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Effectiveness of perineal pelvis rehabilitation combined with biofeedback and radiofrequency diathermy (RDF) in anorectal functional pain syndromes associated with paradoxical contraction of the levator ani muscles. A prospective study

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HIGLIGHTS

- Anorectal functional pain syndrome is a very often disabling disease with a consequent significant negative impact on the patient's quality of life. Chronic proctalgia, in many patients, is secondary to the paradoxical contraction of the pelvic floor and associated with a dissynergy between the thorax-abdomen and the pelvic floor.
- The use of radiofrequency diathermy with a system of static electrodes associated with biofeedback represents a valid rehabilitation option for those patients suffering from anorectal functional pain syndrome because it reduces pain and paradoxical contraction of the levator ani and improves quality of life of the patient.

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ABSTRACT – Background – Anorectal functional pain syndrome, also called chronic proctalgia, represents a neglected clinical entity and often confused with other syndromes such as vulvodynia or acute proctalgia. It is a very often disabling disease with a consequent significant negative impact on the patient's quality of life. Chronic proctalgia, in many patients, is secondary to the paradoxical contraction of the pelvic floor and associated with a dissynergy between the thorax-abdomen and the pelvic floor. To improve symptoms in functional anorectal pain syndromes, various rehabilitation techniques are used with the aim of promoting relaxation of the pelvic floor; however, to improve defecatory dynamics in patients with levator ani syndrome, only biofeedback has shown efficacy in a randomized study. The aim of this work is to evaluate whether a rehabilitation protocol with manometric biofeedback and radiofrequency diathermy (mt100 Fremslife emotion Tecar) reduces pain and paradoxical contraction of the levator ani and improves the quality of life in patients with anorectal pain syndromes. functional. **Methods –** This was a prospective study on 30 patients (20 women and 10 men) with anorectal functional pain syndrome and paradoxical contraction of the pelvic floor enrolled at the UOC of General, Minimally Invasive, Oncological and Obesity Surgery of the AOU "Luigi Vanvitelli" of Naples, Italy, from September 2021 to May 2022. All patients were evaluated with a coloproctological specialist visit followed by anorectal manometry and evaluation of altered clinical physiatric parameters (Brusciano Score). The protocol consisted of 10 rehabilitation sessions of the pelvic floor once a week and

lasting approximately 45 minutes. During the sessions the patients were subjected to diathermy / radiofrequency treatment (10 minutes) with a static resistive electrode on the diaphragm, during which they were required to breathe diaphragmatically and to become aware of the perineal muscles, under the supervision of a physiotherapist; followed by application of diathermy with static capacitive (5 minutes) and resistive (10 minutes) electrode at the lumbar level. This was followed by the use of manometric biofeedback (15 minutes of tonic / phasic exercises) in order to instruct the patient on the reflex mechanism to obtain a voluntary relaxation of the external anal sphincter. The variables evaluated were Pain (VAS 0-10) and the questionnaire on the impact of colorectal and anal pathologies on the quality of life (CRAIQ-7) at the beginning, after 3 months and at the end of the treatment. **Results** – After 10 weeks, the rehabilitation treatment combined with diathermy and manometric biofeedback proved effective in the short term with a reduction in the scores of the Vas scale and CRAIQ-7 questionnaire and an increase in the percentage of release of the anal muscles on anorectal manometry. **Conclusion –** The use of radiofrequency diathermy with a system of static electrodes associated with biofeedback represents a valid rehabilitation option for those patients suffering from anorectal functional pain syndrome because it reduces pain and paradoxical contraction of the levator ani and improves quality of life of the patient.

Keywords – Pelvic pain; anorectal functional pain syndrome; chronic proctalgia biofeedback; diathermy; radiofrequency; pelvic floor rehabilitation.

INTRODUCTION

Chronic or recurrent anorectal pain is a symptom that can affect up to 6% of the population. Although only a third of people seek medical attention, those affected report a significant deterioration in their quality of life, absenteeism from work and psychological stress[1-2].

The Rome IV criteria identify three types of functional anorectal pain: Levator anorectal syndrome (LAS), unspecified functional anorectal pain (UFAP) and proctalgia fugax. LAS and UFAP are described as having chronic or recurrent rectal pain or tenderness lasting at least 30 minutes without evidence of an organic or systemic explanation for these symptoms. In addition, LAS is characterized by the presence of tenderness on palpation of the levator ani muscle during digital rectal examination (DRE). The pain can be accentuated by certain activities such as sitting for long periods, sexual intercourse and defecation; improves when standing or lying down[3,4].

Chronic proctalgia is often secondary to hypertonia of the pelvic floor and associated with a dissynergy between the thorax-abdomen and the pelvic floor[5,6]. Both medical and rehabilitation treatments are all aimed at promoting relaxation of the perineal muscles. Medical therapy often includes the prescription of low-dose tricyclic antidepressant drugs, gabapentin and cyclobenzaprine, but their effectiveness has never been confirmed in randomized studies and side effects, such as dry mouth and constipation, reduce their use[3,4,7]. Rehabilitation therapies aim at the treatment of levator ani hypertonia such as biofeedback and manual massage. From the evidence in the scientific literature, it emerges that anal biofeedback is the treatment of choice for patients with LAS and dissynergic defecation[7].

The purpose of this work is to evaluate whether a rehabilitation protocol with manometric biofeedback and radiofrequency diathermy (mt100 Fremslife Emotion Tecar) reduces pain and paradoxical contraction of the levator ani in patients with functional anorectal pain syndromes, improving their quality of life.

METHODS

Patients and methods

All the consecutive patients with anorectal functional pain syndrome and paradoxical contraction of the pelvic floor observed at the General, Mini-Invasive, Oncological and Obesity Surgery Unit (Master in Coloproctology and Pelvic Floor Rehabilitation) of University of Campania "Luigi Vanvitelli", Naples, Italy, from September 2021 to May 2022, were included in the study. The local ethics committee appro-

ved the study protocol. The study was conducted in accordance with the Declaration of Helsinki.

All patients were briefed on goals, procedures and follow-up; participants signed a written informed consent.

All patients underwent a coloproctological specialist visit and evaluation of altered clinical physiatric parameters (Brusciano Score)[8,9]. The exclusion criteria were oncological pathologies in progress, radiotherapy, chemo-therapy, pregnancy, Pacemaker carriers, neuromuscular diseases, hypersensitivity / skin lesion near the region to be treated with diathermy, severe mental disorders. Each patient was subjected to an objective examination to exclude any organic pathologies such as hemorrhoids, fistulas, anal fissures or prolapses. Rectal exploration in lateral decubitus, Sims position, allowed to evaluate the presence of pain in the levator ani traction maneuver, anal tone at rest and muscular synergies: inviting the patient to contract the sphincter anal, the possible activation of the adductor, gluteal and hamstring muscles (agonist muscles) or abdominal muscles (antagonist muscles) has occurred[8-10]. During the objective evaluation the respiratory dynamics of the patients were observed, all presenting either thoracic or mixed respiration. High-resolution anorectal manometry (HRAM) was performed both before and at the end of treatment. The variables evaluated were Pain (VAS 0-10) and the questionnaire on the impact of colorectal and anal pathologies on the quality of life[10-12] (CRAIQ-7 represents a subscale of PFIQ-7) at the beginning, after 3 months and at the end of the treatment.

"The visual analog scale (VAS) is a validated, subjective measure for measurement of acute and chronic pain. Scores are recorded by making a handwritten mark on a 10-cm line that represents a continuum between "no pain" and "worst pain".

Design of the study

The protocol consisted of 10 rehabilitation sessions of the pelvic floor once a week and lasting one hour. The first session served to inform the patient, obtain signed informed consent, resolve any doubts about the study or questionnaires, and raise awareness of the patient's pelvic floor by showing them images of the different structures involved, to help -re the patient to build proper muscle recruitment.

Radiofrequency diathermy (RFD) is a non-invasive therapy that consists of the emission of high--frequency electromagnetic waves, which produce endogenous heat that increases the metabolism of biological tissue[13]. This process promotes tissue repair and affects pain sensitivity[14,15]. The device used for diathermy / radiofrequency was "MT100 fremslife EMOTION TECAR", which has two polarized components (static electrode and dynamic electrode) and a neutral component (plate). Characteristic of the device is that it allows to work also with static electrodes (capacitive and resistive, applied to the patient), allowing the operator to have his hands free and to combine the analgesic and tissue bio stimulation effect[16-19] with active and passive manual therapy. The working frequency chosen for all treatments was 450 Khz.

During the sessions, the patients underwent treatment with RFD (10 minutes) with a static resistive electrode on the diaphragm muscle, during which diaphragmatic breathing and awareness of the perineal muscles were required, under the supervision of a physiotherapist; followed by application of RFD with static capacitive (5 minutes) and resistive (10 minutes) electrode at lumbar level. The treatment was performed in isothermal. This was followed by the use of manometric biofeedback (15 minutes of tonic / phasic exercises) in order to instruct the patient on the mechanism for obtaining voluntary relaxation of the external anal sphincter.

Follow up

After 10 weeks of treatment, patients were clinically re-evaluated with Brusciano Score, Scala VAS and CRAIQ-7 and instrumentally evaluated with HRAM.

Statistical analysis

Statistical analysis was performed via Excel 2011® (Microsoft, Redmont, WA). Categorical data were reported as raw numbers with percentages in parenthesis. Continuous data were reported as medians with range in parenthesis. The differences between results were analyzed by the Fisher's exact test for categorical data and by the Wilcoxon matched pairs test formpaired contiuoasor by the paired *t*-test, when indicated.

A probability value of less than 0.05 was considered significant.

RESULTS

Thirty patients met the inclusion criteria [20 (66.6%) females and 10 (33.3%) males, median age 54 years (range 38–74)]. Of these, 7 (23.3%) patients had arterial hypertension and 5 (16.6%) patients had type II diabetes without the presence of diabetic neuropathy. 7 (23.3%) female patients reported natural birth and none of these had perineal obstetric damage. Patients' demographics data are summarized in TABLE 1.

In the TABLE 2 shows the clinical and instrumental parameters evaluated in the study population before and after treatment.

At baseline, median VAS value was 8 (6–9) whereas, as regards the CRAIQ-7 domains, (ability to carry out household chores, ability to carry out physical activities, ability to carry out entertainment activities, ability to travel by car or bus for at least 30 minutes, participation in social activities outside the home context, emotional health, frustration), the median values were, respectively, 2 (2–3), 2 (2–3), 3 (1–3), 3 (1–3), 3 (1–3), 2 (1–3) and 2 (1–3).

Before treatment, physical examination showed erroneous synergies involving buttocks and adductors in 21/30 patients (70%) and antagonist synergies of abdominal muscles in only 2/21 patients (10%). All the 30 patients exhibited chest breathing or mixed (P<0.0001; fisher's exact test).

After treatment, a statistically significant improvement of VAS and CRAIQ-7 domains were found. At manometric follow-up, the median percentage of anal sphincter relaxation during bearing down was significantly higher than the corresponding value prior to treatment (P<0.0001; Wilcoxon matched pairs test) whereas the median maximum voluntary contraction and median duration of contraction were not significantly higher. Moreover, at physical examination, erroneous synergies involving buttocks and adductors were found in 3/30 patients (10%) (P<0.0001: fisher's exact test), whereas dia-

TABLE 1. Patients demographics features.

	Patients group (n=30) functional anorectal pain and paradoxical levator ani contraction
Age	54* (50–58)
Gender	20 females (66.6%)
Natural childbirth without perineal lesions	7/20 (35%)
Comorbidities	7 (hypertension) (23.3%)
Comorbities	5 (type II diabetes) (16.6 %)

*Values are expressed as raw numbers with percentages in parenthesis or median.

TABLE 2. Clinical and instrumental parameters before and after treatment.

Element	BIFORE RFD+BFB	AFTER RFD+BFB	*P*
Median vas value	8 (6–9)	6 (2–8)	<0.0001*
CRAIQ-7			
Ability to carry out household chores	2 (2–3)	1 (1–3)	<0.0001*
Ability to perform physical activities	2 (2–3)	1.5 (1–3)	<0.0001*
Ability to perform entertainment activities	3 (1–3)	1 (1–3)	<0.0001*
Possibility to travel by car or bus for at least 30 minutes	3 (1–3)	1 (1–3)	<0.0001*
Participation in social activities outside the home context	3 (1–3)	2 (1–3)	<0.0001*
Emotional health	2 (1–3)	1 (1–2)	<0.0001*
Frustration	2 (1–3)	1 (1–2)	<0.0001*
Brusciano score			
Buttock / adductor synergies	21/30*	30/3*	<0.0001**
Abdominal synergies	2/30*	0/30*	0.49**
Diaphragmatic breathing	0/30	27/30*	<0.0001**
HRAM			
Median percentage of anal sphincter relaxation during bearing down	55 (35–75)	80 (55–90)	<0.0001*
Median maximum voluntary contraction	110 mmHg	115 mmhG	0.78*
Median duration of contraction	14 sec (10–23)	15 (12–22)	0.84*

RFD: radiofrequency diathermy; BFB: mano-metric biofeedback; HRAM: high resolution anorectal manometry. vas scale (0–10); CRAIQ-7 (questionnaire on the impact of colorectal and anal pathologies on quality of life). *Wilcoxon matched paired test; **Fisher's exact test.

phragmatic breathing was visible in 27/30 patients (90%) and abdominal muscles were not stimulated in any of the patients.

After treatment, the percentages of patients with improvement of VAS value, CRAIQ-7 domains values, buttocks/adductors synergies, abdominal synergies and diaphragmatic breathing were, respectively, 80%, 90%, 70% 100% and 90% (TABLE 3).

TABLE 3. Percentages of patients with clinical improvement after treatment.

Element	Patients improved after RFD+BFB	Percentage
VAS SCALE	24/30	80%
CRAIQ-7	27/30	90%
Buttock / adductor synergies	21/30	70%
Abdominal synergies	30/30	100%
Diaphragmatic breathing	27/30	90%

RFD: radiofrequency diathermy; BFB: mano-metric biofeedback; HRAM: high resolution anorectal manometry. Vas Scale: (0–10); CRAIQ-7: questionnaire on the impact of colorectal and anal pathologies on quality of life.

DISCUSSION

Functional anorectal pain without evidence of an organic or systemic explanation often leads to a significant deterioration in quality of life, absenteeism from work and psychological stress[1,3,4]. It is often secondary to hypertonia of the pelvic floor and associated with a dissynergy between the thorax-abdomen and the pelvic floor[5,6].

The rehabilitation treatments are all aimed at promoting relaxation of the perineal muscles, but the primary goal of rehabilitation was to recreate harmony between all the pelvic floor structures rather than treating the symptoms reported by the patient. The first step was to induce awareness of the muscle areas of the pelvic floor; the role of these areas in determining rehabilitation utility has been extensively studied[8].

Among other rehabilitation treatment techniques, anal biofeedback is currently performed routinely and represents the treatment of choice for patients with LAS and dissynergic defecation[7]. In addition to its usefulness, the very low compliance of patients with electrostimulation has often been evaluated in the scientific literature. Patients, in fact, need to undress and experiment with the insertion of an anal plug; both details that strongly determine the embarrassment and discomfort of the patients leading to the avoidance of this treatment. Radio frequency diathermy (RFD) is a non-invasive therapy that consists of the emission of high-frequency electromagnetic waves, which produce endogenous heat that increases the metabolism of biological tissue[13]. This process promotes tissue repair and affects pain sensitivity[14,15], by helping to reduce anal muscle contracture without the need for anal plugs. In particular, the characteristic of the device used in the study is to allow to work also with static electrodes (capacitive and resistive, applied on the patient), allowing the operator to have his hands free and to combine the analgesic and tissue bio stimulation effect[16-19] with active and passive therapy manual.

The application of radiofrequency diathermy in pelvic floor disorders presents interesting prospects, but undoubtedly the evidence is still far from supporting its use as a primary therapy. Indeed, very few studies are of sufficient quality and are free of bias to support the use of RFD as more than a complementary therapy to major rehabilitation treatments[19].

The present study has some limitations. The first is the small sample size, which precluded any analysis of the effect of the covariates. We do not yet have long-term follow-up data after the application of the combined therapy, since the present study was prospective and focused on evaluating the efficacy and feasibility of the combined use of manometric biofeedback and radiofrequency. Furthermore, various radiofrequency application programs can be used by the physiotherapist since there is no standard treatment protocol in the scientific literature; therefore, randomized controlled trials are needed to evaluate the effectiveness of the use of radiofrequency versus conventional rehabilitation treatment of the pelvic floor[20].

Finally, in this study a combination of two treatments (biofeedback plus radiofrequency) was evaluated, arising the question of what could be the weight of each treatment in determining the outcome results. Anyway, in our experience, the treatment of pelvic pain with isolated biofeedback is associated with not enthusiastic results and, in the same way, no one study suggested the employment of isolated radiofrequency diathermy in the treatment of pelvic pain associated with dyssynergy. Therefore, we tried to combine both

procedures to improve the effects on the outcome and, in the current study, reported the results.

CONCLUSION

The use of radiofrequency diathermy with a static electrode system associated with biofeedback represents a valid rehabilitation option for those patients suffering from anorectal functional pain syndrome because it reduces pain and paradoxical contraction of the levator ani, improving the quality of life of those affected. Further long-term and comparative studies are needed to investigate the efficacy of treatment in a large population with pelvic floor disorders.

Authors' contribution

All authors contributed significantly to the present research and reviewed the entire manuscript. Brusciano L, Brillantino A, Flagiello L, Pennacchio M: participated substantially in conception, design and execution of the study and in the analysis and interpretation of the data; also participated substantially in the drafting and editing of the manuscript. Gambardella C, Lucido FS: participated substantially in the statistical analysis. Pizza A and Del Genio G: prepared the tables. Tolone S, and Docimo L: participated substantially in the analysis and interpretation of the data All Authors have reviewed and approve the final manuscript**.**

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Brusciano L, Brillantino A, Flagiello L, Pennacchio M, Gambardella C, Lucido FS, Pizza A, Tolone S, Del Genio G, Docimo L. Eficácia da reabilitação perineal combinada com biofeedback e diatermia por radiofrequência (RDF) em síndromes de dor funcional anorretal associadas à contração paradoxal dos músculos elevadores do ânus. Um estudo prospectivo. Arq Gastroenterol. 2023;60(2):201-7.

RESUMO – Contexto – A síndrome de dor funcional anorretal, também conhecida como proctalgia crônica, representa uma entidade clínica negligenciada e frequentemente confundida com outras síndromes, como vulvodinia ou proctalgia aguda. Trata-se de uma doença frequentemente incapacitante, com um consequente impacto negativo significativo na qualidade de vida do paciente. A proctalgia crônica, em muitos pacientes, é secundária à contração paradoxal do assoalho pélvico e está associada a uma dissinergia entre o tórax-abdômen e o assoalho pélvico. Para melhorar os sintomas em síndromes de dor anorretal funcional, são utilizadas diversas técnicas de reabilitação com o objetivo de promover o relaxamento do assoalho pélvico. No entanto, para melhorar a dinâmica de evacuação em pacientes com síndrome do elevador do ânus, apenas o biofeedback demonstrou eficácia em um estudo randomizado. **Objetivo –** O objetivo deste trabalho é avaliar se um protocolo de reabilitação com biofeedback manométrico e diatermia por radiofrequência (mt100 Fremslife emotion Tecar) reduz a dor e a contração paradoxal do elevador do ânus e melhora a qualidade de vida em pacientes com síndromes de dor anorretal funcional. **Métodos –** Realizado estudo prospectivo com 30 pacientes (20 mulheres e 10 homens) com síndrome de dor anorretal funcional e contração paradoxal do assoalho pélvico inscritos na UOC de Cirurgia Geral, Minimamente Invasiva, Oncológica e de Obesidade da AOU "Luigi Vanvitelli" de Nápoles, Itália, de setembro de 2021 a maio de 2022. Todos os pacientes foram avaliados com uma consulta especializada em coloproctologia, seguida de manometria anorretal e avaliação dos parâmetros fisiátricos clínicos alterados (Escore de Brusciano). O protocolo consistiu em 10 sessões de reabilitação do assoalho pélvico, uma vez por semana, com duração aproximada de 45 minutos. Durante as sessões, os pacientes foram submetidos a tratamento de diatermia / radiofrequência (10 minutos) com um eletrodo resistivo estático no diafragma, durante o qual foram solicitados a respirar através do diafragma e a tomar consciência dos músculos perineais, sob a supervisão de um fisioterapeuta; seguido pela aplicação de diatermia com eletrodo capacitivo estático (5 minutos) e resistivo (10 minutos) no nível lombar. Isso foi seguido pelo uso de biofeedback manométrico (15 minutos de exercícios tônicos /fásicos) com o objetivo de instruir o paciente sobre o mecanismo reflexo para obter um relaxamento voluntário do esfíncter anal externo. As variáveis avaliadas foram Dor (EVA 0-10) e o questionário sobre o impacto das patologias colorretais e anais na qualidade de vida (CRAIQ-7) no início, após 3 meses e no final do tratamento. **Resultados –** Após 10 semanas, o tratamento de reabilitação combinado com diatermia e biofeedback manométrico mostrou-se eficaz a curto prazo, com uma redução nos escores da escala VAS e do questionário CRAIQ-7, e um aumento na porcentagem de relaxamento dos músculos anais na manometria anorretal. **Conclusão –** O uso de diatermia por radiofrequência com um sistema de eletrodos estáticos associado ao biofeedback representa uma opção de reabilitação válida para pacientes que sofrem com a síndrome de dor anorretal funcional, pois reduz a dor e a contração paradoxal do elevador do ânus, melhorando a qualidade de vida do paciente.

Palavras-chave – Dor pélvica; síndrome de dor anorretal funcional; proctalgia crônica; biofeedback; diatermia; radiofrequência; reabilitação do assoalho pélvico.

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