Prospective Evaluation of Endoluminal High Dose Rate Brachytherapy with Concurrent Chemotherapy for Rectal or Anal Cancer Patients: Initial Clinical Results

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Purpose: To present initial clinical results of a prospective dose escalation protocol of endoluminal high dose rate (HDR) brachytherapy with concurrent chemotherapy for rectal or anal cancer patients undergoing non-operative management.

Materials and Methods: All patients were enrolled on a prospective, institutional review board (IRB)-approved dose escalation protocol evaluating endoluminal HDR brachytherapy with concurrent chemotherapy. Inclusion criteria included histologically confirmed locally residual or recurrent cancer of the rectum or anus as well as prior pelvic external beam radiation therapy. Brachytherapy was delivered with the anorectal (AR-1) applicator (Ancer Medical, Hialeah, FL). This applicator consisted of an inner balloon, which supported 8 channels for the radioactive source, and a compliant outer balloon for optimal deformation against exophytic lesions. The applicator insertion and treatment delivery were performed under general anesthesia in 3 weekly sessions. Magnetic resonance imaging (MRI)-based treatment planning was performed while under general anesthesia during the first session only. Capecitabine (825 mg/m^2 BID) was administered from Monday through Friday on the weeks of brachytherapy. Efficacy and toxicity were evaluated by clinical assessment and MRI examinations at pre-defined intervals (3, 6, and 12 months for the first year) after the procedure.

Results: In 2015, six patients with recurrent or residual cancer (3 anal, 3 rectal) were enrolled on this protocol, and treated at the initial dose level of 15 Gy in 3 fractions. For MRI-based dosimetry, the median target volume was 15.2 cc (range, 5.9-36.3). Median values for the V100 and D90 were 98.7% (93.8-99.9) and 599 cGy (537-655) respectively. The median anorectal D0.2cc (excluding the target volume) was 683.6 cGy (492.6-715.7). Treatment was delivered as planned for 5 patients. One patient was treated with a single-channel Bougie applicator for the third fraction, due to the development of severe circumferential narrowing that prevented insertion of the endorectal applicator. At a median follow up of 6.8 months (6.2-8.7), one patient developed a local recurrence at 4.7 months and underwent an abdominoperineal resection. Three patients developed grade 2 proctitis, and the patient with severe circumferential narrowing experienced grade 2 rectal bleeding. One patient died from a synchronous hepatocellular carcinoma at 7.4 months after HDR brachytherapy.

Conclusion: The initial clinical results for endoluminal HDR brachytherapy with concurrent chemotherapy are encouraging. The clinical efficacy and toxicity associated with this treatment will be more clearly defined as the protocol matures.