OTL-38-Guided Fluorescent Imaging in Renal Cell Cancer Robotic Partial Nephrectomy

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Abstract

Introduction and Objective: The folate receptor (FR) protein is upregulated in numerous epithelial malignancies while having limited expression on normal tissues. This overexpression of FR in renal-cell carcinoma (RCC) can be exploited by attaching nearly any therapeutic or imaging agent for delivery to cancer cells. In one of its first applications, platinum-resistant ovarian cancer, folate was used to deliver pegylated liposomal doxorubicin (a folate-linked vinca alkaloid) and improved progression-free survival versus standard treatment. RCCs are thought to be the second highest FR-expressing cancer. OTL-38 is a folate analogue conjugated with a fluorescent dye that emits light in the near infrared spectrum. This longer wavelength allows for deeper penetration of the fluorescent light through tissues with the potential to better image tumors beneath adipose tissue or deeper into organ parenchyma. We are currently conducting a pilot, phase 2, nonrandomized study in patients with RCC, scheduled to undergo primary, partial, or radical nephrectomy. The aim is to explore the use of OTL-38 and fluorescence imaging to observe RCC at the margins of resection in partial nephrectomy and in lymph node(s) or other metastases for radical nephrectomy.

Methods: Currently two patients have participated in the trial to date with an accrual target of 20 patients. The first was a 67-year-old male with an incidental 2.2 cm right-sided renal mass, and the second was a

70-year-old male with an enlarging 2 cm renal mass. Per protocol, both patients were administered OTL-38 in the preoperative area 1 hour before the procedure. Subsequently, both procedures were performed with robotic assistance as per normal routine with the use of Firefly fluorescence to aid in observation of OTL-38 uptake.

Results: Intraoperative guidance through OTL-38 demonstrated minimal to no uptake of the OTL-38 as seen by Firefly fluorescence (green color). Surprisingly, the normal renal parenchyma showed strong uptake of OTL-38 as seen by Firefly fluorescence. Both pathology reports revealed conventional clear cell RCC. Immunohistochemistry slides of the tumor revealed only mild staining for folate. In contrast, immunohistochemistry slides of the normal renal parenchyma in the surgical margin revealed a strongly positive stain for folate.

Conclusions: In conclusion, our first two patients' renal tumors did not stain strongly for folate; however, the normal renal parenchyma did, which served as an intraoperative guide to confirm a negative margin. Further study of patients will reveal whether folate receptors are, in fact, predominant or not in renal cell cancer.

No competing financial interests exist.

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Keywords: OTL38, renal cell carcinoma, robotic, partial nephrectomy

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