A Non-Randomized clinical study to observe the efficacy of Individualized Homoeopathic medicine in the management of Melasma using Synthesis Repertory

Dr. Nitisha Manoj Bhartiya[1], Dr. Priya Rohit Sheth[2]*

[1]PG Scholar, Department of Homoeopathic Repertory and Case Taking Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College and Hospital, Pune – 411043, Maharashtra, India, Email: nbhartiya4@gmail.com

[2]Associate Professor, Department of Homoeopathic Repertory and Case Taking Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College and Hospital Pune – 411043, Maharashtra, India, Email: priya.sheth@bharatividyapeeth.edu

Corresponding Author: Dr. Priya Rohit Sheth, Associate Professor, Department of Homoeopathic Repertory and Case Taking Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College and Hospital Pune – 411043, Maharashtra, India, Email: priya.sheth@bharatividyapeeth.edu

Abstract

Background: Melasma is a recurrent, chronic hyperpigmentation disorder caused by hyperactive melanocytes leading to excessive melanin deposition in the epidermis and dermis. It commonly presents as marginated facial hyperpigmentation and significantly affects psychological well-being and quality of life. Research on its psychological burden and management in India remains limited. Homoeopathy, with its holistic and individualized approach, may provide therapeutic benefit where conventional treatments show limitations. **Methods:** A single-blind, prospective, non-randomized clinical study was conducted at the OPD of Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College and Research Centre, Pune. Thirty patients aged ≥25 years were enrolled and completed follow-up. Individualized homoeopathic medicines were prescribed using the Synthesis Repertory. Outcomes were assessed using the Melasma Severity Index (MSI) and Melasma Quality of Life (MelasQoL) scales before and after intervention. Wilcoxon signed-rank test and paired t-test were applied. A p-value <0.05 was considered statistically significant. **Results:** Among 30 patients, 96.67% were female. Significant reduction was observed in MSI scores ($Z = -4.787$, $p < 0.05$), with median values decreasing from 10.80 to 4.64. MelasQoL scores reduced from 34.90 ± 6.48 to 15.77 ± 4.21, demonstrating statistically significant improvement ($t(29) = 20.53$, $p < 0.05$). Sulphur (30%), Lycopodium (20%), and Sepia (16.67%) were the most frequently prescribed remedies. **Conclusion:** Individualized homoeopathic treatment using the Synthesis Repertory showed statistically significant improvement in both disease severity and quality of life in patients with melasma. Larger controlled studies are recommended to validate these findings.

Keywords: Melasma; Homoeopathy; Melasma Severity Index; Melasma Quality of Life; Synthesis Repertory; Quality of life

1. Introduction

Melasma is a recurrent, chronic, and widespread hyperpigmentation disease produced by hyperactive melanocytes, which accumulate an unusually large amount of melanin in the layers of the skin that are the epidermis and dermis.[1] It is an acquired chronic hypermelanosis of the skin that manifests as irregular brown macules that are symmetrically distributed across sun-exposed body parts, especially the face.[5] Due to its frequent involvement of the face, it has a severe emotional and psychological impact on the quality of life of the patients.[2,5] Most commonly seen in women and people with Fitzpatrick Skin Types III and VI.[5] It is mainly considered a female pigmentation disorder because its occurrence in men is rare.[4]

Melasma classification is based on the site of the lesion and the depth of pigmentation within the epidermis, dermis, or both.[10] Melasma has been divided into three types: epidermal, dermal, and mixed melasma.[4] In melasma, both epidermal and dermal melanin content is increased, but its degree depends on the intensity of hyperpigmentation.[5] The centrofacial pattern is the most common, particularly among women.[4]

Specific causes of melasma are unknown.[3] Changes in female hormone levels and prolonged exposure to UV light are the primary risk factors associated with the development of melasma.[7] Melasma is commonly attributed to pregnancy, oral contraceptives, and hormone replacement therapy.[9] Chronic sun exposure is a key factor in its pathogenesis.[12] Research has confirmed that the hyperpigmentation in melasma is caused by both increased melanocytosis and increased melanogenesis.[13]

Melasma is typically diagnosed by evaluating the clinical presentation and categorized as either epidermal, dermal, or mixed.[1] Dermoscopy is a useful tool for diagnosing melasma and can also be utilized to assess the severity of melasma.[1,6,13]
The Melasma Severity Index (MSI) Score was proposed in 2016.[11] The MSI score is calculated as: MSI = 0.4 ($a \times p^2$) l + 0.4 ($a \times p^2$) r + 0.2 ($a \times p^2$) n.[11]
The Melasma Quality of Life Questionnaire (MelasQoL) was developed and validated in 2003.[3] The total score of the MelasQoL scale ranges from 10 to 70.[3]
In homoeopathic practice, cases are repertorized using the Synthesis Repertory (Repertorium Homoeopathicum Syntheticum) compiled by Dr. Frederik Schroyens and first published in 1987.[8] The main source is the Sixth American edition of Kent's Repertory.[14] It follows the philosophical background of "Generals to Particular" and contains graded remedies and expanded rubrics.[8,14,15]
To study the efficacy of individualized homoeopathic medicine in the management of melasma and improvement in quality of life by using Synthesis Repertory, the present study was undertaken.

2. AIM

To study the efficacy of individualized homoeopathic medicine in the management of melasma and improvement in quality of life by using Synthesis Repertory.

3. Materials And Methods

3.1 Study Setting: The study was conducted at Bharati Vidyapeeth Medical Foundation Homoeopathic Hospital OPD and various rural and urban camps organized by the hospital.
3.2 Study Design: Prospective non-randomized experimental single blind study.
3.3 Sample Size: A total of 30 cases comprising patients of both genders who met the specified inclusion and exclusion criteria were selected.
3.4 Case Definition: All cases presenting with complaints of melasma underwent assessment using the MSI and MelasQoL scales. Cases were repertorized using the Synthesis Repertory. Patients aged 25 years and above were included irrespective of sex.
3.5 Inclusion Criteria:
• Patients with complaints of melasma assessed by MSI and MelasQoL scales
• Patients aged 25 years and above
• Any sex
• Willing to participate and give consent
3.6 Exclusion Criteria:
• Patients having co-morbidities like Thyroid, PCOD and Melanoma
• Patients having other dermatological co-morbidities
• Patients exposed to chemical peeling, laser or topical steroid mixed cream in last 6 months
• Patients taking oral or topical medications for melasma
3.7 Intervention: The remedy was selected on the basis of symptom similarity (Individualized medicine). Potency was selected on the basis of the patient's condition and symptomatology. Selected remedy was administered through the oral route in globule, powder or liquid form.
3.8 Outcome Assessment: Cases were evaluated using the MSI and MelasQoL scales before and after treatment.[3,11]
3.9 Follow-Up: The first follow-up was conducted on the 7th day and subsequent follow-ups every 15 days as per need of the case.
3.10 Statistical Analysis: Wilcoxon Signed Rank Test was used for MSI score analysis and Paired t-test was used for MelasQoL score analysis. A p-value <0.05 was considered statistically significant.
3.11 Trial registration:
This clinical study was registered with the Clinical Trials Registry of India (CTRI No.: CTRI/2024/04/065204).
3.12 Ethical approval and informed consent
The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Ethical approval was obtained from the Institutional Ethics Committee of Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College and Hospital, Pune (IEC Ref: BVDUHMC/2023/09). Written informed consent was obtained from all participants prior to enrollment in the study.
The study is reported in accordance with the CONSORT guidelines for clinical trials.

CONSORT flow diagram of patient enrollment and follow-up
Patients assessed for eligibility (n = 32)
Excluded (n = 2)
Patients enrolled (n = 30)
Received intervention (n = 30)

Completed follow-up (n = 30)
Included in analysis (n = 30)

4. OBSERVATION AND RESULTS

Demographic Characteristics of patients

Table 1. Distribution of patients according to age

Age	Number of patients	Percentage
26-35	**11**	**36.67%**
36-45	**10**	**33.33%**
46-56	**9**	**30.00%**

Among 30 patients, 36.67% were aged 26–35 years, 33.33% were 36–45 years, and 30.00% were 46–56 years (Figure 1).

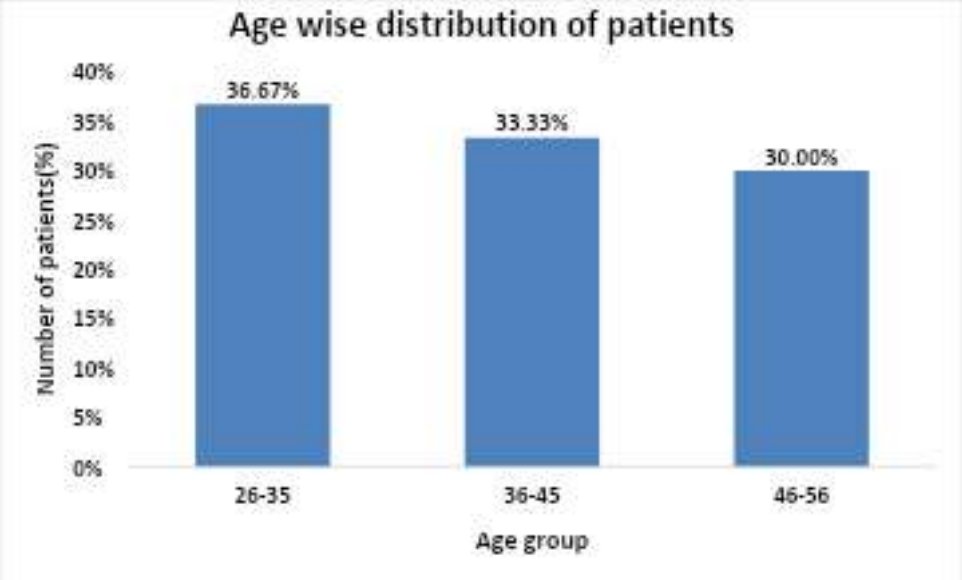

Figure 1: *Bar diagram representing the Age-wise distribution of patients*

Table 2. Distribution of Patients according to Gender

Gender	Number of patients	Percentage
Female	29	96.67%
Male	1	3.33%

Table 2 shows that 96.67% of patients were female and 3.33% were male (Figure 2), indicating marked female predominance.

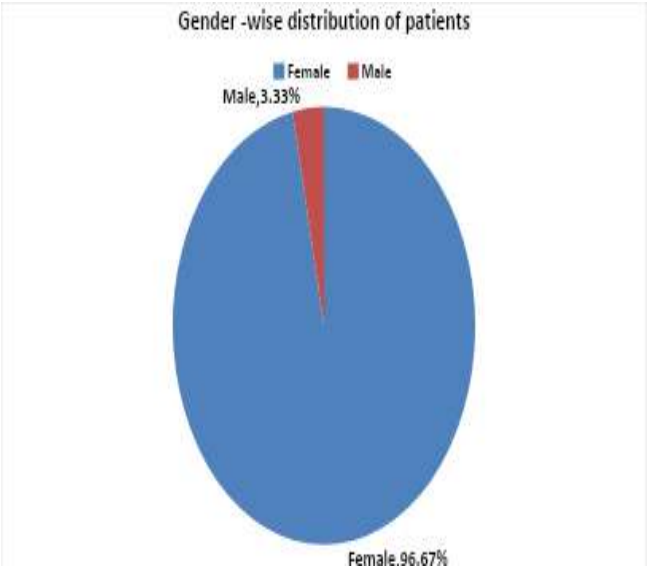

Figure 2: *Gender-wise distribution of patients*

Table 3. Remedy-wise distribution of patients.

Remedy	**Number of patients**	**Percentage**
Arsenic Alb.	4	13.33%
Conium.Mac.	1	3.33%
Ignatia	2	6.67%
Lycopodium	6	20.00%
Natrum Mur.	1	3.33%
Pulsatilla	2	6.67%
Sepia	5	16.67%
Sulphur	9	30.00%

Table 3 presents the remedy-wise distribution. Sulphur was prescribed to 30% of patients, followed by Lycopodium (20%), Sepia (16.67%), and Arsenic Alb. (13.33%). Pulsatilla and Ignatia were prescribed to 6.67% each, while Conium.Mac. and Natrum Mur were prescribed to one patient each (3.33%) (Figure 3).

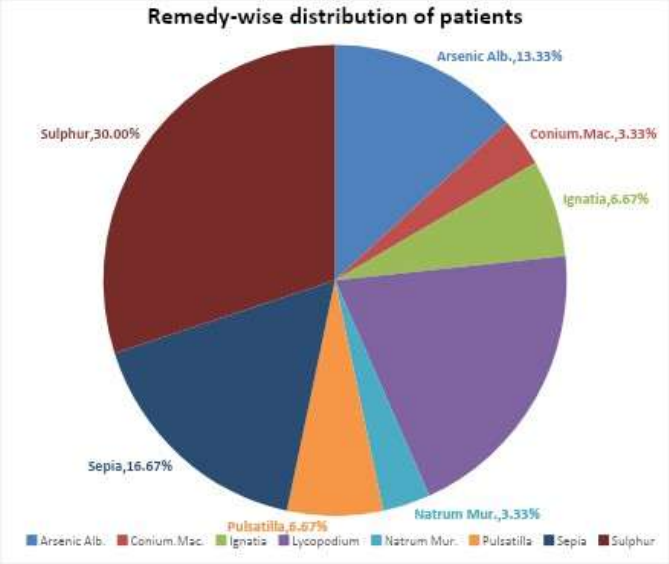

Figure 3: *Remedy-wise distribution of patients.*

Table 4. Wilcoxon Signed Rank Test for MSI score before and after the treatment.

Variable		**N**	**Mean Rank**	**Sum of Ranks**	**Test statistic and P-value**
MSI score difference	Negative Ranks	30	15.50	465.00	Z = -4.787
	Positive ranks	0	0.00	0.00	P < 0.05

Note: Z = Wilcoxon signed-rank test statistic; p < 0.05 indicates statistical significance.
The Wilcoxon Signed Rank Test was applied to compare MSI scores before and after treatment (Table 4).
All 30 cases showed negative ranks, indicating reduction in MSI scores after treatment. The test statistic showed Z = -4.787 with p < 0.05, demonstrating a statistically highly significant difference.

Table 4a. Descriptive statistics of MSI score before and after the treatment.

MSI Score	**N**	**Mean**	**Minimum**	**Median(IQR)**	**Maximum**
Before Treatment	30	15.60±15.16	3.20	10.80(9.95)	60.80
After Treatment	30	7.16±9.11	0.00	4.64(6.36)	34.20

- Mean MSI reduced from 15.60 ± 15.16 to 7.16 ± 9.11
- Median reduced from 10.80 (IQR 9.95) to 4.64 (IQR 6.36)
- Maximum score reduced from 60.80 to 34.20

These findings indicate a significant reduction in disease severity following intervention (Figure 4).

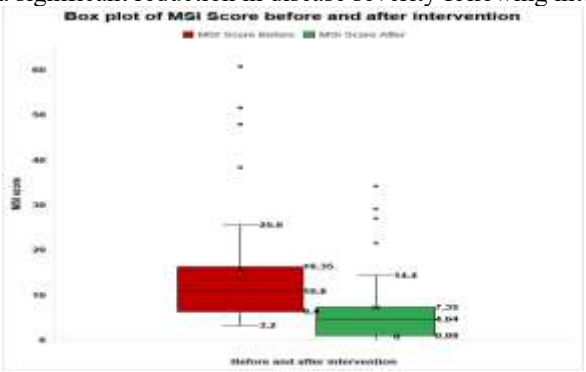

Figure 4*: Boxplot of MSI score before and after treatment.*

Table 5. Paired t-test and Descriptive statistics of the Melasma Quality of Life Questionnaire (MelasQoL) scale before and after the intervention.

Melas QoL scale	N	Mean ± SD	Min	Max	T Statistic Value	P-Value
before		34.90 ± 6.	16.			
	30			48.0		
intervention		48	0			P-
					T (29) = 20.53,	< 0.0 5
After intervention	30	15.77 ± 4. 21	10. 0	25.0		
Mean difference		19.13 ± 5.10				
95% CI for the mean						
		(17.23, 21.04)				
difference						

Paired t-test was used to compare MelasQoL scores before and after intervention (Table 5).

- Mean score reduced from 34.90 ± 6.48 to 15.77 ± 4.21
- Mean difference: 19.13 ± 5.10
- t = 20.53, df = 29
- p < 0.05 (highly significant)
- 95% CI: 17.23–21.04

The significant reduction in MelasQoL scores indicates marked improvement in patients' quality of life.

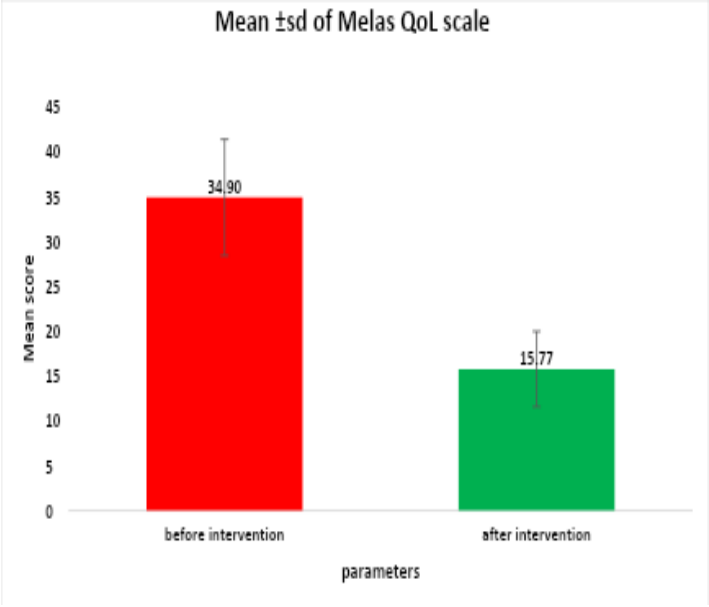

***Figure 5**: Bar diagram representing the Average ± SD of MelasQoL scale before and after intervention.*

Figure 5 shows the bar diagram representing the mean ± SD values of the MelasQoL scale before and after intervention.

Overall, individualized homoeopathic medicine selected through the Synthesis Repertory resulted in statistically significant improvement in both clinical severity (MSI) and quality of life (MelasQoL) in patients with melasma.

5. Discussion

Clinical significance - Melasma significantly affects patients' psychological well-being and quality of life, particularly among women. The findings of this study suggest that individualized homoeopathic treatment based on repertorization using the Synthesis Repertory may provide a safe and effective therapeutic option for improving both disease severity and quality of life in patients with melasma. This prospective non-randomized experimental single blind study evaluated individualized homoeopathic medicine in melasma using the Synthesis Repertory. Significant reduction was observed in MSI scores (Z = -4.787, p < 0.05) and MelasQoL scores (t = 20.53, p < 0.05) after treatment. The median

MSI decreased from 10.80 to 4.64, and the mean MelasQoL reduced from 34.90 to 15.77. These findings indicate improvement in both pigmentation severity and quality of life.

6. Limitations:

The present study had a relatively small sample size and lacked a control group. Larger randomized controlled trials with longer follow-up periods are required to further validate the findings.

7. Conclusion

The present study suggests that individualized homoeopathic medicines selected using the Synthesis Repertory may contribute to improvement in both clinical severity and quality of life in patients with melasma. However, larger randomized controlled trials are required to further validate these findings.

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