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Research Article

TOPICAL APPLICATION OF *ELADI TAILA* AND *GHRITAKUMARI* IN PESTICIDE- INDUCED CUTANEOUS TOXICITY

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ABSTRACT

The vast and liberal use of pesticides in agriculture has resulted in occurrence of cutaneous toxicity; produced by the irritating chemical substances, is one of the most noticeable effects of exposure to chemicals, prominently by cutaneous, oral or inhalation routes. Thus arises the need to identify a topical remedy to prevent, reduce or nullify them. Open Randomized Clinical Trial was conducted and selected patients were randomly allotted into two groups, Control and Trial. The control group consisted of 10 patients whereas the trial group was further subdivided into 3 groups of 10 patients each. Thus, the total sample size of the study was 40, calculated on the basis of rate of incidence of the condition.

Patients of the Group A did not receive any trial drug but followed symptomatic treatment as and when required. Patients of Group T1 were made to apply *Ghritakumari* prior to commencement of pesticidal spraying. Patients of Group T2 were not subjected to pre - spraying application of *Ghritakumari* but post- spraying *Eladi taila* was applied after decontamination. Patients of Group T3 were advised to follow both pre and post spraying regimens of groups T1 and T2 and were continued daily upto 2 days after the end of the complete spraying procedure with daily follow up. The primary end point of the present study was achieved and the results were found to be statistically significant.

Key words: Chemical substances, Cutaneous toxicity, *Eladi taila, Ghritakumari*, Pesticides.

INTRODUCTION

The vast and liberal use of pesticides in agriculture has led to excessive exposure to such chemicals, prominently by cutaneous, oral or inhalation routes. About 97% of such exposure occurs especially during spraying of pesticides i. e. through the skin contact leading to local effects such as itching, burning sensation, reddish discolouration and papule formation. The percutaneous absorption is faster and gains access into the blood circulation directly, thus proving to be more fatal in the long run.[1] A cutaneous toxicity produced by these irritating chemical substances is the most noticeable effect of such exposure that gives rise to the need to identify a topical remedy to prevent, reduce or nullify them.

Vagbhatacharya has recommended *Eladi taila* specifically in *Visha,* (poison), *Varnaprasadan* (complexion enhancer), *Kandu* (pruritis/itching), *Pitika* (papule) and *Kotha* (erythema)[2]. Hence its external application may prove to be an effective remedy in the above condition. Similarly, *Ghritakumari* (*Aloe vera*) known for its *Snigdha* (moist) *Guru* (heavy), *Picchila* (slimy) *Guna* and *Sheeta veerya* (cold potency)[3] is also an effective remedy in dermatological conditions. Besides the pulp within the leaf consist of 99% of water along with lignin and saponin[5] which together helps in forming a layer or coat over the skin thereby preventing the direct absorption of pesticide and thus limiting the severity of cutaneous toxicity.

Eladi taila and *Ghritakumari* were identified as two drugs that can be utilized, either singularly or together as local application to alleviate or prevent the cutaneous hazards of pesticide toxicity. It was with this intention that a study to evaluate the efficacy of both *Eladi taila* and *Ghritakumari* in pesticide induced cutaneous toxicity was designed. It was carried out with the objective of identifying an effective Ayurvedic formulation that can be topically applied to prevent pesticide - induced cutaneous toxicity.

A pilot study was conducted to note the possible manifestations resulting from the spraying of pesticide by farmers over a period of 3 to 4 days. In the study, it was noted that among all pesticides, Organophosphates were found abundantly used and farmers spraying such pesticides showed cutaneous toxicity manifestations as all OP pesticides are primarily irritants, produce acute toxicity when they come in contact with skin. This cutaneous toxicity simulates Contact Dermatitis as a spectrum of inflammatory skin reactions arising from direct skin exposure to pesticides. These commonly observed manifestations on skin were noted as the parameters of assessment.

MATERIALS AND METHOD

Eladi taila (Fig 1) and *Ghritakumari* (fig 2) were purchased from Arya Vaidya Sala Kottakkal, Kerala and Bagewadikar Ayurved Rasashala, Solapur respectively. Standardization certificates of the same were obtained prior to commencement of the clinical study. The *Eladi taila* used was as per the reference of *Ashtang Hrudayam.*[2] This Open Randomized Clinical Trial was conducted at agricultural fields in Tal. Haveli Dist. Pune after the permission of the Institutional Ethics Committee (vide letter no: BVDU/COA/1680-2/2012-13- Annexure 1)

Farmers spraying pesticides for 5 to 6 days at a stretch without proper precautionary measures and showing signs of pesticidal cutaneous toxicity in accordance with criteria of assessment irrespective of type of pesticide sprayed were included in the study.

However, those farmers who were not directly subjected to pesticide exposure were excluded.

The selected patients were randomly allotted into two groups, Control and Trial. The control group consisted of 10 patients whereas the trial group was further subdivided into 3 groups of 10 patients each. Thus, the total sample size of the study was 40, calculated on the basis of rate of incidence of the condition.

Informed Consent of each patient was taken prior to their enrollment in the clinical trials. Patients of the Group A did not receive any trial drug but followed symptomatic treatment as and when required. Patients of Group T1 were made to apply *Ghritakumari* prior to commencement of pesticidal spraying. Patients of Group T2 were not subjected to pre -spraying application of *Ghritakumari* but post- spraying *Eladi taila* was applied after decontamination. Patients of Group T3 were advised to follow both pre and post spraying regimens of groups T1 and T2. (Fig 6)

The application of the trial drugs was continued daily upto 2 days after the end of the complete spraying procedure with daily follow up. All applications were lightly rubbed into the skin in a quantity enough to cover the entire exposed areas of the body viz. hands, forearms and feet.

The criteria of assessment on the basis of the pilot study were Itching, Burning sensation, Reddish discolouration and Papule.

Table 1: Parameters with Gradation Score

Symptoms	Parameters of Assessment	Gradation
Itching	No	0
	Mild	1
	Moderate	2
	Severe	3
Burning Sensation	No	0
	Yes	1
Reddish Discolouration	No	0
	Mild	1
	Severe	2
Papule	Absent	0
	Present	1

OBSERVATIONS & RESULTS

Only male farmers were studied in the trials as this procedure is usually carried out by males. 30 % of the Control group, Trial T1, T2 group and 40 % of T3 group were of 27 yrs indicating the prevalence of youth in this occupation.

3 out of the 4 parameters of Assessment viz: Itching, Reddish Discolouration, Burning sensation were observed in all patients whereas the symptom of papule formation was not observed in any of the groups.

Considering the symptom of Itching, 10 patients (100 %) of Control group showed the

symptom, out of which 60 % were of Grade 2, 30 % of Grade 1 and 10 % of Grade 3 on Day 3 respectively which remained the same till the end of study.

In T1 Group, 7 patients (70 %) showed the reduction in symptom Itching from Grade 2 to 0 on D3. 2 patients (20 %) showed reduction from Grade 2 to 1 and1 patient (10%) showed reduction from Grade 3 to 1 on Day 3. On pre - exposure application of *Ghritakumari* the symptom of itching in Trial group was reduced as compared to the Control group.

In T2 Group, 9 patients (90 %) showed reduction in the symptom of itching out of which 30 % showed reduction on Day 3.

In T3 group, in itching 6 patients (60%) showed reduction from Grade 2 to 0, 3 patients (30%) from Grade 1 to 0 and 1 patient (10 %) from Grade 3 to 0 on Day3. (Fig 5)

A similar reduction was found in case of the severity of symptom of Burning sensation (Fig 3) and Reddish discolouration. (Fig 4)

STATISTICAL ANALYSIS

The efficacy of *Ghritakumari, Eladi Taila* separately and together on Itching, Burning sensation, Reddish Discolouration and Papule were studied using the data obtained on daily follow- up of Control group and Trial groups. This was a graded data, so appropriate non-parametric tests were applied. For analysis of efficacy of trial drugs One Sample Proportional Test was used. Similarly for comparison of Control Group with Trial Groups Double Sample Proportion Test was used. It was observed that in some of the cases all observations in all Trial groups were similar. Hence, 'Mann-Whitney test' to compare the control group and Trial groups could not be used. To study the efficacy easily the difference in grades (Control - Trial) was considered and categorized as '0' and '1' indicating 'no relief' (grading more than zero on 3rd day) and 'relief' (grading equal to zero on 3rd day) respectively.

A) ITCHING

1) Efficacy of *Ghritakumari*

The result of proportion test in case of *Ghritakumari* is tabulated below.

Category	Count of 'relief'	Proportion of 'relief'	P-value of the test	Decision
Relief	7	0. 7	0. 172	Accept H_0
No relief	3	0. 3		

Results: The P-value of the test is more than 0. 05, so Ho is accepted and it can be concluded that the proportion of 'relief' is not significantly more than that of 'no relief'. This reflects the efficacy of *'Ghritakumari'* in itching. Thus, efficacy is clinically significant but statistically insignificant in reducing itching.

2) Efficacy of *Eladi Taila*

The result of proportion test in case of *Eladi Taila* is tabulated below.

Category	Count of 'relief'	Proportion of 'relief'	P-value of the test	Decision
Relief	9	0. 9	0. 011	Reject H_0
No relief	1	0. 1		

Results: The P-value of the test is less than 0. 05, so H_0 is rejected it can be concluded that, the proportion of 'relief' is significantly more than that of 'no relief'. This reflects the efficacy of '*Eladi Taila*' in itching as clinically and statistically significant.

3) Efficacy of *Ghritakumari* and *Eladi Taila* together

The result of proportion test in case of *Ghritakumari* and *Eladi Taila* tabulated below.

Category	Count of 'relief'	Proportion of 'relief'	P-value of the test	Decision
Relief	10	1. 0	0. 001	Reject H_0
No relief	0	0. 0		

Results: The P-value of the test is less than 0. 05, so H_0 is rejected and it can be concluded that, the proportion of 'relief' is significantly more than that of 'no relief'. This reflects the efficacy of '*Ghritakumari* and *Eladi Taila*' as pre and post exposure application respectively in itching. Thus, their efficacy is clinically and statistically significant in reducing itching.

Similar statistical analysis of the other symptoms was also done and it was noted that the efficacy of '*Ghritakumari*' and '*Eladi Taila*' as pre and post exposure application respectively was clinically and statistically significant in reducing burning sensation and reddish discoloration.

DISCUSSION

The dual use of these trial drugs as pre and post spraying application was designed to prevent and treat pesticide induced cutaneous toxicity so as to study the efficacy of Trial Drugs singularly and as a combination. During the observation of patients in the pilot study, it was observed that farmers did not follow any precautionary measures to prevent pesticidal exposure eg. Wearing goggles to protect eyes, covering face and nose with a clean cloth, boot to protect feet. The stratum corneum layer of the epidermis mainly acts as a barrier of the skin. In Contact Irritant Dermatitis, the irritants attack this Stratum Corneum, a easily crossing over and leading to the activation of an inflammatory cascade with the help of Antigen presenting cells viz. cells of Langerhans present in skin, ultimately resulting in dermatitis. In the present study it may be noted that cutaneous toxicity mimics the symptoms of contact dermatitis when compared to commonly observed symptoms in Pilot study, where the contact is with extrinsic factor viz. Pesticides. The result of Trial drugs *Ghritakumari (Aloe vera)* and *Eladi Taila* in pesticide induced cutaneous toxicity is because of *Twachya (skin promoting), Sheeta veeryatmaka*[3] and physical antidote-demulscent[4] action of *Ghritakumari* and *Kandughna* (anti pruritic), *Vishaghna* (anti toxic) properties of *Eladi Taila*.[3] The local cooling effect of both the drugs can be attributed to their *Sheeta Veerya*.

CONCLUSION

From the study it can be concluded that the combined use of *Ghritakumari* and *Eladi Taila* offers optimum preventive and curative topical treatment in pesticide -induced cutaneous toxicity and can hence be promoted for regular application in the field of agriculture. (Fig 7)

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STUDY PHOTOGRAPHS

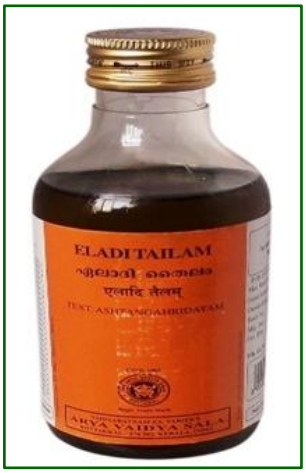

Figure 1: ***Eladi taila***

Figure 2: ***Ghritakumari***

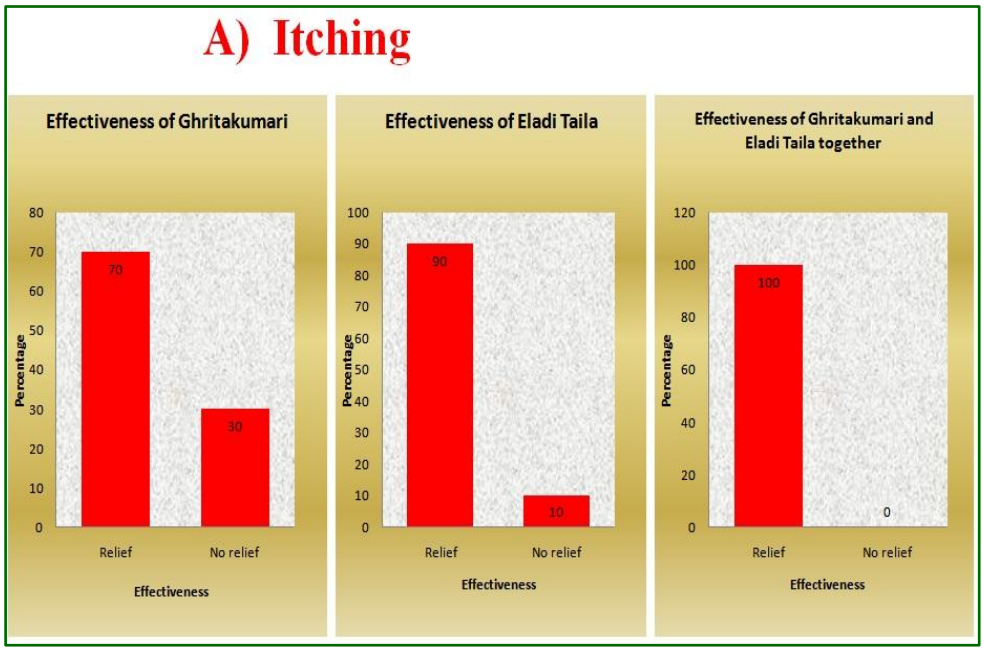

Figure 5: Effectiveness on Itching

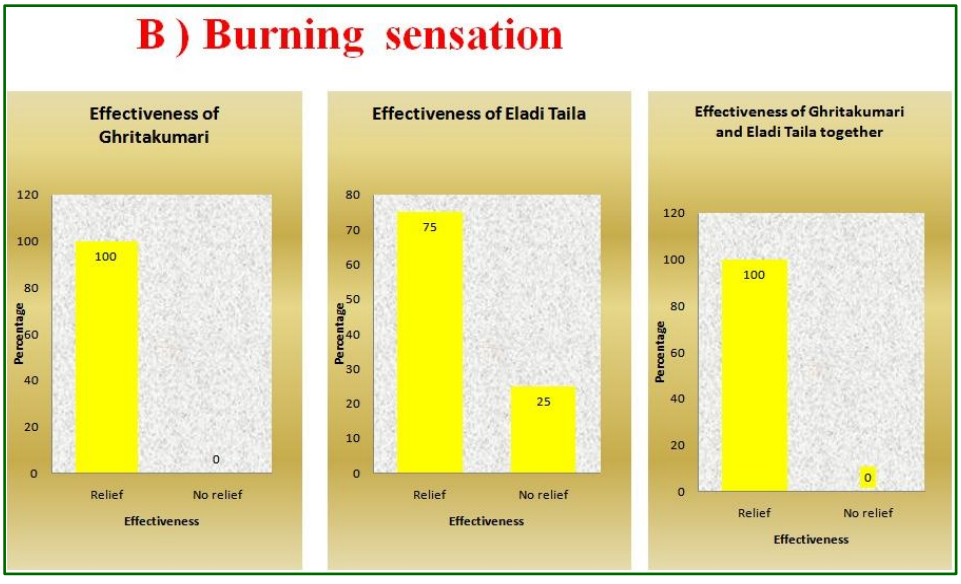

Figure 3: Effectiveness on Burning sensation

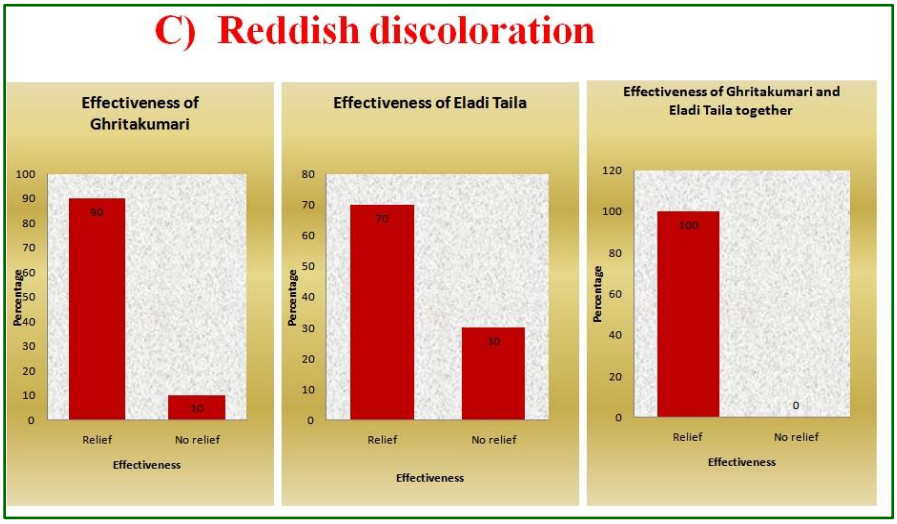

Figure 4: Effectiveness on Reddish discolouration

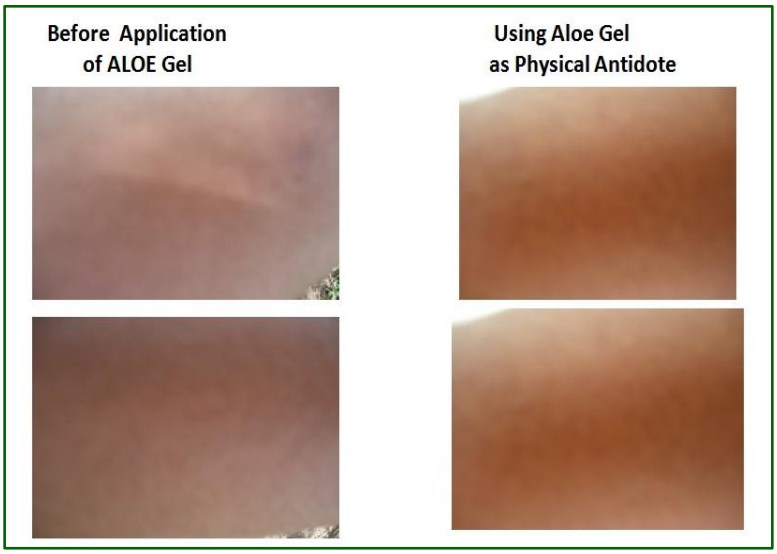

Figure 6: Patients of before and after treatment

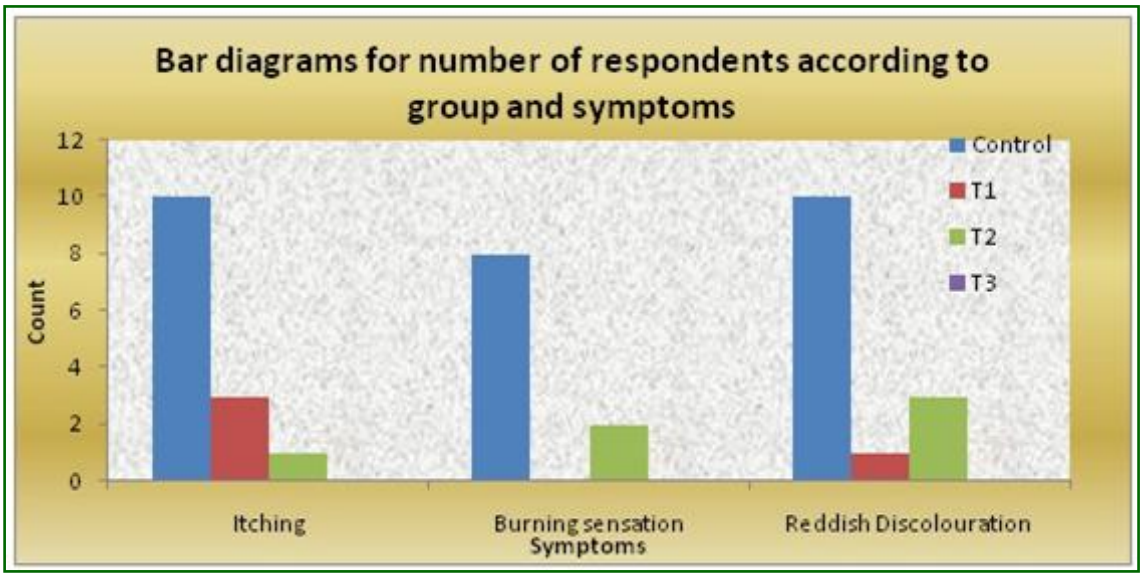

Figure 7: Symptoms responding with treatment in Control and Trial