

# Effects of Individualized Homoeopathic Medicine in Haemorrhoid: a Single Blind, Simple Randomized, Placebo Control Study

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**Abstract:** ***Background:** Haemorrhoid, otherwise known as piles, with a worldwide prevalence of 4.4%, mainly hamper quality of life in terms of physical, mental, social and economic aspect by affecting working days of life, associated with severe pain, bleeding and itching. **Objective:** 1) Primary objectives: To study the response of homoeopathic medicines in haemorrhoids with response to change in disease severity and change in quality of life of the patient. 2) Secondary objectives: To ascertain the frequency of relapse and recurrence of haemorrhoids in patients during the course of treatment. **Methodology:** This observational study was done at Bhubaneswar, Odisha (in India) with the sample population 90 for duration of 2 years upon haemorrhoid outpatients of both genders with certain inclusion and exclusion criteria. **Results:** 53 patients out of 60 from medicine group showed positive response and 26 out of 30 patients from placebo group showed negative response. For WHOQoL, in both the test groups i. e. in centesimal and millesimal groups, the t values were 16.7744 and 18.0385 which shows that the difference was extremely statistically significant at  $p < 0.0001$ . In relapse and recurrence interval and overall response in medicine and placebo group were statistically significant ( $p < 0.0001$ ) as compared to placebo group. **Conclusion:** Efficacy of Homoeopathic treatment in case of haemorrhoid was concluded from this study suggesting a very well and positive response in case of cure, preventing frequent relapses and improving quality of life to live.*

**Keywords:** Homoeopathy, PNR Bleed Classification, WHOQoL score, Relapse recurrence interval, Quality of life

## 1. Introduction

One of the very most common medical condition "haemorrhoid", arises from congestion of the internal and/or external venous plexuses around the anal canal, broadly of two types as internal (above the dentate line) and external (below the dentate line), popular as "piles" in general population. (1) (2) (3).

Haemorrhoid incidence is 24% among the vegetarians in contrast to the people taking mixed diet i. e. veg. and non-veg. (76%) (4). Although overall prevalence is unknown (5) (due to less medical care requirement of asymptomatic piles outpatients), the estimated global prevalence of haemorrhoid disease (HD) is 4.4% in the general population (6) where as in some study the it is 11% based on self-reported signs and symptoms (7). As per certain study, piles affect almost equally in both sex with a maximum incidence within 45 to 65 years age and rarely under 20 years age (8). However certain study reveals male preponderance (9) (10) in contrast to some study suggests older people with co-morbidities and females especially including pregnancy (7). Some study confirms, 50% of the population suffer from haemorrhoid at some point in their life till reaching 50 years age where as 5% suffer at any age of life (11). HD is detected in almost 50% colorectal investigations (7) (12). Some report shows, In India HD is highest in cities like Bangalore, Delhi NCR, Hyderabad and Mumbai (13).

Although true etiopathogenesis of piles still remains elusive (14) (4), etiology includes constipation, increase intra-abdominal pressure (pregnancy, strenuous exercise, erect

position, staining during defaecation, ascites, obesity) (14) (15) (16), decreased vascular tone of sinusoids, sinusoidal arterial hyper perfusion (increased caliber of arterioles, impaired sphincter action.). Risk factors include prolonged sitting time on toilet, repeated use of valsalva maneuver (e.g. for relieving back pain in ankylosing spondylitis), chronic cough, squatting for longer period to defaecate etc. (7) (17) (18). Pathogenesis includes weakening of the anal cushion, leading to prolapse of haemorrhoids followed by internal sphincter spasm (3) (19) (5).

Based on degree of prolapse, haemorrhoid is classified into four grades i. e. (20):

Grade - I: Don't prolapse below the dentate line.

Grade - II: Prolapse below the dentate line, but reduces spontaneously.

Grade - III: Prolapse requires manual reduction.

Grade - IV: Irreducible prolapse below the dentate line.

Clinical features includes pain, bleeding, prolapse, mucus discharge, faecal seepage, pruritus ani (20) (21). To detect any anal pathology, inspection of anus at rest and during straining is necessary (22). Besides precise history, thorough physical examination including digital rectal examination, anoscopy; sigmoidoscopy/colonoscopy is suggested for rectal bleeding cases (especially with risk of colorectal cancer) (16) (17).

### Why we have done this study?

- Currently, HD is considered as major cause of morbidity with economically (affecting quality of life concerning loss of working days and quality of work because of pain, anal bleeding, itching etc. and mental

discomfort/irritability etc.) and socially (due to irregular lifestyle specifically related to food and sexual habits) impacted life in general population (23) (17) .

- Rubber band ligation, cryotherapy, sclerotherapy, bipolar probe, heat probe, infra - red coagulation like surgical interventions meant for grade - I and grade - II HD outpatients (24) . Although band ligation and injection sclerotherapy is most effective, but in minor cases haemorrhoidectomy is needed, which is usually curative (1) . According to the American College of Gastroenterology and the American Society of Colon and Rectal Surgeons guidelines rubber band ligation is the best therapy (25) .
- Well - designed studies show little evidence regarding use of over the counter preparations and low dose anesthetics, protectants, keratolytics, antiseptics, steroids etc. (17) .
- In common sense, conservative treatment is recommended as the first –line effective treatment, before corresponding surgery which is also suggested by most recent guidelines (26) (17) .
- Postoperative pain, incomplete elimination of discomfort, frequent relapses hinder patient's normal life to live (10) (23) (17) .
- Some studies reveal more than 50% complications occurrence frequently after anorectal surgery (17) (27) .
- Although the most common and serious complications of haemorrhoids include perianal thrombosis, strangulation of haemorrhoids and incarcerated prolapsed internal haemorrhoids with subsequent thrombosis; severe pain and higher rates of bleeding are more common as compared to other anorectal procedures (28) (29) (27) (17) .
- Along infection, ulcers, vasovagal reaction, urinary retention, other acute complications like thrombosed haemorrhoids and fissures, fistulas (anal, rectovaginal, ano - vaginal) have higher prevalence in PPH procedures (27) (30) .
- Long term complications include anal stricture, fecal incontinence and chronic pain (27) .
- The most feared complication is sepsis with a significant risk of death (30) .
- Participant characteristics and treatment patterns varied across countries (7) .
- It is challenging to determine the best treatment due to number of shortcomings to the literature and few head - to - head comparisons of individual therapies on the basis of effectiveness/cost effectiveness (25) .
- There are no published patient reported outcomes (PROs) which measure disease effects from patients' perspective (concerning symptoms, quality of life and functional status) regarding haemorrhoids/anorectal symptoms (25) .
- Surgery doesn't target habitual constipation or individual tendencies (31) .
- Homoeopathic treatment is very effective in case of haemorrhoids to cure the disease and to prevent frequent relapses; thus improves quality of life by means of individualized/anti - miasmatic treatment (32) (33) (17) (34) (35) .

In clinical practice many a times it has been seen that the homoeopathic system of medicines are giving promising results in the treatment of haemorrhoids. It is also a method of painless and cost effective treatment. Although promising, this study has been carried out to explore the scope of homoeopathic medicines further and to create more scientific and evidence based research in the treatment of haemorrhoids.

#### Study objectives:

- i) Primary objective: To study the response of homoeopathic medicines in haemorrhoids with response to change in disease severity and change in quality of life of the patient.
- ii) Secondary objectives: To ascertain the frequency of relapse and recurrence of haemorrhoids in patients during the course of treatment.

#### Study hypothesis:

- i) Null hypothesis ( $H_0$ ): There is no significant response to disease severity, quality of life and increase in relapse and recurrence interval of patients of haemorrhoids measured on identified parameters with homoeopathic treatment.
- ii) Alternate hypothesis ( $H_1$ ): There is significant response to disease severity, quality of life and increase in relapse and recurrence interval of patients of haemorrhoids measured on identified parameters with homoeopathic treatment.

## 2. Methodology

- i) Study settings – At International Study and Research Center on Homoeopathy, 92, Dharma Vihar, Khandagiri, Bhubaneswar. Ethical approval was obtained from the Institutional Ethical Committee of ISRCH. Written informed consent was obtained from all patients before to this study.
- ii) Study duration: Two years.
- iii) Sample size: 90  
Group – I - Test group with centesimal potency  
Group – II Test group with fifty millesimal potency  
Group – III Control with Placebo
- iv) Sampling method: Simple randomized.
- v) Study design: single blind simple randomized placebo control prospective observational study
- vi) Inclusion criteria:
  - a) Age - 18 - 60 years
  - b) Gender - Both male and female sexes
  - c) Cases of haemorrhoids presenting with (as per the PNR bleed classification):
    - Bleeding grade 1, 2 & 3
    - Prolapse grade 1, 2, & 3
    - Relation to dentate line 1, 2, 3 & 4
    - Number of haemorrhoids 1, 2, 3, & 4.
  - d) Patients with controlled diabetes and hypertension.
  - e) Patients with written informed consent
- vii) Exclusion criteria:
  - Not taken any treatment for hemorrhoid within last one month
  - Patient using any treatment for any systemic disorders.

- Presence of other disease conditions like rectal polyp, fissure in ano, anal condylomata and cancer rectum).
  - Irreducible prolapsed cases of haemorrhoids
- viii) Treatment plan – Symptoms were collected in a prescribed case taking. Totality was built up as per homoeopathic guidelines. Each case was repertorised and medicine was prescribed basing on reportorial result after due consultation with Materia Medica. Repetition schedule was infrequent both for 50 millesimal and Centesimal. Medicine was procured from a GMP certified pharmaceutical firm i. e. Dr. Willmar Schwabe India Pvt. Ltd. The medicine was given and repeated as per the homoeopathic principles.
- ix) Follow up - Response of medicine was identified and recorded by change with signs & symptoms at every

month along with change in ‘PNR Bleed’ classification of haemorrhoids at 6 months, Quality of life at 6 months and RRI at two years.

x) Outcomes Parameters:

Primary outcome -

- Change in severity of haemorrhoids through ‘PNR Bleed’ classification of haemorrhoids score at baseline and at the end of 6 months.
- Change in patient’s quality of life score through ‘WHOQOL - BREF’ at baseline and end of 6 months.
- Secondary outcome -
- Time to next relapse and recurrence interval (RRI) during the period of follow up assessed at the end of 2 years.

**Assessment Parameters:**

Parameters	Measurement scale
Disease severity	‘PNR Bleed’ classification of haemorrhoids
Quality of life	WHOQOL - BREF
Relapse & recurrence interval (RRI)	(a) Positive response - No relapse, reduced lesion (b) Negative response - Increased, unchanged lesion
Overall response	a) Positive response: ‘PNR Bleed’ classification of haemorrhoids scores reduced & RRI reduced, no relapse after treatment (b) Negative response: ‘PNR Bleed’ classification of haemorrhoids Score increased or standstill & RRI increased /unchanged after treatment

**3. Results**

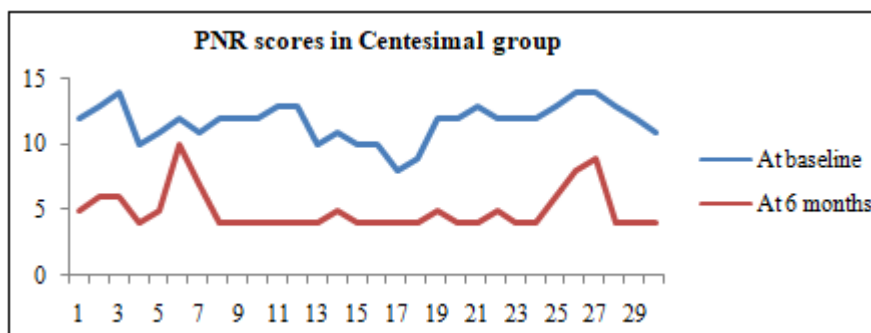
The scores of PNR Bleed classification at the baseline and at the end of 6 months of follow up were recorded as depicted in table - 1. Among the 30 patients from the centesimal study group 29 patients showed improvement scores at the 6

month follow up. Among the 30 patients from the fifty millesimal study group all patients showed improvement scores at the 6 month follow up. Among the 30 patients from the placebo group there was not much change marked in scores at the 6 month follow up.

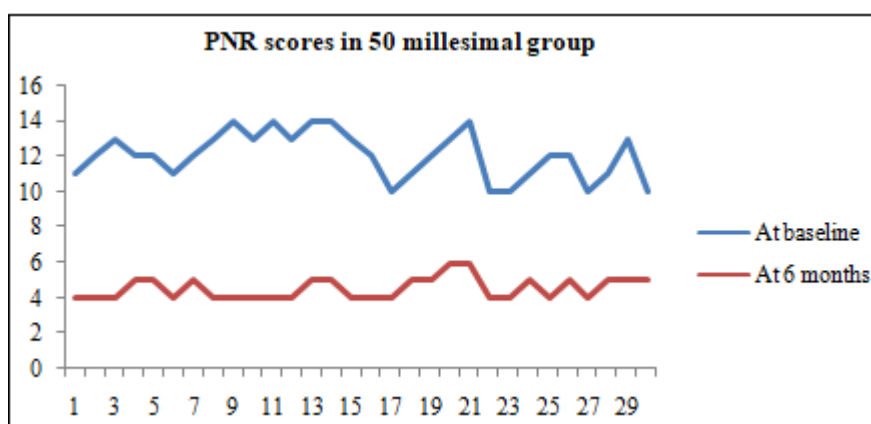
**Table 1:** Results of ‘PNR Bleed’ classification of haemorrhoids

Group – I (centesimal)			Group – II (fifty millesimal)			Group – III (placebo)		
Sl. No.	At baseline	At 6 months	Sl. No.	At baseline	At 6 months	Sl. No.	At baseline	At 6 months
1	12	5	31	11	4	61	12	10
2	13	6	32	12	4	62	11	9
3	14	6	33	13	4	63	12	10
4	10	4	34	12	5	64	13	10
5	11	5	35	12	5	65	14	11
6	12	10	36	11	4	66	12	10
7	11	7	37	12	5	67	12	10
8	12	4	38	13	4	68	14	14
9	12	4	39	14	4	69	14	14
10	12	4	40	13	4	70	12	12
11	13	4	41	14	4	71	11	11
12	13	4	42	13	4	72	12	12
13	10	4	43	14	5	73	13	12
14	11	5	44	14	5	74	14	14
15	10	4	45	13	4	75	12	12
16	10	4	46	12	4	76	10	12
17	8	4	47	10	4	77	9	12
18	9	4	48	11	5	78	8	8
19	12	5	49	12	5	79	9	9
20	12	4	50	13	6	80	10	12
21	13	4	51	14	6	81	9	9
22	12	5	52	10	4	82	10	5
23	12	4	53	10	4	83	14	5
24	12	4	54	11	5	84	12	12
25	13	6	55	12	4	85	11	11
26	14	8	56	12	5	86	10	9
27	14	9	57	10	4	87	11	10

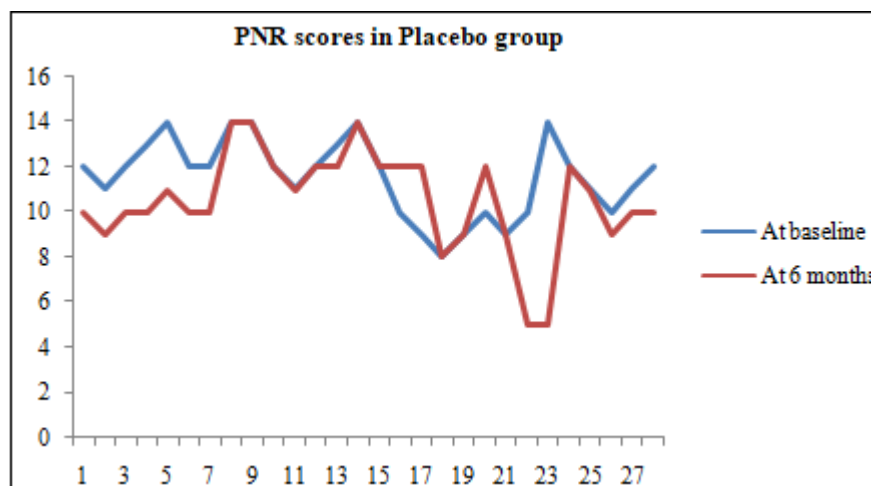
28	13	4	58	11	5	88	12	10
29	12	4	59	13	5	89	14	12
30	11	4	60	10	5	90	12	12



Graph 1: PNR Bleed scores in Centesimal group



Graph 2: PNR Bleed scores in Millesimal group



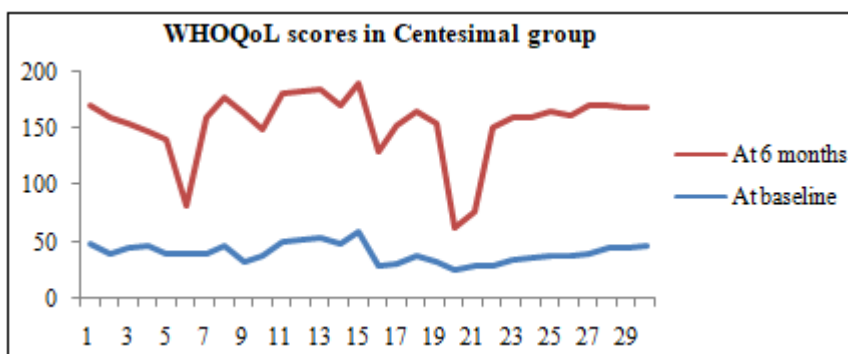
Graph 3: PNR Bleed scores in Placebo group

From the table - 2 it is marked that in centesimal group and fifty millesimal group the WHOQOL scores increased in 27 and 26 patients respectively at 6 months follow up but in placebo group there was no marked changes in WHOQOL scores.

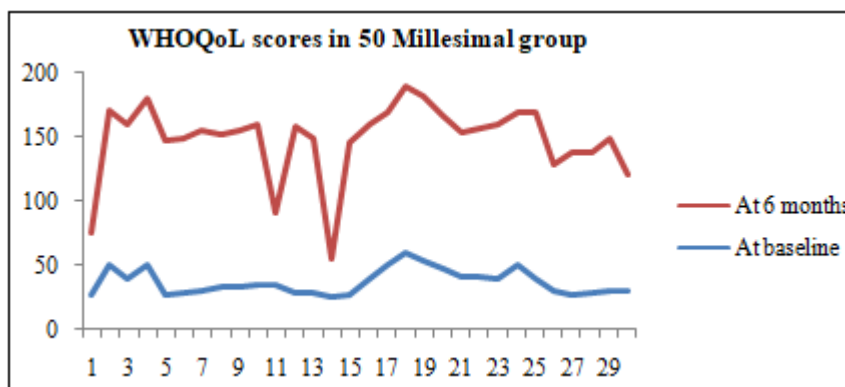
Table 2: Results of Quality of life by 'WHOQOL - BREF'

GROUP - I (centesimal)			GROUP - II (fifty millesimal)			GROUP - III (placebo)		
Sl. No.	At baseline	At 6 months	Sl. No.	At baseline	At 6 months	Sl. No.	At baseline	At 6 months
1	50	120	31	28	48	61	32	30
2	40	120	32	50	122	62	30	30
3	45	110	33	40	120	63	41	41
4	47	100	34	50	130	64	42	40
5	40	100	35	28	120	65	44	48
6	41	40	36	29	120	66	50	54
7	40	120	37	30	125	67	60	60
8	48	130	38	33	120	68	48	42

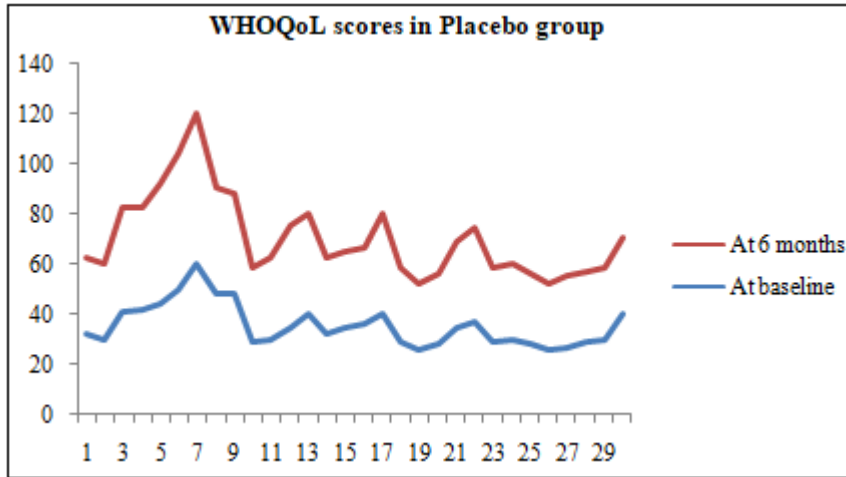
9	34	130	39	34	122	69	48	40
10	38	111	40	35	125	70	29	29
11	51	130	41	36	56	71	30	32
12	52	130	42	29	130	72	35	40
13	55	130	43	29	120	73	40	40
14	49	121	44	26	30	74	32	30
15	60	130	45	28	118	75	35	30
16	30	100	46	40	120	76	36	30
17	32	120	47	50	120	77	40	40
18	38	128	48	60	130	78	29	29
19	34	120	49	54	128	79	26	26
20	26	36	50	48	118	80	28	28
21	29	48	51	42	112	81	35	34
22	30	120	52	42	115	82	37	37
23	35	125	53	40	120	83	29	29
24	37	122	54	50	120	84	30	30
25	38	128	55	40	130	85	28	28
26	39	123	56	30	100	86	26	26
27	40	130	57	28	110	87	27	28
28	45	125	58	29	109	88	29	28
29	46	122	59	30	120	89	30	28
30	48	120	60	31	90	90	40	30



Graph 4: WHOQOL scores in Centesimal group



Graph 5: WHOQOL scores in Millesimal group

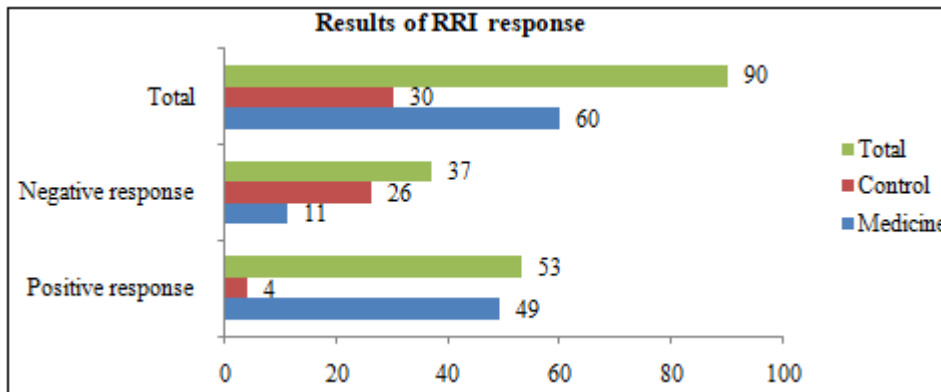


Graph 6: WHOQOL scores in Placebo group

In relapse and recurrence interval which was observed in 2 years of follow up duration positive response was there in medicine study group i. e. the relapse and recurrence interval had increased and negative response was observed in placebo group i. e. the relapse and recurrence interval did not have changed (Table - 3).

Table 3: Results of RRI response

Category	Positive response	Negative response	Total
Medicine	49	11	60
Control	4	26	30
Total	53	37	90

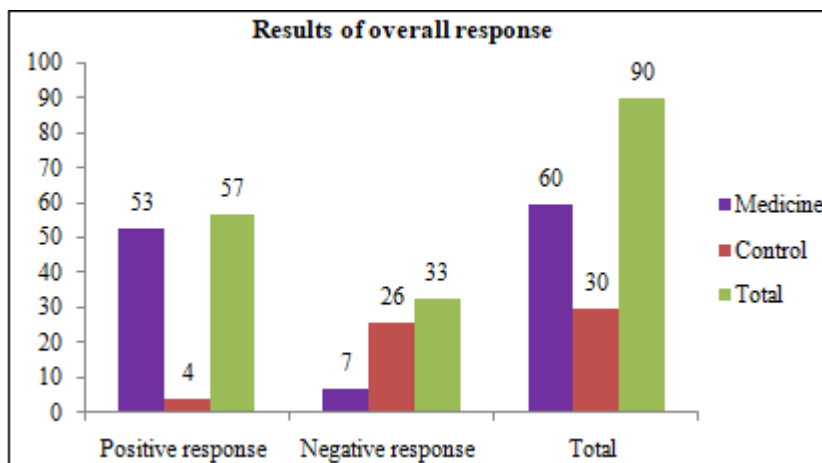


Graph 7: Results of RRI response

In overall response (Table - 4), 53 patients out of 60 from medicine group showed positive response and 4 out 30 patients from placebo group showed positive response, likewise 7 patients out of 60 from medicine group showed negative response and 26 out 30 patients from placebo group showed negative response.

Table 4: Results of overall response

Category	Positive response	Negative response	Total
Medicine	53	7	60
Control	4	26	30
Total	57	33	90



Graph 8: Results of Overall response

**Statistical analysis**

Paired t - test was applied for statistical analysis for responses in PNR bleed classification and WHOQOL (Table - 5). All the statistical calculations were done in GraphPad online calculator. For PNR bleed classification, in both the test groups i. e. in Centesimal and millesimal groups, the t values were 22.3133 and 30.3882 which shows that the difference was extremely statistically significant at  $p < 0.0001$ . In the control group, the t value was 1.3298 and the difference was considered to be statistically insignificant ( $p=0.1940$ ). For WHOQOL, in both the test groups i. e. in centesimal and millesimal groups, the t values were 16.7744

and 18.0385 which shows that the difference was extremely statistically significant at  $p < 0.0001$ . In the control group, the t value was 1.6117 and the difference was considered to be statistically insignificant ( $p=0.1179$ ).

In relapse and recurrence interval and overall response in medicine and placebo group chi - square test was applied for statistical significance (Table - 6). In the test group the relapse and recurrence interval and overall responses were statistically significant ( $p < 0.0001$ ) as compared to placebo group.

**Table 5**

Variables at time interval		N	Mean	Mean difference	SD	Standard Error of Mean	t - value	p - value
PNR value in Centesimal scale group	At baseline	30	11.77	6.18	1.45	0.27	22.3133	< 0.0001
	At 6 months	30	4.97	7.42	1.16	0.29		
PNR value in fifty millesimal scale group	At baseline	30	12.07	7.03	1.34	0.24	30.3882	< 0.0001
	At 6 months	30	4.53	8.04	0.63	0.11		
PNR value in Placebo group	At baseline	30	11.03	- 0.36	2.45	0.45	1.3298	0.1940
	At 6 months	30	10.63	1.69	2.17	0.40		
WHOQOL value in centesimal scale group	At baseline	30	41.23	- 80.48	8.28	1.51	16.7744	< 0.0001
	At 6 months	30	112.97	- 62.99	25.89	4.73		
WHOQOL value in 50 millesimal scale group	At baseline	30	37.30	- 82.72	9.49	1.73	18.0385	< 0.0001
	At 6 months	30	111.60	- 65.88	24.50	4.47		
WHOQOL value in placebo group	At baseline	30	35.53	- 0.26	8.33	1.52	1.6117	0.1179
	At 6 months	30	34.57	2.19	8.44	1.54		

**Table 6**

Response	Medicine			Placebo			Chi - square value	p - value
	+ve	- ve	Total	+ve	- ve	Total		
RRI response	49	11	60	4	26	30	38.574	< 0.00001
Overall response	53	7	60	4	26	30	48.445	< 0.00001

**4. Discussion**

Haemorrhoids are dilated plexus of superior haemorrhoidal veins, in relation to anal canal. Internal haemorrhoids - above the dentate line, covered with mucous membrane. External haemorrhoids are at anal verge and covered with skin. Swollen and inflamed veins in the rectum and anus cause discomfort and bleeding during defecation. Pain and bleeding during stool are common symptoms. Other symptoms like itching around anus may also present. In the present study an attempt was made to see the scope of homoeopathic medicines in haemorrhoids. Homoeopathic medicines were selected basing upon the totality of symptoms and after repertorization the medicines were administered in centesimal and fifty millesimal potencies in group I and Group II respectively. In group III placebo was administered. The study showed positive responses in medicines group patients in PNR Bleed classification scores and there were no such changes on scores of placebo group patients. The relapse and recurrence interval in medicine study groups were increased as compared to that in placebo group. Overall response was good in medicine group compared to placebo.

Statistically, the study was significant in PNR bleed classification scores and WHOQOL ( $p < 0.0001$ ) in medicine group. It was not statistically significant for PNR bleed classification scores and WHOQOL in placebo group as  $p=0.1940$  and  $p=0.1179$  respectively. In relapse and recurrence interval and overall response in medicine and

placebo group were statistically significant ( $p < 0.0001$ ) as compared to placebo group.

**5. Conclusion**

Efficacy of Homoeopathic treatment in case of haemorrhoid was concluded from this study suggesting a very well and positive response in case of cure, preventing frequent relapses and improving quality of life to live, but with an exception in cases of irreducible prolapsed haemorrhoids of PNR Bleed classification.

Increase fiber intake in diet, drinking fluids to maintain hydration, weight loss for obese persons and heavy lifting avoidance are recommended as preventable measures. Leading a healthy lifestyle with regular exercise and diet from very beginning is very important to avoid this health problem. Although homoeopathy acted wonderfully through polycrest remedies in this study there are also ample scopes through prescription of lesser known remedies with further research in various aspects of homoeopathy by means of larger sample size.

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