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Low-Dose Whole Thorax Radiation Therapy for COVID-19 Pneumonia: Inpatient Onboarding Process for a Randomized Controlled Trial

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Purpose/Objective(s): The mortality of the SARS-CoV-2 virus (COVID-19) has been associated with a pulmonary inflammatory response resulting in hypoxemia and rapid clinical decline. Recent work has indicated a potential therapeutic window for treatment to prevent ventilator-dependence thereby reducing mortality. PREVENT is an ongoing prospective multicenter Phase II randomized controlled trial where patients hospitalized with COVID-19 pneumonia are randomized to ultra-low dose radiation therapy (RT) versus control. This study is registered at clinicaltrials.gov, NCT04466683. The following is a description of the inpatient onboarding process of the center contributing the largest number of patients to this trial.

Materials/Methods: COVID-19 hospital admissions from the previous day were attained by the clinical research manager each morning, screened for eligibility, and then sent to the designated radiation oncologist who further delineated from this list. Common exclusion criteria were: 1. Oxygen saturation > 96% on room air, 2. Age < 50, 3. > 9 days from initial COVID-19 symptomatology. From this list, HIPAA-compliant text message contact was made with infectious disease, critical care, and nursing staff with reciprocal discussion of the trial protocol and approval for consulting the patient. Subsequently, a virtual consult was made with the patient, with witnessed informed consent obtained via telephone and in person by our research associate. Patients randomized to RT were treated within 24 hours of consent. Simulation and treatment were performed on a linear accelerator with one personal protective equipment-protected therapist moving in and out of the treatment room, and a second therapist manning the console. On-site dose calculation was performed by physics, after which the radiation oncologist approved the fields prior to treatment delivery. Simulation and treatment were performed without a computer plan; therapists underwent several practice sessions prior to treating patients on trial.

Results: Between August 28, 2020 and October 6, 2020, the first 10 enrolled patients on this multicenter trial were randomized and treated at our institution; no research staff member nor radiation oncology clinical team member contracted COVID-19 while employing this protocol.

Conclusion: This represents the first published protocol to address efficient and safe recruitment of COVID-19 patients for a radiation oncology trial. Despite the procedural hurdles of conducting a trial in the midst of a pandemic, the combination of recruitment efficiency (> 2 patients/week) and safety to the research and clinical teams (no COVID-19 infections) of this protocol has allowed for the PREVENT trial to make substantial progress in meeting recruitment goals (n = 100). This onboarding process serves as a model in conducting recruitment of COVID-19 patients for clinical trials, and is worthy of emulation at additional centers.

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Quantification of Interfraction Gastric Motion by Daily Magnetic Resonance Imaging and Implications for Radiation Treatment Planning

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Purpose/Objective(s): Accurate radiation therapy targeting for stomach cancer is challenging given daily variations in the stomach's size and position. We evaluated daily MR-based imaging to quantify changes in stomach volume and characterized the impact of inter-fractional variation on dosimetry for gastric cancer radiation plans.

Materials/Methods: We assessed inter-fraction changes in the volume and position of the stomach via MR-based imaging for 10 patients who previously underwent abdominal stereotactic body radiation therapy. All patients were simulated and treated over 5 fractions and were instructed to fast for 3 hours before each session. The stomach and regional organs-at-risk (OARs) were contoured on each fraction's MR scan according to standard RTOG guidelines. Inter-fraction variation in the size and position of the stomach was quantified by calculating the percentage volume change and dice similarity coefficient (DSC) as compared to the simulation scan. To determine the potential impact of inter-fraction stomach motion on treatment planning, we generated mock plans to recapitulate neoadjuvant or definitive stomach cancer treatments. For the purpose of this study, the stomach contour was symmetrically expanded by 1.7 cm to generate a planning treatment volume (PTV) and a prescription dose of 45 Gy in 1.8 Gy fractions was applied. Intensity-modulated radiation therapy plans were then generated to meet the following dosimetric goals: PTV V95% of 95%, liver V30 less than 30%, and bilateral kidney V20 less than 20%. Finally, the impact of gastric variation on these dose metrics was assessed.

Results: Despite standard daily preparation and set up procedures, we observed significant variability in the size and location of the stomach between fractions. The mean absolute daily change in gastric volume compared to the planning MRI was 19.1% (total range: -42.0% to 58.4%). The average stomach DSC was 0.69 (range: 0.40 to 0.86). Given this degree of variability, mock gastric cancer treatment plans displayed suboptimal dose metrics. The average PTV V45 was 81.5% (range: 58.8% to 99.2%. 95% CI: 78.8% to 84.2%). Average liver V30 values were 12.7% (range: 3.5% to 20.1%. 95% CI: 11.7% to 13.9%) and bilateral kidney V20 values were 12.3% (range: 0.5% to 31.3%. 95% CI: 9.2% to 15.3%). Target metrics were highly correlated with the percent change in stomach volume—a 10% increase in stomach volume was associated with a 2.4% decrease in the V45 ($P < 0.001$).

Conclusion: We observed significant inter-fraction variability in the dimensions of the stomach using daily MRI-based imaging, leading to dosimetrically inferior mock gastric cancer treatment plans. Our study suggests that larger PTV margins may be necessary for conventional stomach plans, which would come at the expense of greater OAR exposure. Alternatively, MRI-based image guidance and daily adaptive treatments may improve the therapeutic window of radiation therapy for gastric tumors.

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The Utility of Stereotactic Body Radiotherapy for Pelvic Recurrences After Prior Radiation Therapy

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