

Intra-operative margin detection using Cerenkov luminescence Imaging during radical prostatectomy – Initial results from the PRIME study

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Key words (3)

Objectives Cerenkov Luminescence Imaging (CLI) is a new imaging technology for intra-operative assessment of surgical margins and lymph nodes status, based on optical imaging of PET radiopharmaceuticals. The PRIME (PRostate Imaging for Margin Evaluation) study is currently being conducted to evaluate the feasibility and safety of 18F-choline CLI to intra-operatively assess margin status in prostate cancer specimens and lymph node metastases.

Methods The PRIME study will recruit 30 patients with high-risk prostate cancer (clinical stage >T2c, or PSA>20 ng/ml, or Gleason Score b8-10) undergoing radical robotic prostatectomy. Initial data from 3 patients are reported here. Patients received an intravenous injection of 370 MBq ($\pm 10\%$) of 18F-choline given intra-operatively prior to surgery. Prostatectomy and lymph node excision specimens were imaged intra-operatively with an investigational CLI specimen analyser (Lightpoint Medical Ltd, UK) immediately after excision (acquisition time 300 seconds, field-of-view 8 cm, matrix 512x512) The normalised decay-corrected radiance (ph/s/cm²/str/MBq) was calculated for each region of interest and the apparent tumour-to-background ratio (TBR) was reported. Radiation doses to staff were measured using badge dosimeters.

Results Intra-operative CLI images of 3 prostatectomy and 4 lymph node specimens were obtained. No time was added to surgery because of the CLI procedure and no other intra-operative issues were reported. Elevated radiance was observed in all the primary tumours with TBR 3.45, 4.90 and 2.49 respectively for each patient. No CLI signal was detected in the lymph nodes according to pathology. For 2 patients with high grade disease (Gleason 7), CLI analyses agreed with histological reports. For 1 patient, CLI showed a basal signal whereas it was a low-grade apical prostate adenocarcinoma according to pathology. Basal signals, regarded as artefacts from the electrocautery device, were excluded from the analysis. Staff radiation doses resulted from the proximity to the patient and the duration of the procedure. To allow for radioactive decay (18F half-life = 110 min), instruments were stored overnight before sterilisation, minimal solid waste and pathology samples before transfer for analysis. Due to the robotic surgery, the assisting surgeon received the highest body dose followed by the scrub nurse (respectively 110-180 μ Sv and 40-80 μ Sv). Anaesthetic staff received <20 μ Sv and all other staff <10 μ Sv.

Conclusions Intra-operative 18F-choline CLI is a feasible and low risk procedure. The CLI results from the first 3 patients show promise, and more data are warranted to further evaluate this new intra-operative technique for measuring surgical margin

and lymph node status. As CLI has a depth sensitivity of a few millimetres, further development is also required to restrict the signal to the surgical margin depths used in pathology.