Use of intraoperative Gallium-PSMA Cerenkov Luminescence Imaging for surgical margins in radical prostatectomy – a feasibility study

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Introduction
Cerenkov Luminescence Imaging (CLI) is a molecular imaging technique that detects light emitted by Positron Emission Tomography (PET) radiopharmaceuticals. This first-in-men study evaluates 68Ga-PSMA for intraoperative assessment of tumor margins at time of prostatectomy and after preoperative PSMA-PET/CT.

Material and Methods
3-4 hours prior to surgery, PSMA-PET/CT was performed after intravenous injection of 68Ga-PSMA with varying doses. Scan results were assessed by the specialists of nuclear medicine and urology. Radical prostatectomy was performed robotically and the prostate specimen was imaged with a CLI imager (Lightpoint Medical Ltd., UK) intraoperatively immediately after excision in order to assess the radianc on the surface. The agreement of margin distance on histopathology and CLI was assessed.

Results
CLI was used in five patients after preoperative injection of 144 mBq 68Ga-PSMA (mean, range 95-202). Intraprostatic lesions were detected by PSMA-PET/CT in 100%, positive lymph nodes could be seen in 3 of 5 patients. CLI was performed intraoperatively after a mean of 329 minutes after tracer injection. Mean background radianc was 1441 with 2430 photons/s/cm²/sr for prostate radianc. Positive surgical margins (PSM) were found in two patients based on histopathology (patient 1: pT3b, pN1, Gleason score 5+3=8, patient 5: pT3a, pN1, Gleason score 4+5=9). In these patients, elevated radianc levels were found in the tumor positive areas (mean radianc: 4254 photons/s/cm²/sr). In two other patients with suspicious signals, tumor distance to the surface was < 1 mm.

Conclusion
Intraoperative 68Ga-PSMA CLI seems to be a promising technique for intraoperative assessment of surgical margins in robot-assisted radical prostatectomy. A prospective trial is mandatory to elucidate further results concerning sensitivity and specificity.

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# | Tracer Activity (mBq) | Time from injection to CLI (min) | Mean prostate radiation background (photons/s/cm²/sr) | Mean radiation in CLI/tumor positive areas (photons/s/cm²/sr) | PSM | Location | TNM-classification | Gleason-Score |
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1 | 202 | 313 | 2650,4 | 15171,6 | Yes | Right lobe, dorso-basal | pT3b, pN1, L1, V0, Pn1, R1 | 5+3=8 |
2 | 95 | 340 | 2278,7 | 818,95 | < 1 mm | Ventral | pT3a, pN0, L1, V0, Pn1, R0 | 4+5=9 |
3 | 108 | 429 | 1746,3 | 2992,6 | < 1 mm | Ventral | pT3b, pN1, L1, V0, Pn1, R0 | 4+5=9 |
4 | 150 | 285 | 1725,3 | - - - | - - - | - - - | pT2a, pN0, L0, V0, Pn1, R0 | 4+3+7b |
5 | 163 | 282 | 3753,2 | 6259,8 | Yes | Left lobe, apex | pT3a, pN1, L1, V0, Pn1, R1 | 4+5=9 |

Gray-scale prostate image overlaid with Cerenkov signal:
A) 25%, B) 50%, C) 75%