality of life among acne vulgaris patients. International Journal of Research in medical sciences [Internet], 2016 [cited 2017 Aug 15]; 4(11): 4800-4805. Available from: (www. msjonline. org/index. Php / ijrms /article).

15. Haider A, Mamdani M.et al. Socioeconomic status influences care of patients with acne in Ontario, Canada.J am acad dermato [Internet]; 2006 [cited 2017 Dec 20]; 54(2): 331-5. Available from https://www.ncbi.nlm.nih.gov/pubmed.

16. Bhate K et al. Epidemiology of acne vulgaris. Br. Journal of Dermatology [Internet], 2013 [cited 2017 Aug 16]; 168(3): 474-85. Available from: https:// www.ncbi. nlm. nih. gov / pubmed/23210645.