Implementing TomoTherapy in a Community Setting

by Paul Clemments, BS, RT; Richard Crilly, PhD; and Daniel G. Petereit, MD

Radiation oncology has witnessed a boom in technology over the past two decades. All these technologies have one objective: the delivery of higher radiation doses to a specific target while sparing the adjacent normal tissues. It is the subtle dose deliveries of these applications that distinguish one system from another: stereotactic radiosurgery (SRS), intensity modulated radiation therapy (IMRT), and image-guided radiation therapy (IGRT).

Similar technology produced by multiple manufacturers can be confusing for community cancer programs. When one considers the high cost of new radiation oncology equipment, purchasing decisions become even more challenging. Most community cancer programs simply cannot afford every new technology, so physicians and administrators must perform thorough assessments of each system to decide which equipment is the best fit for their clinic and cancer patient needs.

TomoTherapy® in the Community Setting

Unlike Gamma Knife® and CyberKnife®, TomoTherapy is not a stereotactic radiosurgery delivery mechanism, but rather a "souped-up" CT/linear accelerator. At present, TomoTherapy is the only IGRT system using megavoltage computerized tomography (MVCT) images to accurately align the patient prior to treatment. These MVCT images, or data sets, are overlaid on the original CT planning images, and aligned to ensure that each treatment is accurately delivered each day.

TomoTherapy delivers IMRT treatments through a process very similar to a CT scan. The linear accelerator rotates around the patient three times "per-slice," one rotation every 20 seconds, while 64 multi-leaf collimators "sculpt" or "paint" the radiation dose. Radiation is passed through a binary collimating system creating precise pencil-like beams to treat the targeted area.

TomoTherapy has been in the market place for about four years, and now owns five percent of the linear accelerator market, equaling that of Siemens. It is fair to say that TomoTherapy can no longer be thought of as a "novelty" with $96.5 million in sales for the first three quarters of 2006 and another $164 million in back orders.[1]

The John T. Vucurevich Cancer Care Institute at Rapid City Regional Hospital implemented TomoTherapy and started treating patients in March of 2004. We were the third TomoTherapy site in the United States, and the first community site. We had to overcome a number of challenges in the implementation of this technology since only a few centers were clinically "live" at the time. Our pioneering effort required innovation, patience, and teamwork.

While we did not have a "how-to" manual to follow when implementing TomoTherapy, the basic principles in treatment planning and delivery were similar to that of existing conventional IMRT planning and delivery processes. The major difference is in the actual radiation delivery process.

An actual CT scan to assure the correctness of patient positioning does precede TomoTherapy treatment delivery. While this does improve accuracy, it also increases the amount of data that must be reviewed by clinical staff.

Our physicians, physicists, dosimetrists, and therapists reviewed and altered established guidelines to meet the new planning and treatment process demands. Physicians were required to adjust their schedules in order to review and approve the registration process prior to treating each patient to ensure proper alignment to the tumor "target." Prior to initiating the first tomotherapy treatment, and weekly thereafter, the radiation oncologist is required to review and approve the MVCTs. Our team was greatly concerned about patient immobilization due to the escalating radiation doses of the new technology. After considering many immobilization techniques, we decided to use a process very similar to the one we used for immobilizing LINAC patients. This is due to TomoTherapy's ability to scan each patient prior to treatment to ensure that the tumor and patient position is aligned correctly. Before initiating clinical treatment, we performed numerous "dry-runs" to verify and modify the immobilization process.

Patient Benefit

For the American Indian population of western South Dakota, and for our other rural patients, TomoTherapy created new access to healthcare that was previously non-existent.

In 2002, the John T. Vucurevich Cancer Care Institute at Rapid City Regional Hospital received a multi-million dollar National Cancer Institute (NCI) grant to investigate healthcare disparities in the American Indian population of western South Dakota.[2] Since this population lives a median distance of 140 miles away from our cancer center, a cornerstone of the grant is the use of shorter radiation schedules for breast and prostate cancer, utilizing brachytherapy and TomoTherapy technology. In fact, our successful implementation of TomoTherapy technology was one of many reasons that Rapid City was awarded the grant.

Currently, we are participating in a prostate TomoTherapy, hypofractionation trial in which the dose equivalent of 80 Gy is delivered through a dose modifica-

tion schedule at three levels: 2.94 Gy x 22; 3.63 Gy x 16; and 4.3 Gy x 12. Four other cancer centers are involved in this study: the University of Wisconsin; Medical College of Wisconsin; Wayne State University; and M.D. Anderson Cancer Center in Orlando. The initial results of the first 139 patients were presented at the 2006 ASTRO meeting.[3] Minimal toxicities were encountered, with excellent biochemical control rates (preliminary) at two years. Patients are now being treated at the final fractionation level of 12 treatments. As part of this grant, TomoTherapy/IMRT trials are also underway for other cancer sites.

Clinical applications of TomoTherapy parallel those of LINAC-based IMRT systems. Indications include:

- Dose escalation (prostate cancer)
- Conformal avoidance (head and neck, as well as other anatomic sites)
- Re-treatment (vertebral metastases and other).

Some of the miscellaneous indications include unusual situations where radiation was previously not an option for example:

- Internal mammary node recurrence for breast cancer where the chest wall was previously irradiated
- High-dose palliative radiation to the pelvic and para-aortic lymph nodes for hormone refractory prostate cancer
- Chest wall sarcomas, mesotheliomas, and total body irradiation, while sparing the brain, lung, kidneys, heart, bowels, and pelvic organs.

Clinicians must ensure that this technology is used appropriately.

Clinicians must ensure that this technology is used appropriately. For example, as cancer centers and manufacturers market treatment options directly to consumers, patients seen in consultation often inquire about the use of these new technologies. IMRT typically is not used for tumors that can move such as lesions of the lung and abdomen; however, in some clinical scenarios it is still appropriate. Inappropriate use of this technology is likely to lead to significant reductions in reimbursement, and will likely hinder productive research in this area.

Programmatic Costs

Economic considerations related to the acquisition and implementation of TomoTherapy include use of an existing vault versus building a new one, additional staff, marketing-related costs, and the price tag of one IMRT system compared to another. Our initial investment was $3.5 million for a new vault and the TomoTherapy unit and $250,000 for additional staff: one .5 FTE (full time equivalent) physicist, one .5 FTE dosimetrist, and two FTE therapists. Our total project cost for the first year was $3.7 million, based on equipment and construction costs in 2003.

We calculated our payback based on an average of 30 fractions per patient with an average of $19,000 in charges. This calculation did not take into account payer mix, contractual agreements with payers, or state wage index. With this formula, we estimated that a profit margin would be seen after treating 300 patients (or about three to four years after starting our program). A similar calculation is available in TomoTherapy's September 2006 newsletter, *Beamlet*.[4] Keep in mind, individual TomoTherapy reimbursement across radiation centers have not been equal since this technology does not "fit" into a standard category in which reimbursements are determined. In other words, TomoTherapy does not clearly fall into any stereotactic radiosurgery codes, which mandate robotic components during radiation delivery. In TomoTherapy, the only moving component is the rotating gantry and the computer-controlled couch that may or may not fall into any stereotactic radiosurgery category. The MVCT that TomoTherapy employs before treatment is also unique compared to other IGRT technology, and some payers may not reimburse for each daily scan.

Declining reimbursement over the next three years is a challenge facing TomoTherapy and other IGRT/IMRT technologies. While it is expected that the daily treatment code 77418 will be reduced, the planning code 77301 is expected to increase.

The Future of Radiation Oncology Technology

Stereotactic radiosurgery, IMRT, and IGRT technologies were initially available only at major metropolitan cancer centers and universities. In the past, these technologies were thought to be out of reach for community cancer centers due to expense, limited physics and dosimetry staff, and the necessary patient through-put to pay for these newer technologies. As our successful execution of TomoTherapy clearly demonstrates, these technologies can now be a part of the treatment armamentarium for many community cancer centers across the country.

Improving access to healthcare should be a driving force to move future technology from university research settings to a community one. While these technologies have the potential to favorably impact the financial bottom line for cancer centers, it is even more important that they favorably impact the therapeutic ratio for patients. Accordingly, both academic and community cancer centers need to support clinical research in this area.

Paul Clemments, BS, RT, and Richard Crilly, PhD, are with the John T. Vucurevich Cancer Care Institute, Rapid City, S.D. Daniel G. Petereit, MD, is with the John T. Vucurevich Cancer Care Institute and the Department of Human Oncology, University of Wisconsin Paul P. Carbone Comprehensive Cancer Center, Madison, Wisc.

References

[1]Newman J: Emerging star TomoTherapy will go public. *Wisconsin State Journal*. February 13, 2007: Front, Al.

[2]Petereit DG, Rogers D, Govern F, et al. Increasing access to clinical cancer trials and emerging technologies for minority populations: The native american project. *J Clin Oncol.* 2004;22:4452-4455.

[3]Ritter MA, Forman JD, Petereit DG, et al. Dose-per-fraction escalation for localized prostate cancer—a multi-institutional phase I/II trial. *Int J Radiat Oncol Biol Phys*. 2006;66:S11.

[4]A Financial Case Study. *The Beamlet* (ed 6), ThomoTherapy Incorporated, 2006. Available online at: *www.TomoTherapy.com/beamlet/beamlet006.htm*. Accessed July 7, 2007.