Cooled radiofrequency ablation technology for painful bone tumors

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Summary. Bone metastases are a common cause of cancer-related debilitating pain, especially when localized in the vertebral column and not responsive to standard treatment. In such cases, various treatment options are available; among these is Radiofrequency, whose role has been rapidly growing over the past few years. In this study, we used the innovative Osteocool RF Ablation System (Medtronic) on a patient with a painful bone metastasis localized in the 5th lumbar vertebra, with encouraging results. The radiofrequency ablation of bone metastases with palliative aim represents an excellent treatment option, as it is a minimally invasive and safe procedure, and can be repeated multiple times. (www.actabiomedica.it).

Keywords: radiofrequency, bone tumors, ablation, treatment

Introduction

After the lungs and liver, the skeletal system is the third most common localization of metastases, with around 70% of primary tumors originating from the prostate or breasts (1).

One of the more involved segments is the vertebral column, where around 70% of all bone metastases are localized (2); these can be either osteoblastic or osteolytic, single or multiple.

Although they are often asymptomatic, vertebral metastases are an important cause of morbidity and can decrease life quality; around 80% of patients experience serious pain before adequate treatment is planned (3, 4). Pain associated to bone metastases may be due to neural compression, pathological fractures or biological mechanisms which are not yet completely understood (cytokine production by the tumor, stimulation of nociceptors by peristeum stretching, nociceptor production by leukocytes) (5).

In case surgery cannot be performed, many types of palliative treatments are available: the most common therapies involve the use of analgesics such as bisphosphonates, but also external radiotherapy, cryotherapy and radiofrequency (3, 6). In particular, there has been a recent surge in the applications of
radiofrequency, whose indications include the treatment of benign primitive bone lesions (7) - most notably osteoid osteomas for which it represents the best treatment choice (8) - and the palliative treatment of bone metastases (7, 9); furthermore, it is also employed for coagulation and ablation during surgical procedures, and in all cases where conventional treatment is not indicated. As reported by Di Staso et Al. (10), radiofrequency and radiotherapy are not mutually exclusive, as RFA can be performed after RT to reduce eventual pain from bone metastases.

RFA systems are based on the flow of an alternating current through a probe positioned inside the lesion, resulting in tissue death by coagulative necrosis (11).

The aim of the study is to highlight advantages of bipolar radiofrequency systems internally cooled by water circuits in the treatment of bone metastases, with a particular focus on lesions localized in vertebral soma, as they often represent a treatment challenge.

**Device Description**

Bone radiofrequency devices have been studied for the treatment of benign bone tumors and for palliative care of bone metastases. Many different types are in commerce; at our Centre, we employ the osteocool RF Ablation System produced by Medtronic, which consists of a bipolar coaxial probe containing a water cooling system which is inserted into the lesion through a osteointroducer. The advantage of a bipolar probe consists in the presence of both the active electrode and the grounding electrode on the same probe, as opposed to traditional bipolar systems which necessitate of two different probes (12). Moreover, bipolar systems can decrease the ablation time and power, and are less susceptible to the heat sink effect (11).

The internal water cooling system avoids carbonization of surrounding tissues by better dissipating heat and by enlarging the ablation area.

Moreover, if the recorded temperature exceeds a predetermind value, the system automatically adjusts the RF power in order to avoid eventual damage to surrounding organs (13), such as the spinal cord or nerve roots.

The generator produces 40w of power (20w for each channel), allowing the tip of the probe to reach and maintain a temperature of 70°C for a given period of time, thus letting the energy pass to the surrounding tissue and resulting in coagulative necrosis (8, 14). Additionally, additional probes capable of measuring the temperature of surrounding tissues can be independently connected to the system, so as to monitor critical areas such as nerve roots.

Once the ablation procedure is completed, the resulting void can be filled through the osteointroducer with a balloon kyphoplasty or a vertebroplasty, in order to support the pathological vertebral body and avoid its collapse.

**Bone Lesions Treatment Indications**

There are two main indications for radiofrequency: treatment of benign bone tumors and treatment of bone metastases (15). In the first case there is a curative aim: Santiago et Al. (8) reported that RFA of osteoid osteomas has a high success rate, with few complications and a short recovery time, and can therefore be considered the first-choice treatment for most osteoid osteomas localized in the vertebral column and pelvis.

For what concerns bone metastases, treatment often has a palliative aim (7) and is limited by the size of the lesion. A study by Thanos et al. (16) described the possible contraindications of RFA, which include a distance of less than 1 cm between the lesion and the spinal cord, lesions involving the posterior wall of vertebral soma, and lesions causing cortical destruction with involvement of surrounding soft tissues; however, positioning a thermocouple near the dural sac or the peripheral nerve roots reduces the risk of damaging nervous structures (13).

Moreover, during the same procedure it is possible to perform also a kyphoplasty or vertebroplasty. It is worth mentioning that a vertebroplasty is contraindicated in all patient who have a proven allergy to concrete, and in those with an interruption of the posterior wall of the vertebral soma because of the high extravasation risk (17), although the latter is a relative contraindication as it depends on the operator’s experience (3).
Case Description

The procedure was performed on a 55-years-old male patient who had already been operated of a primitive lung tumor localized in the right superior lobe and had later developed a single bone metastasis in the 5th lumbar vertebral body, which caused severe pain and did not respond to common antalgic therapy nor to chemo-immunotherapeutic treatment. The lesion had a mixed ostesclerotic-osteoblastic appearance and was confined to the vertebral body, without destruction of the posterior wall or infiltration of nerve roots (Fig. 1). The case was discussed by a multi-disciplinary team who evaluated the feasibility of the procedure, in particular whether it was possible to reach the tumor with the osteointroducer and the radiofrequency probe without damaging the surrounding structures, and assessed the haematochemical status of the patient and his coagulation pattern.

In consideration of the lesion's characteristics and of the procedure's aim, we utilized the Osteocool RF Ablation System (Medtronic).

An adequate ultra short antibiotic prophylaxis was administered before the procedure by injecting 2g of Cephazoline i.v.

The procedure was thoroughly explained and informed consent was obtained, then the patient was positioned on the table of an angiography platform (Philips Azurion) also capable to acquire a CT cone beam for lesion alignment. Once the patient was sedated with the anesthesiologist’s support, the correct access point was located under angiographic guidance and a local anaesthetic (mepivacaine 2%) was injected to alleviate the discomfort caused by the osteointroducer and RF probe placement (Fig. 2).

With the help of a sterile hammer, a 13G osteointroducer was advanced in the cranio-caudal and lateromedial direction through the transverse process of the 5th lumbar vertebra. The CT cone beam showed the correct alignment of the lesion (18). After its placement, the osteointroducer remains in the same position for the whole procedure, as it is not only useful for the ablation procedure but it is also employed to obtain a preliminary biopptic sample to send to the laboratory for future histo-pathological comparison.

Fig. 1 Pre-procedural CT showing a predominantly osteolytic bone lesion in the soma of L5, with diameters of 27x19mm.
Fig. 2 Intraprocedural fluoroscopic image (latero-lateral projection) showing correct placement of the osteointroducer (2A) and radiofrequency probe (2B).
The ablation system consisted in a 40 W generator (20 w per channel) which can be connected to 2 radiofrequency probes and to 2 independent thermocouples for real-time temperature monitoring of the surrounding tissues.

The ablation was performed through a single bipolar probe with an active 7 mm tip with a diameter of 20G, resulting in an ablation area of 29x21 mm around the probe protruding 2.5 mm from the probe tip; a default ablation time of 6.30 minutes was necessary, as advised by the production company.

The radiofrequency energy is progressively transferred by the ablation system to the lesion until a temperature of 70° is reached and then maintained constant for the rest of the ablation time; the energy is regulated by the system according to the impedance encountered (2).

A 28G thermocouple was positioned into the epidural space near the posterior vertebral wall in order to measure the temperature outside the lesion to avoid damage to nervous structures; if the temperature exceeded 45°, the system would then stop the energy output.

After the procedure was over, the RF probe was removed and vertebroplasty was performed via the osteointroducer: 4 ml of concrete were injected under fluoroscopic guide. The CT cone beam demonstrated the success of the procedure and the absence of concrete spillage along the posterior vertebral wall (Fig. 3).

There was no periprocedural complication.

Already in the first hours after the procedure, the patient had a clear improvement of symptoms with a decrease in VAS (visual analogue scale) grading from 8 to 2.

Fig. 3 Post-procedural cone beam CT showing successful vertebroplasty results with concrete injection in the 5th lumbar vertebra.
Discussion

Many studies in literature describe the possible applications of radiofrequency systems for curative treatment of benign bone tumors and palliative treatment of bone metastases (7, 8). Goetz et al. (19) reported successful employment of RFA in alleviating pain in patients with osteolytic metastases who did not benefit from standard therapies. Our study analyzes the efficacy of a new ablation system, which has considerable advantages over other commercially available devices.

In particular, many systems consist of monopolar probes and need either the application of a grounding electrode on the patient’s skin or the use of a second separate probe in order to produce a dipole. On the contrary, the system we used consists of a single probe containing both the active and grounding electrodes, thus generating a dipole on a single probe; moreover, the internal water cooling system is able to avoid tissue carbonization and to increase the ablation area. Additionally, this RF generator allows the simultaneous connection of two RF probes in order to further enlarge the ablation area: in this case, with each probe introduced through a vertebral pedicle and their tips positioned 8-10 mm from each other, it is possible to create a large predefined ablation area.

Moreover, a great advantage is the possibility to perform RF procedures either alone or after failed RT procedures or simultaneously with RT. As described by Di Staso et Al. (10), RF associated with successive RT is safe and can significantly reduce cancer-related pain in patients with bone metastases, therefore decreasing the need for analgesics.

The reduction in pain has been documented by many authors with the help of VAS (visual analogue scale); in particular, a study by Nakatsuka et Al. (20) demonstrated a VAS reduction from 8.4 ± 2.4 to 1.1 ± 1.8 in a group of 13 patients with pain refractory to standard therapies. Goetz et Al. (19) reports good results of RFA on painful bone metastases, with a significant decrease in symptoms even in patients in which standard treatments failed.

In order to choose a RFA treatment, a multidisciplinary evaluation is mandatory, with a team of radiologists, oncologists and surgeons.

Possible complications include damage to underlying tissues, pulmonary embolism, thermal damage to nerve structure, damage to the spinal cord and nerve roots with risk of radiculopathy, paresis or paralysis; studies on animals demonstrated that damage to adjacent soft tissues depends primarily on bone cortex thickness, treatment length and distance between lesion and periosteum (7). However, Kam et Al. (3) reported that RFA utilization before vertebroplasty results in a thrombosis of paravertebral and vertebral plexi, thus reducing the embolization risk associated to the procedure itself.

Conclusions

Patients with bone metastases often have a poor quality of life and a considerable expenditure of both economic and human resources (medicines, assistance). The radiofrequency ablation system represents an excellent treatment choice in the palliative care of bone metastases as it is a minimally invasive and safe procedure (21), and can be repeated multiple times. Moreover, it does not exclude the possibility of a successive RT in case of treatment failure.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Written informed consent to the CT and the MR exams was obtained from all subjects in this study.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

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Received: 27 July 2020
Accepted: 23 September 2020
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