Feedback on the installation and preliminary tests of the FLASHKNiFE®, a UHDR radiotherapy system

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Résumé

Introduction: Radiotherapy (RT) delivered at ultra-high dose rate (UHDR), known as FLASH RT, proved to widen the therapeutic window of RT by sparing normal tissues on various preclinical models1. This new modality is on the verge of clinical transfer and several clinical trials started worldwide. As part of a European project funded by EIT Health, this work presents the installation procedure and preliminary results of a FLASH radiotherapy system newly installed at Gustave Roussy with clinical investigation to follow.
Material and Methods: The FLASHKNiFE® (THERYQ) is a non-CE-marked radiotherapy system delivering UHDR pulsed electron beams ($>$ 1.2 Gy/pulse of 2 μs, 10 MeV). The operator can set the time structure of the beam by modifying pulse width (PW) between 0.5 and 4 μs and pulse repetition frequency (PRF) between 10 and 250 Hz. Prior to installation, a worst-case radiation protection calculation was carried out and an authorization request for research use was submitted to the French nuclear authority (ASN). After installation, a regulatory external inspection was performed according to the NF-M 62-105 installation standard. Then, the manufacturer's installation was conducted to check safety features and sub-systems operation. Performances of the 10 MeV UHDR beam were evaluated according to the IEC 60976 standard and manufacturer specifications.

Results: This year-and-a-half-long administrative procedure resulted in the successful installation of the system. All specified functionalities and regulatory requirements were validated. Regarding UHDR 10 MeV beam performances, the output repeatability is better than 0.5% for all the pulse widths (PW) and repetition rates (PRF) tested, and the delivered dose is proportional to the number of pulses and to the pulse width (agreement with linear fit below 2%). Percentage depth doses show a depth of 90% and 50% dose of 3.2 cm and 4.5 cm respectively for the 10 cm applicator. Profiles demonstrate symmetry and flatness in agreement with IEC recommendations for all applicators sizes. Finally, the doses per pulse (2 μs) are between 1.5 Gy (for the 10 cm applicator) and 2.8 Gy (for the 2-cm applicator) at depth of maximum dose, enabling an average dose rate of over 130 Gy/s up to 3 cm in depth at 100 Hz.

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Conclusions: Following the FLASHKNiFE installation, basic performances of the 10 MeV UHDR beam were characterized. This first step towards clinical application will be followed by the submission of an investigation file to the ANSM which will ultimately enable clinical authorization to be obtained from the ASN. These procedures are in progress simultaneously in Portugal, Germany and Switzerland.

References

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Mots-Clés: FLASH radiotherapy, ultra high dose rate, dosimetry