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Effective Treatment of Chronic Constipation in a Psychogeriatric Population

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OBJECTIVE: To demonstrate that the use of a high-fiber fruit product effectively treats chronic constipation in an institutionalized elderly population that concomitantly is taking multiple anticholinergic medications.

DESIGN: Nonrandomized clinical trial.

SETTING: Psychogeriatric unit of a public, chronic care psychiatric hospital.

SUBJECTS: Eighteen elderly, long-term psychiatric inpatients with a medical diagnosis of constipation, taking multiple laxatives and anticholinergic medications.

INTERVENTION: After a 3-month baseline observation phase, a high-fiber fruit product was substituted for all previously prescribed laxatives in the experimental group, whereas the control group continued its usual laxative regimen throughout the 6-month treatment phase. During the treatment phase, no other changes of medication regimens were made in either group.

MAIN OUTCOME MEASURES: For each group, the average stools per month during the baseline phase were compared with the average stools per month during the treatment phase. Plain abdominal radiographs were taken during the baseline phase and compared with those taken during weeks 6 and 12 of the treatment phase for each patient. Study authors compared the cost of the fruit product for the last month of the treatment phase in the experimental group with the cost of laxatives during the same period for the control group. The direct care staff of the experimental group participated in a staff satisfaction survey at the end of the treatment phase.

RESULTS: The experimental group had a significantly increased number of stools during each month of the treatment phase, whereas the stool frequency of the control group remained unchanged from the baseline phase.

CONCLUSION: A high-fiber fruit product can effectively treat chronic severe constipation in institutionalized elderly patients who are concomitantly taking anticholinergic medications.

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CHRONIC CONSTIPATION

INTRODUCTION

Constipation is a significant medical problem,^{1,2} especially for elderly, institutionalized patients^{3,4} who also take anticholinergic medications.^{5,6} While making daily rounds on a psychogeriatric ward, two of the authors of this study noted the high prevalence and serious medical consequences of constipation. Many of these patients experienced fecal impactions with fecal incontinence, recurring abdominal pain, exacerbations of psychiatric symptoms, and rectal bleeding. They also required frequent stimulant laxatives when standard laxative regimens failed, which usually occurred. A literature review found no studies documenting effective treatment in similar populations. With this in mind, the authors studied the use of a proprietary fruit product containing soluble and insoluble fiber as an alternative to standard laxative regimens.

METHODS

This study included 20 patients in a psychogeriatric ward of a psychiatric hospital who were selected because of their severe chronic constipation or because their medication administration record documented the greatest use of routine laxatives. The authors obtained Human Subject Committee approval of the protocol, then matched study participants based on similarities of bowel medication regimens and divided them into control and experimental groups.

The authors used anticipated routine acceptance of the fruit product as the criterion for inclusion in the experimental group. Authors estimated the likelihood of agreement to consume the product on a regular basis from longstanding dietary patterns and medication-taking behavior as reported by medication nurses and dietary aides. When possible, patients using more routine laxatives were placed in the experimental group. The authors obtained guardian approval for 19 patients to participate in the study. However, one guardian refused approval for a control group patient, and one experimental group patient was discharged from the institution after 3 months of the treatment phase. This reduced the final total number of patients to 18. The intervention took place from November 1, 1993 through April 30, 1994.

Experimental Intervention

The study protocol replaced all routine laxatives with the fruit product, a proprietary mixture of dates, raisins, prunes, and prune juice with a paste-like texture. One 30-mL dose contains 99 calories, 25 g carbohydrates, 1 g protein, 1.5 g soluble fiber, 1 g insoluble fiber, and 258 mg potassium. It is fat- and sodium-free. The experimental group had all laxatives discontinued on November 1, 1993 and began taking 30 mL of the fruit product twice daily. After 12 weeks, the dosage of the fruit product was decreased to the maintenance dosage of 15 mL twice daily. The control group received the same laxative regimen as previously prescribed. None of the other medications of either the experimental or control group was changed during the treatment phase of the study.

Data Collection and Analysis

Direct care staff kept daily stool records, according to ward routine, for all patients in both groups from August 1, 1993 to October 31, 1993 (baseline phase) and from November 1, 1993 to April 30, 1994 (treatment phase). All patients underwent plain abdominal radiographs during the baseline phase and during weeks 6 and 12 of the treatment phase. An off-site radiologist, unaware of the study, interpreted the radiographs. At the end of the treatment phase, staff completed a questionnaire designed to elicit reactions to the various treatment regimens. Stool records were analyzed using a group-by-time repeated measures analysis of variance (ANOVA) followed by DATA univariate *t*-tests, both between and within groups.

Authors calculated the cost of the fruit product for the last month of the treatment phase using the actual amount administered to the experimental group during that month based on the manufacturer's invoice price. They calculated the cost of laxatives for the same period for the control group based on the pharmacy purchase price for the laxatives actually used.

TABLE I
BASELINE CHARACTERISTICS OF PATIENTS
BY TREATMENT GROUP

	Experimental Group	Continued-Laxative Control Group
Age (years)		
Mean	67.3	68.7
Range	54-86	46-84
Gender		
	3 males 6 females	4 males 5 females
Length of Stay (months)		
Mean	68	46
Range	28-214	24-125

RESULTS

Table I shows the baseline characteristics of the 18 patients. All patients had multiple medical and psychiatric diagnoses, although fewer diagnoses of dementia were noted in the experimental group (*n* = 3) than in the control group (*n* = 6). There was no substantial difference between the groups in the number of cardiac, hormonal, anti-infective, anti-ulcer, and respiratory medications used. All patients took multiple psychotropic medications, many with strong anticholinergic effects — as indicated with an asterisk in Figure 1. Prior to the treatment phase, all patients required multiple daily laxatives (Figure 2). The mean number of routine daily laxatives per patient during the baseline phase was 3.1.

The authors later tallied stools as recorded on the bowel record and calculated average stools per month for both groups (Figure 3). They then compared groups based on the number of recorded stools during the first and last month of the baseline phase and each month of the treatment phase. There were no significant differences between the groups or within each group during the baseline months. No significant change in stool frequency was found in the control group in any month of the treatment phase. A significant increase in stool fre-

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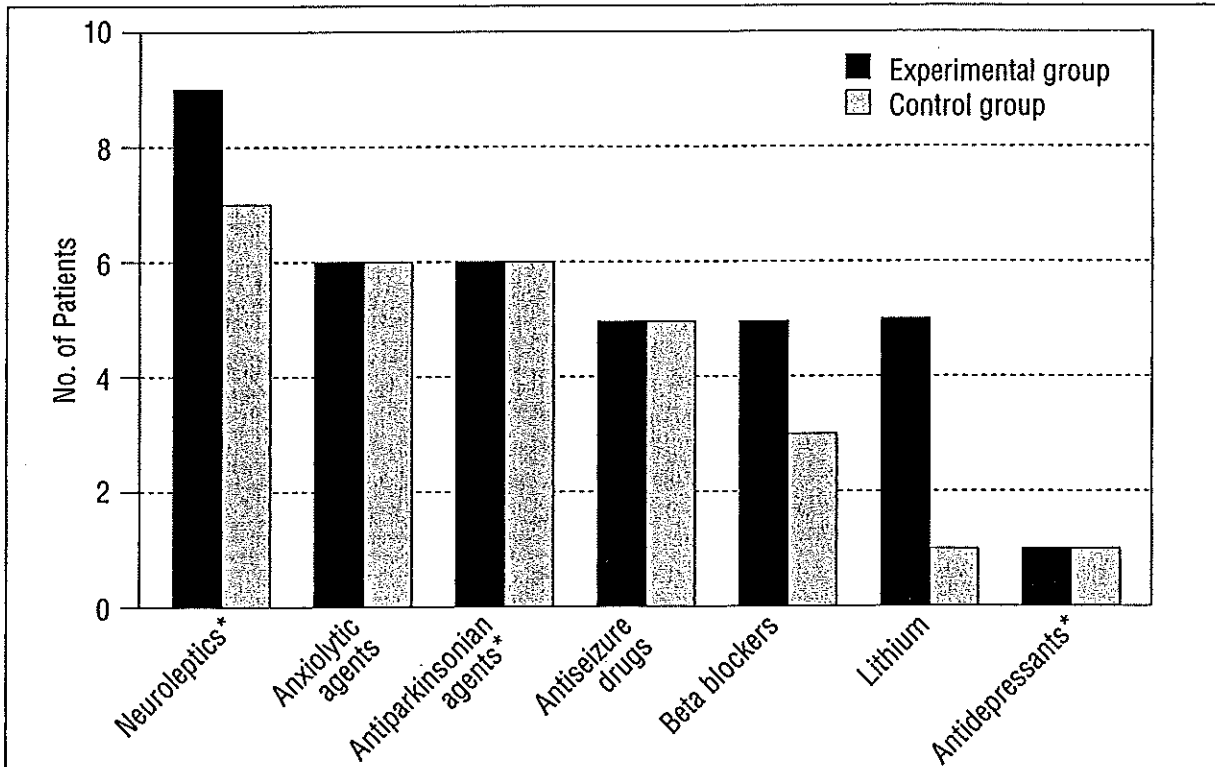


FIGURE 1. Psychotropic Medications Taken by Patients According to Treatment Group.

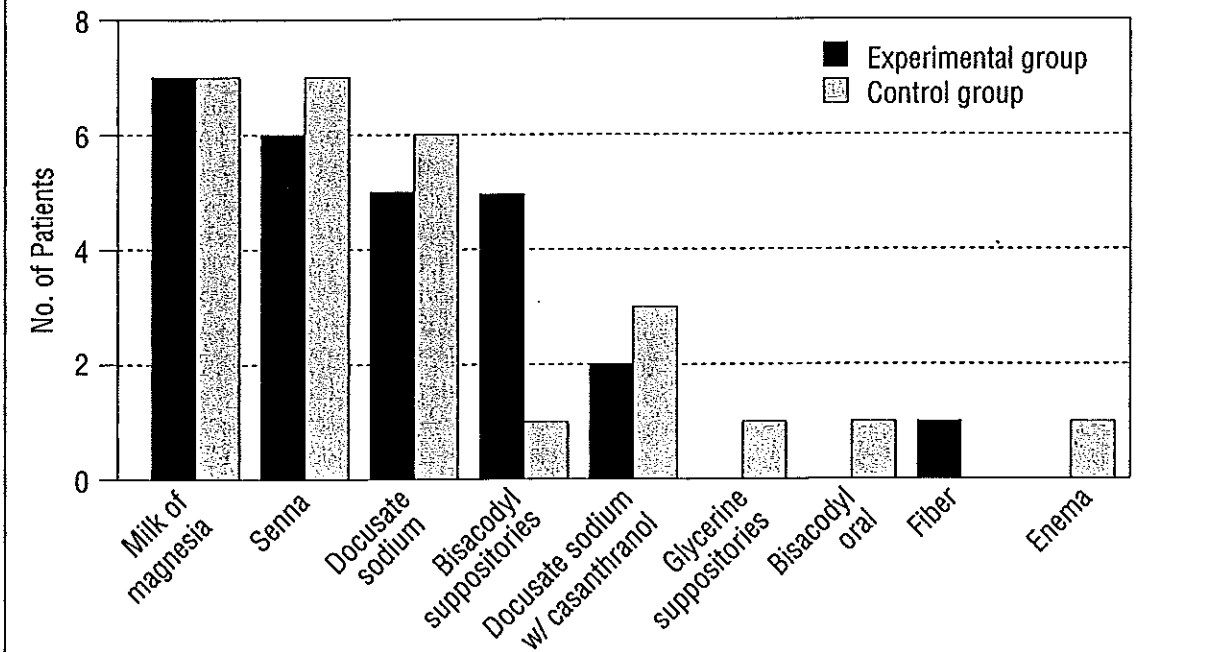


FIGURE 2. Number of Patients Taking Baseline-Phase Laxatives According to Treatment Group.

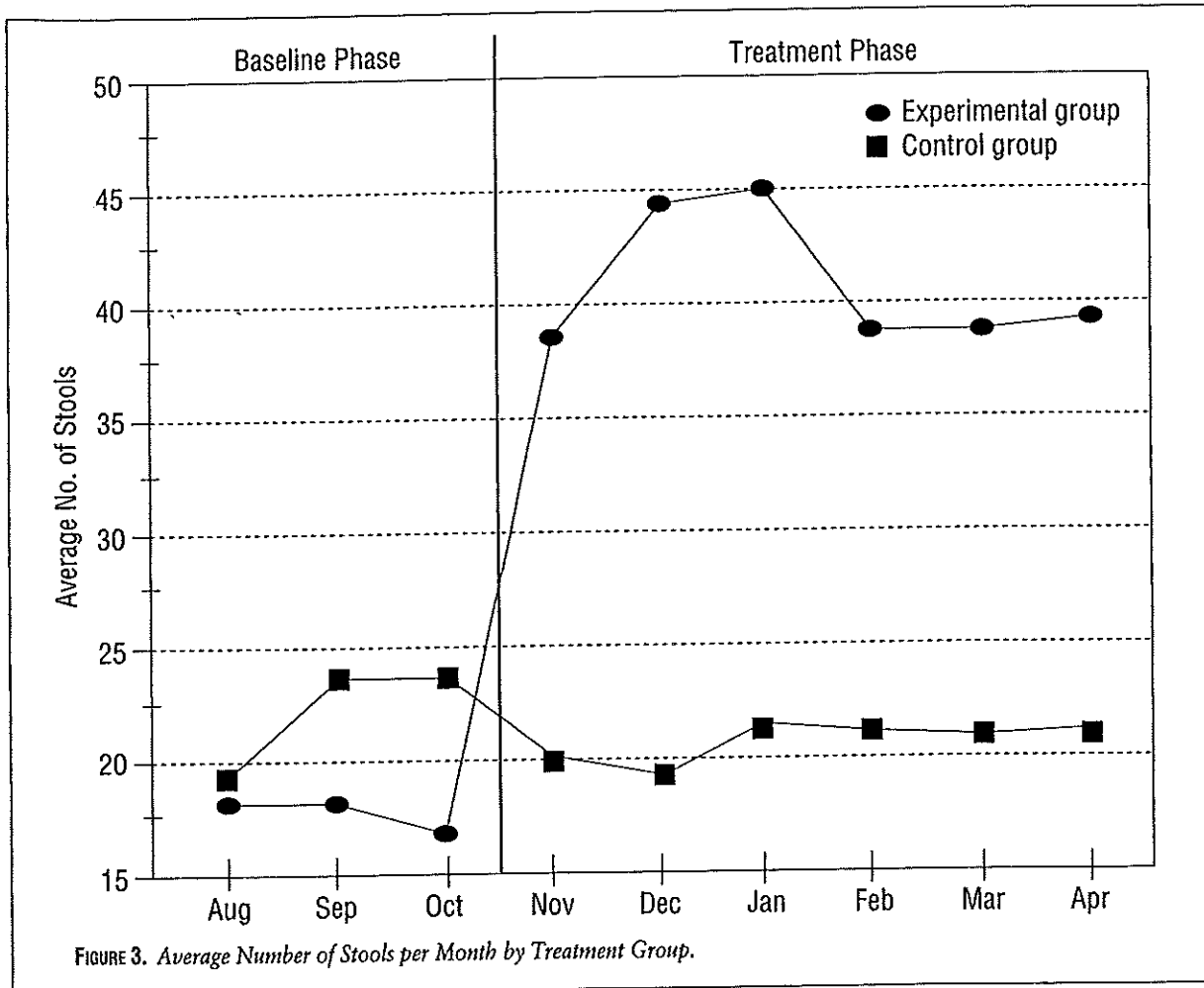


FIGURE 3. Average Number of Stools per Month by Treatment Group.

quency occurred in the experimental group every month while taking the fruit product (Table II).

Treatment phase plain abdominal radiographs in the two groups did not differ significantly. There was stool throughout the colon in 100% of the experimental group films and 89%¹⁶ of the control group films (Fisher's exact, $P = 0.1478$).

All the direct care staff completed the staff satisfaction questionnaire, and all reported their preference in caring for patients taking the fruit product rather than laxatives. Typical staff responses in the "Comment" section referred to more predictable and more "normal" stool patterns in the experimental group. The authors did not survey patient preferences as part of the study design. The actual cost of the fruit product during the last month of the

treatment phase was \$134.19; the actual cost of laxatives during this time was \$77.83.

COMMENT

Although some controversy still exists regarding the precise definition of constipation,^{2,7} there is general agreement about its high prevalence,^{1,8} its relationship to anticholinergic drug use,^{1,5,9,10} and its serious physiological consequences.^{6,11,12} However, few studies focus on the treatment of constipation¹³⁻¹⁵; and none involves patients concomitantly taking anticholinergic medication. This study shows that it is possible to achieve marked and sustained correction of chronic constipation, even in patients who continue taking multiple anticholinergic medications.

No significant difference was found in plain

TABLE II
STATISTICAL ANALYSIS OF EXPERIMENTAL AND CONTROL GROUPS
BEFORE AND AFTER TREATMENT

Group-by-time interaction repeated measures ANOVA (August, October, November, April) $f [3,48] = 38.17, P < 0.001$	
Group-by-time repeated measures ANOVA for baseline period (August, September, October)	
Group effect	$f [1,16] = 2.06, ns$
Time effect	$f [2,32] = 0.87, ns$
Group-by-time effect	$f [2,32] = 1.59, ns$
Between-group <i>t</i> -tests per baseline month	
August	$t [16] = -0.28, ns$
September	$t [16] = -1.88, ns$
October	$t [16] = -1.62, ns$
Group-by-time interaction repeated measures ANOVA for treatment period (November, December, January, February, March, April) $f [5,80] = 5.63, P < 0.001$	
Between group <i>t</i> -tests per treatment months	
November	$t [16] = 6.24, P < 0.001$
December	$t [16] = 16.42, P < 0.001$
January	$t [16] = 13.49, P < 0.001$
February	$t [16] = 10.22, P < 0.001$
March	$t [16] = 10.24, P < 0.001$
April	$t [16] = 13.86, P < 0.001$
Paired <i>t</i> -tests for control subjects, comparing the last baseline month (October) with each treatment month	
November	$t [8] = 1.45, ns$
December	$t [8] = 1.26, ns$
January	$t [8] = 0.61, ns$
February	$t [8] = 0.74, ns$
March	$t [8] = 0.84, ns$
April	$t [8] = 0.76, ns$

f = frequency; ns = not significant.

abdominal radiographic results between the experimental group and the control group despite the marked difference in stool frequency between these groups. Therefore, this diagnostic modality may not be as useful as previously reported when evalu-

ating the treatment of constipation,¹⁶ especially when a high-fiber product is prescribed.

The staff satisfaction survey clearly indicates strong preference for the fruit product. Although the acquisition cost of the fruit product was greater, the costs of morbidity^{6,11,12} of ineffectively treated constipation in the control group was not monitored. A longer study that tracks outcome costs would be needed to show whether there is a total cost reduction with the fruit product.

CONCLUSION

Some limitations in this study are important to note. Because usual care staff served as evaluators, evaluations were not blinded. Also, patients were not allocated randomly to each group. Because the authors conducted this study in a chronic care psychiatric hospital, the prevalence of dementia was lower than in most nursing homes and the prevalence of major psychiatric diagnoses was higher. However, despite these issues, this trial clearly demonstrates that a fruit product can successfully treat even the most refractory chronic constipation, namely, that in institutionalized elderly patients concomitantly taking anticholinergic medications.

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ROLE OF THE MEDICAL DIRECTOR

The medical director's role regarding the treatment of chronic constipation is twofold. First, he or she must ensure that the facility has a reasonable and effective policy and procedure designating how the frequency of resident bowel movements is recorded. Second, the medical director should periodically review the "house algorithm" for preventing and treating constipation, and revise and update it according to current practice standards.

— AMDA

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