A Comparative Study of Efficacy of Jalaukavacharana and Magadhyadi Taila in the Management of Diabetic Foot Ulcer

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ABSTRACT

Vrana means break in continuity of bodily dhatus. Various classifications of Vrana are done depending on different criteria, one among which is prognosis/Sadhyasadhyata. Under Yapya & Kashtasadhya vrana there's mention of Vrana in Madhumehi. This is considered as Dushtavrana as it taken long duration to heal because of its association with disease Madhumeha and certain sthanika karanas like kleda, visha etc. It is made clear that onset of Vrana is with involvement of Rakta dhatu & management of Vrana in Madhumehi in accordance to Dushtavrana. In present study, Raktamokshana by Jalaukavacharana and Magadhyadi taila as Vranaropana in Vrana in Madhumehi is taken. Two groups were made comprising of 20 patients each. In Group A- Magadhyadi taila was applied to vrana once daily for 30 days. In Group B-Jalaukavacharana was done in four sittings with an interval of one week followed by daily dressing with Magadhyadi taila for a period of 30 days. All the references realated to vrana in a madhumehi were screened across the literatures and an attempt was made to understand the same with scientific way. Observations on the clinical study were mentioned in the table and graphical form and the results of two groups were drawn separately to find out the best solution for the same., Total 40 patients were treated in the present study. Out of 40 patients, Group A had 4 patients with good response, 6 with moderate response and 10 with poor response which was insignificant statistically, when compared to Group B, with 10 patient having good response, 6 with moderate response and 4 with poor response. At the end of the study, it was found that the patients treated with Raktamokshana along with the application of Magadhyadi taila externally gave good results when compared to patients treated only with application of Magadhyadi taila.

Key Words: Vrana, Madhumeha, Jalauka, Raktamokshana, Magadhyadi taila.

INTRODUCTION

Vrana means break in continuity of bodily dhatus. Various classification of Vrana are done depending on different criteria, one

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(Received on 16.08.2010, accepted on 28.08.2010)

among which is prognosis/Sadhyasadhyata. Under Yapya & Kashtasadhya vrana there's mention of Vrana in Madhumehi. This is considered as Dushtavrana as it taken long duration to heal because of its association with disease Madhumeha and certain sthanika karanas like kleda, visha etc.

It is made clear that onset of Vrana is with involvement of Rakta dhatu & management of Vrana in Madhumehi in accordance to Dushtavrana irrespective of nija or agantu karanas, which includes kaya shodhana and raktamokshana, vranashodhan, ropana and pathyahara.

Number of Patients suffering from Diabetes Mellitus is on rise, approximately 30-35% of

total population is getting affected. Diabetic foot ulcers are a complication affecting approximately 15% of people with Diabetes. Foot ulceration, sepsis, and amputation are known and feared by almost every person who has diabetes diagnosed.

Of late and uncontrolled blood sugar leads to various complications like infection, metabolic like Hypoglycemia, Ketoacidosis and Angiopathic complications involving small and large vessels. Due to microvascular & neurological pathologies, foot problems are many ranging from cellulitis to ulcer and to gangrene. Commonest site for ulcer under the hallux, on the first and fifth metatarsal heads, and under the heel. Management of ulcers falls into three parts: removal of callus, eradication of infection, and reduction of weight bearing forces, often requiring bed rest with the foot raised. In spite of various treatment the ulcer progresses to gangrene and the treatment of amputations. As this management is costly, needs hospitalization, with less percentage of relief, thus an alternative management is in need for the treatment of Vrana in a Madhumehi. Thus for the present study, Raktamokshana by Jalaukavacharana and Magadhyadi taila as Vranaropana in Diabetic Foot Ulcer is taken. The intention of this being, cutting down the healing process, checking progression of ulcer and treating the basic pathology of ulcer formation.

AIMS & OBJECTIVES

- 1. To study role of Jalaukavacharana in Ropana in Vrana in Madhumehi.
- 2. To study the efficacy of Magadhyadi taila in Ropana of vrana in Madhumehi.
- 3. To compare the effect of Jalaukavacharana and Magadhyadi taila in the mangament of Vrana in Madhumehi.

MATERIAL & METHODS

Conceptual study

1. All literatures related to Vicharchika and Raktamokshana had been collected from the

concern *Ayurvedic* texts and concepts related to eczema from modern medicine.

Drug review

The taila selected for the present clinical study is 'Magadhyadi taila', reference is from Gadanigraha.

The ingredients used in the preparation of Magadhyadi taila are

Magadhi, Madhuka, Rodhra, Kushta, Ela, Harenu, Manjishta, Dhataki, Sariva, Haridra, Daruharidra, Sarjarasa, Priyangu, Padmaka, Padmakeshara, Matulunga Patra, Saindhava, Madhucchishta

Method of Preparation of Magadhyadi Taila:

As there is no mention about the quantity of ingredients, all kalka dravyas are taken in equal quantity; taila and jala are taken as per principle of taila paka vidhi of Sharangadhara. The taila siddha lakshanas are observed, confirmative tests were performed.

SELECTION OF PATIENT

Inclusive Criteria

- 1. Patients of either sex will be selected.
- 2. Vrana confined to foot in Madhumehi will be selected.

Exclusive Criteria

- 1. Patients with other systemic diseases are excluded.
- 2. Patients with diabetic gangrene foot are excluded.

METHODS

40 Patients were selected for the study and divided into 2 groups as Group A & B.

Duration of the Study

- 1. The procedure of Jalaukavacharana in GroupB was carried out once in a week in four sittings.
- 2. Magadhyadi taila was applied once daily for 30 days in both the Groups.

Dosage: As per size of wound

Diabetic Foot Ulcer

Group A

Jalaukavacharana + Magadhyadi taila Application

- 1. The affected part was cleaned with distilled water & dried.
- 2. After cleaning the part, surgical debridement was done wherever necessary and again washed with distilled water and dried.
- 3. Then using a sterile gauze, Magadhyadi taila was smeared and it was kept over the affected part and bandaging done.

Group B

Jalaukavacharana + Magadhyadi taila Application

Poorva Karma

- 1. The Nirvisha jalauka which were selected were taken in water containing Haridra jala.
- 2. Jalauka was kept in this tray for few minutes till it gets activated. Later, it was shifted to clean water.

Pradhana Karma

- 1. The activated Jalauka was taken and were made to adhere near the affected site. Number of Jalaukas depends on the size of the vrana.
- 2. After adhering the Jalauka raised the neck and attained horseshoe shape. Then it was covered with wet pad to facilitate sucking.
- 3. The Jalauka was allowed to suck till the patient gets pain and itching sensation or till they suck to their full capacity and leave the site on their own. If not, Jalauka was made to disassociate by applying pinch of saindhava lavana to its mouth.

Paschat Karma

1. The leech, thus disassociated was taken out is made to vomit by application of lavana

to its mouth & by gentle massage from tail end of the Jalauka to the head part.

- 2. The wound made by leech was cleaned with distilled water and dressed with sterile gauze and bandaged. For the successive days, daily dressing of Vrana with Magadhyadi taila was done
- 3. The Jalaukavacharana was done in 4 sittings with the interval of one week.

Advices given during the treatment in both the groups:

- 1. Local hygiene maintenance
- 2. To continue medications prescribed by physician to control Madhumeha.
- 3. To follow pathyaapathya as adviced by physician for Madhumeha.

Assessment of Response

The results were evaluated by subjective and objective parameters mainly based on the clinical observations by grading method.

DISCUSSION

Diabetic Foot Ulcer is the subject taken up for the present study. Onset of Diabetic foot ulcer may be because of exogenous or endogenous causes and its prognosis is said to be Kashtasadhya. The reasons for the same can be analysed as follows:

Prameha considered as Mahagada, probably because of involvement of majority of dravadhatu & dushtadosha utkatuta and consequence being klinnata. This klinn/kleda being an essential factor in making a vrana Dushta. More than this, Madhumeha being one among the Vataja meha – well known to be asadhya, because of vishama kriya & Ojas being the main factor behind Samprapti(a prime facor guiding immunity), Madhumehi is susceptible to complication.

OBSERVATION & RESULTS

Table Showing Sex wise distribution of Patients in both groups.

	Group A			Group B		
Sex	No.	%	No.	0/0	Total	%
Male	11	55%	12	60%	23	57.5%
Female	9	45%	8	40%	17	42.5%

Table Showing Age wise distribution of Patients in both groups.

Age in	Group-A		Gro	ир-В	Total		
Years	No	%	No	%	No	%	
Below 40	04	20%	1	5%	5	12.5%	
41-50	06	30%	07	35 %	13	32.5%	
51-60	06	30%	05	25%	11	27.5%	
61-70	04	20%	05	25%	09	22.5%	
Above 70	00	-	02	10%	02	12.5%	

Table Showing Marital status wise distribution of Patients in both groups:

Marital	Gro	up-A	Grou	p-B	Total		
status	No	%	No	0/0	No	%	
Married	20	100%	20%	100%	40	100%	
Unmarried	,	1			-	-	

Table Showing the Occupation wise distribution of Patients in both groups:

Oc cupation	Grou	ıp A	Gro	ир В	Total		
	No	%	No	%	No	%	
Housewives	07	35%	06	30 %	13	32.5%	
Businessman	05	25%	04	20 %	09	22.5%	
Office worker	02	10%	03	15%	05	125%	
Agriculture	01	05%	02	10%	03	7.5%	
Factory worker	03	15%	01	05 %	04	10%	
Retired	02	10%	04	20 %	06	15%	

Table. Showing the Religion wise distribution of Patients in both groups:

Religion	Group A		Gro	ирВ	Total		
	No	%	No	%	No	%	
Hindu	16	80%	16	80%	32	80%	
Muslim	02	10%	01	5%	03	7.5%	
Christian	02	10%	03	15%	05	12.5%	

Table. Showing the Literary wise distribution of Patients in both groups:

Literacy	Gro	up A	Grou	ıp B	Total	%
	No	%	No	%	No	70
Illiterates	03	15%	02	10%	05	12.5%
Literates	17	85%	18	90%	35	87.5%

Table. Showing the Socio - economic wise distribution of Patients in both groups:

Socio-	Group A		Gro	ир В	Total		
economic Status	No	%	No	%	No	%	
Upper Class	01	5%	01	5%	02	5%	
Middle Class	14	70%	15	75%	29	72.5%	
Lower Class	05	25%	04	20%	09	22.5%	

Table. Showing the Diet wise distribution of Patients in both groups

	Group A		Gro	Group B		
Diet	Nα	%	No.	% %	Total	%
Mixed	15	75%	15	75%	30	75%
Veg	5	25%	5	25%	10	25%

Table. Showing the Family history of Diabetes in both groups:

	Gro	Group A		ир В		
Family history	No.	%	No.	%	Total	%
Absent	08	40 %	09	45%	17	42.5%
Present	07	35 %	07	35%	14	35 %
Not aware	05	25 %	04	20%	09	22.5%

Table. Showing the Site of Ulcer in Patients of both groups:

614	Group	A	Gro	ир В	Total	
Site	No.	%	No.	%	No.	%
Forefoot	16	80%	15	75%	31	77.5%
Midfoot	0	-	1	5%	01	2.5%
Rarefoot	04	20%	04	20%	08	20%

Table. Showing the Chronicity wise distribution of Patients in both groups:

Duration	Group A		Gro	ир В	Total		
(years)	No	No % No		0/0	No	%	
Upto 2 months	01	5%	02	10 %	03	7.5 %	
2-4month	02	10%	04	20 %	06	15 %	
4-6month	02	10%	01	5%	03	7.5 %	
6-8month	03	15%	05	25 %	08	20 %	
8-10 month	04	20%	01	5%	05	12.5%	
>10 months	08	40%	07	35 %	15	37.5%	

Data related to Periodical changes in Pain during treatment:

Period		(Group A				Gr	oup B		
G	G3	G2	G1	G0	%	G3	G2	G1	G0	%
Before treatment	6	9	5	0	-	6	10	4	0	-
At the end of 1st week	3	12	4	1	5%	0	16	4	0	-
At the end of 2 rd week	0	10	9	1	5%	0	13	4	3	15%
At the end of 3rd week	0	6	11	3	15%	0	6	9	5	25%
At the end of 4th week	0	5	10	5	25%	0	2	8	10	50%

Data related to Periodical changes in Smell during treatment:

Period		Group A		Group B			
renod	G1	G0	%	G1	G0	%	
Before treatment	17	03	-	17	03	-	
At the end of 1st week	15	05	25%	11	09	45%	
At the end of 2nd week	12	08	40%	08	12	60%	
At the end of 3rd week	07	13	65%	04	16	80%	
At the end of 4th week	02	18	90%	00	20	100%	

Data related to Periodical changes in Discharge during treatment:

Period	Group A					Group B				
renou	G3	G2	G1	G0	%	G3	G2	G1	G0	%
Before treatment	04	10	06	00	,	04	11	05	00	1
At the end of 1st week	02	10	08	00	-	0	13	07	00	-
At the end of 2 nd week	00	09	09	02	10%	0	11	07	02	10%
At the end of 3rd week	00	09	07	04	20%	0	08	10	05	25%
At the end of 4th week	00	05	10	05	25%	0	02	10	08	40%

Data related to Periodical changes in Size of Ulcer during treatment:

Period	Group A					Group B				
renou	G3	G2	G1	G0	%	G3	G2	G1	G0	%
Before treatment	02	15	03	00	-	03	15	02	00	-
At the end of 1st week	02	15	03	00	-	03	15	01	01	5%
At the end of 2 nd week	02	15	02	01	5%	02	15	02	02	10%
At the end of 3 rd week	02	08	07	03	15%	01	08	10	05	25%
At the end of 4th week	00	05	11	04	20%	00	02	10	06	30 %

Data related to Periodical changes in Granulation tissue during treatment

Period	Group A					Group B				
renou	G3	G2	G1	G0	%	G3	G2	G1	G0	%
Before treatment	04	06	10	00	-	04	09	07	00	-
At the end of 1st week	02	10	08	00	-	00	12	08	01	5%
At the end of 2 nd week	02	08	08	02	10%	00	11	07	02	10%
At the end of 3 rd week	01	08	08	03	15%	01	09	06	05	25%
At the end of 4th week	00	05	08	07	20%	00	03	08	09	45%

Data related to Periodical changes in Surrounding skin in both the groups

Period		Group A		Group B			
renou	G1	G0	%	G1	G0	%	
Before treatment	19	01	-	18	02	-	
At the end of 1st week	19	01	-	16	04	10%	
At the end of 2 rd week	19	01	-	13	07	35%	
At the end of 3rd week	18	02	10%	11	09	45 %	
At the end of 4th week	17	03	15%	09	11	55 %	

Table showing observation of changes in Pain after the completion of treatment in both

Grade	Group A	%	Group B	%	Total	0/ /0
Grade - 0	04	20%	10	50%	14	35%
Grade -1	08	40%	08	40%	16	40%
Grade -2	08	40%	02	10%	10	25%
Grade-3	-	-	-	-	-	-

Table showing observation of changes in Smell after the completion of treatment in both the groups:

Grade	Group A	%	Group B	%	Total	%
Grade - 0	18	90%	20	100%	38	95%
Grade -1	02	10%	00	х	02	5%

Table showing observation of changes in Discharge after the completion of treatment in both the groups.

Grade	Group A	%	Group B	%	Total	%
Grade - 0	05	25%	6	30%	11	27.5%
Grade -1	10	50%	12	60%	22	55%
Grade -2	05	25%	02	10%	07	17.5%
Grade-3	-	-	~	-	-	-

Table showing observation of changes in Size of ulcer after the completion of treatment in both the groups

Grade	Group A	%	Group B	%	Total	%
Grade - 0	04	20%	06	30%	10	25%
Grade -1	03	15%	02	10%	05	12.5%
Grade -2	12	60%	12	60%	24	17.5%
Grade-3	-	-	-	-	-	-

Table showing observation of changes in Granulation tissue after the completion of treatment in both the groups

Grade	Group A	%	Group B	%	Total	% %
Grade - 0	10	50%	11	55 %	21	52.5%
Grade -1	06	30%	07	35%	13	32.5%
Grade -2	03	15%	03	15 %	06	15%
Grade-3	-	-	-	-	-	-

Table showing observation of changes in surrounding skin after the completion of treatment in both the groups:

Grade	Group A	%	Group B	%	Total	%
Grade - 0	11	55%	16	80%	27	67.5%
Grade -1	09	45%	04	20%	13	32.5%

Table showing Overall assessment of treatment in both the groups:

Grade	Group A	nv 70	Group B	%	Total	%
Good Response	04	20%	10	50%	14	35%
Moderate	06	30%	06	30%	12	30%
Response						
Poor Response	10	50%	04	20%	14	35%

Table showing the comparison of changes in parameters within the study in both the groups:

	't' Test	
Parameters	Group A	Group B
Pain	2.447	6.505
Smell	7.015	10.37
Discharge	4.250	5.219
Size of the ulcer	1.964	2.758
Granulation tissue	4.471	5.741
Colour of Surrounding skin	1.436	3.378

Adhakaya is more susceptible to vrana in Madhumeha a consequence of pidaka, as there is srotodaurbaly leading to vimargagamana of rasayani & then to sanga – acting as sthankika shalya. Thus it is evident from the foot problems ranging from cellulitis to ulcer and den gangrene are more seen in lower extremities of a diabetic. These foot ulcers, a complication affecting approximately 15% of people with diabetes.

Factors like, savishatva, gambhira, krimibhakshana, sirakleda, deergakalanubandha, kshobha, apathya, vyadhikarshana & such other factors makes prognosis in vrana in Madhumehi is kashta/yapya. On the same grounds modern surgeons opine reasons for wound healing deficits are – increased blood sugar impairing blood flow & thus release of oxygen, protein malnutrition, decreased collagen synthesis, impaired local immunity and cell defenses, decreased

anabolic activity with decreased insulin & growth hormone.

Vascular Insufficiency and Peripheral neuropathy are the most common risk factors for developing foot ulcers. Peripheral vascular disease is two to four times more common in patients with diabetes than in those without diabetes. Thus patient experiences acute pain if pathology is vascular & altered sensorium/loss of sensation in neurological pathology. These features are well appreciated in Vataja & Vataraktaja Dushta vrana presenting with either extremes of local sensation with involvement of Rakta dhatu.

It is likely that many of the serious problems associated with cause & resolution of wounds in the diabetic patient are due to the persistent elevated blood glucose and its effects. Control of blood glucose over the years will reduce the incidence of these wound complications and the wound healing deficits. Maintenance of blood sugar level is very much important to keep under control long standing microvascular and macrovascular problem.

Persons who have cognitive impairement/restricted mobility or both are at risk for pressure ulcers. Pressure is the primary pathophysiologic factor causing skin injury in typical ulcer locations in diabetic ulcers. For the purpose of easy analysis, foot is divided into Rear foot, Mid foot and Fore foot, keeping bony landmarks of foot.

The Treatment Aspect

For the present study, comparative efficacy of Jalaukavacharana with Magadhyadi taila application has been taken. As it is being told by Sushruta to treat the vrana in Madhumehi by using Dushtavrana chikitsa sutra. Dushtavrana chikitsa includes urdhwa, adha shodhana, vishoshana ahara and Raktamokshana. Thus in the present study, Ashastra type of Raktamokshana, ie Jalaukavacharana was undertaken. Jalauka, one of the easiest means of Raktamokshana can be made use for different age group of persons, who has low threshold of pain.

Anti-inflammatory, analgesic & antihistamine properties of leech saliva helps in reducing local inflammation & tension. Volume 3 Number 2, April-June 2010

And Hirudin, anticlotting factor corrects the underlying microvascular pathology, which is impaired microcirculation in non-healing ulcers.

As Raktamokshana does local shodhana, in order to heal a vrana, ropana measures were needed. In this regard Magadhyadi taila, from Gadanigraha has been taken in this study. For ropana purpose, Sushruta advocates taila for vrana in Madhumeha. Dalhana commenting on this, as taila one among Saptakalpana & it is being vatahara which is the main dosha in Madhumeha.

Magadhyadi taila contains Lekhaniya dravyas like Kushta, Haridra, Daruharidra, Ropana dravyas like Yashti, Manjishta, Sarja, Priyangu, Madhucchishta, Shodhana dravyas like Pippali, Yashti, Harenu, Haridra & dravyas which have twak prasadana properties. Vrana in Madhumeha considered as Dushtavrana needs lekhana, shodhana to make it shuddha, so that vrana heals in due course of time. So in this view, Magadhyadi taila was chosen for the present study which has lekhana, shodhana, ropana and twak prasadana properties.

On assessing the overall response of the treatment, Group A had 4 patients with good response, 6 with moderate response and 10 with poor response which was insignificant statistically, when compared to Group B, with 10 patient having good response, 6 with moderate response and 4 with poor response.

In Group B, results are highly significant, attributed which can be to Raktamokshana with Jalauka which is having additional benefits like improving local circulation, clearing venous stasis, antiinflammatory, analgesic, fibrinolytic and neovasculogenesis properties. Thus, result can be more effective and cutting down the study period by faster healing rate. Along with systemic medication, controlling of blood sugar level along with topical medication having lekhana, shodhana & ropana is needed.

In Group A result is significant which can be attributed to, keeping blood sugar level under control with previously prescribedoral antidiabetic drugs, local hygiene and only topical application of Magadhyadi taila with ingredients like Magadhi, Madhuka, Lodhra, Kushta, Sarjarasa etc which are having lekhana, shodhana & ropana action, but not counteracting underlying pathology, with comparatively long duration of action.

Thus, it can be concluded that twak prasadana, shonita prasadana effect of Raktamokshana helps in bringing about change/correction needed to correct the pathology in Vrana in Madhumehi.

CONCLUSION

Comparative clinical study was carried out to evaluate the efficacy of Jalaukavacharana and Magadhyadi taia in the management of Vrana in Madhumehi. The following conclusions were drawn after studying observation, results and discussions.

- 1. Vrana in Madhumehi can be considered as a Dushtavrana. It should be treated with atmost care as there is threat to limb or life if neglected.
- 2. Vrana in Madhumehi should be treated in line with Chikitsa sutra of Dushtavrana.
- 3. Incidence of complications of Diabetes Mellitus is more as it becomes chronic & foot problems dominate others, due to affliction of Nervous & Circulatory system.
- 4. Proper glycemic & food control, a must to facilitate early healing of Vrana in Madhumeha along with local treatment.
- 5. Among two different modalities of treatment which were taken for the present study significant results were observed in Group B consists of Jalaukavacharana and Magadhyadi taila application when compared with Group A wherein only Magadhyadi taila application is done.
- 6. Jalauka, being one of simplest & easiest means of Raktamokshana is not only useful in bloodletting but also helps in improving local tissue nutrition and to correct underlying pathology.

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