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## Abstract

**Background:** As a common disease in pediatrics, constipation poses a high burden to the community. In this study, we aimed to investigate the efficacy of dry cupping therapy (an Eastern traditional manipulative therapy) in children with functional constipation.

**Materials and Methods:** One hundred and twenty children (4-18 years old) diagnosed as functional constipation according to ROME III criteria were assigned to receive a traditional dry cupping protocol on the abdominal wall for 8 minutes every other day or standard laxative therapy (Polyethylene glycol (PEG) 40% solution without electrolyte, 0.4 g/kg once daily) for 4 weeks, in an open label randomized controlled clinical trial using a parallel design with a 1:1 allocation ratio. Patients were evaluated prior to and following 2, 4, 8 and 12 weeks of the intervention commencement in terms of the ROME III criteria for functional constipation.

**Results:** There were no significant differences between the two arms regarding demographic and clinical basic characteristics. After two weeks of the intervention, there was a significant better result in most of the items of ROME III criteria of patients in PEG group. In contrast, after four weeks of the intervention, the result was significantly better in the cupping group. There was no significant difference in the number of patients with constipation after 4 and 8 weeks of the follow-up period.

**Conclusion:** This study showed that dry cupping of the abdominal wall, as a traditional manipulative therapy, can be as effective as standard laxative therapy in children with functional constipation.

**Key words:** Functional constipation, cupping, children, musculoskeletal manipulations, Traditional Persian Medicine (TPM)

## Introduction

Constipation is a common disease that compromises 3-5% of a pediatrician's visits (Inaloo et al., 2014). The highest prevalence is at preschool ages with similar sex ratio (van den Berg et al., 2006). Only 5-10% of causes of constipation are organic, while the others are functional (without any known organic etiology) (Farnam et al., 2009). Functional constipation develops because of a decrease in intestinal movements (Gray, 2011).

Different factors such as psychological, low birth weight, and low fiber diets can increase the risk of constipation (Fontana et al., 1989). The economic burden of health care for pediatric patients with constipation in the United States is estimated to be \$2725 per year for each patient (North American Society for Pediatric Gastroenterology and Nutrition, 2006).

Increased parental understanding and support as well as improved toileting habits and using laxatives are used for the control of this distressing condition in children. Single drug therapy hardly leads to the control of the symptoms in afflicted children. The treatment protocol should include lifestyle changes via parental education, long term maintenance therapy and fecal mass removal (Nimrouzi et al., 2015).

Treatment of functional constipation has four stages: education, fecal disimpaction, oral maintenance therapy, and behavioral modification (Walia et al., 2013). Drug therapy may be continued for 3-6 months. Lubricants and osmotic agents are optional laxatives for children (McClung and Potter, 2004). Osmotic laxatives are the most popular drug used to treat constipation in children. Polyethylene glycol (PEG) has been a successful option for laxative therapy in these children (Nimrouzi et al., 2014).

Despite the advances in therapeutic options for children's functional constipation, the outcomes are not satisfactory and the recurrence rate is high (Bongers et al., 2010). The limitations in the current standard treatments have made researchers investigate the complementary and alternative medicine (CAM) treatments in the area of the interest. Different types of manipulative therapies are among the popular CAM options for the treatment of constipation which have shown promising results in multiple studies (Sinclair, 2011). Osteopathy and cupping are traditional forms of manipulative therapies which are also used and studied in patients with constipation (Tarsuslu et al., 2009).

Dry cupping is an intervention that has been widely used in Asian, Middle Eastern and European countries as a CAM therapy. In Korean medicine (KM), cupping has been employed for facilitating the circulation of qi and blood and removing blood stasis using cupping therapy devices through suction and negative pressure (Kim et al., 2012). Traditional Persian Medicine (TPM) scholars such as Rhazes (854 – 925 CE) (Heydari et al., 2015) and Avicenna (980-1037 CE) (Heydari et al., 2013) have suggested cupping for treatment of a wide variety of diseases including constipation (Avicenna, 2005). These traditional therapies are also currently popular in Persian population (Hashempur et al., 2015).

Cupping therapy is based on applying negative pressure suction on the skin. It is generally classified into wet and dry cupping (Nimrouzi et al., 2014). In dry cupping, a glass cup is placed on the skin and a vacuum is created inside it for a few minutes to congest the skin. In wet cupping after the mentioned step, some superficial incisions are placed in the congested area to suck the blood into the cup. This is repeated several times (Firoozabadi et al., 2014). In Chinese medicine, it is classified into weak/light cupping, medium cupping, strong cupping, moving cupping, needle cupping, moxa/hot needle cupping, empty/flash cupping, full/bleeding cupping, herbal cupping, and water cupping (Mehta and Dhapte, 2015).

The clinical efficacy of cupping has been investigated in many clinical trials (Akbarzadeh et al., 2014). Painful conditions are the most popular field of the clinical use of cupping with promising results (Lee et al., 2011). Moving cupping has also been studied in patients with constipation with positive results (Jiang et al., 2005). Because of the popular use of this traditional method among patients (Adib-Hajbaghery and Hoseinian, 2014), this study was designed to evaluate the efficacy of dry cupping therapy of the abdominal wall in children with functional constipation.

## **Methods and Materials**

### **Trial Design**

The study was conducted from September to December 2013 at Imam Reza pediatric gastroenterology clinic affiliated to Shiraz University of Medical Sciences (Shiraz, Iran). The study was approved by ethics committee of Shiraz University of Medical Sciences (Ethics committee ID: CT-P-92-4944). It also registered with ID number: AEARCTR-0000896. The trial enrollment started in September 2013. Before enrollment, informed consent was obtained from the parents after complete explanation about the study and its therapeutic methods (cupping therapy and PEG). In this trial, patients were examined by a pediatrician and their diagnosis (chronic functional constipation) was confirmed by him.

### **Patients**

Patients were selected from 224 children attending Imam Reza pediatric gastroenterology clinic. The children with diagnosis of functional constipation based on Rome III criteria (Inaloo et al., 2014), for at least 3 months before diagnosis and age between 4-18 years old were considered for inclusion in the study. Children having the Rome III criteria for Inflammatory bowel disease or organic causes of defecation disorders such as Hirschsprung's disease, spina bifida occulta, hypothyroidism, cystic fibrosis, neurologic abnormalities, intestinal pseudo-obstruction, and diabetes mellitus were excluded from the study.

### **Study Procedure**

A three month prospective randomized clinical trial was performed. Through a block randomization, patients were divided into two parallel therapeutic groups (60 patients in each group). The sample size was determined based on a previous study. Totally, 120 children were allocated into cupping therapy and PEG groups. The methodologist and the statistician who assessed and analyzed the data were blind to the protocol.

On enrollment, a complete history was taken and physical examination was done by a pediatrician involved in the study. Baseline frequency of defecation, presence of fecal soiling (encopresis), hard stool consistency, retention posturing, and abdominal pain were recorded.

### **Intervention**

In both groups, an expert person instructed routine nutritional and behavioral recommendations for children's constipation. Patients with fecal impaction in both groups were also dissipated with bisacodil suppositories at the first visit before enrolment. The parents were instructed to call the researcher if they observed any adverse effect or had any question.

In the cupping group, a registered operator of cupping therapy explained the method, duration, sites and frequency of cupping therapy to participants' parents and cupped the patients under their parents' view. In a second session, the parents cupped their children under the supervision of the instructor to adopt and correct the procedure. The remained 12 sessions of cupping were done by the parents at home every other day (totally 28 days of cupping therapy). Patients were excluded from the study if they had no bowel movement for seven days or developed fecal impaction at any stage.

Medication was oral administration of PEG (40% solution without electrolyte), 0.4 g/kg once daily for 4 weeks. Parents were requested to call the pediatrician in case they confronted with any complication. Weekly reports were taken by the interviewer. Patients were followed after 2, 4, 8 and 12 weeks of intervention.

**Procedure**

Various sterile disposable cups (manufactured in ABC ®, a Chinese company) from 1.5 cm to 5 cm in diameter (10 – 100 cc) were used (regard to patient age). Four to six cups (regard to patient skin surface) were applied on the abdominal skin (not on umbilicus) in each session. Duration of cupping therapy was 8 minutes. The negative pressure was applied until skin became congested. After that, the cup remained on the skin for 7 minutes. Then, the regulating button on the back of the cup was pulled to release the cup from the skin. The potential changes of skin color until a few days after cupping therapy were explained to the parents.

**Outcome Measures**

The primary outcome was number of patients who had responded to the treatment. Response to the treatment was defined as improvement of constipation for at least three bowel movements, soft stool and convenient defecation, no soiling and bloody stool per week as well as not fulfilling the Rome III criteria for constipation after the 2<sup>nd</sup>, 4<sup>th</sup>, 8<sup>th</sup> and 12<sup>th</sup> weeks of intervention. Secondary outcomes were frequency of defecation, presence of fecal soiling (encopresis), hard stool consistency, retention posturing and abdominal pain, at the mentioned time periods.

**Statistical Analysis**

Descriptive data were presented as mean and standard deviations or numbers and frequencies. The statistical comparison was processed with SPSS software using t-test, Chi-square test, Fisher exact test, Mann-Whitney U-test, and MC Nemar test where appropriate with a significance level of 5%.

**Results**

From September to December 2013, a total of 224 patients were assessed for eligibility and finally, 120 of them were randomized to receive cupping or PEG (60 patients in each group). Two patients in cupping group were stopped the follow-up visits. At last, 118 patients were included in the analysis. Figure 1 reveals detailed descriptions of patients' enrolment, randomization and outcomes.

**Table 1:** Inclusion Criteria for Diagnosis of Functional Constipation in Children

History of two or fewer defecations in the toilet per week
At least one episode of fecal incontinence per week
History of retentive posturing or excessive volitional stool retention
History of painful or hard bowel movements
Presence of a large fecal mass in the rectum
History of large diameter stools that may obstruct the toilet

There were no significant differences between the two arms regarding demographic and clinical basic characteristics including age, gender, number of patients with  $2 \geq$  bowel movement per week,  $1 \leq$  episode of fecal incontinence per week, retentive posturing or excessive volitional stool retention, presence of a large fecal mass in the rectum, painful or hard bowel movements and large diameter stools that may obstruct the toilet. The baseline characteristics (demographic and clinical) of the patients in the two groups are shown in Table 2.

**Table 2:** Baseline characteristics of patients in the cupping and polyethylene glycol (PEG) groups

Variable	Cupping (n=60)	PEG (n=60)	P value
Age (years)	6.3±2.1	6.4±2.3	0.96
Gender(male/female)	25/23	31/29	0.35
Number of patients with:			
2≥ bowel movement/week	54 (93.1%)	58(97.6%)	0.324
1≤ episode of fecal incontinence/week	11(19%)	10 (16.7%)	0.744
Retentive posturing or excessive volitional stool retention	55(94.8%)	53(88.3%)	0.063
Presence of a large fecal mass in the rectum	31(53.4%)	35(58.3%)	0.711
Painful or hard bowel movements	58(96%)	55(91.7%)	0.57
Large diameter stools that may obstruct the toilet	31(53.4%)	35(58.3%)	0.711

\* Data are presented as mean ± standard deviation, number (percent),

After two weeks of the intervention, there was a significant better result in most of the items of ROME III criteria of patients in polyethylene glycol group compared to the results of the cupping group (Table 3). After this time period, 58 patients in the cupping group (100%) and 17 patients in the PEG group (28.3%) remained in the definition of ROME III criteria for functional constipation ( $p<0.01$ ) (Table 4).

**Table 3:** Number of patients with each criteria of ROME III for functional constipation in the cupping and polyethylene glycol (PEG) groups after 2 and 4, 8 and 12 weeks.

Variable	Weeks	Cupping (n=58)	PEG (n=60)	P value
2≥ bowel movement/week	2	49(84.5%)	14(23.3%)	<0.001
	4	4(6.9%)	6(10%)	0.393
	8	5(8.6%)	2(3.3%)	0.268
	12	5(8.6%)	6(10%)	0.797
1≤ episode of fecal incontinence/week	2	13(22.4%)	8(13.3%)	0.234
	4	2(3.4%)	7(11.7%)	0.090
	8	3(5.2%)	5(8.3%)	0.717
	12	3(5.2%)	5(8.3%)	0.717
retentive posturing or excessive volitional stool retention	2	53(91.4%)	14(23.3%)	<0.001
	4	4(6.9%)	13(21.7%)	0.020
	8	6(10.3%)	9(15%)	0.448
	12	6(10.3%)	10(16.7%)	0.316
Presence of a large fecal mass in the rectum	2	31(53.4%)	10 (16.7%)	<0.001
	4	7 (13.1%)	8 (13.3%)	0.830
	8	8(13.8)	5 (8.3%)	0.344
	12	9(15.5%)	8(13.3%)	0.730
Painful or hard bowel movements	2	58(100%)	26(43.3%)	<0.001
	4	5(8.6%)	18(30%)	0.030
	8	7(12%)	9(15%)	0.640
	12	5(8.6%)	10(16.7 %)	0.190
Large diameter stools that may obstruct the toilet	2	38(65.5%)	31(51.7%)	0.127
	4	2(3.4%)	17(28.3%)	<0.001
	8	3(5.2%)	10(16.7%)	0.046
	12	8(13.8%)	11(18.3%)	0.500

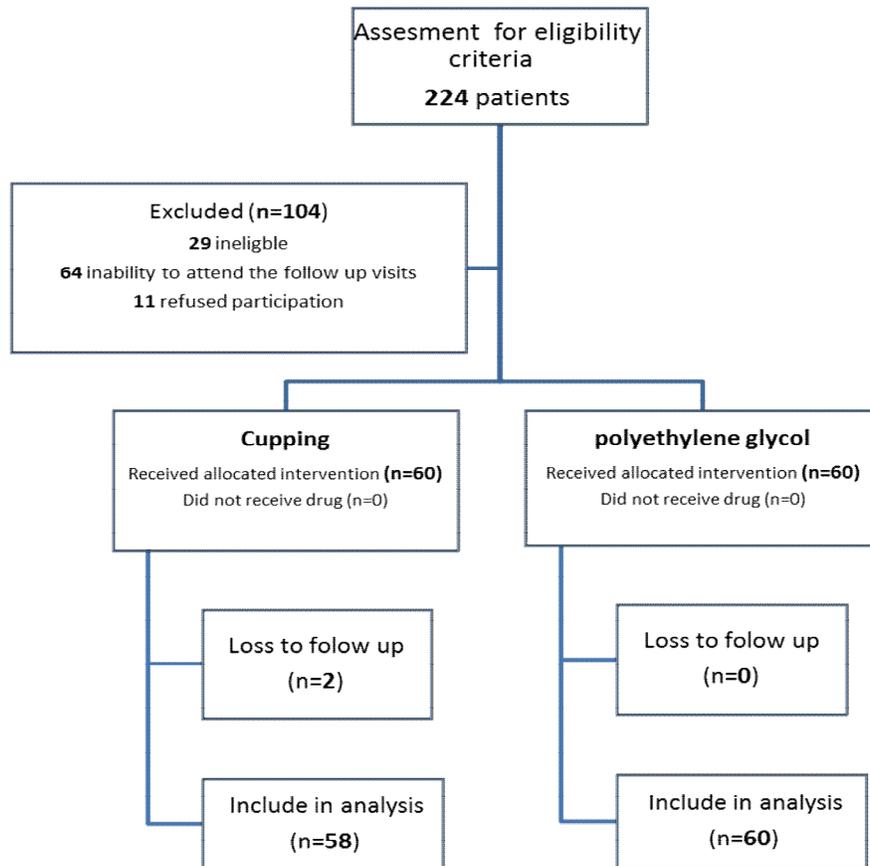
\* Data are presented as number (percent), the interventions are stopped after 4 weeks

**Table 4:** Number of patients with chronic functional constipation based on ROME III criteria in the cupping and polyethylene glycol (PEG) groups after 2, 4, 8 and 12 weeks \*

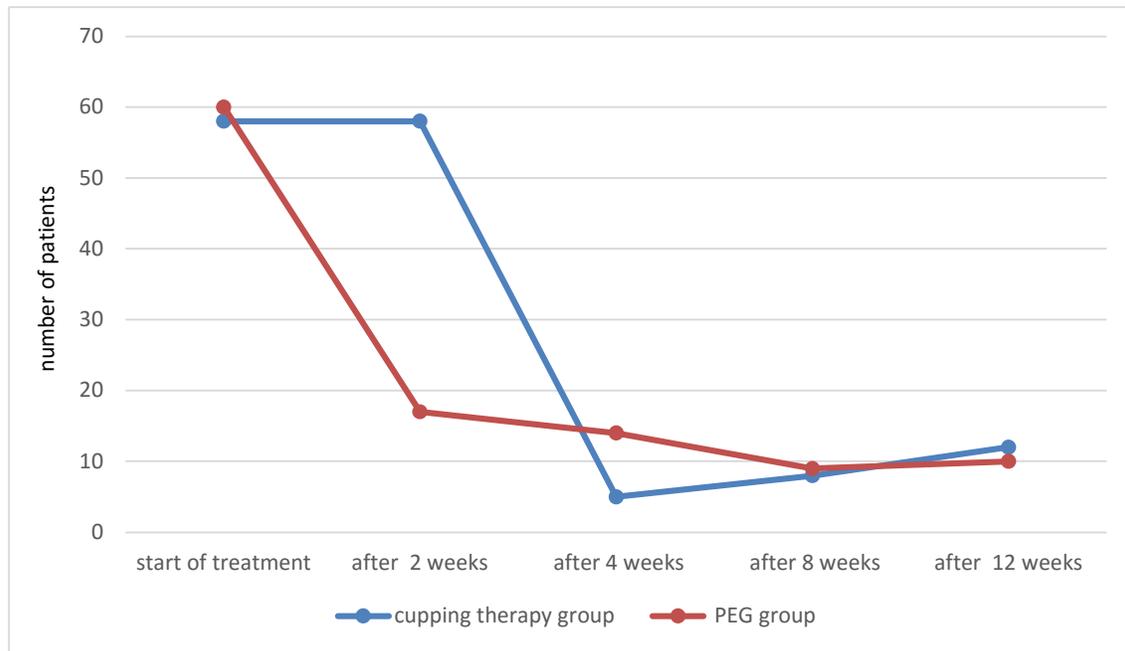
Weeks of the interventions	Cupping (n=58)	PEG (n=60)	P value
2 weeks	58(100%)	17(28.3%)	<0.01
4 weeks	5(8.6%)	14(23.3%)	0.03
8 weeks	8(13.8%)	9(15%)	0.85
12 weeks	12(20.7%)	10(16.7%)	0.57

\*Data are presented as No. (%)

By contrast, after four weeks of the intervention the result was significantly better in the cupping group. There were 5 patients in cupping group (8.6%) and 14 in the PEG group (23.3%) remained in the definition of ROME III criteria for functional constipation after this period of time ( $p=0.03$ ) (Figure 2). In the follow-up visits at 8 and 12 weeks after the start of the interventions, there was no significant difference between the number of constipated children in the two groups ( $p=0.85$  and  $p=0.57$ , respectively). The detailed information on the comparison of the number of patients with each criterion of ROME III for functional constipation in the cupping and PEG groups after 2 and 4, 8 and 12 weeks are summarized in Table 3.



**Figure 1:** Flowchart of the study's inclusion, allocation and follow-up



**Figure 2:** Number of patients with chronic functional constipation based on ROME III criteria in the cupping and polyethylene glycol (PEG) groups after 2, 4, 8 and 12 weeks

## Discussion

This study showed that despite the more rapid effect of polyethylene glycol, dry cupping therapy for four weeks can be as effective as polyethylene glycol in children with functional constipation. There was also no significant difference observed in the recurrence rate of these treatments after 2 months of follow-up.

Jiang et al. have evaluated the effect of moving cupping on senile constipation previously (Jiang et al., 2005). In their study, 64 patients with constipation were randomly assigned to moving cupping with Hechelu plus Shenque (CV 8) Bazhenxue moxibustion or oral phenolphthaleinum. The results showed a significantly better efficacy of moving cupping compared to phenolphthaleinum in short (14 days) and long term (2 months) periods. Our results in pediatric population with functional constipation showed positive effect of cupping in constipation too, but it seems that moving cupping may be more effective in these patients.

Multiple studies have also focused on different types of physical therapies such as abdominal massage and connective tissue manipulation in patients suffering constipation with positive results (Kassolik et al., 2015). A number of studies focused on massage therapy for constipation in pediatric population (Bromley, 2014). These studies also showed that abdominal massage can have a significant effect on the quality of life improvements including relief in symptoms of constipation, reduction in laxative medication and improved dietary intake. Like our study, the positive results were observed after 4 weeks of the intervention in these studies.

Abdominal massage of the ascending, transverse, and descending colons may be effective in regulating bowel movements and decreasing medication used for constipation through improvements in intestinal motility (Harrington and Haskvitz, 2006). Abdominal massage may decrease colonic transit time and increase large bowel peristalsis (Preece, 2002). These mechanisms can be active in other types of abdominal wall manipulation such as dry cupping. Under dry cupping, the applied negative pressure may play a stimulating role on the abdominal wall muscles in the case of their weakness. The most important benefit of such manual therapies is their safety (Preece, 2002).

Lack of a sham therapeutic arm may be the most important limitation of this study. Comparing a laxative with a manual therapy like cupping may not seem to be the most standard study protocol, but ethical limitation of setting one arm of the study on sham treatment made us use a standard treatment in our control group. The limitation of generalizability of the results to children with non-functional constipation is another considerable point. On the other hand, enough sample size, having a control group and 8 weeks follow-up of patients for observing the rate of recurrence are strengths of the current study protocol.

To summarize, this study showed that dry cupping of the abdominal wall, as a traditional manipulative therapy, can be as effective as standard laxative therapy in children with functional constipation. However, this effect appears after at least four weeks of every other day cupping and cannot be used as a short term induction treatment of functional constipation. The recurrence rate after two months also seems to be low in both laxative and cupping therapies.

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**Conflict of Interest:** The authors declare they have no conflict of interest.

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