

New Publication: Racial Difference in Detection Rate of Bladder Cancer Using Blue Light Cystoscopy

Press release – Oslo, Norway, March 28, 2024: Photocure ASA, The Bladder Cancer Company, announces the publication of the study "Racial Difference in Detection Rate of Bladder Cancer Using Blue Light Cystoscopy: Insights from a Multicenter Registry" in the journal Cancers this week. This study aims to evaluate heterogeneity in characteristics of blue light cystoscopy (BLC®) for detection of malignant lesions among various races with non-muscle invasive bladder cancer (NMIBC).

The study author Sia Daneshmand, MD and the participants of the BLC with Cysview Study Group collected clinicopathologic information from adult patients undergoing transurethral resection of bladder tumor (TURBT) or biopsy who were enrolled in the multi-institutional BLC Cysview registry between April 2014 and February 2021. The primary outcome was detection of any malignant lesion on final pathology. Sensitivity, negative and positive predictive values for detection of malignant lesions were calculated for BLC, white light cystoscopy (WLC), and the combination of both modalities.

Overall, 2379 separate samples were identified from 1292 patients, of whom, 1095 (85%) were White/Caucasian, 96 (7%) Black/African American, 51 (4%) Asian and 50 (4%) Hispanic. The sensitivity of WLC, BLC, and the combination of both for any malignant lesion was 88.7%, 95.8% and 99%, respectively, in the total cohort (P<0.001). BLC sensitivity vs. WLC was most significantly pronounced in the Asian population (96% vs 78%, P<0.001). In all races, the sensitivity of BLC was significantly higher than WLC for detection of CIS (P<0.001). Also, the addition of BLC to standard WLC increased the detection rate by 10% for any malignant lesion in the total cohort. This rate increased to 18% in Asian patients. Positive predictive value of BLC was also the highest in Asian population (94.4%).

The authors conclude that regardless of race, BLC increased the detection of bladder cancer when combined with WLC. However, the difference was more pronounced in Asian patients: "Our study showed that regardless of race, BLC increases the detection of bladder cancer when combined with WLC. These results could identify differences in groups that will lead to improved treatment of underserved minority populations. Further research is warranted to understand the underlying etiology of these observations which may ultimately alter interpretation of lesions detected by BLC," said Dr. Daneshmand.

Read the full publication here: http://www.mdpi.com/2072-6694/16/7/1268

About the Blue Light Cystoscopy with Cysview Registry

The U.S. Blue Light Cystoscopy with Cysview Registry (Clinical Trials: NCT02660645) is a large prospective, longitudinal, real-world evidence study in NMIBC* patients who have undergone TURBT** using Blue Light as an adjunct to white light cystoscopy. The Registry study was established by Photocure in 2014 and is projected to enroll 4400 patients.

*NMIBC: Non-muscle invasive bladder cancer **TURBT: Transurethral resection of bladder tumor

Note to editors:

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About Bladder Cancer

Bladder cancer ranks as the 8th most common cancer worldwide – the 5th most common in men – with 1 949 000 prevalent cases (5-year prevalence rate)^{1a}, 614 000 new cases and more than 220 000 deaths in 2022.^{1b}

Approx. 75% of all bladder cancer cases occur in men.¹ It has a high recurrence rate with up to 61% in year one and up to 78% over five years.² Bladder cancer has the highest lifetime treatment costs per patient of all cancers.³

Bladder cancer is a costly, potentially progressive disease for which patients have to undergo multiple cystoscopies due to the high risk of recurrence. There is an urgent need to improve both the diagnosis and the management of bladder cancer for the benefit of patients and healthcare systems alike. Bladder cancer is classified into two types, non-muscle invasive bladder cancer (NMIBC) and muscle-invasive bladder cancer (MIBC), depending on the depth of invasion in the bladder wall. NMIBC remains in the inner layer of cells lining the bladder. These cancers are the most common (75%) of all BC cases and include the subtypes Ta, carcinoma in situ (CIS) and T1 lesions. In MIBC the cancer has grown into deeper layers of the bladder wall. These cancers, including subtypes T2, T3 and T4, are more likely to spread and are harder to treat.⁴

About Hexvix®/Cysview® (hexaminolevulinate HCI)

Hexvix/Cysview is a drug that preferentially accumulates in cancer cells in the bladder, making them glow bright pink during Blue Light Cystoscopy (BLC^{\circledR}). BLC with Hexvix/Cysview, compared to standard white light cystoscopy alone, improves the detection of tumors and leads to more complete resection, fewer residual tumors, and better management decisions.

Cysview is the tradename in the U.S. and Canada, Hexvix is the tradename in all other markets. Photocure is commercializing Cysview/Hexvix directly in the U.S. and Europe and has strategic partnerships for the commercialization of Hexvix/Cysview in China, Chile, Australia, New Zealand and Israel. Please refer to http://photocure.com/partners/our-partners for further information on our commercial partners.

¹ Globocan. a) 5-year prevalence / b) incidence/mortality by population. Available at: http://gco.iarc.fr/today, accessed [February 2024].

² Babjuk M, et al. Eur Urol. 2019; 76(5): 639-657

³ Sievert KD et al. World J Urol 2009;27:295–300

⁴ Bladder Cancer. American Cancer Society. http://www.cancer.org/cancer/bladder-cancer.html

About Photocure ASA

Photocure: The Bladder Cancer Company delivers transformative solutions to improve the lives of bladder cancer patients. Our unique technology, making cancer cells glow bright pink, has led to better health outcomes for patients worldwide. Photocure is headquartered in Oslo, Norway and listed on the Oslo Stock Exchange (OSE: PHO). For more information, please visit us at www.photocure.com, www.hexvix.com, www.cysview.com

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