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**EFFICACY OF HERBAL MEDICINE IN MANAGING FUNCTIONAL
CONSTIPATION: A RANDOMIZED CONTROL STUDY**

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ABSTRACT

In current study the therapeutic efficacy and safety of herbal medicine was studied in comparison with allopathic medicine for management and treatment of functional constipation. The functional constipation is a disorder which is characterized by continuous feeling of defecation, infrequent evacuation due to decreased intestinal movements (once after 3-4 days or off/on pattern). It was a randomized control study done from 2014 to 2015 at Hyderabad and field clinic in Sehwan Sharif Sindh. Total 110 patients was selected and divided into two groups taking herbal and allopathic treatment. Analysis was done by SPSS v20. Results from 110 patients 27 patients showed marked improvement with herbal medication whereas only 8 patient's showed marked improvement with allopathic medication and results were statistical significant ($p < 0.001$).

Keywords: Functional constipation, Herbal Medicine, Laxovil

1. INTRODUCTION

The functional (simple) constipation is explained as a disorder which is characterized by continuous feeling of difficult, infrequent evacuation due to decreased intestinal movements (once after 3-4 days or off/on pattern) [1,2,3]. Functional Constipation is occurs when digested food move through the large colon too slowly and due to its slowly movement fecal material stayed in large colon more than the normal duration so the water contents absorbed more rapidly and resulting in the formation of hard and dry fecal material and associated with straining and passage of pellet like stool [4,5,6,7]. Functional (simple) constipation is most common in young adult age persons and present in 10-15% young adults [3,8]. Functional constipation is treated with many different methods sometime treated with increase dietary fiber or an adequate fluid intake, sometime use traditional medicine and some time need of laxative for management. Many laxatives are available in allopathic medicine to treat the functional constipation condition. However many patient develop resistance or tolerance against these laxative and does not get relief. There is broad use of herbal medicine for treatment and managing constipation which

is relatively safe and effective than those allopathic medicines [9,10,11]. The study was design to evaluate the effectiveness of herbal medicine in managing functional constipation.

2. Herbal Formulation (Laxovil) and Selection criteria

Selection processes of herbs for Laxovil was based on their laxative properties and traditional used for management and treatment of constipations and its symptoms. Following medicinal plants were selected for formulation of Laxovil

2.1 *Cassia angustifolia*,

Chemical constituents of *C. angustifolia* are Sennosides, Rehinanthrone, Anthraquinones, Aloe-emodin, Naphthalene Glycoside, Sterol, Kaempferin [14].

2.2 *Rosa damascene*

Chemical constituents of *R. damascene* are essential volatile oil (Ethyl acetate, 2-Methyl-2-butanol, β -Patchaulene, Elemol, Alpha-Selinene, n-Hexyl benzoate, α -Farnesene, Isospathulenol, t-Cadinol, Bisabolol oxide, Patchouli alcohol, n-Heptadecane (2Z,6E)-Farnesyl acetate, n-Octadecanol) [15].

2.3 *Foeniculum vulgare*

Chemical constituents of are major chemical constitute of *Foeniculum vulgare* are

essential (volatile) oil are trans-anethole (50 to 70%), fenchone (12 to 33%), methyl chavicol (estragole) (2 to 5%); α -pinene, β -phellandrene, γ -terpinene, p-cymene, myrcene, limonene, α - and terpineol, cis-ocimene e γ -fenchone camphene [16].

In traditional system *C. angustifolia*, *R. damascene*, *F. vulgare* are used as laxative, carminative, stimulant of gastrointestinal mobility, antispasmodic, anti-inflammatory, diuretic, expectorant, and analgesic [9,10,17].

3. METHODOLOGY

This study was design as randomized control study, (one to one ratio in test group and control group). Patients were divided into 2 groups.

Group I: Laxovil (*Cassia angustifolia* Linn, *Rosa damascene* Linn, *Foeniculum vulgare* Linn) herbal preparation treated group. Laxovil 500 mg (herbal preparation) was given before the sleep with warm milk or water (once a day at bed time orally). [17,18,19].

Geroup II: Sodium picosulfate in control group (Laxoberon Tab. 0.5 mg) given once aday

The treatment success was measured on basis of Clinical examination, patient complaints.

3.1 Sample Size

Study was conducted on 110 patients (55 patient as test group and 55 as control group) age from 20 -50 years. Study was done at Nazeer natural clinic Hyderabad and Field Clinic badhra mountain Sehwan Sharif, on basis of signs and symptoms of functional constipation according to inclusion or exclusion criteria, patients fulfill criteria for functional constipation was selected. After complete history, examination and consent patients were divided into test and control groups. [1,2,4].

3.2 Sample selection:

Sample was selected from the outpatient department in Nazeer natural clinic (Hyderabad) and field clinic (Sehwan sharif) on basis of sign and symptoms of functional constipation according to inclusion or exclusion criteria, patients fulfill criteria for functional constipation were selected. Study was conducted from 2013 to 2014. [1,2,4].

3.3 Inclusion Criteria:

The patients were selected on basis of following criteria. [1,2,4].

- i) Male patients with age group 20 to 50 years.
- ii) Patient with functional constipation have decrease intestinal peristalsis. (defecation after 2-3 days or less).

iii) Patients are taken from Hyderabad, Sehwan Sharif and Surroundings.

iv) Patients without any serious illness are included.

v) All classes of life style are included (lower, middle and higher classes).

3.4 Exclusion Criteria:

The criteria for exclusion were [1,2,4].

i) Patients live at distant areas of Hyderabad, Sehwan Sharif were excluded because of difficulty

in follow up.

ii) Patient with concurrent physical illness which cause constipation, for example thyroid disease,

hepatic disorders, and diabetes mellitus.

iii) Patients with chronic infectious diseases e.g. leprosy, tuberculosis etc.

iv) Patients who have Infective gastritis, Peptic ulcer, Crohn's disease, Irritable Bowel Syndrome, congenital gastrointestinal disorders and gastrointestinal malignancy.

v) Patients with cardiac disease and renal impairment.

3.5 Statistical Analysis:

Data was analysis by using SPSS v-20. Continuous variables were presented as mean \pm SD, categorical variables were presented as frequency and percentage. Inferential statistics (Willcoxon rank and Chi square

tests) was use to see the difference between the groups [18].

4. RESULTS

4.1 Marked Improvement

Results showed that total 35 patients had marked improvement in their condition, out of 35patients, 27 patients belongs to group I and only 8 belong to group II.

Results were highly significant ($p < 0.001$) when comparing with group II.

4.1 Moderate Improvement

There was moderate improvement in 38 patients. Out of 38 patients, 20 were belong to group I and 18 were from group II. Results were highly significant ($p < 0.001$) when compared when compared with group II.

4.2 No Improvement

There was no improvement in 10 patients. Out of 10 patients, 3 were belong to group I and 7 were from group II.

5. DISCUSSION

This comparative study was conducted at multicentre to determine the efficacy and adverse effects between group I (herbal medicine) and group II (sodium picosulfate). Results of current study shows that herbal formulation showed marked improvement in 27 patients (table 1). And there was moderate improvement in 20 patients. Results of

current study were highly significant as compared with group II

Sodium picosulfate (Laxoberon) absorbed from colon that's why there is no enterohepatic (first pass affect) circulation. After cleavage by bacteria in the intestine /colon sodium picosulfate is converted in its active compound bis-(phydroxyphenyl)-pyridyl-2-methane (BHPM) [12,13]. So traditional herbs selected for managing functional constipation, which contain more efficacy with low side effects, such as (*Cassia angustifolia*, *Rosa damascena*, *Foeniculum vulgare*). [9,10,17].

The *Cassia angustifolia* contain Chrysophynic Acid, Sennosides, and Aloe-emodin chemical constituents which are contain laxative action on human body, *Rosa*

damascena contain Essential volatile oil which have laxative action and *Foeniculum vulgare* contain Essential volatile oil which are act as laxative. [9,10,17].

Current study was carried out on limited number of patients, however further studies are required on large group of patients.

5. CONCLUSION

The result of current study showed that the herbal drug combination is more effective and safe in managing functional constipation.

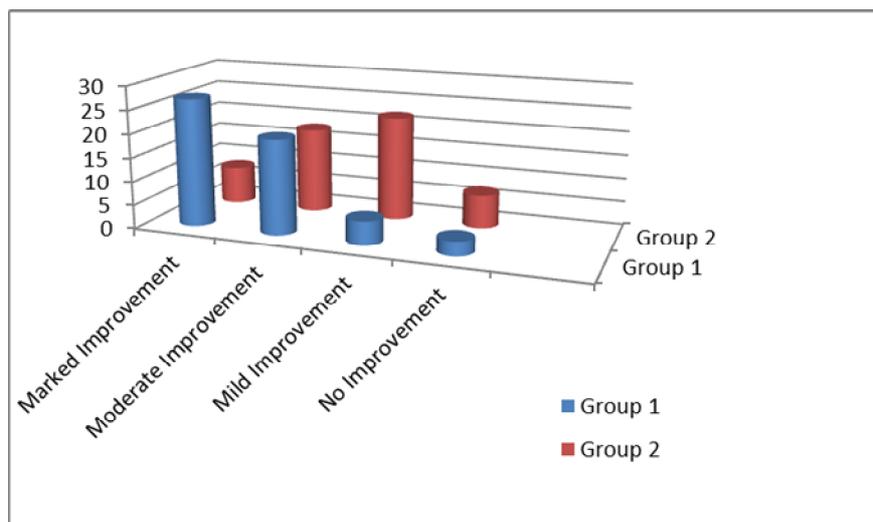
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Table 1: Effect of herbal formulation

Parameters	Total	Group I	Group II
Marked Improvement	35	27**	8
Moderate Improvement	38	20**	18
Mild Improvement	27	5**	22
No Improvement	10	3**	7
Total	110	55	55

*= Significant, **= highly significant



Graph 1: Effect of herbal formulation

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