Use of Continuous Infusion Pumps During Radiation Treatment

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Abstract

Introduction: Despite increasing chemoradiotherapy treatment, there is a paucity of information regarding the effects of radiation exposure on ambulatory infusion pumps used to deliver chemotherapy or other essential medications. The aim of this overview is to present the available evidence on this subject, heighten awareness within the clinical community, provide considerations for minimizing possible negative effects on patient care, and encourage the monitoring of infusion devices after exposure to radiation or electromagnetic interference.

Methods: Published literature was systematically searched using MEDLINE and EMBASE; gray literature was searched using Google and an environmental scan of relevant Web sites. A multidisciplinary working group reviewed the compiled evidence, and a draft of the document was sent to health professionals from various disciplines for an external review.

Results: Four reports and three manufacturer device alerts were identified that suggest a risk of pump malfunction as a result of radiation exposure. The estimated cumulative dose at which pump failure has been reported ranges from 28.5 to 42 Gy; however, additional clinical investigations should be undertaken. Pump relocation, pump shielding, and assessment of the pump after radiation exposure are most commonly suggested to minimize pump malfunction related to radiation exposure. A list of additional considerations is offered for those developing institution specific policies and procedures based on the available evidence and expert consensus.

Conclusion: The varied and unpredictable results of radiation exposure on infusion devices suggest that additional testing should be carried out to determine the limits of dose exposure and to raise awareness around this patient safety issue.

Introduction

Cancer treatment is highly complex, requires collaboration among a variety of health care professionals, and utilizes a number of sophisticated treatment methods and devices. Furthermore, increasing multimodality treatment and concurrent chemoradiotherapy protocols result in a greater incidence of patients undergoing radiation treatment while receiving continuous infusion chemotherapy. Unfortunately, there is a paucity of published information regarding the effects of radiation on ambulatory chemotherapy infusion pumps and, conversely, the steps that should be taken to reduce patient risk. Questions raised through Cancer Care Ontario's (CCO's) clinical discussion forums suggest variability in practice and a lack of consensus around appropriate approaches. CCO is a provincial agency that oversees cancer services in Ontario.

The purpose of this overview is to describe the available evidence on the effects of radiation on ambulatory infusion pumps used to deliver chemotherapy, heighten awareness of this issue within the clinical community, provide considerations for minimizing possible negative effects on patient care, and encourage the monitoring of infusion devices after exposure to radiation/electromagnetic interference (EMI). The recommendations are intended to serve as points of consideration in the development of institution-specific policies and procedures. This overview may also have relevance to electronic in-

fusion pumps used to deliver nonchemotherapy agents, such as insulin, analgesics, and other agents, though they are not specifically addressed in this article.

Methods

Literature Search and Environmental Scan

The published literature was systematically searched using the MEDLINE (1996-2012) and EMBASE (1980-2012) databases, using combinations of the following search terms: electromagnetic interference, EMI, linear accelerators, electronic pump, infusion pump, radiation, and irradiation. Reference lists were searched for relevant articles, and authors were contacted to further inquire about potential studies. Articles pertaining to pacemakers and defibrillators were excluded because they were to be addressed in a separate article. Articles in a language other than English were excluded because resources were not available for their translation.

A general Google search, using the terms listed above, and an environmental scan of various relevant Web sites were also undertaken to identify unpublished documents. The following Web sites were searched: Australian Radiation Protection and Nuclear Safety Agency, American Society for Therapeutic Radiology and Oncology, ASCO, American Association of Physicists in Medicine, American College of Radiation Oncology, Canadian Association of Radiation Oncology, Health Canada,

US Food and Drug Administration (FDA), Medicines and Healthcare products Regulatory Agency, Association for the Advancement of Medical Instrumentation, and ECRI Institute and Healthcare Products Regulatory Agency.

Working Group and External Review

The compiled evidence was reviewed by a multidisciplinary working group at CCO, which included representation from oncology nursing, medical oncology, radiation oncology, radiation therapy, medical physics, and pharmacy. The group met through in-person meetings and used e-mail as the main vehicle of communication. Differences were resolved through consensus. A penultimate draft of the document was sent to 18 health professionals from the disciplines of radiation treatment, systemic treatment, nursing, and medical physics for an external review. Nine individuals provided feedback regarding the content and recommendations; two of the respondents indicated that they each had shared the document with colleagues, bringing the total number of respondents to 14. Of the 14 external reviewers, four approved the report as written, and 10 provided comments and suggested revisions. The working group reviewed and discussed all collected feedback, making changes to the document where appropriate.

Results

The systematic search of the literature identified 152 citations; after title and abstract screening, three articles were deemed relevant for inclusion. Two additional articles were identified from reference lists; however, after full text review one was excluded because 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 Table 1 provides an overview of the four articles. Three manufacturer device alerts were identified in the environmental scan.⁵⁻⁷

Lacerna et al¹ 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 38.6 Gy. 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. In addition, in the second pump, the flow rate of chemotherapy was temporarily decreased by 25% before malfunction without the pump exhibiting any abnormalities. Cumulative radiation exposure seems to be 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 (ie, keeping the pump outside the treatment room) would eliminate the risk of radiation damage; however, this may not be practical for clinical purposes.

Wu and Wang² reported 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 tumor underdosing. As a result of the patient's condition, relocation of the pump was not possible; instead, the pump was turned off before 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 4 days, ceasing spontaneously and without intervention. The patient was closely monitored 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 highlighted the importance of direct communication between the radiation oncologist and the pain management specialist before the start of treatment. Wu and Wang² offer the following recommendations to minimize the likelihood of pump malfunction:

Adequate shielding: Shielding requirements for the pump need careful consideration because they may vary on the basis of radiation technique used (megavoltage, electron, or orthovoltage). For instance, lead shielding may not be sufficient when using megavoltage radiotherapy as a result of its powerful tissue penetration.

Radiation exposure minimization: Measurements of the radiation dose to the pump should be performed for accurate dose estimation on the first day of treatment.

Relocation: If the pump is situated directly in the radiation field, relocation should be considered. In addition, the radiation source should be moved as far as possible from the pump.

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 dose of oral medications before radiation treatment.

In a multidisciplinary expert consensus report on the use of intrathecal therapy for cancer pain management, Stearns et al³ suggested that placing the pump near the radiation field may result in decreased battery life of the implant system, and 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 minimize exposure. In addition, pump placement location should be planned in advance to avoid future radiation fields.

In 2001, the ECRI Health Devices periodical published a hazard report⁴ 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 reset to silence the alarm. The number of incidents or the treatment dose were not specified in the report. The cause of pump failure was not determined; however, it is speculated that the malfunction can

Table 1. Overview of Study Characteristics

Author	Year	Country	Study Type	Pump	Radiation	Pump Failure
Lacerna et al ¹	1999	USA	Case report	Two ambulatory chemotherapy pumps (SIMS Deltec model 5400)	Pump 1: gradually increasing doses; Pump 2: single large dose of 20 Gy followed by smaller doses of 2 Gy	Pump 1: cumulative dose of 38.6 Gy after individual dose of 20 Gy; Pump 2: malfunctioned at doses of 40-42 Gy
Wu and Wang ²	2007	USA	Case report	Implanted, programmable, IT baclofen/morphine pump (SynchroMed)	A total dose of 50.4 Gy (daily dose of 1.8 Gy for 28 treatments)	Occurred after 20 daily treatments, at an estimated cumulative dose ranging from 28.5 to 36 Gy
Stearns et al ³	2005	USA	Consensus report	Programmable pumps	N/A	N/A
ECRI Institute ⁴	2001	USA	Hazard report	Baxter Colleague infusion pumps (both single-channel and multichannel models)	N/A	Failed during radiotherapy treatments, multiple alarms sounded, and the pump stopped

Abbreviations: IT, intrathecal; N/A, not available.

Table 2. ECRI Institute Recommendations⁴

For Any Type of Electronic Device	For Infusion Pumps in Particular
1. Alert radiation therapy personnel to the possibility that any electronic device might fail during treatment.	1. Alert any patient requiring the use of an infusion pump during radiotherapy about the possibility of the pump's alarm sounding during treatment.
2. Do not operate any electronic device during radiotherapy treatment before testing the compatibility of the device with the linear accelerator.	2. Review the necessity of using an infusion pump during a radiotherapy treatment session. If a pump is necessary, try the following solutions:
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.	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.
4. When any device fails during radiotherapy, test it thoroughly before returning it to service.	b. Try enclosing the pump in suitably designed electromagnetic shielding and/or filters.

Abbreviation: EMI, electromagnetic interference.

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. Table 2 outlines the suggested ECRI recommendations for facilities intending to use electronic devices in the proximity of a linear accelerator.

The documents located in the environmental scan⁵⁻⁷ were device alerts from manufacturers, directly related to the malfunction described in the hazard report⁴ 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 alerts stated that Baxter had evaluated the malfunction and attributed it to the corruption of the memory chip as a result of radiation exposure. Baxter stated that they will implement changes that will significantly reduce the likelihood of this malfunction occurring again; however, the nature of the changes was not indicated. Because the potential for corruption cannot be entirely eliminated, Baxter altered the operator's manual to recommend against the use of pumps 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 A scan of infusion pump manufacturer manuals (Table 3) indicates that when recommendations are listed, they most often suggest that radiation exposure should be avoided by either removing or shielding the pump.

Discussion

The findings of this overview suggest that there is a risk of infusion pump malfunction as a result of radiation exposure. The estimated cumulative dose at which pump failure has been reported ranges from 28.5 to 42 Gy; however, additional clinical investigations need to be undertaken to confirm this finding. To minimize radiation exposure to the pump, the authors suggest pump relocation,¹⁻⁴ pump shielding,²⁻⁴ and full disconnection of the pump.^{1,2} Assessment of the pump after radiation exposure is also encouraged.^{1,4} It is recognized that in many cases pump shielding is difficult, if not impossible; it should be attempted, however, if all the other options outlined have been exhausted.

It is evident that despite increased multimodality treatment in cancer care, there is limited information regarding the impact of radiation on ambulatory infusion pumps to deliver chemotherapy. Although there are recent reports on infusion devices, both from the US^{8,9} and the United Kingdom¹⁰ that offer advice on the appropriate pump use and reduction of adverse events, these reports do not make any references to the effects of radiation.

Although Wilkinson et al¹¹ did not specifically report on infusion pumps, the findings of their study may shed some light on the types of errors caused by radiation exposure. The authors examined the potential for soft errors (an error in a signal or datum) in electronics operating in the vicinity of linear accelerators, as high-energy radiotherapy creates an undesirable flux of neutrons. The authors positioned 10 static random-access

Table 3. Summary of Infusion Pump Manufacturer Recommendations With Regard to Radiation Exposure

Pump/Link to Manual	Recommendation/Warning for Radiation Exposure
CADD-Prizm ambulatory infusion pump models 6100 and 6101 http://www.smiths-medical.com/upload/products/pdf/cadd_prizm_vip_system/in19824.pdf	1. Introduction: The pump should not be directly irradiated by therapeutic levels of ionizing radiation because of the risk of permanent damage to the pump's electronic circuitry. The best procedure to follow is to remove the pump from the patient during therapeutic radiation sessions or diagnostic levels of radiographic and fluoroscopic radiation. If the pump must remain in the vicinity during a diagnostic or therapy session, it should be shielded, and its ability to function properly should be confirmed following treatment.
Sychromed Isomed implantable infusion system http://professional.medtronic.com/wcm/groups/mdtcom_sg/mdt@neuro/documents/documents/pump-ifp-sync2iso.pdf	Radiation therapy: Do not direct high radiation sources such as cobalt 60 or gamma radiation at the pump. If radiation therapy is required near the pump, place lead shielding over the pump to help prevent radiation damage.
EUREKA IP and LF infusion pumps http://www.umtinc.com/manual.pdf	4.3 Pump exposure to radiation: Pump should not be subjected to direct irradiation. Exposure risks permanent damage to the pump electronic circuitry. It is recommended that pump not be in use and be removed during radiation treatments. In the event that the pump use not be discontinued then it should be shielded and following treatment it should be checked for proper function.
Paradigm infusion pump model MMT-511 http://www.childrenwithdiabetes.com/pumps/pdf/paradigm.pdf	Chapter 10: If you are going to have an x-ray, CT scan, MRI, or any other type of radiation therapy, take your pump and remote control off, and remove them from the treatment area.
Plum A+ Volumetric Infusion System http://www.elitemedicalmall.com/manuals/Abbott-Plum-A+-Op-Manual.pdf	7.1 Cleaning, maintenance, and storage: Caution: Do not sterilize by heat, steam, ethylene oxide, or radiation.
4000 Plus and 4000 CMS Ambulatory Infusion Systems http://www.ardusmedical.com/manuals/Curlin-4000-User-Manual.pdf	None listed
Model 500 and Micro 505 Volumetric Infusion Pump http://isurplus.com.au/manuals/Graseby%20,500%20&%203000%20Infusion%20Pump%20User%20Manual.pdf	None listed
Flo-Gard 6201 Volumetric Infusion Pump http://www.meql.com/Manuals/Baxter-6201-Operators-Manual.pdf	None listed

Abbreviations: CT, computed tomography; MRI, magnetic resonance imaging.

memory (SRAM) devices known to be sensitive to thermal-neutron-induced soft errors approximately 50 cm from the iso-center of the linear accelerator's beam. Each device was alternately exposed in the following conditions: (1) without EMI shielding, (2) with EMI shielding, (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 radiotherapy linear accelerators cause a high rate of soft errors in electronics that contain this compound.

Cumulative radiation exposure was also highlighted as a key factor in pump malfunction by Lacerna et al,¹ which may suggest that other sources of radiation, such as computed tomography scans, may need to be taken into consideration. In fact, in 2008, the FDA released a health notification surrounding the possible malfunction of electronic medical devices caused by x-rays used during computed tomography examinations.¹² The varied and unpredictable results described in this overview suggest that additional testing is needed, not only to determine the

limits of dose exposure but also to raise awareness around this safety issue.

Conclusion and Considerations for Clinical Practice

The following considerations for clinical practice are derived from a limited evidentiary base and have been supplemented with expert consensus. The recommendations are in keeping with those presented by the authors above, with the exception of the recommendation suggested by Wu and Wang² to switch patients from the pump to oral treatment. Under many circumstances, this is not practical or easy to carry out, particularly when the patient is receiving one or two doses. In addition, 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 with oral doses. Likewise, the recommendation found in the hazard report,⁴ suggesting to simply switch off the device, is not a sufficient precaution and would not limit the potential damage to the pump.

The following considerations should be taken into account in the development of institution-specific policies and procedures:

1. Radiation treatment personnel should be responsible for identifying patients who have infusion pumps at the time of treatment and communicating such information with the other professionals involved in the patients' care.
2. If practical, patients receiving infusional treatments should be disconnected from electronic infusion pumps before 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 used (ie, < 8 MV 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 be managed only by said personnel.
4. If there is a need for decisions to provide a bolus dose of medication before radiation treatment, such as pain medication, a physician order is required, and only a registered nurse who is treating that patient should deliver the bolus dose.
5. If practical, elastomeric pumps, which are not known to be affected by radiation or EMI because they do not contain electronic parts, should be used.
6. All infusion pumps exposed to radiation or 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 that 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 should 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.

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References

1. Lacerna MD, Sharpe MB, Robertson JM: The effect of radiation on an ambulatory chemotherapy infusion pump. *Cancer* 86:2150-2153, 1999
2. Wu H, Wang D: Radiation-induced alarm and failure of an implanted programmable intrathecal pump. *Clin J Pain* 23:826-828, 2007
3. Stearns L, Boortz-Marx R, Du Pen S, et al: Intrathecal drug delivery for the management of cancer pain: A multidisciplinary consensus of best clinical practices. *J Support Oncol* 3:399-408, 2005
4. ECRI Institute: Electromagnetic interference from linear accelerators can affect electronic devices. *Health Devices* 30:259-262, 2001
5. Baxter Healthcare Corporation: Safety alert, 2006. http://www.baxter.com/downloads/information/safety_information/colleague/colleague_linear_letter_12_6_06.pdf
6. ECRI Institute: PA-PSRS patient safety advisory. Baxter Colleague volumetric infusion pump: Product recall notifications. Patient Safety Authority 4:11-15, 2007. https://www.ecri.org/Documents/PA_PSRS/2007.03_Advisory.pdf
7. US Food and Drug Administration: News release -FDA issues statement on Baxter's recall of Colleague infusion pumps, 2010. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm210664.htm>
8. Association for the Advancement of Medical Instrumentation: Infusing patients safely: Priority issues from the AAMI/FDA Infusion Device Summit, 2010. http://www.aami.org/htsi/infusion/summit/AAMI_FDA_Summit_Report.pdf
9. US Food and Drug Administration: Medical devices. White Paper: Infusion Pump Improvement Initiative, 2010. <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/UCM206189.pdf>
10. Medicines and Healthcare Products Regulatory Agency: Device Bulletin: Infusion systems. DB2003(02) v2.0, 2010. <http://www.mhra.gov.uk/home/groups/dts-iac/documents/publication/con007322.pdf>
11. Wilkinson JD, Bounds C, Brown T: Cancer-radiotherapy equipment as a cause of soft errors in electronic equipment. *IEEE Trans Device Materials Reliab* 5:449-451, 2005
12. US Food and Drug Administration: Preliminary public health notification: Possible malfunction of electronic medical devices caused by computed tomography (CT) scanning, 2008. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061994.htm>