Scope of Repertory to the More Characteristic Symptoms of the Materia Medica by Constantine Lippe in the Cases of Photodermatitis - A Randomized Single Blind Control Trial

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Abstract Photo dermatitis is abnormal skin reaction to sunlight and is common now a days esp. in tropical countries like India. This study embraces use of homoeopathic remedies in such cases using Lippe's Repertory which is a type of general repertory. This is a Randomised Control Study which was done taking 50 cases each in interventional and control arms. Response to the treatment was assessed using scales like DLQI, Patient GAI and Physician GAI. The results were quite encouraging as 66 percent cases in control arm showed improvement whereas 30 percent patients improved in control arm. Statistical parameters like DLQI scale showed significant improvement in interventional arm in comparison to the control arm. Study approves efficacy of homoeopathic remedies in cases of Photo dermatitis using a general repertory. More such studies can be conducted in future to establish better cure rates esp. by using anti-miasmatic intercurrent doses.

1. Introduction

Photodermatitis is an abnormal skin reaction to sunlight, or more specifically to ultraviolet (UVB) rays (Lehmann, P. and Schwarz, 2011). It can be acute (sudden) or chronic (on going). Photodermatitis occurs when immune system reacts to UV rays, may develop a rash, blisters, or scaly patches. Exposure levels and reactions differ for every person.

Several factors can make skin sensitive to light UV rays, including having an inherited tendency for photosensitivity, taking certain medications, or being exposed to plants including weeds and edible plants.

Homoeopathy offers a holistic approach, that is its application is based upon individual variations of the sufferers of same ailment. Thus, it not only considers the particular aspect of the disease but also considers the diseased person as an individual entity.

This was an OPD based study in which 100 patients were registered randomly in the study from which 50 patients each were taken for intervention arm and control arm. Medicines were selected
following Homoeopathic Principles considering totality of the symptoms using Lippe Repertory with proper management.

Research Question for this study was, do patients of Photodermatitis receiving Homoeopathic medicines selected with aid of Lippe Repertory have more improvement than patients receiving mere placebo?

Lippe Repertory is the first repertory based on deductive logic that is working out case from general to particular. The mind and generalities chapters are the most important chapters of the repertory. Modalities are given in detail in this repertory. According to Homoeopathic philosophy mental itch or psora is the origin of diseases – acute or chronic; thus, to alleviate the basic cause and establish cure, repertories based on deductive logic will prove to be useful.

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 by strengthening it naturally and completes the healing process with the help of indicated remedy, viz. similimum.

Assessment of clinical condition and general health of the patients was done by using DLQI, Physician Global Assessment Index and Patient Global Assessment Index.

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

Aim

To ascertain the efficacy of Homoeopathic medicines by comparing the effects of Homoeopathic medicinal intervention with placebo in the treatment of Photodermatitis.

Objectives

To study the effectiveness of Homoeopathy over Placebo arm in the cases of Photodermatitis using Lippe Repertory.

To study the extent of improvement in cases using DLQI, Patient GAI, and Physician GAI.

2. Materials and Methods

Tools

- A detailed case taking proforma was especially designed for the study.
- Patient information sheet and patient consent form.
- Repertory to the More Characteristic Symptoms of the Materia Medica by Constantine Lippe.
- Dermatological Life Quality Index (DLQI), Physician global assessment and Patient global assessment index.
- Medicines procured from Sharda Boiron Limited, Sitapura, Jaipur were dispensed from the Hospital's dispensary.
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

- Patients of all age groups, of both sexes were included irrespective of their socioeconomic status presenting with Photodermatitis.
- Patient who gave consent to participate in the study.

Exclusion Criteria

- Patients with no clear history of Photodermatitis or having genetic or metabolic cause.
- Patients with other systemic disease or congenital abnormalities.
- Patients who refused to give their consent for the study.

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 allotted in control group.
- Type of study - Perspective, Experimental, Randomized Placebo Control
- End point classification - Efficacy study Masking - Single blind, the patient was remained blinded to the identity of the treatment group.
- Primary purpose - Treatment

3. Results

Following parameters were fixed according to the type of the response obtained after the treatment:

Cure: Greater than 90% improvement in Patient and Physician Global Assessment Index, Dermatological Life Quality Index (DLQI) for a period of 3 months along with feeling of mental and physical well-being and having no relapse of symptoms up to 6 months or more.

Improvement

- Mild: less than 30% improvement in Patient and Physician Global Assessment Index, DLQI.
- Moderate: 30 to less than 60% of improvement in Patient and Physician Global Assessment Index, DLQI.
- Marked: 60 to less than 90% of improvement in Patient and Physician Global Assessment Index, DLQI.
- Status QUO: When there was no change in Patient and Physician Global Assessment Index and DLQI.
- Worse: When there was no improvement in condition of the patient and instead his /her complaints got worse in respect to DLQI, Patient and Physician Global Assessment Index. This was assessed in view of Homoeopathic aggravation, disease & medicinal aggravation. Counseling of patient was done accordingly; if aggravation was continued for more than 30 days then it was considered as Worse.
- Dropped Out: When patient discontinued the treatment during the course of study or showed poor compliance.

**Benefits of the Study**

Complete disappearance of symptoms of Photodermatitis with betterment in general health. This Study provides strong evidence of efficacy of Homoeopathic intervention. Allows standardization of study maneuver and outcome assessment.

**Figure 1: Intervention & Control arms**

As shown in above figure, in intervention arm 4 (8%) cases got cured, 5 (10%) showed marked improvement, 10 (20%) showed moderate improvement, 14 (28%) got mild improvement, 17 (34%) were status quo, whereas in control arm 3 (6%) cases got cured, 5 (10%) showed marked improvement, 3 (6%) showed moderate improvement, 4 (8%) got mild improvement, 34 (68%) were status quo and 1 case (2%) got worse.

**Test Statistic and Data Analysis**

**Paired t-test:**

Paired t-test is applicable to study the intra-arm (i.e. within Intervention & Control arms) difference of the first and final scores of DLQI, Phy. GAI & Pt. GAI.

Null Hypothesis $H_0$: There is no significant difference in pre and post mean scores of DLQI, Phy. GAI and Pt. GAI.

Alternative Hypothesis $H_1$: There is a significant difference in pre and post mean scores of DLQI, Phy. GAI and Pt. GAI.
Table 1: Paired sample t-test of Interventional Arm

| S. No. | Assessment Scales (First & Final Scores) | Mean | Standard Deviation | T (cal) | d. f. | p-value |
|--------|----------------------------------------|------|--------------------|---------|-------|---------|
| 1      | DLQI                                   | 2.620| 2.791              | 6.637   | 49    | 0.000*  |
| 2      | Phy. GAI                               | 1.780| 1.788              | 7.041   | 49    | 0.000*  |

Significant at 5% level of significance

From Table 1, we can see that the p-values corresponding to the three assessment scores DLQI, Phy. GAI and Pt. GAI are very less than 0.05, indicating a significant positive difference in the first & final scores in intervention arm, which gives us the evidence to reject the null hypothesis. The Quality of Life & Global Assessment Indices from Physician and Patient were significantly improved after the medication was provided.

Table 2: Paired sample t-test of Control Arm

| S. No. | Assessment Scales (First & Final Scores) | Mean | Standard Deviation | T (cal) | d. f. | p-value |
|--------|----------------------------------------|------|--------------------|---------|-------|---------|
| 1      | DLQI                                   | 2.040| 3.912              | 3.687   | 49    | 0.001*  |
| 2      | Phy. GAI                               | 1.160| 1.811              | 4.529   | 49    | 0.000*  |
| 3      | Pt. GAI                                | 1.280| 2.051              | 4.413   | 49    | 0.000*  |

Significant at 5% level of significance

t-test for Difference of two means for Independent Samples

This test is applicable to study the inter-arm analysis (i.e. between Interventional & Control Arms) of differences of first & final scores of DLQI, Phy. GAI and Pt. GAI. The proposed hypothesis is:

Null hypothesis $H_0$: There is no difference in the increment in first and final scores of DLQI, Phy. GAI and Pt. GAI for intervention and control arm.

Alternative hypothesis $H_1$: There is a significant difference in the increment in first and final scores of DLQI, Phy. GAI and Pt. GAI for intervention and control arms.

Table 3: Testing of differences of increments in scores in Interventional & Control Arms

| S. No. | Assessment Scales | Group   | Mean | Standard Deviation | d. f. | T | p-value |
|--------|-------------------|---------|------|--------------------|-------|---|---------|
| 1      | DLQI              | Intervention | 2.620| 2.791              | 3.687 | 49 | 0.001*  |
|        |                   | Control   | 2.040| 3.912              |       |   |         |
| 2      | Phy. GAI          | Intervention | 1.780| 1.788              | 4.529 | 49 | 0.000*  |
|        |                   | Control   | 1.160| 1.811              |       |   |         |
| 3      | Pt. GAI           | Intervention | 1.980| 1.985              | 4.413 | 49 | 0.000*  |
|        |                   | Control   | 1.280| 2.051              |       |   |         |

Significant at 5% level of significance.

Explanation on Statistical Analysis of the Study

From Table 1, we can see that the p-values corresponding to the three assessment scores DLQI, Phy. GAI and Pt. GAI are very less than 0.05, indicating a significant positive difference in the first & final scores in intervention arm, which gives us the evidence to reject the null hypothesis. The Quality
of Life & Global Assessment Indices from Physician and Patient were significantly improved after the medication was provided.

From Table 2, it can be seen that the p-value for the three assessment scores is very less than 0.05, suggesting significant difference in the first & final scores of assessment scales in control arm. The Quality of Life & Global Assessment Indices from Physician and Patient was improved in control arm.

From Table 3, it is clear that the p-value corresponding to DLQI is less than 0.05, which indicates a positive change in the quality of life of the patients of the intervention group, treated with Homoeopathic medicine, as compared to the control group.

p-value for Phy. GAI is 0.209, which is not remarkably significant, leads us to acceptance of the null hypothesis.

p-value corresponding to Pt. GAI is 0.062, which is nearly positively significant but not significant in the normally accepted statistical sense. This leads us to acceptance of the null hypothesis.

Result shows significant improvement according to DLQI scale in intervention group as compared to the control group. Although the results were not statistically significant according to Phy. GAI and Pt. GAI but there was significant improvement of the symptoms of patients in the intervention group as compared to the control group.

4. Discussion

In this study, it has been observed that maximum incidence of Photodermatitis was observed in the age group 21-30 i.e. 30 cases (30%) whereas minimum incidence was in 0-10 (2 cases), 51-60 (3 cases) & above 60 years age group (4 cases). This shows the highest prevalence was in middle age group which has highest outdoor activities. Study by Morrison et al also showed the same result.

It was observed that maximum no. of the cases i.e. 64 cases (64%) were observed from urban areas whereas 36 cases (36%) were from rural areas. This suggests that patients living in urban areas have higher incidence than rural areas. In urban areas, stressful and unnatural life-style and use of cosmetic products for beatification of skin and pill popping for day to day ailments is high as compared to rural areas. This makes their skin more susceptible for Photodermatitis.

As seen in the study in the past history, maximum number of cases i.e. 22(22%) had Skin diseases followed by Infectious diseases in 20 i.e. (20%) of cases whereas Respiratory & Endocrine Disorders were reported as Past illnesses in minimum no. of cases i.e. 4 (4 %), respectively. This may be due to influence of Psora which results in low resistance power and high susceptibility for Skin and Infectious diseases.

The maximum incidence of Photodermatitis was observed in Students i.e. 37 cases (37%), followed by Servicemen in 31 cases (31%), Housewives 27 cases (27%), and minimum incidence in Farmers i.e. 3 cases (3%) & Laborer's 2 cases i.e. (2%). It can be assumed that Students & Servicemen are affected more because of stress and unnatural life style.

In maximum no. of patients i.e. 52 (52%) the probable cause was prolonged exposure to sunlight. While 39 cases (39%) were pointed out by the patients due to use of certain allopathic medicines, 5 cases (5%) were due to use of cosmetic creams. In 3 cases the probable cause was due to soaps
and only 1 case reported due to use of homoeopathic medicines. This shows that in majority of patients there is no evident cause. 39 cases showed drug reaction because of lack of advice regarding the avoidance of sun light and inappropriate dosing.

In this study, Sulphur was prescribed in maximum no. of cases i.e. 19 cases (38%), Natrum carbonicum in 10 cases i.e. 20%, Lycopodium clavatum in 8 cases (16%), Antimonium crudum, Graphitis, Phosphorus in 3 cases (6%), Calcarea carbonicum and Sepia in 2 cases (4%) China officinalis, Nux vomica in minimum no. of cases i.e. 1 case each (2%). Sulphur was prescribed in maximum no. of cases and give maximum relief to the patients. It may be due to the fact that Sulphur although given on the basis of totality of symptoms is also an antipsoric remedy for hypersensitivity to the sun rays in the cases of Photodermatitis. The selection of medicines was according to individuality of the patient.

In this study, 30C potency was prescribed in maximum no. of cases i.e. 35 cases (70%), 30C-200C in 10 cases (20%), 200 C in 3 cases (6%). Minimum prescribed potency was 30C-1M and 200C-1M in 1 case (2%) each. According to the study 30C is most commonly indicated potency based on susceptibility of the patients.

In this study, in interventional group 17 cases (34%) were status quo, 14 cases (28%) had shown mild improvement, 10 cases (20%) got moderate improvement, 5 cases (10%) had shown marked improvement, 4 cases (8%) got cured, and one case was dropped out from the study. Whereas, in control arm 34 cases (68%) were status quo, 5 cases (10%) had shown marked improvement, 4 cases (8%) showed mild improvement; 3 cases (6%) got moderate improvement, 3 cases got cured (6%) and 5 cases were dropped out from the study, 1 case (2%) got worse. There is no significant difference in cure rates in interventional arm and control arm according to statistical analysis. But recurrence rates are higher in control group than intervention group as seen after completion of study period.

5. Conclusion

The inference drawn from the study is as follows:

According to the result obtained, there is no significant difference in cure rates in Intervention and Control arm. But there was marked improvement of the symptoms of patients in the Intervention group as compared to the Control group. The reason behind no significant difference in cure results may be due to limitations in objectives of study of not using various antimiasmatic interventions in all the patients as an intercurrent dose based on repertorial totality.

Lippe Repertory proved to be a useful aid in the selection of the similimum in working out the cases of Photodermatitis. This repertory is based on general to particular. Photodermatitis is an allergic disorder and in allergic disorders mental symptoms are important. This repertory is full of mental symptoms which made selection of medicines easier.

Result showed significant improvement according to DLQI scale in Intervention group as compared to the Control group but the results were not statistically significant according to Pt. GAI and Phy. GAI. This may be due to that the patients were confronted with the exciting cause i.e. sunlight on a daily basis and on the other hand Photodermatitis to certain extent be self-limiting disease, got better in few cases of control arm and due to limitation in our objectives, we could not use various antimiasmatic intermittent doses for curing cases of Photodermatitis which a chronic disease is largely.
Though the limited period and self-limited objectives of not assessing miasmatic approach proved a shortcoming but the study proved fruitful in affirming the efficacy of homoeopathic medicines in the cases of Photodermatitis and suggesting certain modalities to improve the efficacy of homoeopathic approach in future studies.

It is concluded with the hope that more extensive studies would be carried out in the near future using antimiasmatic medicines as intercurrent and preferably taking 50 - Millesimal potency as a tool to have gentle (minimum aggravation), rapid as well as permanent cure.

Limitations

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 millesimal scale potencies should be conducted to prospect the effect of higher potencies on Photo dermatitis 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 this respect as well.

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