Evaluation of the Effect of Local Application of Kalpit Kasisadi Yogain the Managementof Ksharasutra Induced Hyper Granulation at External Opening Offistula-in-Ano: A Randomized Controlled Trial

Prafulla Fadanvis[1], Rashmi Gurao[2], Dhiraj Zade[3], Sonali Wairagade[3], Vasant Gawande[4], Pradip Adhav[5]

[1]Associate Professor, Dept. of Shalya Tantra, DMAMCH & RC, Wanadongri Nagpur, [2]Ph.D (N.I.A), Associate Prof., Dept of Sharir Kriya Mahaveer College of Ayurvedic Science, Rajnandgaon (C.G.), [3]Associate Professor, Dept. of Dravya Guna, DMAMCH & RC, Wanadongri Nagpur, [4]Associate Professor Dept. Of Orthopedics Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Wardha, [5]Associate Professor, Dept. of Shalya Tantra, BMAC & RH, Butibori

Abstract

Background: The *Ksharsutra* therapy is most fascinated para surgical process for fistula–in–ano. But during the procedure hyper granulations are typically seen near the external opening of fistula which may bleed or get infected if remain untreated. Moreover it may obliterate the pus drainage and thus complicate the wound. This consequence needs to be addressed. In *Sushrut Samhita*, raised soft tissues of wound is described as *Utsanna Mrudu Vrana Maansa* and specified to be treated by "*Avasadana Dravya*" with honey.

Aim: To evaluate the effect of LA of *Kalpit Kasisadi Yoga* with *Madhu*in management of hyper granulation, found at external opening of fistula-in-ano during its treatment with *Ksharsutra*.

Material and Method: 60 operated cases of fistula-in-ano with *Ksharsutra*, presenting with hyper granulation at the external opening of fistulous tract were randomly selected and divided into two groups.

Observation: The comparison between both the group indicates that effect of the therapy was very significant on thickness while insignificant result was obtained in area of hyper granulation. However the percentage of relief in both the criteria's in experimental group was above 90%.

Result: The LA of *Kalpit Kasisadi Yoga* in the management of *Ksharasutra* induced hyper granulation at external opening of fistula-in-ano is more effective than LA of *Madhu* alone.

Keywords: *Hyper granulation, Ksharsutra, Utsanna Mrudu Vrana Maansa, Avasadana Dravya.*

Introduction

Ayurveda classics at various places have emphasized on taking care of wounds which occur either as a result of vitiated *Doshas* or due to traumatic origin. In fact a detailed protocol to address various types of wound & their complications is illustrated in *Samhitas* for the management of wound. Being prime topic of the subject *Acharya Sushruta* has described 60 measures[1] in the management of *Vrana*in addition to its indication, contra indication and limitation while *Aacharya Charaka* has described 36measures.[2] These measures deal with each and every aspects of *Vrana* according to its type, condition and stages of healing.

In modern science wound healing has been

Corresponding Author:
Dr. Prafulla Fadanvis
Associate Professor, Dept. of Shalya Tantra,
DMAMCH & RC, Wanadongri Nagpur
e-mail: prafulls26@gmail.com
Mobile No.: 9860460984

described to be completed in 4 stages viz. inflammation, wound contraction, epithelialization and granulation tissue formation followed by scar formation which comprises various pathophysiological stages in itself. In normal circumstances wound heals through these stages, however hyper granulation tissue formation is an unusual event in wound healing.

Hyper granulation is said when granulation tissue grows above the level of wound edges. The presence of this tissue results in inhibition of fibroblast proliferation and prevents wound healing. The treatment consists of destruction of tissue by cautery, shave excision, aluminium chloride, copper sulphate or curettage. But the fact is that these hyper granulation tissue still remain there as a clinical problem.[3],[4]

Fistula-in-ano is itself a complicated wound, with muco-purulent discharge from its external opening. The incidence of a fistula–in–ano developing from an anal abscess ranges from 26% to 38%.[5]According to *Aacharya Sushruta,Vranathat* discharges pus, blood and mucous etc. are referred as *Kruchhraasadhya Vrana.*[6] That is why *Bhagandara*has been incorporated in *Ashtaumahagada* i.e. diseases with poor recovery rate.

Ksharsutra is a widely accepted line of treatment in fistula-in-ano which is designated as *Bhagandara* in ayurvedic texts. During the course of treatment it has been observed that many patients presented with hyper granulation tissue at the external opening of fistula- in-ano. This hyper granulation tissue delays the healing of fistulous tract.

In *Sushrut Samhita*, raised soft tissues of wound i.e. hyper granulation tissue is described as *Utsanna Mrudu Vrana Maansa* and advised to be treated by "*Avasadana Dravya*" with honey.[7]*Avasadana* denotes suppression of the soft tissue eruptions i.e. *Utsanna MruduMaansa*. '*Avasadaneitimaansasfotane'* - Dalhan

AvasadanaKarma is described by all the three acharyas *Sushrut* (Su.Chi. 1/83)*, Charak* (Ch. Chi. 25/39-43) and *Vagbhat*(A.H. Ut. 25/48) in management of *Vrana*. Various drugs are stated for *Avasadana Karma* in *Samhitas*[8] but on the basis of availability, following drugs were selected.

1) *Kasis* 2) *Saindhav* 3) *Kukkutand Twak Bhasma* 4) *Jatikalika* 5) *Karanj*

The above drugs were identified, obtained in purified form and were grinded to fine powder. Each drug of compound was mixed homogeneously in equal proportion. The prepared compound was stored in sterilized glass bottle. As the compound is not directly mentioned in the Ayurvedic classics and the first drug being *Kasis,*the drug of trial is designated as *Kalpit Kasisadi Yoga,* to be applied with *Madhu*. In Control Group only *Madhu*was used.

Hence the present research work is designed to assess the *Avasadana Karma* of the *Kalpit Kasisadi Yoga*in the management of *Ksharasutra* induced hyper granulation at external opening of fistula-in-ano in this trial.

Aims and Objectives:

- To study the effect of local application of *Kalpit Kasisadi Yoga* with *Madhu*in management of hyper granulation found at external opening of fistula-in-ano during its treatment with *Ksharsutra*.
- To compare the effect of local application of *Kalpit Kasisadi Yoga* and *Madhu* with local application of *Madhu*alonein management of hyper granulation found at external opening of fistula-in-ano during its treatment with *Ksharsutra*.

Material and Method

In this clinical trial, 60 operated cases of fistula-in-ano with Ksharsutra, presenting with hyper granulation at the external opening of fistulous tractwere randomly selected from OPD & IPD of Shalya Tantra Department of study center. The special research proforma was prepared for diagnosis and assessment of hypergranulation at external opening of fistula- in-ano.

Informed written consent was taken from all the patients included in this study. The patients were numbered from 1 to 60. The patients with odd numbers were selected in Group A. The patients with even numbers were selected in Group B.

Group A: Experimental Group–30 patients were treated with local application of *Kalpit Kasisadi Yoga* with *Madhu* OD for 10 days.

Group B: Control Group – 30 patients were treated with local application of only *Madhu* OD for 10 days.

Follow up of the patients was taken at 3rd, 7th and 10th day.

Criteria for Selection:

- Inclusion Criteria

1. Patient presenting with signs of hyper granulation at external opening of fistula-in-ano during the *Ksharsutra* therapy, irrespective of the length of the fistula tract.
2. Age of patients: 20 – 60 years.
3. Sex:- Both male and female of caste & religion.

- **Exclusion Criteria**

1. Patients suffering from uncontrolled diabetes, uncontrolled hypertension, tuberculosis, HIV, CA-Rectum, any malignancy in other parts of body.
2. Patients who had discontinued the treatment during follow up and patients who had developed any serious complications were dropped out from the study.

Criteria for Assessment: The assessment of the hyper granulation tissue was done on the basis of their dimensions. The dimensions were recorded before, during and after the treatment. The dimensions of hyper granulation were measured every time before applying the drug on subsequent follow-up day.

1. The length & width of the hyper granulation tissue was be measured by disposable millimeter ruler. Longest axis of tissue was recorded as length and width as the longest dimension perpendicular to length in the same plane. The area of hyper granulation tissue was calculated by Kundin's equation.[9]

This equation is to calculate the area of irregular surface.

$A_{kun} = L \times W \times 0.785\ mm^2$

2. The thickness of hyper granulation was measured by millimeter ruler. Thickness of hyper granulation tissue was its growth above the skin surface. The millimeter ruler was cut at its initial marking so to record thickness accurately. (As measured in mm, more than ½ mm was counted as 1mm and less than ½ mm was counted as 0.)

The area and thickness was measured in subsequent follow up rounds and after treatment.

Statistical Analysis:

- All the calculations were calculated through 'Graph Pad Instat' Software.
- **Paired't' test-**It was used for within the group assessment.
- **Unpaired "t" test-** It was used for comparison in Group 'A' and 'B'.

Observations:

1. Maximum patients of hyper granulation in the study were of age group 40 – 60 years in both the groups-

- Gr. A – 70%
- Gr. B – 60%.

2. In experimental group out of 30 patients 80 % patients were male and 20 % were female,In control group 56.67 % were male and 43.33 % patients were female.
3. Maximum patients in both the groups were Hindu as the trial was conducted in the Hindu dominated area.
4. Maximum patients in both the groups belonged to lower middle class category.
5. In both the groups, 70% patients were having mixed dietary habits.
6. In Group A patients 36.67% were having sedentary and 63.33% patients were active type of work. In control group 43.33% patients were of sedentary work and 56.67% patients were having active type of work.
7. In this study the data shows that in group A 10% patients were habitual alcoholic, 23.33% were smokers, 16.67% Tobacco chewing and 50% were of no habits, while in group B 13.33% patients were habitual alcoholic, 6.67% smokers, 16.67% of Tobacco chewing and 63.33% were not having any habits.

Table No. 1: Statistical Analysis of Area of Hyper Granulation Tissue In Group A & Group B (mm^2)

Area	N	Mean		% of relief	SD	SE	't' value	P value	Result
		BT	AT						
Group A	30	11.62	0.16	98.62	8.01	1.46	7.84	0.000	ES
Group B	30	12.48	3.24	74.04	6.26	1.14	8.08	0.000	ES

In Group A there was 98.62 % relief in Meanarea of hyper granulation tissue which was statistically ***extremely significant***. In Group B, there was 74.04 % relief which was also statistically ***extremely significant***.

Table No. 2. Statistical Analysis of Thickness of Hyper Granulation Tissue in Group A & Group B (mm)

Control group	N	Mean		% of relief	SD	SE	't' value	P value	Result
		BT	AT						
Group A	30	2.80	0.27	90.36	0.94	0.17	14.81	0.000	ES
Group B	30	3.30	1.40	57.57	0.62	0.11	16.26	0.000	ES

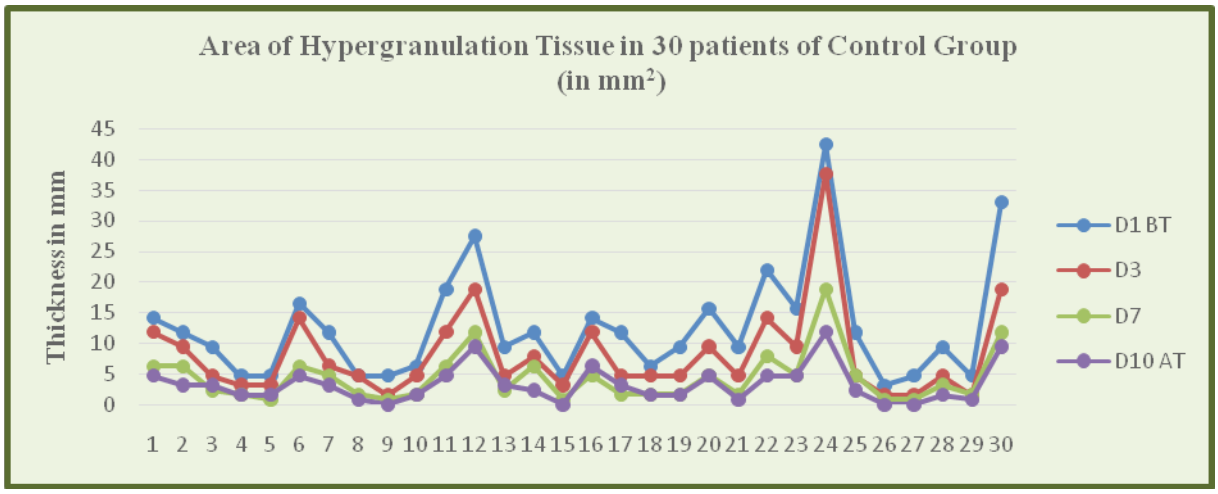
In Group A there was 90.36 % relief in Mean thickness of hyper granulation tissue which was statistically ***extremely significant***. In Group B, there was 57.57 % relief which was also statistically ***extremely significant***.

Table no. 3. Comparison between Group A and Group B

	Group	N	Mean Diff	SD	SE	't' Value	P Value	Result
Area	Group A	30	11.46	8.01	1.46	1.198	0.236	NS
	Group B	30	9.24	6.26	1.14			
Thickness	Group A	30	2.53	0.94	0.17	3.236	0.002	VS
	Group B	30	1.87	0.62	0.11			

Unpaired "t" test with Welch's correction was applied for comparison of Area and Thickness of hyper granulation tissue in Group A and Group B after treatment. It implies that

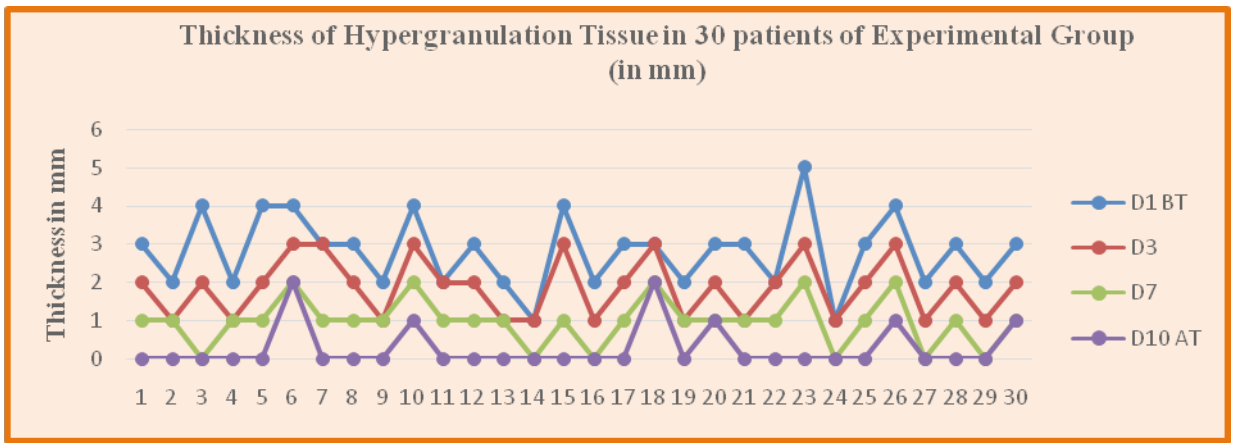
- Difference in Area of hyper granulation tissue after therapy between Group A & B is insignificant.
- Difference in Thickness of hyper granulation tissue after therapy between Group A & B is very significant.

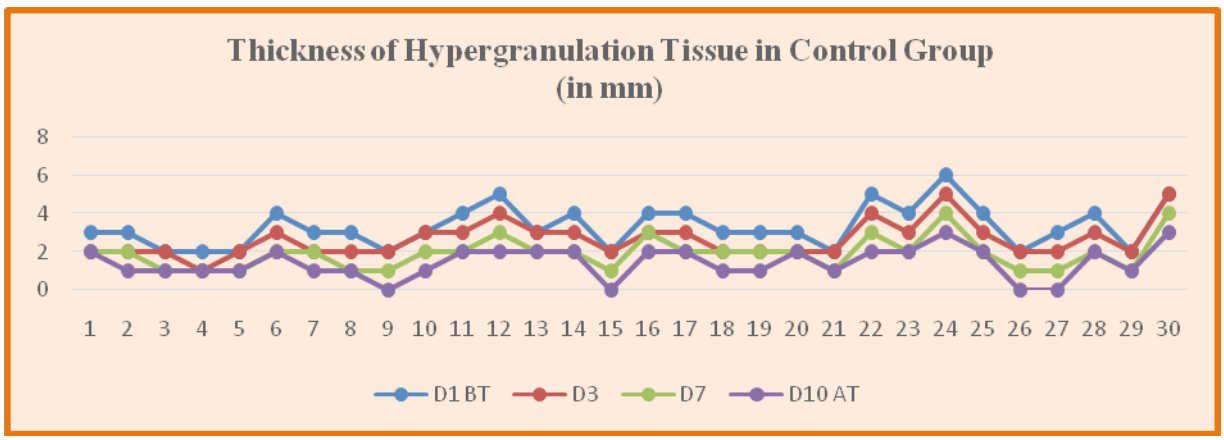


Effect on Area of Hyper Granulation Tissue: There was highly significant decrease ($p<0.001$) in area of hyper granulation tissue after treatment in both experimental and Control Group. In both groups highly significant decrease in area was observed after 3rd day of treatment onwards. On statistical analysis,mean difference in area of hyper granulation in both groups was found insignificant ($p>0.05$). However, the percentage relief was found to be 98.62% in Experimental Group and 74.04 % in Control Group.

The line diagrams shows that diminution of area of hyper granulation tissue in course of treatment is higher in number of patients in Experimental Group than that of Control Group.

Effect on thickness of hyper granulation tissue: There was highly significant decrease ($p<0.001$) in thickness of hyper granulation tissue after treatment in both experimental and Control Group. In both groups highly significant decrease in thickness was observed after 3rd day of treatment onwards. Mean difference in thickness of hyper granulation in both groups was found more significant ($p<0.01$) on statistical analysis. The percentage relief was found to be 90.36 % in Experimental Group and 57.57 % in Control Group.





The line diagrams shows that the reduction in thickness of hyper granulation tissue in course of treatmentis higher in number of patients in Experimental Group than that of Control Group.

Thus LA of *Kalpit Kasisadi oga* with *Madhu* is more effective in decreasing area and thickness of *Ksharasutra* induced hyper granulation at external opening of fistula-in-anothan *Madhu* alone.

Discussion

The *Kalpit Kasissadi Yoga* has dominance of *Kashaya-Tikta Rasa*, *Ushna Virya*, *Laghu Ruksha Guna*, and *Katu Vipaka*. In experimental group, *Kalpit Kasisadi Yoga* along with *Madhu*was used, hence there was an additive effect. *Avasadana Dravyas* have *Ushna Virya* so as *Kasis* is. *Amla, Kashaya, Tikta Ras* of *Kasis* adds to its *Vrana Ropana* and *Avasadana* properties.

In *Ayurvedic* literature, use of *Kasis* in chronic wounds with erupted wound edges and discharge has been postulated.[10] The ferrous sulphate acts as vaso-constrictor due its astringent property thus reducing the size of hyper granulation tissue.

Karanj with its *Tikta, Katu, Kashaya rasa* and *Ushna, Ruksha Guna* acts as *Kled-Shoshan, Stroro-Akunchan*. The seeds contain alkaloids, tannin and picric acids in addition to some reducing substance. The seeds yield a type of oil which has marked fungicidal, antiseptic, cleansing and healing properties when applied locally. *Karanj* is the active principle responsible for the curative effect of the oil in the skin diseases.[11]

Jatikalika is again of *Tikta-Kashaya Rasa* and *Ushna Virya*. The flowers contain pyridine and nicotinate derivatives, alkaloid jasminine and salicylic acid. Thus having anti inflammatory activity. Flowers are astringent and mild anaesthetic hence reduces oedema of hyper granulation tissue.[12]

Saindhav and *Kukkutand Twak Bhasma*possess hygroscopic activity thus dry and up the secretions of fistulous tract. *Kukkutandtwak Bhasma*contains Ca CO_3 which is recently recognized as an accelerator for healing of wounds.[13] *Saindhav* softens the hypertrophied fibrosed tissue.

In control group only *Madhu* was used, still highly significant results were obtained. This is because of multidimensional action of *Madhu* on wound which was established since ancient time. Due to *Kashaya Anurasa* (astringent) of *Madhu* there is constriction of the micro capillaries existing in the bed of hyper granulation tissue thus checking its growth. *Ruksha* and *Sukshma Guna* of *Madhu* causes *Kleda Shoshana* thus reducing the size of hyper granulation tissue.[14] According to modern science being hygroscopic, honey speeds up the healing of wound and dry up the secretions. It has antibacterial properties due to its acidic nature and enzymatically produced hydrogen peroxide. Thus with *Lekhana*, *Vrana Shodhana* and *Ropana* properties, *Avasadana karma* of *Madhu* is established.

Thus the *Kalpit Kasisadi Yoga* becomes very effective on hyper granulation tissue as compared to use of only *Madhu* in treatment of hyper granulation tissue of fistula-in–ano which is proved from the study results.

Conclusion

Hyper granulation, one of the rare consequences of wound is observed very frequently in patients of fistula-in-ano with *Ksharsutra* in it.Excessive secretions due persistent irritation, sensitivity, mal-preparation and faulty ligation technique, all associated with *Ksharsutra*, are the probable causes of hyper granulation tissue formation in fistula-in-ano.

Kalpit Kasisadi Yoga with *Madhu* shows a very effective *AvasadanaKarma*on*Utsanna Mrudu Vrana Maansa* (Hyper Granulation) in *Bhagandara* (fistula-in-ano), during its course of treatment with *Ksharsutra*, however local application of *Kalpit Kasisadi Yoga* is more effective than merely *Madhu*.

Ethical Clearance: Taken from institutional ethics committee.

Source of Funding: Self.

Conflict of Interest: Nil.

References:

1. Yadav T et al. Sushruta, Sushrut Samhita with Nibandhasangraha Commentary of Dalhana & Nyayachandrika 'Kavyatirth'. Reprint. Varanasi, U.P: Chaukhamba Surbharti Prakashana; 2008. 397p
2. Yadav T. Agnivesh, Charaka Samhita with Ayurveda Deepika. Reprint. Varanasi, U.P: Chaukhamba Sanskrit Sansthana; 2004. 593p
3. Brown B.Hyper granulation: a brief outline of definition, assessment and options for management. Tasmanian Wound Care Association Newsletter. 2007; 10:2-3.
4. Vuolo J. Hypergranulation: exploring possible management options. British Journal of Nursing. 2010; 19(6):S4-8.
5. Thakaral K. Sushruta, Sushrut Samhitawith Nibandhasangraha Commentary of Dalhan & Nyayachandrika. Reprint. Varanasi, U.P: Chaukhamba Orientalia; 2014. 272p
6. Thakaral K. Sushruta, Sushrut Samhita with Nibandhasangraha Commentary of Dalhana & Nyayachandrika Commentary of Gayadasa Vol II,Reprint. Varanasi, U.P: Chaukhamba Orientalia; 2014. 187p

7. Thakaral K. Sushruta, Sushrut Samhita with Nibandhasangraha Commentary of Dalhana & Nyayachandrika. Reprint. Varanasi, U.P: Chaukhamba Orientalia; 2014. 410p
8. Kundin J. A new way to size up a wound. AJN The American Journal of Nursing. 1989; 89(2):206-7p.
9. Mishra S. Ayurvediya Rasashastra, 4th edition. Varanasi, U.P: Chaukhamba Orientalia; 1993.435p.
10. Sharma P. Dravyaguna Vijnana Vol II, Reprint. Varanasi, U.P: Chaukhamba Bharati Academy; 2003. 144p.
11. Sharma P. Dravyaguna Vijnana Vol II, Reprint. Varanasi, U.P: Chaukhamba Bharati Academy; 2003.179-80p.
12. Balassa L. Process for using eggshell compositions for promoting wound healing. United States patent US.1971; 3:558,771.
13. Thakaral K. Sushruta, Sushrut Samhita with Nibandhasangraha Commentary of Dalhana & Nyayachandrika Commentary of Gayadasa Vol I, Reprint. Varanasi, U.P: Chaukhamba Orientalia; 2014. 524p.
14. Efem S. Clinical observations on the wound healing properties of honey. BJS. 2010; 75 (7): 679-681.