"Difficult-to treat" ulcers management: use of pulse dose radiofrequency

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AIM: *In this paper we wanted to evaluate the impact of pain reduction on the evolution of "difficult-to treat" ulcers, using Radiofrequency analgesia in pulse-dose modality.*
MATERIALS AND METHODS: *We have performed a randomized trial to evaluate the efficacy of the RF in PD mode to reduce the healing time of ulcers of difficult management as outpatient for spontaneous and provoked pain. We enrolled 23 patients, including 7 males (30%) and 16 females (70%), aged between 53 and 79 years (mean age = 67.2) sorted according to the first letter of the last name in ascending order and assigned alternately to one or another group.*
RESULTS: *In Group A healing was obtained in 33% of patients (4/12), with an average healing time of 6 months while in Group B healing has been obtained in 81% of patients (9/11) with an average time of 3 months (range 1-5 months) Student's T was performed to compare the average recovery time among the two groups; moreover we have analyzed the proportions of healed patients in the group A and B.*
DISCUSSION: *Healing time significantly decreased in group B (p = 0,013079). Even the cure rate has changed favorably, in a statistically significant way.*
CONCLUSIONS: *According to the literature related to the use of the RF pulse dose, there is a greater effectiveness of this technique in respect of the classical PRF, in terms of immediate and long-term reduction of pain and this impacts positively on the course of ulcer healing.*

KEY WORDS: Radiofrequency, Ulce.

Introduction

The RF is a technique used for decades in the management of chronic pain of different origin. The types of pain that are best suited to the use of radio frequency are: trigeminal neuralgia, neck pain, occipital neuralgia, post-surgical and oncological pain. The rationale of this technique is linked to the principle that the heat which causes in target tissues and, therefore, in the nervous structures, determines an irreversible damage that prevents the conduct of the painful impulse.

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In fact, when applied to tissues, this current determines the oscillation of molecules with electric charge (especially proteins) which collide against each other, generating heat. If the temperature produced reaches a specified value, it generates a thermal damage.
To develop the thermal damage by radiofrequency, it is necessary a circuit composed of a current generator and two terminals[3]. A terminal is connected with an electrode, whose end is positioned in close contact with the target tissue; the other end is connected to a large surface plate, positioned on the patient's skin, in proximity to the tissue to be treated. The current flows, in this way, from the electrode to the plate. In this way, in the tissues in direct contact with the electrode tip, it generates a temperature that, in some cases, can reach 90°C, sufficient to ensure an irreversible thermal damage; in the tissues in contact with the plate, instead , thanks to the difference in surface between the latter and the electrode, does not create any type of damage.

This method, now obsolete, has been in recent years gradually replaced by the so-called pulsed radiofrequency (PRF). In 1998, in fact, Sluijter[2] et al. introduced a technique consisting in radio frequency discharges in sequential duration of 20 ms with an amplitude of 45 volts, interspersed with periods of pause of 480 ms. The pause periods are meant to "cool" the affected tissues that, thus, never reach temperatures higher than 42°C; this allows a neuro-modulation[7] of nociceptive pulses with consequent reduction of pain, avoiding the irreversible damage of the treated nerve tissue[6]. The mechanism of action of the PRF has not yet been entirely clarified: it would appear linked to the capacity to induce, thanks to the electric field which generates, an intense and lasting repolarization of the nerve fibers, with a consequent temporary "stupor" effect on the nociceptive signal, which can take several months.
Recently it has been introduced a further variation of this technique, called Pulse Dose (PD) (Fig. 1).
The PD is a technical evolution of PRF. It provides for the emission of electrical pulses, with the lasting of 20 ms, delivered over time at a constant potential of 45 volts. The difference with the PRF is, therefore, substantial because in the PRF the constant is represented by time and not by the voltage.
In fact, when it is used the classical PRF, the equipment delivers 2x20 ms/sec electric shock, at a constant time and the electrical potential which is, at the beginning, of 45 volts, decreases over time in order to provide a temperature which does not exceeds 42°C [4].
The PD, instead, ensures that the temperature in the tissues is always kept at 42 ° C, maintaining constant the voltage and gradually modifying the emission of pulses which are delayed until the temperature reaches the set value (Fig. 2).
This represents a great advantage because it allows to standardize the method, measuring, therefore, the effects of treatment and standardizing the modes of operation, according to the emitted "dose" and no longer in relation to the time taken.

Fig. 1: Neurotherm™ 1100 Pulse-Dose Radiofrequency device.

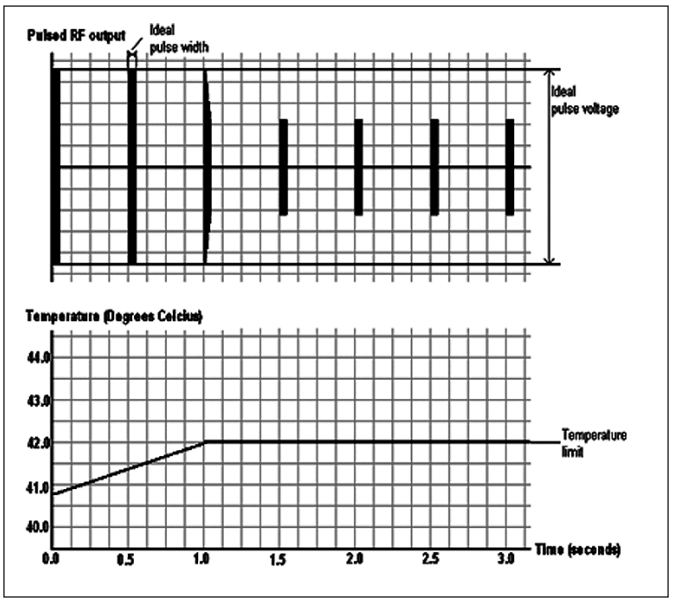

Fig. 2: Differences between PRF and RF-PD.

Materials and methods

This work stems from observations made, almost casually, during the enrollment of patients in a study already published (Apperti et al. Acta Vulnologica, September 2010, 8-3: 101-4)[8]. This was aimed to investigate the opportunities and benefits of adopting a "built in" therapeutic approach patients with "difficult" ulcers, first providing for the resolution of venous insufficiency and then a toilet of the ulcer in anticipation of the plant of artificial dermis[9].
During the development of this work, we became aware that a number of patients did not achieve healing because it was subjected to an incongruous treatment, so it were excluded from the protocol and sent to an appropriate conservative treatment.
However, we also observed a group of patients in which it was almost impossible to implement a fair treatment because the spontaneous and, above all, the elicited pain during the operation of medication was so intense to constitute a definite obstacle to a treatment that could give a healing chance.
These patients, for this reason, were enrolled in this study and sent to the protocol. Not to take into account the benefits of our "integrated" treatment plan, the only option given to these patients was cycles, for an indefinite period, of medications, bandages, pain relief, with the possibility of not getting benefit.
In this study we came across a device that uses RF in PD mode which is used for patients suffering from chronic neuropathic pain unresponsive to medical therapy[11].
We therefore performed a randomized trial to evaluate the efficacy of the RF in PD mode to reduce the

healing time of ulcers of difficult management as outpatient for spontaneous and provoked pain. We enrolled 23 patients, including 7 males (30%) and 16 females (70%), aged between 53 and 79 years (mean age = 67.2). Patients, sorted according to the first letter of the last name in ascending order, were assigned alternately to one or another group. All patients had ulcers of leg dated from 8 months to 5 years, with an extension from 4 cm in maximum diameter up to extensive "sleeve" ulcers. In group A were included 12 patients treated with advanced medications according to T.I.M.E. standards. . In group B were included 11 patients treated with advanced dressings according to to T.I.M.E. standards and subjected to neuro-analgesia using RF in PD mode.
The method PD was administered according to the criteria already considered above, using as the target popliteal sciatic nerve and the femoral nerve (Figures 3a and 3b); the evolution of pain intensity was measured during treatment using a verbal numerical scale of pain (VNS). The outcome variables were:
– Healing time in groups A and B;
– Percentage of healing to 8 months from the date of enrollment of the individual patient in the study.
The results were analyzed by Student's t-test for normalized data.

Results

Group A: healing was obtained in 33% of patients (4/12), with a average healing time of 6 months.
Group B: was obtained healing in 81% of patients (9/11) with an average healing time of 3 months (range 1-5 months). The only failure was a patient with a "sleeve" ulcer dated for five years, with little compliance and obliged to a self-medication.
Then, a Student's T was performed to compare the average recovery time among the two groups; moreover we have analyzed the proportions of healed patients in the group A and B with the Z test.

Discussion

We have verified that the healing time significantly decreased in group B (p = 0,013079). Even the cure rate has changed favorably, in a statistically significant way.
Through the use of VNS it was found that all group B patients have benefited from the use of RF in PD mode, with a decrease in both spontaneous pain than that provoked, with an excellent resolution of the latter during the treatment.
Only two patients had to repeat the procedure within a week, but the end result in terms of pain reduction was the same.

Conclusions

The RF in PD mode represents a technical evolution of the classical PRF and enables a standardization of the technique; in fact, the temperature of the target tissue is maintained equally to 42°C, but not at the expense of the voltage, as occurs in classical PRF, but gradually reducing pulses which are delayed until the temperature does not return again to the predetermined values.
Preliminary studies related to the use of the RF in PD mode indicate a greater effectiveness of this technique in respect of the classical PRF, both in terms of immediate reduction of pain that benefit maintenance. Pain intensity, compared to pre-treatment, is reduced by about 50%, net of stupor effect of the nerve.
This method is also effective in the outpatient management of patients with chronic ulcers in which conservative therapy was difficult to perform for the intense pain caused at the time of medication, permitting to obtain an excellent resolution of pain during the phase of treatment, with a statistically significant benefit in terms of time and percentage of recovery.

Riassunto

Obiettivi: In questo lavoro abbiamo voluto valutare l'impatto della riduzione del dolore sull'evoluzione delle ulcere "difficili da trattare", utilizzando una analgesia con radiofrequenza in modalità PD.
Materiali e metodi: Abbiamo condotto uno studio randomizzato per valutare l'efficacia della RF in modalità PD per ridurre i tempi di guarigione delle ulcere di difficile gestione ambulatoriale per il dolore spontaneo e provocato. Sono stati arruolati 23 pazienti, di cui 7 maschi (30%) e 16 femmine (70%), di età compresa fra i 53 ei 79 anni (età media = 67,2) ordinati in base alla prima lettera del cognome in ordine crescente e assegnati alternativamente all'uno o all'altro gruppo.
Risultati: Nel gruppo A la guarigione è stata ottenuta nel 33% dei pazienti (4/12), con un tempo medio di guarigione di 6 mesi, mentre nel gruppo B la guarigione è stata ottenuta nell' 81% dei pazienti (9/11) con un tempo medio di 3 mesi (range 1-5 mesi). E' stato eseguito un test T di Student per confrontare il tempo medio di guarigione tra i due gruppi ed abbiamo analizzato la proporzione dei pazienti guariti nel gruppo A e B.
Discussione: Il tempo di guarigione è significativamente diminuito nel gruppo B (p = 0,013079). Anche il tasso di guarigione è cambiato favorevolmente, in modo statisticamente significativo.
Conclusioni: In accordo con la letteratura relativa all'utilizzo della RF in PD, vi è una maggiore efficacia di tale tecnica rispetto alla PRF classica, in termini di riduzione immediata e a lungo termine del dolore che si riflette positivamente sul corso della guarigione dell'ulcera.

References

1. Cahana A, Zundert JV, et al.: *Pulsed Radiofrequency: Current clinical and biological literature available.* Pain Med, 2006; 7(5): 411-23.

2. Sluijter ME, Cosman ER, et al.: *The effects of pulsed radiofrequency field applied to the dorsal root ganglion: A preliminary report.* Pain Clin, 1998; 11(2):109-17.

3. Lord SM, Bogduk: *Radiofrequency procedures in chronic pain*. Best Pract Res, 2002; 16(4): 597-617.

4. Chua NHL, Vissers KC: *Pulsed radiofrequency treatment in interventional pain management: mechanism and potential indications: A review.* Acta neurochir, 2011; 153:763-71.

5. Byrd D, Mackey S: *Pulsed radiofrequency for chronic pain*. Curr Pain and Hed Rep, 2008; 12(1): 37-41.

6. Bogduck N: *Pulsed radiofrequency.* Pain Med, 2006; 7(5): 396-407.

7. Abejon D, Reig E.: *Is pulsed radiofrequency a neuromodulation technique?* Neuromod, 2003; 6(1):1-3. Acta Vuln, 2010, 8 (3): 101-4

8. Campitiello F, Della Corte A: *La terapia chirurgica ricostruttiva delle ulcere "complesse" degli arti inferiori mediante l'utilizzo di una matrice dermica "Integra" (Integra Derma Regeneration Template).* Acta Vuln, 2006; 4(3):107-12.

9. Biondi A, Crisafi RM. Di Giunta M, Scuderi G, Motta S, Ciuni R, Basile F: *New trends in the treatment of venous leg ulcer. Personal experience. (Recenti acquisizioni sul trattamento delle ulcere flebostatiche degli arti inferiori. Nostra esperienza).* Ann Ital Chir, 2009; 80 (5):375-78.