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ASSESSING THE EFFECT OF CALCAREA CARBONICA IN CHRONIC CONSTIPATION IN CHILDREN USING CSS SCALE: A TWO ARMED RANDOMIZED CONTROL TRIAL.

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Abstract:

Constipation is a major problem in children since many years but the problem is raising day by day due to bad eating habits, loss of exercise, sedentary habits. Functional constipation is the most common cause of constipation in children. History of delayed passage of meconium, presence of abdominal distension, and absence of fecal impaction point to an organic pathology.

Here, we have used a two arm randomized controlled trial (RCT) which is a clinical study design that compares the effects of one treatment (or intervention) to another treatment, often a control group or standard of care, by randomly assigning participants to either group.

It includes an experimental group & a control group.

Experimental Group: Who receive Homoeopathic Medicine- Calcarea carbonica in chronic constipation.

Control Group: The control group helps establish a baseline for comparison. It receives a standard treatment (allopathic mode of treatment).

In this study we are comparing the effects of Standard treatment or Allopathic medications in cases of Chronic Constipation with an Experimental group which is receiving Homoeopathic medicine- Calcarea carbonica in cases of Chronic Constipation.

Here, we have used the Constipation Scoring System (CSS) Scale for determining the severity of our cases.

We took 30 cases of chronic constipation in children, which were divided into two groups: 15 for homoeopathic treatment and 15 for allopathic treatment.

We took 30 cases of chronic constipation in children, which were divided into two groups: 15 for homoeopathic treatment and 15 for allopathic treatment. In most of the cases, constipation was

associated with passing stool only twice a week, along with straining to pass stool. Other symptoms found were abdominal pain, bloating, diminished appetite, fissures, haemorrhoids, and acne or pimples on the face.
After the entire observation period, the outcome for the homeopathic treatment was 80%, i.e., 13 out of 15 patients were cured. The outcome for the allopathic treatment was 70%, i.e., 12 out of 15 patients were recovered.
Cases in which homeopathic medicine is prescribed, the results are quick and faster in relief of complaints.

Keywords- Chronic constipation, Pediatric age group, randomized controlled trial.

I. INTRODUCTION

Constipation is a major problem in children since many years but the problem is raising day by day due to bad eating habits, loss of exercise, sedentary habits. Functional constipation is the most common cause of constipation in children. History of delayed passage of meconium, presence of abdominal distension, and absence of faecal impaction point to an organic pathology. Clinically, it may present as hard stool consistency, straining, sense of incomplete evacuation, bowel movement infrequency[1], sense of fullness in lower abdomen.

DEFINITION: Chronic constipation is a common condition that's characterized by infrequent, difficult, or incomplete bowel movements. Constipation is broadly defined as an unsatisfactory defecation characterized by infrequent stools, difficult stool passage or both[2].

ETIOLOGY: Constipation can result from several factors, some of which are related to the person's lifestyle such as a diet poor in fiber, insufficient fluid intake, irregular and inadequate time in the toilet, lack of exercise, prolonged bed rest and chronic consumption of drugs that can cause constipation.

Idiopathic				
Functional constipation				
Developmental disorders (behavioral disorders, ADHD, Autism)				
Occasional constipation (forced toilet training, phobia, sexual abuse, exaggerated parental interventions)				
Psychological (eg. depression)				
Lazy colon				
Genetic predisposition				
Environmental (organochlorine insecticides or heavy metals)				
Dietary (low dietary fluid and fiber intake, malnutrition)				
Organic				
Neuromuscular disorders	Anatomical lesions	Systemic diseases	Drugs	Other
Congenital megacolon	Congenital or acquired	Cystic fibrosis	Ferrum	Cow's milk allergy
Intestinal neuronal dysplasia	rectosigmoid stenosis	Connective tissue	Diuretics	Celiac disease
Vertebral lesions	Ectopic anus	disorders	Codeine/	
Embedded filament	Congenital colon	Diabetes Mellitus	Narcotics	
Neurofibromatosis	defects	Diabetes Insipidus	Antidepressants	
Cerebral palsy	Gastroschisis	Hyperthyroidism	Aluminium	
Botulism		Hypokaliemia	antacids	
		Hypothyroidism	Lead	
		Down syndrome	poisoning/	
		Pelvic tumors	Vitamin D	
		MEN 2B Syndrome		

Fig. Causative etiology of constipation [3]

PREVALENCE: Prevalence of childhood constipation has been estimated at 0.7% to 29.6% in the general population worldwide; most children have no obvious aetiological factors. One third of children with chronic constipation continue to have problems beyond puberty[4].The prevalence of functional constipation was estimated to be 14.29% with higher prevalence in females as compared to males i.e. 16.19% vs. 13.42%.
In approximately 95 % of children with constipation, no organic cause can be identified.

PATHOPHYSIOLOGY: The pathophysiology of Functional Constipation is still incompletely understood but is likely to be multifactorial[5]. Constipation can be due to various pathological conditions like poor habits and emotional problems, children affected with an inability to adjust in a group and failure to keep pace in school entities, Children born with imperforate anus[6].
Pathophysiologically, constipation may result from slow colonic transit, faecal evacuation disorders and a combination of slow colonic transit and faecal evacuation disorder[7].
Pathogenesis is multifactorial with focusing on genetic predisposition, socioeconomic status, low fiber consumption, lack of adequate fluid intake, lack of mobility, disturbance in the hormone balance, side effects of medications, or anatomy of the body, etc[8].

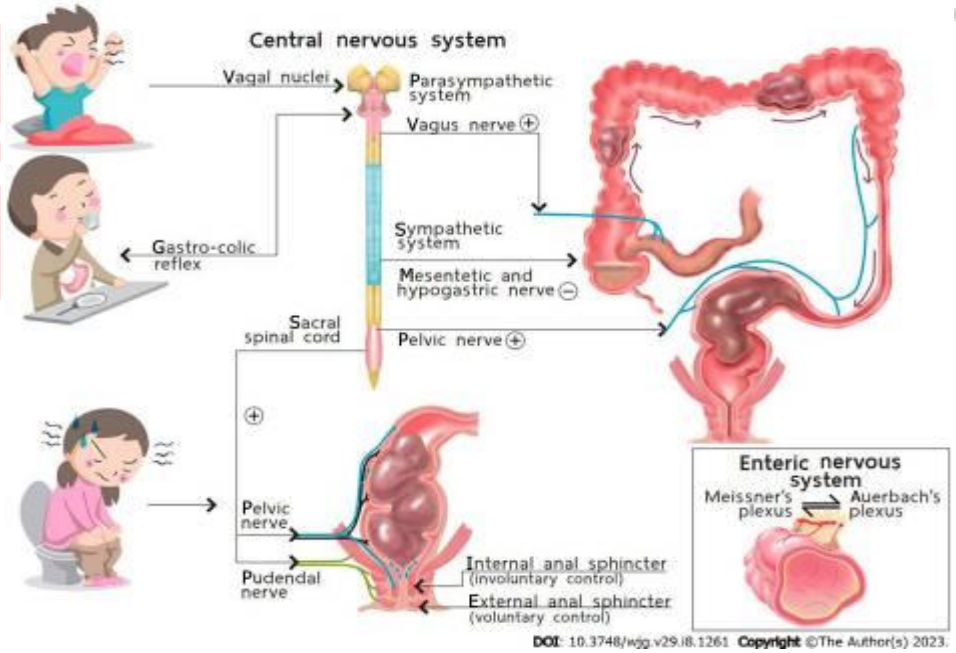


fig. Pathophysiology of constipation[9]

CLINICAL MANIFESTATION: Clinically, it may present as hard stool consistency, straining, sense of incomplete evacuation, bowel movement infrequency[1], sense of fullness in lower abdomen. Other symptoms include- abdominal pain, nausea, loss of appetite, bloating, anemia[8], weight loss[8].

DIAGNOSIS: A detailed clinical evaluation and rectal examination are the two most important steps when diagnosing chronic constipation[10]
A diagnosis of constipation is usually made on the basis of symptoms, a more precise and accurate characterization of the underlying mechanism(s) requires physiological tests of colorectal function[11]

Disorders	Diagnostic criteria
Anismus	Resting anal sphincter pressure >100 mmHg Abnormal balloon expulsion test
Puborectal dyssynergia	Failure of anorectal angle to open by >15° during defecography between resting and defecatory position No relaxation or increase in pressure on attempted defecation Abnormal balloon expulsion test
Perineal descent syndrome	Failure of anorectal angle to open by >15° during defecography between resting and defecatory position Descent of perineum >4 cm during defecation
Rectocele	Herniation of rectal wall with either preferential filling during defecography or failure to empty during defecation
Non-specific syndrome	Symptoms, abnormal balloon expulsion test but other criteria not fulfilled

Fig Diagnostic criteria of constipation[7]

❖ CALCAREA CARBONICA IN CONSTIPATION

The stomach in Calcarea is slow in its action.
"Food taken into the stomach remains."
He has a feeling of tumefaction and fullness; enlargement after eating; and everything sours in the stomach; everything disorders the stomach.
Weak digestion. The Calcarea patient has a very strong longing for eggs. Little children crave eggs; at every meal they will eat eggs, and eggs will digest better than anything else. It is very seldom that little children naturally long for eggs; children with cold feet, emaciated extremities, large heads, enlarged abdomen; stomach distended like an inverted saucer, rounded out; bloated abdomen, and slender extremities; cold and sensitive to cold; pale skin; pale, waxy surface.
Then, there is a complete loss of appetite, no desire for any kind of food. If any desire at all, it is for eggs. Aversion to meat; aversion to warm food.
It is one of the most useful medicines in old, lingering, stubborn cases of constipation.
When this constipation is present, the stool is white, or like chalk.
Often the stool is very light coloured and hard. (11)

Crawling and constriction in rectum. Stool large and hard (Bry); whitish, watery, *sour*. Prolapse ani, and burning, stinging haemorrhoids. Constipation; stool at first hard, then pasty, then liquid. (12)

Pressure in the stomach, as if something were lying heavy and solid in it.
Constipation on the first day; she has no stool without an injection. Increased constipation, from day to day. Great constipation: he had to take castor oil. Extreme constipation. No stool, with constant urging; with confusion of the head. (13)

Feels better in every way when constipated. Stool has to be removed mechanically (Aloe, sanic, sel, sep, sil) (14)

Retarded, hard. Angriness before, and weariness after Constipation. (15)

Stools at first hard, then pasty then liquid.
Prolapsus ani, crawling in rectum. Haemorrhoid painful when walking amel. Sitting. Stools agg. Eating and drinking. Feels best when constipated. (16)

Sour and offensive diarrhoea during dentition with sour vomiting but usually, the child is constipated (17).

Posology-
The concept of minimum dose states that - "It is that dose which is sufficient to overpower and annihilate the disease and capable of producing slight homoeopathic aggravation scarely observable after its ingestion." (Apho.280)
It is that amount of medicine, which is though smallest in quantity produces the least possible excitation of the vital force, and yet sufficient to effect the necessary changes in it (Apho.246).
Thus we can conclude that the most appropriate dose would the one in the smallest quantity which is possible to produce the required changes.
Choosing the potency for minimum dose depends upon -

1. The susceptibility of the patient.
2. The seat of the disease.
3. The nature and intensity of the disease.
4. The stage and duration of the disease.
5. The previous treatment of the disease.

II. METHODOLOGY

Method: Assessing the effects of homeopathic medicine Calcarea carbonica with a randomized controlled trial among paediatric population by prescribing homeopathic medicine Calcarea carbonica to 15 patients and allopathic medication to a control group of 15 patients, thus checking the effects of Calcarea carbonica.

Study Design: A two armed randomized control trial

Study Setting: College OPD and peripheral OPD, Nashik

Sample Size: 30 cases

Sampling Technique: Total 30 samples with complaints of Chronic Constipationselected by Simple Random Sampling Technique.

Method of Selection of Study Subjects:
A case series study was conducted on 30 patients diagnosed with Chronic Constipation, selected using a simple random technique from college OPD and peripheral OPD in Nashik. Calcarea carbonica was prescribed based on a detailed case analysis, considering the totality of symptoms. The patients were followed up over a specified period to assess symptomatic improvement.

Inclusion Criteria:
Patients of age group between 4-14 years of age.
Patients of both sexes.
Patients complaining of unsatisfactory defecation characterized by infrequent stool, difficult stool passage or both at least for previous 3 months.

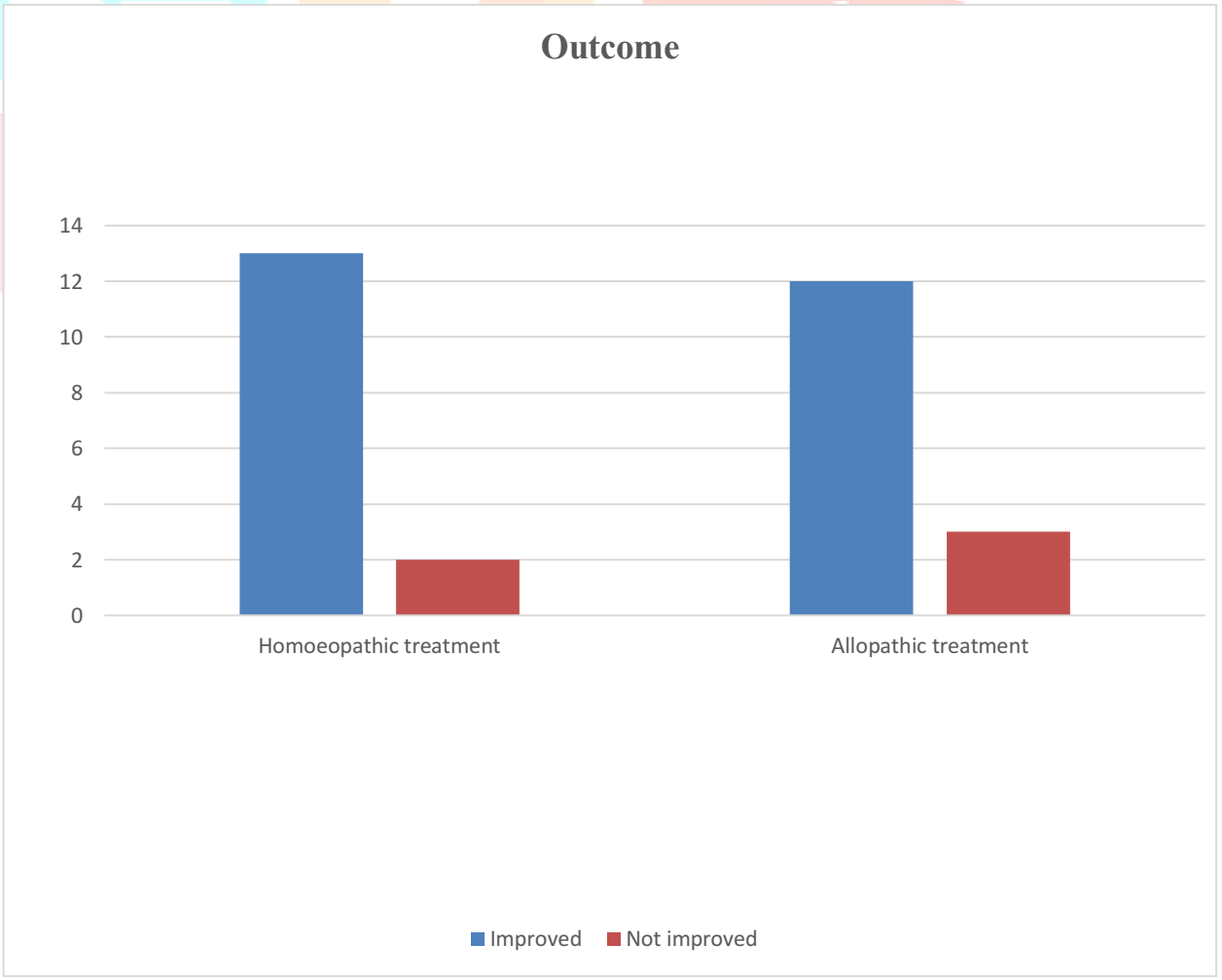
Exclusion Criteria:
Immunocompromised patients
Patients with serious incurable and pathological conditions like colonic cancer, rectal cancer.

Withdrawal Criteria:
Patients not giving consent.
Patients loss to follow up.

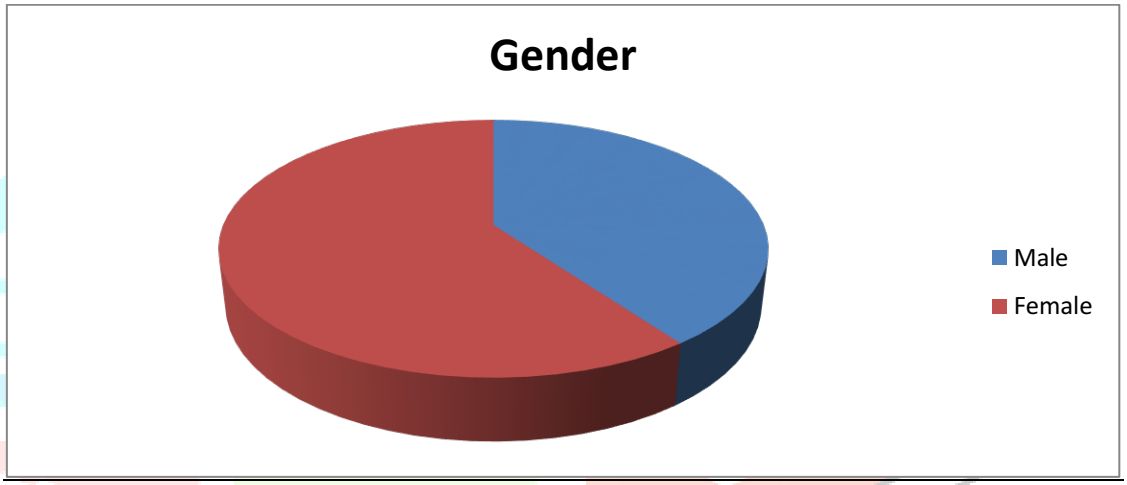
Operational definition:
The definition of constipation has different meanings for different people. For some, it means that stools are too hard or too small.
For others, stools are too difficult to expel or occur too infrequently.
Many physicians define constipation as a stool frequency consistently less than three per week.

III. RESULT/FINDING

OUTCOME OF HOMOEOPATHIC TREATMENT & ALLOPATHIC TREATMENT		
HOMOEOPATHIC	IMPROVED	13
	NOT IMPROVED	2
ALLOPATHIC	IMPROVED	12
	NOT IMPROVED	3



GENDER DISTRIBUTION	
MALE	12
FEMALE	18



IV. DISCUSSION

Out of 30 cases, 25 (75%) showed improvement, while 5 (25%) had no improvement. The cases with no improvement were prescribed standard allopathic management.
This study suggests that Calcarea carbonicamay have a potential role in controlling chronic constipation. Based on the severity and frequency of stool, the dose, repetition, and choice of medication were determined. It was observed that a higher number of females suffered from chronic constipation compared to males, with 75% of female patients and 25% of male patients affected. Of the cases, 13 were diagnosed with constipation with straining, 1 with fissure, and 1 withHemorrhoid.

V. CONCLUSION

Out of 30 cases 25 cases that is 75% showed improvement and 5 cases that is 25% had no improvement. Keeping in mind the severity of chronic constipation cases with no improvement were either prescribed individualized homeopathic medicine or standard management. This study shows that Calcarea carbonica has potential role in controlling constipation. Yet further study with large sample size is needed to explore more properties of Calcarea carbonica in chronic constipation.

STATISTICAL TESTS:

CSS Score		MEAN				
Before	After					
15	6	9				
17	8	9				
19	4	15				
16	15	1				
16	3	13				
18	5	13		X DIFF= 8.166		
21	12	9		STANDARD DEVIATION= 4.077		
16	7	9		T TEST= 8.16/4.07/√30		
13	7	6		T TEST= 8.16/4.07/5.48		
14	5	9		T TEST = 8.16/0.74		
16	5	11		T TEST= 11.02		
17	6	11		P VALUE= 1.796		
19	7	12				
19	7	12				
14	14	0				
13	8	5				
16	6	10				
17	8	9				
16	15	1				
17	6	11				
19	9	10				
16	8	8				
13	7	6				
16	7	9				
16	4	12				
14	13	1				
17	9	8				
18	9	9				
16	9	7				
16	16	0				
16.33333	8.166667	8.166				

Before treatment mean: 16.33

After treatment mean: 8.16

T test

$$\boldsymbol{xdiff}=Beforetreatment-aftertreatment$$

$$=8.16$$

Standard deviation= 4.077

$$\sqrt{n}=30$$

After substituting these values into the formula for *t* we have:

$$t=\frac{xdiff}{\frac{standarddeviation}{\sqrt{n}}}$$

$$t=\frac{8.16}{\frac{4.07}{\sqrt{30}}}$$

$$t=\frac{8.16}{\frac{4.07}{5.48}}$$

$$t=\frac{8.16}{0.74}$$

$$\boldsymbol{t=11.02}$$

Determine critical value for *t* with degrees of freedom = 2 and α = 0.05.

In this critical value is 1.796 (see the table below).

The calculated *t* exceeds the critical value (11.02 > 1.796), so the means are significantly different.

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