IAMJ

INTERNATIONAL
AYURVEDIC
MEDICAL JOURNAL

Research Article ISSN: 2320 5091 Impact Factor: 5.344

RANDOMIZED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF VIDANGADI GUGGULU IN DUSHTA VRANA

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https://doi.org/10.46607/iamj2808102020

(Published online: October 2020)

Open Access

Article Received: 08/10/2020 - **Peer Reviewed:** 10/10/2020 - **Accepted for Publication:** 11/10/2020

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ABSTRACT

Introduction: *Agantu Vranas* are *shudha* at initial stages but due to contamination at the time of accident, poor hygiene and lack of proper care by persons, these get vitiated by *Tridosha* frequently & convert into *Dushta Vrana*. The presence of *Dushta Vrana* worsens the condition of the patient and when associated with complications may become fatal. **Objectives:** To Study the Efficacy of *Vidangadi Guggul* in *Dushta Vrana.* To study the efficacy of *Triphala Guggulu* Orally in *Dushta Vrana.* **Methodology:** Randomized Controlled Clinical Trial, Total 67 patients of *Dushta Vrana* were enrolled in this study selected of age 18 to 60 year irrespective of sex, religion, occupation, economic and educational status. This study was approved by IEC of institute and written informed consent were taken before enrolment in the study. Trial group of 30 patients were given *Vidangadi Guggulu* 500 mg orally and Control group patients were given. *Triphala Guggulu 500 mg* orally were given for 30 days. **Discussion:** *Dushta* is one in which there is localization of three all the *Doshas. Dushta Vrana*, which had a bad odor, has abnormal color, irregular in size, with plentiful discharge, intense pain and takes a long period to heal. *Dushta Vrana* is a long-standing ulcer where removing debris enabling drug to reach healthy tissue is more important. In Ayurveda *Dushta Vrana* are treated effectively by *Guggulu* preparations like *Triphala Guggulu* and *Vidangadi Guggulu.*

Results & Conclusion: In trial group as well as control, there is significant difference observed on Day 0 and Day 30 in Size of *Vrana, Vedana*(pain) *Srava* (Discharge), *Gandha* (Smell), Edge of *Vrana* and Granulation tissue within group.

Keywords: *Vrana, Vedana, Vidangadi Guggulu,Triphala Guggulu, Tridosha*

INTRODUCTION

Vrana is a common problem encountered by medical practitioners. The presence of *Dushta Vrana* worsens the condition of the patient and when associated with complications may become fatal. A clean wound in a normal body heals earlier with a minimum scar as compared to a contaminated wound. Local factors of wound like slough, infection and foreign body, affect the normal process of healing. *Agantu Vranas* are *shudha* at initial stages but due to contamination at the time of accident, poor hygiene and lack of proper care by persons, these get vitiated by *Tridosha* frequently & convert into *Dushta Vrana*. Ancient Indian surgery deals with various types of wound management in detail Acharya Sushruta. Acharya Sushruta has mentioned 60 *Upakramas* in the management of *Vrana*. In present day, wound is said to be healed when epithelialization is complete, but Acharya Sushruta has given much emphasis on *Vaikruthapaham*. Hence good wound healing with minimal scar formation is the prime motto.

The available antibiotics, analgesics and anti-inflammatory drugs used in Modern medicine system are always not useful or effective all the time leaving back the *Dushta Vrana* (non-healing wound).The aim is to minimize the role of modern medicines and complete the wound healing process easily without any adverse drug reactions. So, the study has been taken to evaluate the efficacy of *Vidangadi Guggulu* in *Dushta Vrana.*

Objectives:

1. To Study the Efficacy of *Vidangadi Guggul* in *Dushta Vrana.*
2. To study the efficacy of *Triphala Guggulu* Orally in *Dushta Vrana.*

Materials & Methods:

Study design - Randomized Controlled Clinical Trial.

Sample size - Total no. of 60 patients were taken for the study from IPD & OPD

Duration of work: - 1.5 year

Drug standardization- Drug were standardized in Authenticated laboratory and pharmacy Standardization and authentication of the drugs were done according to API. Authentication & Identification of Drugs were done in an Authenticated pharmacy.

Selection Criteria-

Inclusion Criteria:

1) Patients suffering from Agantu Dushta Vrana on Arm & Leg were selected.
2) Patients were selected of age 18 to 60 yr. irrespective of sex, religion, occupation, economic and educational status.
3) Maximum area of the *vrana* not exceeding than 3cm×3cm×0.5cm (L×B×D) having duration of more than 3 weeks upto 6 weeks.

Exclusion criteria-

1. Known Patients with disorders like Tuberculosis, Leprosy, HIV and HBsAg positive and underlying bony lesions were excluded.
2. Patients of *Sadyo Vrana* (Having *Shuddha Avastha*)
3. Patients suffering from signs of gangrene.
4. All *asadhya dushta vrana* with general and local complications.
5. Patients who are incapacitated, bedridden.
6. Patients with poorly controlled Hypertension (>160/100 mm of Hg)
7. Patients with Diabetes Mellitus {B.S. (F) > 126 mg% and / or B.S. (2 hr. PP) >200 mg% or HbA1c> 6.5%}.
8. Patients with evidence of malignancy, prolonged (> 6 weeks) medication with corticosteroids, antidepressants, anticholinergics, etc. or any other drugs that may have an influence on the outcome of the study.
9. Alcoholics and/or drug abusers, Pregnant / lactating woman.

Ethical Clearance & Consent: This study was approved by IEC of institute and written informed consent were taken before enrolment in the study.

Grouping

Trial group- Total 30 patients were included in this group *Vidangadi Guggulu* 500 mg orally for 30 days.

Control group - 30 patients were included in this group *Triphala Guggulu* 500 mg orally for 30 days.

Table 1: Drug Administration Details

Particular	**Trial Group**	**Control Group**
Drug	*Vidangadi Guggulu vatika*	*Triphala Guggulu*
Matra/Dose	500 mg twice daily	500 mg twice daily
Dosage form	*Vati*	*Vati*
Route of Administration	Oral	Oral
Time of Administration	Twice a day after food	Twice a day after food
Anupana	Lukewarm Water	Lukewarm Water
Duration	30 days	30 days
No. of patient	30	30
Follow up	10^{th} ,20^{th},30^{th} day	10^{rd} ,20^{th},30^{th} day
Duration of therapy	30 days	30 days

Dressing

Dressing were done for both groups.

Betadine +H2O2 dressing on alternate day.

Table 2: Assessment Criteria

A) Subjective Gradation Criteria for Assessment of Non-Healing Wound

Assessment Parameter	**Grade 0**	**Grade 1**	**Grade 2**	**Grade 3**
Size	No Discontinuity of Skin/Mucus membrane	1/4 of the area	1/2 of the area	Total of the area
Pain /*Vedana*	No pain	Localized pain during movement but relieved on rest	Localized pain even during rest	Localized pain even during rest and other side also
Discharge/*Srava*	No discharge /Dry dressing	Scanty/occasional Wet dressing	Discharge need daily dressing	Profuse, continuous discharge needs frequent dressing
Smell /*Gandha*	No smell	Bad smell	Tolerable, unpleasant smell	Foul and intolerable smell
Edge	Adhere edge	Smooth even and regular Edge	Rough and irregular	More rough and total irregular
Floor /Granulation tissue	Smooth Regular with granulation tissue/ no need for dressing	Rough, Regular, Mild discharge, less granulation tissue/needs dressing	Unhealthy, less granulation tissue, needs daily dressing	Unhealthy, no granulation tissue

B) Objective

Patient Global Health Assessment Scale (GH Scale)-

C) Follow Up

Patients were followed on every 10^{th}day

Parameter for Objective criteria: There is 100 mm long scale for assessment of overall relief. There is '0'marking on left hand side and '100' marking on right hand side.'0' indicates severe pain while 100 indicate complete relief. Patient ware asked to grade their severity of pain and allied complaints. Marking was defined accordingly in number.

GH SCALE

0 50 100

Calculation ware done according to following formula

Percentage of relief – $\frac{Iat - Ibt}{Iat} \times 100$

Where, Ibt – intensity of symptom before treatment,

Iat - intensity of symptom after treatment

Statistical Analysis of Data

The data obtained from the study were entered in excel sheet, and statistical analysis were achieved for subjective symptoms by applying "Friedman test" to see the significance within group and for comparison between two group "Mann Whitney Test" test was applied wherever necessary. All the tables and graphs are presented in results section of thesis.

Results:

Total 67 patients of *Dushta Vrana* were enrolled in this study selected of age 18 to 60 year irrespective of sex, religion, occupation, economic and educational status. Total seven patient were dropped out during study.

Clinical Observations:

Table 3: Friedman Test (Repeated measure non-parametric test) for subjective criteria of *Dushtavrana* in Trial Group:

Follow up	**Day 0**		**Day 10**		**Day 20**		**Day 30**		**Fr. Stat**	**P value**
Symptoms	Median	Sum Rank	Median	Sum Rank	Median	Sum Rank	Median	Sum Rank		
Size of *Vrana*	2	99.5	2	91	73.5	2	36	1	68.6	<0.001
Vedana (Pain)	1	96	1	84.5	1	69	0	50.5	43.7	<0.001
Srava (Discharge)	1	91.5	1	87.5	1	70.5	0	50.5	44.9	<0.001
Gandha (Smell)	1	94.5	1	79.5	0	71.5	0	54.5	37.02	<0.001
Edge of *Vrana*	1	87	1	81	1	75	0	57	31.5	<0.001
Granulation tissue	1	92	1	86.5	1	70	0	51.5	42.1	<0.001

Friedman Test (Repeated measure non-parametric test) is applied for subjective criteria of *Dushtavrana* to see the effect of Intervention on every follow up i.e. Day 10, Day 20 and on Day 30. Variation in median is significantly different in all these symptoms. It was observed that p value was <0.001 for the symptoms Size of *Vrana, Vedana* (Pain), *Srava* (Discharge), *Gandha* (Smell), Edge of *Vrana* and Granulation tissue which is considered as highly significant. So, it is concluded that there is highly significant difference among follows up for these subjective criteria of *Dushtavrana* on day 10, 20 and day 30 as compare to day 0.

Table 4: Comparison within each follow up for subjective criteria of *Dushtavrana*:

Follow up	**Day 0 and Day 10**		**Day 10 and Day 20**		**Day 20 and Day 30**	
Symptoms	Rank sum diff	P value	Rank sum diff	P value	Rank sum diff	P value
Size of *Vrana*	8.5	>0.05	26	>0.05	63.5	<0.001
Vedana (Pain)	11.5	>0.05	27	<0.05	45.5	<0.001
Srava (Discharge)	04	>0.05	21	>0.05	41	<0.001
Gandha (Smell)	15	>0.05	23	>0.05	40	<0.001
Edge of *Vrana*	06	>0.05	12	>0.05	30	<0.05
Granulation tissue	5.5	>0.05	22	>0.05	40.5	<0.001

Further Comparison done within each follow up, in Size of *Vrana, Vedana* (Pain), *Srava* (Discharge), *Gandha* (Smell), Edge of *Vrana* and Granulation tissue the effect of intervention was seen significantly different on Day 30 as compare to Day 0 as p value obtained was <0.001. However, p value obtained was >0.05

which is not significant on Day 10 and Day 20 except *Vedana* on day 20.

Table 5: Friedman Test (Repeated measure non-parametric test) for subjective criteria of *Dushtavrana* in Control Group:

Follow up	**Day 0**		**Day 10**		**Day 20**		**Day 30**		**Fr. Stat**	**P value**
Symptoms	Median	Sum Rank	Median	Sum Rank	Median	Sum Rank	Median	Sum Rank		
Size of *Vrana*	3	97.5	2	91	2	71.5	1	40	62.4	<0.001
Vedana (Pain)	1	90	1	85	1	69	0	65	36.7	<0.001
Srava (Discharge)	1	85.5	1	82	1	68	1	64.5	24.8	<0.001
Gandha (Smell)	1	88	1	81.5	1	71.5	1	59.5	26.3	<0.001
Edge of *Vrana*	1	86.5	1	80	1	72.5	1	61	25.6	<0.001
Granulation tissue	1	86	1	82.5	1	71.5	1	60	26.7	<0.001

The effect of Intervention seen on every follow up i.e. Day 10, Day 20 and on Day 30. Variation in median is significantly different in all these symptoms. It was observed that p value was <0.001 for the symptoms Size of *Vrana, Vedana* (Pain), *Srava* (Discharge), *Gandha* (Smell), Edge of *Vrana* and Granulation tissue which is considered as highly significant. So, it is concluded that there is highly significant difference among follows up for these subjective criteria of *Dushtavrana* on day 10, 20 and day 30 as compare to day 0.

Table 6: Comparison within each follow up for subjective criteria of *Dushtavrana*:

Follow up	**Day 0 and Day 10**		**Day 10 and Day 20**		**Day 20 and Day 30**	
Symptoms	Rank sum diff	P value	Rank sum diff	P value	Rank sum diff	P value
Size of *Vrana*	6.5	>0.05	26	>0.05	57.5	<0.001
Vedana (Pain)	05	>0.05	21	>0.05	34	<0.001
Srava (Discharge)	3.5	>0.05	17.5	>0.05	21	>0.05
Gandha (Smell)	6.5	>0.05	16.5	>0.05	29	<0.05
Edge of *Vrana*	06.5	>0.05	14	>0.05	25.5	>0.05
Granulation tissue	3.5	>0.05	14.5	>0.05	26	>0.05

In Size of *Vrana, Vedana* (Pain), *Srava* (Discharge), *Gandha* (Smell), Edge of *Vrana* and Granulation tissue the effect of intervention was seen significantly different on Day 30 as compare to Day 0 as p value obtained was <0.001.

Table 7: Comparison for Subjective Criteria between the groups by Mann-Whitney 'U' Test

No	**Symptoms**	**Mean ± SD**		**Mann-Whitney 'U'**		**P Value**
		TG	**CG**	**U'**	**U**	
1	Size of *Vrana*	0.93±0.7	1.26±0.7	557	343	0.1099
2	*Vedana* (Pain)	0.93±0.7	0.73±0.8	533	367	0.2176
3	*Srava* (Discharge)	0.73±0.5	0.40±0.6	590	310	0.0366
4	*Gandha* (Smell)	0.76±0.67	0.56±0.7	520.5	379.5	0.2954
5	Edge of *Vrana*	0.53±0.57	0.50±0.6	478.5	421.5	0.6740
6	Granulation tissue	0.86±0.77	0.56±0.8	555.5	344.5	0.1163

It was found that the sum of rank for the symptom Size of *Vrana* Mann Whitney U' statistics was 557, Test statistic (U) was 343, where the test statistic U was not between Population Mean ±1.96 SD which was consider as not significant at 5% level of significance, as p value observed was 0.1099 which was >0.05, (p>0.05) therefore the difference between Symptom Score of Size of *Vrana* of Trial Group and Control Group is not statistically different, hence we can conclude that in the parameter Size of *Vrana* both interventions are equally effective statistically. Likewise in symptoms *Vedana* (Pain), *Gandha* (Smell), Edge of *Vrana* and Granulation tissue as p value observed was 0.2176, 0.2954,0.6740, 0.1163 respectively which was not significant at 5% level of significance as the p value > 0.05 hence in these parameters Trial Group and Control Group intervention is equally effective statistically as there is no difference. However, in *Srava* (Discharge) p value observed was 0.0366 which was <0.05, (p<0.05) therefore the difference between Symptom Score of *Srava* (Discharge) of Trial Group and Control Group is statistically different, hence we can conclude that in the parameter *Srava* (Discharge) there is difference between two groups.

Table 8: Showing Wilcoxon Signed Rank Test of Symptom score of GH Scale of Trial Group:

No	GH Scale	Mean ± SD		Median		Sum of +Ranks (T_+)	P Value
		BT	AT	BT	AT		
1	**Trial Group**	12.06±8.06	71.5±18.1	10	79	0.00	<0.0001
2	**Control Group**	6.4±6.04	50.7±17.2	05	50	0.00	<0.0001

In Patient Global Health Assessment Scale (GH Scale), p value obtained was <0.001 which was statistically considerably highly significant (p<0.0001) in both the groups.

Table 9: Comparison between Two Group w.r.t. GH Scale of 60 Patients of *Dushta Vrana* By Mann-Whitney 'U' Test

No	Symptom	Mean ± SD		Statistics		P Value
		Trial Group	Control Group	U'	U	
1	GH Scale	-59.4±19.8	-44.3±19.5	650	250	0.003

Comparison between Two Group w.r.t Symptoms of *Dushta Vrana*: The Difference between before treatment and after treatment score of both groups compared by 'Mann-Whitney U-Test'. In Patient Global Health Assessment Scale (GH Scale), Score of GH Scale, Mean±SD of Trial Group and Control Group, p value observed was <0.05 which was significant at 5% level of significance. (p<0.05) Therefore, there is difference between GH Scale in Trial Group and Control Group and statistically it is significant, so therefore we can conclude that in the Trial Group is more effective than Control Group as relief observed was more in Trial Group.

Table 10: Percentage of Relief (Subjective Criteria) in Each Symptom of 60 Participants of *Dushtavrana*

Sr. No	Symptoms	Trial Group			Control Group		
		D10	D20	D30	D10	D20	D30
1	Size of *Vrana*	09.1	25.8	71.2	05.4	20.3	51.4
2	*Vedana*(Pain)	15.4	35.9	71.8	10.5	34.2	57.9
3	*Srava* (Discharge)	06.9	37.9	75.9	06.5	29.0	38.7
4	*Gandha* (Smell)	27.6	41.4	79.3	10.5	23.7	44.7
5	Edge of *Vrana*	11.1	22.2	59.3	14.7	26.5	44.1
6	Granulation tissue	10.0	40.0	65.0	11.1	27.8	47.2

DISCUSSION

Dushta Vrana is a commonly encountered problem faced in surgical practice. The presence of *Dushta Vrana* worsens the condition of the patient with different complications and may become fatal. A healthy wound in a normal body heals earlier with a minimum scar as compared to a contaminated wound. *Dushta* is one in which there is localization of three all the *Doshas. Dushta Vrana*, which had a bad odor, has abnormal color, irregular in size, with plentiful discharge, intense pain and takes a long period to heal. *Dushta Vrana* is a long-standing ulcer where removing debris enabling drug to reach healthy tissue is more important. In Ayurveda *Dushta Vrana* are treated effectively by *Guggulu* preparations like *Triphala Guggulu* and *Vidangadi Guggulu*.

In this study, totally 47[8.3%] were male and 13 [21.7%] were female while more female was recruited, it may be due random selection of patients.

In Trial Group the percentage of relief noted in Size of *Vrana* was 9.1% on Day 10 , 25.8% on Day 20 and 71.2% on Day 30.The percentage of relief noted in *Vedana* (Pain) was 15.4% on Day 10 , 35.9% on Day 20 and 71.8% on Day 30.The percentage of relief noted in *Srava* (Discharge) was 6.9% on Day 10 , 37.9% on Day 20 and 75.9% on Day 30.The percentage of relief noted in *Gandha* (Smell) was 27.6% on Day 10 , 41.4% on Day 20 and 79.3% on Day 30.The percentage of relief noted in Edge of *Vrana* was 11.1% on Day 10 , 22.2% on Day 20 and 59.3% on Day 30.The percentage of relief noted in Granulation tissue was 10% on Day 10, 40% on Day 20 and 65% on Day 30.Overall, it was observed that Percentage of Relief in Each Patient of 60 Patients of *Dushtavrana* in Trial Group was 71.5% while 47.5 % in Control Group. On an average in both group 59.4 % relief got in each patient of *Dushtavrana*.

Mode of action: *Vidangadi Guggul* - It contains *Vidanga, Triphala, Trikatu, Guggul and Ghruta. Vidanga having Laghu, Ruksha, Tikshana guna* which can improve the *Vranaropak* action as it is *Vata kaphahar, Shoolhar* properties so it helps in reducing *Vedana*, discharge of *Dushtavrana*. *Trikatu* is also excellent *Shoolhar, Shoshka* so it helps in getting relief from symptoms like Discharge, *Vedana* and enhance the healing of wound by its *Kaphahar* action. *Guggulu* has *Kushthghna, Vrana ropana, mamsa lekhana, Sroto vivarana, kanduhara* properties. *Guggulu* is indicated in cases of chronic wound, which is full of slough, deep seated in muscle and reluctant to heal. Due to having *Kashaya* and *Tikta rasa* of *Amalaki, Haritaki, Bhibhitak* and *Guggul* which exerted *Lekhana* (scraping) action that helped in removing slough and prepared the wound bed for healing. Wound became clean with healthy granulation on 25-30 day during intervention as Guggul and *Triphala* is having the ability to disinfect and destroy the micro-organisms and promoted excellent healing.

CONCLUSION

In Trial group *Vidangadi Guggulu* and in Control group *Triphala Guggulu* in dose of 500 mg orally given for 30 days.

1. In this study, total 20[33.3%] were having illness due to accident, 07[11.7%] were having illness due to burn, 09[15%] were having illness due to Injury at work place while 24[40%] having illness due to trauma. Most of participants get trauma at workplace.
2. In trial group as well as control, there is significant difference observed on Day 0 and Day 30 in Size of *Vrana, Vedana* (pain) *Srava* (Discharge), *Gandha* (Smell), Edge of *Vrana* and Granulation tissue within group.
3. In parameter Size of *Vrana, Vedana* (Pain), *Gandha* (Smell), Edge of *Vrana* and Granulation tissue Trial Group and Control Group is not statistically different, both are equally effective. However, in *Srava* (Discharge), the difference between Symptom Score of *Srava* (Discharge) of Trial and Control is statistically different, hence we can conclude that in the parameter *Srava* (Discharge) there is difference between two groups.
4. Trial Group is more effective in-Patient Global Health Assessment Scale than Control Group as relief observed was more in Trial Group. Overall, it was observed that Percentage of Relief in Each Patient of 60 Patients of *Dushtavrana* in Trial Group was 71.5% while 47.5 % in Control Group.

REFERENCES

1. Aathavale PG, editor, (2nd ed.). Sushrut Samhita of Sushruta; Chikitsa Sthana, Chapter 1, Verse 6, Nagpur: Godavari publishers and book promoters,2008;18
2. Aathavale PG, editor, (2nd ed.). Sushrut Samhita of Sushruta; Chikitsa Sthana, Chapter 2, Verse 4-6 Nagpur: Godavari publishers and book promoters,2008;278
3. Shukla V, editor, (2nd ed.). Charaka Samhita of charak, Chikitsa sthan: Chapter 25, Verse 22-26. Varanasi: Chowkhambha Sanskrit Series, 2002; 534.
4. Parashara R, editor, (4th ed.). SharangadharaSamhita of Sharangadhara, Purva Khanda, Chapter 7, Verse 32. Nagpur: Sri Baidyanatha Ayurveda Bhavana,1994; 131
5. Tripathi B, editor, (1st ed.). Ashtangahridaya of Vagbhata, Uttarsthan: Chapter 25, Verse 1. Varanasi: Chowkhambha Sanskrit Series, 2009; 567.
6. Shashtri A D, editor, (1st ed.). Sushrut Samhita of sushrut, Sutrastna: Chapter 22, Verse 9-12. Varanasi: Chowkhambha Sanskrit Series, 2009;256
7. Vd. Anant Athavale. Editor, (1st ed.). Ashtanga Samgraha with Indutika, Uttar sthana, Chapter 29, Verse 4, Shrimad Atreya Prakashana, Nanda-Nandan, Erandavanam, Pune-4, 1980, pg 280
8. Shashtri A D, editor, (1st ed.). Sushrut Samhita of sushrut, Sutrastna: Chapter 22, Verse 9-12. Varanasi: Chowkhambha Sanskrit Series, 2009;656

Source of Support: Nil
Conflict of Interest: None Declared

How to cite this URL: Preeti G. Verma & Sandip Bhosale et al: Randomized Controlled Clinical Study To Evaluate The Efficacy Of Vidangadi Guggulu In Dushta Vrana. International Ayurvedic Medical Journal {online} 2020 {cited October, 2020} Available from: http://www.iamj.in/posts/images/upload/4753_4760.pdf