Evaluating insulin pump functionality during ionising radiation exposure

Clare Alexandra Whicher1
MBBS, MRCP, Clinical Academic Research Fellow

Malik Humayun2
MRCP, Consultant Diabetologist

Emma Jenkins3
BSc (Hons) Nutrition and Dietetics, RD, Diabetes Dietitian

Michael Brooks3
PhD, MIFEM, Head of Diagnostic Radiology Physics

Matthew Benbow3
MSc, DCR, Superintendent Radiographer CT & MRI

Chris Critoph3
BM, MRCP, MD (Res), Consultant Cardiologist

Helen Partridge3
BSc (Hons), MRCP, Consultant Diabetologist

1Southern Health NHS Foundation Trust, Southampton, UK
2Milton Keynes University Hospital, Milton Keynes, UK
3Royal Bournemouth Hospital, Bournemouth, UK
4Poole General Hospital, Poole, UK

Correspondence to:
Clare Alexandra Whicher, Research and Development Department, Moorgreen Hospital, Botley Road, Southampton SO30 3JB, UK; email: clare.whicher@southernhealth.nhs.uk

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Abstract
Concerns exist about the safety of ionising radiation on the components of insulin pumps and whether these will induce electronic failure or dysfunction. We therefore subjected six insulin pumps to two radiation exposure protocols; firstly in the cardiac catheterisation laboratory and subsequently computerised tomography scanning.

The pumps were downloaded and functionality was monitored for four weeks after exposure. All pumps continued to work appropriately with no demonstrated loss of functionality, loss of bolus or basal delivery and no evidence of pump failure. Due to the nature of the method of this study we were unable to assess the accuracy of insulin dosing. From our experience the probability of pump dysfunction being caused by radiation exposure seems unlikely but we would recommend close monitoring of blood glucose measurements before and after scanning. Copyright © 2017 John Wiley & Sons.

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Key words
insulin pump; radiology; radiation; safety

Background
Around 6% of adults in the UK with type 1 diabetes wear an insulin pump.1 The national Insulin Pump Audit published in May 2013 suggested that just over 18 000 people with diabetes in the UK are using an insulin pump. With an increasing use of this technology around the world there is likely to be a rising number of pump users undergoing diagnostic and therapeutic procedures involving ionising radiation exposure. There are currently concerns about the safety of ionising radiation on the electronic components of insulin pumps and whether exposure will induce electronic failure or dysfunction.2

The effects of radiation on insulin pumps have not been studied in a computational phantom model by any of the manufacturers. These are models of the human body that have been used by the radiological science community for ionising radiation dosimetry studies. Many insulin pump manufacturers, therefore, recommend that patients should not expose the pump to X-rays at all.3,4

The general advice from insulin pump manufacturers is to remove the pump and leave it outside the room during any X-ray examinations. This can be particularly challenging during longer procedures such as coronary interventions and may require the use of intravenous insulin infusions.

The aim of this study was to observe the effect of a significant amount of radiation exposure on insulin pumps and whether radiation exposure, during recurrent computed tomography (CT) scanning or prolonged exposure during interventional cardiology procedures, would lead to transient or permanent insulin pump malfunction.

Study objective
The objective was to examine the effects of direct radiation exposure on insulin pump function.

Materials and methods
We subjected six insulin pumps (including Medtronic [one Veo, one 640G], Roche [one Insight, one Combo] and two Animas) to two radiation exposure protocols. Each pump was set up with a basal rate ratios and insulin sensitivity pre-programmed.

We initially exposed them all to radiation in a cardiac catheterisation laboratory over the course of one afternoon. This included six coronary angiograms, one implantable cardio-defibrillator (ICD) lead revision and one cardiac resynchronisation therapy defibrillator (CRTD) device insertion. The pumps were placed on a trolley as close to
the radiation area as possible, adjacent to the procedure table, ensuring maximum scattered radiation exposure to the pump. The pumps were kept active and running with the same basal profile and four boluses daily for four weeks after the radiation exposure. The pumps were subsequently downloaded to check for functionality monitoring basal rates, bolus delivery, software functionality and connectivity to their hand-held device or computer. (Figure 1.)

These same pumps were then exposed to primary beam CT scanning 10 times over. (Figure 2.) The pump functionality was again monitored for four weeks after the radiation exposure. Any technical problem or loss of functionality of the insulin pump was documented.

Results
In the cardiac catheterisation laboratory the insulin pumps were exposed to radiation from eight procedures. This included approximately 13000 cGycm² (six coronary angiograms) plus around 50 cGycm² (ICD) and 1000 cGycm² (CRT-D). While in the primary beam CT scanner, each pump was exposed to 120KVP 500mAs 10 times over. This is the equivalent exposure to 20 routine CT examinations such as CT brain.

All pumps continued to function appropriately with no loss of bolus or basal delivery, loss of contact (with the hand-held device with respect to the Roche pumps) and no evidence of pump failure. Due to the nature of the method of this study we were unable to assess the accuracy of insulin dosing.

Discussion
Our study has demonstrated that a significant dose of prolonged radiation exposure to insulin pumps during interventional cardiology procedures and repeated CT scanning did not cause any problem with insulin pump function.

In general, it is considered safe for patients with electronic devices to undergo CT examinations in which the device moves briefly (less than 3 seconds) through the X-ray beam as occurs in most clinical CT examinations. The problem is only thought to occur when the device is within the direct X-ray beam. This is thought to be due to radiation interacting with the electronics in the devices and producing electric currents that can cause a temporary malfunction while the device is in the X-ray beam.

Most patients with electronic medical devices, such as cardiac implantable electronic devices (pacemakers and ICD) and neurostimulators, undergo CT scans without any adverse consequences. There have been reports in the medical literature of malfunctioning of some cardiac devices following radiation exposure but not with insulin pumps.

The US Food and Drug Administration (FDA) has received a small number of case reports of both hypoglycaemic and hyperglycaemic events due to possible radiation exposure to insulin pumps. They issued a preliminary public health notification for malfunction of some implantable and wearable electronic medical devices possibly caused by CT scanning. They also stated, however, that the probability that this interference can cause clinically significant adverse events is extremely low. Their overall recommendation is that the presence of devices such as insulin pumps should not preclude the performance of an appropriate, medically indicated CT scan.

Problems are considered more likely when using single-location dynamic scanning, perfusion scanning or CT fluoroscopy directly over the device. These all prolong the time that the device is exposed to the radiation. Extra caution should be exercised when performing these procedures. Problems that occur with these devices appear to be rare and do not seem to be a threat to the health or life of the patient.

The physical hardware such as metal casings and wires are not thought to be affected by the radiation exposure. This is not the case for magnetic resonance imaging (MRI) where ferro-magnetic material within devices is strongly affected by the magnetic field. Insulin pumps must be removed and left outside the room for all MRI investigations.

Conclusion
Our experience supports the FDA statement that the presence of an insulin pump should not be seen as a contraindication for a CT scan. The probability of pump dysfunction being caused by radiation exposure seems unlikely. The clinical benefit of an appropriate investigation is likely to greatly outweigh any potential risk. In the instance of interventional radiology each case
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must be assessed individually. Pumps must be disconnected and left outside for all MRI investigations.

Many people will be reluctant to have their pump removed during investigations or cardiac procedures and we have provided evidence that insulin pumps are not adversely affected by exposure to radiation in this context. We would recommend close observation of blood glucose measurements both before and after ionising radiation exposure. This is to monitor both the potential effect of the procedure on blood glucose levels and also to ensure correct functioning of the insulin pump.

Declaration of interests
There are no conflicts of interest declared.

References