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EVALUATION OF VRANAROPANA PROPERTY OF JATYADI GHRITA AND KARPOORA GHRITA IN THE MANAGEMENT OF SADYO VRANA- A RANDOMISED COMPARATIVE CLINICAL STUDY

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ABSTRACT

An injury is the adverse effect of a physical force upon a person. The force involved in most injuries is mechanical. The incidence of wound trauma is very large globally. The number of patients with wounds presenting to the emergency department and to the general practitioners is more as compared to any other health problem. Occasionally, the patients with minor and superficial injuries turn into major complications. Complicated wounds are the major cause of absentees at the working places and hospitalizations The major aspect of the management of the fresh wound is prevention of the infection and speedy healing and Reducing pain. The present study is planned to evaluate the varana ropana property of Karpoor Ghrita & Jatyadi Ghrita in Sadyo vrana.

Methods: The effect of Jatyadi Ghrita and Karpoora ghrita was studied on 30 patients of Sadyo Vrana on the basis of relief obtained on subjective and objective parameters and assessing the result applying paired t-test & percentage of relief on the signs and symptoms of Sadyo Vrana. Duration of the Study was 7 days. Patient were followed up every day till 7 days and their improvement was assessed on 3rd, 5th and 7th day of treatment.

Results: both the Trial drug Karpoora Ghrita and Standard drug Jatyadi ghrita is effective in reducing pain, swelling, discharge, size of the wound and improving granulation tissue

Conclusion: Controlled drug Jatyadi ghrita is an established treatment for wound healing, hence when

we compared it with Trial drug Karpoor ghrita we found no difference in the results of both the drug, which shows that Trial drug is as effective as Jatyadi ghrita in the Management of Sadyovrana.

Keywords: Sadyo Vrana, Traumatic wound, Jatyadi ghrita, Karpoora Ghrita,

INTRODUCTION-

Throughout the history man has had to contend with dermal wounds. In primitive societies, substances derived from animals, plants and minerals formed the basis of crude remedies [1] needed to staunch bleeding, reduce swelling, minimize pain, remove damaged tissue, treat infections, mask foul smells and promote healing. The earliest documented records of topical wound treatments were found in Mesopotamia; these inscriptions on clay tablets have been dated to approximately 2500 BCE. The development and dissemination of later wound treatments can be traced from the ancient Egyptians, via the Greeks to Roman medicine [1], but the history of progress in wound care during the Middle Ages to the present time is incomplete [2].

Healing is a systematic process, traditionally explained in terms of three classic phases' viz. inflammation, proliferation, and maturation [3]. A clot forms and inflammatory cells debride injured tissue during the inflammatory phase. Epithelialisation, fibroplasia, and angiogenesis occur during the proliferative phase. Meanwhile, granulation tissue forms and the wound begin to contract. Finally, during the maturation phase, collagen forms tight cross-links to other collagen and with protein molecules, increasing the tensile strength of the scar.

A large share of economy is spent annually, for the prevention of complications and management of the wounded patients.

The major aspect of the management of the fresh wound is prevention of the infection and speedy healing. Reducing pain, discharge and less discoloration after healing are the other important factors. The proper initial care of the fresh wound will definitely prevent the inadvertent use of the oral and systemic antibiotics.

Antimicrobials showing sensitivity to some organisms. Same is happening with the topical applications. Since then the never ending efforts started for newer and newer antimicrobial agents. Many types of antimicrobial agents were searched and used successfully but the success was only transient. The problem remained the same and many generations of antibiotics have failed to provide long lasting antimicrobial effect. The organism kept adapting to the new antimicrobial and evolutes as multi-resistant strains

Now the scenario is changing and the whole world is looking towards the traditional and herbal medicine for the management of infection. The most frequently used topical antimicrobials in modern wound care practice include iodine [4] and silver [5] containing products. In the past, acetic acid,

chlorhexidine, honey, hydrogen peroxide, sodium hypochlorite, potassium permanganate and proflavine have been used. Some of these products seem to be making a return and other alternatives are being investigated

Sushruta, as we know, is the Father of Surgery. In his text Sushruta Samhita, "Shashti Upakramas" are described for the treatment of the wound (Vrana) [6]. It has been also described in the chapter of fresh wounds (Sadyo-vrana)[7] . Charaka, the great physician of ancient Indian medical science has also described the surgery related portion in brief. He has described 36 types of management of Vrana as 36 Upkramas.[8]

Achaya Sushruta, BhavPrakash, Yogratnakar, Charak and Sharangdhar have described different remedies of Taila preparations having vranashodhana and vranaropana properties. The present study is planned to evaluate the varana ropana property of Karpoor Ghrita [9] & Jatyadi Ghrita [10] in Sadyo vrana.

AIMS AND OBJECTIVE-

1. To explore the subject with special reference to Vrana Ropana both in Ayurveda and Modern literature
2. To compare the efficacy of Karpoor ghrita and Jatyadi Ghrita in the Management of Sadyovrana
3. To decide factors influencing the wound healing.

MATERIALS AND METHODS-

Total 30 patients of Sadyovrana were selected from OPD/IPD of department of Shalya Tantra, PLRD Hospital, Khurja.these 30 patients were randomly divided in to 2 groups, i.e.Trial Group and Control group. Each group consisting of 15 patients on the basis of inclusive and exclusive criteria.

Selection of Drug:-

Trial Group- 15 patients of Sadyovrana were treated with Karpoor Ghrita Local application.

Control Group:- 15 patients of Sadyovrana were treated with Jatyadi Ghrita Local application

Selection criteria of the Patients

Inclusive Criteria

1. Patients between 16-60 years of age irrespective to their sex
2. Patients having only Shuddha Kshata Vrana (fresh Traumatic wounds) were included.
3. Patients with clinical features of Sadyo vrana like Vadana, Varna, Shotha and Srava were selected.

Exclusion criteria:

1. Patient below 16 and above 60 years of age
2. Dushta Vrana (infected/pus discharging traumatic wounds)

3. Wound size greater than 6 X 8 cm at any site.
4. Chinna (part totally separated), Bhinna (perforation of cavity),Viddha (perforation of body parts) and picchita (crushed including bone marrow) type of vrana
5. Punctured, Stab wound.
6. Wound with systemic involvement and morbid changes.
7. Wound with Visceral , Bony and Spinal injuries.
8. Diabetes mellitus (DM), Tuberculosis.

Type of Study:- It is a Single Blind Randomized Controlled Clinical Trial

Duration of Study:- 7 days.

Follow Up:- 3rd day. 5th day and 7th day.

Investigation and Interventions:-

Investigation:

- RBS, HIV, HbsAg.
- Mantoux test (if necessary)
- ESR
- Pus Culture (If necessary)
- Wound Biopsy (If necessary)

Intervention:

- Application of the Karpoor Ghrita Once daily.
- Application of Jatyadi Ghrita Once daily.

The method of Ghrita Application:

The Vrana (wound) was cleaned with normal saline, later prepared Ghrita applied over the wound followed with bandaging.

Time of dressing: Once daily, except if the bandage was wet completely within 24 hours.

Dose- local application depends on size of wound.

The data for assessment was collected in 3rd, 5th & 7th day.

Assessment Criteria:-

The patients were assessed on the basis of subjective and objective parameters before and after treatment.

Subjective Parameters:-

1. Vedana (Pain On Visual Analogue Scale- vas
2. Varna (change In Colour)
3. Srava (Discharge)
4. Shotha (Swelling of the surrounding area)

Objective Parameters:-

1. Parimana (Size of wound)

2. Unit healing time

Gradation Of Parameters:

Pain on VAS- As the suffer himself expressed the pain in his own terms, so this was graded, starting from mild to severe at par with the VAS.

- G0 – 0 -Absence of pain/no pain.
- G1 – 1 to 3 mark on scale - Mild – Pain that can easily be ignored.
- G2 – 4 to 6 mark on scale - Moderate – pain that cannot be ignored, interferes with function, and needs treatment from time to time.
- G3 – 7 to 10 marks on scale - Severe – That is present most of the time demanding constant attention.

Varna:-

- G0 – Twak savarna. – healed wound/equivalent to skin colour.
- G1 – Kapota varna (gray)-healing wound/equivalent to brownish-white.
- G2 – Shwetarakta-Cleaned wound/equivalent to reddish-white.
- G3 – Krishana-Contaminated with dust or soiled wound/equivalent to congested reddish-black.

Sraava:-

- G0 – No discharge
- G1 – If vrana wets 1 pad of4x4 cm gauze piece (mild)
- G2– If vrana wets 2 pads of 4x4 cm gauze piece (moderate)
- G3 – If vrana wets more than 2 pads of 4x 4 cm gauze piece (Profuse)

Swelling of the surrounding area:-

- G0 – Absent
- G1 - Slight swelling around the wound margin without indurations.
- G2 - Swelling around wound margin with little area of indurations.
- G3 - Swelling with marked indurations.

Parimana (size of wound):-

The size was directly recorded. The sterile blotting paper was placed over the wound and pressed with uniform pressure. The impression was directly measured. The depth was directly measured with the help of a sterile probe.

- G0 - 0 to 1 cm2
- G1 –Within 1.1- 4 cm2
- G2 – Within 4.1-9 cm2
- G3 –Within 9.1-16 cm2 or more

Unit healing time (cm2 / day) = Initial surface area of wound – surface area of wound after 7 days of treatment / duration of study (7 days) = surface area healed in sq cm / no of days.

ASSESSMENT OF RESULT: -

For the purpose of the assessment of result some grade points were used considering the severity of different sign and symptoms as follows.

Observations

Table No.1- Showing Incidence of age in the study

AGE (in year)	Trial Group	Control group	Total	percentage
16-30	11	9	20	66.66
31-40	2	3	5	16.66
41-50	2	3	5	16.66
51-60	0	0	0	0

Table No. 2 – showing Incidence of sex in the study

Sex	Trial Group	Control group	Total	percentage
Male	9	10	19	63.33
Female	6	5	11	36.66

Table no. 3- showing Incidence of Chief complaints in the study

Chief complaint	**Trial Group**	**Control Group**	**Total**	**%**
Pain	15	15	30	100
Bleeding	15	15	30	100
Swelling	15	15	30	100

Table no. 4 – showing incidence of Associate Complaints

	Trial Group	**Control Group**	**Total**	**%**
Associate COmplaints				
Burning	15	15	30	100
Woozing	15	15	30	100
Discharge	15	15	30	100

Table No. 5- Showing incidence of intensity of Pain

Intensity of Pain	Trial Group	Control Group	total	Percentage
Severe	9	7	16	53.33
Moderate	5	8	13	43.33
mild	1	0	1	3.33

Table no. 6- Showing Incidence of type of pain

Type of Pain	Trial Group	Control Group	Total	%
Burning	6	8	14	46.66
Cutting	8	6	14	46.6
Pricking	1	1	1	3.33

Table no. 7- Showing incidence of type of discharge

Type of Discharge	**Trial Group**	**Control Group**	**Total**	**%**
Bleeding	12	11	23	76.66
Serous	3	4	7	23.33

Table no. 8- showing incidence of site in the study

Incidence of Site	**Trial Group**	**Control Group**	**Total**	**%**
RUL	4	3	7	23.33
LUL	2	1	3	10
RLL	5	4	9	30
LLL	2	3	5	16.66
HNF	1	2	3	10
T	1	2	3	10

Table no. 9- Showing incidence of tissue involved

Tissue Involved	**Trial Group**	**Control Group**	**Total**	**%**
Twak	9	11	20	66.66
Mamsa	6	4	10	33.33

Table no. 10- Showing Incidence of Dimensions of wound in the study

Dimensions in sq cm	**Trial Group**	**Control Group**	**Total**	**%**
4.1cm-8cm	11	9	20	66.66
8.1cm-12cm	2	4	6	20
12.1cm-16cm	2	2	4	13.33

RESULTS-

Table No. 11 - Showing Results on Pain before and after treatment in both Groups

Pain		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Trial Group	BT	2.53	3.00	0.64	0.17	-3.477[b]	0.0005067	81.58	Sig
	AT	0.47	0.00	0.52	0.13				
Control Group	BT	2.47	2.00	0.52	0.13	-3.571[b]	0.0003551	81.08	Sig
	AT	0.47	0.00	0.52	0.13				

Table no. 12- Showing results on pain in follow up study

Pain	Mean		SD		% Effect	
	Trial Group	Control Group	Trial Group	Control Group	Trial Group	Control Group
BT	2.53	2.47	0.64	0.52	-	-
Day 3	2.33	2.33	0.62	0.49	7.89	5.41
Day 5	1.20	1.27	0.41	0.46	52.63	48.65
Day 7	0.47	0.47	0.52	0.52	81.58	81.08

Table no. 13- showing results on Swelling before and after treatment in both groups

Swelling		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Trial Group	BT	1.73	2.00	0.46	0.12	-3.542[b]	0.0003964	76.92	Sig
	AT	0.40	0.00	0.51	0.13				
Control Group	BT	1.67	2.00	0.49	0.13	-3.542[b]	0.0003964	80.00	Sig
	AT	0.33	0.00	0.49	0.13				

Table no. 14- showing results of medicine on swelling in follow up

Swelling	Mean		SD		% Effect	
	Trial Group	Control Group	Trial Group	Control Group	Trial Group	Control Group
BT	1.73	1.67	0.46	0.49	-	-
Day 3	1.53	1.60	0.52	0.51	11.54	4.00
Day 5	0.80	0.93	0.41	0.46	53.85	44.00
Day 7	0.40	0.33	0.51	0.49	76.92	80.00

Table no. 15- Showing results on colour before and after the treatment in both groups

Color		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Trial Group	BT	2.73	3.00	0.46	0.12	-3.508[b]	0.0004511	82.93	Sig
	AT	0.47	0.00	0.52	0.13				
Control Group	BT	2.67	3.00	0.49	0.13	-3.464[b]	0.0005320	80.00	Sig
	AT	0.53	1.00	0.52	0.13				

Table no. 16- showing results of medicine on colour in follow up

Color	Mean		SD		% Effect	
	Trial Group	Control Group	Trial Group	Control Group	Trial Group	Control Group
BT	2.73	2.67	0.46	0.49	-	-
Day 3	2.60	2.60	0.51	0.51	4.88	2.50
Day 5	1.27	1.27	0.46	0.46	53.66	52.50
Day 7	0.47	0.53	0.52	0.52	82.93	80.00

Table no. 17- showing results on discharge from wound before and after treatment in both groups

Discharge		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Trial Group	BT	2.53	3.00	0.52	0.13	-3.690[b]	0.0002241	84.21	Sig
	AT	0.40	0.00	0.51	0.13				
Control Group	BT	2.53	3.00	0.52	0.13	-3.477[b]	0.0005067	81.58	Sig
	AT	0.47	0.00	0.52	0.13				

Table no. 18- showing results on discharge in follow up

Discharge	Mean		SD		% Effect	
	Trial Group	Control Group	Trial Group	Control Group	Trial Group	Control Group
BT	2.53	2.53	0.52	0.52	-	-
Day 3	2.33	2.40	0.49	0.51	7.89	5.26
Day 5	1.20	1.33	0.41	0.49	52.63	47.37
Day 7	0.40	0.47	0.51	0.52	84.21	81.58

Table n0. 19- Showing Comparison between Trial Trial Group and Control Group.

Variable	Group	N	Iean Rank	ım of Ranks	Mann-Whitney U	P-Value
Pain	Trial Group	15	15.93	239.00	106.000	0.753
	Control Group	15	15.07	226.00		
	Total	30				
Swelling	Trial Group	15	15.50	232.50	112.500	1.000
	Control Group	15	15.50	232.50		
	Total	30				
Colour	Trial Group	15	16.17	242.50	102.500	0.645
	Control Group	15	14.83	222.50		
	Total	30				
Discharge	Trial Group	15	15.80	237.00	108.000	0.817
	Control Group	15	15.20	228.00		
	Total	30				

Table no. 20- showing results of medicine on would size in both groups

Wound Size		Mean	N	SD	SE	t-Value	P-Value	% Change	Result
Trial Group	BT	8.15	15	3.28	0.85	10.776	0.00000004	89.78	Sig
	AT	0.83	15	0.94	0.24				
Control Group	BT	8.60	15	2.63	0.68	11.701	0.00000001	93.26	Sig
	AT	0.58	15	0.86	0.22				

Table no. 21- Showing Results of medicine on Healing Index in both groups

Variable	Group	N	Mean	SD	SE	t-Value	P-Value	Result
Wound Size	Trial Group	15	7.32	2.63	0.68	-0.725	0.474	NS
	Control Group	15	8.02	2.65	0.69			
Healing Index	Trial Group	15	104.57	37.58	9.70	-0.725	0.474	NS
	Control Group	15	114.57	37.92	9.79			

Table no. 22- showing overall results of treatment in both groups

Overall Effect	Trial Group		Control Group	
	N	%	N	%
Marked Improvement	12	80.00%	12	80.00%
Moderate Improvement	3	20.00%	3	20.00%
Mild Improvement	0	0.00%	0	0.00%
No Change	0	0.00%	0	0.00%
TOTAL	15	100.00%	15	100.00%

DISCUSSION-

Proper wound management has been one of the most challenging problems facing a surgeon in day today practice. Proper wound care depends upon ability to enable and aid nature to carry out the sequential step in wound healing.

The present study entitled “Randomised Clinical Comparative study on evaluation of Vranaropana Property of Karpoor Ghrita and jatyadi Ghrita in Sadyovrana” was carried out on 30 wounded patients irrespective of age & sex and having no other systemic pathology. The clinical study was targeted to evaluate the action of Karpoor Ghrita with an aim to minimize the wound surface, reduce discharge, and promote epithelialization and granulation tissue and to avoid hypertrophic scar formation.

All the cases having history of Trauma with lacerated wound and the wounds cannot be healed by first intension were registered with proper data and records. To present the study in a scientific manner, all the data were screened and statistically evaluated.

Discussions on demographic data

The study revealed that a prevalence of incidence was observed more within the age group of 16-30 years and the male, female ratio was19:11 with an average of 2:1. This observation suggests that the occurrence of wound is more in adult age group and male, when compared to female. Because males are doing work outside the home under stress & tension. Hence males are more prone to get wound by external trauma during their routine journey and the type of work they involved. As females are working inside the home, chances of getting wound is less.

Regarding the incidence of religion 76.66% of patients were Hindu, which signifies in present study the Hindus are more prone for traumatic wound, but according to hypothesis no such prevalence was evidenced. This may be due to multiphase random sampling.

In the present series of observations of occupational status, maximum patients were found as students, office workers and businessmen followed by labor and housewife's. This type of incidence was reported because of injuries and exposure to unhygienic situations are more in this group.

Other incidental study like marital status, socio economic status and habitat were also observed. Where more patients were seen in married group (66.66%), upper middle class (36.66%) and Urban (53.33%) people were found more sufferers. Here life style and personal habits may play important role in progress of this condition.

While observing the site and tissue involved, it was found that limbs were more involved rather than torso and 66.66% wounds were within skin limit. Regarding dimension 66.66% of wounds were within 4.1-8 cm2, 20% within 8.1-12 cm2 and only 13.33% were above 12cm2 .It indicates that all the wounds were of grade I type with considerable amount of tissue destruction.

DISCUSSIONS ON RESULTS

During cleaning and dressing of wound, it was noticed in the groups that on first day almost all the wounds were having varying degree of pain, swelling and discharge. On the 3rd day of dressing, Pain was reduced to 7.89% in Trial Group and 5.41 % in control Group, Swelling Was reduced to 11.54% in Trial Group and 4 % in Control group. In case of Discoloration, 4.88% reduction was seen in Trial group and 2.50 % in control group. In case of discharge, 7.81 % relief was seen in Trial group and 5.26 % relief was seen in control group

On the 5th day of dressing Pain was reduced to 52.63 % in Trial Group and 48.65 % in control group. Swelling was reduced to 53.85 % in Trial group and 44 % in control group. Discoloration was reduced to 53.66 % in Trial group and 52.50 % in control group. Discharge was reduced to 52.63% in

Trial group and 47.37 % in control group.. There was similar kind of recovery was seen in both the groups which shows that Karpoor ghrita is as effective as jatyadi ghrita in the management of Sadyovrana.

Out of this study the statistical analysis as a whole signifies that the Trial drug is effective in reducing pain, swelling, discharge, size of the wound and improving granulation tissue. The Trial drug that is Karpoor Ghrita was effective 81.58% on pain, 76.92% on swelling, 82.93% on colour, 84.21% on discharge and 89.78% on size of the wound, Whereas on control group i.e application of Jatyadi Ghrita was effective 81.08% on pain, 80% on swelling, 80 % on colour, 81.58% on discharge and 93.26% on size of wound. Both the Trial and control group has showed significant results in all the parameters of wound. But when we compare it there is no any significant difference in the efficacy. Hence both the drugs are equally effective in wound management.

Regarding the unit healing time, it was calculated by the difference of initial surface area of wound and surface area of wound after 7 days of treatment. To get the healing index, the surface area healed in cm2/day was measured. The mean healing index was 0.99cm2/day in Trial Group and 1.09 cm2/day in control group. It can be observed that, controlled drug Jatyadi ghrita is slightly better in wound healing as compared to Trial drug Karpoor Ghrita but the results are statistically not significant as p value is 0.474

Out of this study, the clinical assessment as a whole signifies the effectiveness of Trial drug that favorable results were obtained in 100 % of patients as 80% got marked Improvement and 20 % got Moderate improvement. In control group also 80% patients got marked Improvement and 20 % got moderate improvement in wound healing of Sadyovrana.

However Karpoor Ghrita was effective on Sadhyo vrana by reducing pain due to progressive healing and by the action of anti-puruitic, surface anaesthetic and prepared with parachrophenol. Healing is accelerated due to the presence of linoleic acid, saturated fatty acid, vitamin A, D, E and K. Vitamin A and E are anti-oxidant and are helpful in preventing oxidative injury to the body. Further the wound was kept moist by ghee base and fatty acids present in the Trial drug, So that the epithelial movement was good and it was easy to change the dressing because it has no tendency for adherence with the wound surface. Hence the administration of Karpoor Ghrita as a local dressing provides better patient comfort and proved effective in the present study.

CONCLUSION-

The present study entitled "Randomised Clinical Comparative study on evaluation of Vranaropana Property of Karpoor Ghrita and jatyadi Ghrita in Sadyovrana" was targeted to evaluate the action of Karpoor Ghrita on traumatic wound by comparing its effect with jatyadi ghrita as a controlled drug. After clinical observation and statistical evaluation, the following conclusions were drawn.

- The traumatic wounds are prevalent in all the age group but less seen in childhood and old age. The prevalence is high due to urbanization and high traffic.
- Wound healing is a natural sequential step still needs cleaning, debridement and asepsis maintenance.
- The Karpoor Ghrita is effective on traumatic wound by reducing pain, minimizing wound surface, reducing the discharge, promoting epithelialisation and granulation tissue and it avoid hypertrophic scar formation.
- Controlled drug Jatyadi ghrita is an established treatment for wound healing, hence when we compared it with Trial drug Karpoor ghrita we found no difference in the results of both the drug, which shows that Trial drug is as effective as Jatyadi ghrita in the Management of Sadyovrana.

The Trial drug by virtue of its properties and chemical constituents effective in treating Sadyovrana.

Since the clinical study was conducted on a limited number of patients, it may not be claimed as final. Detailed study on a large sample size may be conducted in this regard to evaluate the efficacy of Karpoor Ghrita so that may be an effective approach in the management of traumatic wound can be finalized.

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