

Press release

BioXmark® demonstrates good performance and safety for IGRT in bladder cancer

DK-Copenhagen, 12 August 2020 - Nanovi informs about the publication of a study evaluating the performance of BioXmark® in Image Guided Radiation Therapy (IGRT) for muscle invasive bladder cancer. The study was conducted by Dr. Mischa de Ridder and colleagues from Amsterdam University Medical Center in the Netherlands and published in The British Journal of Radiology.

Study introduction

For patients with muscle invasive bladder cancer, the option of bladder-preserving treatment with chemoradiation is gaining interest as an alternative to radical cystectomy (surgical removal of the entire bladder). For bladder-preserving treatment with a focal bladder boost, accurate tumor delineation and IGRT are essential for the sparing of normal tissue as well as for the delivery of an adequate radiation dose to the primary tumor. Therefore, there is a need for a safe, easy to inject, well visible and positionally stable fiducial marker for guidance during the planning and treatment phases.

Study design and results

In the present bladder cancer IGRT study, 3-5 BioXmark® liquid markers of 0.1 ml each were injected in proximity to the bladder tumor, using flexible cystoscopy. In total, 76 markers were implanted in 20 patients and 79% of these were visible on the treatment planning CT. Of those visible markers on CT scan, all (100%) remained detectable without displacement until the end of the treatment, defined as visible on the last CBCT at week four of follow-up. Over the course of the study, the physicians experienced a steep learning curve in terms of implantation technique. This resulted in an improvement of BioXmark visibility rate from 58% in the first 25% of patients to 86% in the last 75% of patients.

No adverse events related to BioXmark® was identified in the study.

It was stated in the publication that: "In patients where it was injected successfully, the BioXmark® liquid fiducial marker was an easy and clinically very applicable tool for IGRT in bladder-preserving chemoradiotherapy. Thereby, blurring, migration, and fading did not occur in our study during treatment". The study concluded "...BioXmark® marker seems to be a very promising tool in daily-adaptive IGRT for bladder preserving chemoradiotherapy in muscle invasive bladder cancer".

For further reading:

de Ridder M, Gerbrandy LC, de Reijke TM, Hinnen KA, Hulshof MCCM. BioXmark® liquid fiducial markers for image-guided radiotherapy in muscle invasive bladder cancer: a safety and performance trial. BJR. 2020 Jun 1;20200241.



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About BioXmark®

BioXmark® is a liquid fiducial marker, developed by Nanovi to enhance target visibility on imaging and enable high precision radiation therapy across cancer types.

BioXmark® has the following features and benefits:

- *Liquid nature* for customizable implantation
- *Sticky and soft markers containing a proprietary contrast agent* for positional stability and visibility on relevant imaging modalities, including MRI
- *Non-metallic* for a low level of artefacts and low dose perturbation ensuring photon and proton compatibility

BioXmark® offers radiation therapy workflow benefits in the form of

- A fast and easy implantation procedure
- Less risk for procedure related complications
- No need for additional training nor special equipment

About Nanovi

Nanovi A/S is a Danish medical device company specialized in precision marking for better cancer therapy. Our corporate dedication is to empower healthcare professionals with the best possible tools to support the delivery of high precision radiation therapy and surgery for the benefit of cancer patients and for healthcare efficiency.

We have a portfolio of unique in-house developed liquid fiducial markers for both human and veterinary use.

All our products are derived from a patented biomaterial technology platform, co-invented with the Department of Health Technology at the Technical University of Denmark, DTU.

The company's corporate offices are situated in Kgs. Lyngby, north of Copenhagen.

For more information, please visit: www.nanovi.com