Clinical and Translational Radiation Oncology 39 (2023) 100561

Contents lists available at ScienceDirect

Clinical and Translational Radiation Oncology

journal homepage: www.sciencedirect.com/journal/clinical-and-translational-radiation-oncology

Technical Note

A pilot study of same-day MRI-only simulation and treatment with MR-guided adaptive palliative radiotherapy (MAP-RT)

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ARTICLE INFO

Keywords:
Physics
MRI
Adaptive radiation
Palliative radiation
Electron density calculations
Treatment
CT Simulation-Free

ABSTRACT

We conducted a prospective pilot study evaluating the feasibility of same day MRI-only simulation and treatment with MRI-guided adaptive palliative radiotherapy (MAP-RT) for urgent palliative indications (NCT#03824366). All (16/16) patients were able to complete 99% of their first on-table attempted fractions, and no grades 3–5 toxicities occurred.

Introduction

Approximately 30 to 70% of all radiotherapeutic treatments are for palliation [1–3], and external beam radiotherapy (EBRT) is a critical aspect in the palliation of lung [4,5] and abdominal metastases [6,7], amongst others. The use of radiotherapy for conditions such as gastrointestinal (GI) bleed [8,9] or cancer-related pain [10,11] is common and requires urgent treatment planning and delivery. The typical EBRT workflow involves consultation, computed tomography (CT) simulation, treatment planning, quality assurance, and final approval, which is a multistep process that may result in delays to the start of radiotherapy.

Magnetic resonance imaging-guided radiotherapy (MRgRT) has excellent soft-tissue contrast that enables the use of daily online adaptive radiotherapy (ART) [12–15]. Traditional MRgART, like CT-simulation based radiotherapy, is limited by the need for pre-treatment CT (and optional MRI) simulation. However, using a bulk electron density override (BDO), it is possible to assign electron densities based on typical values for basic tissue types such as bone and fat and use those values for dose extrapolation, negating the need for CT-simulation as a part of the MRgART workflow [16–18]. While Monte Carlo dose calculation remains the standard in modern radiation oncology, BDO is a feasible method to derive electron densities for MRI-only radiotherapy. We hypothesized that the use of BDO would allow for a MRI-only same day simulation and treatment workflow for MR-guided adaptive palliative radiotherapy (MAP-RT) for urgent conditions and conducted a prospective pilot study to evaluate the feasibility of this paradigm.

Materials and methods

Between 8/1/19–1/15/22, 20 patients with biopsy-proven malignancies requiring urgent palliation were consented to this prospective

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https://doi.org/10.1016/j.ctro.2022.100561
Received 4 October 2022; Received in revised form 2 December 2022; Accepted 11 December 2022
Available online 15 December 2022

trial. Urgent radiotherapy indications included GI bleed or obstruction, cancer-induced pain, and urinary obstruction, amongst others. Patients were required to be at least 18 years of age, able to give informed consent, and have recent imaging of the intended disease site. Recent imaging of the intended disease site was required in order for the treating radiation oncologist to assess eligibility for palliative radiotherapy as well eligibility for this clinical trial. All patients were screened with an MRI screening questionnaire prior to enrollment. Patients who were pregnant or had medical contraindications to MRI were ineligible. The prospective clinical trial (NCT#03824366) was approved by the Human Research Protection Office (IRB #201901172).

An overview of the MRI-only same day simulation and treatment workflow is demonstrated in Supplementary Fig. 1. Patients were initially evaluated in consultation. After obtaining consent, patients were set up for same day MRI-only simulation and treatment. Eligible dose and fractionation for this trial included 800 cGy in 1 fraction, 2000 cGy in 5 fractions, 2500 cGy in 5 fractions, 3000 cGy in 10 fractions, and 3750 cGy in 15 fractions. On the day of treatment, patients were placed on the treatment table and positioned in manners appropriate for their respective treatment sites, most frequently supine with the arms out of the way of the treatment beams. All patients were simulated and treated on a ViewRay MRIdian Linac (ViewRay Inc., Cleveland, OH).

A volumetric MRI using a TrueFISP pulse sequence was obtained on the ViewRay MRIdian Linac in the morning of treatment day. A gross tumor volume (GTV) was delineated by the treating radiation oncologist. A clinical target volume was created at the discretion of the treating radiation oncologist, and a 0.5 to 2.0 cm volumetric expansion was permitted to create a planning target volume (PTV). Given the palliative doses of radiotherapy, organ at risk volumes and constraints were not required but could be used at the discretion of the treating radiation oncologist. Once contours were complete, a treatment plan was created. BDO was used to assign relative electron density values to the MRI dataset to facilitate dose calculations [16]. Major tissues with density override were bones (1.12 g/cm^3), lungs (0.26 g/cm^3), and fat (0.89 g/cm^3). All other tissue was assigned the electron density of water (1 g/cm^3). An example of BDO is shown in Fig. 1. The treatment plan was reviewed by another physicist and approved by the treating physician. The patient was brought back to the vault for treatment in the afternoon. Volumetric MRI scan was obtained, and the structure sets were reviewed and modified by the physician if necessary. Once the adaptive treatment plan was generated, the plan and prescription were reviewed and approved by the treating physician.

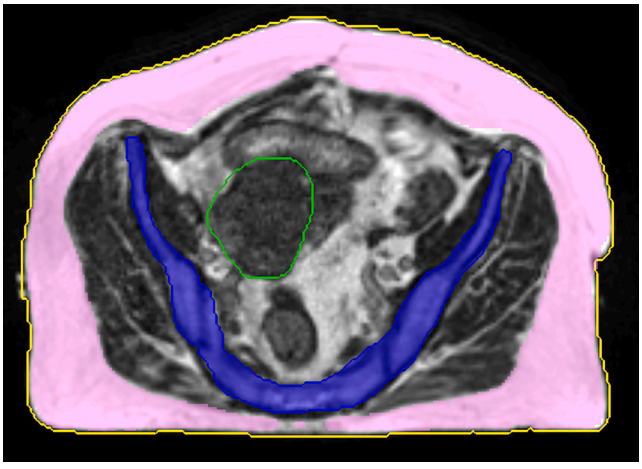


Fig. 1. Example of BDO. Figure X. An example of the BDO method used in MAP-RT in a treatment plan for a patient with a pelvic mass. The yellow, blue, and the pink contours represent water, bone, and adipose BDO, respectively. The water BDO was given the lowest priority in bulk density override compare to other densities.

For patients who received greater than one fraction of radiotherapy, a volumetric MRI was obtained each day of treatment. Previous contours with assigned electron density were reviewed and adjusted if needed and the initial plan was delivered with MRI guidance each day. Patients with tumors subject to motion (e.g. intrathoracic or intraabdominal sites) were treated with sagittal image target gating.

Patient specific quality assurance (QA) was performed for each adaptive fraction prior to treatment. An independent Monte Carlo dose calculation was performed on the image of the day, using the exported beam parameters and mapped electron density. The independently calculated dose distribution was compared to the dose distribution from the MRgRT system using 3D Gamma Analysis. In addition, an in-house plan integrity verification software was utilized to evaluate plan quality and integrity via plan parameters including contours, beam angles, segments, and monitor units. After completion of the automated check, a final review of the treatment plan by physics was required prior to radiotherapy delivery. A measurement-based QA using an ArcCHECK (Sun Nuclear Corp., Melbourne, FL, USA) and an ionization chamber was also performed after the first fraction only.

Patients were assessed for acute toxicity in their standard of care once per week on treatment visit. Additional routine clinical follow-up was performed at the discretion of the treating physician. Patients were surveyed for adverse events, which were graded according to the Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. The incidence of incomplete fractions was recorded.

Baseline and treatment characteristics were collected for all patients, including primary disease type, disease location, and urgent palliative radiation indication, amongst others. Time of simulation as well as treatment time metrics were recorded. Overall survival was assessed from the time of consultation and was estimated using the Kaplan-Meier method. The primary endpoint of the study was feasibility of same-day MRI-only simulation and treatment, with feasibility defined as more than 70% of patients receiving at least 70% of their scheduled treatment fractions on the first on-table attempt for each respective fraction. This was determined to represent an acceptable majority of cases to consider the novel workflow feasible by the adaptive radiotherapy and clinical trial teams.

Results

Twenty patients were initially enrolled on this study. However, one patient passed away prior to simulation, one patient had a previously unidentified metal artifact disqualifying them from MRI treatment, one patient was unable to tolerate lying flat on the MRI table, and one patient unenrolled in the study due to issues with MR-LINAC availability. Due to clinical trial staffing limitations during the pandemic, it was recommended by the departmental clinical trials leadership to close the trial at 16 evaluable patients. Baseline and treatment characteristics for the 16 evaluable patients on this trial are demonstrated in Table 1. Median age for patients was 66 (28–90) years and the majority (10/16) were women. The most common indication for palliative radiotherapy was pain (9/16) followed by GI bleed (3/16), and the most often used dose and fractionation was 2500 cGy delivered in five 500 cGy fractions (10/16). Median PTV volume was 204 (23.4–752.6) cm^3 and median volume receiving at least 95 % of prescription dose was 99.87 % (92.2–100.0). Median PTV margin was 1.0 (0.5–1.5) cm.

With 16 treated patients, 67/68 (99 %) of scheduled treatment fractions were successfully completed at first on-table attempt. Median simulation time was 33 (21–63) minutes. Median time from simulation to start of first treatment was 407 (306–542) minutes. Median time from the patient entering the treatment room to final positioning was 8 (4–28) minutes, and median time from final positioning to treatment completion was 22 (11–106) minutes. Median overall treatment time was 30 (17–120) minutes. Median follow-up in this study was 5.79 (0.23–19.79) months and median overall survival (Fig. 2) was 12.9 (7.70–18.10) months. OS was 76 % (55–100) and 52 % (28–97) at six

Table 1
Baseline and treatment characteristics. Baseline and treatment characteristics for the 16 evaluable patients enrolled on this clinical trial. ACA = adenocarcinoma; NET = neuroendocrine tumor; CA = carcinoma; NSCLC = non-small cell lung cancer.

Patient	Age	Gender	Primary malignancy	Disease location	Radiotherapy indication	Dose (cGy)/# of fractions	Dose per fraction (cGy)
1	70	Female	Small bowel NET	Abdomen	Bowel obstruction	2500/5	500
2	28	Female	Spindle cell CA	Sacrum	Urinary obstruction	2000/5	400
3	50	Male	Pancreatic NET	Pancreas	Pain	2500/5	500
4	71	Male	NSCLC	Pelvis	Pain	800/1	800
5	49	Male	Pancreatic ACA	Spine	Pain	2000/5	400
6	62	Female	Sigmoid ACA	Sigmoid	GI bleed	2500/5	500
7	66	Male	Pancreatic ACA	Pancreas	Pain	2500/5	500
8	70	Female	Cholangiocarcinoma	Liver	Inferior vena cava compression	2500/5	500
9	90	Male	Colon ACA	Colon	GI bleed	2500/5	500
10	68	Male	NSCLC	Jejunum	GI bleed	2500/5	500
11	67	Female	Small bowel NET	Femur	Pain	800/1	800
12	55	Female	Cholangiocarcinoma	Abdomen	Pain	2500/5	500
13	62	Female	Colon ACA	Sigmoid	Urinary obstruction	2000/5	400
14	90	Female	Small bowel NET	Ileum	Pain	2500/5	500
15	62	Female	Large bowel NET	Pelvic	Pain	800/1	800
16	82	Female	Pancreatic adenocarcinoma	Abdomen	Pain	2500/5	500

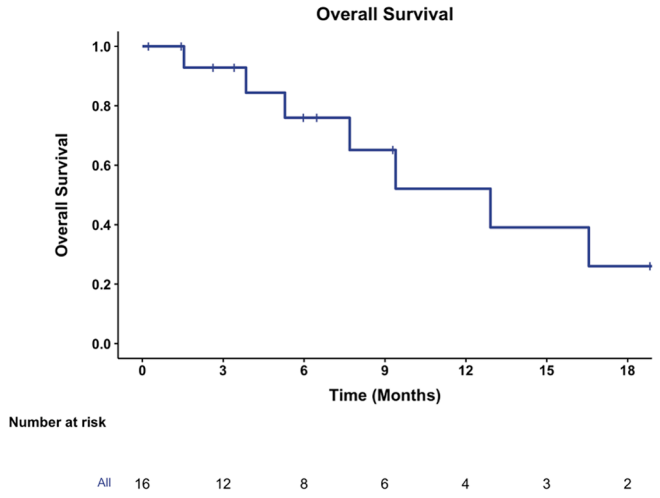


Fig. 2. Overall survival. Nearly half of the patient population had passed away by twelve months, highlighting the need for efficient palliative radiotherapy delivery mechanisms. Overall survival was estimated using the Kaplan-Meier method.

and twelve months, respectively. Representative plans for patients with pelvic and pancreatic masses requiring palliation are demonstrated in Fig. 3.

With regards to patient specific QA, median passing rate for the 2 mm/2% criteria for the Monte Carlo dose calculation was 98.12% (96.3 %-99.67%). Median passing rate for the 3 mm/3% and 2 mm/2% criteria for the ArcCHECK measurement was 98.85% (96.7%-100%) and 93.1% (86.4%-97.2%), respectively. Median passing rate for the ion chamber was 99.65% (97.8%-102.2%). Seven toxicities possibly or probably related to radiotherapy occurred in five patients on this trial. These toxicities included grade 2 diarrhea, grade 2 abdominal pain, grade 2 myalgia, grade 2 back pain, grade 1 back pain, grade 1 anorexia, and grade 1 non-cardiac chest pain. There were no grades 3–5 toxicities in this cohort.

Discussion

This is the first prospective clinical trial of MRI-only simulation and treatment with palliative MRIgRT. We demonstrated that this workflow is feasible, as 67/68 (99%) of scheduled treatment fractions were successfully completed at first on-table attempt. This was performed with tolerable toxicity comparable to prior studies [19–21], as there were only seven events of grades 1–2 toxicity, and no grades 3–5 toxicity. This low toxicity was maintained while providing rapid same day simulation and treatment, which suggests that this paradigm can improve treatment efficiency in a vulnerable patient population in which reducing patient travel time and time in department is critical for patient convenience and quality of life [22–24].

The University of Wisconsin's STAT-ART paradigm previously described adaptive MRI technology into the conventional palliative radiotherapy workflow [25,26]. The authors note that the MRI-platform can improve workflow speed while also providing benefits such as improved soft tissue delineation and increased confidence in the safety of the delivery of high dose per fraction treatments. Key differences between STAT-ART and MAP-RT include the use of a CT-based preplan and deformable rigid image registration in the STAT-ART workflow. Furthermore, the authors reported on the concept of this treatment paradigm but to our knowledge have not reported on any retrospective or prospective patient treatment data.

The MAP-RT paradigm has several potential benefits for this patient population. MAP-RT uses a BDO, eliminating the need for CT-simulation. The traditional workflow uses a CT-simulation followed by treatment, which can often introduce issues with simulation machine availability or prolonged treatment planning. While this workflow still requires a simulation appointment, the simulation is on the MRI-linac, therefore maintaining the entirety of this workflow from simulation to treatment to a single machine. This has an added benefit of freeing up additional CT-simulation appointments in a busy radiation oncology clinic. An interesting future development in this palliative radiotherapy workflow may be to contain to the process to one session, completing simulation and first fraction all while the patient is on the treatment table. In fact, a same-session MRI-only simulation and treatment paradigm for stereotactic body radiotherapy for spinal oligometastases is being actively evaluated at our institution on a prospective pilot study (NCT03878485).

MAP-RT joins diagnostic scan-based planning [1,27], amongst other techniques, as methodologies to remove CT-simulation from the palliative radiotherapy workflow. As evidenced by the poor survival in this study, improving the efficiency and speed of the palliative radiotherapy workflow is critical for these patients. MRI also has improved soft tissue delineation [28] which may be of benefit for disease adjacent to OARs such as what is demonstrated in Fig. 4. The improved soft tissue contrast may be critical for palliation of soft tissue and visceral organ metastases, but likely would be of lesser applicability in the palliation of bone metastases. The improved image quality as well as real-time cine tumor tracking and online adaptive capabilities can improve confidence in the accuracy of higher doses per fraction treatments but may also allow physicians to reduce PTV margins. In our clinic, traditional palliative radiotherapy PTV margins typically range from 1.5 to 2 cm when using

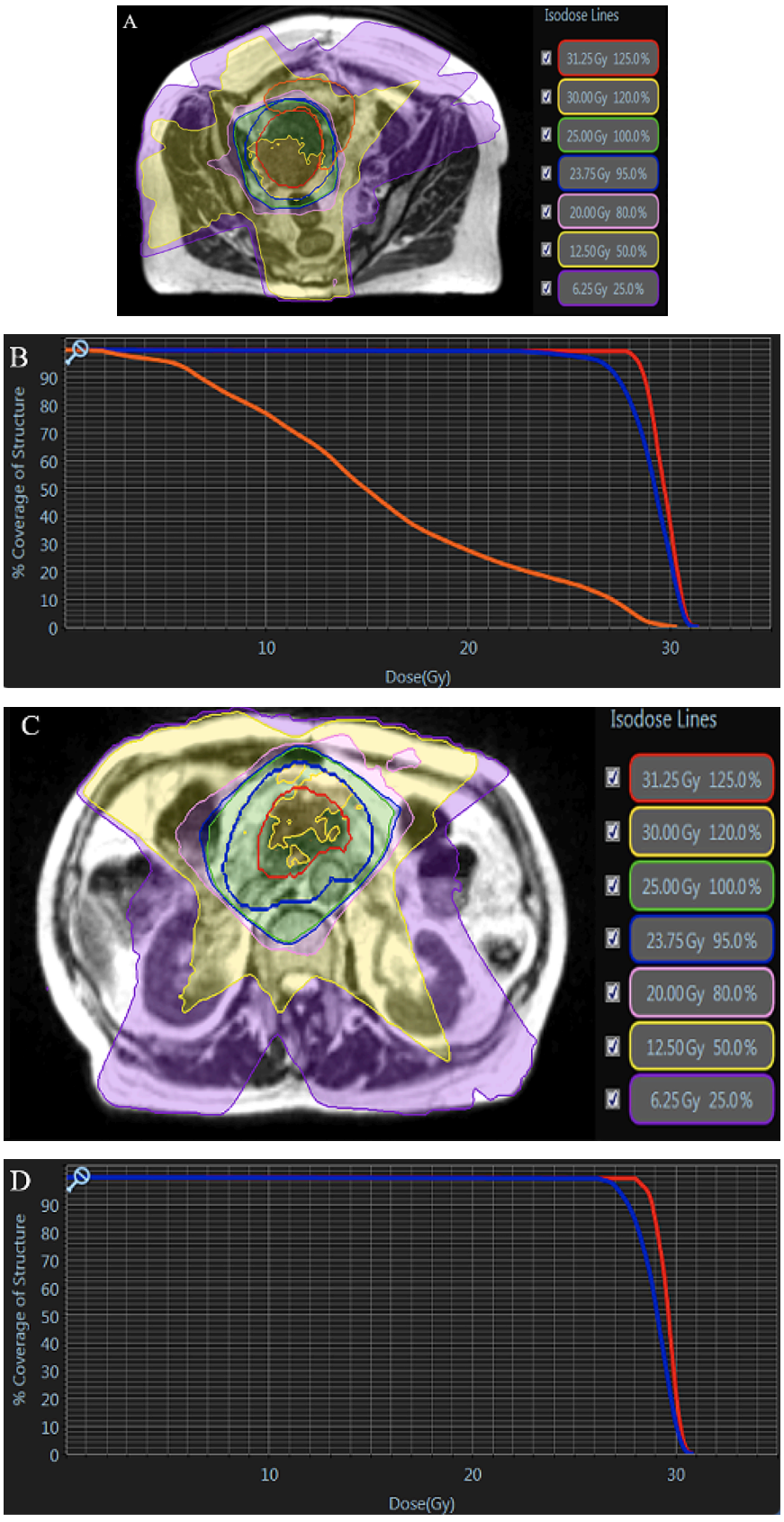
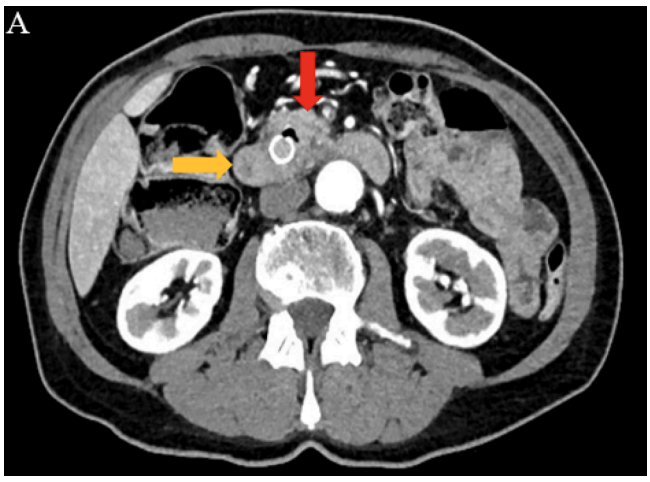


Fig. 3. Examples of MAP-RT treatment plans. An example of a MAP-RT treatment plan for patients with pelvic (A) and pancreatic (C) masses. The GTV's (red) are contoured with volumetric PTV (dark blue) expansions. The small bowel (orange) is also contoured in A. Dose volume histograms are represented in B and D for each respective case.



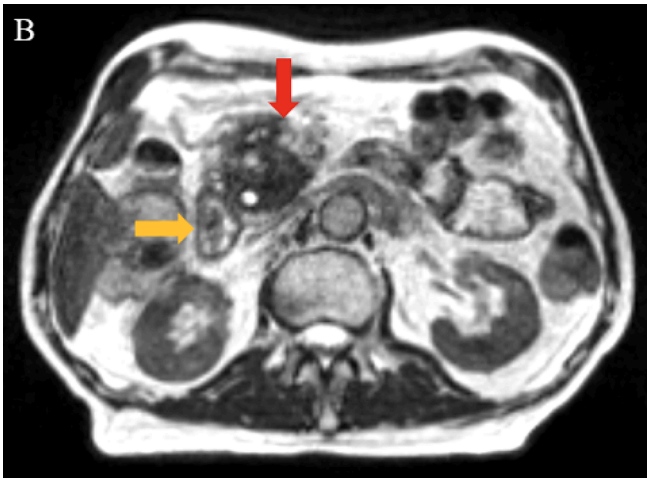


Fig. 4. Advantages of MRI-based imaging. A diagnostic CT (A) and MRI-LINAC T2-weighted MRI (B) are demonstrated for a patient with a pancreatic mass. One advantage of using an MRI-LINAC is the improved soft tissue contrast, which can be highly useful when treating disease adjacent to the radiosensitive luminal gastrointestinal tract. Note that the mass (red arrow) is challenging to delineate on CT but appears hypointense on MRI. Additionally, the adjacent duodenum (yellow arrow) is more easily definable on MRI.

port images alone for target alignment, and the reduction of margins using MRI-guided radiotherapy has been demonstrated to reduce toxicity in other disease sites [29,30]. In this study, median PTV margin was 1.0 cm. The advantages of online adaptation and real-time cine tumor tracking must be balanced with the time it takes to complete these steps of the workflow, as additional time on table can be challenging for patients with painful osseous metastatic disease or shortness of breath in the setting of pulmonary disease.

Limitations of this study include its small sample size and use of a single MRgRT platform. It should be noted that three patients were enrolled but ultimately deemed not to be evaluable for this study due to common issues with MRgRT as detailed in the Results section. In a clinic with a single MR-LINAC, machine issues and technical difficulties may lead to treatment delays which may not be tolerable by our patients. However, the patient numbers and high completion rate per the study endpoint in this study are promising and indicative that this treatment paradigm is truly feasible in the real-world setting. Follow-up was intentionally limited as the purpose of the study was to establish proof of principle for a novel workflow with early toxicity assessment in a patient population with historically poor prognosis. While other MRgRT treatment platforms are available [31], they are at different points of development and capability to offer gated treatments of mobile targets. Notwithstanding these considerations, these data indicate that same day MRI-only simulation and treatment with MAP-RT was feasible with a reasonable toxicity profile. This is a reasonable treatment paradigm for patients requiring urgent palliative radiotherapy.

Conclusion

Same day MRI-only simulation and treatment with MAP-RT proved feasible and did not incur excess toxicity when utilized to treat urgent palliative indications. Improved soft tissue delineation and reduced PTV margins starts must be balanced with potential issues in an MR-only workflow in a clinic with one MR-LINAC when implementing a MR-only simulation and treatment MAP-RT program.

Funding

Funded by the Department of Radiation Oncology, Washington University School of Medicine in St. Louis.

Data Availability

Research data are stored in an institutional repository and will be shared upon request to the Corresponding Author.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ctro.2022.100561.

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