*British Journal of Medicine & Medical Research*
*12(9): 1-7, 2016, Article no.BJMMR.22709*
*ISSN: 2231-0614, NLM ID: 101570965*

**SCIENCEDOMAIN** *international*
www.sciencedomain.org

# Calcium Polycarbophil in the Management of Fecal Incontinence

**Tatsuya Abe[1*], Masao Kunimoto[1], Yoshikazu Hachiro[1], Yoshiaki Ebisawa[1], Houhei Hishiyama[1] and Masanori Murakami[2]**

*[1]Department of Proctology, Kunimoto Hospital, Asahikawa, Japan.*
*[2]Department of Gastroenterology, Kunimoto Hospital, Asahikawa, Japan.*

***Authors' contributions***

*This work was carried out in collaboration between all authors. Author TA designed the study, performed the statistical analysis, managed the literature searches, wrote the protocol and wrote the first draft of the manuscript. Authors MK, YH, YE, HH and MM contributed to acquisition, obtaining follow-up data and analysis. All authors read and approved the final manuscript.*

***Article Information***

DOI: 10.9734/BJMMR/2016/22709
Editor(s):
(1) Syed Faisal Zaidi, Department of Basic Medical Sciences, College of Medicine, King Saud Bin Abdulaziz University-HS, National Guard Health Affairs, King Abdulaziz Medical City, Kingdom of Saudi Arabia.
Reviewers:
(1) Triveni Krishnan, National Institute of Cholera and Enteric Diseases, Kolkata, India.
(2) Mellar P. Davis, Case Western Reserve University, USA.
(3) Ketan Vagholkar, D. Y. Patil University, India.
Complete Peer review History: http://sciencedomain.org/review-history/12468

***Original Research Article***

***Received 21st October 2015***
***Accepted 9th November 2015***
***Published 27th November 2015***

## ABSTRACT

**Background:** Few clinical studies have assessed the efficacy of calcium polycarbophil that is currently recommended as an ideal and initial bulk-forming agent in patients with fecal incontinence.
**Aims:** The aim of this study was to evaluate the short-term outcomes of calcium polycarbophil administration to patients with fecal incontinence due to a range of etiologies.
**Study Design:** This was a retrospective review of a single-institution experience.
**Methodology:** In total, 223 patients treated with calcium polycarbophil were enrolled. Efficacy measures included changes in the Cleveland Clinic Incontinence Score and the Bristol Stool Form Scale.
**Results:** Of the 223 patients who were enrolled, 195 were available for final analysis. Among the 195 patients, 15 (7.7%) experienced side effects; the most common side effects were constipation and hard stools. One month after the start of treatment, the mean Cleveland Clinic Incontinence Score decreased significantly compared with baseline (11.2±4.0 vs. 5.7±5.0, *P* = < .001). The mean

**Corresponding author: E-mail: t-abe@cf6.so-net.ne.jp, abetatsuya99@gmail.com;*

stool consistency decreased significantly, with patients reporting more formed stools by the Bristol Stool Form Scale at 1 month than at baseline (4.4±1.5 vs. 3.9±1.1, *P* = < .001).
**Conclusions:** Our findings suggest that monotherapy with calcium polycarbophil appears to be a safe and beneficial approach in the management of fecal incontinence.

*Keywords: Fecal incontinence; calcium polycarbophil; pharmacotherapy; stool form scale.*

## 1. INTRODUCTION

Fecal incontinence (FI) is a psychologically distressing and disabling condition that has a significant impact on the quality of life and poses a large economic burden [1]. Non-operative therapy is generally the first approach to improve FI symptoms, and the addition of a daily fiber supplement, which acts as a bulking agent to allow for more solid stools, are advised in its management [2]. A randomized, blinded, placebo-controlled study found that daily fiber supplementation improved FI and stool consistency [3].

In addition to fiber supplementation, pharmacologic agents with a constipating effect, including loperamide, diphenoxylate, atropine, and codeine, may be useful for patients with FI [2]. Of these, loperamide is the most commonly used with proposed additional beneficial effects on the anal sphincter resting tone [4]. Although loperamide has been shown as particularly useful in patients with diarrhea and urge-related FI, its use in other FI types is often associated with unsatisfactory results [5].

FI is commonly exacerbated by watery stools or diarrhea; however, it may also arise as a consequence of chronic constipation [6]. In some patients, prolonged rectal retention or incomplete evacuation of the stool may lead to stool seepage or soiling of undergarments. A majority of these patients suffer from obstructive or dyssynergic defecation, and many additionally exhibit impaired rectal sensation [7]. Similarly, in the elderly and children with functional incontinence, the prolonged rectal retention of stool can lead to fecal impaction.

Calcium polycarbophil (CP) is an insoluble, synthetic hydrophilic polymer. Studies in canines demonstrated that CP could absorb up to 70 times its own weight in fluid, improve stool consistency, and decrease the frequency of bowel movements [8]. Alternatively, in a constipation model, CP was shown to increase stool frequency and fecal weight [9]. Although CP is recommended as an ideal and initial bulk-forming agent in patients with FI, there are relatively few clinical studies defining the effect of CP on FI [5,6]. Therefore, we reviewed the outcomes of CP treatment in patients with FI at our institution.

## 2. MATERIALS AND METHODS

Prospectively collected data from patients with FI treated with CP (Polyful®, Mylan, Tokyo, Japan) at our institution between January 2005 and December 2014 were retrospectively reviewed. The inclusion criteria were the presence of at least one FI episode per month for at least 3 consecutive months. The exclusion criteria were the presence of current rectal prolapse, active perineal sepsis, diagnosis of anorectal tumor, and treatment with additional therapeutic modalities. Patients previously treated with other modalities were included if they received CP during the enrollment period.

In all patients, the data collected included demographics, risk factors for FI (anorectal surgery, obstetric-related trauma, systemic neurologic disorder, or spinal pathology), and a completed comprehensive symptom questionnaire. The questionnaire assessed both the nature and frequency of FI episodes and the patterns of defecation, including laxative use and stool form by the Bristol Stool Form Scale, which is a medical aid designed to classify the form of human feces into seven categories. Types 1 and 2 indicated constipation, and types 3 and 4, mostly the latter, described ideal stools. Types 5, 6, and 7 indicated soft to watery stools [10]. FI was additionally classified into passive incontinence (defecation without the patient's knowledge), urge incontinence (failure to defer defecation for 15 min), or mixed incontinence (a combination of passive and urge incontinence). The severity of FI was assessed with the grading system of the Cleveland Clinic Incontinence Score (CCIS), ranging from 0 (complete continence) to 20 (complete incontinence) [11]. The potential underlying causes of FI were determined by questionnaires and anorectal physiologic tests.

All patients underwent comprehensive anorectal physiologic tests with the rectum unprepared. Anorectal manometry (ARM) was performed using a 5-mm diameter, 1- channel, solid-state catheter with a microtipped transducer ARM system. The lubricated catheter was introduced into the rectum, with the patient in the left lateral position with the hips flexed to 90°. The maximal resting pressure (MRP) was recorded by means of a rapid pull-through technique and was defined as the highest resting pressure recorded. Subsequently, the maximal squeeze pressure (MSP), defined as the highest pressure recorded above the baseline (zero) at any level of the anal canal during maximum squeeze effort by the patient, was measured. Next, each patient was evaluated by endoanal ultrasound scanning (EAUS) with a scanner that has a 7-MHz rotating endoprobe. The questionnaires and anorectal physiologic tests were routinely used in our clinical practice.

All patients received oral CP tablets at a dose of either 1.0 g three times per day (3.0 g per day) or 0.5 g three times per day (1.5 g per day), as needed based on age, perceived severity of incontinence, and need for relief, or at the clinician's discretion. The medications were taken with at least one glass of water after meals. Most patients were encouraged to perform Kegel exercises at home to strengthen the puborectalis muscle and the external anal sphincter. The primary efficacy measures of this study were the CCIS and the stool consistency. Patients were evaluated before and after 1 month of therapy.

The data were expressed as mean ± standard deviation for quantitative variables. In the figures, the means were plotted with standard errors. Paired analysis was performed using paired t-test. Two-tailed P values of less than 0.05 were considered significant.

## 3. RESULTS AND DISCUSSION

### 3.1 Results

We included 223 Japanese patients, of which 148 (66%) were female, during the study period. The patients' characteristics are shown in Table 1. Table 2 shows the potential underlying causes for FI based on the questionnaires and the results of the ARM and EAUS. Of the 223 patients who were included, 28 did not return for a visit at our clinic after receiving the study drugs; thus, a total of 195 patients were available for the final analysis. Of these 195 patients, 106 patients (54%) received 1.5 g of CP, and 89 (46%) received 3.0 g of CP.

**Table 1. Characteristics of patients**

| | Men N=75 | Women N=148 | Total N=223 |
|---|---|---|---|
| Mean age (range) | 65 (7-93) | 70 (32-90) | 68 (7-93) |
| Parity | | 135 (90) | |
| Type of incontinence | | | |
| Passive | 46 (61) | 89 (60) | 135 (60) |
| Urge | 12 (16) | 5 (4) | 17 (8) |
| Mixed | 17 (23) | 54 (36) | 71 (32) |
| Prior therapy | 16 (21) | 32 (22) | 48 (22) |
| Laxatives | 26 (35) | 64 (43) | 90 (40) |

*Values in parentheses are percentages unless otherwise indicated.*

**Table 2. Potential underlying causes of fecal incontinence in 75 males and 148 females**

| | No. of patients |
|---|---|
| Anal sphincter injury due to vaginal delivery | 72 |
| Idiopathic | 35 |
| Internal anal sphincter degeneration | 26 |
| Chronic diarrhea | 20 |
| Diabetic mellitus | 16 |
| Anal sphincter injury due to anal surgery | 14 |
| Spinal cord disorders / surgery | 12 |
| Chronic constipation | 13 |
| Central nervous system disorders | 8 |
| Rectal prolapse | 3 |
| Others | 4 |

Among the 195 patients, 15 (7.7%) experienced side effects, which were not serious, and no patient deaths occurred during the study. All side effects are listed in Table 3. The frequency of side effects was higher in the 3.0 g group (11%) than that in the 1.5 g group (4.7%), but this difference did not reach statistical significance (P = 0.089). The most common side effects were constipation (2.1%) and hard stools (2.1%). Most patients were able to tolerate the side effects, but two patients (1.0%) discontinued the study because of drug-related nausea or bloating. One other patient was excluded from the study because the CCIS was not reported at the 1-month visit. Accordingly, a total of 192 patients completed the study and were included in the efficacy analysis.

**Table 3. Side effects experienced by patients**

| Side effects | CP 1.5 g N=106 | CP 3.0 g N=89 | Total N=195 |
|---|---|---|---|
| Constipation | 1 (0.9) | 3 (3.4) | 4 (2.1) |
| Hard stools | 2 (1.9) | 2 (2.2) | 4 (2.1) |
| Nausea | 1 (0.9) | 1 (1.1) | 2 (1.0) |
| Bloating | 0 (0.0) | 2 (2.2) | 2 (1.0) |
| Eczema | 1 (0.9) | 1 (1.1) | 2 (1.0) |
| Loose stools | 0 (0.0) | 1 (1.1) | 1 (0.5) |
| Total | 5 (4.7) | 10 (11.2) | 15 (7.7) |

*Data are numbers with percentages in parentheses.*
*CP = calcium polycarbophil.*

At 1 month, the mean CCIS significantly decreased compared with baseline (11.2±4.0 vs. 5.7±5.0, P = < .001), and all five items of the CCIS also decreased (Table 4). Of the 192 patients, 27 (14%) were completely continent (a CCIS of 0) at 1 month, 136 (71%) had an improved CCIS, and 29 (15%) had either no change or a poor score. The improvements in the CCIS were similar in both the 1.5 g and the 3.0 g groups (Fig. 1).

The analysis of the stool consistency revealed that type 5 (soft) and type 6 (loose) stools were decreased, whereas types 3 and 4 (normal) stools were increasingly reported (Fig. 2). Consequently, the mean stool consistency significantly decreased, indicating more formed stools at 1 month after treatment implementation, than at baseline (4.4±1.5 vs. 3.9±1.1, P = <.001).

**Table 4. Change of Cleveland Clinic Incontinence Score before and after treatment (N=192)**

| Type of incontinence | Baseline value | After 1 month | P-value |
|---|---|---|---|
| Solid | 1.3±1.6 | 0.6±1.1 | < .001 |
| Liquid | 3.1±1.1 | 1.4±1.4 | < .001 |
| Gas | 2.4±1.7 | 1.9±1.7 | < .001 |
| Wears pad | 2.7±1.7 | 1.9±1.8 | < .001 |
| Lifestyle alteration | 1.8±1.7 | 0.9±1.4 | < .001 |
| Total CCIS | 11.2±4.5 | 5.7±.5.0 | < .001 |

*Data are presented as mean ± standard deviation.*
*CCIS = Cleveland Clinic Incontinence Score.*

The ARM was assessed in 110 patients (57%) at 1 month after the start of CP treatment: the results are summarized in Table 5. The patients showed significant improvements in the MSP after treatment, whereas there were no statistical changes in the MRP.

**Table 5. Manometric data before and after treatment (N=110)**

| | Baseline value | After 1 month | P-value |
|---|---|---|---|
| MRP (mmHg) | 29.6±17.7 | 29.8±16.7 | .836 |
| MSP (mmHg) | 131±81.2 | 148±95.7 | < .001 |

*Data are expressed as mean ± standard deviation.*
*MRP = maximal resting pressure.*
*MSP = maximal squeeze pressure.*

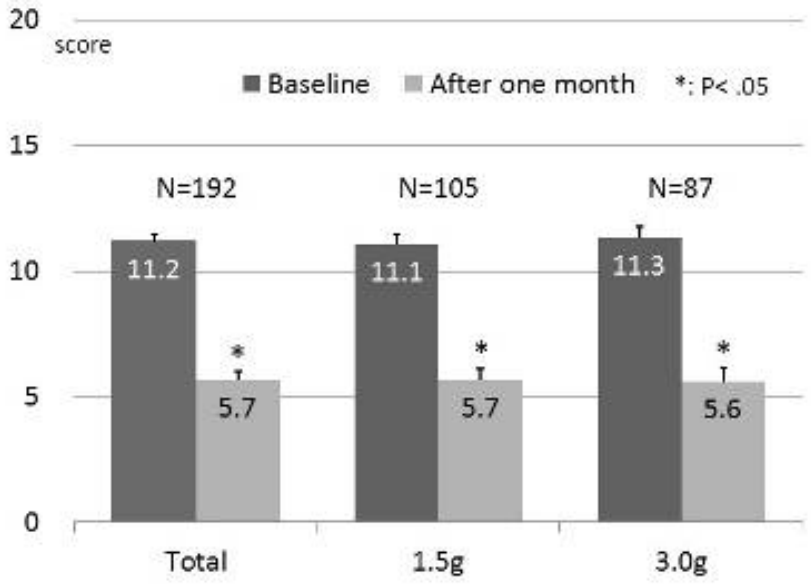


**Fig. 1. Effect of calcium polycarbophil on the cleveland clinic incontinence score in patients with fecal incontinence. There was a similar improvement in both 1.5 g and 3.0 g groups**

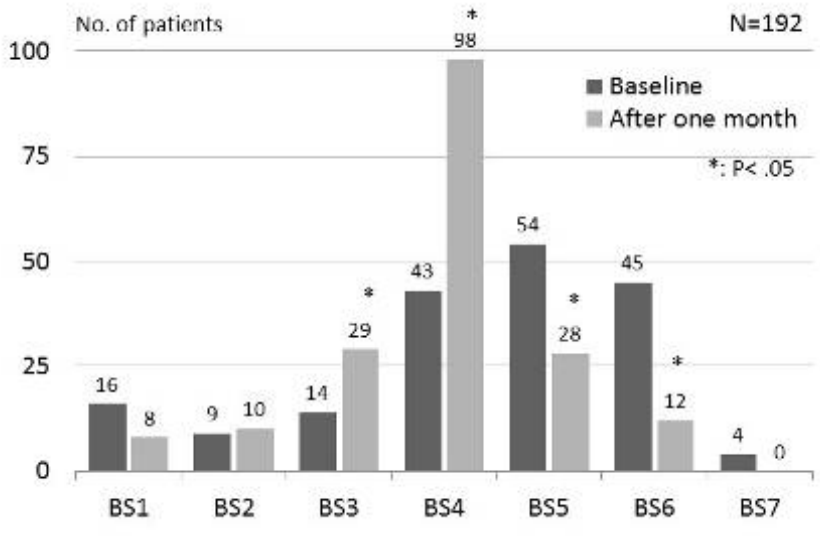


**Fig. 2. Effect of calcium polycarbophil on the Bristol Stool Form Scale (BS) in patients with fecal incontinence. Type 5 (soft) and type 6 (loose) stools were decreased, whereas normal stools (types 3 and 4) were increased**

## 3.2 Discussion

This is the first comprehensive clinical study on the efficacy of CP in patients with FI that has been reported in an English journal [12,13]. The present study shows that CP alone can be an effective intervention for FI treatment. The results were objectively demonstrated not only by clinical scoring but also by stool consistency using established protocols.

CP is a synthetic, high molecular-weight polymer with marked water retention and gel-forming capabilities. The former property reduces constipation, whereas the latter ameliorates diarrhea [8,9]. CP has been shown as an effective therapeutic approach for the treatment of chronic constipation or irritable bowel syndrome [14], whereas its effect as a single treatment option in FI has not been properly investigated.

The CCIS is the most commonly used FI severity index and includes a total of five items that are simple yet robust tools to assess FI [11]. In this study, patients with FI due to a variety of etiologies were administered CP, which resulted in significant improvements in all five CCIS items, including lifestyle alteration. Because more than 80% of the subjects showed an improvement of symptoms and complete continence was achieved in 14%, we believe that single therapy with CP was effective as a treatment of FI.

Our investigation of the safety of CP showed that none of the patients suffered serious adverse drug effects. The most common side effects associated with CP treatment were constipation and hard stools. Because these side effects were experienced by more patients receiving 3.0 g CP/day than those receiving 1.5 g CP/day, we believe that they were due to excessive pharmacological action. A main component of CP is synthetic resin, which is not absorbed by the digestive tract. Thus, adverse effects such as distention and discomfort that occur with the ingestion of psyllium, plantain, or similar fibers, were not experienced with CP, which is a major benefit of CP. While adverse drug effects were more frequently observed with 3.0 g CP/day, the improvements in the CCIS were similar in both 1.5 g and 3.0 g doses. Thus, we believe that a minimum dose of 1.5 g is sufficient for Japanese patients.

Our investigation of anal pressure indicated that although the MSP improved with 1 month of CP treatment, there were no changes in the MRP. Because most of the patients in this study had passive incontinence or mixed incontinence, many showed declines in the MRP alone, while the MSP remained at normal levels. Because CP did not result in an improvement in the MRP, we believe that CP does not have the same ability as loperamide in restoring the MRP. We presume that elevated MSP levels resulted from the Kegel exercises that were recommended to

the patients for strengthening the puborectalis muscle and the external anal sphincter.

Our results show that one main reason for CP-mediated improvements in FI is the improved stool consistency as a result of decreases in the number of loose stools that can cause leakage with reciprocal increases in the number of normal stools. Antidiarrheal medications such as loperamide are used as a treatment for FI; however, in cases where the underlying cause is constipation, these medications worsen the constipation. Because CP has been shown to improve constipation, it can be administered to a wider patient population regardless of the type of bowel movement dysfunction.

Increasing dietary fiber can improve stool characteristics; however, it requires a high amount of intake, 25–30 g a day, a difficult task for continual ingestion [3,6]. Because CP is available in either the tablet or granular form, it is easy to ingest. In addition, there are many generic CP preparations; thus, it does not place an undue economic burden on patients. In most countries, CP is available as an over-the-counter medication; thus, it is easily available even for patients with FI who may hesitate undergoing a medical examination because of embarrassment.

The limitations of this study include its open observational design with no control group, the short observation period, and the inclusion of only Japanese patients.

## 4. CONCLUSION

We found CP as a safe and useful agent in the management of FI. Further studies are required to determine effectiveness in the long term and investigate other treatment combinations.

## CONSENT

All authors declare that written informed consent was obtained from the patients for performing this research.

## ETHICAL APPROVAL

The Institutional Review Board of the Kunimoto Hospital provided approval prior to the conduct of this study.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

## REFERENCES


1. Bharucha AE, Zinsmeister AR, Locke GR, Seide BM, McKeon K, Schleck CD, et al. Prevalence and burden of fecal incontinence: a population-based study in women. Gastroenterology. 2005;129(1):42-9.
2. Van Koughnett JAM, Wexner SD. Current management of fecal incontinence: Choosing amongst treatment options to optimize outcomes. World J Gastroenterol. 2013;19(48):9216-30.
3. Bliss DZ, Jung HJ, Savik K, Lowry A, LeMoine M, Jensen L, et al. Supplementation with dietary fiber improves fecal incontinence. Nurs Res. 2001;50(4):203-13.
4. Hallgren T, Fasth S, Delbro DS, Nordgren S, Oresland T, Hultén L. Loperamide improves anal sphincter function and continence after restorative proctocolectomy. Dig Dis Sci. 1994;39(12): 2612-8.
5. Omer MI, Alexander CE. Drug treatment for fecal incontinence in adults. Cochrane Database Syst Rev. 2013;CD002116:
   DOI: 10.1002/14651858
6. Ehrenpreis ED, Chang D, Eichenward E. Pharmacotherapy for fecal incontinence: A review. Dis Colon Rectum. 2006;50(5): 641-9.
7. Rao SSC. Pathophysiology of adult fecal incontinence. Gastroenterology. 2004; 126(1):S14-S22.
8. Saito T, Yamada T, Iwanaga Y, Morikawa K, Nagata O, Kato H, et al. Calcium polycarbophil, a water absorbing polymer, increases bowel movement and prevents sennoside-induced diarrhea in Dogs. Jpn J Pharmacol. 2000;83(3):206-14.
9. Saito T, Mizutani F, Iwanaga Y, Morikawa K, Kato H. Laxative and antidiarrheal activity of polycarbophil in mice and rats. Jpn J Pharmacol. 2002;89(2):133-41.
10. Lewis SJ, Heaton KW. Stool form scale as a useful guide to intestinal transit time. Scand. J. Gastroenterol. 1997;32(9):920.
11. Jorge JM, Wexner SD. Ethiology and management of fecal incontinence. Dis Colon Rectum. 1993;36(1):77-97.
12. Abe T, Sato Y, Hachiro Y, Kunimoto M. The clinical efficacy of calcium polycarbophil for fecal incontinence. J Japan Soc Coloproctol. 2010;63(8):483-7. Japanese.

13. Shibata C, Funayama Y, Fukushima K, Takahashi K, Ogawa H, Haneda S, et al. Effect of calcium polycarbophil on bowel function after restorative proctocolectomy for ulcerative colitis: A randomized controlled trial. Dig Dis Sci. 2007;52(6): 1423-6.

14. Chiba T, Kudara N, Sato M, Chishima R, Abiko Y, Inomata M, et al. Colonic transit, bowel movements, stool form, and abdominal pain in irritable bowel syndrome by treatments with calcium polycarbophil. Hepatogastroenterology. 2005;52(65): 1416-20.



*Peer-review history:*
*The peer review history for this paper can be accessed here:*
*http://sciencedomain.org/review-history/12468*