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ORIGINAL ARTICLE

DOUBLE BLIND RANDOMIZED CONTROL STUDY ON THE EFFICACY OF HOMOEOPATHIC MEDICINE IN INFLAMMATORY BOWEL DISEASE

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Abstract

Background: Irritable Bowel Disease is a progressive disease in all over the world. **Objective:** The objective of the study was to evaluate the efficacy of homoeopathic medicine and to enlighten that inflammatory bowel disease can treated with homoeopathic medicines without complications. Materials & **Method:** Type of study: double blind randomized control study. Pre diagnosed cases or clinically presenting the symptoms of inflammatory bowel disease was selected with irrespective of age and sex. The cases were evaluated after 15 days, 30 days, and 45 days until end of the research. **Results:** Over a period of 3 to 6 months, there was a significant improvement of homoeopathic medicine in cases of inflammatory bowel disease. Conclusion: There is a significant improvement after the selected homoeopathic medicine after proper case taking and treated without complications.

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INTRODUCTION

The human body is like a finely tuned machine, where all body parts are finely interconnected. Any malfunction either due to external or internal factors leads to suffering is called as diseased state. 21st century is the era full of irregular diet, jung foods, overeating, sedentary life style, mental stress, insomnia, alcohol consumption, palliative and suppressive

treatment, over doses of the medicines, they all are invites several diseases especially gastrointestinal tract and inflammatory bowel disease is one of the leading chronic disease affecting numbers of the individuals with different age groups. Inflammatory bowel disease includes ulcerative colitis, a disorder in which inflammation affects the mucosa and submucosa of the colon, and crohn's disease, in which inflammation is transmural and may involve any or all the segments of the gastrointestinal tract.[3] Ulcerative colitis and crohn's disease are worldwide disorders. The United States, Northern Europe and Scandinavian countries have higher rates compared to countries in southern Europe, South Africa and Australia. In Asia the disease was thought to be uncommon, but recent reports highlighted the increasing incidence of the disease.[2] It typically affects young people, but may have a bimodal incidence with a second peak in later life. Men are slightly more likely to be affected with ulcerative colitis and women with crohn's disease.[1] It is quite possible that ulcerative colitis and crohn's disease of the colon are variations in the host response to the same etiological agent.[3] Both diseases can occur at any age but more frequently in 2nd and 3rd decades of life and primarily affect the bowel but may have systemic involvement in the form of polyarthritis, uveitis, ankylosing spondylitis, skin lesions and hepatic involvement.[5] There is an approximately 50% chance of development of inflammatory bowel disease in monozygotic twins.[5] Risk factors are positive family history, Genetic susceptibility, environmental factors, dietary factors, contraceptives, Nonsteroidal anti-inflammatory drugs, seasonal variations, dysfunctional immune host response to the normal luminal components, defective barrier function, chromosomes 1, 5, 6, 12, 14, 16 and 19 are important, actual identification of NOD2/ CARD15 and the MCH or HLA genes on chromosome 6 have a greater role in modifying the inflammatory bowel disease phenotype than overall disease susceptibility.[2, 3, 5] Microbial factors have been suspect but without definite evidence like Mycobacterium paratuberculosis, Salmonella, Shigella, Helicobacter, Clostridia, bacteroides, Escherichia, Measles virus etc.[5] Psychologic features of patients with ulcerative colitis have been stressed. There have many suggestions of a relation between the onset of the disorder and psychologic stress such as loss of family member.[3] Clinical features for the ulcerative colitis are bloody diarrhoea, ranging from several semi- formed stools, up to 20 times per day of liquid stools with blood and pus.

Sometimes constipation may be present. [1, 4] Abdominal pain which is generally distended tender with hypoactive or absent bowel sound, fever, malaise, lethargy, anorexia, weight loss, exhausted, localized rectal disease with pain, tenesmus, mucus discharge, incontinence or even constipation. In severe ulcerative colitis suggestive of toxic magacolon include fever, tachycardia, raised neutrophil count, electrolyte disturbance and hypotension. History of intolerance to dairy products may be present.[2, 3, 4] In case of crohn's disease predominant symptoms includes diarrhoea without urgency, abdominal pain, weight loss, generalized fatigability, fever, gastro-duodenal involvement can present with epigastric pain, nausea, vomiting or features of gastric outlet obstruction. There are three main pattern of disease distribution involving ileum and caecum in ~40% of patients, diseases confined to small intestine in 30%; disease of only the colon in ~25% which is pan colonic in 2/3rd and segmental in 1/3rd. [1, 2, 3] Diagnosis is based upon clinical presentation, laboratory investigations include CBC, ESR, serum electrolytes, albumin and C-reative protein, stool examination, serological tests, x-ray, abdominal USG, MRI and CT scan of abdomen and pelvis and biopsy may show a granulomatous lesion in less than 25% of cases but when present it is very diagnostic.[3, 4] Differential diagnosis must be distinguished are, tuberculosis, lymphoma, ischemic colitis, and diverticulitis and colon cancer. [1] Complications are stomatitis, nutritional and metabolic changes like loss of muscle mass, electrolytes losses, hypoalbuminemia, iron-deficiency anemia, vitamin deficiency, venous thrombosis and thromboembolism, arthritis, liver disease, renal stones, skin disorder and growth retardation in children.[1] In case of ulcerative colitis toxic magacolon, dilatation of colon, perforation of colon, pseudo-polyp formation, perianal fistula and carcinoma may develop. In case of crohn's disease malabsorption, fistula formation, stricture formation and development of malignancy in the small intestine as a later complication of crohn's disease.[4, 5]

MATERIALS AND METHODS

Period of Study - The study was conducted on the cases available from December 2019 to June 2022.

Place of Study -The work will be done at Sri Ganganagar Homoeopathic Medical College, Hospital and Research Center, Sri Ganganagar, Rajasthan, India, Outpatient department (OPD), In patient department (IPD) and peripheral center.

Sample Size- 100 cases will be selected. 50 cases per each group by using double blind randomized study.

Exclusion criteria:

- The cases with gross pathological changes or associated advanced systemic diseases were excluded from the study.
- The cases not maintain the irregular follow up would be excluded from the study.
- Pregnant lady and patients with serious complications would be excluded from the study.
- Patient who cannot express fairly.
- Patient who did not speak Hindi and English language.
- Patient who suffering with herbal allergy.

Inclusion criteria:

- Pre diagnosed cases or clinically presenting the symptoms of inflammatory bowel disease were selected with irrespective of age and sex.
- Patients are both sexes with irrespective of socioeconomic status.

Methods - 100 inflammatory bowel disease patients (50 –ulcerative colitis patients group and 50- crohn's disease patient group) were selected in this clinical study. Case taking will be done as per guidelines given by Hahnemann in Organon of Medicine. The remedies will be selected on repertorisation based on evaluation of the cases. The cases will be evaluated after 15days, 30days, and 45 days until end of the research.

Remedy Used

Indicated medicines were used the maximum used, 8% (8 cases) of indicated medicine was Cal. Carb., Phosphorus and Opium, 6% (6 cases) of Carbo. Veg. and Kali. Carb. was used, 5% (5 cases) of Argentum Nitricum, Nitric Acid, Nux Vomica, Capsicum and Natrum Muriaticum was used, 4% (4 cases) of Podophylum, Pulsatilla, Sulphur and Gelsemium was used, 3% (3 cases) of Arsenicum Album, Veratrum Album and Natrum Sulph was used, 2% (2 cases) of Mag. Carb, Staphysagria and Aloe Socotrina was used, Minimum used 1% (1 case) of Ferrum Iod., Belladonna, Lycopodium, Gambogia, Asafoetida and Ignatia was used as per the totality of the symptoms according to Hahnemannian guidelines of case taking and prescribed according to the response of the patients as well as diseased condition.

Follow Up and Symptomatic Assessment

The cases will be evaluated after 15days, 30days, and 45 days until end of the research. Response will be analyzed into 4 criteria-

- **Cured**: sense of well-being with no complaint or relapse of complaint with in 6 month and more than 6 months of observation.

- **Significant improvement**: more than 50% relief of presenting complaints within 6 months.
- **Mild improvement**: decrease in intensity and frequency of presenting complaints (less than 50%).
- **Status Quo**: no change in intensity and frequency of presenting complaints.

Research Hypothesis

There is significant relationship between the efficacies of homoeopathic medicines in cases of inflammatory bowel disease.

Null Hypothesis -There is no statistically significant relationship between the efficacies of homoeopathic medicines in cases of inflammatory bowel disease.

RESULT

It is solely based on the different observations and their findings during the study like: During the study distribution of cases based on the Maximum incidence of the inflammatory bowel disease i.e. 28% (28 cases) was observed in the age group of 31-40 years. The minimum incidence of inflammatory bowel disease was observed in age group of 61-70 years 02% (02 cases). There was not a single incidence of inflammatory bowel disease observed in age group 00-10 years. During the study it was observed that maximum no. of cases 62 cases (62%) was male and 38 cases (38%) were female. During the study it was observed that maximum incidence 46 cases (46%) was observed in middle socio-economic patients. 33 Cases (33%) was observed in upper socio-economic patients. 21 Cases (21%) was observed in low socio-economic patients. During the study it was observed that religion wise distribution of diseases shows maximum 55 cases (55%) of Hindu religion were affected, 26 Cases (26%) other cast religion was affected, Minimum cases 19 cases (19%) of Muslim religion were affected. During the study it was observed that 69 cases (69%) had High Susceptibility, 31 cases (31%) had Low Susceptibility. During the study with their respective potency prescribed it was observed that the maximum cases 51 cases (51%) were prescribed 200 C Potency, 31 cases (31%) were prescribed 30C Potency, Minimum cases 18 cases (18%) was observed 1M Potency. And the whole conclusion of the study observed in table -

Table-1:-

Result	Ulcerative Colitis (50 Cases)		Crohn's Disease (50 Cases)		I.B.D (Total)
	Total No. of Cases	%	Total No. of Cases	%	
Cured	16	32%	07	14%	23
Significant Improved	19	38%	22	44%	41
Mild Improved	12	24%	15	30%	27
Status-quo	03	06%	06	12%	09
Total	**50**	**100%**	**50**	**100%**	**100**

During the study the 100 Cases (50 each for the both ulcerative colitis and crohn's disease) observed, **In case of Ulcerative Colitis**, out of 50 cases, 19 cases (38%) was observed in relation to Significant Improvement, 16 cases (32%) was observed in relation to cured, 12 cases (24 %) was observed in relation to mild improvement, 3 cases (6 %) was observed in relation to Status-quo. **In case of Crohn's disease,** out of 50 cases, 22 cases (44%) was observed in relation to Significant Improvement, 15 cases (30%) was observed in relation to mild Improvement, 7 cases (14%) was observed in relation to Cured, 6 cases (12%) was observed in relation to Status-quo, **I.B.D Total** indicates that out of 100 cases of inflammatory bowel disease, 23 cases (23%) was observed as cured, 41 cases (41%) was observed as significant improvement, 27 cases (27%) was observed as mild improvement and 9 cases (9%) was observed as Status-quo.

Discussion

It was observed that along with best selected homoeopathic medicine on the basis of totality of symptoms with irrespective of age and sex, occupation, prescribed to the individuals along with the follow ups criteria after 15 days, 30 days, 45 days as per the severity of the case, we observed significant improvement not only the chief complaints of the patient but also the associated complaints and also the mental status of the patients. The reviews also recommended that further pragmatic trails including clinical trials and observational studies been conducted.

CONCLUSION

The study showed significant improvement in cases of inflammatory bowel disease with homoeopathic medicine without any complication.

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