



## Prospective Clinical Study of Hemorrhoids with Individualized Homeopathic Treatment

Author

**Dr Indrajeet P. Shah**

Prof., Dept of Medicine, MNR HMC, Sangareddy

### Abstract

**Aim and Objective:** To study the efficacy of individualized Homeopathic Treatment in patients suffering from haemorrhoids and to assess change in their quality of life (Short Form-12 Health Survey)<sup>6</sup>

**Methods:** It was a single-centered, prospective, interventional study conducted at MNR UHC Homeopathic OPD in Sangareddy, from Jan 2018 to June 2018. At 0 day (Baseline) and 180 days standardized measuring scale were used like, SF-12 questionnaire, VAS and Anoscopic score. Homeopathic treatment was given to patients suffering from Haemorrhoids.

**Result:** Total 15 patients were included in the study. Statistically significant reductions of mean bleeding (90 days : 6.67, 95% confidence interval [CI]: 0.59, 12.74, P 0.0337; days 180: 21.33, 95% CI 8.58, 34.09, P 0.003 d = 14), pain (90 days: 2.33, 95% CI 2.33, 4.39, P 0.029; 180 days: 32, 95% CI 21.92, 42.08, P <0.01, d = 14), and anoscopic score from 0 day and after 180 days p 0.170) were achieved. Itching VASs reduced significantly only after 6 months (5.33, 95% CI 8.83, 2.29, P = 0.002, d = 14). Significant differences were also found in the Quality of Life (QOL)-SF 12 in physical domain [difference -19 (95% CI: -25.92, 12.08)], and psychological domain [difference -0.47 (95% CI: -7.84, -0.29)] (p ≤ 0.05). Anoscopic score at the end of the study it was less statistically significant.

**Conclusion:** Individualized homeopathic treatment has made significant improvement in the patients suffering from Haemorrhoids pertaining to the symptom's severity and overall perception of QOL in physical and psychological domains.

**Keywords:** Haemorrhoids, Homeopathy, VAS (visual analogue scale), QOL, SF 12.

### Introduction

The word "haemorrhoid" is derived from the Greek word haema (blood) and rhoos (flowing), and it was probably Buqrat (Hippocrates 460 BC) who was the first to apply this name to the flow of blood from the veins of the anus.<sup>8</sup>

Haemorrhoids or piles are dilated vein occurring in relation to anus or these can be called as symptomatic enlarged vascular cushions of anal canal.<sup>1</sup>

Symptoms of Haemorrhoids: The most common symptom of internal haemorrhoids is painless

bright red blood covering the stool, on toilet paper, or in the toilet bowl. Other symptoms are mucus discharge, prolapse accompanied with pain.<sup>2</sup>

However, an internal haemorrhoid may protrude through the anus outside the body, becoming irritated and painful. This is known as a protruding / external haemorrhoid. Symptoms of external haemorrhoids may include painful swelling or a hard lump around the anus that results when a blood clot is formed.<sup>3</sup>

Causes of Haemorrhoids: It is a known fact that constipation and prolonged straining at stool are main causes of Haemorrhoids but there are some other important aspects too.<sup>4</sup>

**Grading of Hemorrhoids:** Grade I - No prolapse, just prominent blood vessels. Grade II - Prolapse upon bearing down, but spontaneous reduction. Grade III - Prolapse upon bearing down requiring manual reduction. Grade IV - Prolapse with inability to be manually reduced.<sup>5</sup>

Hemorrhoid is abnormal dilatation of venous plexus of anus, which causes bleeding per rectum, pain and itching at anus. There was study conducted using ARWL12 Capsule which is a polyherbal formulation. 'ARWL12' capsule is a polyherbal formulation has been evaluated for efficacy and safety in patients of internal hemorrhoids. Thirty-two patients received two 'ARWL12 capsules', twice daily orally after meals for 60 days. On day 60, reduction in proportion of patients showing bleeding per rectum was observed. The episodes and quantity of bleeding per rectum and piles mass decreased at the end of the study. The quality of life of patient also improved significantly. Global evaluation by physician and patient showed excellent improvement in reducing the symptoms of hemorrhoids. Almost all patients of the study showed excellent tolerability to study drug. No significant changes, in most of the safety laboratory parameters were observed. The study provided good evidence for potential efficacy and safety of 'ARWL12' capsule in patients with internal hemorrhoids.<sup>7</sup>

In Homoeopathy individualized prescribing of medicine can cure the condition or in some cases can prevent the surgeries.

Homoeopathic literature shows that the efficacy of homoeopathic medicines in treatment of haemorrhoids is having more significant. Although various practitioners and clinicians quote brilliant cure of haemorrhoids with homoeopathic medicines,<sup>[9]</sup> but there is a lacks-controlled studies.

Measuring quality of life is considered as an important outcome criterion in clinical studies. Generic instruments as the Short Form 12 Health Survey offer the possibility to compare outcomes among different indications. Therefore, a test of the factorial (structural) validity of the method in each indication is necessary. There was a study is based upon SF-12 data from 343 patients with diabetes mellitus, which were pooled together from two rehabilitation research projects. The psychometric properties of the measure were analyzed, and the questionnaires structure was tested using confirmatory structural equation modeling. In a second step age and gender specific analyses were undertaken.<sup>13</sup>

And another Austrian nationwide healthcare programme for colorectal cancer screening at four medical institutions, were enrolled prospectively between 2008 and 2009. A colonoscopy was performed in all patients. Haemorrhoids were classified according to an international grading system and defined as symptomatic in cases with bleeding, itching, soiling or pain. Quality of life was measured by the Short Form- 12 Health Survey.<sup>12</sup>

The above studies emphasise the importance of SF-12 health survey in clinical cases. Hence same criterion was used in this study.

### Material and Methods

The study was single centre, prospective study. This study was carried out at UHC Homoeopathic OPD, Sangareddy. The study was started from Jan 2017 to June 2018. Consultant surgeon was appointed at the UHC OPD to assess the patients before and after the study as per protocol. Before enrolment, written consent was obtained. The study designed was reviewed and Permission was granted by the college ethical committee.

Total 19 patients were screened during the study period. Out of 19 screened patients, 15 patients were included in the study and 4 patients were dropped out due to loss of follow up or other reason. During this study subject of both sexes of age group between 20 to 60 years were included

in the study. Subject with symptomatic internal haemorrhoids of Grade I & II were included and visualised direct by proctoscope. Subject with protruding or irreducible haemorrhoids, anal fistula, rectal cancer was excluded.

During this study subject was evaluated on SF-12 assessment questionnaires to judge the QOL, VAS scale to assess the symptom severity and proctoscopic examination to confirm the diagnosis, position and size of haemorrhoids. The homoeopathic medicines in 200 potencies were procured from a Good Manufacturing Practices (GMP)-certified company. The physician interview with the patient, as per the guidelines laid down by Hahnemann S<sup>14</sup> in the sixth edition of the Organon of Medicine and follow-up of all the patients were done as per homoeopathic principles. On baseline visit administering indicated remedies. Each dose of medicine consisted of four cane sugar globules of 30 size medicated with a two drop of the indicated medicine, was given for once in a day for three days and placebo for 7 days or 15 days, depended on the individual requirement of the case. Following recruitment, selection of the single individualized medicine was based on the presenting symptom totality, repertorization and consultation with Materia Medica, and individualized dose on the judgment of susceptibility of the patients. As per individual requirement of the cases, aid of different repertories was taken with due consultation of Materia Medica.<sup>(15)</sup>

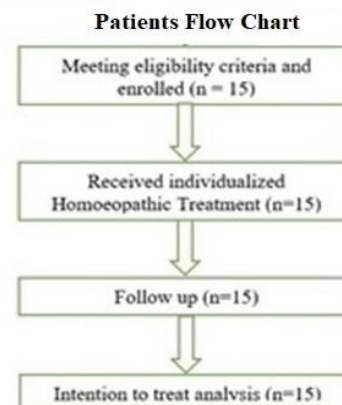
All the participants are advised to take fibres diet and encouraged to correct healthy defaecation habits. Before treatment (at baseline), patients independently rated their severity on five 100 mm visual analog scales (VAS; 0 = no complaints; 100 = maximum severity) measuring intensity of symptoms of hemorrhoids-bleeding, pain, heaviness, discharge, and itching; and a surgeon was performed the anoscopic assessments for each patient at each baseline and at 180 days, on a scale of 0 to 2 as follows: 0 = No signs of inflammation, 1 = a rather active grade,

hemorrhoids without overt inflammatory findings (mild anitis), and 2 = an actively or easily bleeding hemorrhoids with overt signs of inflammation and edema (severe anitis).<sup>17</sup>

The completed data i.e., SF-12, VAS scale and anal scope score were collected, and the data of 15 patients was entered into Microsoft Excel. Descriptive statistics were used for analysis of data. Consultant statistician performed the analysis of data by using graphpad prism8 software.

## Results

The study was conducted during the month of January to June 2018, 15 patients were included in this trail. Figure 1. Shows the patients flow chart.



Total 15 patients, 11 (73.33%) are male while 4 (26.66%) were females. There was 1 (6.66%) subject from 21 to 30 years, 6 (40%) subjects from 31 to 40 years of age, 6 (40%) subjects from 41 to 50 years of age and 2 (13.33%) subjects from 51 to 60 years of age. The SF-12 questionnaire, physical domain and psychological domain were statistically significantly ( $P < 0.001$ ) (Table 1). 6 medicines were used to treat 15 patients with constitutional treatment. The most commonly prescribed medicine was Sulphur ( $n=5$ , 33.3%), Nux Vomica and Phosphorus ( $n=3$ ; 20.2% each), Lycopodium ( $n=2$ ; 13.3%), Natrum Muriaticum and Puls ( $n=1$ ; 6.7 % each). (Figure 2) They are mentioned in the descending order of their prescription: *Sulphur* ( $n=5$ ), *Nux Vomica* & *Phosphorus* ( $n=3$  each), *Lycopodium* ( $n=2$ ), *Nat Mur* & *Puls* ( $n=1$  each).

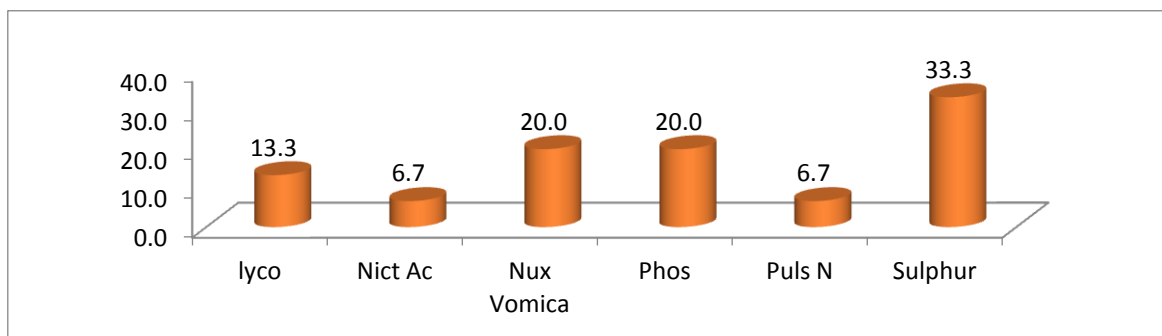
**Table 1** Physical Domain (Paired Samples Test)

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
180 Days – 0 Day Base Line	19.0	12.490	3.2249	12.08327	25.91673	5.892	14	.0001

Psychological Domain (Paired Samples Test)

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
180 Days – 0 Day Base Line	4.73333	7.186	1.855	.7539	8.7128	2.551	14	.023

**Figure 2**



After 180 days of Homoeopathic treatment there was reduction was achieved in Bleeding per rectum, Pain, Mucus discharge, Pruritis and straining on defecation on VAS scale (mm) were

statistically significant. Table 2,3,4,5. However, no statistically significant on Anoscopic score Table 6.

**Table:2**

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std Error Mean	95 % Confidence interval of the difference					
			Lower	Upper				
90 days – 0 Day Base Line	6.67	2.831	12.74	0.59	2.3547	14	0.033 (this difference is considered to be statistically significant)	
180 days – 0 Day Base Line	21.33	5.946	34.09	8.58	3.5881	14	0.003 (this difference is considered to be very statistically significant)	

**Table: 3**

	Paired Differences				t	df	Sig. (2-tailed)
	Mean	Std Error Mean	95 % Confidence interval of the difference				
			Lower	Upper			
90 days – 0 Day Base Line	2.33	0.959	4.39	2.33	2.4318	14	0.0290 (this difference is considered to be statistically significant.)
180 days – 0 Day Base Line	32	4.701	42.08	21.92	6.8077	14	0.001 (this difference is considered to be statistically significant.)

**Table: 4**

	Paired Differences				t	df	Sig. (2-tailed)
	Mean	Std Error Mean	95 % Confidence interval of the difference				
			Lower	Upper			
60 days – 0 Day Base Line	-2.00	10447	-5.10	1.10	1.3817	14	P is equal to 0.1887 (this difference is considered to be not statistically significant.)
180 days – 0 Day Base Line	5.33	1.420	8.38	2.29	3.7564	14	P is equal to 0.002 (this difference is considered to be statistically significant.)

**Table: 5**

	Paired Differences				t	df	Sig. (2-tailed)
	Mean	Std Error Mean	95 % Confidence interval of the difference				
			Lower	Upper			
60 days – 0 Day Base Line	1.00	1.000	-1.14	3.14	1.0000	14	0.3343 (this difference is considered to be not statistically significant)
180 days – 0 Day Base Line	5.33	0.766	3.69	6.98	6.9593	14	P value is less than 0.0001 (this difference is considered to be statistically significant)

**Table 6**

		180 days		Total	Chisquare	P Value
		No signs of inflammation	A rather active grade, haemorrhoids without overt inflammatory findings (mild anitis),			
Base Line 0 day	No signs of inflammation	1	0	1	3.545	0.170
	A rather active grade, haemorrhoids without overt inflammatory findings (mild anitis),	4	7	11		
	An actively or easily bleeding haemorrhoids with overt signs of inflammation and oedema (severe anitis).	0	3	3		
Total		5	10	15		

**Discussion**

This study was conducted at UHC Homoeopathic OPD sangareddy, encompassing a population

from various walks of life in an Urban health-care setting.

Total 15 patients who completed the trial, there were 11 (73.33%) males and 4 (26.66 %) females. The higher incidence of male patients in this trial could be due to the predominant male population attending the OPD and the higher incidence of the disease in males in this region, lack of female patients being aware or not reporting of the disease. It was observed in the current study that the incidence of haemorrhoids was high amongst the young population between 31 to 40 years (40%) and 41 to 50 years (40%).

To Assess the efficacy of the Homoeopathic medicine was done by evaluating the difference in mean and percentage change of grades in the VAS score and in the grade/severity of the various symptoms by comparing at baseline score and at 180 days. Mean, Standard deviation, p values and percentage changes from base line till 180 days were calculated to arrive to conclusions. It was observed that there was a statistically significant reduction in symptoms like bleeding per rectum, straining on defecation etc. So, this therapy has no side effects for patients coming for outpatient department.

### Conclusion

This study illustrates the efficacy of homoeopathic treatment in haemorrhoidal disease. The present study confirms the efficacy and safety of Homoeopathic treatment in relieving symptoms of hemorrhoids. Symptoms such as straining on defecation and constipation was significantly reduced at the end of the study. Hence, it can be concluded that individualised Homoeopathic treatment can be used safely and effectively in the treatment of hemorrhoids. Randomized controlled trials with double-blind design are suggested further.

**Financial Support** Nil.

**Conflicts of Interest** There are no conflicts of interest.

**Acknowledgement** I sincerely acknowledge our Management and the Principal MNR Homoeopathic Medical College and Hospital, Sangareddy for their support for this work.

### References

1. Shah Siddharath H., API Text book of Medicine. 7th edition revised reprint Mumbai; the Association of Physicians India, 2006 573pp.
2. R.C.G. Russel, N.S. Williams, C. J. K. Bulstrode, Baily and love short practice of surgery, 23<sup>rd</sup> edition, London; Oxford press 2003 ;1128pp.
3. Chatterji B P Short textbook of Surgery, vol 2 second edition, Culcutta, Sen J N, New central book agency 1981,258-26pp
4. Kasper D L, Fauci A S Longo D L, Braunwald E, Hauser S C, Jameson J L Harrison's principles of internal medicine, vol 2 16<sup>th</sup> edition, The Mcgrow-Hill companies Inc USA, 2005, 1801pp.
5. en.wikipedia.org/wiki/hemorrhoids.
6. [https://www.rand.org/health/surveys\\_tools/mos/12-item-short-form.html](https://www.rand.org/health/surveys_tools/mos/12-item-short-form.html)
7. Vijay Padmakarrao Ukhalkar<sup>1</sup>, Gopal Rathi<sup>2</sup>, Ramesh Jadav<sup>3</sup> and Sanjay Tamoli<sup>\*4</sup>, An Open Labeled, Single Centre, Prospective, Clinical Study To Evaluate Efficacy And Safety Of Arwl12 Capsule In Patients Suffering From Internal Hemorrhoids, International Journal Of Pharma And Bio Sciences, April; 6(2): (P) 309 – 323.
8. Douglas Mackay. "Haemorrhoids and varicose veins: A review of treatment options. Alternative medicine review 2001 April; 6(2): 126-140.
9. Sudarshan SR. A case of bleeding piles cured with Puls. The Homoeopathic Heritage 1991;16:195-6.
10. S. Riss, F. A. Weiser, T. Riss, K. Schwameis, M. Mittlböck, A. Stift, Haemorrhoids and quality of life, 26 October 2010. (<https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1463-1318.2010.02480.x>)

11. Carsten Maurischat, Peter Herschbach, Achim Peters & Monika Bullinger, Factorial validity of the Short Form 12 (SF-12) in patients with diabetes mellitus, *Psychology Science Quarterly*, Volume 50, 2008 (1), p. 7-20.
12. Hahnemann Samuel. Translated by Boericke William. *Organon of Medicine*, 6th ed. New Delhi: B Jain Publishers; 1979.
13. P. S. Chakraborty, Roja Varanasi, A. K. Majumdar, KishanBanoth, Sunil Prasad, M. S. Ghosh, M. N. Sinha, G. Ravi Chandra Reddy, Vikram Singh, Chaturbhuj Nayak, effect of homoeopathic lm potencies in acute attacks of haemorrhoidal disease: a multicentric randomized single-blind placebo-controlled trial, *Indian Journal of Research in Homoeopathy / Vol. 7 / Issue 2 / Apr-Jun 2013*, page 72 to 76.
14. Vijay Padmakarrao Ukhalkar, Gopal Rathi, Ramesh Jadav And Sanjay Tamoli, An Open Labeled, Single Centre, Prospective, Clinical Study To Evaluate Efficacy And Safety Of Arw12 Capsule In Patients Suffering From Internal Hemorrhoids, *International Journal Of Pharma And Bio Sciences*, *Int J Pharm Bio Sci* 2015 April; 6(2): (P) 309 – 323.
15. Menten B, Gorgui Ahmet, Tatlicioglu E, Ayoglu F, Unal S. Efficacy of calcium dobesilate in treating acute attacks of haemorrhoidal disease. *Dis Colon Rectum* 2001; 44:1489- 94.