

Research Article: An Open Label Double Arm Clinical Study To Compare The Effect Of Gopyadi Ghrita Kavalika And Jatyadi Ghrita Kavalika In The Management Of Dushta Vrana With Special Reference To Diabetic Foot Ulcers.

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ABSTRACT:

Ayurveda defines Vrana as a condition that affects the skin or other parts of the body, with the resulting scar (Vrana vastu) remaining until the person's survival. The term "Dushta" refers to the vitiation of all three Doshas. In the context of diabetic ulcers, a Dushta Vrana is characterized by symptoms such as bad odour, abnormal colour, profuse discharge, intense pain, and a prolonged healing period. Managing this condition with effective Ayurveda formulation is need of the hour. The study was conducted on 40 randomly assigned patients at SJGAUH, Bengaluru. In Group A: Gopyadi ghrita kavalika was used for dressing for 28 days, In Group B: Jatyadi ghrita kavalika was used for dressing for 28 days. On the basis of assessment criteria and on the overall result of treatment, in both the groups Gopyadi Ghrita i.e. group A and Jatyadi Ghrita i.e. group B has been able to reduce Pain, Numbness, Area of ulcer, Discharge, Odour, promoting formation of healthy granulation tissue in the floor of the ulcer with results showing statistically highly significant at p value <0.001. This study showed that Gopyadi Ghrita and Jatyadi Ghrita are equally effective in the management of Dushta Vrana w.s.r Diabetic foot ulcer by its Shodhana and Ropana properties.

Keywords: Dushtavrana; Gopyadidi Ghrita; Jatyadi Ghrita; Kavalika; Diabetic foot ulcer.

I. INTRODUCTION:

Diabetes is a highly prevalent disease worldwide. One of the significant complications associated with diabetes is foot ulceration, which poses a substantial social, medical, and economic burden on individuals. Diabetic patients have a lifetime risk of up to 25% of developing foot ulcers as a complication¹. The incidence of diabetic ulcers is approximately 3%. Globally, there is a

significant burden of amputations among diabetic foot ulcer patients, with millions of amputations occurring each year.

Diabetic ulcers are specifically caused by diabetic neuropathy or atherosclerosis, leading to tissue ischemia or breakdown of glucose-laden tissues, which ultimately results in infection and ulceration. Diabetic foot ulcers, in particular, pose a significant burden on individuals with diabetes, causing morbidity and being a leading cause of hospitalization. Recent studies have identified various risk factors associated with the development of diabetic foot ulcers, including male gender, longer duration of diabetes (over 10 years), advanced age, high body mass index, and comorbidities such as retinopathy, diabetic peripheral neuropathy, peripheral vascular disease, foot deformities, high plantar pressure, infection, and inadequate foot self-care. Early intervention, multidisciplinary management, and active care can reduce the risk of amputation in diabetic ulcers.

Conventional treatment modalities for diabetic ulcers in mainstream medicine typically involve the use of antibiotics, topical applications, and surgical procedures, which can be expensive and require hospitalization. However, there is a growing concern regarding multidrug resistance to antibiotics. Therefore, there is a need for successful and efficient management strategies for diabetic ulcers.

Acharya Sushruta while explaining samprapti of Prameha pidaka emphasizes that the channels (srotas) carrying Rasa (nutrient plasma) in patients with Madhumeha (diabetes) become weakened. As a result, the Doshas fail to return to the upper part of the body, leading to the formation of Pidaka in Adhah kaaya², which ultimately results in Vrana. Sushruta provides detailed information about Vrana (wound) and its treatment, known as

Vrana Chikitsa. He mentions various treatment modalities called as Shastiupakrama's³, which includes the use of sarpi (ghee)⁴, taila (oil), and other therapies (upakrama) for cleansing (shodhana) and healing (ropana) of wounds. Herbal medicine has gained popularity worldwide, and many traditional remedies have been described for wound healing. The present study is taken to compare the effect of application of Gopyadi ghrita⁵ in the form of Kavalika⁶ mentioned in Sahasrayoga parishishta prakarana as group A and Jatyadi Ghrita⁷ in the form of Kavalika which is described in Ashtaga Hridaya as group B for 20 patients in each group for 28 days.

OBJECTIVES OF THE STUDY:

- To evaluate the effect of 'Gopyadi ghrita kavalika' in the management of Dushta vrana w.s.r Diabetic Foot Ulcer.
- To evaluate the effect of 'Jatyadi ghrita kavalika' in the management of Dushta vrana w.s.r Diabetic Foot Ulcer.
- To compare the effect of 'Gopyadi ghrita kavalika' and 'Jatyadi ghrita kavalika' in the management of Dushta vrana w.s.r Diabetic Foot Ulcer.

METHODOLGY

Null hypothesis-

- There is no significant effect of Gopyadi ghrita kavalika in the management of Dushta Vrana w.s.r Diabetic foot ulcer.
- There is no significant effect of Jatyadi Ghrita kavalika in the management of Dushta Vrana w.s.r Diabetic foot ulcer.
- There is no significant difference between the effect of Gopyadi ghrita kavalika and Jatyadi Ghrita kavalika in the management of Dushta Vrana w.s.r Diabetic foot ulcer.

Alternate hypothesis-

- There is significant effect of Gopyadi Ghrita kavalika in the management of Dushta Vrana w.s.r Diabetic foot ulcer.
- There is significant effect of Jatyadi Ghrita kavalika in the management of Dushta Vrana w.s.r Diabetic foot ulcer.
- There is significant difference between the effect of Gopyadi Ghrita kavalika and Jatyadi Ghrita kavalika in the management of Dushta Vrana w.s.r Diabetic foot ulcer.

Materials and methods

Source of data

Subjects with clinical features of Dushtavrana fulfilling the inclusion criteria approaching the OPD and IPD of Shalya tantra, Sri Jayachamarajendra Government Ayurveda and Unani Hospital, Bengaluru were selected for the study. The sample collection was initiated after post approval from the institutional ethics committee.

This study was conducted between September 2022 to August 2023

Methods of collection of data

Study Design

An open label double arm randomized comparative clinical study.

Sampling technique

The subjects who fulfil the inclusion criteria and complying with the informed consent (IC) were selected using method of simple random sampling.

Sample Size

Subjects diagnosed with DushtaVrana w.s.r Diabetic foot ulcer of either gender were randomly assigned into two Groups, Group A and Group B comprising of 20 Subjects each. A special case proforma containing all the necessary details pertaining to the study was prepared.

Inclusion Criteria:

- 1.Selection of patients was done irrespective of sex, age, religion, occupation, economic and educational status.
2. As per Wagner's classification ulcers of Diabetic foot with
 - Grade1: superficial ulcers involving full skin thickness
 - Grade2: deep ulcers, penetrating down to ligaments and muscles but no bone involvement.
- 3.Patients with diagnosed case of diabetes mellitus and having Dushta vrana w.s.r Diabetic foot ulcer.
- 4.Patients on medications (Oral antidiabetic drugs / Insulin) with controlled diabetes mellitus. FBS<140mg/dl, PPBS<180mg/dl, HbA1c upto 7%

Exclusion Criteria:

1. As per Wagner's classification ulcers of diabetic foot with
 - Grade3: deep ulcers with cellulitis or abscess formation often with osteomyelitis
 - Grade4: localized gangrene
 - Grade5: extensive gangrene involving the whole foot

2. Patients with conditions like malignancy, Tuberculosis, Leprosy, Syphilis, HIV, HbSAg and other severe systemic disorders.

INTERVENTION: A minimum of 40 subjects with clinical features of Dushtavrana w.s.r Diabetic foot ulcer were selected and randomly assigned into two groups, Group A and Group B consisting of 20 subjects each.

GROUPS	TOPICAL TREATMENT	Duration
GROUP A	Gopyadi ghrita kavalika	28 Days
GROUP B	Jatyadi ghrita kavalika	28 Days

Group A- Treated with Gopyadi ghrita kavalika Poorva karma

- Subject selected for study was asked to lie down or sit in comfortable position.
- Materials required for dressing were kept ready as mentioned above.

Pradhana karma

- Under aseptic precautions,
- Wound site was cleaned with gloved hand using artery forceps with gauze piece.
- Vrana prakshalana was done with Panchavalkala kwatha.
- Debridement of necrotic tissue wherever necessary was done.
- Sufficient quantity of Gopyadi ghrita was taken in gauze, and in the form of kavalika applied over wound site and pad was kept under aseptic precautions.

Paschat karma

- Roller bandage was applied.
- The same procedure was carried daily for 28 days.
- Patient was advised to come to dressing daily.
- In case of reduction in wound size within the time period of 28 days, then patient was

advised to stop further treatment.

Group B- Patients were treated with Jatyadi ghrita kavalika dressing in the similar way explained above.

Follow-up of Study:

Follow-up of patients was done in interval of 15 days for period of 1 Month.

Assessment criteria

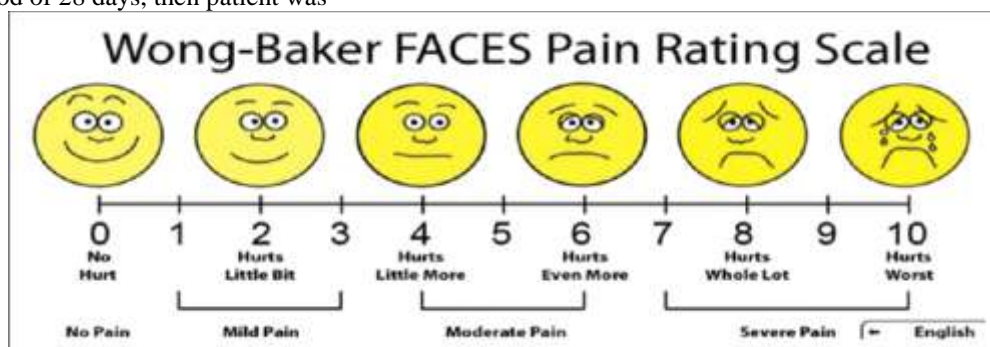
Assessment of the study was done before treatment, during and after treatment and at follow-up on the basis of assessment parameters as per case proforma.

Scoring parameters for assessment: The Subject's responses were assessed on the basis of assessment Criteria by assigning the suitable score to each parameter. The method adopted for Scoring was done as per grading mentioned below: -

Subjective parameters:

Pain-

- Grade (0)- VAS Score 0: No pain
- Grade (1)- VAS Score 1-3: Mild pain
- Grade (2)- VAS Score 4-6: Moderate pain
- Grade (3)- VAS Score 7-10: Severe Pain



As per the Visual Analogue Scale

Numbness (loss of sensation)-

- Absent
- Tingling like pins and needles
- Altered sensations (paraesthesia)
- Distorted sensation (dysthesia)
- Complete absence of sensation

Objective parameters:

Area of the ulcer-

A clean thread is placed over the ulcer in two of its widest directions and length of the thread is measured on measuring tape in cm/mm.

Area of ulcer =length × width of the ulcer in cm/mm

0 - No discontinuity of skin or mucous membrane (healed completely)

1 - 75% of previous area of the ulcer got healed

2 - 50% of previous area of the ulcer got healed

3 - < 25% of previous area of the ulcer got healed / initial size

Discharge-

0 – No discharge

1 – Small stains on gauze after 24 hours

2 – Gauze fully wet, pad stained after 24 hours

3 – Gauze and pad soaked in 12 hours or less, need to change dressing twice or more in 24 hours

Odour-

- No odour
- Faint odour after opening the dressing
- Strong odour after opening the dressing
- Strong odour even with dressing

Floor of the ulcer-

- Smooth, regular floor& with healthy granulation tissue
- Smooth, regular floor, slight discharge, with absence of slough
- Smooth, irregular, slight discharge, less granulation tissue & presence of slough

Pain

- Rough floor & presence of slough with moderate quantity of discharge
- Rough, irregular floor with more slough & profuse discharge, needs frequent dressing.

Overall Assessment of the Effect of the Therapy:

The overall effect of therapy was assessed in terms of Marked Improvement, Moderate Improvement, Mild Improvement and No Improvement.

Complete Improvement: 100% relief in all the signs and symptoms provided by the Therapy.

Marked Improvement: 76-99% relief in all the signs and symptoms provided by the Therapy.

Moderate Improvement: 31-75% relief in all the signs and symptoms provided by the Therapy.

Mild Improvement: 26-50% relief in all the signs and symptoms provided by the Therapy.

Minimum Improvement: 0- 25% relief in all the signs and symptoms provided by the Therapy.

II. RESULTS

The effect of therapy on different subjective and objective parameters were assessed after treatment and the values obtained were subjected to statistical tests to compare the mean values within the group and between the groups.

Statistical test for within the groups:

- Wilcoxon signed rank test –for subjective parameters
 - Paired t test – for objective parameters
- Statistical test for between the groups:
- Mann Whitney ‘U’ test –for subjective parameters
 - Unpaired t test – for objective parameters

The differences in the mean values were considered, the corresponding p value was noted and the obtained results were interpreted as: Highly significant at p<0.001 and p<0.01, significant at p<0.05 and not significant at p>0.05.

Table No.1: Effect of treatment on Pain

Effect of treatment on Pain within the Group A									
Mean Score		B-A	%	SD (±)	Median	z value	p value	Remark	
BT	AT								
2.05	AT	0.30	1.75	85.3	BT: 0.69 AT: 0.47	BT: 2 AT: 0.5	-4.064	<.001	HS

		AF	0.15	1.90	92.6	BT: 0.69 AF: 0.37	BT: 2 AF: 0.5	-4.030	<.001	HS
Effect of treatment on Pain within the Group B										
Mean Score				%	SD (±)	Median	z value	p value	Remark	
BT			B-A							
2.45	AT	0.50	1.95	79.6	BT:0.51 AT: 0.52	BT: 2.5 AT:0.5	-4.008	<.001	HS	
	AF	0.25	2.20	89.8	BT: 0.51 AF: 0.44	BT:2.5 AF:0.5	-4.008	<.001	HS	

In Group A, the treatment had a highly significant effect on Pain (p<0.001) with an average improvement of 85.3%.

In Group B, the treatment had a highly significant effect on Pain (p<0.001) with an average improvement of 79.6%.

Effect of treatment on Pain between the Group A and Group B:

Table No.2: Effect of treatment on Pain between the Group A and Group B (after treatment)

Group	Mean	SD	SE	Median	z value	p value	Remark
Group A	0.20	0.41	0.09	0	-0.78	0.43	NS
Group B	1.50	0.51	0.11	1.5			

Table No.3: Effect of treatment on Pain between the Group A and Group B (after follow-up)

Group	Mean	SD	SE	Median	z value	p value	Remark
Group A	0.40	0.49	0.10	0	-1.27	0.20	NS
Group B	1.50	0.51	0.11	1.5			

The comparative analysis of the treatment's effect on Pain between Group A and Group B resulted in a p-value > 0.05, suggesting a statistically insignificant difference.

• **Numbness**

Table No. 4: Effect of treatment on Numbness

Within the Group A										
Mean Score				%	SD (±)	Median	z value	p value	Remark	
BT			B-A							
1.6	AT	0.70	0.9	56.2	BT: 0.88 AT: 0.80	BT: 1 AT: 0.5	-4.24	<.001	HS	
	AF	0.70	0.9	56.2	BT: 0.88 AF: 0.80	BT: 2 AF: 0.5	-4.24	<.001	HS	
Within the Group B										
Mean Score				%	SD (±)	Median	z value	p value	Remark	
BT			B-A							
1.35	AT	0.7	0.65	48.1	BT:0.93 AT: 0.73	BT: 2 AT:1	-4.008	<.001	HS	
	AF	0.7	0.65	48.1	BT: 0.51 AF: 0.73	BT:2.5 AF:1	-4.008	<.001	HS	

In Group A, the treatment had a highly significant effect on Numbness ($p < 0.001$) with an average improvement of 56.2%.

In Group B, the treatment had a highly significant effect on Numbness ($p < 0.001$) with an average improvement of 48.1%.

Effect of treatment on Numbness between the Group A and Group B:

Table No.5: Effect of treatment on Numbness between the Group A and Group B (after treatment)

Group	Mean	SD	SE	Median	z value	p value	Remark
Group A	0.70	0.76	0.17	0	-0.09	0.93	NS
Group B	1.50	0.51	0.11	1.5			

Table No.6: Effect of treatment on Numbness between the Group A and Group B (after follow-up)

Group	Mean	SD	SE	Median	z value	p value	Remark
Group A	0.70	0.76	0.17	0	-0.09	0.93	NS
Group B	1.50	0.51	0.11	1.5			

The comparative analysis of the treatment's effect on Numbness between Group A and Group B resulted in a p-value > 0.05 , suggesting a statistically insignificant difference.

- Area of the Ulcer**

Table No. 7: Effect of treatment on Area of the Ulcer

Within the Group A									
Mean Score				%	SD(±)	SE (±)	t value	p value	Remark
BT			B-A						
3	AT	0.7	2.3	76.6	0.65	0.15	15.66	<0.001	HS
	AF	0.35	2.65	88.3	0.49	0.11	24.22	<0.001	HS
Within the Group B									
Mean Score				%	SD(±)	SE (±)	t value	p value	Remark
BT			B-A						
3	AT	0.75	2.25	75	0.71	0.16	14.04	<0.001	HS
	AF	0.35	2.65	88.3	0.59	0.13	20.18	<0.001	HS

In Group A, the treatment had a highly significant effect on Area of the ulcer ($p < 0.001$) with an average improvement of 76.6%.

In Group B, the treatment had a highly significant effect on Area of the ulcer ($p < 0.001$) with an average improvement of 75%.

Effect of treatment on Area between the Group A and Group B:

Table No. 8: Effect of treatment on Area of the ulcer between the Group A and Group B

	Group A	Group B	SD	SE	t value	p value	Remark
AT	0.7	0.75	0.68	0.53	-0.23	0.41	NS

AF	0.35	0.35	0.11	0.08	0	0.5	NS
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The comparative analysis of the treatment's effect on Area of the ulcer between Group A and Group B resulted in a p-value > 0.05, suggesting a statistically insignificant difference

• **Discharge**

Table No. 9: Effect of treatment on Discharge

Within the Group A									
Mean Score				%	SD(±)	SE (±)	t value	p value	Remark
BT			B-A						
1.95	AT	0.30	1.65	84.6	0.49	0.11	15.07	<0.001	HS
	AF	0.20	1.75	94.3	0.45	0.10	17.61	<0.001	HS
Within the Group B									
Mean Score				%	SD(±)	SE (±)	t value	p value	Remark
BT			B-A						
2.15	AT	0.35	1.80	83.7	0.52	0.12	15.387	<0.001	HS
	AF	0.20	1.95	90.7	0.51	0.11	17.085	<0.001	HS

In Group A, the treatment had a highly significant effect on Discharge (p<0.001) with an average improvement of 84.6%.

In Group B, the treatment had a highly significant effect on Discharge (p<0.001) with an average improvement of 83.7%.

Effect of treatment on Discharge between the Group A and Group B:

Table No. 10: Effect of treatment on Discharge between the Group A and Group B

	Group A	Group B	SD	SE	t value	p value	Remark
AT	0.30	0.35	0.57	0.46	-0.27	0.39	NS
AF	0.20	0.20	0.09	0.07	0	0.5	NS

The comparative analysis of the treatment's effect on Discharge between Group A and Group B resulted in a p-value > 0.05, suggesting a statistically insignificant difference.

• **Odour**

Table No. 11: Effect of treatment on Odour

Within the Group A									
Mean Score				%	SD(±)	SE (±)	t value	p value	Remark
BT			B-A						
1.65	AT	0.15	1.50	90.9	0.51	0.11	13.07	<0.001	HS
	AF	0.05	1.60	96.9	0.50	0.11	14.23	<0.001	HS

Within the Group B									
Mean Score			%	SD(±)	SE (±)	t value	p value	Remark	
BT		B-A							
1.75	AT	0.25	1.50	85.7	0.51	0.11	13.07	<0.001	HS
	AF	0.10	1.65	94.3	0.49	0.11	15.08	<0.001	HS

In Group A, the treatment had a highly significant effect on Odour (p<0.001) with an average improvement of 90.9%.

In Group B, the treatment had a highly significant effect on Odour (p<0.001) with an average improvement of 85.7%.

Effect of treatment on Odour between the Group A and Group B:

Table No. 12: Effect of treatment on Odour between the Group A and Group B

	Group A	Group B	SD	SE	t value	p value	Remark
AT	0.15	0.25	0.405096	0.266747	-0.78	0.22	NS
AF	0.05	0.10	0.064051	0.042176	-0.58	0.28	NS

The comparative analysis of the treatment's effect on Odour between Group A and Group B resulted in a p-value > 0.05, suggesting a statistically insignificant difference.

• **Floor of the Ulcer**

Table No. 13: Effect of treatment on Floor of the Ulcer

Within the Group A									
Mean Score			%	SD(±)	SE (±)	t value	p value	Remark	
BT		B-A							
2.3	AT	0.1	2.2	95.6	0.52	0.11	18.81	<0.001	HS
	AF	0	2.3	100	0.47	0.10	21.8	<0.001	HS
Within the Group B									
Mean Score			%	SD(±)	SE (±)	t value	p value	Remark	
BT		B-A							
2.75	AT	0.30	2.45	89.1	0.51	0.11	21.47	<0.001	HS
	AF	0.20	2.55	92.7	0.51	0.11	22.34	<0.001	HS

In Group A, the treatment had a highly significant effect on Floor of the Ulcer (p<0.001) with an average improvement of 95.6%.

In Group B, the treatment had a highly significant effect on Floor of the Ulcer (p<0.001) with an average improvement of 89.1%.

Effect of treatment on Floor between the Group A and Group B:

Table No. 14: Effect of treatment on Floor of the Ulcer between the Group A and Group B

	Group A	Group B	SD	SE	t value	p value	Remark
AT	0.1	0.30	0.41	0.30	-1.59	0.06	NS
AF	0	0.20	0.06	0.05	-1.17	0.08	NS

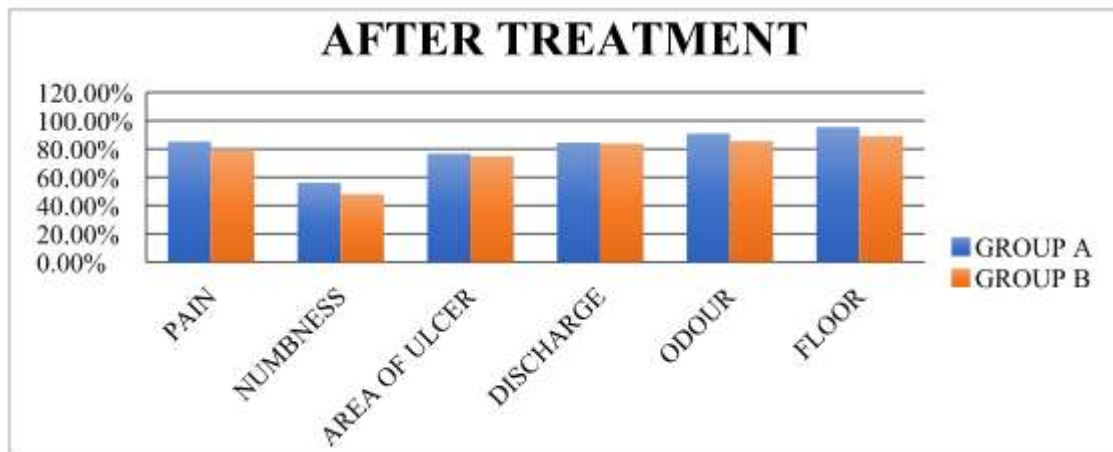
The comparative analysis of the treatment's effect on Floor of the Ulcer between Group A and Group B resulted in a p-value > 0.05, suggesting a statistically insignificant difference.

• **Overall effect of treatment between the Group A and Group B**

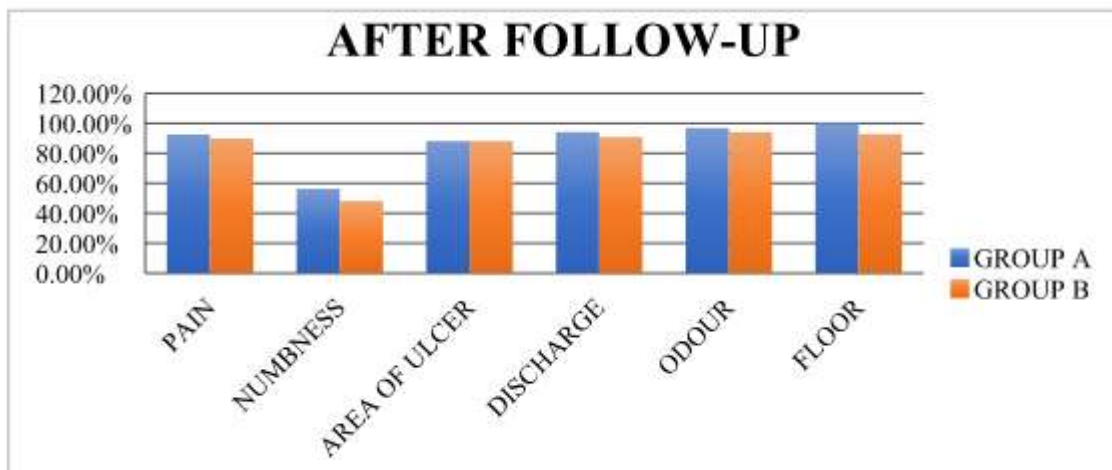
Table No. 15: Overall effect of treatment between the Group A and Group B

	Group A	Group B	SD	SE	t value	p value	Remark
AT	0.37	0.47	0.60	0.09	-1.28	0.09	NS
AF	0.24	0.30	0.52	0.08	-0.86	0.19	NS

The comparative analysis of the effect of treatment between Group A and Group B resulted in a p-value > 0.05 with average improvement of 84.02% in Group A and 76.8% in Group B, suggesting a statistically insignificant and clinically significant difference.



Graph No- 1: Overall effect of treatment between the Group A and Group B (After treatment)



Graph No- 2: Overall effect of treatment between the Group A and Group B (After follow-up)

Table No. 16: Total Percentage of Improvement observed in Group A and Group B

		Result in Group A		Result in Group B	
Minimum	0-25%	0	0%	0	0%
Mild	26-50%	0	0%	2	10%
Moderate	51-75%	6	30%	7	35%
Marked	76-99%	9	45%	9	45%
Complete	100%	5	25%	2	10%

III. DISCUSSION

Discussion on drug

Probable Mode of Action of Gopyadi Ghrita

In the Phalashruti of Gopyadi ghrita it is mentioned that “दुर्वातोयेविषक्वं घृतमितु सकलान् मर्मसंस्थान जातान् । तीष्णानुष्णान् गुरुनप्यपहसति तथैव व्रणान् मेहजातान् ॥” which gives an intuition that this medicine is effective in treating Marmasthana jaata vrana, Teekshna, Ushna, Guru and Mehajaata vrana.

The ingredients of Gopyadi Ghrita are Sariva, Utpala, Yashtimadhu, Chandana, Kushta, Usheera, Durva and Shruna of Vata, Udumbara, Ashwatta, Plaksha. Most of these drugs have Tikta, kashaya rasa, sheeta veerya, vrana shodhaka, shothahara, raktashodhaka, dahaprashamana, raktaprasadaka, vedanashamaka, twakdosahara, vranaropaka, Krimighna, vishaghna, Varnya, kandughna and Pitta-kaphahara properties. By the virtue of these properties Gopyadi Ghrita does Vrana Shodhana, increases blood circulation and also helps in reduction of infection (bacterial growth) and toxicity. Most of the drugs are sheeta veerya, pitta shamaka dravyas hence help in reducing the symptoms like daaha, paaka and vedana at the site of vrana.

Ingredients like Sariva contain chemical constituents like hemidesmin, coumarin which has good antibacterial activity, anti-inflammatory, antifungal, antiulcer and antioxidant properties. The chloroform and alcoholic extracts of roots of Sariva showed marked in-vitro antibacterial (bacteriostatic) activity against E.Coli, Staphylococcus aureus, Staphylococcus adbus, Vibrio cholerae, Salmonella typhosa (ICMR bulletin 1972). The alcoholic extract of Utpala has a significant analgesic activity (Singh et.al 1977). The anti-inflammatory activity of glycyrrhetic acid (chemical constituent of Yashtimadhu) and its diacetate was similar to that of hydrocortisone on formalin induced arthritis in albino rats (Tangri et.al 1964). Constituents like Saponin in Sariva, Glycyrrhizin in Yashtimadhu have Anti-inflammatory activity. This reduces inflammation at the site of vrana.

Probable Mode of Action of Jatyadi Ghrita

The ingredients of Jatyadi Ghrita are Jati, Nimba, Patola, Katuki, Daruharidra, Nisha, Sariva, Manjishta, Usheera, Sikta, Tuttha, Madhuka, karanja beeja. Most of these drugs have shodhana, ropana, vedana sthapana properties. Ingredients like tuttha has lekhana property, which helps in removal of slough effectively. The ingredients Nimba, Patola, Karanja, Katuki have Tikta, kashaya rasa which help in vrana shodhana. Katuki, Nisha and Daruharidra have lekhana, chedana, kanduhara, vishagna, varnya properties. Sariva and Manjishta have rakta prasadana property. Usheera, manjishta, sariva are kapha pitta hara hence help in reducing the symptoms like daaha, paaka and vedana at the site of vrana. Anti-inflammatory action of Nimba, Patola, Haridra, Daruharidra, Katuki and Jati helps in reduction of local inflammation. Jati leaves juice shows antibacterial activity against Staphylococcus aureus. Other drugs like nimba, patola, darvi, nisha, sariva, karanja have anti-inflammatory and immunostimulant properties.

Mode of Action of Panchavalkala Kashaya

Panchavalkala Kwatha enhances the formation of granulation tissue by removing the slough. Due to its Guru Guna and Sheeta veerya it reduces burning sensation. It has kashayarasa which does shoshana and shodhana of Vrana.

Chemical constituents include Tannins which are anti-inflammatory, anti-microbial, increased collagen content, phytosterols and beta sitosteryl-d-glucosides have analgesic property, flavinoids are anti-inflammatory, vitamin A & K helps in epithelialization and maturation.

Discussion on procedure:

In vrana which has Durgandha, with Kleda and Picchilata, shodhana kashaya prakshalana has to be done for vrana shodhana. In vrana which has obtained shuddha vrana lakshana, ropana kashaya prakshalana has to be done for the purpose of vrana ropana. To achieve the main goal of healing, it is necessary to remove the local dosha

dushti and carry out debridement of the non-viable tissue at the site of Vrana. In Vrana with pitta dushti, which is Gambhira, has Daaha and Paaka, medicated ghrita has to be used for application. Ghrita is Snighdha, Vata-pitta hara, Sookshma, along with the properties of the drugs with which it is processed it reaches the minute spaces and also is absorbed well by the tissues.

When the medicated Ghrita applied over the wound in the form of Kavalika will facilitate prolonged contact of medicines to the wound and it protects the wound from getting contaminated.

Discussion on observations

Age:

In the present study 18(45%) subjects belonged to the age group of 51-60 years followed by 12(30%) subjects in the age group of 41-50 years and 9 (22.5%) subjects belonged to the age group of 61-70 years. This revealed that incidence of DushtaVrana w.s.r to Diabetic foot ulcer was more common in age group of 51 -60 years. There are 97.5% of patients in the age group between 40-70 years. Wound heals faster in younger age group, in old age it heals normally unless associated with debilitating causes like systemic illness or ischaemia or Diabetes Mellitus. As age progresses dhatukshaya sets in, which results in durbalatha of rasayanies and finally madhumeahaja vrana occurs in legs. As ulcer healing slows down, these turn to chronic non healing wounds. Hence the increased incidence of Dushtavrana w.s.r Diabetic ulcer is seen in elderly age group.

Diet:

Among the subjects, 31(77.5%) Subjects were having mixed diet. Consumption of anupa mamsa, excess katu, amla, lavana rasa ahara, dadhi, sheeta udaka, nava dhanya causes dosha sanjanana and pooya vardhana which impacts ulcer healing. Kaphakara Abhishyandi Ahara increases discharge and delays healing.

Occupation:

Maximum Subjects, i.e. 8 (20%) Subjects were house wife's, 7 (17.5%) Subjects were retired office workers, 3 (7.5%) Subjects were Office clerks, The nature of work here is either continuous standing or sedentary which reduces the blood circulation and delays ulcer healing.

Family history of Madhumeaha:

In the present study, 18 (45%) subjects had the family history of Diabetes and 22 (55%)

subjects don't have family history of Diabetes. The disease Parmeha is associated with beeja dosha (genetic susceptibility)

Chronicity of ulcer:

In the present study 24 (60%) subjects had chronicity of ulcer from 0 months to <6 months, 8 (20%) subjects had chronicity of ulcer from >6 month to <1 year, 3 (7.5%) subjects had chronicity of ulcer from > 1 year to < 2 years, 2 (5%) subjects had chronicity of ulcer > 2 years, this may be due to negligence towards proper ulcer care and delayed healing of Diabetic ulcers.

Chronicity of Diabetes Mellitus:

In the present study 7 (17.5%) Subjects had chronicity of Diabetes from 0 months to 5 years, 19 (47.5%) Subjects had chronicity of Diabetes from 6 years to 10 years, 11 (27.5%) Subjects had chronicity of Diabetes from 11 years to 15 years, 3 (7.5%) Subjects had chronicity of Diabetes from 16 years to 20 years. Which suggests chances of developing diabetic complications like Diabetic foot ulcer are more after 5 years of Diabetic history.

Discussion on results

Effect of treatment on Pain:

Vrana vedana is of different types according to the doshas as mentioned in classics, i.e Todabhedadi vedana vishesha occurs due vata, Osha chosha paridahadi occurs due to pitta and rakta, Kandu Gurutva suptatadi occur in case of kapha, in case of sannipata all kinds of vedana vishesha may occur. In Group A, Gopyadi Ghrita, Vedanasthapaka quality of the dravyas helps to reduce vedana at vrana site. In non-healing ulcers pain and tenderness occurs due to inflammation, impaired blood circulation, increased pressure in the veins, injury to the small vessels and nerves, etc. Drugs like Sariva, Chandana, Durva, Kushta have raktaprasadana guna, which helps in improving circulation and reduces tenderness. Chandana, Usheera, Sariva, are all sheeta, pittahara and shothahara thus help in reducing inflammation. Glycerritic acid in Yashtimadhu has Anti-inflammatory activity.

In Group B, Jatyadi Gritha, ingredients like tuttha, haridra, daruharidra, katuki, karanja, jati have vrana shodhana property. Anti-inflammatory action of these help to reduce tenderness with reduction of inflammation.

Effect of treatment on Numbness:

Numbness is due to increased Kapha and decreased Vata karma. In group A, Gopyadi ghrita has many drugs which having Kashaya and tikta rasa which increases diminished Vata activity, Kapha hara guna in ingredients like Chandana, Kushta, Usheera. Dahaprashamana and Rakta prasadaka guna of Sariva, Utpala, Chandana, Durva, Usheera would have helped in regaining the lost / diminished sensation in early Diabetic Neuropathy changes.

In Group B, Jatyadi Ghrita has many drugs which are having Kapha hara guna like Nimba, Patola, Daruharidra, Manjishta, karanja, Katuki. Daha-prashamana and Raktaprasadaka guna of Sariva, Yashtimadhu, Usheera, Haridra would have helped in regaining the lost / diminished sensation in early Diabetic Neuropathy changes.

Effect of treatment on Area of the ulcer:

In Group A, Vrana ropana and rakta prasadana guna of the drugs like Sariva, Chandana, Yashtimadhu, Chandana and Usheera in Gopyadi Ghrita helps in faster neo-vascularization and reducing the size of vrana. Wound which is devoid of discharge, slough contracts faster with healthy granulation tissue formation and epithelialization.

Group B- In Jatyadi Ghrita, Ingredients-Haridra, Daruharidra and Tuttha help in shodhana of vrana as they have chedana, lekhana properties, due to the laghu, ruksha guna and shoshana property there is reduction in discharge. Wound which is devoid of discharge, slough contracts faster with healthy granulation tissue formation and epithelialization. Vrana ropana and rakta prasadana guna of the drugs like Manjishta, Sariva,

Katuki, Patola, Nimba and collagen content help in faster neo-vascularization and reducing the size of vrana.

Effect of treatment on Discharge:

In Group A, Gopyadi Ghrita contains drugs like Kushta, chandana, Usheera, Durva, Sariva, Yashtimadhu which have Krimighna, vrana shodhana and ropana property. Shodhana i.e removal of doshas from the ulcer site reduces the discharge. Laghu, Rooksha guna and Kashaya rasa of these help in reducing srava. Ingredients like Sariva has good antibacterial, anti-inflammatory and antioxidant properties which reduces infection and thus reduces discharge also. Tannins is a major component present in all drugs of Nalpalmara (Vata, Udumbara, Ashwatta, Plaksha) which helps in reducing discharge.

In Group B, Jatyadi Ghrita, ingredients like Tuttha which has lekhana, shodhana properties help in removal of slough, helps in shodhana of the vrana, which reduces srava. The ingredients Nimba, Patola, Karanja, Katuki have Tikta, kashaya rasa which help in vrana shodhana. Katuki, Nisha and Daruharidra have lekhana, chedana, kaphahara, shoshana, and shodhana properties which helps in reducing discharge at the vrana sthana. In both the groups, Tannins is a major component present in all drugs of Panchavalkala kashaya which helps in reducing discharge.

Effect of treatment on Odour:

Durgandha/abnormal smell was observed due to Presence of discharge and slough. Group A-Gopyadi Ghrita contains drugs like Sariva, Chandana, Kushta, Utpala, Usheera, which have Durgandha nashaka, Krimighna, vrana shodhana and ropana property. Shodhana i.e removal of doshas from the ulcer site reduces the discharge. Laghu, Rooksha guna and Kashaya rasa of these help in reducing Srava, with the reduction in discharge and removal of slough, abnormal smell also decreases.

In Group B, Jatyadi Ghrita, Tuttha (CuSO₄) helps in the removal of slough and discharge effectively thus helps reduce abnormal smell. The ingredients Nimba, Patola, Karanja, Katuki have Tikta, kashaya rasa which help in vrana shodhana. Katuki, Nisha and Daruharidra have lekhana, chedana, kaphahara, Shoshana, and Shodhana properties which helps in reducing discharge at the vrana sthana, with the reduction of discharge and slough, abnormal smell also decreases.

Effect of treatment on Floor of the ulcer:

Group A- Gopyadi Ghrita contains drugs like Sariva, Chandana, Kushta, Utpala, Durva, Yashtimadhu which have vrana shodhana and ropana property. Shodhana i.e removal of doshas from the ulcer site reduces the discharge and removes the slough which in turn promotes formation of healthy granulation tissue in the floor of the ulcer. Kushta, Vata, Ashwatta, Udumbara have lekhana, chedana, kaphahara, shoshana, and shodhana properties which helps in debridement of slough and producing healthy granulation tissue in the floor of ulcer.

In Group B, Jatyadi Ghrita, Tuttha (CuSO₄) helps in the removal of slough and discharge effectively thus helps in debridement of Vrana. The ingredients Nimba, Patola, Karanja, Katuki have

Tikta, kashaya rasa which help in vrana shodhana. Katuki, Nisha and Daruharidra have lekha, chedana, kaphahara, shoshana, and shodhana properties which helps in debridement of slough and producing healthy granulation tissue in the floor of ulcer.

ADVERSE EFFECTS:

No adverse effects were observed in both the groups during the course of the study.

IV. CONCLUSION

The present study was carried out on 40 Subjects with lakshanas of Dushtavrana w.s.r. Diabetic foot ulcers, these subjects were on medications (Oral antidiabetic drugs / Insulin) with controlled diabetes mellitus. The overall observation in the study revealed that the maximum number of Subjects were males, between 51-60 years of age, maximum number of Subjects belonged to Hindu community, Married, having Mixed diet and with chronicity of ulcer 0 months to < 6 months.

In the present study, the effect of the treatment in both the groups has shown statistically highly significant results in all the assessment parameters like Pain, Numbness, Area of the Ulcer, Discharge, Odour and Floor of the ulcer (BT-AT). The effect of treatment was statistically insignificant between the Group A and Group B with respect to assessment parameters like Pain, Numbness, Area of the Ulcer, Discharge, Odour and Floor of the ulcer (BT-AT). However, statistically when mean rank and mean were compared between groups, Group A was comparatively better than Group B in parameters like Pain, Numbness, Odour and Floor of the ulcer. While Group A and Group B showed approximately similar results in parameters like Area of the Ulcer and Discharge.

The study was concluded by stating that “There is no significant difference between the effect of Gopyadi ghrita kavalika and Jatyadi Ghrita kavalika in the management of Dushta Vrana w.s.r Diabetic foot ulcer. However, Gopyadi ghrita has an edge over Jatyadi ghrita in reduction of Pain, Numbness, Odour and producing healthy granulation tissue in the Floor of the Ulcer”.

Materials used in Group – A (Gopyadi ghrita kavalika)



DRESSING MATERIALS

Materials used in Group-B (Jatyadi ghrita kavalika)



DRESSING MATERIALS

Before and After treatment Photographs in Group-A





Before and After treatment Photographs in Group-B



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