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TomoTherapy HI-ART System®: Radiotherapy planning and treatment for cancer patients.

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PRIORITISING SUMMARY

REGISTER ID: **000180**

NAME OF TECHNOLOGY: **TOMOTHERAPY HI-ART SYSTEM®**

PURPOSE AND TARGET GROUP: **RADIOTHERAPY PLANNING AND TREATMENT FOR CANCER PATIENTS**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☒	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☐	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	ARTG number
☒	No	
☐	Not applicable	

The TomoTherapy HI-ART System® received approval in the United States in November 2003.

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Canada	✓		
Switzerland	✓		
United States	✓		

IMPACT SUMMARY:

TomoTherapy Inc. provides the TomoTherapy HI-ART System® for radiotherapy planning and treatment of cancer.

BACKGROUND

Standard radiation therapy in cancer patients uses high energy X-rays to damage the DNA in cancer cells and is delivered over a number of weeks. Radiation therapy is a localised therapeutic approach which aims to deliver a high radiation dose to the tumour, while minimising the radiation dose, and therefore damage, to the surrounding normal tissue. A typical course of radiation treatment may extend over several weeks, during which time a patient's organ volume and location may change. Changes in tumour size and location may affect the position of the radiation target area, resulting in irradiation and damage of normal tissue. In addition, radiation misalignment may result in under-treatment of the tumour.

Tomotherapy addresses the limitations of standard radiation therapy as it allows the physician to accurately visualise target areas so that position adjustments can be made just prior to treatment. Tomotherapy delivers an advanced form of intensity modulated radiation therapy

(IMRT). IMRT is a cancer treatment modality that uses angles and radiation beam shapes to treat tumours and involves changing the size, shape and intensity of the radiation beam during treatment to conform to a patient's tumour, while sparing the surrounding healthy tissue (TomoTherapy Inc.). The interest in tomotherapy is in its enhanced precision (compared to conventional IMRT) in accurately distributing the radiation dose while delivering less radiation to the surrounding healthy tissue and altering radiation dose to compensate for patient movement—reducing side effects experienced by patients.

The Tomotherapy HI-ART System® is the first device to provide 3-D computerised tomography (CT) imaging immediately prior to treatment to verify the location of a patient's tumour, allowing for changes in tumour size and location. The TomoTherapy System® can record the dose and location of the radiation given to a patient, providing physicians a record of the previous session, and to accommodate adjustments as required.

The TomoTherapy HI-ART System® is intended to be used as an integrated system for the planning and delivery of IMRT for the treatment of cancer. During treatment, the patient moves through the TomoTherapy machine on a couch platform while radiation is delivered to the tumour site in a 360 degree helical (spiral) pattern. While conventional radiotherapy delivers a wide beam of radiation from just a few directions, the TomoTherapy system can deliver small beams of radiation from every point on a spiral (Figure 1). The system consists of a linear accelerator mounted on a ring gantry, which moves in unison with a multileaf collimator (MLC).

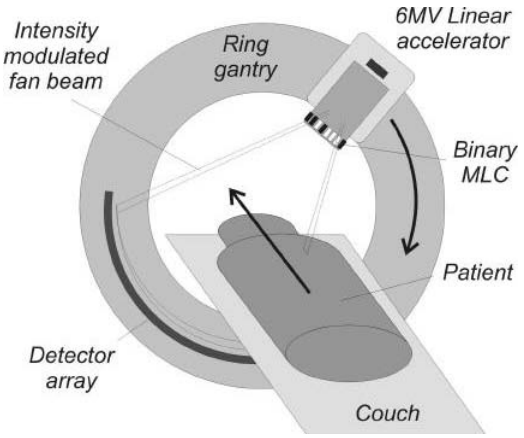

Figure 1. Schematic drawing of helical tomotherapy unit (Kron et al 2005)

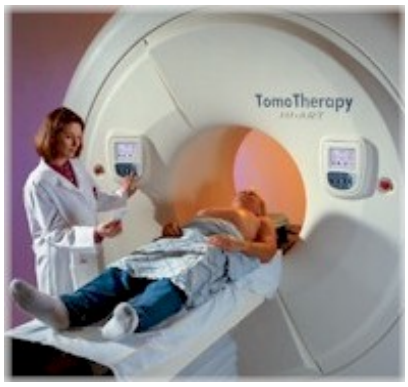

Figure 2 Hi-Art Tomotherapy unit Printed with permission

The computer-controlled MLC has two sets of interlaced leaves that move in and out rapidly, constantly modulating the radiation beam as it leaves the accelerator. The patient couch moves simultaneously, guiding the patient slowly through the centre of the gantry. With each rotation of the linear accelerator, the radiation beam is directed at a slightly different plane, irradiating a different section of the tumour (Figure 2).

CLINICAL NEED AND BURDEN OF DISEASE

Tomotherapy may be applied to a range of cancers including breast, lung and prostate. In Australia during the year 2000, incidence rates for all cancers were 536 and 390 per 100,000 for males and females, respectively. The corresponding mortality rates for the same period were 245 and 148 per 100, 000, for males and females, respectively (AIHW & AACR 2003). A recent health survey in New Zealand reported that 1 in 20 adults (5% of the population) had ever been diagnosed with a cancer (Ministry of Health 2004).

DIFFUSION

The HI-ART System® was first used in 2002 in Canada. There are currently 30 TomoTherapy installations world wide. There are currently no Hi-ART Systems installed in Australia.

COMPARATORS

Several imaging techniques are employed for radiation therapy planning and external treatment for cancer patients. Typically a patient will receive high radiation doses of 60-70 Gy, given in 30 to 40 daily fractions at the rate of 5 fractions per week (van Dyke et al 2002). Imaging modalities include: 3-D imaging using CT, magnetic resonance imaging (MRI), single photon emission tomography (SPECT), or positron emission tomography (PET). For radiation dose delivery linear accelerators, generating electron energies between 4 and 25 MeV, are generally used for producing x-ray beams for the treatment of tumours.

Brachytherapy is a treatment option that involves *internal* delivery of radiation by the use of radioactive implants that deliver high radiation doses to specific cancer cells, without damaging adjacent normal tissues. Brachytherapy is often used in addition to external beam irradiation in the treatment of patients with prostate, breast, head and neck cancer.

An alternative treatment for internal radiation delivery is the use monoclonal antibodies, which target tumour antigens. Radioactive substances my be attached to monoclonal antibodies, which in turn target tumour antigens, delivering radiation while sparing normal tissue.

EFFECTIVENESS AND SAFETY ISSUES

At the time of preparing this summary there were limited studies which described clinical planning[1] of tomotherapy or compared tomotherapy planning to conventional radiotherapy treatment planning or other IMRT technologies for lung and brain cancer (Kron et al 2004, Yartsev et al 2005). Two case studies were identified reporting on its use for breast and brain cancer (Hui et al 2004 abstract only, Bauman et al 2005). There were no studies that compared clinical use of tomotherapy to other radiotherapy modalities.

One low quality study (level III-3 intervention evidence) compared the results of tomotherapy *treatment planning*, for 12 patients with brain tumours, to previous planning results for five other radiation therapy techniques (Yartsev et al 2005). The study examined in particular the theoretical performance of the techniques in avoiding radiation to organs at risk in close proximity to the tumours. All radiation treatment modalities were programmed into planning software that calculated planning target volumes of the tumours to radiate (maximum radiation dose) and other organs at risk (minimised radiation dose). When data were entered into the computer program for each patient for all radiotherapy modalities tomotherapy demonstrated significantly better minimum target dose coverage than three other radiotherapy techniques and was as effective as photon methods ($p<0.05$). It should be stressed that this study provided planning data only, and that patients did not undergo tomotherapy treatment.

In a separate study (level III-3 intervention evidence) tomotherapy plans were developed for 15 patients with stage III inoperable lung cancer, which were then compared to IMRT planning. The quality of tomotherapy planning correlated well (accurately targeted tumour

[1] Planning of tomotherapy involves a complex series of steps which generates individualised patient radiation therapy planning data. Planning takes into account the size and position of the tumour, as well as other organs at risk of radiation exposure. This data is transferred to the tomotherapy treatment planning computer. An optimised treatment planned is then developed, which provides inverse planning capabilities, radiation dose, radiation exposure time and determines the leaf positions for all gantry angles and couch positions. This data are then transferred to the tomotherapy treatment unit for patient delivery.

area with high dose radiation and avoided irradiating organs at risk), or was slightly improved, compared to IMRT planning (Kron et al 2004).

COST IMPACT

It is not possible to estimate at this stage the likely cost impact of establishing tomotherapy in clinical practice as there are no available data on cost effectiveness. It is not known whether the use of tomotherapy would result in the need for less and/or shorter treatment sessions for cancer patients as this has not been studied to date. The estimated cost of the Hi-Art® system is between $AUD 5.3-5.5 million (personal communication, Australian distributor).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

An internet search for tomotherapy at the time of preparing this summary revealed several ongoing clinical trials of tomotherapy for different cancers in the United States and United Kingdom. Presentations on the use of tomotherapy for the treatment of prostate cancer will be delivered at an international conference to be held in Wollongong (5-8th December, 2005) (Micro- and Mini-Dosimetry & International Prostate Cancer Treatment).

CONCLUSION:

There is limited clinical evidence available to date describing the use of tomotherapy either in Australia or overseas. However, it is currently being investigated in clinical trials worldwide.

HEALTHPACT ACTION:

Tomotherapy is not funded under the Medicare Benefits schedule. However, given the high level of interest in the potential for tomotherapy, in conjunction with the current lack of clinical evidence, it is recommended that this technology be monitored.

SOURCES OF FURTHER INFORMATION:

AIHW & AACR (2003). Cancer in Australia 2000. AIHW cat no CAN 18, Australian Institute of Health and Welfare (AIHW) and Australasian Association of Cancer Registries (AACR), Canberra.

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Kron, T., Grigorov, G. et al (2004). 'Planning evaluation of radiotherapy for complex lung cancer cases using helical tomotherapy', *Phys Med Biol*, 49 (16), 3675-3690.

Ministry of Health (2004). *A Portrait of Health: Key results of the 2002/03 New Zealand Health Survey.* Wellington: Ministry of Health.

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Van Dyk, J. et al (2002). 'Tomotherapy: A "revolution" in radiation therapy' *Physics in Canada* 3/4, 79-86.

Welsh, J. S., Patel, R. R. et al (2002). 'Helical tomotherapy: an innovative technology and approach to radiation therapy', *Technol Cancer Res Treat*, 1 (4), 311-316.

Yartsev, S., Kron, T. et al (2005). 'Tomotherapy planning of small brain tumours', *Radiother Oncol*, 74 (1), 49-52.

LIST OF STUDIES INCLUDED

Total number of studies
Level III interventionevidence 2

SEARCH CRITERIA TO BE USED:

Neoplasms/ radiotherapy/ therapy
Radiotherapy Dosage
Radiotherapy Planning, Computer-Assisted
Radiotherapy, Conformal/ methods
Tomography, X-Ray Computed