

Use of Continuous Infusion Pumps During Radiation Treatment

Recommendation Report

A special project developed by the Radiation Treatment Program, Nursing and Psychosocial Oncology Program, and Systemic Treatment Program of Cancer Care Ontario for circulation to Regional Cancer Programs.

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ISSUE

Radiation/electromagnetic interference (EMI) may adversely affect the operation of electronic infusion pumps during the delivery of radiation treatment and compromise patient care. It is important to provide recommendations for clinical practice regarding this issue.

ISSUE SUMMARY

Cancer treatment is highly complex, requires collaboration among a variety of health care professionals and utilizes a number of sophisticated treatment methods and devices. With this increasing trend toward multimodality treatment and concurrent chemoradiation therapy protocols, there is likely to be an increased incidence of patients undergoing radiation treatment while simultaneously receiving continuous infusion chemotherapy. However, there is limited published information regarding the effects of radiation on ambulatory chemotherapy infusion pumps as well as what should be done to reduce the risks to patients.

The purpose of this document is to heighten awareness of this issue within the clinical community, provide considerations for minimizing possible negative effects on patient care, avoiding potential corruption of the memory chip, avoiding potential infusion errors and to encourage the monitoring of infusion devices after exposure to radiation/ EMI. The recommendations included in this report are intended to serve as suggested points of consideration in the development of institution-specific policies and procedures. Please note that this document may also have relevance to electronic infusion pumps used to deliver non-chemotherapy agents, such as insulin, analgesics and other agents though they are not specifically addressed in this document.

METHODS

Questions raised through Cancer Care Ontario (CCO) clinical discussion forums suggest variability in practice and a lack of consensus around an appropriate approach across the province. The scope of this document is to address patient safety issues and to provide advice on reducing the risks related to the effect of radiation/electromagnetic interference (EMI) on infusion pumps.

The published literature was systematically searched using MEDLINE (1996-2008) and EMBASE (1980-2008) databases. The complete search strategies are included in Appendix 1 and Appendix 2. Articles pertaining to pacemakers and defibrillators were excluded since they were to be addressed in a separate document. Articles in a language other than English were also excluded, because resources were not available for their translation. Reference lists were searched for relevant articles and authors were contacted to further inquire about potential studies. In an effort to keep the document current and update the evidence base the MEDLINE (2008-2012) and EMBASE (2008-2012) databases were searched using the same search strategies (Appendix 3 and 4). However, no additional studies were identified.

An environmental scan of unpublished documents from websites of various radiation organizations was carried out and the search terms were also entered in a general Google™ search. The environmental scan utilized combinations of the following search terms: electromagnetic interference, EMI, linear accelerators, electronic pump, electronic infusion pump, infusion treatments, infusion pump, ambulatory chemotherapy, ambulatory chemotherapy infusion pump, radiation therapy, radiation and RT. The websites of the following organizations were

searched for the effects of radiation/EMI on infusion pumps (Table 1). This search was also updated in 2012, however no new information was identified.

Table 1. Environmental scan of web sites for the effects of radiation on infusion pumps.

Organizations

Australian Radiation Protection and Nuclear Safety Agency
American Society for Therapeutic Radiology and Oncology (ASTRO)
American Society of Clinical Oncology (ASCO)
American Association of Physicists in Medicine (AAPM)
American College of Radiation Oncology (ACRO)
Canadian Association of Radiation Oncology (CARO)
Health Canada
U.S. Food and Drug Administration (FDA)
Medicines and Healthcare products Regulatory Agency (MHRA)
Association for the Advancement of Medical Instrumentation (AAMI)
ECRI Institute
Healthcare Products Regulatory Agency (HPRA)

The compiled evidence was reviewed by a multidisciplinary working group, which included representation from oncology nursing, radiation oncology, radiation therapy, medical physics, pharmacy and medical oncology. The group met through in-person meetings and used e-mail as the main vehicle of communication. Differences were resolved through consensus and the use of evidence that informs this document.

A draft copy of this recommendation report was reviewed by a multidisciplinary external review panel which included representation from nursing, radiation oncology, radiation therapy, medical oncology, and medical physics (See Appendix 5 for more information on this process).

RESULTS

The systematic search of the literature identified 152 citations; following title and abstract screening three articles were deemed relevant for inclusion. Two additional articles were identified from the reference lists, however after full text review one was excluded since it was not related to radiation oncology. Of the four included articles two were case reports (1, 2), one was an expert consensus report (3) and one was a hazard report (4). Three manufacturer device alerts were identified in the environmental scan (5-7). An additional article was suggested by a member of the external review panel and considered relevant for inclusion (8).

In 1999 Lacerna *et al.* (1) examined the effects of megavoltage radiation exposure on two new ambulatory infusion pumps. The first pump received gradually increasing doses of radiation and its complete malfunction was attributed to exposure from a single dose of 20 Gy. The cumulative dose for the first pump was 38 Gy. Based on these results, the second pump received 20 Gy of radiation in one setting followed by 2 Gy per dose until complete malfunction at a total cumulative dose of 42 Gy. Additionally, in the second pump the flow rate of chemotherapy was temporarily decreased by 25% prior to malfunction without the pump exhibiting any abnormalities. These findings suggest that cumulative radiation exposure is a key factor in semiconductor damage and the authors caution that even after the pump is removed from direct radiation it can accumulate enough radiation for complete failure to occur during the treatment of fewer than 20 patients. The authors point out that completely disconnecting the pump and removing it from the radiation field (i.e. keeping the pump outside the treatment room) would eliminate the risk of radiation damage; however this may not be practical for routine purposes.

More recently Wu and Wang (2) reported a single case description of a radiation induced malfunction of an implanted programmable intrathecal pump. The intrathecal pump was located

directly over the patient's sarcoma therefore shielding during the course of radiotherapy was not feasible without incurring the risk of tumour under-dosing. Due to the patient's condition relocation of the pump was not possible; instead the pump was turned off prior to the start of treatment. The patient received a total dose of 50.4 Gy (daily dose of 1.8 Gy) using tomotherapy and 6 MV photons. The intrathecal pump began to alarm, with a constant soft beeping, after 20 treatments (the estimated cumulative dose was in the range of 28.5 to 36 Gy). The alarm could not be stopped and lasted for four days, ceasing spontaneously and without intervention. The patient was closely monitored during this time and successfully completed the remaining course of treatment. Technical analysis of the pump indicated that the battery was completely depleted and that the electronic circuit was damaged which may have caused the alarm to sound. Wu and Wang called for additional studies on the radiation dose-damage relationship and highlight the importance of direct communication between the radiation oncologist and the pain management specialist prior to the start of treatment. The report offers the following recommendations to minimize the likelihood of pump malfunction:

- 1) *Adequate shielding.* Shielding requirements for the pump need careful consideration since they may vary based on the radiation technique used (megavoltage, electron or orthovoltage). For instance, lead shielding may not be sufficient when using megavoltage radiotherapy due to its powerful tissue penetration.
- 2) *Radiation exposure minimization.* Measurements of the radiation dose to the pump should be performed for accurate dose estimation on the first day of treatment.
- 3) *Relocation.* If situated directly in the radiation field, pump relocation should be considered. Additionally, the radiation source should be moved as far as possible from the pump.
- 4) *Switching the pump off during the course of treatment.* The pump medication can be replaced with normal saline and the patient can be started on equivalent doses of oral medications before radiation treatment.

In a multidisciplinary expert consensus report on the use of intrathecal therapy for cancer pain management Stearns *et al.* (3) suggest that placing the pump near the radiation field may result in decreased battery life of the implant system while complete battery drain or electric failure may occur if the pump is placed directly in the field. The authors recommend moving the radiation source, shielding with lead, and relocation to minimizing exposure. Additionally, they suggest that pump placement location should be planned in advance to avoid future radiation fields.

In 2001, the ECRI Health Devices periodical published a hazard report (4) discussing multiple incidents of Baxter Colleague infusion pumps malfunctioning during the course of radiotherapy using linear accelerators. In each case, the alarms sounded and the pump stopped working during the course of treatment. The pumps had to be turned off and re-set to silence the alarm. The number of incidents or the treatment dose is not specified in the report. The cause of pump failure was not determined, however it is speculated that the malfunction can be attributed to EMI from the linear accelerators. The report cautions that effects of EMI on medical devices are unpredictable, and the potential to cause an infusion pump to increase its infusion rate cannot be ignored. Testing the device's ability to resist EMI from a linear accelerator is suggested. The report states that facilities intending to use electronic devices in the proximity of a linear accelerator should adhere to the following recommendations:

For any type of electronic device:

1. Alert radiation therapy personnel to the possibility that any electronic device might fail during treatment.
2. Do not operate any electronic device during radiotherapy treatment before testing the compatibility of the device with the linear accelerator.

3. Do not use any device during radiotherapy that is adversely affected by EMI from the linear accelerator. Note: that the device can still be in the room and attached to the patient, but must be switched off.
4. When any device fails during radiotherapy, test it thoroughly before returning it to service.

For infusion pumps in particular:

1. Alert any patient requiring the use of an infusion pump during radiotherapy about the possibility of the pump's alarming during treatment.
2. Review the necessity of using an infusion pump during a radiotherapy treatment session. If a pump is necessary, try the following solutions:
 - a. Attempt to position the pump so it is unaffected by EMI. The position should be identified through initial compatibility testing performed without a patient being connected.
 - b. Try enclosing the pump in suitably designed electromagnetic shielding and/or filters.

The three documents located in the environmental scan (5-7) were device alerts from manufacturers, directly related to the malfunction described in the hazard report (4) above. In 2006 and again in 2007 Baxter Corporation issued communications providing additional information regarding the use of Colleague Volumetric Infusion pumps in linear accelerator radiation suites. These safety alert letters stated that Baxter had evaluated the malfunction, and attributes it to the corruption of the memory chip due to radiation exposure, and will be implementing changes that will significantly reduce the likelihood of this malfunction. The nature of the changes was not indicated. The communication also stated that since the potential for corruption cannot be entirely eliminated Baxter had altered the operator's manual to recommend against the use of the pump in linear accelerator suites. In 2010 the FDA ordered a recall of all Baxter Colleague Volumetric Infusion Pumps due to the company's longstanding failure to correct the numerous problems with the pumps (7).

As cited in Wilkinson *et al.* (8), Baumann *et al.* reported on the potential for thermal neutrons to cause soft errors (an error in a signal or datum which is wrong) in integrated circuits by way of interacting with the isotope boron-10, which is found in the lower intermetal dielectric layers of electronics' integrated circuits. Building upon this work, Wilkinson *et al.* examined the potential for soft errors in electronics operating in the vicinity of linear accelerators since high-energy radiotherapy creates an undesirable flux of neutrons. The authors positioned 10 static random-access memory (SRAM) devices known to be sensitive to thermal-neutron-induced soft errors approximately 50 cm from the isocenter of the linear accelerator's beam. Each device was alternately exposed in the following conditions: 1) without shielding; 2) with shielding from EMI; 3) with shielding from thermal neutrons; and 4) while held outside the treatment room as a control. A total of four soft errors were detected, three from the unshielded devices and one from an EMI-shielded device. It was noted that no errors were detected when the devices were shielded from thermal neutrons or held outside the treatment room. During the exposures, a larger capacity SRAM device was positioned 50 cm off axis and continuously monitored. During 10 minutes of exposure a total of 89 errors were recorded on this device. The authors also examined 14 electronic devices that might be typically found near linear accelerators and determined that all of the devices contained boron-10. Their findings suggest that many integrated circuits used in electronics typically found in radiotherapy settings contain boron-10 compounds and that a radiotherapy linear accelerator causes a high rate of soft errors in electronics which contain this compound.

DISCUSSION

The recommendations put forth in the documents summarized in the previous section are similar to the opinions of the working group. However some discussion arose around the

recommendation to switch patients from the pump to oral treatment, presented by Wu and Wang (2). Under many circumstances this recommendation is not practical or easy to carry out, particularly when the patient is receiving one or two doses. Additionally switching patients to oral treatment would not be feasible for analgesics and other medications with a narrow therapeutic index. In many cases, intravenous chemotherapy cannot be substituted by oral doses.

The group also pointed out that the recommendation found in the hazard report, suggesting to simply switch off the device is not a sufficient precaution and would not limit the potential damage to the pump.

RECOMMENDATIONS FOR CLINICAL PRACTICE

The following considerations for clinical practice are derived from a limited evidentiary base and have been supplemented with consensus of the working group. The working group recommends that the following considerations be taken into account in the development of institution-specific policies and procedures.

1. Radiation treatment personnel should be responsible for identifying patients that have infusion pumps at the time of treatment and communicating such information with the other individuals involved in the patients' care.
2. If practical, patients receiving infusional treatments should be disconnected from electronic infusion pumps prior to receiving radiation therapy and reconnected once radiation treatment is completed for each session. While a patient is receiving radiation therapy the electronic infusion pump should be kept outside the treatment room. If the patient cannot be disconnected from the electronic infusion pump for medical reasons, low-energy radiation should be employed (i.e. <8MV x-rays) to avoid the risk of exposing the pump to neutrons, and the pump should be placed out of the direct radiation beam and as far away as possible.
3. Given that Registered nurses, or individuals with equivalent knowledge and training, have the clinical competencies related to intravenous line management (either peripheral or central), infusion pumps should only be managed by said personnel.
4. If there is a need for decision to provide a bolus dose of medication prior to radiation treatment, such as pain medication, a physician order is required; and only a Registered nurse who is managing that patient should deliver the bolus dose.
5. If practical, Elastomeric Pumps, which are not known to be affected by radiation/EMI since they do not contain electronic parts, should be used.
6. All infusion pumps exposed to radiation/EMI anywhere inside the treatment room should be assessed by a Registered nurse, or individual with equivalent knowledge and training, to ensure proper functioning after each treatment is completed. If a pump passes its 'self-test', it should be tagged to indicate the exposure date so that it can be monitored for a period of time which has been predetermined by the institution. If a pump does not pass its 'self-test' or displays an error code, the Registered nurse, or individual with equivalent knowledge and training, should ensure that the patient receives a replacement pump and send the defective pump to the Biomedical Engineering department for assessment and if necessary, repair.
7. In the case that a patient receives radiation treatment at an institution other than the one that originally connected the infusion pump, radiation treatment personnel should ensure that the original institution is aware that the infusion pump has been exposed to radiation. In the event that an infusion pump is found to be defective before the patient leaves the radiation treatment unit, radiation treatment personnel should notify the original institution of the malfunction.

It is CCO's intention to disseminate this report to the Regional Cancer Programs and advisory committees within the province and to make the document available to Ontario healthcare providers and the general public on the CCO website (www.cancercare.on.ca). This report will be reviewed every two years to determine whether the information is still accurate and relevant to current practice and revised accordingly.

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