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Continuous Subcutaneous Insulin Infusion and Radiation Precautions – Practical Approach

Sistemas de Perfusão Subcutânea Contínua de Insulina e Precauções de Radiação – Abordagem Prática

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Continuous subcutaneous insulin infusion (CSII), commonly known as insulin pump therapy, has become the preferred method for managing diabetes mellitus, particularly type 1 diabetes (T1DM), with a notable rise in adoption rates globally. In Portugal, the number of insulin pump users has steadily increased from 500 patients in 2010 to approximately 3000 patients in 2018. [(1)]

T1DM has been associated with a significant reduction of life expectancy in countries like Australia and Sweden. [(2,3)] Moreover, advancements in diabetes self-management education, reliable continuous glucose monitoring, and widespread adoption of insulin and sensor-augmented pump therapy have led to a remarkable enhancement in life expectancy over recent decades. Specifically, studies indicate an average increase of 15 years in life expectancy for individuals diagnosed with T1DM in 1980 or later compared to those diagnosed in the 1960s. [(4)]

With an increasing life expectancy, there is a rising number of insulin pump patients who will undergo diagnostic and therapeutic procedures involving electromagnetic fields and ionizing radiation exposure. Radiation affects micro-electronics, by causing semiconductor damage and degradation in transistors and integrated circuits which could result in device malfunction. [(5,6)] Although insulin pump manufacturers generally advise against exposing pumps to ionizing radiation, these recommendations lack a solid foundation in published data and are largely precautionary.

Comparison can be sought with other medical devices such as implantable cardioverter-defibrillators and pacemakers. [(7)] There have been rare occurrences of radiation affecting these devices, with no reported life-threatening consequences. [(7)] Employing methods to lower the radiation exposure (either by lowering the radiation dose or the time of exposure) is prudent but to the best of our current knowledge, the risk of an adverse clinical event is remote. [(7)]

For people with diabetes (PwD) using insulin pumps, the dilemma arises during medical procedures that necessitate pump removal, as even a brief interruption can lead to significant glucose elevation and subsequent challenges in glycemic control. Although 1 hour interruption is considered safe, it is known that even a 30-minute interruption of basal insulin infusion may result in significant glucose elevation with subsequent impact of glucose control up to 3 hours after the inciting event. [(9)] This is especially true during longer procedures such as coronary interventions. [(8)] The Food and Drug Administration issued a statement in 2017 highlighting the potential interference between CT scans and insulin pumps, resulting in adverse events such as hypoglycemia and hyperglycemia. However, these events are deemed extremely rare and should not deter individuals with pumps from undergoing necessary medical imaging. [(10)]

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Another area of uncertainty lies in the use of radiopharmaceuticals (RP) for diagnostic or therapeutic interventions and their potential impact on insulin pumps. With no existing published data or official recommendations, this aspect remains a significant gap in knowledge. A radiopharmaceutical consists of a molecule specifically designed to target a particular molecular site within the body. This molecule is coupled with a radionuclide that emits radiation. The administration of these drugs typically involves systemic delivery, with the majority of uptake occurring in the target tissue of interest. In nuclear medicine, approximately 90% of radiopharmaceuticals are utilized for diagnostic purposes. [11] During diagnostic interventions, β+ particles and γ rays are commonly employed as the types of radiation emitted, targeting specific molecular sites within the body. [11,12] The body clearance of a radiopharmaceutical involves both the physical decay of the radionuclide (physical half-life) and the biological elimination of the drug (biological half-life), primarily through renal and hepatic pathways. The combination of these two mechanisms results in an effective half-life of the radiopharmaceutical. The effective half-life of a radiopharmaceutical varies according to the specific compound. PET radiopharmaceuticals isotopes typically exhibit shorter physical half-lives, which prevails over the biological half-lives, compared to those used in gamma-camera/SPECT imaging (e.g., physical half-lives of 110 minutes for 18F-FDG and 68 minutes for 68Ga-DOTA-SSA with even shorter effective half-lives if biological elimination is considered). This characteristic minimizes patient radiation exposure, as the radiopharmaceuticals only irradiate the patient until they are metabolized and eliminated. [11,12] To the best of the authors knowledge, there is no published robust data or official recommendation regarding the effect of radiation emitted from RP and its impact on insulin pumps.

While recommendations exist for managing patients requiring imaging studies [13,14] it is essential to recognize that these directives primarily rely on general precautions rather than robust, research-backed data. Our effort to enhance these recommendations, especially within the domain of nuclear medicine, involves a thorough review of studies that deliberately exposed various insulin pump models to diverse scenarios (refer to Table I). However, caution is warranted due to the limited number of pumps formally tested and variations in models.

In conclusion, CSII is a pivotal component in diabetes treatment, and its widespread adoption in ambulatory settings necessitates a closer examination of its compatibility with diagnostic and therapeutic procedures involving ionizing radiation. While recommendations currently rely on a lack of evidence rather than evidence of harm, studies exploring the impact of X-ray exposure on insulin pump functionality have shown no negative effects. Further research in this domain is imperative and will significantly impact patient care. <

Conflicts of interests/*Conflitos de interesses:*
The authors declare that they have no conflicts of interests./*Os autores declaram a inexistência de conflitos de interesses.*

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Table I - Recommendations for insulin pump during imaging studies and procedures (adapted from references 13 and 14).

Imaging study	General recommendation	Historical malfunction	Radiation dose received and Insulin pump tested.	Ref.
Cardiac catheterization	Cover pump by a lead apron.	None	NA	NA
Colonoscopy/ Endoscopy	Pump can remain in place and continue to run	None	NA	NA
CT scan and fluoroscopy	The pump should be removed if possible. If removal is not possible, a lead apron should be used for shielding.	None in this study	Exposure: 14050 cGy x cm^2 (dose-area product) + subsequent 32 mGy. Insulin pumps exposed: 1 Medtronic Veo, 1 Medtronic 640G,1 Roche Insight, 1 Roche Combo, 2 Animas .	6
		"Prime Alarm" and Darkened screen in 1 out of 4 insulin pumps Inconclusive whether the malfunction was secondary to radiation exposure	Exposure: 0.36 mGy with malfunction Insulin pumps exposed: 1 Animas Ping (no further testing was conducted). Exposure: 85.76 mGy. Insulin pumps exposed (no malfunction): 1 Animas Ping, 1 Medtronic 523, 1 Medtronic 630G.	8
		None in this study	Exposure: 0.1 mGy Insulin pumps exposed: 60 Omnipod Exposure: 16 mGy Insulin pumps exposed: 60 Omnipod Exposure: 64 mGy Insulin pumps exposed: 60 Omnipod	15
External Beam Radiotherapy	No formal recommendations. Cover pump by a lead apron and discuss with the radiation oncology group for a practical solution regarding different treatment modalities (proton, neutron, heavy ion, or magnetic resonance−guided linear accelerator)	None	NA	16
MRI	Pump and metal infusion should be removed and kept in another room.	High-risk of damaging components that monitors and controls movement of motor (e.g: over-delivery of insulin)	Electromagnetic field (not radiation)	17
Nuclear medicine diagnostic procedures: Conventional (non-CT)	No formal recommendations. If intervention is expected to benefit patient it should not be precluded.	None	NA	NA
Nuclear medicine diagnostic procedures: Hybrid (PET/CT and SPECT/CT)	No formal recommendations. The pump should be removed if possible. If removal is not possible, a lead apron should be used for shielding. If intervention is expected to benefit patient it should not be precluded.	None	NA	NA
Nuclear medicine therapeutic procedures	No formal recommendations. If intervention is expected to benefit patient it should not be precluded.	None in a single case report	Exposure: 14.8 mGy (Radioactive iodine: I-131) Insulin pumps exposed: 1 Animas Ping	18
Pacemaker/AICD placement	Cover pump by a lead apron.	None	NA	NA
Ultrasound	No need to remove pump but transducer should not be pointed directly at the pump.	None	NA	NA
X-Ray or bone density scans	The pump should be removed if possible. If removal is not possible, a lead apron should be used for shielding.	None	NA	NA

Legend: AICD: Automated implantable cardioverter defibrillator; CRT-D: Implantable cardiac resynchronization therapy; ICD: Implantable cardioverter-defibrillator; mGy: Milligray; cGy: Centigray; NA: Not available; PET/CT: Positron emission tomography/computed tomography; Ref: References; SPECT: Single-photon emission computed tomography; SPECT/CT: Single-photon emission computed tomography/computed tomography.

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