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Effect of homoeopathic LM potencies in acute attacks of haemorrhoidal disease: A multicentric randomized single-blind placebo-controlled trial

P. S. Chakraborty, Roja Varanasi, A. K. Majumdar[1], Kishan Banoth[2], Sunil Prasad[3], M. S. Ghosh[4], M. N. Sinha[5], G. Ravi Chandra Reddy[6], Vikram Singh, Chaturbhuja Nayak

Central Council for Research in Homoeopathy, New Delhi, [1]Dr. Anjali Chatterjee Regional Research Institute (Homoeopathy), Kolkata, [4]Clinical Research Unit (Homoeopathy), Siliguri, West Bengal, [2]Regional Research Institute (Homoeopathy), Gudivada, [6]Clinical Research Unit (Homoeopathy), Tirupathi, Andhra Pradesh, [3]Clinical Research Unit (Homoeopathy), Agartala, Tripura, [5]Regional Research institute (Homoeopathy), Jaipur, Rajasthan, India

Address for correspondence:
Dr. Roja Varanasi,
Research Officer (H)-Scientist 1,
Central Council for Research in Homoeopathy, 61-65 Institutional Area, Janakpuri, New Delhi, India.
E-mail: varanasiroja@gmail.com

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ABSTRACT

Background and Objectives: Anecdotal data on the usefulness of homoeopathic medicines in acute haemorrhoids shows grade V evidence. So, the efficacy of individualized homoeopathic medicines in LM potencies, in Acute Haemorrhoidal Attacks (AHAs), was investigated in this study against placebo.
Material and Methods: In a multicenter randomized controlled single-blind parallel group trial conducted at six centers under the Central Council for Research in Homoeopathy, patients who presented with any symptom such as bleeding, pain, discharge, heaviness, and itching were included. The patients were randomized to receive either individualized homoeopathic medicine or placebo for a period of 90 days. Changes in haemorrhoidal symptoms were the main outcome measures.
Results: Two hundred and seventy-eight patients (Homoeopathy: n = 140, placebo: n = 138) were analyzed. After 90 days of treatment, a significant difference (P = 0.0001) was found in the median area under the curve (AUC) for bleeding {difference: −64.0 [95% confidence interval (CI): −90.0, −31.4]}, pain [−243.0 (−280.9, −202.4)], heaviness [−208.0 (95% CI: −245.5, −174.9)], and itching [−198.5 (−246.4, −158.5)] between the Homoeopathy and placebo groups. Significant differences (P < 0.001) were also found in the World Health Organization Quality of Life-BREF (WHOQOL-BREF) physical domain [difference 7.0 (95% CI: 6.0, 12.0)], psychological domain [7.0 (6.0, 12.0)], and environmental domain [6.0 (−0.001, 11.9)]. However, no difference was found in discharge [0.0 (−21.0, −0.0); P = 0.1386] and social domain of the WHOQOL-BREF [0.0 (−0.001, 5.9; P = 0.0803)].
Conclusion: In this study, homoeopathic intervention relieved acute haemorrhoidal symptoms early compared to the placebo group. Randomized controlled trials with double blinding are suggested further.

Keywords: Acute haemorrhoidal attacks, Haemorrhoids, Homoeopathy, Randomized controlled trial

INTRODUCTION

Haemorrhoids have been referred to in the literature dating back to the pre-Christian era and are a common condition. Prevalence in western population statistics varies from 4.4% in the general population to 36.4% in general practice.[1] In India with the advent of western culture and diet, the scenario is no better despite the diet being richer in fibre, that is, 2.4 to 40%.[2,3]

Haemorrhoids may be internal or external in nature depending on its location above or below the dentate line in the anal region. Internal haemorrhoids are the symptomatic, exaggerated, submucosal vascular tissue located above the dentate line and covered by transitional and columnar epithelium. It can be divided into four categories. Grade 1: These bulge into the lumen of the anal canal and may produce painless bleeding. Grade 2: These protrude at the time of a bowel movement but reduce spontaneously. Grade 3: These protrude spontaneously or at the time of a bowel movement and require manual replacement. Grade 4: These are permanently prolapsed and irreducible despite attempts at manual replacement. In a classic case, bleeding is bright red and painless and occurs at the end of defaecation. The patient complains of blood dripping or squirting into the toilet bowl. External haemorrhoids comprise the dilated vascular plexus that is located below the dentate line and covered by the squamous epithelium.[1]

Controversies and lack of agreement still exist on treatment strategies. On the one hand, nonsurgical treatment modalities such as rubber band ligation, injection schlerotherapy, photocoagulation, and cryotherapy are well established and acceptable to patients. However, they are not suitable for all grades of haemorrhoids and have recognized complications.[4-8] On the other hand, surgical haemorrhoidectomy is associated with a significant morbidity, complications, and may lead to delays in return to work. It is worth noting that 26% of the patients who require a haemorrhoidectomy may have a recurrence, and 11% need further treatment. Similarly, approximately half of those who undergo office procedures may require further treatment or surgery in 5 to 10 years.[1,9] Laxatives and a high-fibre diet help to some extent in reducing the symptomatic haemorrhoids.[10-12] The cost to the community, both financial and in lost working days is great and by any standards this condition must be considered a major health hazard.[2]

Homoeopathic literature shows anecdotal data on the efficacy of homoeopathic medicines in haemorrhoids. Although various practitioners and clinicians quote brilliant cure of haemorrhoids with homoeopathic medicines, there is low evidence[13-19] and lacks controlled studies.

Homoeopathic dynamized medicines are given in 'uncommonly small doses'. Hahnemann, the father of Homoeopathy aimed at achieving 'a rapid, gentle and permanent restoration of the health', which seemed to him easier to achieve with his last dynamization method, known as 50 millesimal, Quinquagintamillesimal (Q-potencies), or LM potencies, in which the medicine is diluted ≈50,000 times at each step (potency) of the dynamizing process.[20]

There is no controlled study of the homoeopathic use of LM potencies in acute attacks of haemorrhoidal disorders. Nevertheless, LM potencies have been recently tested in randomized, controlled studies showing therapeutic effects in fibromyalgia, attention deficit hyperactivity disorder, and depression as compared to placebo/active control.[21-23]

The present study was aimed at investigating the effectiveness of individualized homoeopathic medicines (LM potencies) in Acute Haemorrhoidal Attack (AHA), as compared to placebo in a prospective, randomized, single-blind, parallel trial, and secondary changes in quality of life.

MATERIAL AND METHODS

Trial Design

This is a multicenter randomized placebo-controlled parallel group study. Six investigators from six study centers participated in the trial for screening, treating patients, and collecting data. Investigators were trained in the protocol before initiation of the study. Consultant surgeons were engaged at each study center to assess the patients as per protocol. All patients gave their written informed consent before enrollment in the study. The study protocol was approved by the ethical committee of the council. The study has been registered in the Clinical Trials Registry - India, CTRI/2012/04/002541.

Patients and Setting

Inclusion criteria for patients were: Male and female patients between 25 and 60 years suffering from internal haemorrhoids presenting with any of the symptoms, namely, bleeding, pain (including discomfort and tenesmus during defaecation or any other time), heaviness, pruritus, and mucus discharge with or without anitis. Patients with controlled diabetes (HbA1C < 8%) and controlled hypertension and thyroid disorders were also eligible for the

study. Patients using topical agents for haemorrhoids were included after a washout period of one week, subject to persistence of symptoms and signs of haemorrhoids.

Patients with the following conditions were excluded: Anal fissure, fistula in ano, inflammatory bowel disease, chronic alcoholism, recreational drug abuse, coagulation disorders, external haemorrhoids, previous history of surgery for haemorrhoids, hypertrophic anal papillae, haemoglobin of <7 gm/dL, malignancies of the rectum, history of leukemic disorders, patients with obstruction of portal circulation, pregnancy leading to obstruction of the portal circulation, lactating mothers, patients with psychiatric diseases, and inability to comply with the study protocol.

The study was conducted at six centers under the Central Council for Research in Homoeopathy which was decided. Regional Research Institute for Homoeopathy, Jaipur, Rajasthan, Regional Research Institute for Homoeopathy, Gudivada, Andhra Pradesh, Dr. Anjali Chatterjee Regional Research Institute for Homoeopathy, Kolkata, West Bengal, Clinical Research Unit for Homoeopathy, Siliguri, West Bengal, Clinical Research Unit for Homoeopathy, Agartala, Tripura, and Clinical Research Unit for Homoeopathy, Tirupathi, Andhra Pradesh.

Study Interventions

The homoeopathic medicines in LM potencies were procured from a Good Manufacturing Practices (GMP)-certified company. The investigators were instructed to have an in-depth interview with the patient, as per the guidelines laid down by Hahnemann S[20] in the sixth edition of the Organon of Medicine and follow-up of all the patients were done as per homoeopathic principles. However, the final decision was taken after consultation with the Materia Medica.

All the participants, irrespective of the medicine or placebo group, were encouraged to correct constipation and unhealthy defaecation habits such as ignoring the need to pass stools, irregular meals, spending a long time in the lavatory, straining, and lack of exercise. They were also advised about the importance of a fibre-rich diet in health and encouraged to consume food rich in natural fibre such as unpeeled fruits, vegetables, and whole-grain bread, and so on, and prohibited from high consumption of spices.

Homoeopathic Intervention

Patients randomized to the intervention group received individualized homoeopathic medicine and the same was selected as per homoeopathic principles[20] for 90 days customized to each patient which started with 0/1 potency, followed by the next higher potency, serially, as per need of the case. The investigator or the pharmacist on instruction from the investigator dispensed the medicine/placebo as follows: One globule (poppy seed size) of the desired potency was dissolved in 120 mL of distilled water, containing 2.4 mL (2% v/v) of dispensing alcohol, premixed in it, followed by 10 uniformly forceful downward strokes given against the bottom of the phial. The medicine was given two to six hourly, even oftener: six hourly in mild cases, four hourly in moderate cases, two hourly in severe cases, and less than two hourly for very intense conditions. Each patient was advised to give 10 uniformly forceful downward strokes to the bottle with the hand on a hard surface and to take three teaspoonfuls (15 mL) of this solution and mix it in eight teaspoonfuls (40 mL) of water in a clean glass after stirring the solution for each dose of medicine taken. One teaspoonful (5 mL) of this solution constituted one dose. If any change was triggered after administration (improvement/deterioration), change of remedy followed homoeopathic principles.

Control Group

Patients randomized to the control group received placebo for the duration of the study (90 days). It constituted unmedicated poppy-sized sugar globules impregnated with dispensing alcohol. Mode of dispensing of the placebo was similar to that of the medicine. Any change triggered after administration (improvement) was followed by placebo only. However, if a patient worsened after 14 days of taking placebo, the investigator was instructed to give these patients rescue homoeopathic medicine due to ethical reasons.

Outcomes

The primary outcome measure was changes in symptoms of haemorrhoids, that is, bleeding followed by pain, heaviness, discharge, and itching.[24,25] The secondary outcome measure was changes in quality of life using the World Health Organization Quality of Life-BREF (WHOQOL-BREF). Follow-up period was of a duration of three months (90 days). Symptomatic assessments were done at baseline, day 0 (before treatment), 3rd, 7th, 14th,

28th, 60th, and 90th day by the study investigator and consultant surgeons at the respective centers. Bleeding was assessed on a scale of 0-3:[25] A score of 3 was considered as severe if it occurred more than five times a week, a score of 2 was considered moderate if it occurred less than three to five times a week, a score of 1 was considered as mild if it occurred one to less than three times a week, and if the bleeding did not occur at all, then it was scored as zero. Pain, heaviness, discharge, and itching were measured on a Visual Analogue Scale ranging from 0 to 10, where zero corresponded to no symptoms and 10 corresponded to the worst possible symptoms as described by previous researchers.[24,25] However, due to ethical considerations, on the 14th day of assessment, if symptoms of a patient were worsened, the investigator was instructed to give the patient in the placebo group a rescue homoeopathic medicine. Investigators were allowed to follow-up the patients telephonically if required.

Anoscopic examination was done by consultant surgeons at baseline, 7th, 14th, 28th, 60th, and 90th day, on a scale of 0 to 2 as follows:[25] 0 = no signs of inflammation, 1 = a rather active grade, haemorrhoids without overt inflammatory findings (mild anitis), and 2 = an actively or easily bleeding haemorrhoids with overt signs of inflammation and oedema (severe anitis).

Haemoglobin (Hb), packed cell volume (PCV), mean cell volume (MCV), mean cell haemoglobin (MCH), and mean cell haemoglobin concentration (MCHC) were done at baseline and every month to assess changes during treatment, if any. The WHOQOL-BREF questionnaire has been designed to be applicable to people living in different conditions or cultures. This questionnaire has been validated in the Indian population. It contains 26 items divided into four domains: physical, psychological, social relationships, and environmental. All the patients were assessed on this scale for their quality of life at baseline and at end of study (90th day).

Sample Size

From various clinical records, it was found that AHAs can be managed with homoeopathic medicines.[14-19] The natural history of symptomatic haemorrhoids suggests the self-limiting nature of this disease.[26] With this in mind, it was assumed that there would be 50% change in signs and symptoms in patients taking placebo and that a further 20%, that is, 70% patients would improve in symptoms and signs in the Homoeopathy group, with an α - 0.05 and power of 85%. A sample-sized table by Fleiss[27] was used for estimating the sample. A total of 250 patients (125 patients in each group) were needed to prove or disprove the hypothesis. Therefore, a total of 280 patients were considered including 12% dropouts.

Randomization and Blinding

Random numbers were generated from a computer-based software available at www.randomizer.org. Twenty-three sets of two unique numbers per set were generated using block design. The same set of random numbers was used in each center. Both placebo and homoeopathic medicines were made identically so that they were indistinguishable. Due to the individualized nature of homoeopathic prescription, blinding of the investigator was not done. The investigator was aware of the intervention given to enrolled patients. Only the patients were blinded to the intervention.

Statistical Methods

Reporting adhered to the Consolidated Standards of Reporting Trials statement for reports of parallel group randomized designs. Data are presented as number (%) or median [interquartile range (IQR)] as appropriate. As the data did not follow normal distribution, all the analyses were done using nonparametric tests. Baseline characteristics between the groups are presented. MedCalc version 11 was used for calculation of Area Under the Curve (AUC), Minitab version 16 for calculating 95% confidence intervals (CIs) of median, and SPSS version 20 for descriptive statistics. Where telephonic follow-up was not possible or the patient was not available for it, their missing values were replaced by last observation. AUC was calculated at seven time points (baseline, 3rd day, 7th day, 14th day, 28th day, 60th day, and 90th day) for bleeding, pain, heaviness, discharge, and itching. AUC for anitits score was calculated at six time points (baseline, 7th day, 14th day, 28th day, 60th day, and 90th day). Patients who entered early escape were counted in the treatment regimen to which they were originally assigned. Efficacy data and changes in WHOQOL-BREF are also presented by actual treatment received based on the early escape status. In all analyses, if a patient entered early escape at day 14, the baseline values were carried forward to impute missing values. $P < 0.05$ was considered as significant.

RESULTS

Between June 2009 and September 2010, 501 patients were screened for the trial. Treatment and follow-ups of the patients were completed by December 2010. Figure 1 shows the patient flow in the study. The baseline characteristics of the patients were almost similar in the two groups [Table 1]. Male:Female ratio was 2:1 in both the groups; 83% of the patients were nonvegetarians.

After 90 days of treatment, the median AUC bleeding was 18.0 (95% CI: 15.4; 26.0) in the Homoeopathy group which was significantly better ($P = 0.0001$) than for the placebo group, which had a median AUC of 90.0 (56.5; 146.9). The results were similar for AUC pain [Homoeopathy: 105.0 (82.2; 121.0) vs. placebo: 342.7 (304.5; 423.8); $P = 0.0001$)], AUC heaviness [Homoeopathy: 82.5 (69.0; 103.0) vs. placebo: 292.2 (270.0; 343.4; $P = 0.0001$], AUC itching [Homoeopathy 57.5 (41.9; 69.0) vs. placebo: 270.0 (216.0; 332.9; $P = 0.0001$]. However, no difference was found in AUC discharge (Homoeopathy 21.0 (10.4; 37.1) vs. placebo 30.7 (0.0 to 57.0); $P = 0.1386$] [Table 2].

Time to bleeding and pain clearance was analyzed by survival methods [Figures 2 and 3]. The median bleeding clearance time was 14 days and 90 days and median pain clearance was 60 days and 90 days for the Homoeopathy and placebo groups, respectively. Log rank test showed significant difference between the groups ($P = 0.0001$). At day 90, bleeding clearance in Homoeopathy group was found in 97% patients, much higher than in the placebo group, that is, 38.4%. Similar results were found for pain clearance (75 vs. 13.7%).

The WHOQOL-BREF physical domain, psychological domain, and environmental domain were significantly better ($P < 0.001$) in Homoeopathy compared to placebo group [Table 2]. In parallel with symptomatic healing, the median AUC for anitis rated through anoscopy was significantly better ($P = 0.0001$) in the Homoeopathy group: 21.0 (95% CI: 10.5; 25.5) compared to placebo 90.0 (95% CI: 75.0; 90.0) [Table 2].

19 medicines were used to treat 140 patients randomized homoeopathic group. They are mentioned in the descending order of their prescription: *Phosphorus* ($n = 30$), *Sulphur* ($n = 25$), *Nux vomica* ($n = 22$),

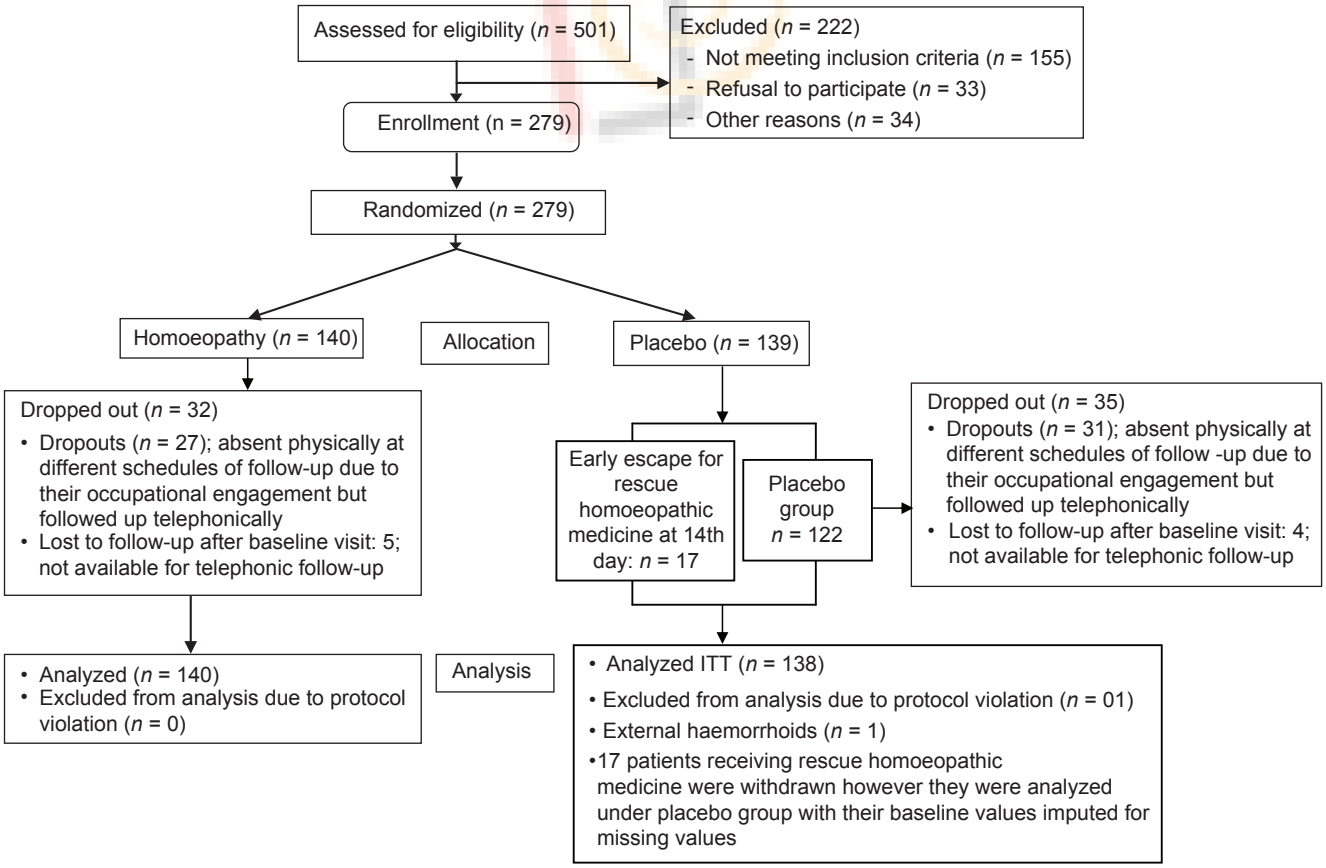

Figure 1: CONSORT flow chart of the patients in the study

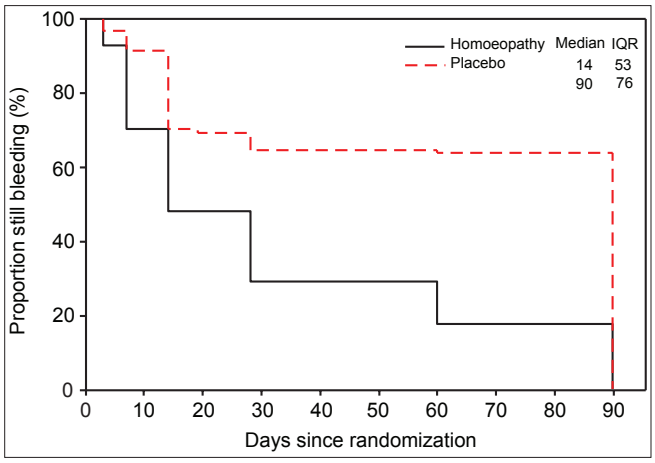

Figure 2: Kaplan Meir curve of time-to-bleeding clearance

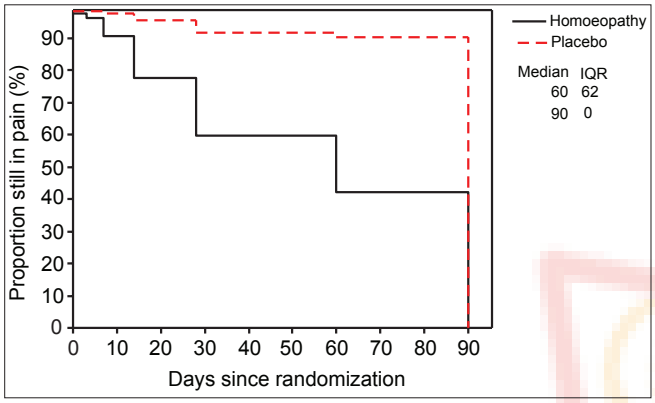

Figure 3: Kaplan Meir curve of time-to-pain clearance

Nitric acid ($n = 17$), *Lycopodium clavatum* ($n = 9$), *Arsenicum album* ($n = 7$), *Pulsatilla pratensis* ($n = 6$), *Ignatia* ($n = 5$), *Aesculus hippocastanum* ($n = 4$), *Carbo vegetabilis* ($n = 2$), *Calcarea carbonica* ($n = 2$), *Chamomilla* ($n = 2$), Fluoric acid ($n = 2$), *Natrum muriaticum* ($n = 2$), *Aloes socotrina* ($n = 1$), *Graphites* ($n = 1$), *Kalium carbonicum* ($n = 1$), *Lachesis* ($n = 1$) and *Mercurius solubilis* ($n = 1$).

Table 3 demonstrates the improvement, status quo, and worsening of patients on 90th day of treatment cum follow-up for bleeding, pain, discharge, heaviness, and itching. The proportion of patients with bleeding improvement was higher in the homoeopathy group (94.3%) versus placebo (43.5%). Similarly for status quo, it was 8 (5.7) versus 65 (47.1) and for worsened status, 0 (0) versus 13 (9.4%) which is statistically significant ($\chi^2 = 84.5$, $P = 0.0001$).

Table 1: Baseline characteristics of intention-to-treat population

Variable	Homoeopathy (*n*=140)	Placebo (*n*=138)
Age (years)	38 (30,47.7)	38.5 (30,48)
Sex		
Male	96 (68.6)	85 (61.6)
Female	44 (31.4)	53 (38.4)
Duration of haemorrhoids in years	2 (1;3)	2 (1;3)
Food habits		
Vegetarian	23 (16.4)	22 (15.9)
Non-vegetarian	117 (83.6)	116 (84.1)
Grade of haemorrhoids		
Grade 1	61 (43.6)	67 (48.6)
Grade 2	69 (49.2)	59 (42.8)
Grade 3	25 (17.8)	28 (20.2)
Grade 4	0	01 (0.7)
Position of haemorrhoids		
3 o'clock	93 (66.4)	92 (66.7)
5 o'clock	25 (17.9)	25 (18.1)
7 o'clock	86 (61.4)	83 (60.1)
9 o'clock	0	01 (0.7)
11 o'clock	79 (56.4)	66 (47.8)
Symptoms/signs present		
Bleeding (0-3)	137 (97.8), 2 (1,2)	127 (91.0), 2 (1,2)
Pain (VAS: 0-10)	137 (97.8), 6 (5,8)	135 (97.8), 6 (3.7,7)
Discharge (VAS: 0-10)	74 (52.8), 1 (0,5)	51 (36.9), 0 (0,3)
Heaviness (VAS: 0-10)	133 (95), 5 (3,6)	129 (93.4), 5 (3,6)
Itching (VAS: 0-10)	119 (85), 5 (2,6)	130 (94.2), 5 (3,6)
Anitis (0-2)	100 (71.4),1 (0,1)	90 (65.2), 1 (0,1)
WHOQOL-BREF		
Physical domain	56 (44,63)	50 (38,63)
Psychological domain	50 (44,56)	44 (31,56)
Social domain	50 (44,73.5)	50 (40.7,69)
Environmental domain	50 (39.5,63)	47 (38,56)
Blood parameters		
Hb	12.4 (11.2,13.7)	12.2 (11.2,13.6)
PCV	39 (36, 43)	39 (35, 43.2)
MCV	90 (85.2,96.7)	90 (84,102)
MCHC	32 (29.2,33)	32 (30,33)
MCH	29 (26,31)	29 (25,32)

WHOQOL: World health organization quality of life; VAS: Visual analogue scale, Values are presented in *n* (%), median (Q1, Q3), haemoglobin (Hb) in mg/dL, packed cell volume (PCV) in %, mean cell volume (MCV) in fl, mean cell haemoglobin concentration (MCHC) in g/dL, mean cell haemoglobin (MCH) in pg; the values under position of haemorrhoids and grade of haemorrhoids may not correspond to total number of patients as one patient may have more than one position or grade of haemorrhoids

DISCUSSION

To the best of our knowledge, this is the first randomized trial evaluating the effect of individualized homoeopathic treatment in AHA. We observed statistically significant differences in AHA patients who received individualized Homoeopathy for 90 days compared to patients who took placebo

Table 2: Outcome variables at the end of study

Variable	Homoeopathy (*n*=140)	Placebo (*n*=138)	Median diff (95% CI)*	*P* value
	Median (95% CI)			
Primary outcome				
AUC bleeding	18.0 (15.4; 26.0)	90.0 (56.5; 146.9)	–64.0 (–90.0, –31.4)	0.0001
AUC pain	105.0 (82.2; 121.0)	342.7 (304.5; 423.8)	–243.0 (–280.9, –202.4)	0.0001
AUC discharge	21.0 (10.4; 37.1)	30.7 (0.0 to 57.0)	0.0 (–21.0, –0.0)	0.1386
AUC heaviness	82.5 (69.0; 103.0)	292.2 (270.0; 343.4)	–208.0 (–245.5, –174.9)	0.0001
AUC itching	57.5 (41.9; 69.0)	270.0 (216.0; 332.9)	–198.5 (–246.4, –158.5)	0.0001
Secondary outcome				
AUC anitis score	21.0 (10.5; 25.5)	90.0 (75.0; 90.0)	–25.5 (–46.0, –14.9)	0.0001
WHOQOL-BREF				
Physical domain	63.0 (63.0; 69.0)	56.0 (56.0; 56.0)	7.0 (6.0, 12.0)	0.0001
Psychological domain	56.0 (56.0; 63.0)	50.0 (44.0; 56.0)	7.0 (6.0, 12.0)	0.0001
Social domain	53.0 (50.0; 56.0)	50.0 (44.0; 55.9)	0.0 (–0.001, 5.9)	0.0803
Environment domain	50.0 (50.0; 56.0)	44.0 (38.0; 50.0)	6.0 (–0.001, 11.9)	0.0005
Blood parameters				
Hb	12.4 (12.2; 12.8)	12.2 (12.0; 12.6)	0.2 (0.0, 0.6)	0.1268
PCV	40.0 (38.0; 41.0)	40 (38.0; 40.9)	0.0 (–1.0, 2.0)	0.4876
MCV	92.0 (90.0; 94.4)	90 (89.0; 93.0)	1.0 (–0.9, 3.6)	0.2242
MCHC	32.0 (31.0; 32.2)	32 (31.4; 32.0)	0.0 (–0.9, 0.7)	0.9976
MCH	29.0 (28.7; 29.7)	29 (28.7; 30)	0.0 (–0.7, 1.0)	0.7408

WHOQOL: World health organization quality of life, CI: Confidence interval, Hb: Haemoglobin, PCV: Packed cell volume, MCV: Mean cell volume, MCHC: Mean cell haemoglobin concentration, MCH: Mean cell haemoglobin, AUC: Area under the curve, *Mann-Whitney U test was used for comparing between the groups

Table 3: Proportion of patients improved/status quo/worsened in primary outcome variables at the end (90th day)

Symptoms/ signs	Homoeopathy (*n*=140) *n* (%)			Placebo (*n*=138) *n* (%)			Chi square**
	Improved	Status quo	Worsened	Improved	Status quo	Worsened	
Bleeding	132 (94.3)	8 (5.7)	0 (0)	60 (43.5)	65 (47.1)	13 (9.4)	84.5
Pain	130 (92.9)	7 (5.0)	3 (2.1)	70 (50.7)	51 (37.0)	17 (12.3)	61.2
Heaviness	125 (89.3)	13 (9.3)	2 (1.4)	59 (42.8)	62 (44.9)	17 (12.3)	67.5
Discharge	70 (50.0)	68 (48.6)	2 (1.4)	35 (25.4)	81 (58.7)	22 (15.9)	29.4
Itching	115 (82.1)	23 (16.4)	2 (1.4)	66 (47.8)	48 (34.8)	24 (17.4)	40.6

****P** value is highly significant at <0.0001, Improved: score became zero or decreased from baseline, status quo: Score remained same with baseline, worsened: Score increased from baseline

in most of the outcome measures after 90 days. This study was done at six centers in five states of India, encompassing a population from various walks of life in a primary health-care setting. The findings show a significant ($P = 0.0001$) symptom-free state or improvement in virtually all haemorrhoidal symptoms and physical, psychological, and environmental domains of WHOQOl-BREF after 90 days of treatment, having both internal and external validity and creating a strong supportive evidence for case reports of a lower evidence level.[14-19]

The planned sample size was 250 with 50% improvement in the placebo group and 70% improvement in the homoeopathy group with a power of 85%. The analysis supports the difference of 20% which further gives strength to the study design. On the other hand, advice about a fibre-rich diet and avoiding irregular bowel habits may be the confounding factors but these practical recommendations were required for patients to adopt a healthy lifestyle as 83.8% of the patients, irrespective of the intervention, were on a lower

fibre diet before commencement of treatment and might have adopted the changed lifestyle. So, the improvement can be attributed to a change in lifestyle also. Further, we find it inappropriate and unethical to not instruct them and only to create control groups. Our ethical committee too was against this restriction. The investigators were trained to teach a healthy lifestyle to all the patients. Another strength was involvement of surgeons, who were responsible for anoscopic scoring, adding credibility to the study.

One potential limitation of the study is lack of investigator blinding which was not possible due to the individualized nature of the intervention; one could, therefore, argue that our results might have been biased by a lack of sufficient blinding. Although this bias cannot be ruled out, a major bias seems unlikely to us because patients were informed in a manner suggesting that two different types of treatment would be compared. And, due to the nature of dispensing, the homoeopathic medicine and placebo were indistinguishable to the patient in taste and colour, favouring homoeopathic clinical trials. Another limitation of the study is advice for lifestyle changes, which the investigators might have given differently to the homoeopathic and placebo groups. These biases can be removed in a double-blind study design.

The results of our study shows improved benefit of 93.4% in bleeding with no adverse events from the homoeopathic therapy. There are at present no studies in the homoeopathic field to compare these findings; however, a double-blind placebo-controlled study by Mentes *et al*.,[25] with *Calcium dobesilate* showed 86.2% success rate after two weeks of treatment with few adverse events.

India is a country with a diverse population and with 52% people constituting a labor force occupied in agriculture and 25% people below the poverty line.[28] So, a therapy with no side effects for patients coming to outpatient departments of dispensaries in the primary health-care setting will be immensely helpful. This will cut the cost of medication as well as prevent suffering from invasive techniques which can lead to considerable side effects and complications.[4-8]

CONCLUSION

This study illustrates the efficacy of homoeopathic treatment in haemorrhoidal disease as compared to placebo in acute attacks. Randomized controlled trials with double-blind design are suggested further.

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पृष्ठभूमि और उद्देश्य: किस्सा सम्बन्धी आंकड़े तीव्र बवासीर में होम्योपैथी औषधियों की उपयोगिता का ग्रेड–5 प्रमाण प्रस्तुत करते हैं । इस अध्ययन में प्रायोगिक औषधि के खिलाफ एलएम पोटेंसी में विशिष्ट होम्योपैथी औषधियों का तीव्र बवासीर आक्रमण में प्रभाव की यादृच्छिक जांच की गयी ।

विधि: केन्द्रीय होम्योपैथी अनुसंधान परिषद के तहत छह केन्द्रों पर एक बहुकेंद्रीय यादृच्छिक नियंत्रित सिंगल ब्लाईंड समानांतर समूह परीक्षण किया गया । इस परीक्षण में रक्तस्त्राव, दर्द, स्राव, भारीपन और खुजली जैसे लक्षणों वाले रोगी शामिल किए गए थे। मरीजों को 90 दिनों की अवधि के लिए अनियमित तौर से विशिष्ट होम्योपैथी चिकित्सा या प्रायोगिक औषधि दी गयी । बवासीर के लक्षणों में परिवर्तन मुख्य परिणाम मापदंड था ।

परिणाम: कुल 278 रोगियों (होम्योपैथी, एन = 140, प्लासिबो, एन = 138) का विश्लेषण किया गया । 90 दिनों के उपचार के बाद, होम्योपैथी और प्रायोगिक औषध समूह में महत्वपूर्ण अंतर (पी = 0.0001) पाया गया । जिसमें रक्तस्त्राव में (अंतर: –64.0 (95: सीआई –90.0, –31.4), दर्द में (–243.0 (–280.9, –202.4), भारीपन में (–208.0 (95: सीआई –245.5, –174. 9), खुजली में (–198.5 (–246.4, –158.5) देखा गया । WHOQOL ब्रेफ के शारीरिक डोमेन (अंतर 7.0 (95: सीआई 6.0, 12.0) , मनोवैज्ञानिक डोमेन (7.0 (6.0, 12.0) और पर्यावरण डोमेन (6.0 (–0.001, 11.9) में भी महत्वपूर्ण अंतर (पी ढ0.001) पाया गया । हालाँकि, स्त्राव में (0.0 (–21.0, –0.0) पी = 0.1386) और WHOQOL के सामाजिक डोमेन (0.0 (–0.001, 5.9, पी = 0.0803), में कोई अंतर नहीं पाया गया ।

निष्कर्ष: इस अध्ययन से, तीव्र बवासीर के लक्षणों में, प्रायोगिक औषधि की तुलना में होम्योपैथिक हस्तक्षेप से जल्दी राहत मिली । इससे आगे डबल ब्लाईंड के साथ यादृच्छिक नियंत्रित परीक्षण किये जाने चाहियें ।