

Artificial intelligence software CystoSmart™ for papillary or flat lesions during bladder endoscopy: a prospective observational pilot study protocol

Francesco Del Giudice,^{1,2,3*} Roberta Corvino,¹ Valerio Santarelli,¹ Eleonora Razeto,¹ Stefano Impaloni,¹ Sarah Carvalho Ribeiro,¹ Matilde Verde,¹ Bernardo Rocco,⁴ Ettore De Berardinis,¹ Jan Laszkiewicz,⁵ Benjamin I. Chung,² Amir Khan,⁶ Yasmin Abu-Ghanem,³ Elsie Mensah,³ Ramesh Thurairaja,³ Muhammad Shamim Khan,³ Rajesh Nair³

¹Department of Maternal-Infant and Urological Sciences, "Sapienza" University of Rome, Umberto I Hospital, Rome, Italy

²Department of Urology, Stanford University School of Medicine, Stanford, CA, USA

³Guy's and St. Thomas' NHS Foundation Trust, Guy's Hospital, London, UK

⁴Department of Urology, IRCCS A. Gemelli University Polyclinic Foundation, Sacred Heart Catholic University, Rome, Italy

⁵Department of Minimally Invasive and Robotic Urology, University Center of Excellence in Urology, Wroclaw Medical University, Wroclaw, Poland

⁶Division of Urology, Department of Surgery, University of Maryland School of Medicine, Baltimore, MD, USA

DEL GIUDICE F, CORVINO R, SANTARELLI V, RAZETO E, IMPALONI S, CARVALHO RIBEIRO S, VERDE M, ROCCO B, DE BERARDINIS E, LASZKIEWICZ J, CHUNG BI, KHAN A, ABU-GHANEM Y, MENSAH E, THURAIRAJA R, KHAN MS, NAIR R. Artificial intelligence software CystoSmart™ for papillary or flat lesions during bladder endoscopy: a prospective observational pilot study protocol *Can J Urol* 2026;33(50):1251–1259.

Objectives: White light cystoscopy (WLC) remains the standard tool for the diagnosis and surveillance of bladder cancer (BC), but it may miss up to 20% of lesions, highlighting the potential role of artificial intelligence (AI) assisted systems such as CystoSmart™. The study aims to evaluate the sensitivity and specificity of CystoSmart™ in detecting papillary and flat lesions, using histopathology as the reference standard.

Methods: This is a prospective observational, non-interventional study with retrospective AI application, led by "Sapienza" University of Rome. Patients undergoing primary or follow up WLC for

suspected BC will be enrolled and will provide informed consent for anonymized recording. Frames will be retrospectively analyzed by the software without influencing clinical decision-making. Exclusion criteria include metastatic disease, inability to provide consent, inadequate video quality, and contraindications to cystoscopy. A total sample size of 158 patients was determined to ensure at least 138 positive cases. Statistical analyses will apply confidence intervals and exact binomial testing.

Results: Based on the sample size calculation and the preliminary internal validation data, CystoSmart™ is expected to achieve sensitivity exceeding 90% for BC detection, with specificity also anticipated to exceed 90%. Diagnostic accuracy, sensitivity, specificity, positive and negative predictive values will be estimated at both the per-patient and per-lesion levels. Exploratory subgroup analyses will assess performance across primary diagnostic, intraoperative, and surveillance settings.

Conclusion: AI-assisted cystoscopy has the potential to facilitate the integration of AI-based tools into routine BC clinical practice.

Key Words: Bladder cancer, non-muscle-invasive bladder cancer, cystoscopy, white-light cystoscopy, endoscopy, CystoSmart

Received date 26 January 2026

Accepted for publication 07 April 2026

Published online 30 October 2026

*Corresponding Author: Francesco Del Giudice.

Emails: francesco.delgiudice@uniroma1.it or

fdelgiu@stanford.edu or francesco.delgiudice@nhs.net

Introduction

Bladder cancer (BC) remains a major public health concern within the European Union (EU), ranking as the sixth most commonly diagnosed cancer and

representing a significant source of cancer-related morbidity and mortality.¹⁻³ Each year, approximately 124,000 new cases are reported, along with more than 40,000 related deaths, placing a considerable economic strain on healthcare systems.¹⁻³ Globally, BC remains highly prevalent, with hundreds of thousands of new diagnoses annually and a marked sex disparity, as incidence and mortality rates are consistently higher in men compared to women.¹ Importantly, epidemiological projections suggest that the burden of BC will continue to increase over time, largely driven by population aging and the growing proportion of elderly individuals requiring long-term surveillance and treatment.⁴ By 2030, the annual incidence of BC is expected to reach 219,000 cases, with approximately 40% of this increase linked to the aging population in Europe.⁴ Most of the BC cases—approximately 75–80%—are diagnosed at an early stage, with tumours confined to the mucosa (stage Ta or carcinoma *in situ* [CIS]) or submucosa (stage T1), as classified by the TNM system.⁵ This contrasts with the less frequent but significantly more aggressive muscle-invasive bladder cancer (MIBC; stages T2–T4), which requires multimodal treatment strategies and carries poorer oncological outcomes.² Nevertheless, even non-muscle-invasive bladder cancer (NMIBC) is characterized by a high propensity for recurrence and progression, requiring repeated endoscopic examinations and interventions, thereby contributing to one of the highest lifetime treatment costs among malignancies. In this context, enhancing the diagnostic and surveillance accuracy of bladder endoscopy is of paramount importance to reduce missed lesions, improve early detection of clinically relevant disease, and potentially optimize downstream treatment planning.

White light cystoscopy (WLC) is the current standard for the detection and monitoring of BC, enabling direct visualization of the bladder mucosa. Despite its widespread use, WLC has well-recognized limitations, particularly in the identification of flat lesions such as CIS, subtle papillary tumours, and difficult-to-visualize regions in the presence of bleeding, inflammation, prior intravesical therapy, or post-treatment changes. Likewise, the accuracy of cystoscopies can also be affected by an insufficient overview, macroscopic hematuria, fibrin, infection, and small tumour size, leading to low specificity.⁶ These limitations contribute to reported false-negative rates up to 20%, with significant implications for patient outcomes.^{7,8}

The clinical implications of missed lesions are not trivial, as missed lesions during cystoscopy

or intraoperative inspection may result into residual tumour after transurethral resection of bladder tumour (TURBT), early recurrence, and potential delays in appropriate risk stratification and treatment decision-making.⁸

To address these shortcomings, several enhanced cystoscopy techniques have been introduced over the past decades. Blue light cystoscopy (BLC) and photodynamic diagnosis (PDD) have demonstrated improved lesion detection, particularly for CIS and additional lesions not visible under WLC.⁹ However, their widespread implementation remains limited by the need for exogenous agents, dedicated equipment, additional workflow complexity, and higher direct procedural costs.⁹ Notably, hexaminolevulinate (HAL)-guided fluorescence cystoscopy has shown a clinically relevant reduction in recurrence when compared with standard WLC in NMIBC populations, supporting the concept that improved lesion visualization may have measurable oncological implications beyond diagnostic performance alone.⁶ Despite these advantages, access to enhanced imaging remains heterogeneous among institutions and healthcare settings, thus reinforcing the need for additional solutions that are scalable, user-friendly, and capable of integration into standard-of-care workflows.

In parallel with technological progress in endoscopic imaging, artificial intelligence (AI), particularly deep learning-based computer vision, has recently emerged as a promising strategy to enhance diagnostic performance in medical imaging, including radiology, dermatology, ophthalmology, and gastrointestinal endoscopy.¹⁰ Within urology, preliminary investigations suggest that AI-assisted cystoscopy may improve detection accuracy reducing the amount of missed lesions and potentially standardize interpretation by providing objective decision support.¹¹ However, most published work in AI-assisted bladder endoscopy has been limited by retrospective datasets, still image-based analyses, single-center design, platform-specific constraints, and insufficient external validation across different cystoscopes, acquisition settings, and real-world clinical conditions. Furthermore, translating AI tools into daily practice requires demonstration of feasibility, robustness, and reproducibility in clinically representative cohorts, as well as a clear understanding of how model performance may vary across different endoscopic contexts, including primary diagnostic cystoscopy, surveillance examinations, and intraoperative settings.

CystoSmartTM is a novel deep learning-based software solution developed to assist urologists

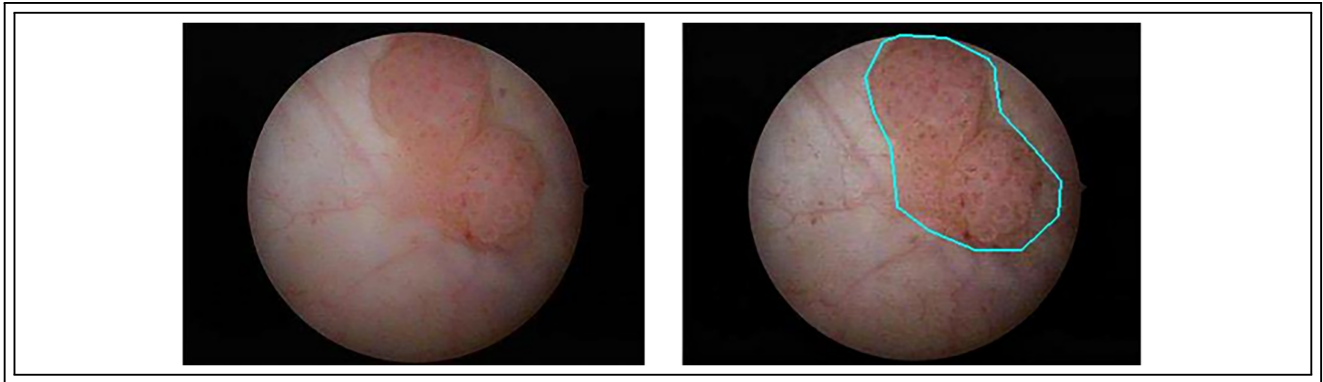


FIGURE 1. Example of the input and output images together with the generated JSON file. The recognized regions are defined by colored polygons, and they may be colored inside by dots. When a video is processed, the segmentation is carried out for every frame independently. Processing controls include file name and resolution, display mode, split position, fit window, vertical and horizontal flip, dot interior, detected features, and processing section.

during bladder endoscopy by supporting the identification and delineation of suspected bladder lesions during WLC. Unlike several prior approaches, CystoSmart™ is designed to operate independently of image format, resolution, and endoscope manufacturer, supporting both flexible and rigid instruments, and allowing analysis of both recorded and real-time cystoscopic media. The software generates polygonal overlays to localize suspicious regions, while preserving the original raw video data through non-destructive annotation formats (e.g., JSON files), enabling retrospective review and potential downstream model refinement (Figure 1). Such characteristics may represent key advantages for broad adoption, as they facilitate integration into heterogeneous clinical environments without requiring hardware replacement or proprietary imaging platforms. Existing AI-based software have largely been developed and validated within single-center settings, often limited to specific imaging platforms or acquisition protocols, thus limiting their real-world generalizability.

This research proposal presents a prospective observational, non-interventional, clinical video-validation study of CystoSmart™ based on retrospective analysis of anonymized WLC recordings collected during routine diagnostic or follow up cystoscopy. By focusing on both papillary and flat lesions in a high-prevalence population, the study aims to provide clinically meaningful evidence regarding software sensitivity and specificity against histopathological reference standards, while generating insights into the role of AI-based support tools across the NMIBC care

pathway, addressing the current gap by evaluating a deep learning-based system that is independent of image platform and data format, across different endoscopic environments and clinical settings.

Methods

Study design

This study is designed as a prospective, observational, non-interventional investigation with retrospective application of AI to collected cystoscopic data. “Sapienza” University of Rome and the Dept of Maternal, Infant and Urologic Sciences are the research promoters of the present study. The protocol has been fully reviewed and approved by the Institutional Review Board (IRB) of the “Sapienza” University of Rome (Dept. of Maternal, Infant and Urologic Sciences-Protocol No. 116-0001009-22-9-2025).

Patients undergoing primary or follow up WLC for suspected BC will be prospectively enrolled. Cystoscopic procedures will be performed according to standard clinical practice, and video recordings will be captured exclusively under white light. In patients undergoing TURBT, recordings will include both white and blue light conditions. The AI-driven CystoSmart™ software (Intelligent Scopes Corp-Claritas HealthTech) will be applied retrospectively to these stored frames to evaluate lesion detection performance without influencing real-time clinical decision-making or patient management. Histopathological confirmation from biopsies or resected specimens will be used as the reference

standard. In order to reflect the multifocal nature of BC and the complexity of endoscopic interpretation in daily practice, diagnostic performance will be evaluated at both the per-patient and per-lesion levels. The design ensures that no intervention or modification of the standard diagnostic pathway occurs, preserving the observational and non-interventional nature of the study.

Endpoints

The primary endpoint is the sensitivity of CystoSmart™ in detecting papillary and/or flat bladder lesions, with sample size and statistical parameters selected to validate diagnostic performance in a high-prevalence population. Specificity will be evaluated as a secondary endpoint.

Eligibility criteria

Subject selection

Eligible participants will be prospectively recruited from those referred to the urology outpatient clinic for WLC due to suspected or recurrent BC, based on prior clinical or imaging findings. For this observational study, participants will be further approached to provide additional informed consent for the use of anonymized cystoscopic video recordings in the retrospective evaluation of the AI-driven CystoSmart™ software. Recruitment will occur consecutively, prior to the scheduled cystoscopy or TUR procedure. Patients will be fully informed about the nature, purpose, and non-interventional design of this study, and will be assured that their participation or refusal will not impact their clinical care.

Patients will be considered eligible for registration in this study if they fulfil all inclusion criteria and none of the exclusion criteria listed below.

Inclusion criteria

Eligible participants are male and female patients aged 18 years or older, referred for primary or follow up diagnostic WLC for suspected BC, after prior clinical findings or imaging suggestive of bladder lesions. Patients scheduled to undergo intraoperative cystoscopy and/or TURBT under white or blue light are considered eligible. All participants are required to provide written informed consent for video recording and retrospective analysis.

Exclusion criteria

Patients with known metastatic BC prior to cystoscopy, based on history, imaging, and clinical staging, were excluded. Additional exclusion criteria included contraindications to cystoscopy or TURBT

procedures, inability or unwillingness to provide informed consent for video recording or study participation, and poor video quality or incomplete cystoscopic recordings preventing retrospective analysis by CystoSmart™ software.

Sample size calculation

The overall sample for this prospective observational study was calculated primarily to validate the sensitivity of the AI-driven CystoSmart™ software for detecting papillary and/or flat bladder lesions during WLC, based on diagnostic accuracy benchmarks reported in the literature for white-light procedures. The expected sensitivity in this study is greater than 90%, compared to the reference sensitivity of approximately 81%.⁶ Considering the clinical relevance of minimizing false-negative findings during diagnostic and surveillance cystoscopy, the sample size was designed to ensure adequate statistical power to demonstrate that the sensitivity of CystoSmart™ exceeds a minimum clinically acceptable threshold of 85%, according to standard methodological approaches for diagnostic accuracy studies.¹²

To test this hypothesis, standard formulas for diagnostic accuracy studies were applied, assuming a one-sample binomial framework for sensitivity testing. Specifically, the study is powered to show that the true sensitivity is $>85\%$ with 80% statistical power, using an α level of 0.05. Given the high-prevalence study population (i.e., patients undergoing WLC after prior imaging suspicious for BC), a disease prevalence of approximately 90% was anticipated. Therefore, the sample size estimation was driven by the number of cancer-positive cases required to yield sufficiently narrow confidence intervals around the sensitivity estimate and to ensure the robustness of the planned hypothesis test. Based on these assumptions, at least $n = 138$ BC-positive patients were required. Accounting for the expected prevalence and potential exclusions due to inadequate video acquisition quality or incomplete recordings, a total sample size of $n = 158$ patients was calculated to achieve the target number of positive cases.

This sample size is expected to provide sufficient precision to estimate sensitivity with adequate confidence and to formally demonstrate a statistically significant improvement over the literature benchmark for WLC sensitivity.⁶ Moreover, the planned cohort size is considered appropriate for the study's prospective observational nature, enabling systematic acquisition of real-world cystoscopic video data and allowing exploration of the software's diagnostic

performance across clinically heterogeneous conditions, including tumour morphology (papillary vs. flat) and different procedural contexts.

Secondary analyses will include subgroup evaluations according to the clinical context in which cystoscopy is performed, including: (1) primary diagnostic WLC, (2) follow up/surveillance WLC, and (3) intraoperative cystoscopy performed during TURBT under white and/or blue light conditions. In particular, performance during TURBT and under blue light will be considered exploratory due to the increased variability of lighting conditions, the presence of resection artifacts (e.g., bleeding, cautery-related changes), and potential differences in lesion visualization compared to diagnostic outpatient procedures. Therefore, these subgroups are not powered for definitive comparative conclusions and should be interpreted as hypothesis-generating rather than confirmatory. Specificity is included as a secondary endpoint and will be estimated with appropriate confidence intervals; however, given the lower expected proportion of disease-negative patients in this enriched cohort, specificity was not the primary driver of the sample size calculation.

Statistical analysis

The primary endpoint of this study is the sensitivity of the CystoSmart™ software in detecting histologically confirmed papillary and/or flat bladder lesions during WLC based on retrospective video analysis. Histopathological findings from biopsies or resected tissue will serve as the reference standard according to a per-patient and per-lesion level analysis. At the per-patient level, sensitivity will be defined as the proportion of patients with at least one histologically confirmed malignant lesion (papillary and/or flat) who are correctly classified as positive by CystoSmart™ (i.e., at least one lesion detected by the software). Patients with no histologically confirmed malignant lesions will contribute to the specificity analyses. At the per-lesion level, sensitivity will be calculated as the number of true positive lesions identified by CystoSmart™ divided by the total number of histologically confirmed lesions, defined as true positives (TPs) plus false negatives (FNs). TP lesions correspond to histologically confirmed specimens, based on anatomical location and spatial correspondence within the cystoscopic video. On the contrary, FN lesions are histologically confirmed specimens that are partially or completely not detected by the software, failing to consider them malignant. Lesions showing clear overlap and/or concordant localization will be classified as TP. This per-lesion analysis will provide additional insights into the software's

capacity to detect multifocal disease and to identify small or flat lesions that may be more frequently missed during standard visual inspection.

For both per-patient and per-lesion sensitivity estimates, 95% confidence intervals will be calculated using the Wilson score method, which provides reliable interval estimation for proportions and is appropriate for diagnostic accuracy outcomes. The primary hypothesis test will assess whether per-patient sensitivity significantly exceeds the pre-defined reference threshold of 85% (derived from published data on standard WLC performance⁶). This will be performed using a one-sided exact binomial test with $\alpha = 0.05$. In addition to hypothesis testing, the study will report absolute sensitivity estimates with confidence intervals to support clinical interpretation and to contextualize the magnitude of improvement compared with standard benchmarks.

Secondary analyses will include the evaluation of specificity at both per-patient and per-lesion levels. Specificity will be defined as the proportion of TNs among all disease-negative patients (or lesions), and 95% confidence intervals will be provided for descriptive purposes. Given the expected enrichment of positive cases in this cohort, specificity estimates will be interpreted cautiously, particularly for subgroup analyses where the number of negative cases may be limited.

Exploratory subgroup analyses will be performed to evaluate the diagnostic accuracy of CystoSmart™ across different clinical scenarios, including: (1) primary diagnostic WLC, (2) follow up/surveillance WLC, and (3) intraoperative cystoscopy during TURBT under white and/or blue light. Additional exploratory analyses may include comparisons of detection performance between papillary lesions and flat lesions (including CIS), as well as the assessment of the impact of video quality on software output (e.g., presence of bleeding, bladder distension, motion artifacts, or incomplete visualization). Where feasible, these subgroup analyses will be reported with point estimates and confidence intervals, acknowledging that the study is not primarily powered for formal between-group comparisons.

All statistical analyses will be conducted using validated statistical methods. A p -value < 0.05 will be considered statistically significant for the primary endpoint. Secondary endpoints and exploratory subgroup analyses will be interpreted as hypothesis-generating and will not be adjusted for multiple testing. Results will be presented in accordance with reporting standards for diagnostic accuracy studies, with clear differentiation between confirmatory and exploratory analyses.

Results

Based on the study hypothesis and the sample size calculation, CystoSmart™ is expected to demonstrate a per-patient sensitivity exceeding 90% for papillary and flat lesions detection during WLC. With at least 138 patients histologically positive for BC, the estimated sensitivity is expected within the range of 90–95%. The primary hypothesis test will assess whether the observed sensitivity significantly exceeds the predefined reference threshold of 85%. Therefore, reaching the expected sensitivity of $\geq 90\%$ will define a sufficient statistical power to demonstrate a statistically significant improvement over the benchmark reported for standard WLC.

Secondary analyses will provide estimates of specificity, and both positive and negative predictive values, at both the per-patient and per-lesion levels, along with their corresponding 95% confidence intervals. Exploratory subgroup analyses will evaluate diagnostic performance across different clinical settings, including primary diagnostic, follow up surveillance, and intraoperative procedures. These findings are expected to provide preliminary evidence on the potential role of AI-assisted cystoscopy analysis as a supportive tool for improving BC detection.

Discussion

BC is a high-priority area for research into both clinical and cost-effective management. Currently, AI has increasingly been applied across multiple domains, including medicine, as it provides many theoretical and practical insights that would be otherwise difficult to obtain through traditional methods. Current ongoing research is widely exploring AI versatile applications, especially in BC detection through cystoscopy and its subsequent management strategies.

During standard WLC, misdiagnosis rates of up to 43% have been reported, especially because flat cancerous lesions such as CIS or very small tumours may be overlooked, resulting in a 25.2%–53.1% incidence of residual pathological tissue.¹³ This diagnostic failure is particularly dangerous in CIS, which carries a high risk of progression to muscle-invasive disease if not treated early.¹⁴ Literature suggests that the sensitivity of WLC for CIS can be as low as 50% in the hands of non-experts, highlighting the potential role of AI-based systems such as CystoSmart™ as a valuable tool for democratizing diagnostic competence across different clinical settings and reducing the learning curve for junior urologists.^{6,15}

and inter-operative variability, mitigating the impact of human factors, such as visual fatigue and cognitive bias, which are often responsible for missing small or multifocal lesions during prolonged endoscopic examinations.^{16,17}

According to literature, recently, several studies were conducted to evaluate the use of AI in assisting BC detection from images taken during cystoscopy (Table 1), reporting high pooled sensitivity and specificity (0.953 and 0.957, respectively). Despite the reported promising diagnostic accuracy, reported in the literature, it is widely acknowledged that clinicians are reluctant to omit biopsy or histopathological confirmation based solely on AI output. In this context, CystoSmart™ is conceived as an adjunctive decision-support tool rather than a replacement for clinical judgment.

In addition, integrating AI outputs with tumour risk stratification and patients' quality of life may help tailor surveillance and optimal treatment strategy.^{18,19}

Another important aspect to consider is the reproducibility of AI models in development. Studies are encouraged to follow the Checklist for Artificial Intelligence in Medical Imaging (CLAIM), leading to researchers' collaboration and external validation of models, facilitating translation into routine practice.²⁰ As highlighted in recent systematic reviews, the lack of standardized reporting has historically hindered the transition of AI into the clinical setting, but new benchmarks are now enabling more robust external validation.^{21–24}

Real-time AI application has already shown feasibility, as Chang et al.¹¹ demonstrated how this setting could generate active biofeedback to the surgeon, limiting the median error rate at 3.6% frames per cystoscopy and 16.7% per TURBT.

The novel AI-based software CystoSmart™ aims to assist urologists during WLC, independently of several setting conditions (such as image features and endoscope characteristics), and in both real-time and recorded imaging, integrating cutting-edge AI technology into the retrospective analysis of cystoscopic video recordings to potentially enhance lesion detection accuracy for both papillary and flat bladder lesions during primary and follow up procedures. Preliminary internal validation has demonstrated promising diagnostic performance, with CystoSmart™ achieving sensitivity greater than 95% and specificity above 98% for tumour detection. These results markedly outperform baseline clinician accuracy rates reported in the literature, particularly among less experienced operators. The

TABLE 1. Baseline characteristics of the included studies

Study, year	Country	Cystoscopy type	AI algorithm or model	Total samples included	Comparison	Sensitivity (%) in prediction results
Ali et al., 2021 ²¹	Germany	Blue light	CNN (VGG16, ResNet50, MobileNetV2 and InceptionV3)	216 images (1 per patient)	AI detection vs. physician vs. pathology	VGG16: 93.66 ResNet50: 91.55 MobileNetV2: 95.77 InceptionV3: 95.07 Physician 1: 88.03 Physician 2: 87.32
Ikeda et al., 2020 ¹⁶	Japan	White light	CNN (GoogleNet)	2102 images from 109 patients	AI detection vs. pathology	89.7
Shkolyar et al., 2019 ¹⁵	US	White light	CNN (CystoNet)	198 videos (55,938 frames) from 154 patients	AI detection vs. pathology	90.9
Wu et al., 2022 ¹⁷	China	White light	CNN (PSPNet)	69,204 images from 10,729 patients	AI detection vs. physician vs. pathology	SYSMH and RJH (internal validation set): 98.7 SZSH (external validation set): 87.5 STCH (external validation set): 97.7 AMUFH (external validation set): 95.8 NJFH (external validation set): 95.1
Yoo et al., 2022 ²²	Korea	White light	CNN (ResNeXt-101-32 × 8d-FPN)	10,991 images	AI detection vs. pathology	95

Note. PSPNet, Pyramid Scheme Parsing Network; CNN, Convolutional neural network; AI, Artificial intelligence; US, United States; ML, Machine learning.

tool also achieved a mean Dice similarity coefficient exceeding 90%, indicating high concordance between AI-generated lesion maps and expert-annotated ground truth, demonstrating the model’s precision in demarcating tumour boundaries, which is essential for achieving complete tumour resection. In pilot testing, sensitivity improved from 83% to 97% and specificity from 92% to 98%, reinforcing its potential clinical value.^{13,15} By validating the CystoSmart™ software within a prospective non-interventional study, this project addresses current limitations in diagnostic accuracy that impact clinical decision-making and patient outcomes. The proposal’s ambition lies in demonstrating that AI can provide a robust, reproducible, and objective adjunct to conventional cystoscopy, thus reducing observer variability and potentially enabling earlier detection of clinically significant lesions. CystoSmart™ extends this concept by combining video-based segmentation, non-destructive annotations, and evaluation across heterogeneous clinical workflows.^{16,22}

These features may improve surveillance strategies and timing of therapeutic interventions such as TURBT, and ultimately potentially enhance patient prognoses and healthcare costs in the future. Given that BC is one of the most expensive malignancies to manage over a patient’s lifetime,^{2,14} the implementation of a software-based diagnostic aid could significantly reduce the economic strain on healthcare systems by decreasing the frequency of missed tumours that later require radical surgery.²²

Furthermore, the study includes exploratory subgroup analyses assessing diagnostic accuracy across diagnostic, intraoperative and follow up settings, thereby generating novel insights into the utility of AI across the BC care continuum.

Limitations of this study include the retrospective analysis of recorded videos rather than real-time implementation, the single-center design, the potential variability in video quality, and the high disease prevalence population, which may not fully reflect the performance and workflow integration of the software during live procedures, thus limiting the

generalizability of the findings to broader screening or lower-risk populations.

Conclusions

By advancing the state of the art, CystoSmart™ aims to set a new standard for BC diagnostics, fostering the integration of AI tools into routine clinical practice and paving the way for future innovations in uro-oncological imaging and personalized patient management.

Acknowledgement

The authors thank Claritas HealthTech and Intelligent Scopes Corp for providing, free of charge, the AI software and related technical infrastructure used in this study.

Funding Statement

The authors received no specific funding for this study.

Author Contributions

Conceptualization: Francesco Del Giudice, Rajesh Nair. Study design, interpretation of data, drafting of the report, and approval of the final report: Francesco Del Giudice, Roberta Corvino, Valerio Santarelli, Eleonora Razeto, Stefano Impaloni, Sarah Carvalho Ribeiro, Matilde Verde, Bernardo Rocco, Ettore De Berardinis, Jan Laszkiewicz, Benjamin I. Chung, Amir Khan, Yasmin Abu-Ghanem, Elsie Mensah, Ramesh Thurai Raja, Muhammad Shamim Khan and Rajesh Nair. All authors reviewed and approved the final version of the manuscript.

Availability of Data and Materials

Not applicable.

Ethics Approval

This study does not involve interventional research on human participants. It is a pilot,

non-interventional protocol proposal on post-hoc retrospective analysis of fully de-identified cystoscopic videos prospectively collected. All patients will provide written informed consent for video recording as part of standard clinical care. Additionally, the Dept of Maternal, Infant and Urologic Sciences, “Sapienza” University of Rome is the sole owner of the collected information, clinical data and videos. The protocol has been fully reviewed and approved by the Institutional Review Board (IRB) of the “Sapienza” University of Rome (Dept. of Maternal, Infant and Urologic Sciences–Protocol No. 116-0001009-22-9-2025). Informed consent will be obtained from all subjects involved in the study for data collection and storage.

Conflicts of Interest

Rajesh Nair is a paid advisor in his capacity as a Consultant Urological Surgeon for Intelligent Scopes Corp. All other authors declare that they have no financial or non-financial relationships with Intelligent Scopes Corp or Claritas HealthTech that could be perceived as potential conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

AI	Artificial Intelligence
BC	Bladder Cancer
WLC	White light cystoscopy
NMIBC	Non-Muscle-Invasive Bladder Cancer
EU	European Union
CIS	Carcinoma <i>in situ</i>
TNM	Tumour, node and metastasis
MIBC	Muscle-invasive bladder cancer
BLC	Blue light cystoscopy
TURBT	Trans-urethral resection of bladder tumour
MRI	Magnetic resonance imaging
PDD	Photodynamic diagnosis
CLAIM	Checklist for Artificial Intelligence in Medical Imaging
PSPnet	Pyramid Scheme Parsing Network
CNN	Convolutional neural network
US	United States
ML	Machine Learning

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