

BiBB reports positive results from clinical pilot study with EndoDrill URO

The cancer diagnostics company BiBBInstruments AB ("BiBB" or the "Company") today reports that the first clinical study with EndoDrill® URO for muscle-invasive bladder cancer has been scientifically published in European Urology Open Science. The study shows that EndoDrill® URO safely can take treatment-based tissue samples earlier in the care chain in case of suspicion of deep-growing tumors in the urinary bladder. The research group concludes that it is now warranted to follow up the pilot study with a randomized efficacy study, which is already planned and regulatory approved.

"It is gratifying to see such a solid initial scientific trial of EndoDrill® URO conducted by a broad group representing several medical areas such as oncology, radiology, pathology, molecular diagnostics, nursing and urology. These initial results look promising and show that it is possible to take diagnostic and treatment-based tissue samples (biopsies) early in the investigation of bladder cancer. We will follow the next phase, a randomized efficacy study, with excitement. Hopefully, the added value for patients with the possibility of early treatment start, as the initial results suggest, can be further confirmed in a larger patient population. It would be of great importance for patients affected by this serious disease", says Dr Charles Walther, CMO at BiBB.

Last year, Professor Fredrik Liedberg and colleagues at Skåne University Hospital completed a pilot study on 10 patients with EndoDrill® URO for the indication muscle-invasive bladder cancer (MIBC). The study has now been published in the scientific journal European Urology Open Science 53 (2023) 78-82 titled "Urodrill - a novel MRI-guided endoscopic biopsy technique to sample and molecularly classify muscle-invasive bladder cancer without fractionating the specimen during transurethral resection" (note that "Urodrill" is identical to the product EndoDrill® URO).

The purpose of the study was to investigate whether it is possible to take tissue samples of deep-growing tumors for the first time already at the initial endoscopic examination of the bladder. With an early diagnosis, the more invasive standardized surgical procedure (TURB) could be avoided and treatment of patients with MIBC could be started earlier. The study compared biopsies taken with EndoDrill® URO with tissue samples taken during the surgical procedure.

The publication shows good results with the new biopsy instrument EndoDrill® URO. EndoDrill® URO managed to take a biopsy in 9 out of 10 examined patients and in the tenth case the tumor was very close to large blood vessels, which meant that you could not go so deep in the individual case. In 6 out of 9 cases, muscle-invasive bladder cancer could be confirmed and in 7 out of 9 cases, the muscle layer of the bladder wall, i.e., deep growth, could be assessed. In 8 cases, genetic mutation analysis was performed and in 7 of these, the analysis was technically successful. No complications related to tissue sampling with EndoDrill® URO were noted. The large research team concluded that it is possible to take treatment-based tissue samples with EndoDrill® URO early on if bladder cancer is suspected. "The current proof-of-concept study demonstrates that the Urodrill instrument can facilitate both histological confirmation of MIBC based on MRI findings and molecular classification."

The authors state that the next step warranted is a randomized clinical trial, in which early sampling with EndoDrill® URO during the initial endoscopic examination will be compared with the current standard of care tissue sampling using the TURB procedure. This randomized efficacy study is already planned and holds regulatory approvals.

More information about the study results is available via the following link: [https://www.euroopenscience.europeanurology.com/article/S2666-1683\(23\)00248-3/fulltext](https://www.euroopenscience.europeanurology.com/article/S2666-1683(23)00248-3/fulltext)

About the indication muscle-invasive bladder cancer (MIBC)

Bladder cancer is the fourth most common cancer for men and affects approximately 570,000 people in the world annually (WCRF 2020). In about 25% of cases, cancer has grown into the bladder muscle (MIBC), and it is this population that constitutes EndoDrill® URO's target group. This means that more than 140,000 patients per year are future candidates for early biopsy sampling with EndoDrill® URO. Since this is a possible paradigm shift with a modified standard of care with EndoDrill® biopsy, a solid clinical evaluation is required to convince the world's urologists. Success for EndoDrill® URO opens a whole new market segment, currently without competing biopsy instruments.

Background to the urology study

For many cancers, diagnosis can be established relatively early after tissue sampling at the initial endoscopic examination. In bladder cancer, however, biopsies are normally not taken at the initial endoscopy due to the lack of effective biopsy instruments. In these cases, the camera instrument is only used to visually examine the inside of the bladder. The next step is followed by a major surgical so-called TURB procedure (Transurethral resection of bladder tumor) that requires the patient to be anesthetized, and only at this later stage biopsies are taken to determine whether the tumor has grown into the underlying muscle layers surrounding the bladder, MIBC. Disadvantages of the TURB procedure are that it delays the start of treatment, potentially spreads tumor cells into the bloodstream and is associated with the risk of complications such as bleeding and perforation.

In 2020, a leading clinical research group visited BiBB when they heard that the biopsy instrument EndoDrill® could take deep, solid tissue samples during endoscopic examinations. Fredrik Liedberg, professor in Urothelial Cancer, and chairman of the Swedish National Register for Urinary Bladder Cancer, and his colleagues at Skåne University Hospital had for decades experienced that diagnosis, treatment and survival rates for patients affected by muscle-invasive bladder cancer had not improved significantly, which worried them.

The hypothesis was that an early diagnosis using EndoDrill® biopsy could ensure how deep the tumor has grown in the bladder much earlier, which could potentially mean earlier start of radical treatment and increased survival for a group of patients with five-year survival of only about 50%. In addition to the time savings, the health care and these patients would avoid a major procedure (TURB) according to the current standard of care. Professor Liedberg's research group wrote protocols for a safety study and follow-up randomized efficacy study, including health economic investigation. After permission from the Swedish Ethical Review Authority and the Medical Products Agency, the initial pilot study was conducted in 2021–2022 and this press release describes the study's results.

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This is a translation of the Swedish press release. If there should be any discrepancies, the Swedish language version prevails.

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About BiBBInstruments AB

BiBBInstruments AB is a medical technology company that develops and markets diagnostic instruments under the brand name EndoDrill® for early detection of cancerous tumors. EndoDrill® is the world's first FDA-cleared electric-driven endoscopic biopsy instrument. The product is designed to provide larger and more high-quality tissue samples (core biopsies) of suspected tumors than existing products. The product family will include sampling instruments for many of the most serious cancers, such as stomach, pancreas, liver, lung and bladder cancer. EndoDrill® targets the global market for endoscopic biopsy instruments with a focus on the ultrasound-guided biopsy instruments (EUS-FNA/FNB, EBUS-TBNA) segment, which is the fastest growing area in endoscopy. The company was founded in 2013 by Dr Charles Walther, cancer researcher at Lund University and chief physician in clinical pathology at Skåne University Hospital in Lund.