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A comparative study on the effectiveness of Negundium Americana Q in haemorrhoids under constitutional treatment using symptom severity score as an outcome parameter

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Abstract
Hemorrhoids are a very common anorectal disorder affecting a large portion of the global population, and significantly impairing quality of life. This randomized, placebo-controlled clinical trial was conducted to assess the additional benefit of Negundium Q, a homoeopathic preparation in the management of Hemorrhoids along with Constitutional Homoeopathic treatment. Forty patients were enrolled and randomly allocated into two groups: a study group (n=20) receiving Negundium Q and a control group (n=20) receiving a placebo. Outcome measures include improvement in quality of life, evaluated using the Symptom Severity Score. Result demonstrated significant improvements in the anal symptoms, emotional function of those patients who have taken Negundium Q along with constitutional medicine than those who have been taken Constitutional medicine alone. Results indicate Negundium Q provides additional benefits in reducing hemorrhoid symptoms and improving quality of life, although more extensive research is needed.

Keywords: Hemorrhoids, Negundium q, homoeopathy, symptom severity score

Introduction

Hemorrhoids are swollen inflamed veins located around the anus or lower rectum [1].They impact millions globally, posting a significant medical and socioeconomic issue. Both men and women commonly experience Hemorrhoids, affecting roughly 1 in 20 Americans. Among adults over 50, about half have Hemorrhoids [2].
Common symptoms include

- Bleeding
- Protrusion of skin
- Itching in anal area
- Sensitive lumps [3]

In India, recent survey data shows about 40 million people are affected by hemorrhoids. People who are pregnant, obese, or consume a diet low in fiber are more likely to develop hemorrhoids. Common causes include straining during bowel movements, chronic constipation and diarrhea, low fiber intake, and lifting heavy objects [4]
The symptom severity score is a validated tool for assessing hemorrhoid outcomes, considering the multiple symptoms of the condition and their impact on quality of life [7] SSS score of Anal of hemorrhoids (e.g.)

Score	Itching	Pain	Prolapse	Bleeding	Soiling	Gas Incontinence	Result
0	Never	None	Never	Never	Never	Never	No trouble
1	Occasional	With stool	With straining	Spotting	Mucus discharge	Occasional	Mild
2	Regular	Constant	Reducible	Dripping into pan	Occasional	Frequent	Moderate
3	Persistent	Pressure	Permanent	Without stool	Incontinence	Persistent	Moderate
4	Persistent	Pressure	Permanent	Staining under pad	Incontinence	Persistent	Really bad

Homoeopathy is the most favoured traditional treatment for hemorrhoids because it's cost-effective. Clinical experiences have shown notable healing of hemorrhoids through homoeopathic medicine [4]. A homoeopathic remedy called Negundium Americana is made from authentic raw materials [8]. It involves using the bark of the root, macerated twice with its weight in alcohol - a back potency form that's both expensive and uses the purest alcohol. Chronic painful swollen piles with the sensation of sharp sticks and constricted feeling with great burning an itching in the anus are the key indication to use this medicine [9]. This comparative study aims to find out the effect of Negundium Americana Q in patients with hemorrhoids under constitutional treatment by comparing changes in symptoms and quality of life.

Review of Literature

Hemorrhoidal disease is a pathological condition due to abnormal enlargement of the arteriovenous plexus beneath the anal mucosa [10]. The condition affects 39-52 percentage of adults [4]. The prevalence of hemorrhoids is extremely high in western and industrialized societies. However, the true burden of diseases is difficult to capture as many patients are reluctant to seek medical suggestions for various personal, cultural and socio-economic reasons. Several risk factors have been claimed to be the etiologies of hemorrhoid development including aging, obesity, depression, pregnancy, chronic constipation and diarrhea, low fiber diet [4].

Treatment choices depend mainly on the type and severity of hemorrhoids, the patient's preference, and the physician's expertise. Although remarkable cures of hemorrhoids with homeopathic medicines have been observed in casual clinical prstudies [4]. Only recently has a single-blind, randomized, placebo-controlled trial using 50-millesimal potencies for acute Hemorrhoidal attacks been published, supporting the effectiveness of individualized homeopathic treatment [4]. A comparative study on 40 patients also reported beneficial results, particularly with remedies such as Sulphur, Lycopodium, Phosphorus, and Calcarea.

There are only few studies done to evaluate the effectiveness of Negundium in hemorrhoids. In a comparative study done to elicit the effectiveness of lesser-known homoeopathic medicines, it was found that Negundium has significance in the symptomatic management of hemorrhoids [9]. So, more studies are needed in this field.

Aims and Objectives

Aim

To study the add-on benefits of Negundium Q in the management of hemorrhoids in patient under constitutional treatment.

Hypothesis

Null Hypothesis

There will be no Variation in the effectiveness of Negundium Americana Q along with constitutional medicine to constitutional medicine alone in the treatment of hemorrhoids.

Alternate Hypothesis

There will be significant Variation in the effectiveness of Negundium Americana Q along with constitutional medicine and constitutional medicine alone in the treatment of hemorrhoids.

Objectives

Primary Objectives

1. 1 To determine the therapeutic efficacy of Negundium Americana Q in patients with hemorrhoids within the framework of constitutional homeopathic treatment.
2. 2 To analyze the effectiveness of Negundium Americana Q by comparing pre-treatment and post-treatment symptom scores between the study group and the control group.

Secondary Objective

To evaluate and compare the enhancement in quality of life among patients from both groups following treatment.

Materials and Method

- **Type of study:** Comparative study
- **Study design:** Quasi experimental
- **Study population:** Patients with hemorrhoids' diagnosed by clinical symptoms.
- **Sample size:** Minimum 40 case as per inclusion criteria
- **Sampling method:** Consecutive sampling
- **Source data:** Hemorrhoidal patients attending outpatient department of homoeopathic medical College hospital.
- Study setting-out patient department of as homoeopathic medical College hospital, kurichy Kottayam.
- **Period of study:** MAY 2024 - AUG 2024
- **Method of data collection:** Patients presenting with clinical symptoms of hemorrhoids will be selected. All collected data will be recorded in the outpatient department case sheets. The quality of life of the patients will also be evaluated using a symptom severity score as an outcome measure. Liver function tests will be performed before and after the study to determine any possible toxic effects of the tincture.
- The symptom severity score for hemorrhoids is a validated, disease-specific assessment tool that considers both the multisymptomatic nature of hemorrhoids and the impact of these symptoms on the patient's quality of life.

Selection Criteria

Inclusion Criteria

- Patients presenting with first and second-degree hemorrhoids
- Individuals aged 18-70 years
- Patients of all gender categories

Exclusion Criteria

- Patients presenting with third and fourth-degree hemorrhoids
- Immunocompromised individuals

Method of Intervention

Patients who provide written informed consent will be randomly divided into two groups. Out of the total 40 patients, 20 patients will receive Negundium americana Q along with constitutional medicine, while the remaining 20 patients will receive only constitutional medicine. The

clinical changes observed in both groups will be compared based on the evaluation of clinical symptoms. Constitutional medicine for all participants will be administered as a single morning dose each month in an appropriate potency. In addition, the patients in the study group will receive five drops of Negundium americana Q for the same duration.

Data Analysis

Differences in symptom patterns between the two groups, before and after the intervention, will be assessed. The improvement in the quality of life in both groups will be analyzed using the Symptom Severity Score.

Statistical Design: The data will be processed using SPSS software version 22, and the variations in quality of life between the two groups will be evaluated using the Mann-Whitney U test.

Results

1) Severity Score (SSS)

a) SSS -Anal symptoms

Table 1: Descriptive statistics of study and control groups before and after intervention

Descriptive Statistics - Study Group								
	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Before	20	3.8	0.410391	3	4	4	4	4
After	20	0.4	0.502625	0	1	0	0	1
Descriptive Statistics - Control Group								
	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Before	20	3.3	0.864505	2	4	2.75	4	4
After	20	0.55	0.510418	0	1	0	1	1

The mean of anal symptom scores for study and control groups before the treatment were 3.8 and 3.3 respectively. The corresponding figures after the treatment were 0.4 and 0.55.

As the figures in the table indicate, there is a Variation in the average scores for the study and control groups. To test for its statistical significance, difference between before and after scores were worked and Mann-Whitney U test was carried out.

Hypothesis

- **H_0:** There is no significant Variation in anal symptom score for the Study and Control groups
- **H_1:** There is significant Variation in anal symptom score for the Study and Control groups

On testing it is revealed that the average anal symptom scores for Study group significantly lower than Control group ($U = 114.50$, $p = 0.01$).

b) SSS- practical problems

Table 2: Descriptive statistics of study and control groups before and after intervention

Descriptive Statistics - Study Group								
	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Before	20	3.05	0.759155	2	4	2.75	3	4
After	20	0.6	0.502625	0	1	0	1	1
Descriptive Statistics - Control Group								
	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Before	20	2.85	0.812728	2	4	2	3	3.25
After	20	0.8	0.615587	0	2	0	1	1

The mean of practical problem symptom scores for study and control groups before the treatment were 3.05 and 2.85 respectively. The corresponding figures after the treatment were 0.6 and 0.8.

As the figures in the table indicate, there is a Variation in the average scores for the study and control groups. To test for its statistical significance, difference between before and after scores were worked and Mann-Whitney U test was carried out.

Hypothesis

H_0: There is no significant Variation in practical problem symptom score for the Study and Control groups

H_1: There is significant Variation in practical problem symptom score for the Study and Control groups

On testing it is revealed that the average practical problems symptom scores for Study group is not significantly lower than Control group ($U = 144.50$, $p = 0.05$).

c) SSS-emotional function

Table 3: Descriptive statistics of study and control groups before and after intervention

Descriptive Statistics - Study Group								
	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Before	20	3.65	0.48936	3	4	3	4	4
After	20	0.45	0.510418	0	1	0	0	1
Descriptive Statistics - Control Group								
	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Before	20	2.9	0.307794	2	3	3	3	3
After	20	0.65	0.48936	0	1	0	1	1

The mean of emotional function scores for study and control groups before the treatment were 3.65 and 2.9 respectively. The corresponding figures after the treatment were 0.45 and 0.65.

As the figures in the table indicate, there is a Variation in the average scores for the study and control groups. To test for its statistical significance, difference between before and after scores were worked and Mann-Whitney U test was carried out.

Hypothesis

- **H_0:** There is no significant Variation in emotional function score for the Study and Control groups
- **H_1:** There is significant Variation in emotional function score for the Study and Control groups

On testing it is revealed that the average emotional function scores for Study group significantly lower than Control group ($U = 67.50$, $p = 0.00$).

d) SSS-sleep symptoms

Table 4: Descriptive statistics of study and control groups before and after intervention

Descriptive Statistics - Study Group								
	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Before	20	3.8	0.410391	3	4	4	4	4
After	20	0.75	0.444262	0	1	0.75	1	1
Descriptive Statistics - Control Group								
	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Before	20	3.75	0.444262	3	4	3.75	4	4
After	20	0.95	0.223607	0	1	1	1	1

The mean sleep symptom scores for Study and Control groups before treatment were 3.8 and 3.75 respectively. The corresponding figures after the treatment were 0.75 and 0.95.

As the figures in the table indicate, there is a difference in the average scores for the Study and Control groups. To test for its statistical significance, difference between before and after scores were worked and Mann-Whitney U test was carried out.

Hypothesis

- **H_0:** There is no significant Variation in sleep symptom score for the Study and Control groups
- **H_1:** There is significant Variation in sleep symptom score for the Study and Control groups

On testing it is revealed that the average Symptom score for Study group is not significantly lower than Control group ($U = 158.50$, $p = 0.09$).

e) SSS-activity limitation

Table 5: Descriptive statistics of study and control groups before and after intervention

Descriptive Statistics - Study Group								
	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Before	20	3.55	0.759155	2	4	3	4	4
After	20	0.7	0.801315	0	2	0	0.5	1
Descriptive Statistics - Control Group								
	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Before	20	3.45	0.759155	2	4	3	4	4
After	20	0.6	0.502625	0	1	0	1	1

The mean of activity limitation scores for study and control groups before the treatment were 3.55 and 3.45 respectively. The corresponding figures after the treatment were 0.7 and 0.6.

As the figures in the table indicate, there is a difference in the average scores for the study and control groups. To test for its statistical significance, difference between before and after scores were worked and Mann-Whitney U test was carried out.

Hypothesis

- **H_0:** There is no significant Variation in activity limitation score for the Study and Control groups
- **H_1:** There is significant Variation in activity limitation score for the Study and Control groups

On testing it is revealed that the average activity limitation scores for Study group not significantly lower than Control group (U = 193.00
, p = 0.43).

f) SSS - other symptoms

Table 6: Descriptive statistics of study and control groups before and after intervention

Descriptive Statistics - Study Group								
	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Before	20	3.85	0.366348	3	4	4	4	4
After	20	0.65	0.48936	0	1	0	1	1
Descriptive Statistics - Control Group								
	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Before	20	3.65	0.67082	2	4	3.75	4	4
After	20	0.75	0.444262	0	1	0.75	1	1

The mean of other symptom scores for study and control groups before the treatment were 3.85 and 3.65 respectively. The corresponding figures after the treatment were 0.65 and 0.75.

As the figures in the table indicate, there is a difference in the average scores for the study and control groups. To test for its statistical significance, difference between before and after scores were worked and Mann-Whitney U test was carried out.

Hypothesis

- **H_0:** There is no significant Variation in other symptom score for the Study and Control groups
- **H_1:** There is significant Variation in other symptom score for the Study and Control groups

On testing it is revealed that the average other symptom scores for Study group not significantly lower than Control group (U = 174.50
, p = 0.22).

Symptom severity score shows significant changes between study group and control group for the categories like anal symptoms and emotional function but no significant changes was observed in the categories like practical problems, sleep symptoms, activity Limitation and other symptoms with Negundium Americana Q.

Discussion

This study evaluates the effectiveness of Negundium Americana Q on Hemorrhoidal outcomes, focusing on parameters such as changes in patients' quality of life. The findings indicate that when Negundium Q is administered along with constitutional medicine, it provides significant benefits in managing Hemorrhoidal symptoms compared to constitutional medicine alone. Noticeable improvement was observed in anal symptoms and emotional functioning among patients who received Negundium Q along with constitutional treatment.

Using the Mann-Whitney U test, it was identified that the average anal symptom score in the study group was significantly lower than that of the control group (U = 114.50, p = 0.01), demonstrating the effectiveness of Negundium Americana Q in reducing hemorrhoidal symptoms.

The patient's quality of life was assessed using the validated Symptom Severity Score (SSS). The results demonstrated improvement in quality of life in both study and control groups; however, when comparing symptom severity between the two groups using the Mann-Whitney U test, significant differences were found in categories such as anal symptoms (U = 114.50, p = 0.01) and emotional function (U = 67.50, p = 0.00). No significant changes were observed for practical problems (U = 144.50, p = 0.05), sleep symptoms (U = 158.50, p = 0.09), activity limitation (U = 193.00, p = 0.43), and other related symptoms (U = 174.50, p = 0.22).These results confirm that Negundium Q is effective in improving the quality of life among patients with hemorrhoids.

This study compares and explores how Negundium Americana Q can benefit patients with hemorrhoids. It shows the medicine helps manage symptoms and improves the quality of life for these patients. Since there's no randomization, observer bias might be a factor. Future studies, like randomized-controlled trials, could evaluate this further for more conclusive results.

Conclusion

Symptom severity scores indicate notable differences between the study and control groups regarding anal symptoms and emotional function. However, for practical problems, sleep symptoms, activity limitations, and other symptoms associated with Negundium Americana Q, no significant differences were found.

To draw a more conclusive outcome, studies with longer durations and larger sample sizes are necessary. This research serves as a catalyst for additional assessments in this area, particularly those utilizing more rigorous designs like randomized controlled trials.

Ethics, Consent and Permission

Ethical approval for the study was granted by the Institutional Ethical Committee (IEC/ANSS/01/23.24). Patients provided written informed consent to participate

and allowed their data to be fully published.

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Author Contribution
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Dr. Girijadevi M: Conceptualization, Methodology, Software, Formal analysis, Investigation, Resources, Data Curation, Writing Original Draft, Writing - Review & Editing.
Jayalakshmi J: Validation, Formal analysis, Supervision, Investigation, Resources.

Author Consent for Publication
All authors consent to the manuscript's submission and publication in the World Allergy Organisation journal.

Declaration
The authors declare no conflicts of interest.

Summary
A comparative study was conducted to assess the impact of Negundium Q on patients with hemorrhoids undergoing constitutional treatment. 40 patients with hemorrhoids were divided into a study group and a control group. The study group received Negundium Q along with constitutional medicine, while the control group received only constitutional medicine. Outcome analysis compared quality of life in both groups. Significant differences were found between the study and control groups in terms of Anal Symptoms and emotional function based on symptom severity scores. However, no significant changes were observed for practical problems, sleep symptoms, activity limitation, and other symptoms when using Negundium Americana Q. Due to limited research on Negundium Americana tinctures effectiveness, this study seeks to offer patients with hemorrhoids a secure and cost-effective treatment that improves quality of life.

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