



EVALUATION OF THE EFFICACY OF AVACHURNANA UPAKRAMA BY RAJANI DWAYA ON DUSHTA VRANA W.S.R. TO DIABETIC FOOT ULCER

1. Dr Santosh Naik*, 2. Dr Jyothi T 3. Dr Girish Danappagoudar *****

* HOD & Associate Professor, Department of Shalyatantra,

**Associate Professor, Dept. of Shareera Rachana,

***HOD, Professor, Dept. of Rasashastra,

Shri VeeraPulikeshi Rural Ayurvedic Medical college, Hospital and Research Centre, Badami, Karnataka-587201

ABSTRACT:

Diabetic foot ulcer is a common burning problem in the society and one of the major complication requiring amputation of the limb. The number of Patients suffering from Diabetes Mellitus is on rise, approximately 30- 35% of total population is getting affected. Foot ulcer is a complication affecting approximately 15% of people with Diabetes. Rajani dwaya Avachurna is taken up for this study. Rajani and Daruharidra has the property of vrana shodana, vrana ropana, krimighna, vishaghna etc and the overall efficacy is compared with Kaseesadi churna avachurnana which is already established. In this study, 40 patients of Dushta Vrana w.s.r to Diabetic foot ulcer were randomly selected and assigned in to two groups of 20 Patients each . Group-A as Trail group, was treated by Avachurnana with Rajani dwaya churna for Thirty days and Group-B , as Control group was treated with Kaseesadi Avachurnana for same duration. It was observed that Rajani dwaya Avachurnana group had better effect in reliving the Discharge ,when compared to Kaseesadi churna. Where as in rest of parameters like Pain, Numbness, Foul smell, Size and Floor of ulcer, Kaseesadi churna fared better. No untoward effect was noticed during the study period.

KEY WORDS: *Dushta Vrana, Rajani Dwaya, Diabetic Foot Ulcer*

INTRODUCTION:

Vrana means break in continuity in any of bodily dhatus¹. Various classification of Vrana are described depending on different criteria, one among which being prognosis / Sadhyasadhyata. Under Yanya & Kashtasadhyva vrana, there is mention of Vrana in Madhumehi. Madhumehaja vrana can be considered as Dushtavrana, as it takes long duration to heal because of its association with disease Madhumeha and certain sthanika karanas like kleda, visha.

Diabetic foot ulcer is a common burning problem in the society and one of the major complication requiring amputation of the limb. Diabetes mellitus is a complex metabolic disorder hence the defects observed in delayed Diabetic wound healing are thought to be the result of altered protein and lipid metabolism and thereby abnormal granulation tissue formation. Diabetic ulcer is caused due to injury to the glucose laden tissue and may follow chronic infection. Ulceration in Diabetes may be precipitated by ischemia due to atherosclerosis, Infection or Peripheral neuropathy or a combination of all these factors².

The number of Patients suffering from Diabetes Mellitus is on rise, approximately 30- 35% of total population is getting affected. Foot ulcer is a complication affecting approximately 15% of people with Diabetes. Current treatment modalities for Diabetic foot ulcers include conservative and surgical intervention. Medical management includes oral and topical application which comprises antibiotics, protein analogues growth factors, moist wound therapy etc. These have drawbacks like toxicity, gastric irritation and more over causes depression of body's general immunity. Surgical intervention comprises of extra cellular matrix replacement therapy, bio-engineered tissue or skin substitute and negative pressure wound therapy. This intervention has failure rates due to reasons like occasional rejection by the body due to histo-incompatibility, wound contraction, fluid retention and is supposed to be expensive³.

So there is a need for Holistic management which directs towards cleansing of ulcer, early healing, with histo-compatibility & least complications. In the management of vrana, Sushruta has explained about 60 upakramas. Among them Avachurnana⁴ method of vrana management is one and **Rajani dwaya Avachurna** is taken up for this study. Rajani⁵ and Daruharidra⁶ has the property of vrana shodana, vrana ropana, krimighna, vishaghna etc and the overall efficacy is compared with Kaseesadi churna⁷ avachurnana which is already established. Moreover Rajani Dwaya being one of the constituents of Kaseesadi churna, this study is been taken up to see the efficacy with regards to minimal drugs, cost effectiveness and easy availability.

OBJECTIVES OF THE STUDY

- To evaluate the efficacy of Rajani dwaya avachurnana in the management of Diabetic foot Ulcer .
- To evaluate the efficacy of Kaseesadi Churna avachurnana in the management of Diabetic foot Ulcer.
- To compare the results of both the groups to ascertain the efficacy of Rajani Dwaya in comparison to Kaseesadi churna.

MATERIALS AND METHODS

Source of Data:

Patients with features of Diabetic foot ulcer were selected from Out Patient and In Patient Department of S.J.I.I.M Hospital Bangalore.

Method of Collection of Data:

Clinically diagnosed 40 Patients of Diabetic foot ulcer presenting with the features of ulcer on the foot with pain, numbness, discharge and foul smell were randomly assigned into two groups with 20 patients each as Group A and Group B.

Group A: The patients under this group were subjected to Avachurnana karma with *Rajanidwaya* churna, once a day for 30 days.

Group B: The patients under this group were subjected to Avachurnana karma with *Kaseesadi* churna, once a day for 30 days.

a) Inclusion Criteria:

- Ulcers of diabetic foot with grade 1 of Wagner's classification of ulcers. (Grade 1 – Superficial ulcers involving full skin thickness)
- Patients with features of ulcer on the foot with pain, numbness, discharge and foul smell.
- Diabetic Patients with well controlled Diabetes mellitus status.

b) Exclusion criteria :

- As per Wagner classification, Ulcers of diabetic foot with Grade 2 to Grade 5.
- Patients with disorders like Malignancy, Tuberculosis, Leprosy and any other systemic disorders.
- Leg ulcers due to any other cause other than Diabetes mellitus.

Wagner's classification :

Grade 0-No risk in a high risk foot

Grade 1-superficial ulcers involving full skin thickness but not underlying tissue

Grade 2-Deep ulcers,penetrating down to ligaments and muscle but no bone involvement

Grade 3- Deep ulcers with cellulitis or abscess formation often with osteomyelitis

Grade 4- Localized gangrene

Grade 5- Extensive Gangrene involving the whole foot.

Treatment procedure:

Group A :

Poorva Karma:

- Consent was taken.
- Things essential for the procedure were kept ready.
- Patient was made to sit / lie down comfortably.
- The affected part was cleaned with Normal saline, debridement was done where ever necessary and again ulcer was cleaned with normal saline and part dried.

Pradhana Karma :

After cleaning the part and drying it thoroughly, Avachurnana of *Rajani dwaya* churna was done once daily, preferably in the morning, over the entire surface of floor of ulcer. A sterile gauze sprinkled with the same powder was placed over the ulcer. The procedure was done until the ulcer heals completely or for a stipulated period of 30 days.

Paschat Karma:

After avachurnana karma , the affected part was covered with sterile pad and bandaging was done .

Group B :

Poorva Karma:

- Consent was taken.
- Things essential for the procedure were kept ready.
- Patient was made to sit / lie down comfortably.
- The affected part was cleaned with Normal saline, debridement was done where ever necessary and again ulcer was cleaned with normal saline and part dried.

Pradhana Karma :

After cleaning the part and thoroughly dried, Avachurnana of *Kaseesadi* churna was done once daily, preferably during morning, over the entire surface of floor of ulcer. A sterile gauze sprinkled with the same powder was placed over the ulcer. The procedure was done until the ulcer heals completely or for a stipulated period of 30 days

Paschat Karma: After Avachurnana karma, the affected part was covered with sterile pad and bandaging was done.

Observation & Assessment:

The patients of both the groups were observed daily during dressing. The changes in the parameters were observed on 1st, 11th, 21st and 31st day of treatment and the same was recorded in the proforma of case sheet prepared.

Parameters for the study:

Subjective parameters -

1. Pain

0 – Absent.

1 – present.

2. Numbness

0 – Absent.

1 – present.

Objective parameters -

1. Foul Smell

Grade 0 – Absent.

Grade 1 – present.

2. Discharge :

Grade 0 – Absent.

Grade 1 – present.

3. Size of the ulcer [measured in sq. cms]

0) Completely healed

1) 1 to 3 sq.cms.

2) 3 to 5 sq.cms.

3) 5 sq.cms & above.

4. Floor

Grade 0 – Completely healed.

Grade 1 – Evenly distributed healthy granulation tissue.

Grade 2 – Evenly distributed pale granulation tissue.

Grade 3 - No granulation tissue and with slough.

RESULTS:

Pain	BT	11 th day	21 st day	31 st (AT)	% change	P value
RAJANI DWAYA GROUP (n=20)						
Absent	4(20%)	4(20%)	6(30%)	9(45%)	+25.0	
Present	16(80%)	16(80%)	14(70%)	11(55%)	-25.0	
KASEESADI GROUP(n=20)						
Absent	2(10%)	2(10%)	3(15%)	8(40%)	+30	0.025*
Present	18(90%)	18(90%)	17(85%)	12(60%)	-30	
P value	0.661	0.661	0.451	1.000	-	-

Numbness	BT	11th day	21st day	31st (AT)	% change	P value
RAJANI DWAYA GROUP (n=20)						
Absent	2(10%)	5(25%)	7(35%)	9(45%)	+35.0	
Present	18(90%)	15(75%)	13(65%)	11(55%)	-35.0	
KASEESADI GROUP (n=20)						
Absent	3(15%)	7(35%)	11(55%)	11(55%)	+40.0	
Present	17(85%)	13(65%)	9(45%)	9(45%)	-40.0	
P value	1.000	0.490	0.204	0.527	-	-

Foul smell	BT	11th day	21st day	31st (AT)	% change	P value
RAJANI DWAYA GROUP (n=20)						
Absent	0(0%)	5(25%)	8(40%)	12(60%)	+60.0	
Present	20(100%)	15(75%)	12(60%)	8(40%)	-60.0	
KASEESADI GROUP (n=20)						
Absent	0(0%)	6(30%)	8(40%)	13(65%)	+65.0	
Present	20(100%)	14(70%)	12(60%)	7(35%)	-65.0	
P value	1.000	0.723	1.000	0.744	-	-

Discharge	BT	11th day	21st day	31st (AT)	% change	P value
RAJANI DWAYA GROUP (n=20)						
Absent	0(0%)	7(35%)	14(70%)	17(85%)	+85.0	
Present	20(100%)	13(65%)	6(30%)	3(15%)	-85.0	
KASEESADI GROUP (n=20)						
Absent	0(0%)	8(40%)	12(60%)	15(75%)	+75.0	
Present	20(100%)	12(60%)	8(40%)	5(25%)	-75.0	
P value	1.000	0.744	0.507	0.696	-	-

Size of Ulcer	BT	11th day	21st day	31st (AT)	% change	P value
RAJANI DWAYA GROUP (n=20)						
0	0(0%)	0(0%)	3(15%)	6(30%)	+30.0	0.005**
I	5(25%)	7(35%)	6(30%)	8(40%)	+15.0	0.204
II	11(55%)	10(50%)	9(45%)	4(20%)	-35.0	0.031*
III	4(20%)	3(15%)	2(10%)	2(10%)	-10.0	0.206
KASEESADI GROUP (n=20)						
0	0(0%)	0(0%)	3(15%)	7(35%)	+35.0	0.002**
I	5(25%)	7(35%)	7(35%)	8(40%)	+15.0	0.204

II	10(50%)	9(45%)	8(40%)	3(15%)	-35.0	0.022*
III	5(25%)	4(20%)	2(10%)	2(10%)	-15.0	0.128
P value	1.000	1.000	1.000	1.000	-	-

Floor of Ulcer	BT	11 th day	21 st day	31 st (AT)	% change	P value
RAJANI DWAYA GROUP (n=20)						
0	0(0%)	0(0%)	4(20%)	6(30%)	+30.0	0.005**
I	1(5%)	3(15%)	7(35%)	6(30%)	+35.0	0.006**
II	2(10%)	7(35%)	4(20%)	8(40%)	+20.0	0.076+
III	17(85%)	10(50%)	5(25%)	0(0%)	-85.0	<0.001**
KASEESADI GROUP (n=20)						
0	0(0%)	0(0%)	4(20%)	7(35.0%)	+35.0	0.005**
I	2(10%)	3(15%)	6(30%)	8(40%)	+30.0	0.025*
II	2(10%)	5(25%)	5(25%)	5(20%)	+15.0	0.076+
III	16(80%)	12(60%)	5(25%)	0(0%)	-80.0	<0.001**
P value	1.000	0.905	1.000	1.000	-	-

Overall response	RAJANI DWAYA GROUP (n=20)	KASEESADI GROUP (n=20)
Poor response	0	0
Mild response	3(15.0%)	1(5.0%)
Moderate response	10(50.0%)	11(55.0%)
Marked response	7(35.0%)	8(40.0%)

There was no comparative significant statistical change with respect to reliving of pain in both groups with p value 1.000. In Group A the result was 25% where as in Group B its 30%. The percentage of improvement i.e. 5% better in group B than group A. It may be due to shoolahara quality of vacha and vata shamak property of saindava lavana.

There was no comparative significant statistical change with respect to relief of Numbness in both groups, with p value 1.000. There is 5% better improvement in group B than group A.

There was no comparative significant statistical change with respect to relieving of Foul smell in both groups with p value 0.744. But clinically there was significant outcome i.e. 60% in group A and 65% in group B. It may be due to drugs like Haridra, Vacha and Kaseesa possesin qualities like krimighna and shoshana.

There was no comparative significant statistical change with respect to relieving of Discharge in both groups with p value 0.692. But clinically there was significant outcome i.e. 85% in group A and 75% in group B. The percentage of improvement i.e. 10% better in group A than group B.

There were no comparative significant statistical changes with respect to size of ulcer in both groups with p value 1.000. But clinically there was significant outcome i.e. 30 % in group A and 35% in group B. The percentage of improvement i.e. 5% better in group A than group B. Ulcer size doesn't have early outcome as healing of ulcer depends on infection, ischemia, neuropathy, uncontrolled glucose level and immune compromised state in DM. Less result can be attributed to chronic nature of ulcer which is callus and seen on pressure points which is devoid of rest.

There was no comparative significant statistical change with respect to Floor of ulcer in both groups with p value 1.000. But clinically there was significant outcome i.e.30 % in group A and 35% in group B. The percentage of improvement i.e. 5% better in group B than group A. It may be due to presence of kaseesa, vacha and saindav which helps in clearing the slough, controlling infection, thus helping in growth of healthy granulation tissue.

DISCUSSION:

The Statistical outcome of the clinical study shows that Overall response is statistically similar in two groups studied with P=0.802. wherein out of 6 parameters considered for the study in both the group, 4 parameters showed highly significant results, whereas in 2 parameters like pain and numbness showed minimal significant results. This may be due to the underlying pathology i.e peripheral neuropathy and vascular disorder, which require additional treatment with considerable duration of time.

Probable Mode Of Action

Rajani Dwaya Churna by its Lekhana, Shoolahara, Amapachana, Kapha Vata Shamana, Kledashoshaka, Sthambhana, Jantughna, Varnya property checks the Vrana Varna, Vedana, Gandha, Srava, and removes the slough in the Vrana. These drugs also have Ushna Veerya, and probably it stimulates the proliferation of healthy granulation tissue.

Due to the lekhana guna it debrides the slough and unhealthy granulation tissue, The shoolahara guna passifies the pain, due to amapachana the local unprocessed metabolites are cleared and there by increases the local blood circulation. Due to kapha-vata shamaka. Ruksha and kledashoshana guna it cleares the secretion and local infection. The jantugna property takes care of infection.

On the basis of different Research analysis done over the ingredients separately, Rajani dwaya Churna it is proved to have Antisepic, Antibacterial, Anti inflammatory, prostaglandin inhibitor, Antihistaminic and Antimicrobial Properties.

Due to the alkaloid Curcumin in haridra, platelet aggregation and vascular prostacyclin synthesis, healing capacity of ulcer will be increased as it's a good vasodilator.

Bereberine in Daruharidra acts on acute , subacute and chronic models of inflammation- thus has an anti inflammatory property.

Kaseesadi churna-

This yoga has tikta, kashaya, katu rasa, Ushna virya, and kapha pitta shamaka, shoolahara, vrana ropaka properties. Tikta rasa present in Kaseesadi churna does the lekhana(scraping/removal of slough). Kashaya rasa does the shoshana(dries up the secretion). Snigdha guna in kaseesa and saindav helps in reducing the burning ssensation. And can induce new cell growth (epithelialisation).

Vacha will suppress inflammation significantly and it also act as antimicrobial, antipyretic and analgesic. Due to shooksma guna of saindav lavana which helps in better penetration and absorbtion of the drug.

CONCLUSION:

The Avachurnana of Rajani dwaya Churna on the Diabetic foot ulcer has provided significant relief of 30% in Pain, 35% in Numbness, 85% in Discharge, 60% in Foul smell, 30 % in size of ulcer, and 30% in bringing up the granulation tissue.

It was observed that Rajani dwaya Avachurnana group had better effect in reliving the Discharge ,when compared to Kaseesadi churna. Where as in rest of parameters like Pain, Numbness, Foul smell, Size and Floor of ulcer, Kaseesadi churna fared better.

REFERENCES:

1. Sushruta. Susruta Samhita-Text, English Translation, Notes, Appendices and Index, translated by Prof. K. R. Srikantha Murthy. 2nd ed. Varanasi: Chaukhamba Orientalia; 2005. Vol. II, pp. 516.
2. Martin, P. Wound healing aiming for perfect skin degeneration. 1997. Science 276, 75–81
3. Russel RCG, William NS, Bulstrode CJK, editors. Bailey and Love's short practice of surgery. 24th ed. London: Arnold; 2004. pp. 1522
4. Sushruta. Susruta Samhita-Text, English Translation, Notes, Appendices and Index, Translated by Prof. K. R. Srikantha Murthy. 2nd ed. Varanasi: Chaukhamba Orientalia; 2004. Vol. I, pp. 656.
5. Bhavamishra, Bhavprakash Niganthu- commentary by K.C.Chunekar; edited by Dr. G.S. Pandey. Varanasi: Chaukhamba Bharati Academy; 2006. pp. 984.
6. Kashiraj. Dhanvantari Niganthu- by P.V.Sharma. Translated by Dr. Guruprasad Sharma. 3rd ed. Ayurveda Granth Mala; 2002. pp. 358.
7. Sushruta. Susruta Samhita-Text, English Translated by Prof. K. R. Srikantha Murthy. 37th chapter, shloka 19, 2nd ed. Varanasi: Chaukhamba Orientalia; 2004. Vol. I, pp. 262

