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Pancreas Cancer Patient with Vagus Nerve Stimulator Successfully Treated Off-Label on a 0.35T MR-Linac

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ABSTRACT

Adaptive MR-guided Stereotactic Body Radiation Therapy (MRg-SBRT) is an effective treatment for malignant pancreatic lesions. However, its implementation may be hindered by the presence of active implants with restrictive scanning conditions.

A pancreatic cancer patient with an implanted vagus nerve stimulator (VNS) underwent treatment simulation and five treatment fractions of 10 Gy each at a 0.35T MR-Linac. The VNS manufacturer guidelines for RF exclusion zone with transmitting scanner body coil and for limiting scanning time were not practicable for this patient. The normal operating mode condition was adhered to for specific absorption rate (SAR) but could not be followed for peripheral nerve stimulation.

VNS mis-activations were observed when the stimulator was inadvertently left on but were prevented when the implant was turned off. No other adverse effects were reported.

Pancreatic adaptive MRg-SBRT with the VNS turned off was completed successfully, suggesting that these implants may be safely scanned off-label on a 0.35T MR-Linac.

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INTRODUCTION

Radiation treatment of the pancreas is hindered by respiratory motion and abutting gastrointestinal organs at risk. Hence, adaptive MR-guided Stereotactic Body Radiation Therapy (MRg-SBRT), as offered by the 0.35T MRIdian MR-Linac, may be an optimal option for such patients.

Patients may present with MR conditional implants for which no manufacturer guidelines are available for 0.35T because implants are usually tested at the field strength of common clinical scanners (1.5T and 3T). Attraction, torque as well as radiofrequency (RF) field-induced and gradient magnetic field-induced heating risks are lower at 0.35T [1], generally rendering passive implants safer for scanning at this static field strength.

However, patients may have active implanted devices such as neurostimulators with strict MR scanning conditions. Risks of electronic device malfunction arising from electric fields generated by gradient switching and RF pulses are considerable even at 0.35T. We investigated imaging and treatment of a pancreatic cancer patient with an implanted vagus nerve stimulator (VNS) at the MRIdian MR-Linac.

METHODS AND MATERIALS

Subject: A 50-year-old male patient with renal carcinoma metastasis in the pancreatic head presented for adaptive MRg-SBRT.

Impant: An AspireHC model 105 LivaNova VNS was implanted in the patient's chest wall for epilepsy management but was reportedly off and no longer used. Implant MRI guidelines were provided for 1.5T and 3T scanners.

Risk-benefit analysis: The pancreas lay in the scanning exclusion zone for RF transmission using the body coil, violating the manufacturer guidelines. Surgical device removal would risk vocal cord paralysis and was deemed unwarranted. MRg-SBRT at a ViewRay 0.35T MR-Linac was attempted as sole treatment option for this patient.

Imaging/Treatment: The patient underwent one simulation session and five treatment fractions of 10Gy each. The patient and MR safety parameters were monitored throughout imaging and treatment.

Sequence	Simulation	Fraction 1	Fraction 2	Fraction 3	Fraction 4	Fraction 5
Pilot	15 s	15 s	15 s	15 s	15 s	15 s
Low-res TRUFI	15 s	-	-	-	-	-
High-res TRUFI	25 s	2*25 s	3*25 s	25 s	25 s	25 s
cine	2 min	21 min	27 min	12 min	11 min	12 min
Total duration	2 min 55s	22 min 5s	28 min 30s	12 min 40s	11 min 40s	12 min 40s

Table 1. Employed sequences and their duration for each MRIdian MR-Linac visit of a patient with a VNS neurostimulator. TRUFI denotes a TrueFISP sequence, with spatial resolution 2x2x2 mm^3 voxels (low-res) or 1.5x1.5x1.5 mm^3 voxels (high-res). The high-resolution sequence was repeated 2 and 3 times for fractions 1 and 2, respectively.

RESULTS

RF transmission was performed using the scanner built-in body coil as usual for MRIdian MR-Linac imaging. The treatment target area for the reported patient lay between the L1 and L2 vertebras (Figure 1). Thus, image isocenter was inside the body region covered by vertebras C7-L3 where the manufacturer of the investigated VNS interdicts MRI with body coil transmission.

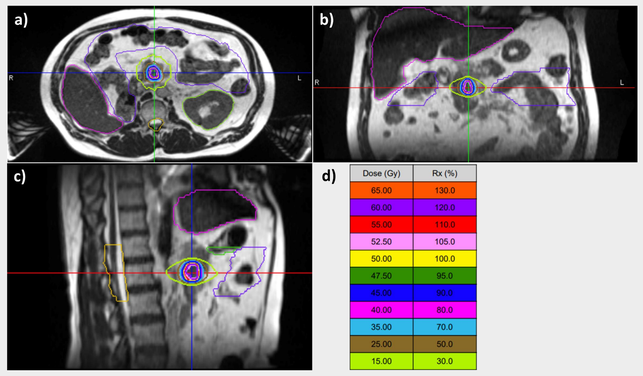

Figure 1. a) Axial, **b)** coronal and **c)** sagittal view of the initial treatment plan, with crosshairs indicating the target location (pancreatic head). **d)** shows the prescribed dose for each isodose contour.

At every scanning session, pilot and breath-hold set-up sequences were completed in 15s or 25s each (Table 1). The average duration of the cine tumor tracking sequence (Figure 2) over all fractions was 17 ± 7 min and exceeded the manufacturer stated 15 min active scan time restriction for 2 out of 5 fractions (Table 1).

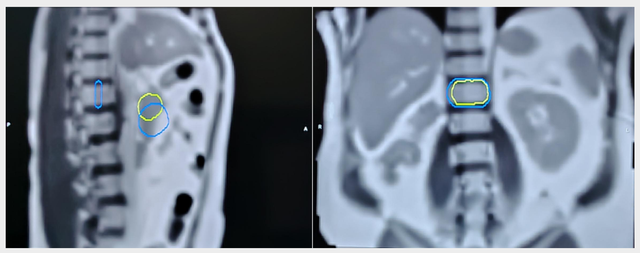

Figure 2. Sagittal (left) and coronal (right) cine images acquired during treatment delivery, with the target area contoured in yellow

The value of B_1+rms (root-mean-square value of the transmitted B_1 RF energy averaged over 10 seconds) displayed during cine imaging was 3.94 µT. The estimated specific absorption rate (SAR) was 0.45 W/kg, fulfilling the manufacturer condition for normal operating mode. Nevertheless, the rate of change of magnetic field (dB/dt) reached 59.7 T/s, representing 84.95% of the mean threshold for peripheral neural stimulation and corresponding to first level controlled operating mode.

MR imaging at simulation was uneventful. During the first treatment session, multiple successive mis-activations of the VNS happened with a rate of few seconds and caused temporary patient coughing. The VNS was determined to have been on and was turned off by a manufacturer representative for the subsequent treatment fractions, during which no further nerve stimulation was perceived by the patient.

No thermal injuries or other adverse effects were observed over the six MR-Linac visits of this patient.

DISCUSSION

Pancreatic tumors are highly aggressive and difficult to treat. The target tracking possibility offered by MR-Linacs makes them the optimal radiotherapy modality for pancreatic cancers. Nevertheless, patients may have electrical devices such as nerve stimulators implanted in their torso. As in the presented case study, the treatment target and consequently scanning isocenter may lie inside an area specified as MRI exclusion zone for 1.5T and 3T scanners by the implant manufacturer. Therefore, it is important to evaluate whether patients can be safely treated off-label at 0.35T even if manufacturer defined MR conditions are violated.

The manufacturer of the studied stimulator recommended a transmit-receive head or extremity coil for RF transmission in the pancreatic area, but such coils are not available for the MRIdian MR-Linac. The anticipated therapeutic benefits of the treatment outweighed theoretical risks, especially because the patient was no longer dependent on the device.

The normal operating mode condition was adhered to for SAR but could not be followed for peripheral nerve stimulation. The stimulator activation when inadvertently left on is consistent with the high rate of change of magnetic field dB/dt. Lack of triggering after the VNS was turned off suggests that this device can be safely scanned at 0.35T if properly deactivated. Exceeding the manufacturer scanning time restrictions by a few minutes did not cause any thermal injuries or other safety concerns.

The innocuously completed off-label scanning of this stimulator at 0.35T agrees with reports of cochlear implant[2] and cardiac rhythm management device imaging[3] at low field, which did not observe any adverse effects. This case study sets a precedent which may allow adaptive MRg-SBRT at a low field MR-Linac for more patients with similar electronic implants in the future. Potential clinical benefits of improved tumor control may lead to prolonged survival and better quality of life.

CONCLUSIONS

Pancreatic adaptive MRg-SBRT with a VNS turned off was completed with no adverse effects, suggesting that these implants may be safely scanned off-label on a 0.35T MR-Linac.

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