



Image-guided radiofrequency ablation (RFA) of spinal tumors

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Abstract

Purpose: To evaluate retrospectively the efficacy and safety of radiofrequency ablation (RFA) in patients with spinal tumors.

Materials and methods: Forty-one patients (25 men, 16 women; age range, 46–82 years) with nonresectable primary or secondary tumor involvement of the spine unresponsive to chemo- and radiotherapy received RFA treatment.

Two radiofrequency ablation systems, one with a cool-tip electrode and one with an expandable electrode catheter, were used. Both systems work impedance controlled with a power output of 150–200 W. Each coagulation cycle lasted 12–15 min depending on tumor impedance. Several single RFA cycles of 15 min each were used for overlapping RFAs in tumors with diameters of more than 3 cm. Temperature was kept between 50 °C and 120 °C and was chosen according to spinal cord distance and patient heat tolerance during the ablation. Multi-slice computed tomography (CT) combined with C-arm fluoroscopy guided the intervention.

Efficacy outcomes were assessed after about 6 weeks, 6 months, and more than 6 months using standardized questionnaires and indices regarding tumor pain, pain disability, functional activities, quality of life, neurological status, and tumor progression.

Results: RFA significantly reduced tumor-induced pain within 6 weeks, improved daily activities, and maintained quality of life. Mean time to tumor progression was 730 ± 54 days (Kaplan–Meier estimate). No RFA-associated complications were reported.

Conclusion: RFA of primary and secondary spinal tumors, which were unresponsive to chemo- and radiotherapy and prone to progression, is a safe, resource-saving, and highly effective percutaneous technique in patients with nonresectable spinal tumors.

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Keywords: Radiofrequency ablation; Tumor therapy; Spine; Computed tomography; CT guidance; Percutaneous technique

1. Introduction

Thermoablative procedures like radiofrequency ablation (RFA), laser-induced thermotherapy, and kryoablation are established methods for percutaneous ablation of soft tissue tumors in liver [1–8], lung [9–12], and kidney [13–16]. However, there is only anecdotal evidence for radiofrequency ablation of bone tumors or bone metastases [16–21]. The purpose of this study was to retrospectively evaluate the efficacy and safety of radiofrequency ablation of spinal tumors in a larger number of patients over a short-term (about 6 weeks), mid-term (about 6 months), and longer-term (more than 6 months) period.

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2. Materials and methods

2.1. Subjects

After they provided written informed consent, 41 ambulatory and hospitalized patients (25 men, 16 women; age range, 46–82 years; mean age, 62.7 years) with primary or secondary tumor involvement of the spine were treated in our institution between March 2000 and August 2002.

This retrospective analysis included patient with disease progression despite previous surgery, maximal chemotherapy, maximal radiation, and hormone therapy; lack of or highly-invasive surgical option; lack of other therapeutic options; metastases in bone or spine; severe local tumor pain insufficiently responsive to opiates and other analgesics; intravertebral tumor spread; risk of paraplegia or fracture because of tumor progression; and osteolytic and mixed metastases.

Patients were excluded in case of progressive metastases (involving more than three organs) with a reduced

life expectancy; poor general condition; intradural and intramedullary tumors; risk of bleeding (acetylsalicylic acid, anticoagulants); and osteoblastic metastases.

2.2. Diagnostic procedures

These included a neurological examination by a neurologist, hematology/clinical chemistry (blood count, platelets, C-reactive peptide, blood sedimentation rate, thromboplastin time, partial thromboplastin time), as well as magnetic resonance tomography (MRT) and computed tomography (CT) of the affected spinal area performed within four weeks prior to RFA.

2.3. Radiofrequency ablation technique

RFA was performed with two different devices, one provided by Radionics Inc. (Burlington, MA, USA) and the other by RITA Medical System Inc. (Mountain View, CA, USA) were used. All procedures were performed by the same investigator. The impedance-guided Radionics system (150-W generator) had cool-tip probes with a straight design, a 13-gauge diameter, and an active tip of 3 cm and the functions impedance guided and temperature controlled. Energy output started with 0.5 mA, which was increased by 0.25 mA every 2 min depending on patient tolerability. The optimal coagulation size was reached with 80–120 W at 1.25–1.50 mA for at least 10 min Total RFA time including slow increases in electric current was 15 min per probe. Several single RFA cycles of 15 min each were used for overlapping RFAs.

The impedance-guided and temperature-controlled RITA system used a 50-W radiofrequency generator which was connected to an expandable electrode catheter. This active catheter consisted of an insulated stainless steel shaft and an exposed tip with retractable arrays. The active arrays could be deployed laterally and retracted by a manual control mechanism on the handle of the catheter. The probes had an active tip of 3 cm in diameter. This allowed for a variable diameter of ablation. The power output of the generator (up to a maximum of 50 W) was adjusted, either manually or automatically, to keep temperatures between 50 °C and 120 °C. Temperature was chosen according to spinal cord distance and patient heat tolerance during the ablation.

Interventions were guided by multi-slice computed tomography interactively combined with C-arm fluoroscopy.

To update findings and plan procedures, contrast MRT (Somphonie-1.5 T, Siemens, Germany) was carried out before and after the intervention to control the postoperative outcome. Therapies were exclusively carried out under local anesthesia and mild sedation. Patients received a single intravenous injection of gentamycin (1 million U). Vital signs, heart rate, and pulse oxymetry were monitored. Depending on tumor location, patients were placed on the CT table in a comfortable prone or side position. Next, a neutral electrode pad was placed on each thigh. Preintervention CT determined the puncture coordinates (depth and angle).

For intravertebral interventions, a transpedicular approach to prevent destabilization of the vertebral body was preferred.

For probe placement in intravertebral tumors involving bone, an 11-gauge bone biopsy trocar was used to guide the catheter into tumor tissue in order to prevent infection of healthy paravertebral tissue with tumor cells.

In patients with tumor sizes of more than 3 cm in diameter, multi-step ablation (2–3 times) was performed with coagulation diameters of 3 cm in all directions. In this way, lesions of up to 9 cm in diameter were produced. Whenever repositioning of the needle was necessary, needle position was secured by additional CT control to prevent the involvement of sensitive nearby structures, such as the spinal cord and the pleura.

Following RFA, the arrays were retracted (with ongoing coagulation to prevent bleeding and metastases in the puncture canal), the catheter withdrawn, and patients were monitored for 2–4 h. Thereafter, patients left the institution to return home or into further inpatient care.

2.4. Efficacy parameters

Outcomes were assessed after about 6 weeks (2–97 days), 6 months (99–231 days), and more than 6 months (278–617 days) using a variety of standardized questionnaires and indices regarding tumor pain, pain disability, functional activities, quality of life as well as reporting neurological status and tumor progression. These tests included a visual analogue scale (VAS) for tumor pain (0–100 mm scale with 0 mm indicating no pain and 100 mm the maximum imaginable pain); Pain Disability Index (PDI) to assess daily activities (family/home responsibilities, recreation, social activity, occupation, sexual behavior, self-care, and life-support activity; 0–10-point scale with 0 indicating no interference and 10 indicating total interference with the respective activity) [22]; quality of life using the Karnofsky index [23]; the Frankel neurological classification [24]; and MRT to assess tumor progression.

2.5. Statistical methods

All metric variables were presented descriptively using mean, standard deviation, and median. The Wilcoxon test was used for comparisons between variables assessed at baseline and follow-up. The marginal homogeneity test for dependent samples was used for baseline versus follow-up evaluation of the Frankel Index. All tests were two-sided with a significance level of $\alpha = 0.05$. Time to tumor progression was assessed using the Kaplan–Meier estimate. Statistical tests were calculated using the Statistical Product and Service Solutions (SPSS) of Windows, Version 11.0.1.

3. Results

A total of 41 patients with a mean age of 62.7 years were enrolled into the study, 25 of them being men. Overall mean impairment of quality of life (Karnofsky index) and functional activities at baseline was moderate. For details on demographic characteristics and baseline functional status and quality of life see Table 1.

Table 1
Demographics and Baseline Characteristics (n = 41)

Variable	Mean ± S.D. (range)	Median
Age (y)	62.7 ± 9.0 (46-82)	62
Number of RFAs/patient	1.8 ± 1.1 (1-6)	2
Karnofsky index ^a	65.9 ± 14.3 (60-90)	60
Pain Disability Index ^b		
Family/home responsibilities	5.8 ± 3.4 (0-10)	7
Recreation	6.4 ± 3.5 (0-10)	7
Social activity	5.6 ± 3.5 (0-10)	6
Occupation	6.0 ± 3.8 (0-10)	7
Sexual behavior	7.2 ± 3.3 (0-10)	8
Self-care	5.0 ± 3.7 (0-10)	5
Life-support activity	2.8 ± 2.8 (0-10)	2

Note: S.D., standard deviation; y, years; RFA, radiofrequency ablation.

^a Performance scales definitions rating (%) criteria: 100% = normal, no complaints, no evidence of disease; 90% = able to carry on normal activity, minor signs or symptoms of disease; 80% = normal activity with effort, some signs or symptoms of disease; 70% = cares for self, unable to carry on normal activity or to do active work; 60% = requires occasional assistance, but is able to care for most of his personal needs; 50% = requires considerable assistance and frequent medical care; 40% = disabled, requires special care and assistance; 30% = severely disabled, hospital admission is indicated although death not imminent; 20% = very sick, hospital admission necessary, active supportive treatment necessary; 10% = moribund, fatal processes progressing rapidly; 0% = dead.

^b 10-Item scale: 0 = no interference, 10 = total interference.

Table 2
Types of Spinal Tumors (n = 41)

Tumor type	n
Primary tumors	
Osteosarcoma	1
Leiomyosarcoma	1
Secondary tumors	
Breast cancer	8
Multiple myeloma	6
Cancers of the gastrointestinal tract	5
Prostate cancer	5
Kidney cancer	4
Thyroid cancer	4
Malignant melanoma	3
Cervical cancer	2
Urinary bladder cancer	1
Pancreatic cancer	1

Two patients had a primary tumor of the spine (osteosarcoma, leiomyosarcoma) and 39 patients had metastatic spinal disease due to other primary malignancies (Table 2).

Table 3 summarizes information on the observation and follow-up periods. The range of follow-up after RFA was 12-834 days.

Table 3
Observation periods and follow-up

Period	n	Mean ± S.D. (range)	Median
6 weeks	28	43.6 ± 30.5 (2-97)	37
6 months	24	174.8 ± 36.6 (99-231)	174.5
>6 months	16	396.8 ± 107.6 (278-617)	386
Follow-up	41	277.7 ± 220.9 (12-834)	187

Note: S.D., standard deviation.

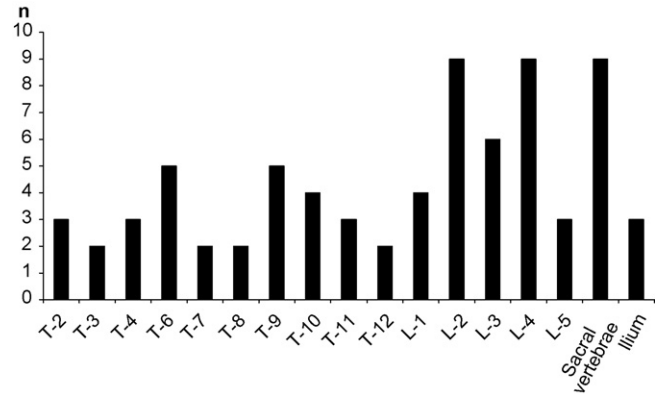


Fig. 1. Localization of radiofrequency ablations (n = 74). Note: n, number of radiofrequency ablations; T-2-T-12, 2nd-12th thoracic vertebra; L-1-L-5, 1st-5th lumbar vertebra.

In total, 29 patients received treatment with the Radionics system (Cool Tip) and 7 with the RITA system; 5 patients were treated with both systems for different localizations of the tumors. In total, 74 RFAs were performed. Fig. 1 summarizes the localizations of the procedures. The largest number of RFAs with 9 each were performed at L-2, L-4, and the sacral vertebrae. The localizations T-3, T-7, T-8, and T-12 had the least frequent number of procedures with two RFAs each. In 1 patient with metastasizing renal cell carcinoma, six RFAs were performed.

Four patients received pethidine and midazolam prior to the procedure because of severe pain. The 37 remaining patients received local anesthesia without analgesia and sedation.

In addition, 22 patients underwent 1-3 stabilizing vertebralplasties of the same vertebrae in which RFA had been performed. Vertebroplasty was performed following RFA in patients in whom 50% of the bone mass had been destroyed by the tumor resulting in instability of the bone structure and an inherent risk for fracture.

Although no complications were observed, four patients reported RFA-associated side-effects:

- Two patients experienced increasing pain and numbness in their contralateral lower limbs during RFA, which subsided upon temperature reduction with the procedure. Both patients received high-dose corticosteroids following RFA.
- One patient reported a unilateral monoradiculopathy at the level where RFA had been performed 2 days following the procedure. A neurological examination did not reveal sensory or motor function abnormalities. Opiates were necessary for pain relief. A repeat MRT did not demonstrate any changes and gave no indication for any neurological lesion. Following two CT-guided intraforaminal perineural applications of 40 mg triamcinolone, the patient was free of pain.
- One patient reported "heavy legs" with paresthesia starting 1 day following RFA. Because of a lack of control over his legs, he had fallen once. Symptoms had subsided within 1 week and were considered to be an incomplete, thermally induced paraplegia. The patient received a CT-

guided intraspinal application of 40 mg triamcinolone into the affected thoracic spine region and was free of symptoms within 12 h.

3.1. Pain relief

Fig. 2 shows reductions in tumor-induced pain in the spine compared to baseline as assessed by VAS. Due to a number of incomplete questionnaires, the number of patients is different at each time point of the assessment. Pain relief in the spine was present already 6 weeks after RFA (decrease by 36.2%, $n = 26$). A reduction in spinal pain by 50% was observed at 6 months ($n = 19$) and later for patients with available data ($n = 14$). Considering pain reduction at the last observation of each patient ($n = 35$), the percentage still reached 38.5% indicating a general median pain reduction for all patients with available information. All differences compared to baseline were statistically significant.

3.2. Functional activities

Fig. 3 shows absolute median changes from baseline of the overall functional activity PDI scores over time. Again, the number of patients is different at each time point of the assessment due to a number of incomplete questionnaires. Overall functional activity scores improved significantly with improvements being greatest 6 weeks (8%) and >6 months (10%) following RFA. Improvements were smaller after 6 months (4%) and at the patients' last observation (4%), but were still statistically significant.

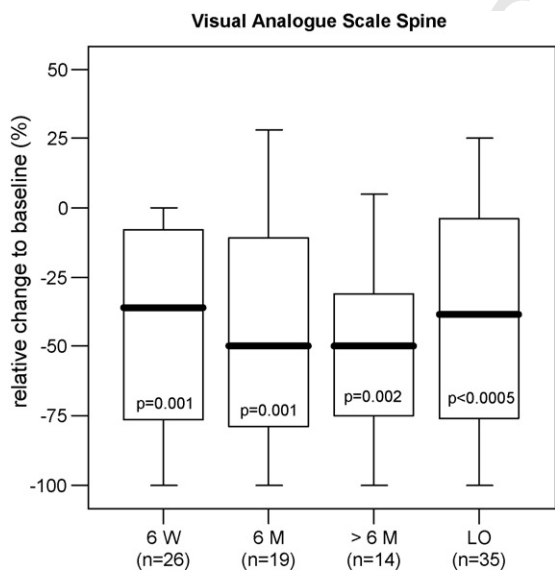


Fig. 2. Pain relief spine (relative changes from baseline using visual analogue score). Note: n , number of patients; W, week; M, month; LO: last observation; p values were generated using the Wilcoxon test for related samples; seven outliers with values above 100% were excluded from the graph (6 W: three outliers, >6 M: one outlier, LO: three outliers). Tumor pain was assessed using a visual analogue scale (VAS) for tumor pain (0–100 mm scale with 0 mm indicating no pain and 100 mm the maximum imaginable pain).

Pain Disability Index

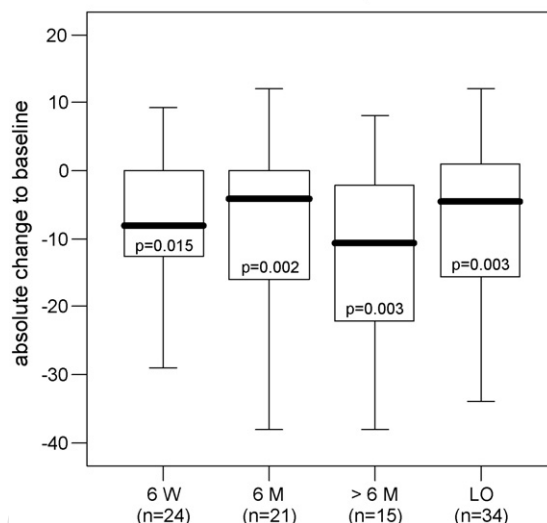


Fig. 3. Pain Disability Index. Note: n , number of patients; W, week; M, month; LO: last observation; absolute changes to baseline; p values were generated using the Wilcoxon test for related samples; one outlier for 6 W was excluded from the graph (value = 35).

3.3. Quality of life (Karnofsky index)

There were no changes of the median percentage changes in the Karnofsky index at any time point indicating an overall stable general condition of the patients.

3.4. Frankel neurological classification

Fig. 4 depicts the number of patients by Frankel classification A–E at baseline and the different time points of follow-up. The data show no statistically significant difference in the distribution of classifications over time indicating in general a stable neurological condition of those patients for whom data were available (p values ranged between 1 and 0.133 for the different time points).

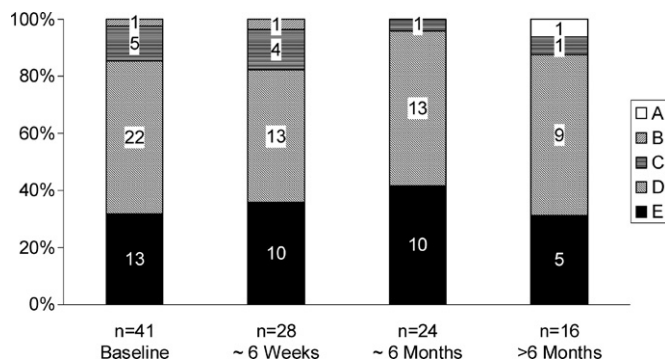


Fig. 4. Frankel classification. Note: A, Frankel A – complete lesion (paraplegia); B, Frankel B – only sensory function; C, Frankel C – motor function present, but no practical use (nonambulatory); D, Frankel D – motor function present, sufficient to allow walking (ambulatory); E, Frankel E – no neurological signs or symptoms.

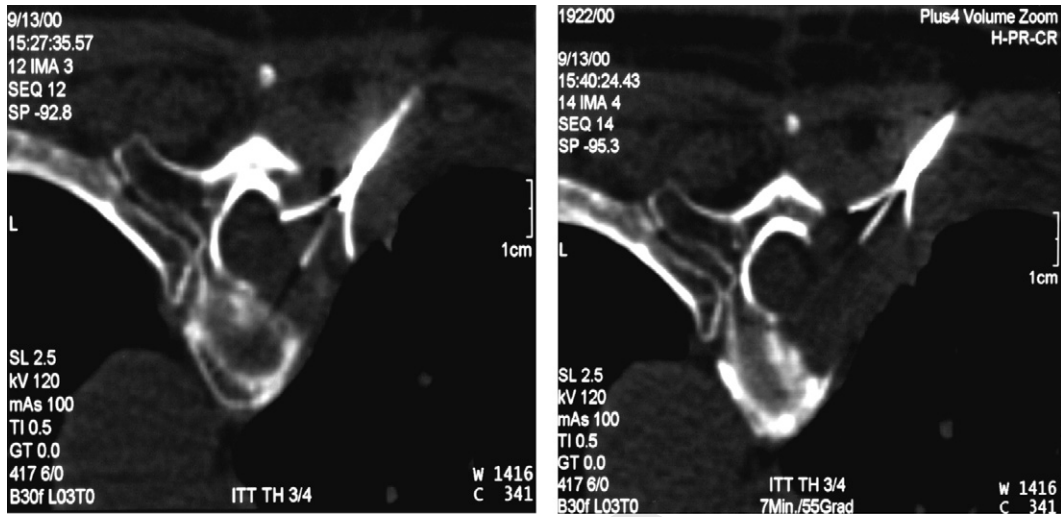


Fig. 5. Case report #1. This 63-year-old patient suffered from malignant melanoma metastasizing into vertebrae T-3, T-4, T-10, and T-11. She was at high risk for paraplegia due to intraspinal tumor growth and lack of bone stability. Neither surgery nor chemo- nor radiotherapy were feasible. RFAs followed by vertebroplasties were performed in the respective vertebrae within 9 months. The patient has regained mobility and experienced continuous pain relief. Repeat MRT did not reveal any tumor progression during 15 months of follow-up.

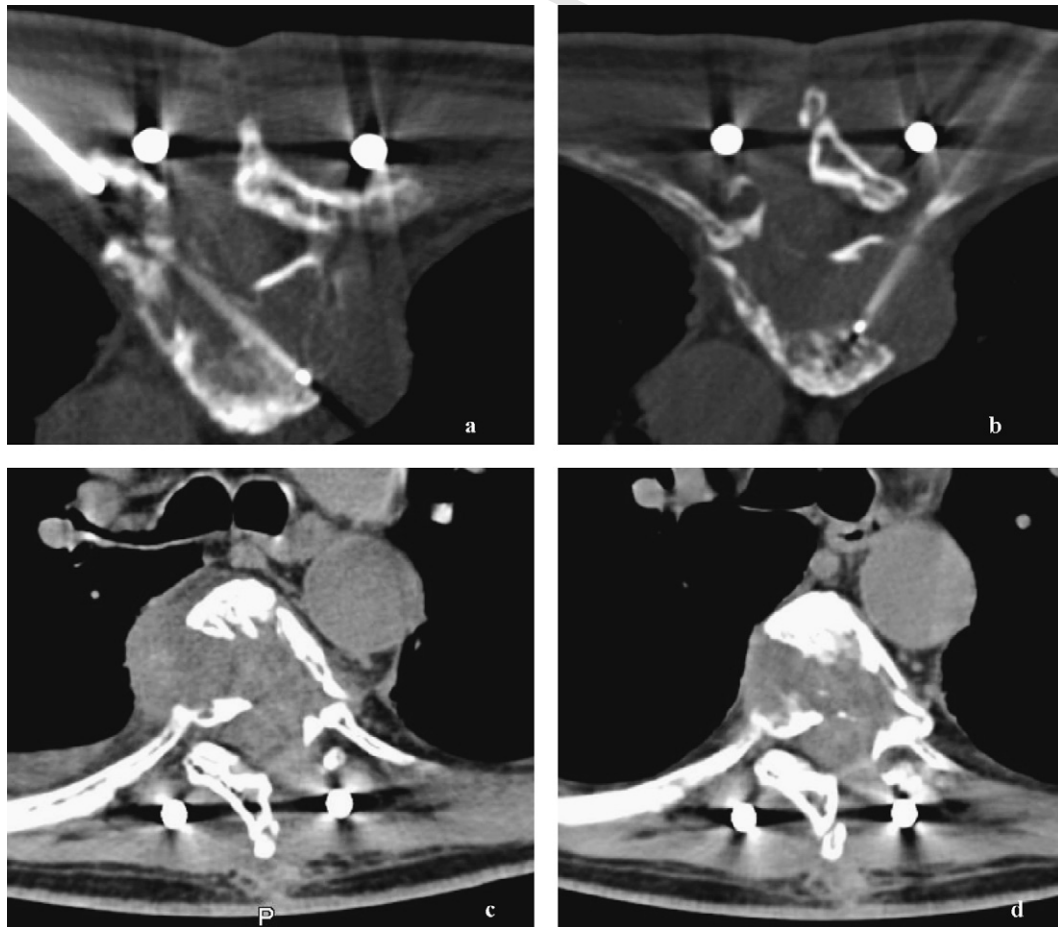


Fig. 6. Case report #2. This 59-year-old patient suffered from renal cell carcinoma metastasizing into vertebrae T-6 and T-7. Dorsal decompression of T-6 and dorsal stabilization of T-4–T-9 had been performed prior to the patient’s presentation at our institute with tumor progression, pain, and signs of paraplegia. RFA was performed in T-6 and T-7 (slides a and b). Repeat CT was not suggestive of tumor progression at the intervention sites up to 9 months later (slides c and d). Because of spondylolysis, MRT was not performed. The patient regained mobility and experienced regression of paraplegia signs.

3.5. Tumor progression

Data on tumor progression were available for 33 of the 41 patients enrolled in the study. Of these 33 patients, 28 (85%) were free of tumor progression, while 5 patients showed local tumor progression, which was demonstrated 10, 63, 70, 90, and 834 days following the RFA procedure in the respective patients. Mean time to tumor progression was 730 ± 54 days.

The 5 patients with tumor progression underwent a repeat RFA with a reduced energy output (<50 W) under local anesthesia. The usual energy output of >80 W with a duration of 15 min per lesion was not used because of local and severe radicular pain. RFA was performed in paravertebral parts of the tumors in 2 of these 5 patients, in whom the tumors had already infiltrated segmental nerves.

Two case reports give examples of RFAs and follow-up in patients with metastases to the spine and signs of paraplegia. In both cases, signs of paraplegia improved and the patients regained or maintained their mobility (Figs. 5 and 6).

4. Discussion

As demonstrated in this study, image-guided RFA is an effective option for the treatment of nonresectable spine tumors unresponsive to chemo- and radiotherapy. A clinically relevant and statistically significant reduction in spinal pain was achieved within 6 weeks following RFA, which had decreased further at 6 months and was maintained on the same level for some time. Similar improvements were observed in functional activities (7-item scale of the PDI), which were also maintained over time. Karnofsky index and Frankel classification remained constant during the observation period, which demonstrated a lack of deterioration of the patients' quality of life and neurological status despite a general disease progression.

The absence of RFA-related complications and the lack of need for surgical revision in this study underline the safety of this procedure. Side-effects such as pain and paresthesia occurring during RFA in two patients were successfully managed by immediate temperature reduction and administration of corticosteroids. One case of monoradiculopathy and one case of transient incomplete thermally induced paraplegia occurring a few days after the RFA were treated with CT-guided intraforaminal and intraspinal administration of corticosteroids resulting in complete pain relief in the former and to major improvement in the latter case. Local heat sensation during RFA was well tolerated in most cases, and constant communication with the patient during the procedure was possible because general anesthesia or heavy sedation was avoided. In cases of radiating pain, which can be caused by heat irritation of spinal nerves or the sympathetic cord, which lies ventrally of the vertebral body, RFA should be stopped and restarted with lower temperatures.

To our knowledge, there have been no reports on major complications of RFA in the treatment of bone metastases, although such a potential exists. Since high temperatures are applied in both techniques, accurate placement of the intervention tools and the creation of a controlled lesion are crucial especially in high-risk areas such as the spine. Experimental studies suggest

that a probe placed within the bone is unlikely to cause unintentional thermal lesions to neural structures [25,26]. Although bone tissue seems to have an insulating effect and decreases heat transmission, surrounding tissue such as muscle may be injured when too much heat is applied. Possible risks of RFA include bleeding, infection, injury to adjacent structures, and abscesses. Skin burn from the electrosurgical return current flow may occur when the grounding pads are not accurately placed equidistant from the ablation site [27].

The two RFA systems used in this study were the cool-tip Radionics system and the RITA Star BWA[®] electrosurgical device with an expandable needle. The systems differ with regard to their probe designs and details of the procedure. In the tissue-impedance controlled Radionics system, radiofrequency energy is controlled manually. In the temperature-controlled RITA system, the desired target temperature is determined and the necessary radiofrequency energy is applied automatically. In our experience, there were no relevant advantages or disadvantages in the use of these systems with respect to their use in spinal RFA. The major difference between the two systems is the design of the electrodes: the expandable RITA electrodes can be used for osteolytic metastases only and do not expand in the harder tissue of mixed metastases. This explains their use in only 29% of patients in this study. However, they are rather useful for interventions in tumors in the spinal canal close to the spinal cord. We did not observe any electrode-associated lesions of structures at risk, e.g. spinal cord or pleura. This is due to the electrode design leading to a rapid drop of temperature at the tip of the electrode.

Accurate imaging is essential for successful in situ tumor ablation. Percutaneous tumor ablation is virtually always performed with tomographic imaging guidance. For safety reasons, computed tomography is regarded as the standard procedure in spinal interventions [28]. With CT, the precision of tip guidance is 1 mm^3 [29], the edges of the instruments are sharply displayed and the tip can be defined to within $\pm 0.2 \text{ mm}$. For RFA of spinal metastases, we prefer CT combined with C-arm fluoroscopy. The fluoroscopy unit can be installed close to the CT gantry with sufficient space for the therapist in all directions [30].

Few reports on RFA of spinal tumors have been published and each includes only 1–2 case reports [21,26,31,32]. To our knowledge, our data provide for the first time a larger series of 41 patients with spinal tumors undergoing RFA.

Our study does, however, have a few limitations. First of all, it was a retrospective analysis without a control group using the combination of RFA and vertebroplasty, both leading to pain reduction in the spinal area. In addition, different tumors have different tissue impedance. While tissues of colorectal tumors tend to have hard structures, those of renal cell carcinoma and multiple myeloma tend to be soft, thus making individual approaches regarding the intervention necessary. Furthermore, a more close check of the ablation volume is highly desirable, which may be achieved by using MRT control including temperature mapping and could lead to individually targeted ablation duration depending on the actual temperatures achieved in the area of ablation. Although MRT-compatible probes are

available, respective experience and MRT protocols are not yet available.

The time intervals (6 weeks, 6 months, >6 months) for description of the results have been stratified arbitrarily and are not intended to be precise, but rather to give a rough estimate about the time period during which the data were collected. In our study, no confirmatory test had been prespecified. Therefore, all tests are descriptive only and significant results could have happened by chance; however, because the patterns of statistical results shown are consistent, we feel confident in our findings. Other limitations relate to the fact of the open-label study design, where observers were not blinded to the efficacy variables. Consequently, some bias may have been introduced.

In summary, RFA of primary and secondary nonresectable spinal tumors, which were unresponsive to chemo- and radiotherapy and prone to progression, is a safe, resource-saving, and highly effective percutaneous technique. The procedure reduces tumor-induced pain within weeks, improves daily activities, and maintains quality of life for months.

5. Conclusions

Radiofrequency ablation of primary and secondary spinal tumors, which were unresponsive to chemo- and radiotherapy and prone to progression, is a safe, resource-saving, and highly effective percutaneous technique in patients with nonresectable spinal tumors. It may prevent or delay tumor progression and the risk for fracture, thus preventing and delaying paraplegia. The procedure reduces tumor-induced pain within weeks, improves daily activities, and maintains quality of life for months.

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