

# Comparative Study of Effectiveness and Safety of Herbal Compound Medicine (Constinil) and Allopathic Medicine (Sodium Picosulfate) in Managing Constipation.

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## Author's Contribution

All the authors contributed significantly to the research that resulted in the submitted manuscripts

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## ABSTRACT

**Background:** This present study was conducted to observe the effectiveness and safety of the herbal compound medicine (constinil) and allopathic medicine (sodium picosulfate) in managing the constipation. The functional constipation is a condition which can be described by evacuation of small quantity of feces, may be irregular, infrequent evacuation, hard and forceful pass stool, may defecation occur off/on pattern, delay in defecation once after 48-72 hours.

**Methods:** It was comparative case control study conduct on 110 from Oct-2014 to May-2015 at Hyderabad and Sehwan Sharif, Sindh. Patients only male gender (age between 20-50 years) with clinical diagnosis of functional constipation. Analysis was done by SPSS v20.

**Results:** this study show significant difference in post-treatment of between both groups (test and control group), signs and symptoms and duration of constipation. majority  $n=56$ , (91%) belong to hard stool, & feeling of evacuation complaints,  $n=14$  (25%) out of  $n=56$  belong test group and  $n=42$  (75%) belong to control group  $P 0.014$ .

**Conclusion:** Hence it is concluded constipation manage with herbal formulated capsule (constinil) is safer and effective.

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## INTRODUCTION

The constipation is a condition which can be described by evacuation of small quantity of feces, may be irregular, infrequent evacuation, hard and forceful pass stool, may defecation occur off/on pattern, delay in defecation once after 48-72 hours [1,2,3]. Many laxatives are available in allopathic medicine to managing the

constipation but these medicine contain Adverse effects (Table 1.1) [4,5]. In the traditional medicine methods many herbs are use for managing constipation on basis of their effectiveness and safety, and also these herbs are use in different form (Decoction, Powder, syrup) and many other different methods are using to relief constipation and laxative required

for managing constipation some time. allopathic medicine consist numerous laxatives to treat the constipation. However these laxatives developed tolerance and resistance in many patients so doesn't get relief [6,7,8]. This experimental study was plan to evaluate the safety and efficacy of herbal medicine for treating and managing constipation.

### Formulation (Constinil)

Formulation of constinil is basis on ingredients (herbs) their traditional uses, folk uses and mostly their laxative properties with constituents act as laxative for treating and managing constipation. Following are herbal ingredients were elected for Constinil formulation.

### Preparation of the formulation:

Batch Size: 03 Kg.

No. Units: 6,000.0 capsules / 600 Blasters (10 capsules/Blaster).

Weight of each capsules: 500mg.

**Table1.1:** Composition and action of Herbs (constinil) capsule

Composition and action of Herbs (constinil) capsule.		
INGREDIENTS	g/capsules	ACTION
<i>Cassia angustifolia</i>	750 gram powder after grinding raw herb	Stimulant laxative, purgative,
<i>Rosa damascene</i>	166.66 milligram	Laxative, astringent, tonic for stomach & intestine.
<i>Foeniculumvulgare</i>	166.66 milligram	Tonic for digestive tract, stimulant, carminative

### Manufacturing procedure:

All the medicinal herbs were purchased from the Jodia Market Karachi. The components were *Cassiaangustifolia* (Sanna Maki leaves), *Rosa damascene*(Gul-e-Surkh petals), *Foeniculumvulgare* (Badyan fruit). The organoleptic properties of all drugs were carried out under the supervision of pharmacognosit.

All these herbal drugs were cleaned and crushed with crusher and then transferred into pulverizer so that the powder of 100 number mesh was obtained. Then the powder filled in capsule with though the capsule filling machine.

### Prescription:

Cap. Constinil 500 mg given before the sleep with warm milk or water.

**Table1.2:** Active constituents of herbs

S.N	Name of Herb	Active contituents.
1	<i>Cassia angustifolia</i>	Aloe-emodin, Sennosides, Sterol, Rehinanthrone, Naphthalene Glycoside, Anthraquinones, Kaempferin [11].
2	<i>Rosa damascene</i>	essential volatile oil ( $\beta$ -Patchaulene, Ethyl acetate, Elemol, n-Heptadecane (2Z,6E)-Farnesyl acetate, 2-Methyl-2-butanol, Patchouli alcohol, Bisabolol oxide, Alpha-Selinene, $\alpha$ -Farnesene, t-Cadinol, Isospathulenol) [12].
3	<i>Foeniculum vulgare</i>	essential volatile oil are fenchone (12 to 33%), trans-anethole (50 to 70%), methyl chavicol (estragole) (2 to 5%); $\beta$ -phellandrene, and cis-ocimene terpineol, $\gamma$ -terpinene, p-cymene, $\alpha$ -pinene, myrcene, e $\gamma$ -fenchone camphene, [13].

In conventional system *C. angustifolia*, *F. vulgare*, and *R. damascene*, are given as carminative, laxative, antispasmodic, tonic of gastrointestinal, anti-inflammatory, and diuretic [6,7,14].

### Objectives of study:

### Primary objectives:

To investigate the efficacy of herbal coded formulation "constinil" (test group) in comparison with Sodium Picosulfate (control group) for the management of constipation.

### Secondary objectives:

To evaluate the efficacy of herbal coded formulation by assessing improvement in symptoms (i.e. straining on defecation, sensation of incomplete evacuation, time spent on the average for evacuation of bowel), other related symptoms. The safety and side effects were also observed in patients.

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## METHODOLOGY

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Aim of this study was to find out the safety and efficacy of plant medicine as compare to allopathic medicine in managing of constipation. constipation's affected patients divided in parallel two arm (equal numbers of patients).

Group I: Herbal formulated capsule constinil 500 mg in test group was take before going to bed with warm water or milk (orally taken once a day) [14,15,16].

Group II: Laxoberon Tab. 0.5 mg (Sodium picosulfate) in control group was given (once a day at bed time orally) [10].

The success of treatment was depend on outcome of patient complaints, clinical examination.

### Sample (size)

110 patients were selected as sample size for study and divided in equal arms (55 patient for herbal drug (test group) and 55 patients for allopathic drug (control group) and Gender only male patients are selected and age between 20 -50 years [1,2,4].

### Sample selection:

Sample was selected from the outpatient departments of Multi-centers of Hyderabad and Sehwan sharif Sindh. Sample select on basis of clinical history, examination and patients fulfill criteria (exclusion and inclusion criteria) for constipation were selected. (see Performa) [1,2,4].

### Inclusion Criteria:

The selection of patients was on following criteria [1,2,4].

- i) Male gender patients with within 20 to 50 years age limit.
- ii) Patient with complain of constipation or defecation after 2 to 3 days.
- iii) Patients were selected from city and nearby towns of Hyderabad, and Sehwan Sharif.
- iv) Those patients include which were not serious ill.

### Exclusion Criteria:

The rejection of patients was on following criteria [1,2,4].

- i) Patients lives in for areas of cities and town Hyderabad, and Sehwan Sharif were rejected (excluded) because of complexity in rotten follow-up.
- ii) Patient with coexisting physical and chronic sickness which reason of constipation, for example hepatic disorders, diabetes mellitus and thyroid disorders.
- iii) Chronic infectious diseases coexisting patients e.g. tuberculosis, leprosy etc.
- iv) Patients who have gastrointestinal malignancy, Irritable Bowel Syndrome, Crohn's disease, congenital gastrointestinal disorders, Peptic ulcer, and Infective gastritis.

v) Patients who have renal impairment and cardiac disease were excluded.

### **Statistical Analysis:**

Using SPSS v-20 for data analysis. Incessant variables were existing as mean  $\pm$  SD, unconditional variables were presented as percentage and frequency. Inferential statistics (Chi square tests and Willcoxon rank) was apply to evaluate for difference within the groups [15].

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## **RESULTS**

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### ***Pre-treatment in Demographic data: table: 1***

Demographic characteristics are presented in table 1 majority  $n=55$ , (50%) the participants belong to age group 20-30 years, whereas majority  $n=57$ , (51.8%) belong to weight in between 71-100 kg.

### ***Pre-treatment participants history characteristics Table: 2***

This demographic data is concerning patient history regarding constipation in table 5 majority  $n=74$ , (67.3%) belong to less physical activity.

According to history of diet majority of patients participants  $n=69$  (62.7%) belong to the abnormal diet (fried/ fast food/ low fiber food).

According to history of meal timing majority of participants  $n=84$  (76.4%) belong to improper (irregular) meal taken time.

According to physical examination majority of participants  $n=88$  (80.0%) belong to the no physical abnormality finding.

### ***Pre-treatment disease and finding characteristics Table: 3.1 & 3.2***

This demographic data concerning presenting complaints presented in table.2 majority  $n=99$ , (90%) belong to hard stool, & feeling of evacuation complaints,  $n=44$  out of  $n=99$  belong test group and  $n=55$  belong to control group.

Signs and symptoms majority of patients participants  $n=45$  (40.9%) have signs and symptoms of dry feces, forceful defecation,  $n=20$  out of  $n=45$  belong to test group and  $n=25$  out of  $n=45$  belong to control group.

Duration of constipation majority of patients participants  $n=61$  (55.5%) has habit of 2-3 days interval of constipation,  $n=31$  out of  $n=61$  belong to test group and  $n=30$  out of  $n=61$  belong to control group

### ***Post treatment comparison of disease and finding characteristics: table 4***

Post treatment result show significant difference between the present complaints of both test and control group, signs and symptoms and duration of constipation.

This demographic data concerning presenting complaints presented in table.4 majority  $n=56$ , (91%) belong to hard stool, & feeling of evacuation complaints,  $n=14$  out of  $n=56$  belong test group and  $n=42$  belong to control group  $P$  0.012.

Signs and symptoms majority of patients participants  $n=28$  (25%) have signs and symptoms of dry feces, forceful defecation,  $n=9$  out of  $n=28$  belong to test group and  $n=19$  out of  $n=45$  belong to control group  $P$  0.014.

Duration of constipation majority of patients participants  $n=48$  (58%) has habit of 2-3 days interval of constipation,  $n=8$  out of  $n=48$  belong to test group and  $n=20$  out of  $n=48$  belong to control group  $P$ .0.017

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## **DISCUSSION**

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This study was multicentre randomized study conducted from October 2014 to May 2015 to ovulate the efficacy and safety with adverse property between test group I (herbal medicine) and control group II (sodium picosulfate).

Results of post-treatment show significant difference between the present complaints of both test and control group, signs and symptoms and duration of constipation. This demographic data concerning presenting complaints presented in table.4 majority  $n=56$ , (91%) belong to hard stool, & feeling of evacuation complaints,  $n=14$  out of  $n=56$  belong test group and  $n=42$  belong to control group (table 4).

Complain of faecal incontinence, nausea, abdominal cramps and reoccurrence of constipation are common in use of sodium picosulfate [17,18], complain of no relief in constipation by sodium picosulfate also observed [19]. while on herbal formulated capsule constinil show more effective and sage no any complain of faecal incontinence, nausea, abdominal cramps and reoccurrence of constipation, Constinil also regulate the bowel movements and soften the stool.[20,21,]. These efficacy and safety of constinil is due to its ingredients chemical constitutes i.e *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 also have laxative action and *Foeniculum vulgare* contain Essential volatile oil which are act as laxative. [21,22].

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## CONCLUSION

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The constipation manage with herbal formulated capsule (constinil) is safer and effective.

### Acknowledgement

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### Pre-treatment

#### Demographic data (Table 1)

Demographic characteristics are presented in table 1 majority  $n=55$ , (50%) the participants belong to age group 20-30 years, whereas

majority  $n=57$ , (51.8%) belong to weight in between 71-100 kg.

**Table 1: Pre-treatment in Demographic data**

Age	Frequency N=110	Percent
20-30	55	50.0
31-40	50	45.5
41-50	5	4.5
Weight		
40-70 kg	53	48.2
71-100 kg	57	51.8

This demographic data is concerning patient history regarding constipation in table 5 majority  $n=74$ , (67.3%) belong to less physical activity.

According to history of diet majority of patients participants  $n=69$  (62.7%) belong to the abnormal diet (fried/ fast food/ low fiber food).

According to history of meal timing majority of participants  $n=84$  (76.4%) belong to improper (irregular) meal taken time.

According to physical examination majority of participants  $n=88$  (80.0%) belong to the no physical abnormality finding.

**Table 2:** Pre-treatment participants history characteristics

History of physical activity	Total	Frequency N=110	Percent
More physical active	36	36	32.7
Less physical active	74	74	67.3
<b>History of Diet</b>			
Normal diet.	41	41	37.3
Abnormal diet (fried/fast food/ low fiber food)	69	69	62.7
<b>History of meal timing</b>			
Proper time meal taken	26	26	23.6
Improper (irregular) time meal taken	84	84	76.4
<b>Physical examination</b>			
Dehydration, Anemia.	22	22	20.0
No physical abnormality findings	88	88	80.0

This demographic data concerning presenting complaints presented in table.2 majority  $n=99$ , (90%) belong to hard stool, & feeling of evacuation complaints,  $n=44$  out of  $n=99$  belong to test group and  $n=55$  belong to control group.

Signs and symptoms majority of patients participants  $n = 45$  (40.9%) have signs and symptoms of dry feces, forceful defecation,  $n= 20$  out of  $n=45$  belong to test group and  $n=25$  out of  $n=45$  belong to control group.

Duration of constipation majority of patients participants  $n =61$  (55.5%) has habit of 2-3 days interval of constipation,  $n=31$  out of  $n=61$  belong to test group and  $n=30$  out of  $n=61$  belong to control group.

**Table 3.1:** Pre-treatment disease and finding characteristics

Presenting complains	Frequency N=110	Percent
Stool with mucus, Hemorrhoids, bleeding per rectum.	11	10.0
Hard stool, & feeling of evacuation	99	90.0
<b>Signs and symptoms</b>		
Abdominal pain, bloating, flatulence.	33	30.0
Dry feces, forceful defecation,	45	40.9
Nausea, vomiting, headache,	20	18.2
Appetite	12	10.9
Other symptoms		
<b>Duration of constipation</b>		
2-3 days	61	55.5
Off/On	49	45.5

### Comparison of disease and finding characteristics.

**Table 3.2:** Pre-treatment disease and finding characteristics

Presenting complains	Total	Grouping case or control	
		test	control
Stool with mucus, Hemorrhoids, bleeding per rectum.	11	11	0
Hard stool, feeling of evacuation.	99	44	55
Total	110	55	55
<b>Signs and symptoms</b>			
Abdominal pain, bloating, flatulence.	33	15	18
Dry feces, forceful defecation.	45	20	25
Nausea, Vomiting, Headache.	20	15	5
Weight loss, decrease appetite, other symptoms	12	5	7
Total	110	55	55
<b>Duration of constipation</b>			
2-3 days	61	31	30
Off/on	49	24	25
Total	110	55	55

**Table 4:** Post treatment comparison of disease and finding characteristics

Presenting complains	Total	Grouping case or control		P. Value
		test	control	
Stool with mucus, Hemorrhoids, bleeding per rectum.	5	5	0	0.012
Hard stool, feeling of evacuation.	56	14	42	
Total	61	19	42	
<b>Signs and symptoms</b>				
Abdominal pain, bloating, flatulence.	20	7	12	0.014
Dry feces, forceful defecation.	28	9	19	
Nausea, Vomiting, Headache.	6	2	4	
Weight loss, decrease appetite, other symptoms	5	2	4	
Total	59	20	39	
<b>Duration of constipation</b>				
2-3 days	28	8	20	0.017
Off/on	20	6	14	
Total	48	14	34	

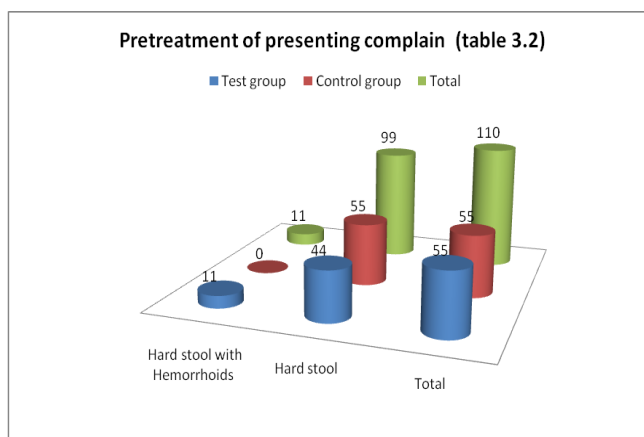
There is significant difference between the present complaints of both test and control group, signs and symptoms and duration of constipation.

This demographic data concerning presenting complaints presented in table.4 majority  $n=56$ , (91%) belong to hard stool, & feeling of evacuation complaints,  $n=14$  out of  $n=99$  belong test group and  $n=42$  belong to control group  $P 0.012$ .

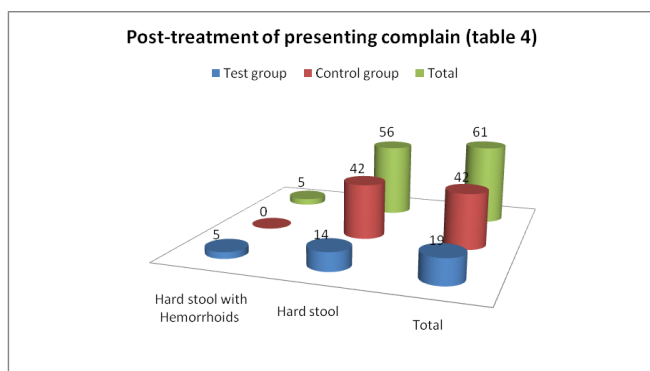
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Duration of constipation majority of patients participants  $n =48$  (58%) has habit of 2-3 days interval of constipation,  $n=8$  out of  $n=48$  belong

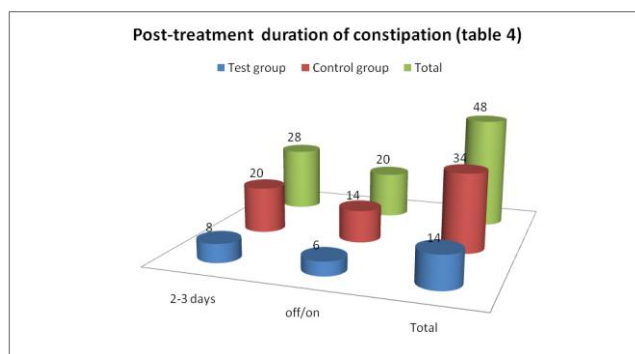
to test group and  $n=20$  out of  $n=48$  belong to control group  $P.0.017$



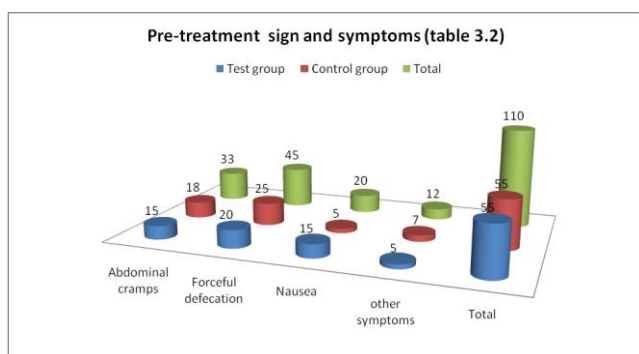
**Figure 1:** Pre-treatment of presenting complain



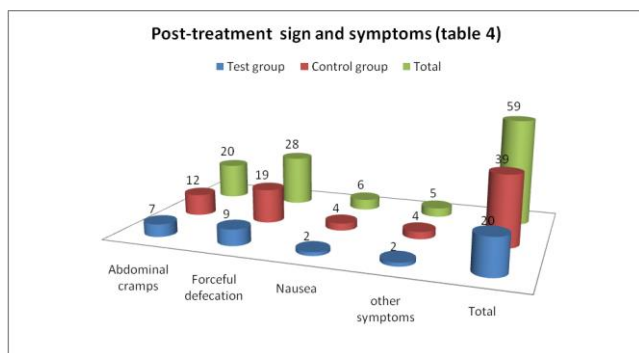
**Figure 2:** Post-treatment of presenting complain



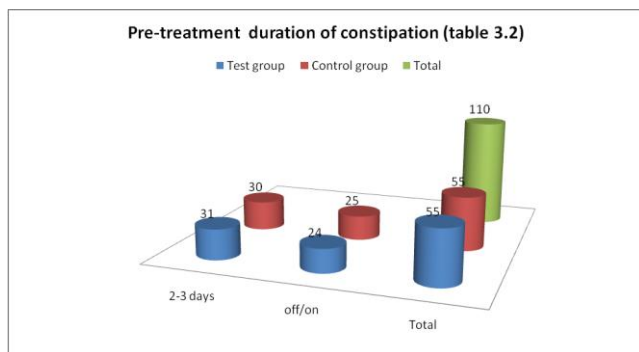
**Figure 6:** Post-treatment duration of constipation



**Figure 3:** Pre-treatment sign & symptoms



**Figure 4:** Post-treatment sign & symptoms



**Figure 5:** Pre-treatment duration of constipation

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