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## Tumoricidal Temperature-Related Treatments

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**Chicago**—Preliminary studies of several new devices that use heat or cold to kill certain cancer cells have shown promise, but whether all these methods will remain viable or a different one will emerge superior remains a question.

Data highlighted at the Scientific Assembly of the Radiological Society of North America in November showed positive results from using radiofrequency ablation to treat kidney tumors, cryosurgery to destroy prostate cancer tumors, and external beam radiation to augment surgical removal of breast cancer tumors.

The common thread among all these methods is the attempt to treat cancer in minimal or noninvasive ways to reduce time and cost, avoid destruction of nearby healthy tissue, and improve morbidity and mortality.

"The biggest thing coming into play is time—how large a lesion can you treat in the shortest amount of time," said Damian E. Dupuy, MD, of Brown University School of Medicine, a leader in performing radiofrequency ablation for liver cancer.

Dupuy advocates using radiofrequency to treat liver tumors because of the ability to control the modality and its ability to treat large lesions, but he said microwave studies from Asia show great promise. "Radiofrequency is the leader based on equipment availability, but as soon as microwave hits the market, it will be the winner," he said. Meanwhile, here are some results researchers are showing for these various devices:

### RADIOFREQUENCY

Researchers reported encouraging results using radiofrequency ablation (RFA) to treat kidney tumors. In this method, a small needle with an electrode on the tip is inserted through the skin and placed directly into a tumor using computed tomography (CT), magnetic resonance imaging, and/or ultrasonography. After 10 to 30 minutes

RADIOFREQUENCY in the tumor tissue, the radiofrequency energy "cooks" a 1-in to 3-in diameter sphere, killing the tumor cells. The dead cells are not removed but become scar tissue that eventually shrinks.

CRYOSURGERY

EXTERNAL BEAM RADIATION This procedure is performed on an outpatient basis with the patient lightly sedated. Patients reported minimal pain.



In a 4-year study by a team headed by Debra A. Gervais, MD, of Massachusetts General Hospital and Harvard Medical School, Boston, 31 cancerous kidney tumors in 26 patients, who were not good surgical candidates, were treated with RFA under CT guidance. The results showed 23 tumors (74%) completely ablated. Four tumors were treated solely for pain control. Tumor size ranged from 1.1 cm to 8.9 cm, with a mean of 3.2 cm. There were no recurrences after complete treatment with RFA.

In another study, a phase 2 clinical trial conducted by Jonathan S. Lewin, MD, and colleagues at the University Hospitals of Cleveland/Case Western Reserve University School of Medicine, tumor ablation occurred in 10 of 11 patients treated with radiofrequency energy, and there were no cancer recurrences in nine of the 11 patients. The average follow-up period was 14 months. All patients had tumors of 4 cm or less and were not candidates for surgery or refused surgery. The study was funded by the National Cancer Institute, Siemens AG, and Radionics.

## CRYOSURGERY

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A focused form of cryosurgery offers a minimally invasive prostate cancer treatment that can help some men maintain potency.

About 65% of men with this cancer have more than one tumor, requiring that the entire gland be treated. But about 35% of men with prostate cancer have only one tumor, affecting only a portion of the gland. For those with a single tumor, focused cryosurgery may be able to destroy the tumor while sparing nerves crucial to maintaining potency.



RADIOFREQUENCY

CRYOSURGERY

EXTERNAL BEAM RADIATION



Researchers headed by Gary M. Onik, MD, of the Center for Surgical Advancement in Celebration, Fla, found that seven of nine men treated with focused cryosurgery maintained potency after the procedure. The average follow-up was 3 years, with one patient followed up for 6 years. In addition, none of the patients showed cancer recurrence and none had incontinence or diarrhea.

There was no outside funding for this study, in which two to five probes were inserted through the skin directly into the prostate using ultrasonographic guidance. The probes were cooled with argon gas to - 40°C. Once the tissue was frozen, it was allowed to thaw, then it was frozen and thawed again, which caused it to die.

## EXTERNAL BEAM RADIATION

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Two studies showed results of new ways to deliver radiation therapy that promise to reduce treatment time for breast cancer. Women undergoing lumpectomies usually need additional daily radiation treatment that can last for 6 weeks. These new therapies reduced the time for additional radiation treatment to less than 1 week.

Martin E. Keisch, MD, and his team at Mt Sinai Medical Center, Miami Beach, Fla, oversaw a multicenter study that used a single-balloon catheter inserted in the breast to deliver radiation evenly to the tissue surrounding the balloon. The procedure was done twice daily for 5 days. The deflated balloon was inserted via a catheter into the cavity created by removal of the tumor. The balloon was then filled with saline solution to conform to the cavity. A radioactive seed welded to a cable was advanced into the balloon through the catheter. The study was funded by Proxima Therapeutics Inc.

In the study, 26 women received the device to evaluate its performance and safety. Adverse effects were mild. Currently, 43 women have been treated with the device. The researchers said they hope to launch a large trial this year to study the treatment's effects on recurrence rates.

In another study, headed by Jeffrey Tobias, MD, of University College London Medical School in England, researchers presented data on "intra-operative radiotherapy," which involves inserting a metal sphere immediately after surgery into the cavity created by the removal of the tumor and irradiating breast tissue from within. These researchers suggest that their method shows that a single dose of radiation may be enough to replace traditional radiation therapy in early breast cancer treatment. The continuing randomized study is funded by Photoelectron Corp.

In the study, 29 patients who had undergone lumpectomies to remove a single breast cancer of 3.5 cm or smaller were randomized to a standard 6-week course of radiation therapy (14 patients) or to one-time intraoperative radiotherapy (15 patients). No patients in either group have had a recurrence of cancer after 1.5 years.

The researchers noted the short follow-up time but reported that in an earlier pilot study, after 2.5 years there have been no recurrences. They expect an 8% recurrence rate over the long term — a recurrence rate similar to that after standard 6-week radiation therapy.

In intraoperative radiotherapy, a 2.5 cm- to 5 cm-sized sphere is inserted into the breast cavity created by removal of the tumor. An electron generator sends soft x-rays equaling a total dose of 20 Gy into the sphere over a 21- to 28-minute treatment period. The patient receives a "biologically effective" dose of radiation roughly equivalent, 50 to 120 Gy, to the total dose given in standard 6-week radiation therapy.





While the news is promising, Frank Hussey, MD, a radiation oncologist at Lutheran General Hospital in Park Ridge, Ill, warned

that the results are preliminary and that further research is needed before any of these methods become standard practice. Hussey, speaking specifically about the new radiation therapies for breast cancer, said he is concerned that the lure of billions of dollars may put devices into practice before they are ready.

"The industrial people have already made a decision and are going to produce a machine to sell without knowing all the answers," Hussey said. "It may be great, but we don't know yet."

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