

Image-Guided Radiofrequency Ablation of Spinal Tumors: Preliminary Experience with an Expandable Array Electrode

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PURPOSE

Metastases to the spine are a challenging problem. Percutaneous, image-guided tumor ablation with a thermal energy source, such as radiofrequency, has received increasing attention as a promising technique for the treatment of focal malignant disease.

We used radiofrequency ablation for patients with unresectable, osteolytic spine metastases under computed tomographic and fluoroscopic guidance. The purpose of this study was to determine the feasibility, effectiveness, and safety of radiofrequency ablation as a palliative procedure to reduce pain and back pain–related disability in patients with vertebral and paravertebral spine tumors who were not able to benefit from radiotherapy, chemotherapy, or surgery.

PATIENTS AND METHODS

Between November 1999 and January 2001, 10 patients with unresectable spine metastases were treated with radiofrequency ablation. For the ablation we used a 50-W radiofrequency generator that is connected to an expandable electrode catheter (RITA Medical System Inc., Mountain View, CA). The mean patient age was 64.4 years. Metastases were ablated in the thoracic spine, the lumbar spine, and/or the sacral bone. Tumor diameter ranged from 1.5 to 9 cm. Combined computed tomographic and fluoroscopic guidance was used to guide the procedure.

Operations were carried out without heavy sedation with the patient under local anesthesia only. The thermal lesion was produced by applying temperatures of 50° to 120°C for 8–12 minutes. Vertebroplasty was performed in four patients by use

of 3 to 5.5 mL of polymethyl methacrylate. Therapy outcome was documented by magnet resonance imaging. Before the therapy and on follow-up of an average of 5.8 months, pain was assessed with the help of the Visual Analogue Scale. Back pain–related disability was measured with the Hannover Functional Ability Questionnaire. Neurologic and health status were documented on the Frankel score and the Karnofsky index.

RESULTS

At follow-up, 9 of 10 patients reported reduced pain (Visual Analogue Scale). In patients who experienced pain relief, there was an average relative pain reduction of 74.4%. Back pain–related disability was reduced by an average of 27%. Neurologic function was preserved in nine patients and improved in one. General health was stabilized in six patients, slightly increased (by 10%–20%) in two patients, significantly enhanced (by 50%) in one patient, and slightly reduced in one patient. No complications were reported. In the treated region, magnetic resonance imaging showed no further tumor growth after the therapy.

DISCUSSION

Radiofrequency ablation was successfully performed in all 10 patients. Needles were placed accurately under image guidance, and a controlled lesion was created. Pain- and back pain–related disability was clearly reduced, and neurologic function was preserved or stabilized. When confirmed by further investigation, this therapy may be a new option for patients with unresectable spine tumors that do not respond to radiotherapy and chemotherapy. (*Cancer J* 2002;8:33–39)

KEY WORDS

Radiofrequency, RFA, tumor therapy, spine, computed tomography

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Metastases to the spine are a challenging problem for both the patient and the therapist and greatly affect the patient's overall prognosis. Conventional tumor therapies can control local tumor growth, preserve or improve

neurologic function, restore mechanical stability, reduce pain, and therefore improve quality of life. Standard treatment options for spine tumors include surgery, radiotherapy (RT), and chemotherapy.^{1,2} In cases of restricted effectiveness of chemotherapy and RT, tumors may progressively grow and limit the patient's options. Surgery represents a high risk for patients with advanced disease or poor physical status. In patients with tumors close to the spinal canal or the spinal cord, surgery may not be feasible. Tumor-related vertebral body fractures or osteoporotic loss of bone substance and polypathia can make stabilization of the spine impracticable. Left untreated, spine tumors may cause severe pain and may ultimately lead to neurologic deficits up to paraplegia.

Radiofrequency ablation (RFA) has received increased attention as an effective, minimally invasive method for the destruction of various primary and secondary malignant neoplasms, especially in the liver, but also in the kidney, brain, pancreas, lung, breast, thyroid, and parathyroid glands and in bone.³⁻⁹ Percutaneous vertebroplasty is used to strengthen the pathological vertebral body and reduce pain in some diseases involving the main spine, indications being osteoporosis, vertebral fractures, spine angiomas, and metastases.^{10,11}

To establish an alternative therapeutic option for patients with unresectable spine tumors that do not respond to RT and chemotherapy, we used RFA with an expandable array electrode and a 50-W generator in 10 patients in a prospective observational study. Four of these patients received vertebroplasty in addition to RFA. The purpose of this study was to investigate the feasibility of RFA in bone tumors close to the spinal cord and to ask whether this method can reduce pain and back pain-related disability in our group of patients.

PATIENTS AND METHODS

Ten patients with 21 unresectable spine metastases were selected from a group of patients referred to our institution between November 1999 and January 2001. Inclusion criteria were unsuccessful or ineffective previous treatment (surgery, RT, chemotherapy), severe pain despite pain medication, high risk of neurologic deficits, increased risk of fractures, risk of immobilization, and incompatible side effects of systemic chemotherapy. Patients with osteoblastic tumors, existing paraplegia, insufficient general condition, or hemorrhagic diathesis were not included in the study. The mean age of the five female and five male patients was 64.4 years (range, 57–76 years).

Pretreatment ranged from chemotherapy or RT only to chemotherapy, RT, and decompression surgery. Metastases were ablated in the thoracic spine, the lumbar spine, and/or the sacral bone. Tumor diameter ranged from 1.5 to 9 cm. Diagnosed primary tumors were mela-

noma ($N = 2$), renal cell carcinoma ($N = 2$), mammary carcinoma ($N = 2$), uterine cervix carcinoma ($N = 1$), multiple myeloma ($N = 1$), and combined rectum- and adeno- or prostate carcinoma ($N = 2$).

Technique

For the ablation we used a 50-W radiofrequency generator that is connected to an expandable electrode catheter (RITA Medical System Inc., Mountain View, CA). This active catheter consists of an insulated stainless steel shaft and an exposed tip with retractable arrays. The active arrays can be deployed laterally and retracted by a manual control mechanism on the handle of the catheter. This allows for a variable diameter of ablation. The power output of the generator is adjusted, either manually or automatically, to keep temperatures between 50° and 120°C. Temperature was chosen according to spinal cord distance and patient heat toleration during the ablation. Multislice computed tomography (CT) (Somatom Volume Zoom, Siemens, Germany) and C-arm fluoroscopy (Siremobil 2000, Siemens, Germany) guided the intervention. The C-arm fluoroscope was positioned in front of the CT gantry to enable three-dimensional assessment of the position of the instruments (Fig. 1).

To update findings and plan procedures, contrast magnetic resonance imaging (Somphonie-1,5 T, Siemens, Germany) was carried out before and after the intervention to control the postoperative outcome. Therapies were exclusively carried out in local anesthesia without sedation. As is customary in interventions involving bone tissue, patients received a single-shot intravenous antibiotic injection. Vital signs, cardiac rhythm, and pulse oximetry were monitored. Depending on tumor location, patients were placed on the CT table

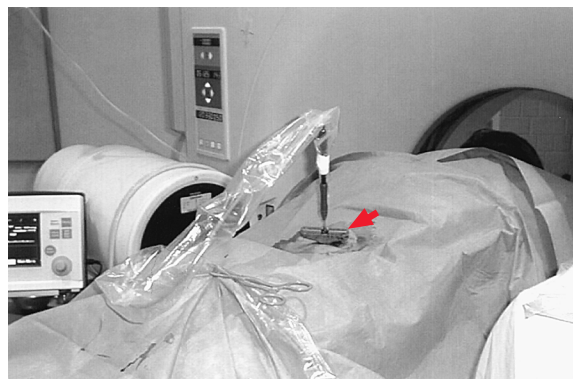


FIGURE 1 Image of the operative site: the Volume Zoom CT (gantry diameter, 70 cm) leaves enough room to position the C-arm fluoroscope in front of the gantry, allowing the operator to comfortably work in front of the computed tomographic system. The trocar and radiofrequency system (arrow) are placed intratumorally. The patient is positioned prone.

in a comfortable prone or side position. Next, a neutral electrode pad was placed on each thigh. On the lateral computed tomographic topogram of the spine, the height of the affected segment was defined by the physician responsible. Additional axial computed tomographic scans (3-mm slices) of the previously defined therapy plane were performed, and we defined the puncture coordinates (depth and angle) on the monitor and marked them accordingly on the patient's skin.

For intravertebral interventions, we prefer a transpedicular approach to prevent destabilization of the vertebral body. For catheter placement in intravertebral tumors involving bone, we used an 11-gauge bone biopsy trocar to guide the catheter into tumor tissue. In this way, possible infection of healthy paravertebral tissue with tumor cells can be prevented. Paravertebral tumors that did not involve bone were punctured without use of the trocar, but tissue surrounding the puncture canal was coagulated in a special preset mode for needle track ablation during the withdrawal of the catheter after RFA. Before placement of the trocar or catheter, respectively, the paravertebral and periosteal tissue was anesthetized with 10–15 mL of 0.1% Scandicain. Under constant computed tomographic/fluoroscopic guidance, the trocar was then placed in the tumor through a small incision in the skin.

Once the catheter was led through the trocar and securely positioned intratumorally, the electrodes were deployed and the ablation was started by running the generator. Depending on the tumors' distance to the spinal cord, the power output was slowly increased up to target temperatures of 50°–120°C. Temperature was measured by the catheter tip, and tumors were ablated for 12–15 minutes. In each session, the radiofrequency catheter was repositioned two to three times, and we

ablated again for 12–15 minutes to obtain an overlapping, larger lesion. In this way, we were able to produce lesions of up to 9 cm in diameter. Whenever repositioning of the needle was necessary, needle position was secured by additional computed tomographic control to prevent the involvement of sensitive nearby structures, such as the spinal cord and the pleura (Fig. 2).

After RFA, the arrays were retracted and the catheter withdrawn. Patients were then rested and monitored for 2–4 hours. They were then able to leave our institution and return home or into further inpatient care.

Cases 1, 2, 6, and 8 underwent additional percutaneous cement vertebroplasty with 3 to 5.5 mL of polymethyl methacrylate (PMMA) between 3 and 7 days after RFA. Vertebroplasty was performed with the placement of an 11-gauge trocar biopsy needle. Once the needle is positioned in the center of the ventral third of the vertebral body, we applied a contrast medium for vertebral venography to identify the paravertebral venous drainage and therefore prevent the direct flow of cement into the azygos vein or the spinal canal, risking PMMA pulmonary emboli or spinal canal stenosis. The cement injection was controlled by CT and fluoroscopy. To control cement flow, a computed tomographic scan was carried out after each applied milliliter. With the help of multislice CT, we were able to display a vertebral body passage of 2 cm in succeeding slices. In that way, the cement spread could be judged in a transverse and axial direction. The injection was stopped immediately whenever the cement reached the posterior vertebral wall or filled paravertebral veins, to prevent spinal canal or neuroforaminal extravasation. Finally, a last postoperative computed tomographic control was performed (Fig. 3).

Case documentation included the Karnofsky index

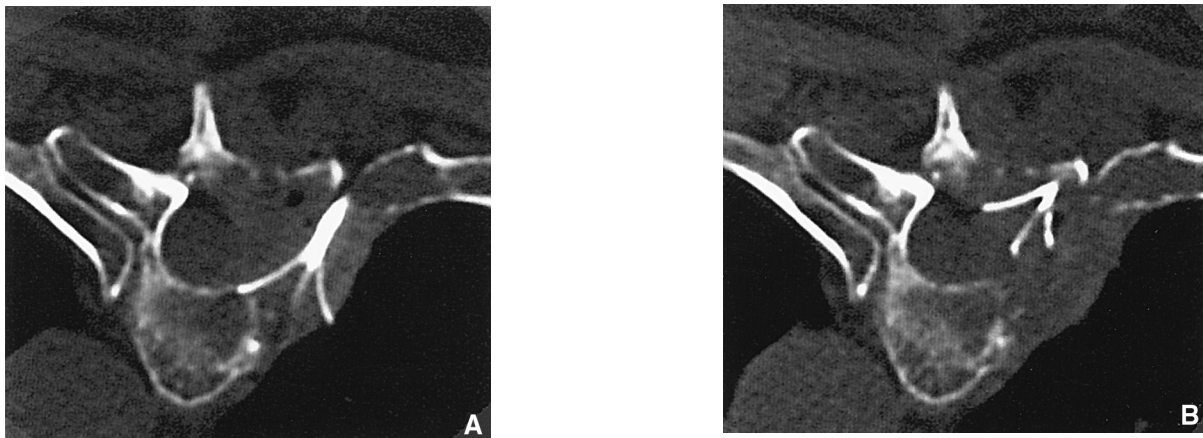


FIGURE 2 Intraoperative computed tomographic (CT) image of vertebral body T4 showing the deployed array electrodes in direct proximity to the spinal cord, the pleura, and the spinal nerves (A). Because of multislice CT imaging, a precise placement of the radiofrequency system is possible without injuring nearby sensitive structures. An overlapping, larger lesion was obtained by repeated ablation after catheter replacement (B).

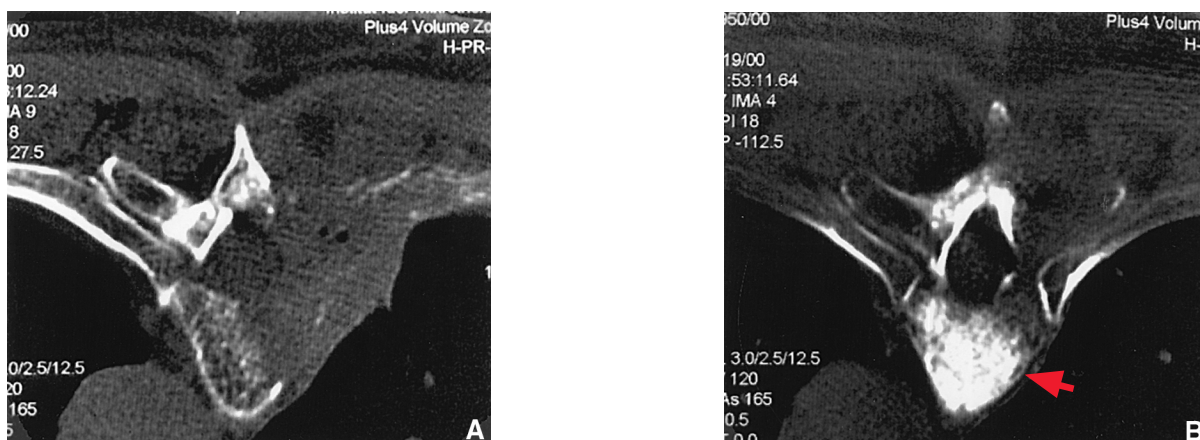


FIGURE 3 A, The lesion after RFA in vertebral body T4. Affected structures include the vertebral body, the right vertebral arch, the right rib, and the paravertebral muscles. B, The remaining contralateral bone structure was stabilized with 4 mL of polymethyl methacrylate (arrow).

to assess the patient's general health and the Frankel score to measure neurologic function.¹² We assessed pain with the help of the Visual Analogue Scale, and back pain-related disability was measured with the Hannover Functional Ability Questionnaire.¹³ Informed written consent was obtained in all cases. Follow-up time ranged from 2 months to 11 months (mean, 5.8 months).

RESULTS

At last follow-up (range, 2–11 months) 9 of 10 patients had reduced pain (Table 1). Average relative reduction in pain (Visual Analogue Scale) in patients who re-

sponded to therapy was 74% (range, 30%–100%), and pain was completely relieved in three patients. Back pain-related disability was reduced by an average of 27% (Hannover Functional Ability Questionnaire) (Table 1). Pain relief and decreased pain-related disability was experienced in patients treated with RFA alone and in those treated with RFA plus vertebroplasty.

One patient reported an increase in pain from 50 to 80 (0–100 scale) and a 16.6% increase in back pain-related disability as a result of a new metastasis in another spine segment. At follow-up, none of the patients experienced paraplegia. There was no intravertebral tumor pro-

TABLE 1 Effect of Radiofrequency Ablation in 10 Patients with Unresectable Spinal Tumors

Patient No.	Age	Primary Tumor	Treated Level	No. of RFAs	Vertebroplasty	Follow-up (Months)	Pain Before Therapy ^a	Pain Follow-up ^a	Percentage Relative Pain Reduction	Percentage of Pain-Related Disability Reduction ^a
1	63	Melanoma	T3, T4, T10, T11	4	Yes	5	90	50	44	62.5
2	76	Renal Cell	L3	1	Yes	2	50	0	100	12.6
3	66	Prostate, Rectum	Sacral Bone	3	No	4	10	0	100	16.6
4	57	Mammary	T12	1	No	3	50	80	–60	–16.6
5	62	Mammary	L4, L5	5	No	11	100	70	30	75
6	66	Multiple Myeloma	L3	1	Yes	6	50	10	80	12.5
7	65	Renal cell	T8	1	No	10	70	10	86	25
8	60	Uterine Cervix	L4, L3	2	Yes	3	100	10	90	45.8
9	71	Rectum, Adeno	Sacral Bone, L5	2	No	6	50	30	40	12.5
10	58	Melanoma	T10	1	No	8	25	0	100	25

^aData on pain was assessed with a Visual Analogue Scale; data on back pain related disability was assessed with the Hannover Functional Ability Questionnaire (FFbH-R). A change of 12 percentage points on the FFbH-R has been shown to be clinically relevant by Kohlmann et al.¹³

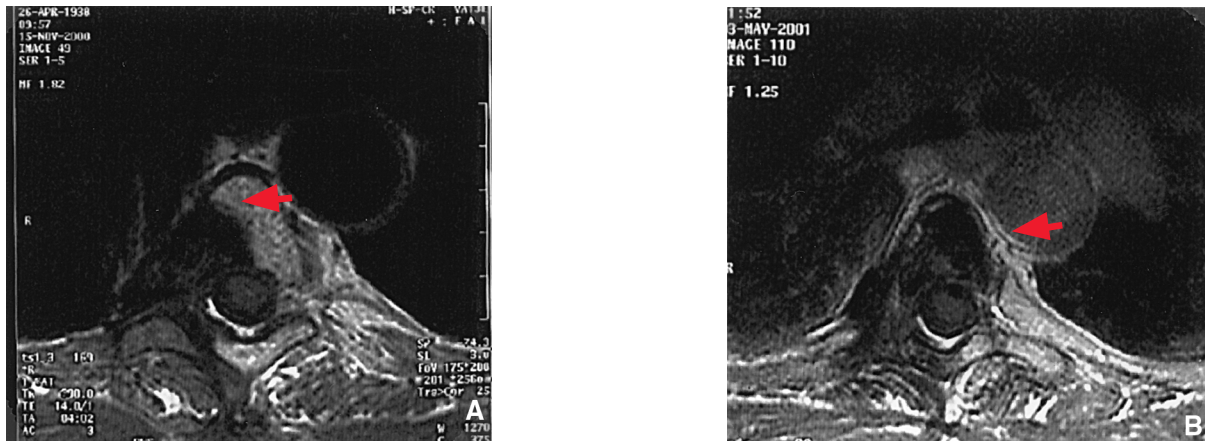


FIGURE 4 A, Magnetic resonance image of vertebral body T4 shows the status before radiofrequency ablation (RFA). The osteolytic tumor mass can be clearly identified (arrow). B, The same segment 6.5 months after RFA. The tumor has been ablated, and there is no visible tumor progression in vertebral as well as in paravertebral structures and the pleura. The remaining vertebral body has been filled with polymethyl methacrylate (arrow).

gression (magnetic resonance imaging control) and no sinterization or fracture in the treated region (Fig. 4).

Neurologic function was preserved in nine patients and improved in one. General health was stabilized in six patients, slightly increased (by 10%–20%) in two patients, significantly enhanced (by 50%) in one patient, and slightly reduced in one patient (Tables 2 and 3).

Patients who underwent vertebroplasty reported a

clear increase in spine stability and felt more secure in motion.

There were no intraoperative or postoperative complications in patients who underwent RFA or vertebroplasty. One patient reported a passage-related, contralateral paresthesia in level T4 that lasted for about 20 minutes after RFA.

DISCUSSION

This study shows that image-guided radiofrequency ablation can be a safe modality in the therapy for nonresectable spine tumors that do not respond to RT and chemotherapy. There were no complications or adverse effects in any of the observed patients, despite the use of electrodes at maximum output. Local heat sensation during RFA was well tolerated in most cases, and constant communication with the patient during the treatment was possible because general anesthesia or heavy sedation was avoided.

TABLE 2 Classification of Neurological Status by Frankel et al.

Frankel A	Complete lesion (paraplegia)
Frankel B	Only sensory function
Frankel C	Motor function present, but no practical use (nonambulatory)
Frankel D	Motor function present, sufficient to allow walking (ambulatory)
Frankel E	No neurologic signs or symptoms

TABLE 3 Neurological and Health Status Before the Therapy and at Follow-up

Patient No.	Frankel Score Before RFA	Frankel Score at Follow-up	Karnofsky Classification Before RFA	Karnofsky Classification at Follow-up
1	D	D	20%	70%
2	D	D	70%	70%
3	E	E	80%	80%
4	E	E	70%	60%
5	C	D	60%	60%
6	E	E	70%	90%
7	D	D	60%	60%
8	C	C	50%	60%
9	D	D	60%	60%
10	C	C	50%	50%

All participants seem to have profited from the therapy, and the patients' pain reduction after our procedure is encouraging; however, freedom from symptoms for several months is not a guarantee of long-term cure. During RFA, patients may sense very moderate local pain. In cases of radiating pain, which can be caused by heat irritation of spinal nerves or the sympathetic cord, which lies ventral of the vertebral body, RFA should be stopped and restarted with lower temperatures.

Although local tumor recurrence was not observed on the magnetic resonance images, further investigation is necessary to judge tumor vitality and growth after RFA. The choice of treatment for spine tumors depends on many factors, including patient age and physical status. RT is a generally accepted first-choice treatment for most patients with metastatic spine tumors. Higher doses of RT to achieve higher levels of local tumor control can expose the patient to an increased risk for pathological radiation myelopathy and functional spinal cord transection. Therefore the effectiveness of RT is limited, especially in patients with metastases close to the spinal cord. Chemotherapy is restricted to chemosensitive tumors and is most effective for early-stage tumors.

From our data, it appears that RFA may present a new therapeutic option for patients who cannot profit from RT, chemotherapy, and surgery because of insufficient therapy results or poor patient condition. Further investigation is necessary in this regard.

Reports on RFA of vertebral body metastases are rare. Dupuy et al¹⁴ reported on one case of a 54-year-old woman with a focal lesion in vertebral body L2 who was treated with RFA, with remarkable results. This patient remained asymptomatic 13 months after treatment. Additional RFA of metastatic deposits in the sacrum were also reported, but the results were not mentioned. Another 14-year-old patient with a T11 pedicle osteoid osteoma was also treated with RFA and was still pain-free after 6 months, without any lower-extremity weakness or sensory loss. For osteoid osteomas, RFA has been proved to be as effective as surgery with a similar outcome and recurrence, but with shorter hospitalization and fewer complications.¹⁵

Radiofrequency electrodes are currently available as straight, internally cooled electrodes or expandable electrodes with thermocouples for temperature monitoring—the latter were used in this study. A clear advantage of this system is that the maximum temperature output is limited to the area within the array electrodes and the immediate proximity of the electrodes' tip. In this way, a very precise and controlled lesion can be produced, which is essential in the direct neighborhood of sensitive structures, such as the spinal cord, nerves, and large vessels or the lung and the pleura. Under combined computed tomographic/fluoroscopic guidance, the expand-

able electrodes can be comfortably placed in osteolytic metastases. In mixed osteolytic/osteoblastic metastases, however, the multiple arrays might not be deployed to their full extent once they touch more solid tissue, like bone. This may be a limitation of the system because the size of the lesion is directly related to the length of the electrodes. The expandable electrodes used in this study can be deployed to a diameter of either 2 or 3 cm and produce a globular coagulative necrosis. Currently available electrodes offer a range of up to 5 cm, and newer generators offer a power output of 150 W.

In conclusion, the clinical cases that we present show that patients with unresectable osteolytic spine tumors can be treated with RFA. With the help of multislice computed tomographic and fluoroscopic guidance, we were able to place the instruments precisely and to cause a controlled lesion. Pain- and back pain-related disability were clearly reduced, and neurologic function was preserved or stabilized. A limitation of this study is the small number of patients who underwent vertebroplasty in addition to RFA ($N = 4$), so it remains unclear whether vertebroplasty in combination with RFA has a significant effect on pain reduction other than RFA alone. Further investigation with larger study groups and longer follow-up will be necessary as this technique gains more widespread acceptance as a therapeutic option for patients with unresectable spine tumors that do not respond to RT and chemotherapy.

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