

ADD ON EFFECT OF GRÑJANAKA PĒYA ALONG WITH A THERAPEUTIC DIETARY PROTOCOL IN RAKTĀRŚAḤ (BLEEDING PILE) – A NON-RANDOMIZED CONTROLLED TRIALBindu K.T¹, M. C. Shobhana², P. E Prema³

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Article Received: 30/06//2021 - **Peer Reviewed:** 04/07/2021 - **Accepted for Publication:** 05/07/2021**ABSTRACT**

A non-randomized controlled trial was carried out in 40 participants with intervention for 15 days and a follow up of 7 days. Clinical signs and symptoms of *raktārsāḥ* were assessed before and after the intervention and after following up, by using the subjective parameters scale including, Frequency of bleeding, Nature of bleeding, Change in colour of the mucosa of pile mass, Character of defecation and Period of straining. *Grñjanaka pēya* along with a therapeutic protocol in *raktārsāḥ* has shown significant positive changes in subjective parameters like frequency of bleeding ($p<0.01$ level), nature of bleeding ($p<0.01$ level), changes in the mucosa, period of straining and character of defecation after the 15 days of intervention in the study group.

Keywords: *Raktārsāḥ*, *Grñjanaka pēya*, Therapeutic dietary protocol, Subjective parameters**INTRODUCTION**

In the present era, people are inviting many health problems due to their food habits and lifestyles. Among them, Hemorrhoids are shooting one. Haemorrhoids are certainly one of the commonest ailments

that afflict mankind. It is dilated veins within the anal canal in the subepithelial region formed by radicals of the superior, middle and inferior rectal veins¹. In *Āyurveda* Hemorrhoids are often compared with

arśaḁ. It is considered as *mahāroga* by *Suśṛta* and *Vāgbhata*. It is an *adhimāmsavikara* formed at *guda vali* due to vitiated *doṣas* along with the vitiation of *twak, mamsa and medas*. It is classified in to 6 major types namely *vatika, paittika, kaphaja, raktaja, sannipātaja* and *sahaja*². Other divisions are *ardrarśaḁ* and *sushkarśaḁ*. Bleeding is the major symptom of *ardrarśaḁ* and it requires prior management. Bleeding is more profuse in first- and second-degree piles. Regular blood loss leads to weakness, anaemia and further complications. So the major concern of patients is to arrest bleeding. In classics, several factors are mentioned as *nidāna* for *arśaḁ* such as *ajeer-na bhōjana, akala bhōjana, virudhasana* etc. Haemorrhoids are inflamed and swollen veins around the anus and lower rectum, which usually occur as a result of altered dietary patterns, altered lifestyle, genetics and pregnancy. *Arśaḁ* is a *yāpya roga*. So, it can be managed only by *ouśadha* and *ahāra*. *Āhāra* is mentioned as *Mahābhaishajyam* in *Kāśyapa samhita*³. *Pathya* and *apathya* of *arśaḁ* are mentioned in our classics. Management of *arśaḁ* without following *pathya* is difficult. In the context of *arśochikista* *Gṛñjanaka pēya* is mentioned as *raktapravāhajith*⁴. *Ācharya* mentioned *Gṛñjanaka* is *pathya* in *arśaḁ*. In common practice *Gṛñjanaka* (*swalpa nala palāndu-Allium ceppa*)⁵ is used to stop bleeding in bleeding piles. There are many home remedies for bleeding piles, which are incorporated with small onion⁶. Mode of administration of *Gṛñjanaka* through *Pēya*. It is one of the preparations of *Krutāna kalpana*. It is *laghu, pathya* and having the properties such as *vātanulomana*, and *agnideepana*⁷. *Pēyādi kalpana* is the one which mentioned in almost all the classical texts indicated as *pathyāhāra* in different clinical conditions and for healthy people in various seasons, and as the dietary regulation after *śōdhana* therapy. In conventional medicine, only symptomatic treatment is mentioned for *arśaḁ*. Along with the proper treatment, the dietary principles in *Āyurveda* provides an added advantage. *Āyurveda* accepts *āhāra* as a drug and an important entity for treatment purposes. All the *samhitās* of *Āyurveda* emphasize the importance of diet in day to day life as well as in the

prevention and treatment of diseases. *Āyurveda* has given much more importance to the rule of dietetics and this disease itself can be relieved by following the therapeutic diet. If people, follow *pathyāhāra* (wholesome diet) there will be no need of giving further medication; and if people do not follow the *pathyāhāra* the mere medication is in vein⁸. A therapeutic diet is the controlled and specific utilization of the food article as a beneficiary tool to tackle the diseased conditions⁹. *Āhāra kalpanās* (dietary *pathyāhāra*) is mentioned elaborately in the context of *arśo chikitsa*, but it is not yet explored significantly. There are fewer numbers studies are available related to safe and cost-effective preparation such as *pēya* and *pathyāhāra* in bleeding pile (*Raktarśaḁ*). So, this trial is to assess the effect of *Gṛñjanaka pēya* along with therapeutic dietary protocol in the subjective parameters of bleeding pile (*Raktarśaḁ*) such as frequency of bleeding, nature of bleeding, the character of defecation etc.

2 Materials and Methods

2.1 Trial Design: This study was a Non-Randomized open clinical trial, as these are more accurate for determining the efficacy in the initial step of new preparation. Ethical clearance was obtained for the study from the institutional ethics committee of V.P.S.V. Ayurveda College, Kottakkal. Approval no (IEC/CL/20/16) dated 28/04/2016) and amended on 04/05/2018.

2.2 Study Participants: Eligible participants satisfying inclusion criteria were screened from those who are coming in Salyatantra OPD at Ayurveda College Hospital. Among the screened participants 40 participants satisfying inclusion criteria and willing to give informed written consent were included in the study. Exclusion criteria were third and fourth-degree haemorrhoids, Bleeding per rectum other than haemorrhoids (such as gastric ulcer, rectal injury, IBS etc.) Patients undergoing anticoagulant therapy. Major systemic illnesses like uncontrolled hyperglycemia and uncontrolled hypercholesterolemia. Pregnant and lactating women.

2.3 Intervention: Preparation of *Gṛñjanaka pēya*

15 gm broken rice cooked with 210 ml of water and processed with crushed onion, *surasa* leaves & *yamaka snēha*¹⁰. Intervention gave for the selected participants *Gr̥ñjanaka pēya* and Dietary intervention. The dose was 100 ml and the time of intervention was between 11 am and 5 pm. Written diet chart with *pathyās* & *apathyās* given to the Participants along with daily assessment chart. Properties of *Gr̥ñjanaka pēya* mentioned in table 1.

2.4 Outcomes: Most of the signs and symptoms of the disease described in *Āyurvedic* classics are subjective. Hence, to provide some objectivity to the subjective results and to make easy the statistical analysis, the multidimensional scoring system was adopted for the patients. The assessment of the effect of the intervention was done based on the relief in the clinical signs and symptoms of *arsah* using Bleeding pile (*Raktārsah*)-Subjective parameter Clinical assessment Scale. This symptoms score was calculated before, after the intervention and follow up, The parameters were assessed before intervention(0th day), 15th day, 21st day and after follow up.

2.5 Sample size: Sample size was calculated by the formula - $(Z\alpha + Z\beta)^2 (p_1q_1) + (p_2q_2) / d^2$ Prevalences of 60% ,70% and Precision-15. Considering dropouts sample size was fixed to 40(cases 20, controls 20). Among the screened participants 40 participants were satisfying the inclusion and exclusion criteria were selected for the study.

2.6 Statistical Analysis: Data was checked, analyzed and presented with the help of tables, graphs. Normality of data was tested by Q-Q plot in SPSS version 16. Repeated measures ANOVA was done to assess the effect of intervention between assessments. Bonferroni multiple comparisons test was used for pairwise comparisons. A Paired t-test was used to assess the effect of intervention between the groups. Statistical analysis was done by using Microsoft Office 2013 Excel and IBM SPSS Statistics version 16.

3 RESULT

3.1 Study population: Sixty-two participants within the age group twenty to sixty years were screened for assessing eligibility. Twelve met exclusion criteria. Among fifty eligible, forty participants were selected.

Those who were satisfying inclusion criteria and those who were willing to give informed written consent were included. From those 20 participants conveniently allocated in to study and control group; no drop out were observed (Figure Flow Diagram of participants)

3.1.1 Baseline data: Participants were in the age group 20 to 60 years of having a male and female ratio in the percentage of study group 55:60 and control group 45:40. In dietary habits, 65% of participants in the study and control group were following mixed dietary pattern. 30% in the case and 20% in the control group were following a non-vegetarian diet and only 5% in the case and 15% in the control group were vegetarian. Distribution according to dietary habits are described in table 2

3.2 Effect analysis: The subjective parameters such as frequency of bleeding, nature of bleeding, change in the mucosa, the character of defecation and period of straining were analyzed in both study and control groups. The first two was statistically significant at the level of $p < 0.01$. Change in mucosa and Character of defecation were clinically significant but statistically insignificant. The parameter period of straining was showed statistically significant at the level of $p < 0.01$. As an objective parameter, Haemoglobin level in the blood was analyzed before and after therapy in both groups. In the study group, 5.76% increase was noted but in the control group, only .77% was increased. Mean values of assessments in case group and control group on subjective parameters mentioned in the table 3

3.3 Adverse events: During intervention or the follow-up period, any adverse events or complications were not reported. After the completion of the study, those participants who need further treatment or follow up were directed to the ARC Clinic of the VPSV Ayurveda College Hospital.

DISCUSSION

Diet has a major role in the management of *arsah* it was told by Dr Jasir Ahammed in his study and without the proper following of diet, no treatment will be effective in the case of *arsa*¹¹. The present study was

undertaken to evaluate the effect of *Gr̥ñjanaka pēya* which was given in the dose of 100ml morning 11 and evening 5 along with a therapeutic dietary protocol for 2 weeks in bleeding piles as an add on effect. This play is mentioned as *rakta pravahajit*, so it will help to arrest the bleeding, and it is indicated in *raktarśah* and *raktatisara* also. It has *madhura rasa, guru, snigdha guna madhura vipaka* and *rak-tastambana* in action¹². *Gr̥ñjanaka* (*Allium cepa*) which is Conventionally used by the practitioners for the management of the *raktarśah* in bleeding piles. Jalokath in 2013 on Ayurvedic influences in home remedies, mentioned that onion (*Allium cepa*) can be used as a home remedy in bleeding piles.¹³ In this *pēya yamaka sneha* is used for *bharjana* purposes, which is also helpful for avoiding *vāta kopana* due to blood discharge. The mode of administration of *Gr̥ñjanaka* is through *pēya*. *Pēya* is *laghuthara, vātānulomini, pathya* which is very much essential for the patients who are having *arśah*¹⁴. Therapeutic dietary protocol which is suggested for the study group is based on the *pathyas* mentioned for *arśah* in classics and strictly restricted to intake of *apathyas* also. Diet chart which is recommended to take lots of vegetables which is having *tikta* predominant *rasa*. *Tikta rasa* is indicated for *raktarśah*. More than this diet is fibre rich which in turn ensure normal digestion: Perez-Miranda et al in 1996 mentioned that fibre addition should be ensured in patients who refuse invasive treatment¹⁵. While considering the participant's distribution according to bowel habits showed that 72.5% were having irregularity in their motion that is it may be constipated, loose no regular time etc.. this presentation was supported by the study conducted by Johanson HO et, al observed that irregular bowel is the leading factor for *arsah*¹⁶

CONCLUSION

The present study entitled “Add on the effect of *pēya* along with therapeutic Dietary Protocol in *Raktārśh* (Bleeding pile)-Non-Randomized controlled trial” was an attempt to find out the efficacy of a simple cost effective therapeutic dietary preparation along with dietary intervention. After an elaborate review

of literature, clinical observation, analysis of the data and discussions, the following conclusions are evolved. *pēya* along with a therapeutic dietary protocol has a statistically significant effect in subjective parameters like frequency of bleeding, nature of bleeding, change in the mucosa, character of defecation and period of straining of *Raktārśh* (bleeding pile) among 20-60 years of age group.

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Table 1

Name	Rasa	Guna	Virya	Vipaka	Doṣaghnata	Karma
Gr̥ñjanaka ⁹¹	Madhura Katu	Guru Snigdha Teekshna	Ishatushna	Madhur	Vatakaphahāra Pittavārdhaka	Dipana, pachana, rochana' Anulomana Raktastambana, balya, Ojovārdhanam Chedanam, Kapha nisārakam Nidrajananam Chārdhi nigraham
Surasa ⁹²	Katu Tikta	Laghu Snigdha Teekshna	Ushna		Katu	Kapha vataghna Janthughna Vedanastapana Sothahāra Tvagoṣahāra

Table 2

Dietary habit	Case		Control		Total	
	Number	%	Number	%	Number	%
Vegetarian	1	5	3	15	4	10
Non-vegetarian	6	30	4	20	10	25
Mixed	13	65	13	65	26	65

Table 3

Subjective parameters	Mean differences	
	Case	Control
Frequency of bleeding	1.55	0.85
Nature of bleeding	1.55	0.85
Change in mucosa	0.85	0.8
Character of defecation	1.1	0.4
Period of straining	0.947	0.631

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