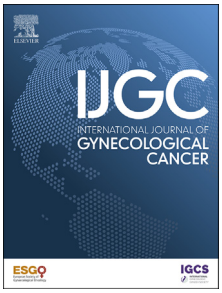
ORIGINAL RESEARCH

Critical view of safety assessment in sentinel node dissection for endometrial and cervical cancer: artificial intelligence to enhance surgical safety and lymph node detection (LYSE study)



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ABSTRACT

Objective: This study aims to evaluate the feasibility of video-based assessment rate of Critical Views of Safety criteria for sentinel lymph node dissection in endometrial and cervical cancer. Goal of these Critical Views of Safety is to help standardize the evaluation of surgical quality, improve the precision of sentinel lymph node identification, and lead to better patient outcomes.

Methods: This international multi-center observational prospective study was conducted from April to September 2024. Surgical videos from patients with cervical and endometrial carcinoma undergoing minimally invasive sentinel lymph node dissection were collected. A total of 3 Critical Views of Safety criteria (lateral pararectal space, lateral paravesical space, internal iliac artery) were proposed based on the anatomical structures defined as mandatory to be identified before sentinel node dissection, according to previously published expert consensus. A total of 3 independent surgeons, blinded to each other's assessments, evaluated whether the proposed criteria were identifiable in the endoscopic surgical video to establish applicability (content validity) and inter-rater agreement (reliability).

Results: A total of 80 patients were enrolled, of these, 71 cases (88.8%) had videos suitable for annotation, 64 (90.1%) underwent sentinel lymph node dissection for endometrial cancer, and 7 (9.9%) for cervical cancer; the median age was 52 years (IQR 34-71) and median body mass index was 28.8 kg/m^2 (IQR 23.7-32.17). The lateral pararectal space was identified in 62% of videos, the lateral paravesical space in 94%, and the internal iliac artery in the 32%. Inter-rater reliability was high for the lateral pararectal and paravesical spaces (Fleiss κ of 0.90) and moderate for the internal iliac artery (Fleiss κ of 0.73).

Conclusions: The low assessment rate of the internal iliac artery criteria should raise concerns about missing sentinel lymph nodes in the internal iliac and pre-sacral area. The assessment of such standardized safety criteria could potentially standardize the procedures, thereby improving adherence to guidelines. The introduction of the video assessment of these criteria lays the foundation for exploring the feasibility of artificial intelligence algorithms to automatically assess and document the Critical Views of Safety in surgical videos.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Sentinel lymph node dissection has replaced systematic lymphadenectomy, which is associated with higher morbidity in endometrial and cervical cancer. However, the rates of peri-operative complications, empty node packets, and mapping failures cannot be neglected, particularly, during the early stages of the learning curve.

WHAT THIS STUDY ADDS

This study evaluates the feasibility of video assessment rate of 3 Critical Views of Safety through the analysis of laparoscopic and robotic videos of sentinel lymph node dissection in endometrial and cervical cancer to enhance the efficacy of sentinel lymph node technique. The low assessment rate of the internal iliac artery criteria should raise concerns about missing sentinel lymph nodes in the internal iliac and pre-sacral area.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE, OR POLICY

This study represents an initial step for video assessment of recommendation or international guidelines opening the path toward developing objective computer vision-based artificial intelligence algorithms to enhance the safety and implement detection of the sentinel lymph node in endometrial and cervical cancer.

Keywords:
Computer Vision; Sentinel Lymph Node; Robot-Assisted Surgery; Image-Guided Surgery; Artificial Intelligence; Digital Surgery; Gynecologic Oncology

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INTRODUCTION

Lymph node assessment is crucial to determine the extent of disease spread in women with endometrial and cervical cancer, guiding adjuvant therapy.[1,2] Traditionally, lymphadenectomy was the sole method for nodal assessment, but it comes with increased risk of complications.[3] However, the introduction of sentinel lymph node biopsy techniques, supported by the recommendations of the European Society of Gynecologic Oncology, and the adoption of the sentinel lymph node approach have facilitated less extensive procedures providing essential staging information while reducing patient morbidity.[1,2,4,5]

Although advances in sentinel lymph node detection, such as using indocyanine green and standardization of injection techniques, have improved outcomes, the technique fails in 20% to 25% of cases.[6] Furthermore, the rates of intra-operative (0.4%) and post-operative (10.8%) complications related to the surgical technique remain high.[7] In addition, in 2% of procedures, no lymph node tissue is found, resulting in empty packets.[8] This percentage can increase to 8% in obese patients[9] and up to 20% if the surgeon is at the beginning of the learning curve.[10] Moreover, the limited sensitivity of frozen section analysis (65%) in detecting lymph node metastases restricts its use for intra-operative decision-making.[11,12]

Despite recent guidelines recommending the sentinel lymph node dissection, a variability in surgical procedures across institutions has been observed.[13,14] Consequently, expert consensus has been developed to standardize sentinel lymph node dissection in cervical[15] and endometrial cancer.[16] These recommendations aimed to enhance the bilateral mapping of the proper sentinel lymph nodes by establishing mandatory procedural steps and promoting the intra-operative recognition of definite retroperitoneal anatomical structures.

Systems for the assessment of mandatory steps are desirable to aid surgeons during their learning curve, limiting the rate of mapping failure, empty packets, and surgical complications.[15,16] Video-based assessment and reporting have shown promise for assessing and improving the quality and safety of laparoscopic procedures. In laparoscopic cholecystectomy, the video-based assessment of the Critical Views of Safety is an approach universally recommended to prevent major bile duct injuries.[17] In addition, deep learning tools have been developed to automatically and univocally assess the Critical Views of Safety in operative videos and are being studied to enhance safety during surgical procedures.[18-20]

This study aims to evaluate the feasibility of the video-based assessment rate of Critical Views of Safety criteria proposed through mandatory anatomical structures defined in the expert consensus on sentinel lymph node dissection in endometrial and cervical cancer. By identifying these Critical Views of Safety, the goal is to standardize the assessment of surgical quality, enhance the accuracy of sentinel lymph node detection, and improve patient outcomes.

METHODS

Data Collection

This is a multi-center, observational, prospective study conducted at the Oncology Gynecology unit of the Fondazione Policlinico Universitario Agostino Gemelli IRCCS in Rome, Italy and the Department of Gynecologic Surgery of Hautepierre Hospital in Strasbourg, France. Surgical videos from patients with cervical and endometrial carcinoma undergoing minimally invasive (laparoscopic/robotic) sentinel lymph node dissection were prospectively collected from April to September 2024. The selection criteria for the videos required that the surgeries adhered to the mandatory procedural steps outlined in the expert consensus, including tracer use, injection location, technique and needle selection, uterine manipulator use, white light inspection, and dissection technique.[15,16] In accordance with the journal's guidelines, we will provide our data for independent analysis by a selected team by the Editorial Team for the purposes of additional data analysis or for the reproducibility of this study in other centers if requested.

Critical View of Safety Criteria

According to the expert consensus, certain anatomical structures must be identified before completing sentinel lymph node dissection (Table 1).[15,16] These include the ureter, obliterated umbilical artery, external iliac vessels, and internal iliac artery. These structures formed the foundation for defining the Critical Views of Safety as follows: lateral pararectal space, involves identifying the space between the ureter and obliterated umbilical artery beneath the uterine artery; lateral paravesical space, identified as the space between the external iliac vessels and the obliterated umbilical artery; and the internal iliac artery, defined as the identification of at

Table 1 Mandatory and Optional Surgical Steps of Sentinel Lymph Node Dissection by Minimally Invasive Surgery in Endometrial and Cervical Cancer According to Expert Consensus[15,16]

	Endometrial cancer	Cervical cancer
Anatomical landmarks to identify		
External iliac vessels	Mandatory	Mandatory
Internal iliac artery	Mandatory	Mandatory
Obliterated umbilical artery	Mandatory	Mandatory
Ureter	Mandatory	Mandatory
Paravesical space	Mandatory	-
Uterine artery	Optional	-
Dissection direction		
Start the lymph node mapping at the level of the uterine artery and continue dissection laterally away from the uterus	Mandatory	Mandatory
Start sentinel lymph node mapping at the level of the uterine artery and continue medially toward the uterus	Optional	-
Start sentinel lymph node mapping at the level of the uterine artery and continue toward the pre-sacral area	Optional	-
Start sentinel lymph node mapping at the most highlighted node and dissect proximally (toward the cervix)	Optional	-

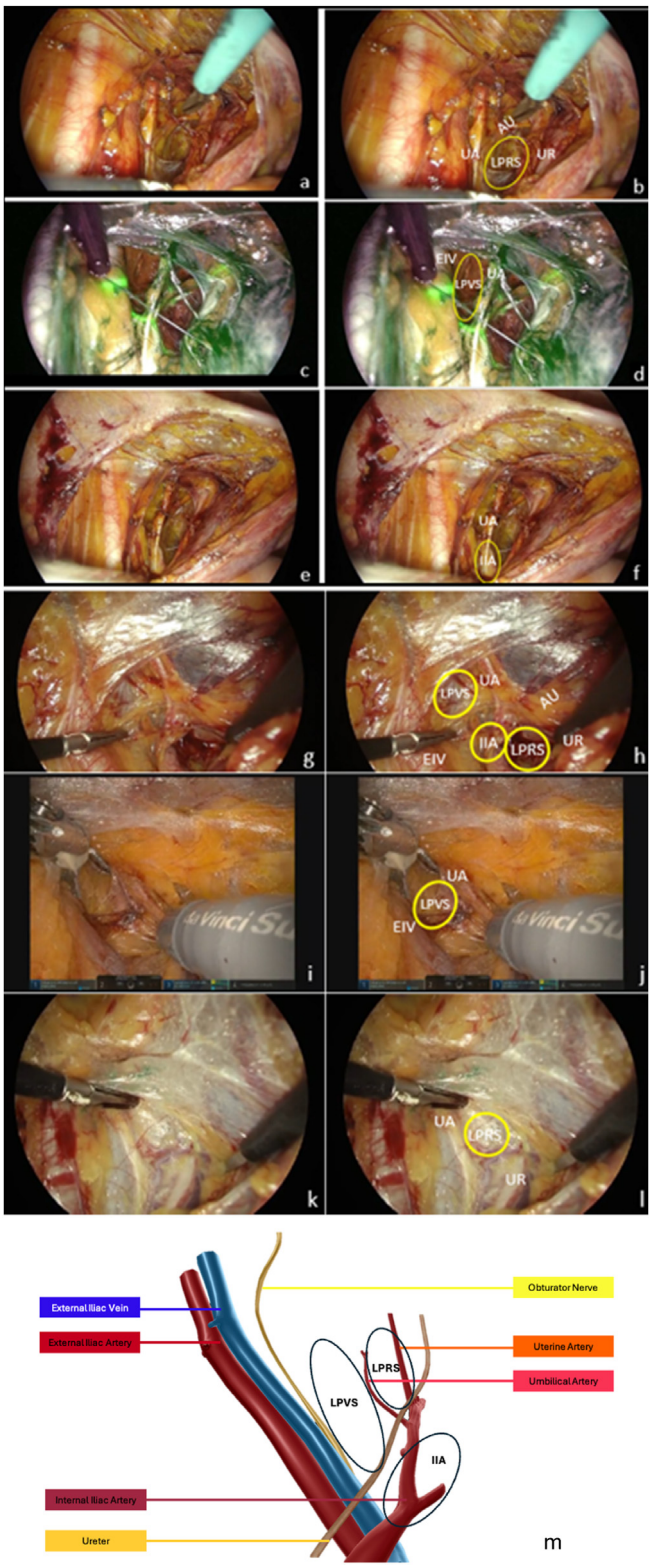

Figure Anatomical definition of the Critical Views of Safety criteria (CVS). **(A-B)** Lateral pararectal space (LPRS), a space below the uterine artery (AU) bounded laterally by the obliterated umbilical artery (UA) and medially by the ureter (UR); (**C-D)** lateral paravesical space (LPVS), a space bounded laterally by the external iliac vessels (EIV) and medially by the obliterated umbilical artery UA; (**E-F)** internal iliac artery (IIA), identification of at least 1 margin of the vessel or identification of a white tubular shaped vessel structure medial to the ureter and below the obliterated umbilical artery (UA) or identification of the emergence of the obliterated umbilical artery (UA). (**G-H)** Lateral pararectal space (LPRS), lateral paravesical (LPVS) space, and internal iliac artery (IIA); (**I-J)** lateral paravesical space (LPVS) dissected by robotic-assisted approach; (**K-L)** lateral pararectal space (LPRS); (**M)** illustration of lateral pararectal space (LPRS), lateral paravesical (LPVS) space, and internal iliac artery (IIA).

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least one margin of the vessel or identification of a white tubular shaped vessel structure medial to the ureter and below the obliterated umbilical artery or identification of the emergence of the obliterated umbilical artery (Fig. and Table 2).

Video Annotation

The surgical phase of left sentinel lymph node dissection, from the opening of the left round ligament to the *ex vivo* testing of lymph node fluorescence in the pelvis, was selected as the region of interest to facilitate consistency among annotations. A total of 3 independent annotators, with experience in gynecologic surgery, blinded to each other, analyzed the videos, following a pre-established annotation protocol defining the Critical Views of Safety written according to the published expert consensus.[15,16] MOSaiC,[21] an online cloud-based collaborative video annotation platform developed at the IHU-Strasbourg (Institute of Image-Guided Surgery, Strasbourg France) was used to annotate the videos for the identifying whether the defined Critical Views of Safety criteria is achieved by the surgeon.[15,16] In addition, the direction of the retroperitoneal space's dissection (lateral from the uterus, medial to the uterus, pre-sacral area, from the first highlighted lymph node to/away from the cervix) was annotated in accordance with the expert consensus steps.[15,16]

Statistical Analysis

Descriptive statistics (averages, median, percentages) were carried out by analyzing the results of the patient's characteristics and rate of Critical Views of Safety achievement. This was considered achieved if at least 2 of the 3 annotators agree on its identification. The agreement of the individual criteria was calculated using Cohen κ for the pair of raters and Fliess κ for the 3 raters together. The inter-rater reliability is considered as perfect ($k > 0.90$), strong ($0.80 < k < 0.90$), moderate ($0.6 < k < 0.79$), weak ($0.4 < k < 0.59$), minimal ($0.21 < k < 0.39$), or no agreement ($0 < k < 0.20$).

RESULTS

A total of 80 patients were enrolled in the study, of whom 9 (11.1%) were excluded for having videos that did not fully include the region of interest to be annotated. Of the 71 patients (88.8%) whose surgical videos were annotated, 64 (90.1%) underwent sentinel lymph node dissection for endometrial cancer and 7 (9.9%) for cervical cancer. A total of 64 patients (90.1%) underwent surgery with a laparoscopic approach, whereas 7 (9.9%) underwent robotic surgery using the da Vinci Xi system (Intuitive). The median age of the patients was 52 years (interquartile range [IQR] 34-71) and the median body mass index was 28.8 kg/m^2 (IQR 23.7-32.17). The clinical characteristics of the patients are summarized in Table 3. The median number of sentinel lymph nodes removed from the left side was 1 (IQR 1-2). A total of 64 patients (90.1%) had no metastases in the left sentinel lymph nodes, whereas 7 (9.9%) had macro- or low-volume metastases. Of these, 2 patients (2.8%) had isolated tumor cells, 2 (2.8%) had micro-metastases, and 3 (4.2%) had macro-metastases.

The lateral pararectal space was identified in 44 videos (62%), the lateral paravesical space in 67 videos (94%), and the internal iliac artery in 23 videos (32%). The results of the inter-rater reliability among annotators were found to be strong for lateral pararectal space and lateral paravesical space, with a Fleiss κ of 0.90 for both and moderate for internal iliac artery, with a Fleiss κ of 0.73 (Table 4). In 46 patients (64.8%), the dissection of the retroperitoneal spaces was annotated as proceeding lateral to the uterine artery, in 8 patients (11.3%), as proceeding medial to the uterine artery, and in 17 patients (23.9%), the dissection proceeded both laterally and medially before the sentinel lymph node dissection. No intra- or post-operative complications were reported.

Table 2 Adaptation of Expert Consensus: Views of Safety Criteria and Correlation With the Anatomical Structure

Critical View of Safety criteria	Anatomical structure
Lateral paravesical space	External iliac vessels and obliterated umbilical artery
Lateral pararectal space Internal iliac artery	Ureter and obliterated umbilical artery Internal iliac artery

DISCUSSION

Summary of Main Results

The feasibility of video-based Critical Views of Safety assessment in sentinel lymph node dissection for endometrial and cervical cancer is supported by the achievement rates (62% and 94%, respectively) and the strong inter-rater agreement among annotators in identifying the lateral pararectal and lateral paravesical spaces. This highlights the reliable clinical applicability of the mandatory steps, including the identification of the lateral pararectal and paravesical spaces, as well as key anatomical landmarks, such as the external iliac vessels, obliterated umbilical artery, and ureters, before sentinel node dissection. However, the lower achievement rate (32%) in identifying the internal iliac artery suggests the greater difficulty in adhering to this mandatory step because of its deeper anatomical location and increased surgical complexity in accessing it.

Results in the Context of Published Literature

International guidelines recommend sentinel lymph node mapping as the initial surgical step in the management of early-stage cervical and endometrial cancer, increasingly preferred over full lymphadenectomy because of its reduced risk of intra- and post-operative complications.[1,2] To ensure consistency across institutions, experts have established consensus on key aspects of this procedure.[15,16] These include the use of indocyanine green as a tracer, initiating dissection at the uterine artery, proceeding laterally from the uterus, and completing the dissection on one pelvic side before moving to the contralateral side.[15,16]

The mandatory identification of critical anatomical structures translated in the proposed Critical Views of Safety, such as the ureter, obliterated umbilical artery, external iliac vessels, and internal iliac artery, is crucial in surgical procedures to minimize the risk of intra-operative complications resulting from inadvertent injuries.[7] Proper identification not only prevents damage but also ensures comprehensive visualization of the lymphatic pathways: anterior paracervical (preureteric) and posterior paracervical (retroureteric).[6] This approach increases the likelihood of accurately

Table 3 Patients' Characteristics

	Total	Endometrial cancer	Cervical cancer
Patients enrolled	71 (100%)	64 (90.1%)	7 (9.9%)
Surgical approach			
Laparoscopy	64 (90.1%)	57 (89%)	7 (100%)
Robotic	7 (9.9%)	7 (11%)	0 (0%)
Age (median, IQR)	52 (IQR 34-71)	63 (IQR 56-71)	41 (IQR 34-51)
Body mass index (kg/m^2) (median, IQR)	28.8 (IQR 23.7-32.17)	28.9 (IQR 25.4-32.42)	23.7 (IQR 23.25-26.18)
Previous abdominopelvic surgery (median, IQR)	1 (IQR 0-1)	1 (IQR 0-1)	1 (IQR 0-1)
Operative time	134 (IQR 107-162)	134 (IQR 107.5-161)	120 (IQR 87-245)
Intra-operative complications	0 (0%)	0 (0%)	0 (0%)
Estimated blood loss	50 (IQR 0-100)	50 (IQR 0-100)	50 (IQR 0-100)
Number of left retrieved nodes (median, IQR)	1 (IQR 1-2)	1 (IQR 1-2)	1 (IQR 1-2)
Left metastatic sentinel lymph nodes, *n* of patients, (%)	7 (9.9%)	6 (9.3%)	1 (14%)
Left macro-metastasis, *n* of patients, (%)	3 (4.2%)	2 (3.1%)	1 (14%)
Left micro-metastasis, *n* of patients, (%)	2 (2.8%)	2 (3.1%)	0 (0%)
Left isolated tumor cells, *n* of patients, (%)	2 (2.8%)	2 (3.1%)	0 (0%)
Left sentinel lymph node location, n, (%)	External iliac: 48 (67.6%); obturator: 14 (19.7%); internal iliac: 3 (4.2%); pre-sacral: 3 (4.2%)	External iliac: 41 (64%); obturator: 14 (21.8%); internal iliac: 3 (4.6%); Pre-sacral: 3 (4.6%)	External iliac: 7 (100%)
Post-operative final stage, n, (%)		IA: 34 (53%); IB 11 (17.18); II: 6 (9.3%); IIIA: 4 (6.2%); IIIC1: 9 (14%)	IA: 3 (42.8%); IBI: 1 (14%); IIA: 1 (14%); IIIC1: 1 (14%); IVB: 1 (14%)

Abbreviation: IQR, interquartile range.

Table 4 Rate Achievement and Inter-Rater reliability Scores for CVS Criteria

Number of videos where each individual feature was agreed upon by at least 2 annotators			
CVS 1. Lateral pararectal space	44/71 (61.9%)		
CVS 2. Lateral paravesical space	67/71 (94.3%)		
CVS 3. Internal iliac artery	23/71 (32.3%)		
Number of videos with specific pair combinations of features agreed upon by at least 2 annotators			
Lateral pararectal space + lateral paravesical space	44/71 (61.9%)		
Lateral pararectal space + internal iliac artery	21/71 (29.5%)		
Lateral paravesical space + internal iliac artery	23/71 (32.3%)		
Number of videos with all 3 features agreed upon by at least 2 annotators			
Lateral pararectal space + Lateral paravesical space+ Internal iliac artery	21/71 (29.5%)		
Inter-rater reliability scores for CVS			
	CVS 1. Lateral pararectal space	CVS 2. Lateral paravesical space	CVS 3. Internal iliac artery
	Cohen's Kappa		
A1 vs A2	0.91	0.85	0.65
A1 vs A3	0.88	1	0.85
A2 vs A3	0.91	0.85	0.68
	Fleiss Kappa		
A1 vs A2 vs A3	0.90	0.90	0.73

Abbreviations: A1, annotator one; A2, annotator two; A3, annotator three; CVS, Critical View of Safety.

detecting the proper sentinel lymph node, which is the most proximal or a single mapped node, regardless of its nodal station. Moreover, following the recommended direction of dissection is essential in minimizing the disruption of lymphatic channels, further reducing the risk of complications.[15,16]

Video analysis of laparoscopic or robotic surgeries offers valuable data, already leveraged in other specialties to improve patient outcomes. Through video annotation and data analysis, it is possible to objectively assess the correlation between surgical steps and outcomes. This leads to the development of predictive models that can anticipate surgical actions and offer real-time assistance to surgeons during procedures.

Although the high achievement rates (64% and 94%) and strong inter-rater agreement emphasize the effectiveness of identifying the lateral pararectal and paravesical spaces, the lower achievement rate (32%) and moderate inter-rater agreement for the internal iliac artery highlight the greater difficulty operators face in consistently identifying this structure. This inconsistency in detection may compromise the ability to reliably identify the proper sentinel lymph node in the internal iliac and pre-sacral area, potentially impacting the success of the procedure.[22]

To the best of our knowledge, this study is the first to clinically translate the application of expert consensus guidelines by a video-based assessment, potentially laying the foundation for the concept that adherence to these standardized Critical Views of Safety can reduce the failure rate of sentinel lymph node mapping, which occurs in 20% to 25% of cases.[6] Furthermore, it may help decrease intra- and post-operative complications (11.2%)[7] and reduce the incidence of empty node packets, which can reach 20% among surgeons who are early in their learning curve.[10]

Mascagni and colleagues[18] have previously proposed a framework for video-based assessment of the Critical Views of Safety technique in laparoscopic cholecystectomy based on the concept proposed by Strasberg and colleagues[23] in 1995 to minimize bile duct injury risks. Recently, deep learning tools have been introduced to assess the quality of laparoscopic cholecystectomy by evaluating the achievement of these Critical Views of Safety, offering a promising approach to enhancing surgical precision and outcomes.[19,24] Our study defines the Critical Views of Safety for sentinel lymph node dissection and provides quantitative measures for video assessment. This lays the foundation for developing objective assessment tools that could improve surgical workflow.

Strengths and Weaknesses

One notable strength of this study is its effort to address the ambiguity in existing consensus regarding the full visualization of anatomical structures. By adopting defined spaces, such as the lateral pararectal and paravesical spaces, as the criteria for the Critical View of Safety instead of focusing on single anatomical structures, the study minimizes the potential for misidentification. This improvement is reflected in the reduced inter-rater agreement observed in the initial steps of the study, which highlights the challenge of clearly defining individual structures.

Furthermore, the development of a rigorous annotation protocol, incorporating at least 2 spatial anatomical coordinates to define each space, plays a crucial role in reducing bias among annotators. This methodological rigor enhances the reliability of the visual assessments. To further mitigate discrepancies between surgeons' achievement rates and video-based assessments, a consensus approach was applied, whereby a Critical View of Safety criterion was considered achieved if at least 2 of 3 annotators agreed. This decision adds robustness to the study's evaluation process.

Despite these strengths, the study has certain limitations. For the third Critical View of Safety, the deep retroperitoneal position of the internal iliac artery and its partial visualization during the procedure posed challenges in assigning it clearly to a specific space. This difficulty may have contributed, albeit to a minimal extent, to its lower achievement rate by the surgeons. In addition, the focus on the left side of the pelvis could be perceived as a limitation. Although the study's context as a feasibility assessment justifies this approach because we want to establish the consistency of the Critical Views of Safety assessment among different annotators and different centers. However, given the study's specific objectives, analyzing the contralateral side would not have provided additional insights. Future studies should address this limitation by exploring the clinical significance of Critical Views of Safety assessment across both sides of the pelvis and evaluating intra-surgeon consistency.

This study represents the first step toward utilizing surgical videos for development of Critical Views of Safety criteria and thereby facilitating deep learning tools in gynecologic oncology, promoting a culture of safety, as has been demonstrated in laparoscopic cholecystectomy. In laparoscopy, such Critical Views of Safety criteria defined by identifying key anatomical landmarks and structures across various scenarios enhanced surgical outcomes.[24]

Implications for Practice and Further Research

The video assessment of the defined Critical Views of Safety criteria could be clinically validated with the help of prospective and multi-institutional studies. This study paves the path to scale the research on how such Critical Views of Safety criteria could clinically impact the sentinel lymph node technique in endometrial and cervical cancer. The study shows objective analysis of safety criteria by video assessment and supports the development of automated video-based artificial intelligence tools. Such tools enable assessing the achievement of recommended surgical steps and standardizing safety checklists across institutions. Quantifying and analyzing intra-operative events, such as the achievement rate of recommended surgical steps or the rate of intra-operative adverse events (ie, minor bleedings, extreme tractions, hesitancies, etc), is crucial for optimizing guideline adherence and implementation identifying new strategies to reduce operative risks.

CONCLUSION

After defining the feasibility of Critical Views of Safety criteria for sentinel lymph node dissection in endometrial and cervical cancer, this study showed a low assessment rate of internal iliac artery, which could raise the concern about potential miss of lower pathway sentinel lymph node. This study represents a first step toward developing artificial intelligence algorithms that enable the automatic assessment and documentation of the Critical Views of Safety through laparoscopic and robotic surgical videos. Such tools could support guidelines adherence improving the safety and the accuracy of minimally invasive sentinel lymph node dissection.

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Ethical Statement Approval from the ethics commitee ("Dipartimento Universitario Scienze della Vita e di Sanità Pubblica" Fondazione Policlinico Universitario A. Gemelli IRCCS, CET Lazio Area 3 ID 6150) was obtained. The study adheres to the principles of the Declaration of Helsinki. In the pre-operative assessment phase, patients were requested to provide in advance consent for the subsequent utilization for scientific purposes of their anonymized data.

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Declaration of Competing Interests None declared.

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Data Availability All data generated or analyzed in this study are included in the manuscript and its figures/tables. Further inquiries can be directed to the corresponding author.

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