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• *CLINICAL RESEARCH* •

Use of a device that applies external kneading-like force on the abdomen for treatment of constipation

Konstantinos Mimidis, David Galinsky, Efraim Rimon, Vassilios Papadopoulos, Yehuda Zicherman, Dimitrios Oreopoulos

Konstantinos Mimidis, Vassilios Papadopoulos, Democritus University of Thrace, Alexandroupolis, Greece
David Galinsky, Faculty of Health Sciences, Ben-Gurion University, Beer-Sheva, Israel
Efraim Rimon, Kaplan Medical Center, Rehovot, Israel
Yehuda Zicherman, ADM Ltd, Bnei-Brak, Israel
Dimitrios Oreopoulos, Toronto Western Hospital, Toronto, ON, Canada
Correspondence to: Dr. Konstantinos Mimidis, 8, Chrisostomou Smirnis str, GR-68 100 Alexandroupolis, Greece. kmimidis@otenet.gr
Telephone: +30-255-1074090 Fax: +30-255-1030324
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Abstract

AIM: To evaluate the efficacy of a recently developed device that applies kneading-like motion on the abdomen in improving constipation in elderly long-term care patients.

METHODS: Thirty constipated elderly patients were randomly selected from two nursing homes. They were instructed to use the device once daily for 20 min. Rate of bowel movements, volume and consistency of stool and the use of laxantia were all recorded during a 3-wk baseline period and for 12-wk treatment period. Colonic transit time (CTT) was measured in 13 patients by radiopaque markers during the baseline and at the end of treatment.

RESULTS: Bowel movement rate (BM/week) increased from 1.4±0.4 BM/wk during baseline to 3.9±0.8 BM/wk during treatment ($P<5.0\times10^{-7}$). Stool amount that was "low" in 30 patients during baseline increased in 21 patients at the end of the study period ($\chi^2 = 19.048$-$P = 1.3\times10^{-5}$). Stool consistency, that was "hard" in 25 patients and "soft" in 5 patients during baseline, ameliorated in 23 patients at the end of the study (only 2 patients referred "hard" stool) ($\chi^2 = 21.043$-$P = 4.0\times10^{-6}$). The mean baseline CTT measured was 92.3±32.3 h at baseline and decreased to 49.4±31.3 h during the study period ($P = 0.000208$). No side effects were observed during the study period.

CONCLUSION: External mechanical vibration of the abdomen reduced CTT and helped to relieve severe constipation in elderly constipated patients.

Key words: Constipation; Laxatives; Colon transit time

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INTRODUCTION

Constipation is a common problem affecting 2% of the general population and 25% of the elderly population. Constipation is defined as when at least two of the following four complaints have been present during the past 6 mo: straining on defecation, feeling of incomplete evacuation, hard stool - all the three in at least >25% of the evacuations, and less than three bowel movements a week[1]. In most instances, no clear cause is identified and patients are considered to have idiopathic or functional constipation[2]. Medical treatment consists of high fiber diet, high fluid intake, adherence to regular bowel routine and use of enemas or laxatives[2].

A major methodological drawback of research in this field is the fact that it is based on self-reported defecation frequency and on the use of laxatives as an indicator of constipation[1]. The best way to assess "objectively" the colorectal function is by studying colonic transit time (CTT) with the use of ingested radio-opaque markers. Overall CTT correlates with the pattern of defecation[3] and is comparable to the transit time measured with scintigraphic studies[4,5].

Recently, we developed a vibrating device to improve the clearance and ultrafiltration in patients on chronic peritoneal dialysis[6]. Early in our experiments, it became obvious that this device has a beneficial effect on the constipation that plagues most of these patients.

In response to these findings and the known beneficial effect of physical activity on bowel habits[7], the hypothesis was put forward that external vibration might have a positive effect on constipation, similar to physical activity. Since the elderly suffer from constipation frequently, we decided to conduct a trial on them to evaluate the effect on CTT of low-frequency external vibrations on the abdomen and the possibility that the device may help in relieving constipation.

MATERIALS AND METHODS

Materials

Thirty constipated elderly patients (mean age 78.1 years, range 65-89 years) were selected from the register of patients suffering from constipation in two nursing homes in Greece and Israel with 110 and 40 residents, respectively.

Before a potential participant was included in the study he/she had to attend two meetings at which his/her eligibility was confirmed. At the first meeting, three weeks before the beginning of the treatment, suitability was determined on the basis of the inclusion and exclusion criteria and a physical examination by a study physician. Patients were included in the study if they had a colonoscopy or barium enema examination during the last five years. Constipation was defined as less than three bowel movements per week. Patients were excluded if they had an abdominal malignancy, abdominal wall hernia, vertebral fracture or severe low back pain or an active ischemic heart disease. At this stage each patient signed an informed consent as approved by the local ethics committee. Patients who met all the criteria began a baseline phase in which they filled in bowel diaries for 3 wk. The diaries included report on bowel movements, bowel consistency (hard or soft), bowel amount (regular or small) and use of laxatives.

The baseline diaries were brought to the second meeting, one week before the initiation of the treatment phase. Patients who still met the study's criteria on the basis of the diaries, began the treatment phase.

Treatment was done once daily for 20 min. Study duration was 12 wk. Patients continued filling in the bowel diaries during the treatment phase. Diet was kept stable during the study.

CTT was measured in 13 patients during baseline and on the 11th wk of treatment. CTT was performed by giving the patient pills, each containing 24 radio-opaque markers (Sitzmark, Konsil Pharmaceuticals, Inc., TX, USA), according to manufacturer's instructions for segmental test - one pill is taken every morning during three successive days and abdominal X-ray is performed at d 4 and 7. Transit time was calculated as the sum of markers observed at d 4 and 7 of the procedure.

Methods

We used an electro-mechanical device (Free-Lax, ADM Israel, Figure 1). The device had two disks that pushed the abdomen in two opposite sides in an inward-outward oscillating motion at frequencies 1.25, 1.5 or 1.75 Hz. (The first setting was 1.25 Hz and the patients were instructed to change frequency according to his/her preferences.) The device sat on the patient's lap while attached to the abdomen by a belt that surrounded the back.

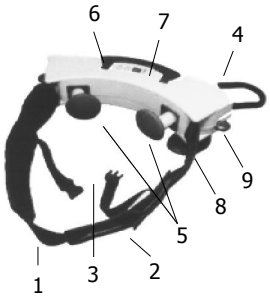

Figure 1 The examined device for relieving constipation. 1. Belt that surrounds the back; 2. Comfort pads; 3. Buckle; 4. Power-supply's cord; 5. Moving disks; 6. Handle; 7. Control panel; 8. Leg base; 9. Height adjusting button.

An internal recorder was used to measure the actual time the device was in use. Patients were not informed of its existence.

Statistical analysis

Data were based on the diaries, CTT count and recorder.

Weekly bowel movement rate concerning both baseline (three records) and treatment phase (12 records) was summed for every patient.

The normal distribution of weekly bowel movement rate in baseline phase and treatment phase for the entire group was checked by using both the Kolmogorov-Smirnov and Lilliefors tests. The nonparametric Wilcoxon's test for paired samples was applied to compare between phases. The nonparametric Spearman's correlation coefficient was used for correlation analysis.

Comparison of the recorded stool amount and consistency was done between the three weeks at baseline and wk 10-12 of treatment. The sign test was applied on these results.

CTT results of every patient were counted for baseline and treatment phases. The normal distribution of CTT was checked by using both the Kolmogorov-Smirnov and Lilliefors tests. Paired Student's *t*-test was used to compare the phases. Correlation analysis was based on the parametric Pearson's correlation coefficient.

RESULTS

Recorded results showed that the average duration of the daily treatment along the 12 wk was 18 min, which is 90% of the time recommended.

Group's average weekly bowel movement rate (BM/wk) increased from 1.4 (±0.4 SD) BM/wk during baseline to 3.9 (±0.8 SD) BM/wk during treatment. The normal distribution of weekly bowel movement rate in baseline phase and treatment phase for the entire group failed to be confirmed by both the Kolmogorov-Smirnov and Lilliefors tests (K-S $d = 0.322$, $P<0.01$; Lilliefors $P<0.01$ for baseline phase and K-S $d = 0.179$, $P>0.2$; Lilliefors $P<0.05$ for treatment phase) and thus nonparametric tests were applied. Wilcoxon's test for paired samples ($n = 30$) yielded to $T_1 = 0$, $T_2 = 465$, $P<5\times10^{-7}$. Spearman's correlation coefficient yielded to $r_S = 0.651$, $P<0.001$. Detailed data are presented in Table 1.

The average level of 3.9 BM/wk was reached after the second week of the treatment phase and was kept stable till the end of the 12th wk, as shown in Figure 2.

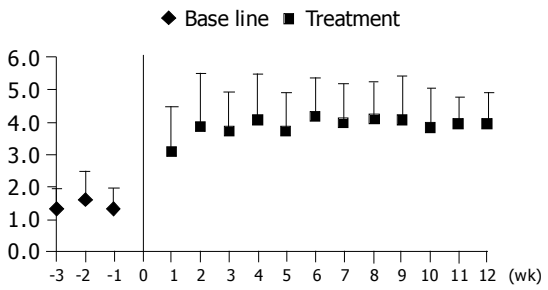

Figure 2 Average bowel movements/week in baseline and treatment.

Table 1 Bowel movements per week for every patient and for the whole group. Application of the Wilcoxon's test for paired samples

Pt.#	Baseline BM/week		Treatment BM/week		
	Average	SD	Average	SD	Increase %
1	1.3	0.58	2.9	0.29	119
2	1.3	0.58	6.6	1.00	394
3	1.3	0.58	3.3	0.65	150
4	2.7	0.58	6.9	1.31	159
5	1.0	0.00	2.9	0.79	192
6	1.0	0.00	3.9	1.00	292
7	2.0	1.00	3.8	0.83	92
8	1.3	0.58	3.7	0.65	175
9	1.0	0.00	3.4	0.79	242
10	1.0	0.00	4.1	0.90	308
11	1.3	0.58	4.0	1.13	200
12	1.7	0.58	3.3	0.87	95
13	1.0	0.00	3.4	0.79	242
14	1.3	0.58	4.3	1.07	225
15	1.0	0.00	4.3	1.29	325
16	2.0	1.00	4.0	0.95	100
17	2.0	1.00	3.8	1.47	92
18	2.7	0.58	4.3	1.36	59
19	1.0	0.00	4.6	0.67	358
20	1.0	0.00	4.2	0.39	317
21	1.3	0.58	3.6	0.67	169
22	1.0	0.00	3.8	0.62	275
23	1.3	0.58	3.5	0.67	163
24	1.0	0.71	4.8	1.90	383
25	1.3	1.41	4.7	1.66	250
26	1.0	0.00	2.9	0.29	192
27	1.0	0.00	2.9	0.29	192
28	1.0	0.00	2.9	0.29	192
29	1.0	0.00	3.0	0.00	200
30	1.0	0.00	2.9	0.29	192
Average	1.4	0.40	3.9	0.80	211
			$P<5\times10^{-7}$		

Table 2 Stool amount and consistency in baseline and treatment. Application of sign test

Pt.#	Stool consistency		Stool amount	
	Baseline	Treatment	Baseline	Treatment
1	Hard	Soft	Low	Low
2	Hard	Soft	Low	Regular
3	Hard	Soft	Low	Low
4	Hard	Soft	Low	Low
5	Hard	Hard	Low	Low
6	Hard	Soft	Low	Regular
7	Hard	Soft	Low	Low
8	Hard	Soft	Low	Low
9	Hard	Soft	Low	Regular
10	Hard	Soft	Low	Regular
11	Hard	Soft	Low	Regular
12	Hard	Soft	Low	Low
13	Hard	Soft	Low	Low
14	Hard	Soft	Low	60% Regular
15	Hard	Soft	Low	Regular
16	Hard	Soft	Low	Regular
17	Hard	Soft	Low	Low
18	Hard	Soft	Low	Regular
19	Hard	Soft	Low	66% Regular
20	Hard	Soft	Low	Regular
21	Hard	Soft	Low	33% Regular
22	Hard	Soft	Low	Regular
23	Hard	Soft	Low	36% Regular
24	Hard	Soft	Low	Regular
25	Hard	Hard	Low	Regular
26	Soft	Soft	Low	33% Regular
27	Soft	Soft	Low	55% Regular
28	Soft	Soft	Low	Regular
29	Soft	Soft	Low	Regular
30	Soft	Soft	Low	55% Regular
Better	23		21	
Same	7		9	
Worse	0		0	
P	1.3×10^{-5}		4.0×10^{-6}	

Stool amount that was "low" in 30 patients during baseline increased in 21 patients at the end of the study period. Sign test yields to $\chi^2 = 19.048$, $P = 1.3\times10^{-5}$. Stool consistency that was "hard" in 25 patients and "soft" in 5 patients during baseline ameliorated in 23 patients at the end of the study (only 2 patients referred "hard" stool). Sign test yielded to $\chi^2 = 21.043$, $P = 4.0\times10^{-6}$. Average and data are presented in Table 2.

The mean baseline CTT was 92.3±32.3 h at baseline and decreased to 49.4±31.3 h during the study period. The hypothesis of normal distribution of CTT was not rejected by both the Kolmogorov-Smirnov and Lilliefors tests. Thus, parametric tests were preferred. Paired Student's *t*-test yielded to $t = 5.239$, $P = 0.000208$. Pearson's correlation coefficient was computed to be 0.5697 ($P = 0.042$) (Table 3).

All the study participants were asked to continue on the treatment after study completion. No adverse side effects were observed during the study. Three patients were dropped from the study due to reasons that are irrelevant to device efficiency (one for personal reasons and two for very poor compliance at the beginning of the study).

DISCUSSION

Frail elderly and immobile patients often suffer from constipation that can complicate into fecal impaction[8-10]. The impact of immobility on constipation in these patients is also well documented[11-13]. Moreover, neurological and mental conditions, such as depression, Parkinson's disease, stroke and dementia, which are highly prevalent in elderly patients, are also associated with constipation[14,15].

In this study, we have shown that external oscillatory motion applied on the abdomen significantly improves bowel movement rate and alleviated constipation in elderly patients. Indeed, after 12 wk of treatment, we found an increase of 211% (Table 1) in bowel movement rate and a significant reduction of 47% (Table 3) in total CTT.

The beneficial effect of treatment has not only proved to be statistically significant to an extent beyond any doubt ($P<5\times10^{-7}$ for BM/week, $P = 2.08\times10^{-4}$ for CTT, $P = 1.3\times10^{-5}$ for stool amount, $P = 4.0\times10^{-6}$ for stool consistency) but also to be firmly applied to all patients, as can be deduced by the statistically significant correlation coefficient between baseline and treatment phase values, as

Table 3 CTT results for day 4, 7 and their sum. Application of Student's *t*-test for paired samples and Pearson's correlation coefficient

	Markers count d 4 and 7			Markers count d 7			Markers count d 4		
	B-L	Treatment	%	B-L	Treatment	%	B-L	Treatment	%
Average CTT	92.31	49.38	47	40.23	15.46	62	52.08	33.92	35
SD	32.35	31.30		17.71	19.0		16.14	17.47	
K-S d[1]	0.168	0.139		0.123	0.212		0.114	0.177	
K-S P[2]	>0.2	>0.2		>0.2	>0.2		>0.2	>0.2	
Lilliefors P	>0.2	>0.2		>0.2	>0.1		>0.2	>0.2	
Student's									
t-value		5.239		5.228				3.317	
Student's P		0.000208		0.000212				0.00614	
Pearson's r		0.570		0.569				0.313	
Pearson's P		0.042		0.042				0.298	

[1]Kolmogorov-Smirnov distance. [2]Kolmogorov-Smirnov P-value.

far as BM/week and CTT are concerned. Correlation studies are very crucial, as reject all claims that the beneficial effect of treatment reaches a statistically significant result due to (very large) differences in a minority of patients.

As already mentioned, the data taken during the study was based on two sources, patient reports and CTT measurements. Patient's report focused on the actual outcomes - relieving constipation in all relevant parameters (number of bowel movements, consistency and amount, Table 1 and 2). However, one may suggest that patient's report may be subjected to mistakes, especially with the elderly. In order to overcome this, the staff of the nursing homes were instructed to fill in the diaries after asking the patient or after taking him to the toilet. To overcome some of the subjectivity of these indices, we measured CTT with the use of ingested radio-opaque markers in order to provide an objective measure of the effect of the device on constipation. Overall CTT correlates with the pattern of defecation[3] and is comparable to the transit time measured with scintigraphic studies[4,5].

Furthermore, measurement of CTT overcomes, to some degree, the need for a double-blind study. We have observed that when a patient is getting a "placebo" non-functioning device (or any other variation of it) he stops using it within a month. Therefore, we did not succeed to complete a "placebo" study in a way that can be compared to the "real" one. Therefore, we use the objective CTT outcomes to support the validity of the patient's diaries. In this respect, the recorder's data reflects also the fact that patients felt a benefit from the device; otherwise, they would not use it.

Another approach that we took in order to overcome the lack of "placebo" was by planning the length of the study to a period that is long enough to eliminate a "placebo" effect. As shown in Figure 2, we did not observe any decrease in device efficiency during the treatment phase - an effect that could be expected if device's effect was not evident.

All patients that completed the study were asked to continue with treatment. After getting approval from the Ethics Board, they were allowed to continue. Diaries filled by 22 of these patients showed that the effect of the treatment on constipation remained the same during the first 6 mo of treatment. Interviews with patients show that the effect further continues, even for more than a year. These outcomes support our conclusion that a "placebo" effect is not playing a role in study results.

The mechanisms by which external motion applied on the abdomen relieves constipation have not been proven yet. A possible explanation might be that the motion transmitted to the colon resembles the natural peristaltic contraction. Another mechanism of the device's effect may be attributed to the enhancement of the low intra-abdominal pressure due to abdominal wall muscle weakness in elderly persons.

A great variety of therapeutic options is offered today for constipated patient; however, most of them only modestly improve bowel movement[16]. Moreover, every medication used to treat constipation has side effects, some of them life threatening, and even locally acting enemas can cause significant morbidity and mortality[16,17]. As our vibrating device has no known side effects and no potential drug interaction, we thought it very suitable for elderly patients who usually suffer from polypharmacy. For this population, any additional drug, even for treating constipation, can add to the risk of drug interaction.

From the financial point of view, the device is already marketed in Israel and Europe and costs about $ 400. This is a one-time expense, in contrast to oral or rectal medications annual cost of which can reach between $ 70 and $ 500. As constipation is a chronic disease, the expense of long-term use of this device will be less than most other therapies commonly used today.

In conclusion, this study shows that external mechanical vibration of the abdomen, by means of a new vibrating device, helps to relieve severe constipation in elderly constipated patients. We also showed that patients are compliant to this treatment. Further studies to determine the minimum time required in achieving this beneficial effect, and the mechanisms that lead to it are in progress.

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