



The First National Experience of Intravesical Injection of the TraceIT™ Tissue Marker under a Local Anesthesia for Imaging Visualization of Recurrent Muscle-invasive Bladder Cancer for the Targeted IMRT



J. Bass¹, N. Mariados¹, P. Lam¹, C. Pieczonka¹, P. Campbell², D. Albala¹, H. Williams¹, V. Mouraviev¹

¹Associated Medical Professionals of NY, PLLC, Syracuse, NY; ² Augmenix, Waltham, MA; USA

Abstract

Background:

The treatment of muscle-invasive bladder tumors remains challenging for urologic oncologists. Targeted radiation therapy coupled with chemotherapy has become as a promising treatment modality comparable with a radical cystectomy according to the cancer control results. Radiation oncologists often combine, or fuse, MR and CT images to improve dose planning and accuracy. However, most markers do not have equivalent visibility on both CT and MR, creating a permanent image artifact in areas of particular interest and limiting their usefulness for image fusion. The TraceIT Tissue Marker (Augmenix, Waltham, MA) is an injectable polyethylene glycol based hydrogel marker designed to be visible under CT, cone beam computed tomography (CBCT), MR and ultrasound imaging for three months after implantation, and then to absorb within seven months.

Methods:

Patient M., 80 years with history of left nephroureterectomy for upper tract urothelial carcinoma 1.5 years ago diagnosed with recurrent bladder cancer. Cystoscopy was performed where a large papillary tumor more than 5 cm on posterior wall was found and resected by TURBT. The histology confirmed a high-grade muscle-invasive urothelial carcinoma with possible lymphatic invasion. Patient declined radical cystectomy and chose combination radiotherapy and chemotherapy. In order to outline a bladder tumor margins, the patient agreed to undergo an injection of TraceIT Tissue marker before IMRT. Under local anesthesia (intraurethral 2% lidocaine gel and intravesical 1%-lidocaine) a rigid 20 Fr. injection cystoscope was introduced into bladder, systematic cystoscopy was performed and the tumor bed was localized. TraceIT was injected using a 23G needle with 0.3 ml into 6 locations around tumor resection bed within 1 cm from cancer border. A total of 1.8 ml of TraceIT tissue marker was injected into the bladder wall.

Results:

Patient tolerated a procedure well and immediately underwent planning CT scan following the injection. The patient was discharged following completion of the planning CT scan. Three days later, IMRT radiation therapy was started for a planned dose of 45 Gy in total to the entire field with a 20 Gy boost to the outlined tumor bed on the Varian image-guided linear accelerator using Rapid Arc technology. The exact outlining of tumor margins on CBCT provided with TraceIT hydrogel allowed us to use a targeted boost IMRT regimen that led to successful cancer eradication with minimal toxicity.

Conclusions:

TraceIT hydrogel injected endoscopically under a local anesthesia can be considered a feasible option to exactly map the tumor location and margins to facilitate a targeted radiation therapy.

Objectives

TraceIT Tissue Marker (Augmenix, Waltham, MA) is an absorbable radiopaque hydrogel consisting of iodinated polyethylene glycol (PEG) hydrogel particles (avg size 350 μm) in a viscous carrier. Being injectable through fine needles, the PEG iodination makes the hydrogel CT and CBCT visible, while the high water content renders the gel MRI and ultrasound visible. Following implantation the hydrogel particles remain visible for 3 months, and then undergo hydrolysis causing them to liquefy, be absorbed and cleared via renal filtration within approximately 7 months. When injected the soft particles form blebs within the tissue that withstand migration.

The objective of this pilot evaluation was to assess hydrogel marker injectability, imaging visibility and stability during IMRT treatment.

Methods and Materials

80 year old male with prior TURBT resection of a large (>5 cm) posterior wall papillary bladder tumor underwent radiopaque hydrogel injection to delineate tumor margins prior IMRT (patient declined cystectomy).

TraceIT Tissue Marker was aseptically prepared per the product IFU and attached to a Williams Cystoscopic 23G needle (Cook Medical). Under local anesthesia a rigid 20 Fr. Injection cystoscope was introduced into bladder, and the catheter was advanced into the bladder. Using the catheter six hydrogel injections, 0.3ml each (1.8 ml total), were placed around the tumor periphery, within 1cm from the cancer border.

Patient then underwent imaging and dose planning in preparation for IMRT bladder treatment.

Results

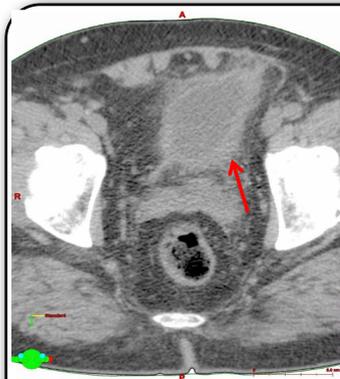


Figure A.



Figure B.

Figure A. CT Scan of the bladder with no clear visualization of tumor borders on the left lateral wall (red arrow).

Figure B. Hydrogel injection was performed endoscopically within 1 cm of the tumor border.

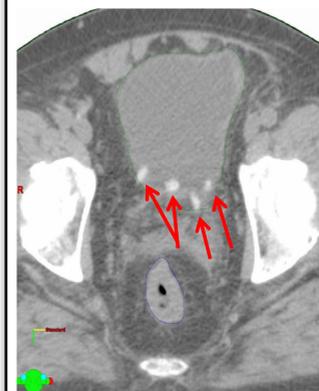


Figure C.



Figure D.

Figure C. CT Scan (axial projection) after injection (red arrows) delineating exact location of the tumor.

Figure D. CT Scan (sagittal projection) after injection (red arrows) suggesting extent of the tumor.

Figure E. Three days later, a targeted IMRT radiation therapy mapped by TraceIT markers was started for a planned dose of 45 Gy to the entire field with a 20 Gy boost to the outlined tumor bed on the Varian image-guided linear accelerator using Rapid Arc technology.

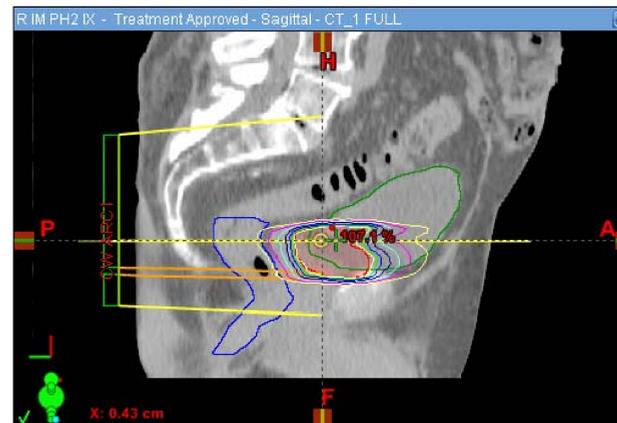


Figure E.

Patient tolerated procedure and IMRT very well. Currently, the patient does not have complaints of hematuria or other voiding disorders. Three months follow-up visit did not show recurrence of the tumor.

Future Proposals

Forthcoming phase II clinical trial will collect more robust data in order to prove efficacy of this approach in patients who are not surgical candidates for removal of tumor.

Conclusions

TraceIT hydrogel injected endoscopically under local anesthesia can be considered a feasible option to precisely map the tumor location and margins to facilitate targeted radiation therapy.

Acknowledgements

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