

EVALUATION OF THE EFFICACY OF A SAVARNAKARAKA DRUG USED IN POST-OPERATIVE PROCEDURES OF VRANA TREATMENT

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According to Ayurveda health is not merely considered to be a state of freedom from ailments or disease, but rather a state of enjoying uninterrupted physical, mental and spiritual happiness and fulfillment. Physical attraction is an asset to be a cynosure in society. In physical attraction, the texture of the skin is of utmost importance. Cosmetic disfigurement, caused by any discolouration of the skin, has great impact on the psychological, social and professional relationship of the affected individual, especially when the lesions are present on the face and exposed parts of the body. In many occasions physicians are either unsympathetic or discouraging about a patient's problem of this type.

Dark colouration of the skin surface is termed as krsnatwa, which occurs generally as a symptom of many diseases. The most commonly occurring cosmetic problem is the rudimentary hyperpigmentation of the healed ulcers.

If there is a drug to correct hyperpigmentation with cost effective values and with easy availability it can be used in this occasion.

The incision made by the surgeon may be unavoidable in the process of surgery to cure the patient. But it is a disgrace if a surgeon neglects the wound after an operation. Susruta, father of surgery has clearly mentioned that removal or minimizing the scar is an essential task of the surgeon. According to the Ayurvedic definition if there is a scar the healing is not completed. Therefore Susruta mentions so many medicinal preparations to remove the deformities of the wound including scars.

In ancient times they treated these types of cases successfully. It is evident from 1st chapter of Chikitsa Stana of Susruta Samhita.

MATERIALS AND METHODS

Clinical study was planned utilizing the following materials and methods.

Population studied

The selection of patients was made from amongst the patients attending to the surgery clinic of out patient department of the Ayurvedic teaching hospital, Colombo 8 and from the volunteers who were willingly participated in this study.

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The persons having hyperpigmented scar were selected for the study. Hyperpigmented spots, which occur not due to wounds or ulcers and malignancies, were excluded from the study.

Sampling Technique

The patients fulfilling the criteria were registered for the study irrespective of their age, sex, occupation etc; Simple random sampling technique was adopted for grouping the patients into two groups.

Criteria for the diagnosis

On the basis of the proforma the detailed clinical assessment was recorded by observation, history taking and physical examination.

To get the accurate account of the condition of the disease, the presenting complaints, history of present illness, previous history of illness, treatment history, family history, social history and occupational history etc. were specially taken into the consideration. In addition to that Ayurveda and modern parameters were utilized to evaluate the nature of the scar.

Criteria for clinical assessment

In this research study the main criteria of assessment was krsnata of the scar (the darkness of the colour of the scar comparative to surrounding healthy skin). Clinical assessment of the patients was recorded adopting two methods.

(a) Subjective criteria

The subjective criteria included the signs and symptoms on Ayurvedic diagnosis.

(b) Objective criteria

Photography and computer technology was introduced for the sound statistical analysis and to present the colour change objectively. The entire clinical study was carried out with the use of the prescribed drug, without any diet or behavioral restrictions.

grouping of the patients

To find out the optimum result of the therapy and to avoid the possible errors the control study was planned. The patients fulfilling the criteria of the study were divided into two groups.

Group I - This group of patients were subjected to the external application. Total number of cases 20 completed the course of treatment.

Group II - This group received no medicine at all and considered as control group. Total 15 patients were studied in this group.

Drug administration

The used research drug named 'Savarnikarana Lepa' has been mentioned in 1st chapter of Susruta Samhita cikitsa stana. That pralepa (paste) was prepared according to the formula.

The drugs consisting of this formula are :-

1. Newly made earthen ware
2. Embul vewel (Calamus rotang)
3. Hal dummala
4. Kasisa
5. Vel mi (Glycyrrhiza glabra)
6. Bee honey

Savarnikarana Lepa was applied in a thin layer over the scar, which was previously cleaned with warm water once a day and covered with a gauze piece and kept 12 hours. Total duration of the treatment was limited to one month.

Follow up study

All the patients were asked to attend Shalya O.P.D. monthly in follow up period. This follow up period was carried out for three months duration in each patient.

ASSESSMENT

The effects of treatment were assessed through the clinical observation and with the help of computer technology.

The method of scoring

It is difficult to measure the colour of the scar with normal measurements adopting generally. Therefore an especial method was used for evaluating scar blackness effectively. According to the colour definitions employed in computer graphics, each colour can be expressed as red green or blue (RGB) coordinates.

Photographs of the scars of treated patients were taken before the treatment and after the treatment. After subjected to scanning those pictures were put into the computer and RGB values were taken. RGB values of the scar and of the surrounding skin area were taken separately.

The degree of scar krsnata was defined by the following formula.

Krsnata score = $(R_0 - R_1) + (G_0 - G_1) + (B_0 - B_1)$
 R_1, G_1, B_1 represent the scar colour and R_0, G_0, B_0 represent the surrounding skin colour.

In this method the selected points subjected to find out RGB values with the help of computer. To enhance the accuracy of the colour difference 10 points within the scar and 10 points of the surrounding skin were selected and studied. Finally, the difference of colour change, before and after treatment were calculated.

Observation and results

All these results and observations were recorded under two main groups separately i.e. control and treated and the same time and whenever needed the statistical analysis also included along with the results and observations. The main statistical analysis based on paired t test and unpaired t test. The final results were put forward with the help of unpaired t test.

EFFECT OF THE TREATMENT ON HYPERPIGMENTATION

Effect of the treatment of this study was calculated using statistical analysis as follows. The results obtained from this study have been taken with the help of computer graphics by using RGB colour definitions. Through those the colour of the scar could be expressed as a krsnata score. Getting down the krsnata score shows the improvement of the therapy.

The significance of difference before and after treatment for the change of scar colour has been tested applying paired t test. The formula used is as below.

$$t = \frac{x \sqrt{n}}{SD}$$

- x = mean of the difference before and after treatment of krsnata score
- SD = standard deviation of the difference
- n = sample size

Further probability test has been applied to see the association of the drug upon the improvement observed. To get the real and accurate picture of the result the statistical analysis has been done by using unpaired t test. The formula used as below.

$$t = \frac{\text{Mean (group 1)} - \text{mean (group 2)}}{\sqrt{SE^2 (\text{group 1}) + SE^2 (\text{group 2})}}$$

SE = Standard error

Table 01

**OVERALL IMPROVEMENT OBSERVED
AMONG PATIENTS**

group	number	mean	SD	t	p	%
Treated	20	146.85	72.70	9.03	< 0.001	64.01
control	15	53.86	26.31	7.92	< 0.001	24.60

Unpaired t test

P values : treated Vs control < 0.001

The difference of mean score between before and after treatment in the treated group was 146.85 and the percentage of relief observed 64.1%, has been shown statistically indicating highly significant results at the level of $p < 0.001$.

24.6% relief was observed in control group and that also was statistically highly significant ($p < 0.001$) according to paired t test. The difference of mean score was 53.86. (Table 01)

Finally in the unpaired t test it is shown that the improvement of treated group was statistically highly significant against the controlled group at the level of $p < 0.001$.

Table 02

**IMPROVEMENT OBSERVED AMONG PATIENTS
ACCORDING TO THE AGE**

age	Group	n	Mean	SD	T	P	%
5 - 15	Treated	6	114.50	38.85	7.21	< 0.001	68.76
	Control	5	44.60	21.37	4.66	< 0.01	23.30
16 - 25	Treated	8	198.50	81.50	6.38	< 0.001	64.94
	Control	10	58.50	28.32	6.53	< 0.001	25.23
26 - 35	Treated	4	86.25	-	-	-	49.14
	Control	-	-	-	-	-	-
36 - 45	Treated	2	158.50	-	-	-	71.71
	Control	-	-	-	-	-	-

Unpaired t test

P values : Age 5 - 15 treated Vs control < 0.01

Age 16 - 25 treated Vs control < 0.001

Age 5 - 15 treated Vs age 16 - 25 treated < 0.05

Incidence of age of the patients has been studied in this work. The response of the treated and controlled cases is statistically analyzed and results are shown in table 02.

According to paired t test 5 - 15 years treated group has shown statistically highly significant results at the level of $p < 0.001$ where as the controlled group of the same age has shown significant results at the level of $p < 0.01$

Further both treated and controlled groups in 16 - 25 years age group has shown statistically highly significant results at the level of $p < 0.001$.

Finally unpaired t test, which exhibits the actual improvement of the drug, gives statistically significant results at the level of $p < 0.01$ in the 5 - 15 years treated group against the controlled group of same age.

Further the improvement of 16 - 25 years treated group against the same age controlled group gives statistically highly significant results at the level of $p < 0.001$.

The improvement of 5 - 15 years treated group against 16 - 25 years treated group gives statistically significant results at the level of $p < 0.05$.

The cases belong to age groups of 26 - 35 years and 36 - 45 years were not uniform and a sufficient number of cases was not available in either group. Hence statistical analysis of those results was not possible.

Discussion

Effects of the treatment on hyperpigmentation

The reduction of colour was shown in both treated and controlled groups and that improvement was statistically highly significant according to paired t test. It is obvious that paired t test is not suitable to know the actual and significant effect of the drug.

But unpaired t test has revealed the effectiveness of the drug having highly significant results in the treated group against the controlled group.

It is a known fact that some sort of reduction of pigmentation appears physiologically. But it improves very slowly and takes months or even years. Owing to that improvement paired t test has shown a highly significant

result in controlled group also. Though the result given by unpaired t test has proved the fact that the improvement of the treated group is higher than that of the controlled group significantly. In other words the trial treatment has its own effect on the treated cases in addition to the physiological effect. Hence it can be said that the trial treatment has effect on making depigmentation on hyperpigmented areas.

The variances of the drug effect on other changes has also been considered. According to age also this improvement was taken into consideration. Table 02 shows that the improvement in 16 – 25 years treated group against 5 – 15 years treated group has indicated statistically significant results. From these results it is clear that the drug is more effective in 16 – 25 years age group. In this age pitta dosa is taking predominance. The drug also consists of more pitta samana qualities. Hence it can be suggested as a reason for

that result. If a sufficient number of cases were presented in 26 – 35 years and 36 – 45 years age group it would be more beneficial to consolidate that suggestion.

According to the previous findings of various results and observations it can be clearly showed that the effect of the trial drug when compared to the controlled group is much more significant. With all these discussions finally it can be concluded that the research drug of this study has shown statistically highly significant effect over the reduction of hyperpigmented scar. Further it also was confirmed that drug is more effective in younger group of people.

Another important finding of the research work was zero percent complication occurred during the research work period. It is clear that the trial drug does not having any adverse effect or side effect or complication. Hence it is a totally safe drug.

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