

Automated afterloading in brachytherapy

A report by the

National Health Technology Advisory Panel

July 1989

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National Health Technology Advisory Panel

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Automated afterloading in brachytherapy

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Executive summary

- Brachytherapy is an established form of radiotherapy involving implantation of a radioactive source at the site to be treated.
- A major disadvantage of brachytherapy is that it involves exposure of medical, technical and nursing staff to radiation during insertion and removal of the source, and care of the patient while the source is in place.
- To overcome this problem, automated afterloading systems have been developed. With these, sources are inserted under computer control in a shielded room, and automatically withdrawn into a lead safe when persons enter the room.
- Low dose rate treatment delivered by automated afterloading systems is equivalent to traditional brachytherapy and can be expected to have similar clinical efficacy.
- With automated systems, use of high dose rates with shortened treatment times is also possible. The clinical value of high dose rate treatment has not been fully established.
- The case for automated afterloading rests primarily on the reduction in radiation exposure of staff.
- Current levels of radiation exposure for brachytherapy staff, would result in around one cancer every hundred years. Genetic disorders would be induced at a comparable rate. The use of automated afterloading to avert occupational cancers would cost about \$40 million per fatal cancer prevented.
- The use of automated afterloading is difficult to justify on economic grounds but other factors need to be taken into account, particularly the principle that occupational radiation doses should be as low as reasonably achievable, and the need to maintain staff confidence.
- Patients may also benefit from increased nursing care and contact with other persons, in comparison with manual treatment, but these benefits may be offset by the discomfort of being linked by a tube to the afterloading device throughout the treatment period (up to several days if low dose rates are used).

The Panel considers that:

- the use in Australia of automated afterloading systems is desirable for low dose rate brachytherapy in view of perceived occupational health benefits to medical, nursing and other staff;
- use of automated afterloading systems may also provide benefits through allowing high dose rate therapies and increased levels of nursing care, although these are less certain.

Introduction

The Commonwealth Department of Community Services and Health has asked the National Health Technology Advisory Panel (NHTAP) for an evaluation of a remote automated afterloading technique for brachytherapy with particular reference to its cost-effectiveness and clinical efficiency.

The Panel has sought the views of a number of professional organisations on:

- the role of brachytherapy in comparison with other forms of radiotherapy;
- the estimated reduction in the amount of exposure to nursing, technical and medical staff by the introduction of afterloading techniques.
- the potential benefits of automated afterloading techniques in terms of operator and patient safety;
- the effect of the use of automated afterloading techniques on the clinical efficacy of brachytherapy.

Background

Brachytherapy is a technique of radiotherapy involving implanting a solid radioactive source within a malignant tumour, applying it to the surface of a tumour, or inserting it into an applicator within a body cavity.

Brachytherapy is an established part of the speciality of radiation oncology, and is most commonly used in the treatment of gynaecological cancers. It is also used to treat malignancies in the head, neck, breast, anus, lung, prostate, oesophagus and brain. It may be used either as sole treatment or to provide a boost dose in an area treated by external beam radiation⁽¹⁾. Some 2500 brachytherapy procedures were carried out in Australia in 1987/88.

The advantages of brachytherapy are (Trinker, personal communication):

- a high radiation dose in the immediate vicinity of the radioactive source;
- a rapid fall-off of radiation with distance allowing sparing of tissue away from the tumour;
- ability to design individual configurations to suit particular situations;
- greater radiobiological effects than external beam therapy on some tumour types and a higher therapeutic ratio;
- shortened hospitalisation compared to a surgical alternative.

Disadvantages of brachytherapy include the inability to treat deep seated organs such as the pancreas, inability to treat radically any tumour with a high potential for regional or distant metastases, some acute radiation reactions in mucosa, and delayed radiation reaction if the source is malpositioned⁽¹⁾.

In addition, a perceived major disadvantage of brachytherapy has been the exposure of medical, technical, and nursing staff as well as visitors and other patients to radiation. To avoid exposure, automated afterloading devices have been developed. These machines allow radioactive sources to be automatically loaded by remote control, via flexible delivery tubes, into hollow applicators previously inserted into the areas to be treated⁽²⁾. The device is installed in a shielded ward. Protection for nursing and other staff is provided by a cut-off mechanism so that whenever a person enters the ward, the radioactive material is automatically retracted into a lead safe.

Automated afterloading devices are in use in several institutions in Australia. At the Peter MacCallum Cancer Institute in Melbourne, six devices called Curietrons have been in use for ten years. They are being replaced by Selectrons, which permit greater flexibility in the selection of sources (Millar, personal communication).

In contrast to automated afterloading systems, manual loading systems involve the handling of radioactive material by staff. In the manual preloading procedure, the radioactive source is inserted into the selected site in an operating theatre, after which the patient is transported through hospital corridors to the radiotherapy ward.

The preloading procedure has now been superseded by manual afterloading, in which an applicator to hold the source is put into position in the operating theatre and the source is subsequently manually inserted into the applicator. Manual afterloading is used in approximately half the institutions in Australia which treat gynaecological cancers with brachytherapy⁽¹⁾.

In a comparison of automated afterloading with manual preloading, it has been noted that the ability to spend time adjusting the inactive applicators in the operating theatre, taken together with the greater flexibility of source positioning in the applicators, made it easier to optimise the dose distribution for individual patients⁽²⁾. To some extent these advantages would also apply to manual afterloading.

Automated systems may be designed for the delivery of low or high radiation doses. Low dose rate techniques deliver dosages equivalent to those provided by traditional brachytherapy. The treatment usually involves hospitalisation and radiation exposure for the patient for one to five days. The source most commonly used is caesium-137.

High dose rate techniques using high activity sources such as cobalt-60 or iridium-192 permit much shorter treatment times. While they have been used most commonly for the treatment of gynaecological malignancies, they allow application of brachytherapy to areas not amenable to the continuous use of applicators such as the bronchus or oesophagus⁽¹⁾ (Trinker, personal communication). A device used for high dose rate brachytherapy requires a more heavily shielded room than low dose rate equipment.

An overview of the techniques of brachytherapy has been provided by the Radiation Oncology Standing Committee of the Royal Australasian College of Radiologists (RACR)⁽¹⁾ and is included at Appendix 1.

Reduction of radiation exposure to staff

Although it is clearly true that automated afterloading reduces radiation exposure, there are few quantitative studies on the extent of the reduction and its implications for health. In a report by Fleishman et al⁽³⁾, the automated procedure was compared with an outdated technique, manual preloading with radium. Using this earlier technique for gynaecological radiotherapy, the radiation exposures of staff were below the International Commission on Radiological Protection annual dose limit of 50 mSv (5 rem), but for a significant number were within 30%–90% of the limit. It was noted that in other areas of radiotherapy, staff exposures rarely exceed 10% and are frequently at 1% of the occupational dose limit.

Current practice is to replace radium with caesium-137 which has an exposure rate constant of 3.26 (R/cm²/mg-h) as compared with 8.25 for radium-226⁽¹⁾. Data from the Queensland Radium Institute⁽¹⁾ indicate that substantial reductions in staff radiation exposure have resulted from a changeover in 1985 from manual preloading with radium to manual afterloading with caesium. In 1984–85 the average annual dose equivalent for permanent staff was 2.33 mSv. In 1985–86 it fell to 2.04 mSv and by 1987–88 was down to 760 μ Sv. Over the same period caseload ranged from 202 to 213 annually. However, individual variation in occupational radiation dose was high and for some individuals exposure was much higher than the average.

In a report on the use of automated afterloading in brachytherapy for cancer of the prostate, Porter et al⁽⁴⁾ have noted that where manual loading was used the exposure at the bedside of the patient was 80 mR/h and immediately above the patient 100 mR/h. The average nursing time provided to patients treated by automated afterloading would have resulted in an exposure of 300 mR if manual treatment had been used.

there would be justification for the use of automated afterloading techniques even though manual techniques do not result in radiation doses to staff above acceptable limits.

The NHMRC Code of Practice for the Control and Safe Handling of Radioactive Sources used for Therapeutic Purposes recommends that where practicable, 'afterloading' techniques shall be used⁽⁷⁾.

The RACR has recommended that 'wherever possible, afterloading brachytherapy techniques be undertaken. As automatic afterloading systems virtually eliminate staff exposure, this technique should be introduced into those Departments of Radiation Oncology in Australia which do not currently have automatic afterloading systems'⁽¹⁾.

Clinical efficacy

Low dose rate brachytherapy with automated afterloading essentially delivers treatment similar to that provided by manual techniques. Accordingly it would not be expected that there would be any significant difference in clinical efficacy. The ECRI has noted that results of treatment with manual and automated techniques do not appear to be different⁽²⁾.

There have been no suggestions to the Panel that automated afterloading improves clinical efficacy, although Wigg (personal communication) has pointed out that modern techniques add great flexibility to the loading of sources, permitting better tailoring of the dose to the actual volume needing treatment. Nor is there any evidence that the automated technique results in any reduction in efficacy.

High dose rate brachytherapy delivers treatment which is not comparable to traditional brachytherapy. A high dose rate regime has been compared with manual treatment with radium for gynaecological cancers. Results in terms of survival and complication rates were not significantly different (Trinker, personal communication). The radiobiological effects of high dose rate techniques have not yet been fully worked out (Trinker, Mason, personal communications).

It has been suggested to the Panel that comparative trials of low dose rate automated brachytherapy and manual techniques would be ethically doubtful because of the increased radiation dose to staff with the older techniques (Trinker, personal communication). Comparison of high and low dose rate automated brachytherapy in terms of effects on local control, survival, complications and quality of life, would be desirable but would need to be undertaken in a major centre with a relatively high patient throughput. It seems unlikely that such studies would be undertaken in Australia.

Patient benefits and risks

The capacity of automated afterloading systems to withdraw radioactive sources automatically when treatment rooms are entered has benefits for patients in that nursing staff are willing to spend more time with them in the absence of radiation exposure. A study on patients undergoing treatment for cancer of the prostate has shown that in comparison with manual afterloading, the use of automated afterloading had the result that approximately twice as much time was spent with patients by nursing staff⁽⁴⁾.

In a study of parallel series of manual and automated procedures Joslin et al found that the number of nursing visits to patients was 33% higher when automated afterloading was used (Mason, personal communication). In addition, it is possible for patients to receive visitors. With automated systems, therefore, patients are less isolated and morale may be improved.

Patients may also benefit from computer control of insertion of radioactive sources, which may reduce the risk of incorrect positioning and any consequent radiation damage to healthy tissue. Computerised monitoring of the radiation dose to the patient may reduce the risk of complications.

On the other hand, when automated afterloading is used, the patient is essentially tethered to the device throughout the treatment period. As well as reducing freedom of movement and possibly causing discomfort, some patients may find the situation psychologically unpleasant or even distressing, even with the reduction in isolation. From the patient's point of view the disadvantages of automated afterloading may to some extent outweigh the advantages. However, the Panel has been advised that at the Peter MacCallum Cancer Institute, experience has taught how the level and duration of discomfort can be minimised.

There may also be a possibility of accidental injury, although the Panel is unaware of any cases which have occurred. High dose rate systems would allow much shorter treatment times, but there would be increased risk of radiation damage to the patient and possibly to some staff if equipment failure resulted in the source being in position longer than planned.

Costs

In comparison with manual afterloading, automated afterloading will have additional costs associated with the cost of the equipment, building modifications and installation, and equipment maintenance. The contribution of automated afterloading to the cost of brachytherapy, at a throughput of 150 patients per annum, is given in Table 1.

The Table indicates that the additional cost per patient of using automated rather than manual afterloading at this throughput will be in the region of \$485.

Table 2 gives approximate ranges for the total cost of brachytherapy for a single 24-48 hour procedure with a low dose rate, for manual and automated afterloading at a throughput of 150 patients per annum.

Table 1: cost of automated afterloading

	\$
Capital cost (equipment, room shielding minor surgical equipment)	352,000
Annualised capital cost (10 years depreciation for equipment, 20 years for shielding)	42,500
Equipment maintenance	30,000
Total annualised costs	72,500
Annualised cost of automated system per treatment	485

Table 2: Costs of brachytherapy for a single 24–48 hours treatment with low dose rate

<i>Cost component</i>	<i>Costs</i>	
	<i>Manual afterloading</i>	<i>Automated afterloading</i>
Insertion of applicator (including specialist fees and theatre costs) ^(a)	200–700	200–700
Preparation and insertion of source (including specialist fee and support staff costs)	170	655 ^(b)
Purchase of source	45–65	45–65
Removal of source and applicator	50	50
Hospital accommodation ^(c)	140–280	140–280
Nursing care ^(d)	220–460	220–460
Totals	825–1725	1310–2210

Notes: (a) Costs of insertion of applicator will vary with the site being treated, and complexity of the procedure.

(b) This component includes the cost per treatment of the automated system. The cost of automated afterloading may be lower if two patients can be treated simultaneously on the one machine (possible with some models) allowing a higher throughput.

(c) This component includes costs of accommodation, meals, medication and routine tests. It does not include nursing care.

(d) Although patients on automated systems receive additional nursing care, the cost of nursing would not necessarily be increased. In accordance with some State government regulations, a person must be available full time to be responsible for the radioactive source. With the automated system, more nursing time is usefully employed in direct care of the patient. The cost covers three 8 hour shifts, providing a nurse 24 hours per day.

Conclusions

The case for the use of automated afterloading techniques in brachytherapy rests primarily on improved safety for medical, technical and nursing staff through the reduction of radiation exposure. There is only a very small risk of cancer or genetic damage associated with existing levels of radiation exposure to staff engaged in the care of brachytherapy patients. Reduction of risk by the further use of automated systems is difficult to justify on economic grounds.

However, the use of automated afterloading is in accordance with the generally accepted principle that occupational radiation doses should be as low as reasonably achievable. There is likely to be increasing concern among staff over the radiation exposure involved in manual techniques, particularly when they are aware that an automated technique is available which virtually eliminates exposure.

It is possible that in comparison with the outdated manual preloading techniques, automated afterloading results in an improvement in the clinical efficacy of low dose rate brachytherapy, although the Panel is unconvinced that there is any improvement in efficacy in comparison with manual afterloading.

The automated procedure also allows the provision of high dose treatment which would not be undertaken with manual techniques. High dose treatment shortens treatment time but at this stage its clinical value is not fully established.

Replacement of manual by automated afterloading will increase the cost of brachytherapy, possibly by \$485 per low dose treatment. At the same time, it is likely that with the increasing use of more conservative surgery and post-operative radiotherapy for the treatment of breast cancer, the use of brachytherapy in Australia will increase (Wigg, personal communication). The two factors could lead to a substantial increase in the cost of brachytherapy to Australian health care.

The advantages to the patient of improved nursing care and reduced isolation has to be weighed against the discomfort of being tethered to a machine for the period of the treatment. Treating institutions need to ensure that efforts are made to ameliorate the discomfort, taking into account feedback from the patients themselves.

The Panel considers that the use of automated afterloading for brachytherapy in Australia is desirable in view of occupational health benefits to staff. It may also provide benefits through allowing high dose rate therapies and increased levels of nursing care, although these are less certain. It is suggested that in view of the costs involved, further replacement of manual by automated afterloading in Australia might be phased over a number of years.

Appendix 1: Techniques of brachytherapy (information provided by the Royal Australasian College of Radiologists)

Essentially three methods are used:

• Manual Preloading

Brachytherapy techniques of this type involve the manual insertion of the isotope into tissues (interstitial) or onto the surface of tumours (surface application) or into applicators placed in body cavities (intracavitary). The isotope is maintained in place by suturing and/or packing and is not removed until the desired dose is delivered. For permanent implants the sources such as gold grains or iodine-125 seeds remain in the patient indefinitely.

The isotope is inserted in theatre under a general anaesthetic and hence there is exposure to nursing staff, radiation oncologists, surgeons and to other personnel in theatre; as well as during transit from theatre to the ward and to ward staff during the patient's stay in hospital prior to removal of the isotope.

This method provides the least protection to persons other than the patient and is nowadays only undertaken when afterloading techniques cannot be used.

• Afterloading Techniques

With these techniques hollow needles, tubes or intracavitary containers are positioned in or on the body and maintained in place by suturing and/or packing etc, usually requiring a general anaesthetic and/or a surgical procedure such as a uterine dilatation. At the completion of surgery the patient has check films taken on a simulator and the patient is transferred back to the ward. The dosage distribution is calculated and the appropriate isotope is manually loaded from a storage safe and placed in the patient for the duration of treatment. Low dose rate irradiation is given and the treatment time may vary from 24 hours or less to six days or more, at which time it is removed from the tubes and placed manually into the radioactive storage safe. During the period of treatment the patients always have radioactive isotopes present in their bodies and medical, nursing and other staff and visitors to the ward are exposed to irradiation, albeit in small doses (see later).

The technique of manual afterloading in the treatment of gynaecological malignancy is currently undertaken in approximately half of the facilities in Australia which treat gynaecological malignancies with brachytherapy.

• Automatic Afterloading

— Low Dose Rate

With this method the hollow tubes and devices are positioned as for the manual afterloading method described above. However, special adaptations connect these tubes to a remote storage safe from which the isotopes are transported in the tubes by the activation of a pneumatic or filament fibre drive attached to the source. The isotope is maintained within the patient whilst the patient is alone, but when there is a requirement for someone to enter the patient's room, the interlocks automatically withdraw the isotope from the patient and return it to a safe position within the remote safe.

This technique obviously affords the greatest protection for staff and visitors virtually eliminating exposure to everyone except the patient. It has also been suggested that as this method virtually eliminates exposure to nursing staff, patients receiving this treatment are more likely to receive greater nursing care than where the sources are permanently in the patient as occurs with manual afterloading techniques.

— High Dose Rate

This technique has been used most widely for the treatment of gynaecological malignancies, although there is obvious application to other tumours, such as endobronchial and oesophageal carcinomas. The hollow tubes are likewise attached to a remote radioactive storage safe and high activity sources, generally of cobalt or iridium, are used. In general this involves multiple treatments of short duration (up to 20 minutes) although this is not always the case, but due to the high dose rate these machines require housing of the patient in a specialised room of heavier construction for shielding than applied for low dose rate and low intensity sources.

Appendix 2: Automatic afterloading in brachytherapy: occupational dose reduction (comments from the Australian Radiation Laboratory)

There are few comparative studies that clearly demonstrate the effects of changing methodology in brachytherapy procedures insofar as exposure of staff is minimised. A recent study⁽⁵⁾ of occupational doses at the Royal Marsden Hospital over the past 15 years, showed that, for Cs137 treatments, the typical total dose to all those involved in the delivery of a treatment had decreased from as much as 600 person. μ Sv for older traditional and manual preloading techniques to less than 250 person. μ Sv for manual afterloading methods and, more recently, to around 20 person. μ Sv as automatic, remote afterloading equipment was introduced. Ward nurses were found to receive more than 85% of the dose in the case of manual afterloading (200 person. μ Sv), but only 50% when using automatic afterloading (10 person. μ Sv). Radiotherapists received no dose in the latter case.

An ARL report⁽⁸⁾ gave estimates for the year 1978, of occupational doses monitored through our Personal Monitoring Service. In that year, nurses attending patients with sealed sources in situ received mean weekly dose equivalents of between 140 and 400 μ Sv. At that time in this country, it was likely that most of the procedures contributing to these doses would have involved manual afterloading or traditional techniques, which would be consistent with the Royal Marsden study. The total annual collective dose equivalent in 1978 for the above occupation category monitored by the PMS, was close to 1 person.Sv (100 person.REM) corresponding to an individual average annual dose equivalent of about 4.4 mSv. This figure agrees with other estimates of doses to nursing staff from manual afterloading treatments^(9,10).

A recent analysis of the PMS database showed that the current figure for the total annual collective dose equivalent for attending nurses in brachytherapy, is approximately 80 person.mSv and the individual average annual dose equivalent is 900 μ Sv. Because the services does not cover all states uniformly, it is estimated that the figures represent half to two-thirds of the dose to the Australian population from occupational exposure resulting from these procedures. Including radiotherapists in brachytherapy, for whom the annual collective dose received in manual afterloading treatments would appear from the ARL data to be less than 10% of that received by the nursing staff, the total annual collective dose could be in excess of 200 person.mSv nationally.

What appears to have happened in the intervening decade, is that various factors, including the introduction of automatic remote handling equipment, have affected the dose to brachytherapy staff, not only by reducing individual exposures but also by roughly halving the number of nursing staff receiving measurable doses. Radium treatments were largely discontinued by 1980. The risk factor for radiation induced fatal cancer has been estimated to be about $4.5 \times 10^{-2} \text{ Sv}^{-1}$ ⁽¹¹⁾. This gives the current likely induction rate of around 10^{-2} occupational cancers in brachytherapy staff throughout Australia annually.

A reasonable perspective might be to consider that a typical dose to staff from manual afterloading could be around 250 person. μ Sv per treatment⁽⁵⁾ and that most of this could be saved by the use of automatic remote afterloading. Assuming a patient throughput of up to 3 per week per machine, the installation of an automatic afterloading machine could result in the saving of as much as 40 person. mSv annually, which represents 1.8×10^{-3} fatal cancers per year. If the capital cost is of the order of \$300,000 with a machine life of roughly 10 years, then the effective cost to prevent one occupational cancer death could be as much as \$17,000,000. For the occupational annual induction rate of 10^{-2} noted above, we would need to spend \$1.7m over the ten years, or \$170,000 per year, equivalent to roughly five machines.

It is possible to use cost-benefit concepts suggested by the ICRP⁽¹²⁾ from which on the basis of Australia's GNP, it might be considered reasonable to spend between \$10,000 and \$20,000 a year to reduce the occupational risk from the present annual level. This estimate involves factors that are subject to review which might increase the estimate by two or three times. However, it would seem that there is not strong justification, on occupational grounds, for many more automatic afterloading machines to be installed at the present time, and other cheaper ways should be sought to improve staff protection from radiation. This presumes that the need for brachytherapy treatment in this country does not increase and that treatments remain limited generally to low dose sources (less than 10 GBq, although source strengths up to 20 GBq are not uncommon in low dose automatic systems). It is possible that demand will grow, with a need for more staff or for stronger sources that permit shorter treatment times.

In manual afterloading treatments exceeding 24 hours, corrections can be made reasonably accurately to patient doses, for source loading and retrieval times which can be as much as 1-2 hours. For decreasing treatment times the uncertainty would become increasingly unacceptable and, with increasing source strengths, automatic systems would have to be introduced. Remote afterloading machines are essential for high dose delivery systems (sources of the order of 100 GBq), and other factors will contribute to the cost of dose reduction in such treatments.

There is probably a need for closely monitoring the occupational doses in this field over the next few years. The change in the last ten years has been complex with the effects of staff movements and procedural changes hard to interpret from the data. Questions regarding the diversity of brachytherapy treatments and other aspects of the field, which affect the degree that automation can be applied could not be addressed but would be worthy of more detailed study. Furthermore, the estimation of a reasonable expenditure for the reduction of the radiation detriment should be fully evaluated for Australian circumstances and attitudes.

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