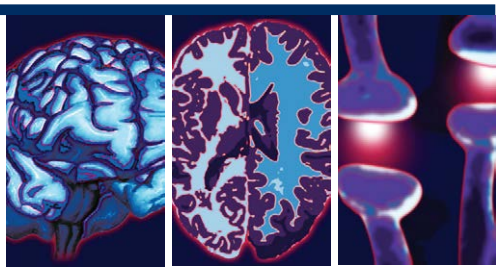

Effects of Dielectric Monopolar Radiofrequency with Vacuumtherapy in the Treatment of Chronic Constipation in Patients with Intellectual Developmental Disorders

Alfonso Javier Ibáñez-Vera[1,†], Andrea Ginestra-Puyalto[2], María Ángeles Isarria-Vivancos[2], David Cruz-Diaz[1], Alexander Achalandabaso[1], Rafael Lomas-Vega[1]

ABSTRACT

Aim

Chronic constipation is a high prevalence complication in patients with intellectual developmental disorders due to medication intake and physical activity reduction. Several manual therapy techniques have achieved good results at its treatment, being these a considerable option as no adverse effects have been shown. Nevertheless, the use of electrotherapy devices has not been studied on chronic constipation treatment. These may be considered as a potential tool which may supplement treatment. Thermotherapy by dielectric monopolar radiofrequency (DMR) linked to vacuum therapy could activate local blood irrigation at the colon level and peristaltic movements due to mechanic push-pull. The aim of this study is therefore to prove the efficacy of DMR linked to vacuum therapy for the treatment of chronic constipation in intellectual developmental disorders patients.

Methods

Nineteen patients which met the inclusion criteria were chosen. Number of stools and shape of them (Bristol Stool Questionnaire) were measured in a period of 14 days, when patients received their common care techniques for chronic constipation. After that, patients received 14 days of DMR linked to vacuum therapy treatment. The same variables were measured in the meantime so as to observe possible differences.

Results

DMR linked to vacuum therapy proved an improvement in number of stools per day and the shape/quality of them. No adverse results were observed.

Conclusion

DMR linked to vacuum treatment seems effective for the treatment of chronic constipation in intellectual developmental disorders patients.

Keywords

Chronic constipation, Radiofrequency, Vacuum, Massage, Intellectual developmental disorders, Intellectual disability

[1]Department of Health Sciences, University of Jaén, Spain

[2]Centro ATADES Huesca, Spain

[†]Author for correspondence: Alfonso Javier Ibáñez-Vera, Department of Health Sciences,University of Jaén, Spain, email: ajibanez@ujaen.es

Introduction

Chronic constipation is one of the complications with the highest prevalence rate in patients with intellectual developmental disorders. According to several studies, this rate may be of 31.3% in the case of patients with schizophrenia [1] and of 26.6% in adults with any intellectual disabilty [2].

It may be caused by several disturbances, for instance structural dysfunctions, biochemical abnormalities or endocrine disorders, alterations of the nervous function, muscle weakness and intestinal atresia [3]. Nevertheless, the intake of some drugs belonging to the family of antiparkinsonians, antipsychotics, antiepileptics, antidepressives, antihypertensives, antienemics and opioids [4] when linked to a reduction in movility makes these patients more susceptible to suffering from chronic constipation [5].

Diagnosis is usually based on anamnesis as well as on the finding of alarming signs and symptoms. Rectal examinations, colonoscopies and less invasive tools are also used in most cases. Rome IV questionnaire may be mentioned here as an example of these tools. It evaluates stool frequency, presence of pain or discomfort and consistency of evacuation among others [6].

Chronic constipation patients usually receive advice on nutrition. For instance, they are recommended to increase their water and fiber intake, which may be supplemented with pharmacologic treatment. Laxative drugs are frequently prescribed; however, these are specifically recommended to normalize constipation periods of several days because its common use may generate tolerance towards treatment and a consequent decrease in effectiveness. That is why it is essential to use them as the last option [7].

An interesting non invasive alternative to laxatives may be the abdominal massage. This technique consists on a manual mobilization of tissues in the abdominal cavity to favor their motility. There is some evidence on the utility of manual techniques to treat chronic constipation [8] using masotherapy [9], massage on the connective tissue [10,11] or Maitland therapy [12]. Nevertheless, difficulties in quantifying and parameterizing manual therapy which has been developed to improve chronic constipation makes it necessary to perform more studies to reduce heterogeneity among different ways of application of manual techniques.

Additionally, there are several mechanical mobilization devices through soft-tissue pump (aspiration cycle plus compression cycle or 'push-pull'). They are called 'vacuum therapy' and their action may be compared with the manual task carried out when performing abdominal massage. At the same time, they allow an increase in local vasodilatation and can activate tissue metabolism through emission of Dielectric Monopolar Radiofrequency (DMR) [13-16]. Combination of the vacuum therapy mechanic agent may stimulate peristaltism and increase the frequency of colon movements, while radiofrequency would stimulate blood circulation and reduce discomfort linked to chronic constipation [17]. This tool may be effective as chronic constipation treatment in multiple patients.

To determine efficacy of treatment using Dielectric Monopolar Radiofrequency linked to vacuum therapy for chronic constipation in patients with intellectual developmental disorders.

Materials and Methods

■ Participants

A cross trial with 19 participants (six men and thirteen women) was performed. Their average age was 45,6 ± 12,96 **(Table 1)**. The recruitment process was performed in accordance with the Declaration of Helnsinki and the corresponding Ethics Comitte's approvals. The participants recruited were over eighteen years old, interned in the center ATADES Huesca (Spain) and diagnosed with chronic constipation according to Rome IV criteria [7]. Those patients who did not fulfill any of these criteria, where unable to understand the information about the treatment or the informed consent and those whose guardians did not agree on their participation in this study were excluded.

■ Materials

A DMR system, model DCD System Vacuum® was used for treatment. This system has been created by Biotronic®, a company in Granada (Spain). Manufacturers recommend using dielectric substances only. That is why sweet almond oil was used to facilitate the gliding of the system head on the intervened patients' skin. At the same time, patients were placed in supine decubitus position on a wooden table which was suitable for treatment using electrotherapy systems and which was placed outside the physiotherapy room. Air conditioning was set at 21°C.

Table 1: Sociodemographic characteristics of participants.

		Age			Weight			Height			Body Mass Index			Time constipated		
	n	M		SD	M		SD	M		SD	M		SD	M		SD
f	13	46	±	12.88	74.8	±	14.6	1.64	±	0.08	27.81	±	2.65	4.6	±	1.5
m	6	44.5	±	11.42	79.2	±	11.2	1.73	±	0.11	26.46	±	3.02	3.5	±	1.2
T	19	45.6	±	12.96	76.3	±	14.7	1.69	±	0.14	27.13	±	3.22	4.2	±	1.6

M (mean), SD (standard deviation) f (female), m (male), T (total), n (sample), Weight (kilograms), Height (centimeters), Time constipated (weeks)

■ Procedure

Prior to the start of this study, potential participants and patients' guardians were invited to participate in an informative meeting. They were explained what kind of study was going to be performed with the aim of agreeing on patients' participation. They were warned on possible side effects of the technique to be used (local transitory erythema and local heat sensation). Participants and guardians were asked to sign an informed consent form concerning participation in this study. Ethical principles in conformity with Helsinki declaration were respected in any case.

Three patients' related variables were considered: number of stools in each phase of the study (period of 14 days), number of irritability episodes in these 14 days (considering irritability episode as number of times the participant verbally complaints about constipation) and Bristol stool scale [18]. These variables were measured and written down on a daily basis by nursing assistants in charge. Register forms previously designed for this aim were filled.

Treatment with vacuum therapy at 1 Hertz push-pull rhythm **(Figure 1)** and 840 kHz DMR emission in dielectric transmission with wave modulation and pulse signal at 50% was applied in 24 minutes on patients' abdomen during treatment phase. Patients were placed on the table in supine decubitus position. A cushion was used to facilitate slight hip flexion. The area to be treated was skin covering colon path. A 2kg/cm^2 compression was performed, using an applicator on the skin area corresponding to the inferior part of the ascending colon. This procedure was continuously repeated until reaching the end of the application time. Pulse emission guaranteed treatment was innocuous before the apparition of a possible exceed in tissue heat. Dielectric transmission avoided surpassing 40°C of temperature on skin [13]. In order to reduce possible risk of bias because of increasing physical activity of the patients during the treatment, the treatment was developed at the physioterapy room instead of another facility.

■ Study chronogram: intervention was performed in two phases

First phase: measurement of participants' number of stools, quantity of irritability episodes and Bristol stool scale in a 14-days period. In this period, patients were subject to common treatment protocol received during the current year –that is, following a fiber-rich diet and the absence of any pharmacologic treatment against chronic constipation until at least the fourth day with no stools.

Second phase: intervention using the vacuum therapy system with a simultaneous DMR emission on patients' abdomen following colon path. Treatment was applied in a 14-days period divided into 24-minutes sessions. Patients were placed in supine decubitus position with their knees and hips slightly flexed and followed the same nutrition and pharmacologic patterns described in the previous phase.

■ Statistical analysis

A dependent sample T-test was performed with a 5% confidence interval, using StatPlus software for Mac (version 6.1.7.0.) The aim was to compare marks concerning number of stools before and after treatment, number of irritability periods and Bristol scale from participants in this study.

Results

The results show a stadistical significant increasement in the number of stools after the treatment when compared with the previous to treatment period (p<0.05). In the same line, the number of irritability episodes also improves showing a significant reduction(p=0.03). However, is the Bristol stool scale the point which greater improvement (p>0.01) **(Table 2)**. No adverse effect was detected along or after the treatment.

Discussion

Chronic constipation is an important complication in the quality of life of patients with

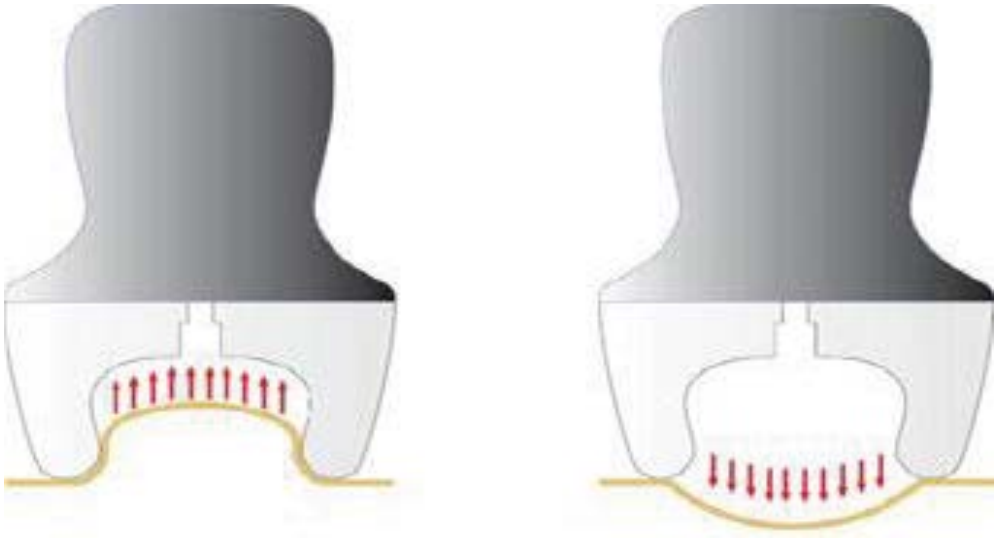

Figure 1: Treatment with vacuum therapy at 1 Hertz push-pull rhythm.

Table 2: Study variables before and after diathermy plus vacuum therapy treatment.

	BEFORE Treatment			AFTER Treatment			
	M		SD	M		SD	*p*
Number of stools	8.85	±	2.34	10.23	±	2.32	<0.05
Bristol scale	1.89	±	0.65	2.47	±	0.61	<0.01
Number of irritability episodes	15.95	±	7.05	14.	±	4.26	<0,02
M (mean), SD (standar deviation), *p* (statistical significance)							

intellectual developmental disorders. As a result, it is not uncommon to find diverse studies on the effectiveness of different therapies. In the field of manual therapy, several masotherapy protocols on the abdominal region and activation of metameric levels that control lower digestive system have been studied with the aim of increasing intestinal transit mobility [8,9]. Some studies show even better results than those in which the most frequently prescribed medicaments for this complication when the etiology is abdominal surgery [9] have been employed.

With regards to the information provided by this study, we can confirm that DMR treatment seems to improve not only the number of patients' stools but also the quality of stools as well as the discomfort produced by constipation. Related studies agree on the fact that there is an improvement in the number of stools [9,11,12,19] and the quality of them according to Bristol scale [9].

According to data found in this study, DMR treatment linked to vacuum therapy may have quicker positive effects if compared with Maitland therapy [12], abdominal massage [20] and conjunctive tissue manipulation between C7 levels and sacrum [10]. The evidence of these treatments has already been contrasted [20]. On the one hand, Koo et al. Show significant improvement using Matiland therapy to stimulate levels from T9 to L2 in 20 minutes on a daily basis if compared with treatment using fiber-rich diets [12]. McClurg et al. performed clockwise abdominal massage (ascending colon, transverse colon and finally descending colon) in a 6-weeks period. Results obtained were better than those observed when applying common care techniques for constipation[19]. Concerning connective tissue manipulation, Gursen et al. prove that linking this treatment to common care techniques for constipation may be more effective after four weeks. Teatment session times in these studies were similar to those used in the present study (24 minutes). It can therefore be concluded that long treatment sessions are not required to observe favourable changes. However, it should be remarked that studies by Koo et al., McClurg et al. and Grusen et al. required eight, six and four weeks of treatment respectively, whereas only two weeks were required using our DMR plus vacuum therapy protocol. This fact may justify that DMR treatment linked to vacuum therapy action is quicker.

According to Kassolik et al., abdominal massage based on tissue tensegrity shows better results than those observed when using classical abdominal massage [21]. This improvement may be justified by the activation of lymphatic vessels and blood irrigation within the area when tensioning local tissues. This fact may be compared with the use of vacuum therapy, as classical abdominal massage would be similar to DMR applicator displacement through colon path, whereas synergy using push-pull vacuum therapy performs a pumping action which may stimulate lymphatic action as well as blood irrigation within the area through tensioning. This fact may justify an increase in effectiveness. However, more studies concerning this topic would be further required, as the one performed by Kassolik et al. compared classical abdominal massage in 10 minutes time with a massage based on tensegrity in 20 minutes. It can be stated here that a longer intervention time may have increased therapeutic response.

Regarding other physical devices for treating constipation, Vaucher et al. demostrated in porcine models how electrical stimulation could increase safely the activity of colon[15]. On the other hand, Bokkon et al. proved the efficacy of the electromagnetic signals at chronic constipation and diarrhea in children[22], treatment similar to the effects atributed to radiofrequency deviced used on this study. When comparing the mechanical action of the vacuum, Mimidis et al. demonstrated the improvements that a kneadling-like motion device obtain in chronic constipation on elderly patients by using it 20 minutes per day [23]. The 24 minutes used on our study follows the line of this study and also link toghether the effects of electromagnetic signals and mechanical action. This point make us think that the combination of both aproaches could be more effective than them alone. Future studies will compare the radiofrequency plus vacuum versus other treatments.

Although patients with intellectual developmental disorders are specially prone to constipation, few studies have been published on the effectiveness of physiotherapy against chronic constipation in these patients. Orhan et al. Show that not only the use of kinesiotape on the abdominal and lumbrosacral region but also the performance of conjunctive tissue manipulation from C7 levels to sacrum may seem effective to improve chronic constipation in children with cerebral paralysis [11]. Efficacy of this kind of techniques is essential in the case of patients with intellectual developmental disorders, as these treatments have not shown any side effect and as a result, they can be used with therapeutic security in the long term.

Chronic constipation produces discomfort, which at the same time may cause irritability episodes in patients with intellectual developmental disorders. A reduction in the number of irritability was assessed by the therapist of this study. Nevertheless, no more studies specifically assessing this aspect have been found and as a result, no comparisons of this point could be established.

In the recent years studies Martins and Wellman et al.[24-26] highlighted the role of some heat shock genes such as Sirtuin 1 in the appearance of chronic diseases, being its inactivation a risk factor. Although heat could alterate the expression of this gene, the heat reached in this study by the application of DMR is not enough to cause inactivation [13]. However, blood test should be done in future studies to prevent from bacterial lipopolysaccharides (LPS), another factor that repress heat shock gene [24] and which has not been controled in this study.

Results in this study should be carefully considered due to its limitations. As there was no control group and because samples were limited, obtained results may not be generalized. Therefore, it will be necessary to perform a randomized clinical trial so as to give higher quality evidence on this treatment. Although risk of bias has been limitated by maintaining physical activity, diet, liquid ingestion and medication, a placebo group will be recommended in future studies to assure the effects of the treatment.

Conclusion

Treatment using vacuum therapy and DMR emission may seem effective to treat chronic constipation in patients with intellectual developmental disorders. Nevertheless, further studies with higher methodological quality are required to prove its utility.

Conflict of Interest

Authors declares no Conflict of Interest

Author Contributions

Author Alfonso Ibáñez, Rafael Lomas and Alexander Achalandabaso did the conception

and design the methodology of the study. Author Alfonso Ibáñez-Vera participated in the information session to participants. Author Andrea Ginestra took part in the treatment of the participants, and Maria Isarria registered all the measures. Rafael Lomas did the statistical analysis and Alexander Achandalabaso prepared the figures and tables. Author David Cruz-Díaz wrote the documents and Rafael Lomas modified them to the final version, which was translated by author Alfonso Ibáñez-Vera and revised once again by all the authors.

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