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## Diagnostic Yield and Safety of Advanced Endoscopic Technologies in a Retrospective Cohort of 14,000 Gastrointestinal Procedures at a Tertiary Center

#### Amil Hüseynov<sup>1</sup>, Azamet Çezik<sup>2</sup>

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#### IIIIIIIII ABSTRACT I

Aim: Technological advancements in gastrointestinal (GI) endoscopy have substantially improved the diagnostic and therapeutic management of GI disorders. High-definition (HD) imaging, narrow-band imaging (NBI), and artificial intelligence (AI)-assisted systems represent transformative innovations aimed at increasing lesion detection and reducing human error. To evaluate the clinical impact of advanced endoscopic technologies, including HD endoscopy, NBI, and AI-assisted detection systems, on polyp detection rates and procedural safety in a high-volume, real-world setting.

**Method:** This retrospective single-center study included 14,000 patients who underwent endoscopic procedures between January 2018 and December 2022. The primary outcome was the adenoma detection rate (ADR) across different imaging modalities. Secondary outcomes included lesion characteristics and complication rates. Data were analyzed using SPSS version 25.0, with significance set at p<0.05.

**Results:** Across 8,000 colonoscopies, the ADR was 18.4% for standard HD endoscopy (n=4,000), 27.2% for NBI (n=2,000), and 33.4% for AI-assisted systems (n=4,000). Recognition of small ( $\leq 5$  mm) and flat lesions (p<0.05) was substantially improved with AI-assisted detection. Complication rates remained low (1%) and comparable across modalities, with no increase in adverse events associated with advanced technologies.

**Conclusion:** Polyp detection is substantially enhanced with NBI and AI-assisted endoscopy without compromising safety, offering promising adjuncts to standard endoscopic practice. The integration of such innovations may reduce interval cancer risk and support more consistent quality in GI diagnostics.

Keywords: Advanced imaging modalities, artificial intelligence, diagnostic accuracy, endoscopy, gastroenterology, pathology

#### Introduction

Gastrointestinal (GI) endoscopy has evolved into a critical tool for both the diagnosis and management of a wide spectrum of GI disorders, ranging from benign conditions such as polyps to more severe pathologies, including early-stage malignancies.<sup>1,2</sup> Over the past two decades, remarkable advances in endoscopic imaging technologies have transformed the quality and precision of visual assessment. Historically, fiber-optic systems provided limited resolution and suboptimal clarity, often hindering accurate lesion detection.<sup>3</sup> The advent of high-definition (HD) video endoscopes has dramatically improved

image clarity and detail, allowing endoscopists to identify subtle mucosal abnormalities with greater confidence and reduce the rate of missed lesions. For example, the improved visualization offered by HD endoscopes contributes to earlier detection of potentially pre-malignant or malignant lesions, a critical factor that can substantially influence patient outcomes and long-term prognosis. 6

Despite the progress facilitated by HD endoscopes, conventional endoscopy still faces certain inherent limitations. Anatomical complexities, including sharp angulations, folds, and areas of poor distension, can obscure the endoscopist's field of view and potentially lead to undetected lesions.<sup>7</sup> In addition,



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the quality of bowel preparation remains a pivotal factor; inadequate preparation may reduce visibility, thus hampering polyp recognition. Dependent variability also plays an important role; less experienced endoscopists may have lower adenoma detection rates (ADRs), potentially leading to interval cancers and less effective screening programs. Against this backdrop, the introduction of novel endoscopic adjuncts seeks to overcome these limitations. Narrow-band imaging (NBI), for example, enhances mucosal surface and vascular pattern delineation by using specific light wavelengths that increase contrast between normal and abnormal tissue. In This technique has been shown to improve lesion characterization, aiding endoscopists in distinguishing neoplastic from non-neoplastic lesions more accurately.

advanced dye-based techniques, chromoendoscopy, can be employed to better highlight subtle mucosal irregularities, particularly in conditions such as inflammatory bowel disease (IBD) where early dysplasia detection is paramount.13,14 However, perhaps the most transformative development in recent years has been the integration of artificial intelligence (AI) into the endoscopic workflow. AI-assisted polyp detection systems utilize deep learning algorithms and computer vision to provide realtime lesion alerts, thereby acting as a "second observer" that can help reduce the incidence of human error and lapses in attention caused by fatigue. 15,16 Emerging data suggest that these systems can substantially increase ADRs by identifying lesions that might otherwise go unnoticed, potentially narrowing the gap in performance between experienced and novice endoscopists. 17,18

This study aimed to evaluate the impact of such innovative endoscopic technologies on diagnostic yield and clinical outcomes in a large cohort of 14,000 patients who underwent endoscopic procedures at a single center. Specifically, we assess the performance of standard HD endoscopy, NBI, and AI-assisted detection systems in polyp identification and characterize the associated complications. By analyzing these modalities in a high-volume, real-world setting, we sought to provide robust evidence for the clinical utility of these advanced techniques. Through this evaluation, we hope to determine whether these technological adjuncts can indeed bridge current diagnostic gaps, improve early lesion detection, and ultimately contribute to better patient care and GI health outcomes.

Table 1. Distribution of the 14,000 endoscopic procedures

## Procedure typeNumber of procedures (n)Percentage (%)Colonoscopies8,00057.1Gastroscopies5,00035.7Other endoscopic interventions1,0007.1Total14,000100.0

#### **Materials and Methods**

This retrospective study was conducted at a single tertiary care center, including 14,000 patients who underwent endoscopic procedures between January 2018 and December 2022. All patients were between 18 and 85 years of age, with a gender distribution of 7,400 men (52.9%) and 6,600 women (47.1%). Of the total procedures, 8,000 were colonoscopies, 5,000 were gastroscopies, and 1,000 were other types of endoscopic interventions, such as endoscopic retrograde cholangiopancreatography and endoscopic ultrasound (Table 1).

The baseline technology for all patients was HD endoscopy. Across the colonoscopies, NBI was employed in 2,000 cases to enhance mucosal detail and vascular patterns in suspicious areas. In 4,000 colonoscopies, an AI-assisted polyp detection system was integrated to identify potential lesions in real-time. In addition, chromoendoscopy with dye application was performed in 500 patients with IBD to improve the visualization and delineation of mucosal changes.

This study was approved by the Ethics Committee of University of Health Sciences Türkiye, Kanuni Sultan Süleyman Training and Research Hospital, with approval number: 2024.l0.235, dated: 01.11.2024. All procedures were conducted in accordance with the principles outlined in the Declaration of Helsinki. Informed consent was obtained from all participants prior to their inclusion in the study, and patient anonymity and confidentiality were strictly maintained.

#### **Exclusion Criteria**

Patients were excluded if they (1) had incomplete demographic or endoscopic records; (2) demonstrated poor bowel preparation, defined as a Boston Bowel Preparation score <6; (3) had a history of colorectal surgery that altered colonic anatomy; (4) were known to have colorectal cancer diagnosed before the index procedure; or (5) underwent emergent endoscopy for active bleeding or perforation. After applying these criteria (n=412 exclusions), 14,000 procedures remained for analysis.

#### **AI System Description**

The AI platform used was an FDA- and CE-cleared computeraided detection (CADe) solution (GI-Sense $^{\text{TM}}$ , version 3.2; MedVision Technologies, Boston, MA, USA). It employs a convolutional neural network architecture trained on more than 1.2 million annotated colonoscopy frames. Real-time inference is achieved with <30 ms latency, and alerts are displayed as bounding boxes on the primary endoscopy monitor. Quarterly federated-learning updates are pushed to the system to maintain performance across diverse image sets.

#### **Statistical Analysis**

Relevant patient data, including demographics, clinical characteristics, endoscopic findings, lesion morphology, and subsequent treatment interventions, were extracted from electronic medical records. The primary outcome was the rate of polyp detection under different imaging technologies, specifically comparing standard HD endoscopy, NBI, and AI-assisted systems. All statistical analyses were conducted using SPSS version 25.0 (IBM Corp., Armonk, NY, USA), and a p-value of <0.05 was considered indicative of statistical significance.

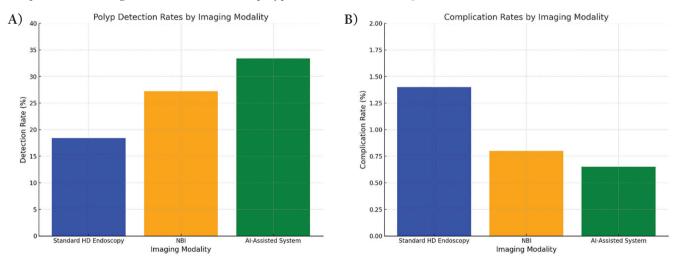
#### **Results**

In total, 14,000 patients underwent endoscopic procedures during the study period. The overall number of detected polyps varied according to the imaging modality and technology used (Figure 1). Standard endoscopy procedures, conducted on 4,000 patients, resulted in the detection of 735 polyps, yielding a detection rate of approximately 18.4%. The application of NBI in 2,000 procedures identified 543 polyps, corresponding to a detection rate of around 27.15%. In comparison, the integration of an AI-assisted polyp detection

system in 4,000 procedures led to the identification of 1,337 polyps, reflecting a notably higher detection rate of nearly 33.4% (Table 2).

These findings indicate that both NBI and AI-assisted techniques improved the detection of polyps compared to standard endoscopy (Figure 2). The substantial increase achieved with the AI-assisted system, in particular, underscores the potential of advanced image analysis algorithms to enhance endoscopic visualization, especially for challenging lesions. Not only did the AI-assisted technology outperform conventional methods in overall polyp detection but it also showed a marked advantage in identifying smaller (≤5 mm) and flatter lesions that are often more difficult to visualize using traditional methods. Statistical analysis confirmed that the difference in detection rates between AI-assisted and standard endoscopy was significant (p<0.05), reinforcing the clinical relevance of these innovative approaches.

Complications associated with the procedures were infrequent and did not differ markedly between the various technologies. The overall complication rate remained at around 1%, with a small number of severe events, including perforation in 5 patients and bleeding in 20 patients (Table 3). Notably, NBI and AI-assisted endoscopies demonstrated complication profiles comparable to or even more favorable than standard endoscopy. These results suggest that employing advanced imaging technologies not only improves diagnostic yield but also maintains a similar safety profile, providing reassurance regarding the implementation of such innovations in routine clinical practice.

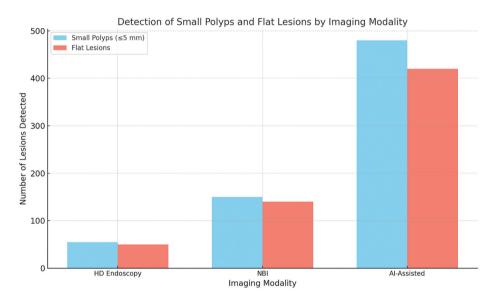


**Figure 1.** Polyp detection rates by imaging modality (left graph), complication rates by imaging modality (right graph). A) This bar graph illustrates the polyp detection rates (%) for three imaging modalities: standard high-definition (HD) endoscopy, narrow-band imaging (NBI), and artificial intelligence (AI)-assisted systems. AI-assisted systems demonstrate the highest detection rate at 33.4%, followed by NBI at 27.2%, and standard HD endoscopy at 18.4%. The graph highlights the superior performance of advanced technologies, particularly AI, in identifying polyps. B) This bar graph displays the complication rates (%) associated with each imaging modality. AI-assisted systems have the lowest complication rate (0.65%), followed by NBI (0.8%) and standard HD endoscopy (1.4%). The graph shows that advanced imaging technologies not only improve diagnostic performance but also maintain or even reduce complication rates, ensuring patient safety

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Imaging modality	Number of colonoscopies (n)	Total polyps detected (n)	Detection rate (%)	≤5 mm polyps (n, %)	Flat lesions (n, %)
Standard HD endoscopy	2,000	368	18.4	55 (15.0)	50 (13.6)
Narrow-band imaging (NBI)	2,000	543	27.2	150 (27.6)	140 (25.8)
AI-assisted polyp detection system	4,000	1,337	33.4	480 (35.9)	420 (31.4)
Total	8 000	2 248	28.1*		

**Table 2.** Polyp detection according to different imaging modalities in the colonoscopy subgroup

<sup>\*28.1% (</sup>average detection rate), HD: High-definition, AI: Artificial intelligence



**Figure 2.** Detection of small polyps and flat lesions by imaging modality. The above grouped bar chart illustrates the detection performance for small polyps (≤5 mm) and flat lesions across three imaging modalities: high-definition (HD) endoscopy, narrow-band imaging (NBI), and artificial intelligence (AI)-assisted systems. Blue bars represent the number of small polyps detected. Red bars represent the detection of flat lesions

**Table 3.** Complication profile by imaging modality in colonoscopies

Imaging modality	Number of colonoscopies (n)	Perforation (n)	Bleeding (n)	Other minor complications (n)	Total complications (n)	Complication rate (%)
Standard HD endoscopy	2,000	3	10	15	28	1.4
Narrow-band imaging (NBI)	2,000	1	5	10	16	0.8
AI-assisted polyp detection system	4,000	1	5	20	26	0.65
Total	8,000	5	20	45	70	0.88

HD: High-definition, AI: Artificial intelligence

#### **Discussion**

Following the promising results achieved with AI-assisted endoscopic systems, subsequent studies have validated the role of CADe and computer-aided diagnosis tools in enhancing lesion characterization and improving overall endoscopic efficacy. Pecent meta-analyses indicate that the implementation of AI-driven technologies consistently increases ADRs, reduces miss rates, and supports endoscopists in distinguishing hyperplastic from adenomatous polyps more reliably. Notably, the advantage of AI extends across varying levels of endoscopist experience, potentially narrowing the performance gap between expert and novice practitioners, thereby fostering more standardized care.

In our single-center study involving 14,000 endoscopic procedures, we observed a comparable trend: AI-assisted detection not only outperformed standard HD endoscopy in overall polyp detection but also demonstrated a particular advantage in identifying smaller (≤5 mm) and flatter lesions. Such findings align with the broader literature, suggesting that advanced image processing algorithms hold the potential to detect challenging lesions that might otherwise be missed. 21,22 In addition to polyp detection, emerging literature highlights the potential utility of AI in risk stratification and procedural efficiency. For example, novel machine learning algorithms have been tested to predict polyp histopathology and guide real-time decision-making, allowing for targeted resection and potentially obviating the need for indiscriminate biopsies. 23,24 Furthermore, AI-integrated platforms are being explored to optimize procedural parameters, such as withdrawal times, bowel preparation assessment, and the identification of blind spots within the colon, thereby ensuring a more systematic evaluation of the mucosa.<sup>25,26</sup> Some systems even integrate advanced imaging modalities, including magnifying endoscopy and endocytoscopy, to provide in vivo "virtual biopsies", accelerating the diagnostic process and reducing patient anxiety related to pending pathology results.<sup>27</sup>

Recent randomized controlled trials have reinforced the notion that AI-assisted platforms can sustain high ADRs over time and are not merely transient enhancements confined to research settings.<sup>28</sup> Longitudinal follow-up studies suggest that sustained integration of AI technologies can also influence downstream clinical outcomes, such as reducing interval colorectal cancer rates and improving adherence to screening guidelines.<sup>29</sup> As computational capabilities grow and machine learning models are trained on larger, more diverse datasets, the specificity and sensitivity of AI-assisted detection are expected to continue improving, ultimately translating into better prevention strategies and patient prognoses.<sup>30</sup>

However, the widespread adoption of AI in endoscopy is not without its challenges. Practical considerations, such as the cost of acquisition, the need for seamless integration with existing endoscopy systems, and requirements for stable internet connectivity and data security, must be addressed.<sup>31</sup> Training endoscopists and support staff to effectively use AI-based tools is another important step, ensuring that technology supplements, rather than supersedes, clinical judgment and expertise.<sup>32</sup> Ethical and medicolegal questions also arise with increasing automation, particularly with respect to responsibility for missed lesions and false positives. As AI assumes a more prominent role in guiding diagnostic decisions, it will be essential for professional societies and regulatory bodies to establish guidelines and best practices that uphold patient safety and maintain high standards of care.<sup>33</sup>

Our findings demonstrated that although AI-assisted endoscopy substantially improved polyp detection rates, including in populations such as patients with IBD, where chromoendoscopy is often considered the reference standard, it did so without increasing the complication rate. These observations bolster the body of evidence supporting AI as a safe adjunct to conventional methods. Nevertheless, larger, multicenter studies are needed to validate our single-center experience, especially to confirm whether these advantages hold across different operator skill levels and patient demographics.

Looking ahead, research is moving toward multimodal AI systems that integrate endoscopic imaging with other data sources, including genetic profiles, serum biomarkers, and patient history, to offer a more holistic risk assessment and individualized screening strategy.<sup>34</sup> These integrative approaches may ultimately shape a new paradigm of precision medicine in gastroenterology, where AI-driven insights guide not only lesion detection and characterization but also tailored surveillance intervals, therapeutic interventions, and patient counseling.<sup>35</sup>

Despite the encouraging results from our large cohort, this study also has some limitations. First, it was a single-center retrospective analysis, which could limit the generalizability of the findings. Second, operator experience may have played a role in the outcomes, particularly in the AI-assisted group. Finally, long-term follow-up data on interval cancers were not included in our analysis. Future prospective multicenter trials are warranted to address these gaps and further assess the long-term impact of AI-driven technologies on colorectal cancer prevention and overall patient outcomes.

#### Conclusion

In summary, this study adds to the growing body of evidence that advanced imaging modalities, especially AI-assisted systems, can markedly improve polyp detection rates. As gastroenterologists continue to seek strategies to reduce colorectal cancer incidence and mortality, these technologies offer a promising approach to refining diagnostic accuracy, minimizing missed lesions, and moving toward a more personalized, efficient, and precise endoscopic practice.

#### **Ethics**

**Ethics Committee Approval:** This study was approved by the Ethics Committee of University of Health Sciences Türkiye, Kanuni Sultan Süleyman Training and Research Hospital (approval number: 2024.10.235, dated: 01.11.2024).

**Informed Consent:** Informed consent was obtained from all participants prior to their inclusion in the study, and patient anonymity and confidentiality were strictly maintained.

#### **Footnotes**

#### **Authorship Contributions**

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### **Ambulatory Colorectal Surgery Following Enhanced Recovery After Surgery Guidelines: A Cohort Study of** a Multidisciplinary Protocol

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#### IIIIIIII ABSTRACT

Aim: To evaluate the clinical outcomes of an ambulatory colorectal surgery protocol based on the enhanced recovery after surgery (ERAS) recommendations.

Method: A retrospective observational cohort study was conducted involving adult patients who underwent major colorectal surgery under ERAS between 2022 and 2024. To qualify for ambulatory surgery, patients were required to undergo preoperative counseling, have family support, demonstrate medical adherence, and be classified as American Society of Anesthesiology (ASA) I or II. Patients who underwent complex procedures, required intensive care, or were considered at high social risk were excluded. The outcomes assessed included gastrointestinal recovery, complications, reinterventions, hospital readmissions, and length of stay exceeding 30 days.

Results: A total of 114 patients were treated according to the institutional protocol, of whom 14.9% (17/114) were eligible for outpatient colorectal surgery. The median age was 60 years, and 82.4% (14/17) were men classified as ASA II who underwent anterior rectal resection or right hemicolectomy for primary adenocarcinoma. The median length of hospital stay was 19 hours [interquartile range (IQR): 15-21], with a median time to oral recovery of 6 hours (IQR: 4-6) and a median time to flatus passage of 10 hours (IQR: 6-11). There were no reinterventions or readmissions within 30 days postoperatively.

Conclusion: Ambulatory colorectal surgery performed under the ERAS protocol can be conducted safely. The success of such protocols relies on careful patient selection, a multidisciplinary approach, and care tailored to each patient and their treatment plan.

Keywords: Ambulatory surgical procedures, colorectal surgery, enhanced recovery after surgery, patient readmission, surgery

#### Introduction

The postoperative management of patients undergoing colorectal surgery has been widely discussed in the past, as colorectal surgery is associated with high in-hospital costs and frequent postoperative hospitalizations worldwide, mainly related to colorectal cancer.<sup>1,2</sup> As a result of these high costs and the high morbidity associated with colorectal surgery, strategies have been implemented to improve surgical outcomes and reduce expenses, including the enhanced recovery after surgery (ERAS) protocol.3 This consists of a



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series of medical interventions at different stages of the surgical procedure, aimed at improving perioperative outcomes through a multidisciplinary and comprehensive approach.<sup>3</sup> First implemented in colorectal surgery, ERAS has since been associated with a reduction in complications, as well as shorter hospital stays, faster bowel recovery, better management of pain and nausea, and lower costs.<sup>4-6</sup>

Although ERAS has proven to be a strategy that improves clinical outcomes and reduces costs, new questions have emerged regarding the future of ambulatory colorectal surgery and the feasibility of performing ambulatory colorectal resections under multidisciplinary care. Recent publications have also suggested more personalized approaches to the ERAS protocol, based on the procedure and patient preferences. Ambulatory colorectal surgery is defined as the performance of major colorectal surgery or major bowel resection with a postoperative stay of less than 24 hours. The first series published on this approach was performed in Lyon by a group of general surgeons using a multidisciplinary protocol based on ERAS recommendations, in which five patients underwent outpatient colectomy with satisfactory clinical results.

Currently, although there are some publications on outpatient colorectal surgery with or without ERAS recommendations, their implementation continues to be questioned by those who argue that it is not possible to anticipate all adverse postoperative events that may benefit from hospital management. On the other hand, proponents of these initiatives suggest that their success depends on adequate and accurate patient selection for ambulatory colorectal resections, with outcomes comparable to those of standard care. However, in many regions, there are no reports regarding the use of ERAS in ambulatory colorectal surgery. This study, therefore, aims to evaluate the clinical outcomes of an ambulatory colorectal surgery protocol under ERAS in a high-complexity institution.

#### **Materials and Methods**

#### Study Design, Setting, and Patients

A retrospective observational cohort study was conducted that included patients over 18 years of age with colorectal pathologies requiring major colorectal surgery (defined as a procedure duration of more than two hours), who were submitted to the outpatient colorectal surgery protocol according to ERAS recommendations between December 2022 and June 2024.

This study was conducted in a high-complexity institution that has been implementing the ERAS protocol for major colorectal surgery since October 2022 and was certified as an ERAS institution on October 30, 2023. This clinical project was approved under code 2023.023E1 by the Institutional

Ethics Committee and was conducted in accordance with the standards established by the Declaration of Helsinki.<sup>13</sup> For this type of study, formal consent is not required.

The reporting of this study follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement guidelines to ensure clarity, transparency, and completeness in observational research.

## Inclusion and Exclusion Criteria for Ambulatory Colorectal Surgery Under the ERAS Protocol

The inclusion criteria for the protocol were as follows:

- Patients classified as American Society of Anesthesiology (ASA) I or II, according to the ASA scale.<sup>14</sup>
- Adequate family support, defined as the presence of a close family member or constant caregiver who understands the patient's medical situation and care before and after surgery, and who has a history of adherence to agreed-upon treatments for other procedures, either for the patient or for themselves.
- Preoperative counseling for ambulatory care, in which the patient and their companion were informed about the planned discharge 24 hours after surgery and asked whether they wanted this type of care. If accepted, the patient was enrolled in the protocol; if refused, hospital management with the ERAS protocol was provided.
- Constant sources of contact, defined as having at least two means of telephone communication through social networks or access to a signal network to receive calls, verified before the patient's discharge. Additionally, proximity to the health facility was considered for possible readmission, defined as living in the city where the procedure was performed.

The exclusion criteria were as follows:

- Patients undergoing complex colorectal surgery involving ileoanal pouch creation, abdominoperineal resection, enterocutaneous fistula repair, or the need for multiple or synchronous colectomies.
- Previous major abdominal surgery.
- Perioperative intensive care unit (ICU) admission.
- Need for anticoagulation due to medical comorbidities.
- High social risk, defined as living outside the city where the procedure was performed, lacking an adequate support network, using psychoactive substances, or being a chronic smoker (with more than two years of tobacco use).
- Stoma creation, defined as any type of ileostomy or colostomy.

## Preoperative, In-Hospital, and Postoperative Management Under the ERAS Protocol

Preoperative, in-hospital, and postoperative management was shared among the multidisciplinary team. The colorectal surgeon was responsible for the preoperative medical assessment, surgical intervention, and postoperative follow-

up, including medication prescriptions and evaluation of the patient's clinical status. In the postoperative period, the surgeon also managed the regular diet and hospital discharge. Anesthesiologists performed the preoperative evaluation (such as the Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity scale), administered preoperative medications, managed hydration and hemodynamic support during surgery, and controlled postoperative pain with oral or epidural analgesics.<sup>15</sup>

A nurse assigned to patients under the ERAS protocol provided preoperative instructions, monitored patients up to six hours before surgery, and managed bowel preparation, antibiotic prophylaxis, and maltodextrin administration. Postoperatively, the nurse conducted telephone follow-ups for up to 30 days after surgery. The nutrition service assessed nutritional status and provided personalized nutrition plans, whereas the physiotherapy team focused on cardiovascular and musculoskeletal improvement before and after surgery, promoting early mobilization and respiratory stimulation.

#### **Hospital Discharge and Outpatient Follow-Up**

To define a safe discharge under the ambulatory colorectal surgery protocol, the following criteria were used: independent ambulation, tolerance of oral intake between the first 4 and 8 postoperative hours, stable vital signs, paraclinical tests without abnormalities or within expected limits, pain controlled with oral medication, and consent from both the patient and companion for discharge.

Before leaving the hospital, the discharge procedure was explained to the patient, who could choose to accept or decline it and continue under standard ERAS management if uncomfortable with early discharge. Patients were provided with the telephone numbers of their attending colorectal surgeon and the ERAS protocol nurse to contact in case of any warning signs or symptoms. Each patient was offered two follow-up appointments with their attending surgeon within 30 days of surgery, scheduled according to the patient's preference.

All patients were followed up by telephone on the day after discharge and at 5, 7, 10, 15, and 30 days postoperatively by the nurse responsible for the ERAS protocol, who actively sought out symptoms and warning signs during conversations with the patient's companion. During this period, patients also had follow-up appointments with their attending physician, who conducted a detailed interview and physical examination to rule out any complications. At the end of the 30-day period, follow-up was concluded in accordance with the ERAS protocol.

#### Variables and Data Source Measurements

Clinical characteristics collected included age, sex, medical history, ASA classification, and preoperative nutritional status.

Intraoperatively, the type of primary anastomosis, blood loss, and the need for supportive measures such as vasoactive agents or transfusions were recorded. In-hospital outcomes included hours to oral tolerance, time to passage of flatus and stool after surgery, and total hours of hospitalization since admission. In the postoperative period, medical and surgical complications by system, severity of complications according to the Clavien-Dindo scale, and surgical reinterventions were measured. 16 Hospital readmission was defined as any visit to the emergency department within 30 days of surgery. The presence of complications, ICU admission, and reinterventions were also recorded after discharge. To measure adherence to ERAS recommendations at different stages, the percentage of compliance was obtained using the European Network for Child and Adolescent Research and Education (ENCARE) software. All outcomes were assessed during hospitalization

#### Bias

and within 30 days after surgery.

Although bowel recovery times are available in clinical records through the progress or follow-up notes of the attending surgeon, these times may vary, as the notes are often uploaded into the system hours or minutes after the patient was interviewed during rounds. To reduce this bias, the institutional ERAS program provides patients with a physical form on which they, along with their companion or floor nurse, must record the date and time of oral tolerance, flatus, and stool passage immediately after each event (Supplementary Material). This form is collected at discharge and stored in the confidential files of the institutional ERAS program, available upon request.

#### Statistical Analysis

Hospital data were entered into the ENCARE system, accessed through the institutional license of the ERAS Society. These data were subsequently verified against the physical forms completed by nurses and patients and corrected if necessary. For analysis, the data were transferred to REDCap. Statistical analysis was conducted using RStudio Version 4.4.3.

Quantitative variables are presented as medians and interquartile ranges (IQRs) due to their asymmetric distribution. Qualitative variables are reported as absolute and relative frequencies. Given the descriptive nature of this study, no statistical tests were performed to compare groups or variables.

#### **Results**

#### **Characteristics of Patients**

Since the implementation of the ERAS protocol in the institution in 2022, 114 patients have undergone surgery under these recommendations and completed their 30-day follow-up after discharge. Figure 1 shows the patients who met the

inclusion and exclusion criteria. Of these, 14.9% (17/114) met the criteria for inclusion in the ambulatory colorectal surgery program. In this group, the median age was 60 years (IQR: 48-73), 64.7% (11/17) were men, and 82.4% (14/17) were classified as ASA II. The most common procedure was anterior rectal resection, performed in 58.8% (10/17) of patients, followed by right hemicolectomy, with primary anastomosis performed in all cases. All surgical procedures were performed laparoscopically for the management of benign or malignant pathologies. The most common diagnosis, based on the institutional pathology reports from surgical specimens, was primary adenocarcinoma in 76.5% (13/17) of patients. Other clinical characteristics are listed in Table 1.

#### Adherence to ERAS Recommendations

The overall compliance with ERAS recommendations in patients undergoing ambulatory colorectal surgery was

91.4%. Since the protocol's implementation, compliance with the preoperative, intraoperative, and perioperative phases has consistently ranged from 85% to 95%. Specific items-such as nutritional status assessment, maltodextrin administration, anemia screening and treatment, nausea and vomiting prophylaxis, avoidance of surgical drainage, and thromboprophylaxis-achieved 100% compliance. Among active smokers, 50% (1 out of 2) achieved smoking cessation prior to surgery. In the postoperative phase, compliance was the lowest at 77.9%, primarily due to early mobilization, which had a compliance rate of 76.5% among the analyzed patients.

#### In-Hospital and 30-Day Post-Discharge Outcomes

In-hospital and 30-day outcomes are shown in Table 2. The median length of hospital stay was 19 hours (IQR: 15, 21). For in-hospital outcomes, the median time to oral tolerance was 6

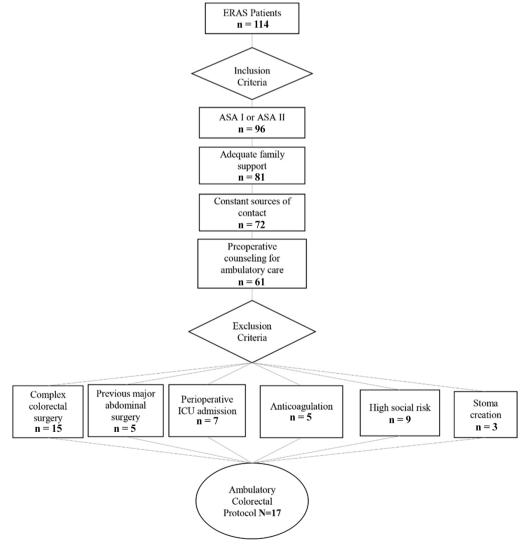


Figure 1. Selection of patients undergoing ambulatory colorectal surgery ERAS: Enhanced recovery after surgery, ASA: American Society of Anesthesiology, ICU: Intensive care unit

hours (IQR: 4, 6), the median time to flatus passage was 10 hours (IQR: 6, 11), and the median time to first postoperative bowel movement was 12 hours (IQR: 9.75, 15.25). Prior to discharge, the median white blood cell count was  $6.43 \times 10^9$ /L (IQR: 5.22, 12.20), whereas the median hemoglobin level was 13 g/dL (IQR: 11.8, 13.97).

Complications occurred in 5.9% (1/17) of patients undergoing the outpatient colorectal surgery protocol. This involved a patient who presented with an episode of vomiting after ingesting clear liquids one hour after the procedure. A dose of metoclopramide was administered, and the oral route was reattempted with clear liquids, which were fully tolerated by 7 hours postoperatively. Given the tolerance of the oral route and

**Table 1.** Sociodemographic and clinical characteristics of patients undergoing ambulatory colorectal surgery under ERAS

Variable	Patients in the ambulatory ERAS group (n=17)
Age, median [IQR]	60 [48, 73]
Gender, (%)	
Men	11 (64.7)
Women	6 (35.3)
BMI, median [IQR]	24.68 [21.30, 28.64]
Smoker, (%)	2 (11.8)
Diabetes mellitus, (%)	1 (5.9)
Pulmonary or heart disease, (%)	1 (5.9)
Preoperative chemotherapy, (%)	2 (11.8)
Preoperative radiotherapy, (%)	1 (5.9)
Procedure performed, (%)	
Right hemicolectomy	5 (29.4)
Left hemicolectomy	1 (5.9)
Anterior rectal resection	10 (58.8)
Hartmann colostomy closure with rectal stump remodeling	1 (5.9)
ASA classification, (%)	
ASA I	3 (17.6)
ASA II	14 (82.4)
Final diagnosis	
Primary adenocarcinoma or other malignant neoplasm	13 (76.5)
Diverticular disease	2 (11.8)
Mild non-specific sigmoiditis	1 (5.9)
Other benign disorders or benign neoplasms	1 (5.9)
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ERAS: Enhanced recovery after surgery, IQR: Interquartile range, BMI: body mass index, ASA: American Society of Anesthesiology

the passage of flatus and stool without issue, the patient was discharged 22 hours after the procedure. In non-ambulatory ERAS patients, the most common in-hospital complication was postoperative ileus (9/24), followed by gastrointestinal bleeding (4/24) and postoperative nausea and vomiting (3/24) (deleted). During the subsequent 30 days of follow-up, the median time to the in-person postoperative visit was 30 days (IQR: 13, 30), with the remainder of follow-up conducted by telephone with the attending physician and the ERAS nurse on the established postoperative days. At the end of follow-up, none of the patients who underwent the ERAS-recommended outpatient colorectal surgery protocol experienced readmissions, reinterventions, or other complications.

Table 2. In-hospital and 30-day follow-up clinical outcomes

Table 2: In hospital and so a	ay ionow-up chinear outcomes
Variable	Patients in the ambulatory ERAS group (n=17)
First passage of stool, hours, median [IQR]	12.00 [9.75, 15.25]
Tolerance to oral intake, hours, median [IQR]	6.00 [4.00, 6.00]
Complications, n (%)	1 (5.9)
Postoperative nausea and vomiting (%)	1 (100.0% of complications)
Hospital stay, hours, median [IQR]	19.00 [15.00, 21.00]
Variable	Ambulatory ERAS patients (n=17)
Pre-discharge vital signs and la	bs
Systolic blood pressure (mmHg), median [IQR]	131.00 [120.00, 145.75]
Pulse rate (bpm), median [IQR]	72.00 [65.00, 78.00]
Glasgow Coma scale, median [IQR]	15.00 [15.00, 15.00]
Hemoglobin (g/dL), median [IQR]	13.00 [11.80, 13.97]
White blood cell count (x 10°/L), median [IQR]	6.43 [5.22, 12.20]
Sodium (mmol/L), median [IQR]	141.00 [139.00, 142.00]
Potassium (mmol/L), median [IQR]	4.35 [4.03, 4.60]
30-day clinical outcomes	
Readmissions, (%)	0 (0.0)
Reinterventions, (%)	0 (0.0)
Complications, (%)	0 (0.0)
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IQR: Interquartile range, ERAS: Enhanced recovery after surgery

#### **Discussion**

In this study, the implementation of an outpatient colorectal surgery protocol according to ERAS recommendations resulted in favorable clinical outcomes in a safe manner. The most important measurable outcome of outpatient colorectal surgery protocols, in terms of safety and clinical effectiveness, is the readmission rate of patients undergoing these protocols. 11,17 In the available literature, hospital readmission rates for outpatient colorectal surgery range from 1.4% to 13.7%, depending on the series analyzed, the care protocol used, and the medical center. One of the largest patient series was recently published by Curfman et al. 18 in 2023, in which 326 patients undergoing major colorectal surgery were analyzed, of whom 35.3% (115/326) underwent an outpatient surgical protocol according to ERAS recommendations. The inclusion and exclusion criteria were very similar to those proposed in this analysis, excluding patients with stoma creation, previous abdominal surgery, and major comorbidities. The results showed that 4.3% (5/115) returned to the emergency department, and one patient presented with postoperative urinary retention requiring readmission.

Despite these satisfactory clinical results, those who disagree with such protocols have raised several points that should be considered in their implementation. First, it is argued that some patients prefer standard care and that those who undergo outpatient protocols may have a less favorable clinical experience. However, a recent publication by Curfman et al. compared the experiences of 50 patients undergoing outpatient surgery under ERAS with 50 patients treated under conventional ERAS. They found that most patients appreciated being included in the protocol and that 85.37% would choose it again. On the other hand, the protocol presented in this article, like others, offers the option of continuing with conventional ERAS management if preferred. 18-21

Second, it is suggested that in addition to having access to the health system and the necessary tools, there must be direct resources available either from the treating institution or the patient. 10 This was previously shown by Geyer et al. 22 in 2020, where they found that people in rural areas tended to have higher mortality from colorectal cancer due to their distance from the ambulatory surgical center. In such cases, it is recommended that the distance from the patient's residence to the medical center be considered in the inclusion and exclusion criteria, as in resource-limited contexts, this can become a conditioning factor that may affect patient safety and the possibility of readmission if needed. However, the protocol presented in this article was carried out in an institution that mainly treats patients within the primary health care system of a middle-income country.<sup>23</sup> Therefore, outpatient colorectal surgery under ERAS could be performed in regions with limited health care systems and not only in areas with greater resources.

Another point of discussion is the heterogeneity of the inclusion and exclusion criteria established for these protocols, since each institution that has published its results has done so according to its clinical data or the available evidence. 10 Although there is still no consensus among the institutions implementing these protocols, stoma creation, social risk, patient deterioration, and substantial associated comorbidities are commonly established criteria in most of the published results, which brings us closer each day to a unified standard. 17 A systematic review conducted by Siragusa et al.24 showed that despite this heterogeneity, among the 1,296 patients analyzed across 11 studies, readmission and surgical reoperation rates were 5% and 1%, respectively. This suggests that, while further progress is needed in unifying criteria, outpatient colorectal surgery can be a safe alternative in selected cases, with favorable clinical outcomes and low rates of readmission or reoperation.

In the present analysis, the main limitation encountered was the sample size available after two years of protocol implementation. Nevertheless, one of the key factors in the success of ambulatory colorectal surgery remains the appropriate selection of patients.<sup>24</sup> The objective of these initiatives is not for all major colonic resections to be ambulatory, but for all eligible cases to be safely included, achieving favorable clinical results.

This study has several limitations that should be acknowledged. First, the small sample size substantially limits the statistical power and generalizability of the findings, making it difficult to draw broad conclusions or identify rare adverse outcomes. Second, the absence of a control group precludes any comparative analysis to determine whether ambulatory management confers superior outcomes. Third, the retrospective design is inherently subject to selection bias, particularly given the strict inclusion criteria, which favored younger, healthier patients with adequate social support and technological access. This highly selected population of patients undergoing colorectal surgery may not reflect the broader cohort. Additionally, the reliance on self-reported postoperative recovery times-recorded by patients and companions-introduces the possibility of measurement bias. Finally, the lack of adjustment for potential confounding factors may affect the interpretability of the results.

#### Conclusion

In conclusion, ambulatory colorectal surgery represents a substantial advancement in surgical practice, offering a patient-centered approach that can be safely implemented under the right conditions. This analysis demonstrates that, when guided by the ERAS protocol, this modality is feasible. Moreover, meticulous postoperative outpatient follow-up is essential to monitor recovery, address potential complications,

and maintain patient safety. The success of this approach depends not only on the availability of resources but also on a strong commitment to comprehensive and continuous monitoring throughout the postoperative period, allowing for safe and effective implementation tailored to the needs of the institution and its patients.

#### **Ethics**

**Ethics Committee Approval:** This clinical project was approved under code 2023.023E1 dated: 19.06.2025 in the Biomedical Research Ethics Committee of the Fundación Valle del Lili.

**Informed Consent:** This study was conducted using data from the clinical records of ERAS patients, which consists of deidentified patient information. Therefore, obtaining individual informed consent was not required.

#### **Footnotes**

#### **Authorship Contributions**

Surgical and Medical Practices: J.C.P., H.F.P.I., A.G., J.G.H., A.O., Y.C., M.B., E.B., F.A.G., M.B., A.K., Concept: J.C.P., H.F.P.I., J.G.H., A.O., Y.C., M.B., E.B., F.A.G., M.B., A.K., Design: J.C.P., H.F.P.I., A.G., Y.C., M.B., M.B., A.K., Data Collection or Processing: J.C.P., H.F.P.I., A.G., J.G.H., A.O., Y.C., E.B., F.A.G., A.K., Analysis or Interpretation: J.C.P., H.F.P.I., A.G., J.G.H., A.O., Y.C., M.B., E.B., F.A.G., A.K., Literature Search: J.C.P., H.F.P.I., A.G., J.G.H., A.O., Y.C., M.B., E.B., F.A.G., M.B., A.K., Writing: J.C.P., H.F.P.I., A.G., J.G.H., A.O., Y.C., M.B., E.B., F.A.G., M.B., E.B., F.A.G., M.B., A.K.

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## Controversies in the Management of Pilonidal Disease: Expert Recommendations from a Modified Delphi Survey and Review of the Literature

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#### IIIIIIIII ABSTRACT

**Aim:** This study aimed to identify key controversies in the management of pilonidal disease (PD) and to develop expert-based recommendations using a modified Delphi process, highlighting critical areas for future research.

**Method:** A working group established by the Turkish Society of Colon and Rectal Surgery conducted a systematic literature review and invited national and international experts with relevant publication records to participate in a Delphi survey. A four-round Delphi process was conducted between July 2023 and February 2024. Statements that reached ≥70% consensus (agree/strongly agree) were accepted.

**Results:** Of the 172 experts invited, 98 agreed to participate, and 52 completed at least two rounds. Expert opinions were evaluated across nine key aspects of PD management: classification, diagnosis, acute abscess, minimally invasive and excisional treatments, recurrence, hair removal, perioperative care, and postoperative management.

**Conclusion:** This Delphi study presents expert consensus on unresolved clinical questions in the management of PD. The findings provide practical recommendations for surgeons and emphasize the need for prospective, high-quality studies to establish standardized treatment pathways.

Keywords: Consensus, Delphi, pilonidal disease, expert opinion, minimally invasive, excisional procedures



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#### Introduction

Pilonidal disease (PD) is a prevalent condition among young individuals that considerably affects their quality of life. Despite its benign nature, the wide range of both operative and non-operative treatment options, along with a lack of standardization -even within the same approach- complicates the development of universally accepted management algorithms.

The current literature highlights several areas of PD management that lack high-quality evidence. These include classification, disease complexity, management of acute abscesses, the long-term efficacy of minimally invasive treatments, regional care practices, hair removal strategies, and antibiotic use. Existing guidelines provide limited direction on contentious topics such as the ideal classification system, the precise definition of complex disease, and the distinction between recurrent and non-healing disease. Although prospective studies are needed to address these knowledge gaps, surgeons require practical guidance to support decision-making in the meantime.

To address this need, a consensus process was initiated to promote consistency in the management of PD and to support clinical decision-making in areas where high-level evidence is lacking. The outcomes of this expert-based consensus process aim to help surgeons navigate controversial aspects of PD and serve as a foundation for future research. This study seeks to reach expert consensus on unresolved and frequently debated issues in the management of PD using a modified Delphi method.

#### **Materials and Methods**

#### Steering Committee

The steering committee comprised a group of surgeons practicing in Türkiye, certified by the Turkish Society of Colon and Rectal Surgery or the European Board of Surgical Qualification (Appendix 1). As a first step, the group conducted a nationwide survey to assess clinical attitudes toward PD.<sup>5</sup> This survey revealed a lack of uniformity among surgeons regarding certain aspects of treatment. To address these uncertainties, a comprehensive literature review was conducted to identify controversial issues in PD that are either not explicitly covered in the current guidelines or that require further exploration.

The committee was responsible for defining the research objectives and timelines, developing the initial survey items based on the literature review, analyzing voting outcomes and related data, documenting the findings, preparing the manuscript, and promoting the dissemination of results through publication and presentations at conferences and other events, in accordance with the Accurate Consensus Reporting Document guidelines.<sup>6</sup>

#### **Literature Review and Invitation of Experts**

The search strategy included the Medline, PubMed, Cochrane Review Library, CINAHL, and Embase databases. Searches were conducted using the keyword "pilonidal". All articles published in the last 10 years (2013-2023) with English abstracts were reviewed. Articles related to the pediatric population (under 16 years) and those concerning PD located outside the natal cleft (e.g., umbilical, interdigital) were excluded. A total of 459 articles were analyzed to inform the survey questions.

Following the comprehensive literature review, colorectal surgeons with two or more publications (excluding case reports) in the Science Citation Index (SCI) or SCI-Expanded databases between 2013 and 2023 were identified as PD experts. These experts were invited to participate in the Delphi study through two email invitations sent 1 week apart. In total, 172 experts were contacted, 98 agreed to participate, and 52 successfully completed at least two rounds of the Delphi process (Appendix 2). One expert voluntarily withdrew after reporting a perceived conflict of interest with another participant. Those who did not proceed to subsequent rounds failed to respond to follow-up email invitations and did not provide a reason for their discontinuation. The geographical distribution of experts is presented in the graph (Figure 1).

To maintain the integrity and neutrality of the process, all participants were asked to declare any potential conflicts of interest. All, except for the one who withdrew, reported no conflicts.

#### Preparation of the Survey and the Delphi Method

The steering committee initially developed 38 questions, organized into the following main topics: 1) classification, severity, and complexity; 2) diagnosis and mapping; 3) acute abscess; 4) minimally invasive treatments; 5) excisional treatments; 6) recurrent/persistent PD; 7) regional care and hair removal; 8) perioperative care and antibiotics;

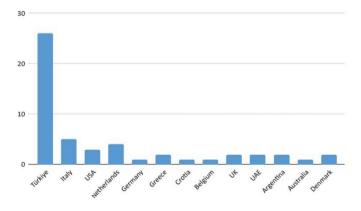


Figure 1. The geographical distribution of experts

and 9) postoperative care. These questions were sent to the experts as the first round of the Delphi survey (Appendix 3). The Delphi survey was conducted in four rounds. The first round aimed to gather expert opinions to clarify definitions and refine the questions. Following this round, an online meeting was held with all participating experts, and additional feedback received via email was considered in finalizing the survey. Ultimately, 28 questions were agreed upon in the first round and were subsequently voted on in the second and third rounds, using a Likert-scale threshold for acceptance. Responses with at least 70% "agree" or "strongly agree" ratings were advanced to the next round. The fourth round involved voting on statements developed by the steering committee and participating experts based on the results from the previous rounds.

In the first round, open-ended comments were allowed for each question. Based on the qualitative feedback collected, revised versions of the questions were drafted for the second round. These draft questions were shared via email with all participants, and further suggestions were collected. Before launching the second round, a Zoom meeting was held with all participants to finalize the questions. Similarly, before round three, draft statements were circulated via email, and a follow-up Zoom meeting was held to collaboratively confirm and finalize the statements.

#### Statistical Analysis

Basic descriptive statistics were performed. The mean value was used to represent the general opinion of the participants, whereas the standard deviation indicated the variability of their responses. The mode identified the most frequent response. A coherence measure was used to analyze the alignment of participants' answers in each round. Qualitative data were reviewed and categorized into groups by one researcher (ÇA). Statistical analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA).

#### Results

#### Classification, Severity, and Complexity

Expert recommendation: A classification system should be implemented for the documentation and grading of PD (consensus, 83.3%).

Expert recommendation: Current classification systems for PD are inadequate. Either a new system needs to be developed or existing ones need to be validated through large prospective studies (consensus, 76.2%).

The integration of a valid classification system would enhance healthcare delivery by supporting evidence-based treatment decisions and providing reliable outcome predictions. Although numerous classification systems have been described in the literature, none have been validated in studies with sufficient levels of evidence or adequately compared with each other.<sup>7</sup>

Expert statement: An ideal PD classification should include the following components: the number of secondary orifices; extension in relation to the midline (lateral, unilateral, or bilateral spread); extension below coccyx level; distance to the anal margin; and presentation (acute abscess, recurrent, or unhealing) (consensus, 92.7%).

In the only meta-analysis on PD classification, Beal et al. 7 identified that the main components of classification systems were the location and number of sinuses, the degree of secondary extent, extension below the level of the coccyx, and treatment failure. Treatment failure, defined as recurrence and non-healing, was addressed in seven of the classification systems. However, the presence of an acute abscess was considered in only three. Additionally, patient-related factors such as hirsutism, obesity, and gender were generally not taken into account.7 All components reported in this meta-analysis were voted on in the Delphi survey, and the following components reached the threshold for acceptance: the number of secondary orifices, lateral extension in relation to the midline, the unilateral or bilateral spread of the lateral extension, extension below coccyx level, distance to the anal margin, presence of an acute abscess, and recurrent or unhealing presentation (Appendix 4).

None of these classifications currently has sufficient evidence to be incorporated into guidelines. Nevertheless, treatment recommendations are provided in the guidelines and consensus statements, generally categorizing PD into two broad categories: simple and complex.<sup>1-3,8</sup>

Expert statement: There is no clear consensus on the definition of the term "complex PD". It can be broadly defined as disease extending beyond the midline, and/or a cyst size greater than 5 cm, and/or a distance to the anal margin <3 cm, and/or recurrent or unhealing presentation, and/or accompanying inflammatory diseases (consensus, 90.3%).

There is often confusion between staging and severity (complexity) in disease classification. Patient-related factors are largely omitted from classification systems. However, in chronic conditions, disease complexity can be influenced by factors beyond anatomical features. Among the participating experts, cyst size and accompanying inflammatory disease were identified as complexity factors, despite the lack of consensus for their inclusion in classification systems. Factors such as age, gender, obesity, and hair density were not found to be influential. In clinical practice, most surgeons choose treatment based on a simple-versus-complex distinction, as recommended in the guidelines. <sup>1-3,8</sup> If a new classification system is developed, complexity could potentially serve as one of its components.

#### **Diagnosis and Mapping**

Expert statement: Routine preoperative and/or intraoperative mapping methods (imaging, dye, endoscopic tract identification) of the tracts are not recommended (no consensus, 56%).

The diagnosis of PD is based on clinical symptoms and physical examination. The presence of pits observed in the natal cleft and/or lateral areas during physical examination is sufficient for diagnosis.<sup>2</sup> Laboratory investigations are generally unnecessary, except in cases involving complicated abscesses or systemic disease.<sup>9</sup>

The results for mapping and imaging are controversial. In a randomized trial analyzing patients who underwent the Karydakis procedure, it was concluded that methylene blue might be associated with lower rates of wound infection. There is limited data supporting the benefit of preoperative or intraoperative imaging or other mapping methods. In clinically suspicious cases, particularly those near the anal canal, studies suggest that anorectal examination, proctoscopy, transrectal ultrasound, or other diagnostic imaging techniques may help differentiate PD from other perianal conditions, such as perianal fistula or hidradenitis suppurativa. 11-14 In selected patients with clinical suspicion, mapping of the extent can be selectively performed.

#### **Acute Abscess**

Expert statement: Pilonidal abscess should be drained using an off-midline incision at the site with the greatest fluctuation (consensus, 90%).

Expert statement: The shape of the incision (vertical, horizontal, cruciate, unroofing) is not critical. The incision should allow simultaneous curettage (consensus, 90%).

Expert statement: Needle aspiration is not recommended (consensus, 90%).

Currently, systematic reviews or meta-analyses examining treatment approaches for acute pilonidal abscesses are lacking. In a study involving 242 patients, Webb and Wysocki<sup>15</sup> compared midline incisions with lateral incisions and found that midline incisions took an average of 3 weeks longer to heal. Conversely, some surgeons suggest that a midline incision directly targets the primary area, whereas others prefer enlarging the existing pit or connecting it with other pits. Additionally, some recommend draining through the area with the greatest fluctuation.<sup>5</sup> In another study, 100 patients with acute abscesses were treated with needle aspiration and antibiotic therapy, and 10% required incision and drainage during a 29-month follow-up. 16 However, this study lacked a control group and did not provide long-term results regarding the need for definitive surgery. The method of drainage remains a focus for future research; however, the general recommendation is adequate drainage through a

lateral incision, which also allows simultaneous curettage of the cavity.

Expert statement: There is no consensus on the necessity or optimal timing for definitive treatment following drainage of a pilonidal abscess (consensus, 85%).

Expert statement: Abscess drainage combined with simultaneous debridement of the cavity [curettage, unroofing, excision, phenol, laser, endoscopic pilonidal sinus treatment (EPSIT), etc.] can be a standalone curative approach (consensus, 85%). There are two randomized and very few retrospective studies<sup>17,18</sup> that compare simultaneous curative approaches during pilonidal abscess drainage. Mahjoubi et al. 17 reported a 19% recurrence rate for excision of the abscess compared with 54% for incision-drainage (p=0.02). Girgin and Kanat<sup>18</sup> compared unroofing-curettage with incision-drainage and a delayed Karydakis procedure and reported similar recurrence rates at 14 months (3.5% vs. 4%). A randomized controlled trial (RCT) by Hosseini et al.19 investigated the outcomes of excision and laying open compared with incision-drainage and delayed excision-closure. They found that the incisiondrainage and delayed closure group experienced more wound infections (5.6% vs. 2.5%) and recurrence (14% vs. 0%) than the excision and laying open group. Another randomized trial by Vahedian et al.20 involved 150 patients with acute pilonidal abscesses randomized to either incision and drainage or unroofing and curettage. The results indicated that the curettage group had significantly lower recurrence rates after 65 months of follow-up (11% vs. 42%, p<0.001) than the other group. A recent survey indicated a significant tendency among Turkish surgeons to apply treatments such as irrigation, curettage, phenol application, EPSIT, or laser to the abscess cavity, with 40% expressing an intent for curative one-stage surgery.5

Although Stauffer et al.'s<sup>21</sup> meta-analysis reported that 40% of patients who underwent abscess drainage experienced recurrence within a 60-month follow-up period, more recent data challenge this finding. In a Dutch audit published by Huurman et al.,<sup>22</sup> simple incision and drainage resulted in recurrence-free healing in 91% of patients. Although recurrence rates may increase with longer follow-up periods, the data suggest that at least half the patients achieve complete disease resolution through simple incision and drainage. This approach merits consideration, at least until the patient becomes symptomatic again, highlighting the value of giving abscess drainage a chance as a viable initial treatment option.

#### **Treatment of Pilonidal Disease**

Expert statement: Patients' preferences should be taken into consideration when choosing a treatment method (consensus, 100%).

PD primarily affects young, working adults who have high expectations for quick recovery and good cosmetic outcomes. A patient survey conducted by the Pilonidal Sinus Treatment – Studying the Options group found that the risk of infection or persistence was the strongest predictor of treatment choice, followed by shorter recovery time.<sup>23</sup> However, patients reported a willingness to trade off between recovery time and the risk of infection or persistence. In two survey studies by the same group, decision regret was mainly due to the unexpected burden of wound care and the recovery time being longer than they expected.<sup>23,24</sup> These surveys also showed that although younger patients prioritized more guaranteed outcomes, patients over 30 were more willing to accept higher risks of infection or persistence in exchange for a quicker return to work.<sup>23,24</sup>

Minimally invasive procedures allow patients to resume daily activities sooner and result in smaller scars. However, they often carry higher recurrence rates and may require more treatments than traditional excisional methods.<sup>25</sup> Therefore, treatment decisions should be made collaboratively between doctors and patients. This shared decision-making approach has been shown to improve treatment outcomes, optimize healthcare resource use, and increase patient satisfaction.<sup>26</sup>

#### **Minimally Invasive Treatments**

Expert statement: Initial treatment for simple PD should be a minimally invasive method (consensus, 95%).

Expert statement: Minimally invasive treatments can be used in combination with each other (consensus, 87.5%).

Minimally invasive methods such as pit picking, phenol application, endoscopic treatments, and laser procedures primarily involve the evacuation of hair and debris from the cavity, debridement, and destruction of the inner border of the sinus without wide tissue excision. All these procedures are fundamental variations of pit picking. An initial study by Gips et al.,27 which included 1,358 patients, reported postoperative infection, secondary bleeding, and early failure rates of less than 5%, with a mean complete healing time of 3.4±1.9 weeks. In another series involving 2,347 consecutive patients, Di Castro et al.<sup>28</sup> reported a median operative time of 28 minutes (range: 21-75) and a median hospital stay of 6 hours (range: 2-36). Moreover, 77% of patients were able to resume daily activities within 2 days after treatment, and the median time for complete healing was 4 weeks (range: 2-21).<sup>13</sup> Although these functional outcomes are promising, a recent meta-analysis showed a recurrence rate of 38.2% when the follow-up period exceeded 2 years,<sup>29</sup> with some studies reporting even higher recurrence rates of 50-60%. 30,31

EPSIT is a relatively new approach based on direct visualization of sinus tracts using a fistuloscope or endocamera, mechanical cleaning of the tracts with forceps, irrigation, and ablation via electrocautery. 32,33 Gulcu and Ozturk 34 reported a median return to activity of 1 day (range: 1-4) and return to work of 3 days (range: 1-11), with no wound complications and an incomplete healing rate of only 4.6%. Another study from Gulcu's group compared conventional EPSIT with laserassisted EPSIT and found that the addition of laser enhances wound healing, patient comfort, and return to work; however, the success rates remained similar. 35 Recently, they compared EPSIT and pit picking without video assistance in another study, reporting similar success rates but higher costs for EPSIT. 36 A randomized trial comparing EPSIT with Bascom's cleft lift revealed similar recurrence rates (1 year: 3.9% vs. 5.8%; 5 years: 24.3% vs. 23.8%, p=0.03) but considerably less time off work, better cosmetic results, and higher patient satisfaction with EPSIT. 18 These results highlight the known advantages of minimally invasive treatments; however, further evidence is needed to demonstrate the specific contribution of adding an endoscopic technique to pit picking and to evaluate its cost-effectiveness.

Another method, laser treatment, also requires evidencebased validation. In one study, the addition of laser to pit picking showed no significant impact on recurrence rates during a 36-month follow-up; however, laser demonstrated advantages in terms of postoperative complications, pain, and return to work. The recurrence rate was approximately 10% in both groups.<sup>37</sup> Conversely, another study comparing pit picking with or without laser reported a reduced recurrence rate for the laser group (8.2% vs. 32.9%), although the follow-up for the pit picking-only group was longer.38 A systematic review including 10 studies reported a 94.6% healing rate after laser treatment for primary PD; for non-healing wounds or recurrences, repeated applications resulted in an overall healing rate of 96.6%.<sup>39</sup> The recurrence rate was 4.7%, with a median follow-up of 12 months (range: 8-25). Additional small studies with short follow-ups favor laser treatment over excisional and flap procedures in terms of hospital stay, return to normal activities, pain, and patient satisfaction. 40,41

Phenol is a widely accessible and inexpensive chemical agent that has antiseptic, sclerosing, and caustic effects, causing tissue protein denaturation. Several studies comparing excisional methods with phenol application favor phenol in terms of procedural time, hospital stay, and time to return to work or daily activities. 42-46 A recent meta-analysis by Gan et al. 47 reported fewer wound-related complications, shorter operation time, and shorter recovery periods for phenol treatments than for surgical excision. Phenol can be combined with other procedures; Gecim et al. 48 reported no recurrence after EPSIT with crystallized phenol over a follow-up period of 22 months.

Expert statement: Among the minimally invasive therapies, no single option stands out as the preferred choice of management (no consensus, 60%).

All minimally invasive treatments primarily consist of ablative methods combined with pit picking. Although this might suggest that pit picking alone could serve as a first-line treatment, the literature lacks high-quality evidence to allow a comprehensive comparison of all minimally invasive methods and to identify the superior approach. A recent systematic review including 3,780 non-excisional procedures revealed recurrence rates of 5.8-16.2% over follow-up periods ranging from 12 to 120 months.<sup>49</sup> However, Doll et al.<sup>30</sup> reported a 50% recurrence rate over 5 years, whereas Koskinen et al.<sup>31</sup> reported a 60% recurrence rate over 9.3 years with pit picking alone. Nevertheless, pit picking alone or in combination with additional techniques should be considered the first-line treatment, particularly in cases of simple disease.<sup>1-3,8</sup>

Expert statement: Minimally invasive treatments can be repeated in case of failure after the initial application (consensus, 87.5%).

Among minimally invasive treatments, phenol treatment is the one most frequently reported to require repeated application. Studies indicate that 11-70% of patients needed repeated applications, resulting in complete healing rates of 93-95%. <sup>50,51</sup> Additionally, repeated applications of EPSIT<sup>52,53</sup> and laser<sup>54,55</sup> are also associated with increased healing rates.

Expert statement: There is no consensus on the safety of phenol application (no consensus, 67.5%).

Phenol is a monohydroxy derivative of benzene that denatures cell membrane proteins, leading to tissue damage. It denatures keratin, which is a component of hair structure. Additionally, phenol has antimicrobial, sclerosing, antiseptic, and anesthetic properties. Since its initial use in PD in 1964, various forms (liquid, crystallized) and concentrations have been widely used as an effective minimally invasive treatment, either alone or in combination with other techniques. 18,42-48,50,51,56-60 Although the local complications of phenol treatment, such as skin irritation, abscess, and cellulitis, are well established, there is limited understanding of potential systemic effects related to its application site and dosage in PD. This uncertainty has led some countries to consider phenol treatment unsafe for PD. Although there is no consensus on the safety of phenol, there is also no clear evidence of systemic effects in the treatment of PD. The latest European guideline states that phenol application can be offered as a treatment option in PD.8

#### **Excisional Treatments**

Expert statement: Excision and advancement flap closure methods (Karydakis, Bascom) can be offered as the first choice among invasive methods (no consensus, 67.5%).

Expert statement: Initial treatment for complex PD is controversial. Minimally invasive and excisional methods can be performed selectively (no consensus, 67.5%).

The literature indicates a considerable gap in the systematic evaluation of surgical techniques specifically for complex PD. The definition of complex disease remains inconsistent, generally encompassing recurrent disease, failed healing, or extensive primary presentations, including bilateral involvement, perianal extension, or substantial wound size.<sup>8</sup> Evidence suggests that recurrent PD in both adult and pediatric populations can be treated with minimally invasive methods; hence, excisional surgery should not be the sole option for complex PD.<sup>23,53,61</sup> Minimally invasive treatments, incisional procedures, and excisional surgeries with laying open or off-midline closure should be discussed individually in the context of shared decision-making. However, midline closure techniques should be avoided.<sup>62</sup>

Surgical approaches typically fall into two categories: primary closure techniques (including midline, off-midline, and various flap procedures) and open healing by secondary intention. Notable off-midline techniques include Bascom's cleft lift, the Karydakis procedure (advancement flaps), and the Limberg and Dufourmental methods (which use rotational flaps). A large-scale analysis of 89,583 patients revealed significant differences in long-term outcomes. Primary midline closure showed higher recurrence rates (up to 32% by 120 months) compared with off-midline techniques such as Karydakis or Bascom's procedures (2.7% recurrence) and Limberg or Dufourmental flaps (11.4% recurrence).<sup>21</sup>

Excision and laying open, with or without marsupialization, can be considered for selected patients.<sup>8</sup> A meta-analysis examining 343 patients demonstrated recurrence rates of 1.8% at 12 months and 5.6% at 24 months following laying-open surgery.<sup>21</sup> However, these favorable recurrence rates should be weighed against prolonged healing times and delayed return to work.

Current evidence supports off-midline closure as the optimal approach following excisional surgery, although no single technique has been proven to be clearly superior. The selection of a specific surgical approach should take into account the surgeon's expertise and individual patient factors, whereas midline closure should be avoided.

Expert statement: Routine histopathologic examination of the specimen is not recommended, but it can be offered based on individual surgeon preference (no consensus, 60%).

The role of histopathological examination in PD specimens lacks evidence from systematic reviews or RCTs. However, a key retrospective cohort analysis conducted by Akin et al., 63 which evaluated surgical specimens from 2,486 patients,

found no evidence of malignant transformation in any of the specimens. Despite the absence of supporting evidence, insurance reimbursement requirements and medicolegal concerns-particularly in Türkiye-explain the continued practice of routine pathological examination by some surgeons.

#### Recurrent/Persistent Pilonidal Disease

Expert statement: In cases of recurrent or persistent disease, treatment decisions should be based on the severity of the condition (simple or complex) rather than on the type of previous intervention (minimally invasive or non-minimally invasive) (consensus, 92.5%).

Despite limited evidence specifically for recurrent cases, treatment principles often mirror those for initial presentations. A comprehensive review by Stauffer et al.21 indicates a progressive increase in recurrence over time, with an initial rate of 2.0% at 12 months post-treatment, rising to 4.4% by 24 months. A more substantial increase is observed at 60 months (10.8%), continuing to 16.9% at 120 months. These findings emphasize the chronic and recurrent nature of PD, suggesting that many patients may require multiple interventions over time and highlighting the importance of long-term follow-up. Most surgeons favor excisional methods for persistent or recurrent disease following initial treatment. Similarly, when the primary intervention was an excisional/flap procedure, there is often hesitation to use minimally invasive techniques in cases of recurrence or non-healing. However, evidence suggests that minimally invasive procedures can still play a role in treating recurrent PD, even after prior excisional surgery. Meinero et al.53 enrolled 122 consecutive patients with recurrent PD in a prospective study on EPSIT and reported 95% complete wound healing, with a mean healing time of 29±12 days. The recurrence rate was only 5.1%. In recurrent cases with multiple tracts, EPSIT provides direct visualization of the entire sinus and offers a promising minimally invasive approach. 32,53 Another commonly used minimally invasive method, phenol treatment, has demonstrated success rates of up to 91% and failure rates of 8% in treating recurrent PD, with minimal side effects. 50,64,65 It is worth noting that although some primary cases present as highly complex, with multiple fistula openings and infection, some recurrences may manifest as simple midline disease with only 1-2 pits. Unfortunately, the literature lacks studies that define and compare these scenarios, and no classification system currently exists. Regardless of whether the disease is recurrent or the type of initial treatment received, the severity of the current presentation should be the primary factor guiding the choice of treatment.

Expert statement: Among excisional techniques, methods such as Karydakis and Bascom advancement flap closure can be considered initial treatment options for complex recurrent or persistent disease (consensus, 75%).

Several flap techniques have been described in the literature, suggesting that advancement flap closures offer superior outcomes. Reported benefits include lower infection rates, fewer recurrences, shorter hospital stays, earlier return to work, and improved quality of life<sup>4,66-73</sup>. In a study on Bascom's cleft lift for complex or recurrent PD, Ojo et al.<sup>4</sup> reported a treatment failure rate of only 3% and a recurrence rate of 5.3% over 12 months of follow-up.

#### **Regional Care and Hair Removal**

Expert statement: Regional care in the natal cleft (showering, cleaning, keeping the area free of debris or shed/occipital hair) and hair removal should be recommended routinely, regardless of the treatment method (consensus, 87.5%).

Expert statement: There is no consensus on the optimal timing for initiating and terminating hair removal. Hair removal can be performed using either temporary (razor, blade, depilatory cream) or permanent methods (laser depilation, intense pulsed light, needle epilation) (consensus, 77.5%).

The exact cause of PD remains unclear. Earlier theories, such as folliculitis, ingrown gluteal hair, or local hair penetration, have largely been dismissed due to insufficient evidence. Recent research by Doll's team has revealed that sharp hair fragments, particularly from the occipital region, are the primary components found within pilonidal sinus cavities. 74,75 Additionally, individuals with a hairy intergluteal sulcus tend to retain hair in this area for longer periods, which may explain the higher risk of PD among those with more body hair. 75 As a result, hair removal and regional care, including keeping the intergluteal area free of shed hair, have become standard recommendations. Given this evidence, it is more important to emphasize consistent hygiene of the intergluteal region rather than focusing solely on hair removal immediately before surgery. Practices such as showering after a haircut or regularly cleaning the area may play a more valuable role in preventing the recurrence or development of pilonidal sinus disease. Halleran et al. 76 examined the use of laser depilation in the postoperative period by reviewing 35 studies (including two RCTs) and found reduced recurrence rates with laser compared with other methods. Similarly, Pronk et al.77 analyzed 14 studies (including two RCTs) involving 963 patients and found that laser hair removal was associated with a recurrence rate of 9%, which was lower than that observed with no hair removal (19%) or shaving/depilation (23%).

In summary, although depilation is not a definitive treatment, keeping the intergluteal sulcus free from debris and hair is a feasible and practical approach to preventing PD and reducing the risk of recurrence. Currently, there is no consensus on when this practice should be initiated or how long it should be maintained, highlighting the need for further research to establish clear guidelines.

#### **Perioperative Care and Antibiotics**

Expert statement: Antibiotics should be used for perioperative prophylaxis in excision and flap procedures (consensus, 87.5%). Expert statement: Antibiotic use in abscess drainage and in procedures other than excision and flap procedures-whether perioperative, intraoperative, or postoperative-is controversial (consensus, 87.5%).

There is no evidence supporting the positive effects of antibiotics in the treatment of PD. A systematic review by Mavros et al., 78 which included seven studies and 690 patients, found no difference in outcomes between long-course antibiotics and single-dose prophylaxis. Unfortunately, current guidelines do not provide clear recommendations regarding antibiotic use. In this survey study, experts indicated that antibiotics have a prophylactic role in flap surgeries; however, their benefit in other applications remains uncertain. In cases of severe cellulitis, immunosuppression, or associated comorbidities, antibiotic therapy should be considered selectively.

Expert statement: Drains can be selectively placed after excision and flap closure (consensus, 82.5%).

Although a meta-analysis by Milone et al.,<sup>79</sup> which included seven studies and 1,252 patients, found that drainage did not significantly reduce postoperative infection or recurrence rates compared with no drainage, drains may still be placed at the surgeon's discretion following wide excision and flap closures to remove excess fluid from the surgical site.

Expert statement: Intraoperative use of antibiotics or topical antimicrobial solutions (e.g., zinc oxide, cinchona tree powder) on the wound is not necessary (consensus, 75%).

Expert statement: Irrigation of the surgical site with saline or antimicrobial solutions (e.g., hydrogen peroxide, chlorhexidine gluconate) is controversial (no consensus, 60%).

Expert statement: The use of wound-healing adjuncts, such as vacuum-assisted closure (VAC), platelet-rich plasma (PRP), hemoglobin spray, fibrin glue, and autologous fat transplantation, remains controversial. However, VAC may be considered in the management of large pilonidal wounds (no consensus, 60%).

The intraoperative use of irrigation solutions, <sup>80</sup> antibiotics, or dressings, <sup>81</sup> as well as coated sutures <sup>82</sup> to prevent wound infection, remains a topic of debate. A systematic review by Nguyen et al. <sup>83</sup> found no significant benefit of gentamicin collagen sponges in reducing healing time or recurrence rates in pilonidal surgery. Current evidence does not support the use of intraoperative adjuncts to improve outcomes.

A Cochrane review conducted by Herrod et al.<sup>81</sup> found no evidence that VAC reduced healing time in PD cases. Their findings also indicated no benefit from other agents aimed at accelerating wound healing. However, some retrospective and prospective case series have suggested that VAC may be

beneficial for managing large and complex pilonidal wounds, particularly in cases of wound breakdown.<sup>8</sup>

#### **Postoperative Care**

Expert statement: After laying-open procedures, it is recommended that patients shower daily and manage dressing/packing of the surgical site on their own (consensus, 92.5%). Expert statement: After minimally invasive procedures, it is recommended that patients shower daily and manage dressing/packing of the surgical site on their own. Additionally, depilation or inspection for new hair insertions should be recommended (consensus, 90%).

Expert statement: After excision and closure procedures, there is no consensus on the necessity of daily showering (no consensus, 66%) or dressing/packing of the surgical site (no consensus, 65%). However, depilation or inspection for new hair insertions should be recommended (consensus, 75%). The literature does not provide evidence that dressing reduces the healing time for open wounds. Meta-analyses published in 201581 and 201984 indicated that the use of dressings and other topical agents does not shorten the healing period. However, one randomized trial showed that PRP may accelerate wound healing compared with traditional dressing.85 Practices regarding dressing application after PD treatment vary considerably among surgeons. In our survey, some surgeons preferred to perform all dressing changes themselves, whereas others considered dressings unnecessary. Due to the limited data on this topic, this statement is based entirely on expert opinion. Most experts appear to support the idea that patients can wash their wounds and manage self-dressing in cases of open wounds and minimally invasive procedures, showing more caution following flap surgeries. There is a substantial need for prospective studies addressing this issue.

Expert statement: After excision and cleft lift/flap procedures, patients should avoid squatting, riding a bicycle, and participating in activities that increase the risk of falls (e.g., football, basketball). No other physical restrictions (e.g., lying supine or prone, or sitting) are recommended (consensus, 82.5%).

There is no literature providing data on patients' physical activities or sitting positions following excision and cleft lift/flap procedures. No recommendation can be derived from the literature. Expert opinion suggests only minimal restrictions.

#### **Discussion**

Several guidelines and consensus statements have been published regarding the management of pilonidal sinus disease, notably from German (1), Italian (2), and American (3) groups. However, considerable gaps remain in the classification systems and treatment algorithms currently

available. The primary aim of this study is to provide a more comprehensive framework for the classification of pilonidal sinus disease. We specifically discussed which elements should be included in a more robust classification and how complex disease should be defined. Additionally, we have addressed perioperative mapping and elaborated on postoperative abscess management-areas that have been either insufficiently addressed or not explored in depth in previous guidelines and studies. All expert opinions have been compiled and

presented in a comprehensive flowchart to clearly illustrate the consensus and decision-making pathways (Table 1).

The existing guidelines primarily rely on expert opinion and lack high-level evidence from clinical studies. Therefore, the classification and management model presented here is intended to facilitate clinical use by surgeons and to promote a more standardized approach. This is designed to support decision-making in the management of heterogeneous disease presentations.

Table 1. Questions and responses

Questionnaire	Agreement
Q1. A classification system should be used for the documentation and grading of PD.	Agree: 83.3% Disagree: 16.7%
Q2. Current classification systems for PD are deficient. There is a need for either the development of a new system or the comprehensive validation of existing ones through large prospective series.	Agree: 76.2% Disagree: 23.8%
Q3. An ideal PD classification should include the following components: the number of secondary orifices, extension in relation to the midline (lateral, unilateral, or bilateral spread), extension below coccyx level, distance to the anal margin, and presentation (acute abscess, recurrent, or unhealing).	Agree: 92.7% Disagree: 7.3%
Q4. There is no clear consensus on the definition of the term complex pilonidal disease. It can be broadly defined as disease extending beyond the midline and/or with a maximum cyst diameter >5 cm and/or a distance to the anal margin <3 cm and/or a recurrent/unhealing presentation and/or the presence of accompanying inflammatory diseases.	Agree: 90.3% Disagree: 9.7%
Q5. Preoperative and/or intraoperative mapping methods (imaging, dye, endoscopic tract identification) of the tracts are not routinely recommended.	Agree: 56% Disagree: 44%
Q6. Pilonidal abscesses should be drained through an off-midline incision at the site of maximum fluctuation.	Agree: 90% Disagree: 10%
Q7. The shape of the incision (vertical, horizontal, cruciate, unroofing) is not important. The incision should allow for simultaneous curettage.	Agree: 90% Disagree: 10%
Q8. Needle aspiration is not recommended.	Agree: 90% Disagree: 10%
Q9. There is no consensus on the necessity or optimal timing of definitive treatment after draining a pilonidal abscess.	Agree: 85% Disagree: 15%
Q10. Abscess drainage with simultaneous debridement of the cavity (curettage, unroofing, excision, phenol, laser, endoscopic pilonidal sinus treatment, etc.) can be a standalone curative approach.	Agree: 85% Disagree: 15%
Q11. Patient preferences should be considered when choosing treatment methods.	Agree: 100%
Q12. Initial treatment should be a minimally invasive method for simple pilonidal disease.	Agree: 95% Disagree: 5%
Q13. Minimally invasive treatments can be used in combination with each other.	Agree: 87.5% Disagree: 12.5%
Q14. Among the minimally invasive therapies, no single option stands out as the preferred choice of management.	Agree: 60% Disagree: 40%
Q15. Minimally invasive treatments can be repeated in case of failure after the initial application.	Agree: 87.5% Disagree: 12.5%
Q16. There is no consensus on the safety of phenol application.	Agree: 67.5% Disagree: 32.5%
Q17. Excision and advancement flap closure methods (Karydakis, Bascom) can be offered as the first choice among invasive methods.	Agree: 67.5% Disagree: 32.5%

Table 1. Continued

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Questionnaire	Agreement
Q18. Initial treatment for complex PD is controversial. Minimally invasive and excisional methods can be performed selectively.	Agree: 67.5% Disagree: 32.5%
Q19. Routine histopathologic examination of the specimen is not recommended. It can be offered based on individual surgeon preference.	Agree: 60% Disagree: 40%
Q20. In cases of recurrent or persistent disease, treatment decisions should be based on the severity of the condition (simple or complex) rather than on the type of previous intervention (minimally invasive or non-minimally invasive).	Agree: 92.5% Disagree: 7.5%
Q21. Among excisional techniques, methods such as Karydakis and Bascom advancement flap closure can be considered initial treatment options for complex recurrent or persistent disease.	Agree: 75% Disagree: 25%
Q22. Regional care in the natal cleft (showering, cleaning, keeping clear of debris or shed/occipital hair) and hair removal should be recommended routinely regardless of the treatment.	Agree: 87.5% Disagree: 12.5%
Q23. There is no consensus on the optimal timing for initiating and terminating hair removal. Hair removal can be performed by either temporary methods (razor, blade, depilatory cream) or permanent methods (laser depilation, IPL, needle epilation).	Agree: 77.5% Disagree: 22.5%
Q24. Antibiotics should be used for perioperative prophylaxis in excision and flap procedures.	Agree: 87.5% Disagree: 12.5%
Q25. Antibiotic use in abscess drainage and procedures other than excision and flap procedures, in any setting (perioperative, intraoperative, postoperative), is controversial.	Agree: 87.5% Disagree: 12.5%
Q26. Drains can be selectively placed after excision and flap closure.	Agree: 82.5% Disagree: 17.5%
Q27. Intraoperative application of antibiotics or topical antimicrobial solutions (zinc oxide, cinchona tree powder) to the wound is not necessary.	Agree: 75% Disagree: 25%
Q28. Irrigation of the surgical site with saline or antimicrobial solutions (hydrogen peroxide, chlorhexidine gluconate) is controversial.	Agree: 60% Disagree: 40%
Q29. The use of wound-healing adjuncts such as vacuum-assisted closure (VAC), platelet-rich plasma, hemoglobin spray, fibrin glue, and autologous fat transplantation remains controversial. However, VAC may be considered in the management of large pilonidal wounds.	Agree: 60% Disagree: 40%
Q30. After laying-open procedures, daily showering and dressing/packing of the surgical site by the patient are recommended.	Agree: 92.5% Disagree: 7.5%
Q31. After minimally invasive procedures, daily showering and dressing/packing of the surgical site by the patient are recommended. Depilation or inspection of new hair insertions should also be recommended.	Agree: 90% Disagree: 10%
Q32. After excision and closure procedures, there is no consensus on daily showering.	Agree: 66% Disagree: 34%
Q33. After excision and closure procedures, there is no consensus on daily dressing/packing of the surgical site.	Agree: 65% Disagree: 35%
Q34. After excision and closure procedures, depilation or inspection of new hair insertions should be performed.	Agree: 75% Disagree: 25%
Q35. After excision and cleft lift/flap procedures, patients should avoid squatting, riding a bicycle, and activities prone to falls (e.g., football, basketball). No other physical restrictions (lying in supine or prone position or sitting) are recommended.	Agree: 82.5% Disagree: 17.5%

PD: Pilonidal disease, IPL: Intense pulsed light, VAC: Vacuum-assisted closure

#### **Ethics**

**Ethics Committee Approval:** This study was approved by Institutional Ethics Committee of Medipol University International Faculty of Medicine (approval number: E-10840098-202.3.02-5416, dated: 09.09.2024).

**Informed Consent:** Retrospective study.

#### **Footnotes**

#### **Authorship Contributions**

Surgical and Medical Practices: Ç.A., C.T., T.E., T.B., R.K., Concept: Ç.A., C.T., T.E., Design: Ç.A., C.T., T.E., T.B., Data Collection or Processing: Ç.A., C.T., T.E., Analysis or Interpretation: Ç.A., C.T., T.E., R.S., S.C.I., P.W., B.B.T., B.C., Y.Y., T.B., R.K., Y.M., M.A.A., Literature Search: Ç.A., C.T., T.E., T.B., R.K., Y.M., Writing: Ç.A., C.T., T.E., T.B.

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#### Appendix 1. Pilonidal disease study group

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#### Appendix 2. Experts

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#### Appendix 3. The survey draft

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#### Appendix 4. Raund 1 and 2 results

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### Turkish Adaptation of the Stoma-Specific Quality of Life Questionnaire: A Validity and Reliability Study

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#### IIIIIIIII ABSTRACT

Aim: This methodological study aimed to evaluate the validity and reliability of the Turkish version of the Stoma-Specific Quality of Life (SQOL-TR) questionnaire, developed to assess the Quality of Life in individuals with enteral and urinary ostomies.

Method: The study was conducted with 125 patients with ostomies at the stoma therapy unit of a university hospital in Ankara. Data were collected using a demographic information form, the Quality-of-Life Scale for Individuals with an Ostomy (O-QOL), and the SQOL-TR. In the first stage, linguistic validation and a pilot test were conducted. In the second stage, construct validity was assessed using confirmatory factor analysis, and concurrent validity was evaluated through comparison with the O-QOL. Reliability was tested via Cronbach's alpha, composite reliability, and item analysis.

Results: Participants had a mean age of 59.66±12.70 years and an average ostomy duration of 16.47±21.86 months. Of these, 40.0% had colostomies, 29.6% ileostomies, and 26.4% urostomies. Psychometric analyses revealed a content validity index of 1.00. The questionnaire consisted of four subdimensions: elimination concerns, psychological impact, daily activities, and social relationships. It showed a strong positive correlation with the O-QOL (r=0.78, p<0.001) and a reliability coefficient of 0.964. All items demonstrated high discriminative power.

Conclusion: The SQOL-TR is a valid and reliable instrument for individuals with colostomies, ileostomies, or urostomies. Adapted into six cultures, it is suitable for use in multicenter and multinational research as well as clinical follow-up.

Keywords: Quality of Life, colostomy, ileostomy, reliability, urostomy, validity

#### Introduction

Cancers of the colon, rectum, small intestine, and bladder are major contributors to global cancer-related morbidity and mortality.<sup>1,2</sup> According to data from the International Agency for Research on Cancer, colorectal cancer ranks as the fourth most frequently diagnosed malignancy worldwide, whereas bladder cancer ranks eleventh.3 Although cancers of the small intestine occur less frequently, they still represent a critical clinical concern. In Türkiye, according to 2019 data published in 2023 by the Ministry of Health, gastrointestinal cancers rank eighth among all malignancies.4

The standard treatment modalities for these cancers include surgery, radiotherapy, and chemotherapy. Depending on the tumor site and extent, surgical resection may lead to the formation of either a temporary or permanent ostomy.5,6 In colorectal and small bowel cancers, anastomosis or ostomy formation is often required. In cases of muscleinvasive or high-risk non-muscle-invasive bladder carcinoma unresponsive to intravesical Bacillus Calmette-Guérin therapy, radical cystectomy followed by continent or incontinent urinary diversion is employed to ensure urinary excretion.<sup>7</sup> An estimated 700,000 individuals in Europe live with an ostomy, including colostomy, ileostomy, and urostomy, with



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prevalences of 0.12%, 0.07%, and 0.02%, respectively.<sup>8,9</sup> In Italy, over 70,000 individuals live with an ostomy,<sup>10</sup> whereas in the United States, this number reaches nearly one million.<sup>11</sup> In Türkiye, Yılmaz et al.<sup>12</sup> reported that 22,557 new ostomies were created nationally between 2017 and 2019.

Living with an ostomy can considerably impact a patient's Quality of Life (QoL) across physical, psychological, and social dimensions.<sup>5,13,14</sup> Patients frequently experience defecation or urinary control issues, odor, and skin irritation, along with psychological symptoms such as anxiety, depression, and social withdrawal. 13,14 These complications can lead to challenges in personal relationships, decreased intimacy, isolation, increased familial or social rejection, and even financial stress due to job loss or career changes. 5,13,14 Although QoL assessment tools have evolved over the years, 15,16 many studies continue to rely on general QoL instruments that are not tailored to ostomy-specific concerns.7,17,18 A growing body of research has supported the use of ostomyspecific tools in recent years; 15,16 however, these often focus narrowly on selected QoL dimensions such as sexuality or social interactions. 19,20 Furthermore, most tools are validated only in individuals with enteral ostomies (colostomy, ileostomy)<sup>13,16,19,21</sup> or solely in urostomy populations.<sup>7,17,20</sup> This highlights the need for an inclusive, culturally validated tool capable of evaluating QoL in individuals with both enteral and urinary ostomies. In Türkiye, the only existing adapted instrument is the Quality-of-Life Scale for Individuals with an Ostomy (O-QOL), developed by Karadağ et al. in 2011.<sup>22</sup> Although the O-QOL has been accepted as a reliable measure, its scoring procedure is complex due to reverse-coded items and formula-based subscales. Furthermore, some items are irrelevant for patients without school or employment responsibilities, those without sexual partners, or individuals with urostomies.22

In response to these limitations, the Stoma-specific Quality of Life (SQOL) questionnaire was developed to comprehensively evaluate QoL in patients with ostomies. Unlike the O-QOL, it assesses sleep, sexual activity, family and social relationships, and broader psychosocial dimensions. Validated across multiple cultural contexts, including Italy, Spain, Brazil, Canada, and China, the SQOL has been shown to be appropriate for use in individuals with colostomy, ileostomy, and urostomy. R23-26 Although the original version did not include patients with urostomies, later studies emphasized the need to evaluate its reliability and validity in this group. The studies emphasized the need to evaluate its reliability and validity in this group.

#### Aim of the Study

There is a need for a culturally valid and reliable instrument tailored to the Turkish population to identify ostomy-related challenges, guide care practices, and assess the impact of clinical interventions aimed at improving QoL following ostomy surgery. Therefore, this study aims to examine the validity and reliability of the Turkish version of the SQOL (SQOL-TR) in individuals with enteral or urinary ostomies. Research question: Is the SQOL questionnaire a valid and reliable tool for use among Turkish patients with ostomies?

#### **Materials and Methods**

#### **Study Design and Sample**

This methodological study followed standard cultural adaptation procedures and was conducted between February 2022 and February 2023 at the Stoma and Wound Care Unit of the Department of General Surgery, Hacettepe University Hospital. The study population included patients who had received ostomies at least 1 month prior and were being followed up in the same unit. In 2022, the unit monitored 132 patients with ostomies.

As stated by İlhan et al.<sup>28</sup>, in methodological research, sample size calculations should consider the ratio of the sample size to the number of scale items. Various scholars made the following suggestions: Everitt (1975) proposed a minimum ratio of 5:1, Cattell (1978) recommended at least 6:1, and Nunnally (1978) suggested a ratio of at least 10:1.<sup>28</sup> Based on this data, the minimum sample size for the SQOL-TR, which consists of 20 items, was determined to be 100. The study was completed with 125 participants.

The inclusion criteria were as follows: voluntary participation, age 18 or older, having an ostomy for at least 1 month, literacy, and fluency in Turkish.

The exclusion criterion was as follows: any condition impairing communication (e.g., cognitive or neuropsychiatric disorders).

#### **Data Collection Tools**

#### **Introductory Information Form**

This form comprised 18 items designed to collect demographic information (e.g., age, gender, marital status, education level) and clinical characteristics related to the ostomy.

#### **SQOL Questionnaire**

Originally developed in English, the SQOL includes 20 items that evaluate the QoL in individuals living with an ostomy. The Cronbach's alpha ( $\alpha$ ) was reported as 0.92. The questionnaire targets four key domains: Sleep, Sexual Activity, Relations to Family and Close Friends, and Social Relations Outside Family and Close Friends. The original study confirmed a unidimensional structure for the questionnaire.

Although adaptations in Canada, Italy, Brazil, and Spain also recognized these four domains as sub-dimensions, no consensus was reached on item-to-domain mapping.<sup>23,29-31</sup> In contrast, Shao et al.<sup>32</sup> restructured the Chinese version into four factors. Factor I, Social Relationship, merged items

regarding both close and extended social relations. Factor II, Psychological Impact, included items addressing discomfort, embarrassment, concealment, body image, and sexual attractiveness, and the original Sexual Activity dimension was incorporated here. Factor III, Defecation Concerns, included items related to leakage, odor, and toilet access. Factor IV, Daily Function, reflected core tasks such as sleep and dressing, largely aligning with the original Sleep domain.<sup>32</sup>

Shao et al.<sup>32</sup> reported Cronbach's  $\alpha$  coefficients of 0.93 for the total questionnaire and 0.73-0.83 for the sub-dimensions. The Turkish version adopted this factor structure:

• Elimination concerns: Items 1-4

• Psychological impact: Items 5, 9, and 11-14

Daily activities: Items 6-8 and 10Social relationships: Items 15-20

Each item is rated on a 4-point Likert scale (1= always, 4= never). The total score ranges from 20 to 80, with higher scores indicating better QoL.

#### QoL Scale for O-QOL

To evaluate norm-referenced reliability, the O-QOL developed by Baxter et al.  $^{33}$  and validated in Turkish by Karadağ et al.  $^{22}$  was used. It contains 21 items and has an overall Cronbach's  $\alpha$  of 0.87. Subscales include Work/Social Life (6 items,  $\alpha$ =0.77), Sexuality/Body Image (5 items,  $\alpha$ =0.72), and Stoma Function (6 items,  $\alpha$ =0.76). The first 2 items assess general satisfaction. The first part is scored 0-100, and the second part uses a 5-point Likert scale. The instrument also includes 2 single items addressing financial concerns and skin irritation. Subscale scores are calculated using specific formulas and range from 0 to 100, with higher scores reflecting greater QoL.  $^{22}$ 

#### Implementation of the Study

#### **Linguistic Validation**

To ensure linguistic validity, the original questionnaire was translated into Turkish by five bilingual experts with experience in ostomy care. These translations were synthesized into a single version and reviewed by another expert for accuracy. This Turkish version was then back-translated into English by a native-level speaker unfamiliar with the original questionnaire. The back-translation was compared with the original for semantic consistency, and necessary revisions were made. Finally, another bilingual expert evaluated both versions for conceptual equivalence, after which the final Turkish version was confirmed.

#### **Content Validity**

To evaluate the content validity of the linguistically adapted SQOL-TR, Davis's<sup>34</sup> technique was employed. In this method, each item in the questionnaire is assessed using a four-point

structure: (a) appropriate, (b) needs revision, (c) needs major revision, and (d) not appropriate. The content validity index (CVI) for each item is calculated by dividing the number of experts selecting "a" or "b" by the total number of experts. A CVI greater than 0.80 indicates that the item is content-valid. Accordingly, the evaluation form was reviewed by 10 doctoral-level experts in nursing with research experience in scale validation and ostomy care. Experts were also asked to provide suggestions regarding each item. Based on their feedback, items were scored on a 4-point scale: 4= very appropriate, 3= appropriate with minor revision, 2= requires modification, and 1= not appropriate. These evaluations were used to determine the appropriateness of each item.

#### **Pilot Study of the Questionnaire**

A pilot study was conducted with five participants to identify potential semantic or structural issues in the linguistically and content-validated the SQOL-TR. No modifications were required following the pilot phase. Participants involved in the pilot were excluded from the main data analysis.

#### **Construct Validity**

To assess the construct validity of the SQOL-TR, confirmatory factor analysis (CFA) was employed. The four-factor structure previously validated by Shao et al.  $^{32}$  was tested. Factor loadings and model-data fit indices were used to determine whether this model was validated. The fit indices included chi-square to degrees of freedom ratio ( $\chi^2$ /df), comparative fit index (CFI), non-normed fit index/Tucker-Lewis index (TLI), standardized root mean square residual (SRMR), and root mean square error of approximation (RMSEA).

#### **Concurrent Validity**

To assess concurrent validity, the SQOL-TR and the O-QOL were administered concurrently to 125 participants, and the correlation between the two instruments was calculated. Following the completion of validity analyses, reliability assessments were conducted.

#### **Reliability Analyses**

For the reliability assessment of the SQOL-TR, Cronbach's  $\alpha$  was calculated for the total questionnaire and all sub-dimensions. Additionally, the composite reliability coefficient was evaluated using McDonald's omega, and item analysis was performed through a 27% sub-upper group comparison.

#### Statistical Analysis

Data were analyzed using the Statistical Package for the Social Sciences for Windows (version 23.0; IBM Corp., Armonk, NY, USA) and jamovi (version 2.6; the jamovi project, Sydney, Australia). Descriptive statistics (frequency, percentage, mean, and standard deviation) were applied. Pearson's correlation measured relationships. CFA was conducted in jamovi.

Normality was assessed via skewness and kurtosis, with ±1 considered acceptable.<sup>36</sup> Statistical significance was set at p<0.05.

#### **Ethical Considerations**

Permission was obtained from the original authors of the SQOL to conduct a validity and reliability study. Ethical approval was granted by the Hacettepe University Ethics Committee (GO21/1034), along with institutional permission. (approval number: 2021/20-02, dated: 05.10.2021). Informed consent was obtained from all participants, and the study was conducted in accordance with the principles of the Declaration of Helsinki.

#### **Results**

Participants had a mean age of 59.66 (±12.70) years and had lived with ostomies for an average of 16.47 (±21.86) months. Of the sample, 48.8% were men, 50.4% had permanent ostomies, and 48.0% reported income below expenses. Nearly half (45.6%) experienced at least one ostomy-related complication. Most participants (76.8%) contributed financially to ostomy supplies, and 32.0% were receiving chemotherapy. Preoperative ostomy site marking was performed by stoma and wound care nurses in 78.6% of applicable cases. Further demographic and clinical data are presented in Table 1.

# **Validity Analyses**

# **Content Validity**

The CVI for all items of the linguistically validated questionnaire was 1.00, indicating high content validity; therefore, no modifications were made to the items.

#### **Construct Validity**

Factor loadings ranged from 0.76 to 0.85 for Elimination Concerns, 0.55 to 0.81 for Psychological Impact, 0.71 to 0.82 for Daily Activities, and 0.78 to 0.93 for Social Relationships. Overall loadings ranged from 0.55 to 0.93, all exceeding the recommended threshold of 0.32 for construct validity.<sup>37</sup> The detailed factor structure and factor loadings of the SQOL-TR are given in Table 2.

CFA yielded acceptable fit indices:  $\chi^2$ /df =2.17, CFI =0.92, TLI =0.90, SRMR =0.05, and RMSEA =0.09. These results confirm the construct validity of the SQOL-TR.<sup>38</sup> Details are presented in Table 3.

# **Concurrent Validity**

Analysis revealed a significant positive correlation between the SQOL-TR and the O-QOL (r=0.78, p<0.001). This indicates that as QoL scores obtained from the SQOL-TR increased, O-QOL scores also increased, confirming the concurrent validity of the SQOL-TR. Following completion of the validity assessments, reliability analyses were conducted.

**Table 1.** Distribution of descriptive and clinical characteristics of the patients

of the patients		
Characteristics	$\overline{X} \pm SD$	
Age	59.66±12.70	
Duration of having an ostomy (month)	16.47±21.86	
Sex	n	%
Female	64	51.2
Male	61	48.8
Employment		
Working	13	10.4
Retired	59	47.2
Not working	53	42.4
Educational status		
Literate	5	4.0
Primary education	60	48.0
High school	35	28.0
Higher education and postgraduate	25	20.0
Socioeconomic status		
Income less than expenses	60	48.0
Income equal to expenses	46	36.8
Income higher than expenses	19	15.2
Marital status		
Single	14	11.2
Married	99	79.2
Separated from/deceased spouse	12	9.6
Cohabitants		
Lives alone	12	9.6
Spouse/child	108	86.4
Family/friend	5	4.0
Preoperative diagnosis		
Bladder cancer	35	28.0
Colon cancer	38	30.4
Rectal cancer	29	23.2
Other*	23	18.4
Type of ostomy		
Colostomy	50	40.0
Ileostomy	37	29.6
Urostomy	33	26.4
More than one ostomy*	5	4.0
Who takes care of the stoma		
Oneself	44	35.2

Table 1. continued

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Characteristics	$\overline{X} \pm SD$				
Family/caregiver	67	53.6			
Oneself with relatives	14	11.2			
Financial source of stoma care supplies					
Oneself only	24	19.2			
Health insurance	5	4.0			
Health insurance and supplementary payment	96	76.8			
Stomal complications (n=64)					
Peristomal skin problems	45	70.3			
Parastomal hernia	8	12.5			
Prolapse	3	4.7			
Peristomal bleeding	3	4.7			
Other**	5	7.8			
Bag-changing frequency					
Once every 1-3 days	64	51.2			
Once every 4-7 days	54	43.2			
Twice a day	7	5.6			

 $\overline{X}$ : mean, SD: standard deviation, \*: small intestine tumor (n=4), inflammatory bowel disease (n=3), familial adenomatous polyposis (n=2), hidradenitis suppurativa (n=1), colovesical fistula (n=2), cervix/ ovarian/uterus tumor (n=9), prostate tumor (n=1), bladder and colon tumor (n=1), \*: urostomy and temporary colostomy (n=2), urostomy and permanent colostomy (n=1), urostomy and temporary ileostomy (n=1), \*: stenosis (n=1), fistula (n=1), retraction (n=1), mucocutaneous separation (n=1), pyoderma gangrenosum (n=1)

#### **Reliability Analyses**

The SQOL-TR demonstrated excellent reliability, with a Cronbach's  $\alpha$  of 0.964 and sub-dimension values ranging from 0.846 to 0.947. Composite reliability ranged from 0.852 to 0.949. Coefficients above 0.70 indicate strong reliability.<sup>38</sup> The results are presented in Table 4.

# **Item Analysis**

To determine the discriminative power and total score prediction levels of the items, corrected item-total correlations and 27% sub-upper group comparisons were conducted. The t-values between the sub and upper groups ranged from 15.74 to 21.66 for Elimination Concerns, 9.02 to 25.53 for Psychological Impact, 10.73 to 13.29 for Daily Activities, and 17.04 to 30.52 for Social Relationships (p<0.001), indicating significant discriminative power.

Item-total correlations ranged from 0.72 to 0.85 for Elimination Concerns, 0.48 to 0.79 for Psychological Impact, 0.61 to 0.75 for Daily Activities, and 0.74 to 0.88 for Social Relationships.

**Table 2.** Factor structure and factor loads of the SQOL-TR questionnaire

questionnaire			
Factor	Item no.	Statements	Factor loads
Factor 1.	SQOL-TR_1	I become anxious when the pouch is full.	0.79
	SQOL-TR_2	I worry that the pouch will loosen.	0.81
Elimination concerns	SQOL-TR_3	I feel the need to know where the nearest toilet is.	0.76
	SQOL-TR_4	I worry that the pouch may smell.	0.85
	SQOL-TR_5	I worry about noises from the stoma.	0.74
	SQOL-TR_9	My stoma makes me feel sexually unattractive.	0.55
Factor 2.	SQOL-TR_11	I worry that the pouch rustles.	0.79
Psychological impact	SQOL-TR_12	I feel embarrassed about my body because of my stoma.	0.81
	SQOL-TR_13	It would be difficult for me to stay away from home overnight.	0.80
	SQOL-TR_14	It is difficult to hide the fact that I wear a pouch.	0.81
	SQOL-TR_6	I need to rest during the day.	0.82
Factor 3. Daily	SQOL-TR_7	My stoma pouch limits the choice of clothes that I can wear.	0.73
activities	SQOL-TR_8	I feel tired during the day.	0.81
	SQOL-TR_10	I sleep badly during the night.	0.71
Factor 4. Social relationships	SQOL-TR_15	I worry that my condition is a burden to people close to me.	0.78
	SQOL-TR_16	I avoid close physical contact with my friends.	0.91
	SQOL-TR_17	My stoma makes it difficult for me to be with other people.	0.93
	SQOL-TR_18	I am afraid of meeting new people.	0.89
	SQOL-TR_19	I feel lonely even when I am with other people.	0.82
	SQOL-TR_20	I worry that my family feels awkward around me.	0.83

SQOL-TR: Turkish version of the Stoma-specific Quality of Life questionnaire

Table 3. Fit index values obtained from confirmatory factor analysis

Fit indexes examined	Fit indexes obtained	Recommended values for acceptable fit <sup>37,38</sup>	Result
$\chi^2/df$	2.17	$2 \le \chi^2 / \mathrm{df} \le 3$	Acceptable Fit
CFI	0.92	0.90≤ CFI ≤0.95	Acceptable Fit
TLI (NNFI)	0.90	0.90≤ TLI (NNFI) ≤0.95	Acceptable Fit
SRMR	0.05	0.00≤ SRMR ≤0.05	Perfect Fit
RMSEA	0.09	<0.10	Acceptable Fit

 $<sup>\</sup>chi^2$ : Chi-square, df: Degrees of freedom, CFI: Comparative fit index, TLI (NNFI): Tucker–Lewis index (non-normed fit index), SRMR: Standardized root mean square residual, RMSEA: Root mean square error of approximation

**Table 4.** Reliability coefficients of the SQOL-TR questionnaire

Subscales	Cronbach's Alpha	McDonald's Omega
Elimination concerns	0.901	0.904
Psychological impact	0.887	0.892
Daily activities	0.846	0.852
Social relationships	0.947	0.949
SQOL-TR	0.964	0.964

SQOL-TR: Turkish version of the Stoma-specific Quality of Life questionnaire

Correlations above 0.30 are considered adequate for discriminative power. These findings confirm that all SQOLTR items are sufficiently capable of distinguishing the quality being measured. Detailed results are presented in Table 5.

#### Interpretation of the SQOL-TR Questionnaire Scores

The SQOL-TR consists of 20 items; each is rated on a 4-point Likert-type scale ranging from always (1) to never (4). The questionnaire includes four sub-dimensions: Elimination Concerns (4 items), Psychological Impact (6 items), Daily Activities (4 items), and Social Relationships (6 items). No items were excluded from the final version.

Scores range from 4 to 16 for sub-dimensions with 4 items and from 6 to 24 for those with 6 items. Higher scores on each sub-dimension and the total questionnaire indicate better QoL among individuals with ostomies.

# **Discussion**

This study aimed to evaluate the validity and reliability of the SQOL-TR among individuals with ostomies living in Türkiye. The factor loadings obtained for both the total questionnaire and its sub-dimensions were high. In comparison, the Chinese adaptation of this questionnaire reported overall factor loadings ranging from 0.48 to 0.81.<sup>32</sup> In the same study, factor loadings were 0.71-0.75 for Defecation Concerns, 0.52-0.71 for Psychological Impact, 0.48-0.78 for Daily Function, and 0.50-0.83 for Social Relationship.<sup>32</sup> The present study demonstrated even higher factor loadings across all sub-

dimensions and the total questionnaire, indicating that the SQOL-TR has strong construct validity.

A key condition for establishing construct validity is ensuring model-data fit. In this study, CFA demonstrated fit indices ranging from acceptable to excellent, indicating that the hypothesized four-factor structure fits the data well. These findings are consistent with those from the Spanish<sup>29</sup>, Canadian<sup>31</sup>, and Chinese<sup>32</sup> adaptations of the questionnaire. Therefore, the structural model validated in the Turkish context is comparable with those observed in previous international adaptations.

Another essential step in cultural adaptation studies is to demonstrate concurrent validity by correlating the adapted scale with an instrument already accepted as valid and reliable within the same cultural context.<sup>31</sup> In this regard, the O-QOL, adapted to Turkish by Karadağ et al.<sup>22</sup>, is a well-established tool for measuring QoL in Turkish patients with ostomies. The current study found a considerable positive correlation between the SQOL-TR and the O-QOL, supporting the claim that the SQOL-TR accurately measures QoL among patients with ostomies.

Internal consistency, measured through Cronbach's  $\alpha$  and composite reliability, is one of the most frequently used techniques in scale validation. <sup>22,23,37</sup> In this study, the SQOL-TR demonstrated excellent reliability, with Cronbach's  $\alpha$  and composite reliability values exceeding conventional thresholds. The internal consistency of the original English version was reported as  $0.92^{27}$ , whereas the Italian<sup>23</sup>, Spanish<sup>29</sup>, Brazilian<sup>30</sup>,

Table 5. Item analysis of the SQOL-TR questionnaire (factor 1 and factor 2)

Factor	Item no.	Cronbach's a if the item is deleted	Adjusted item total correlation	$\bar{\mathbf{X}}$	SD	t	Analysis
Factor 1.	SQOL-TR_1	0.859	0.813	2.50	1.14	-21.66	
	SQOL-TR_2	0.846	0.851	2.52	1.10	-21.38	Jf 71
Elimination concerns	SQOL-TR_3	0.891	0.727	2.43	1.13	-15.74	df =71 p=0.000
	SQOL-TR_4	0.891	0.727	2.72	1.14	-16.52	P 0.000
Factor 2. Psychological impact	SQOL-TR_5	0.874	0.655	2.71	1.09	-12.98	
	SQOL-TR_9	0.901	0.484	2.51	1.16	-9.02	
	SQOL-TR_11	0.855	0.780	3.06	1.09	-14.80	
	SQOL-TR_12	0.852	0.790	3.12	1.13	-16.27	df =66
	SQOL-TR_13	0.860	0.742	2.67	1.24	-25.53	p=0.000
	SQOL-TR_14	0.855	0.775	3.07	1.16	-18.08	

SQOL-TR: Turkish version of the Stoma-specific Quality of Life questionnaire, SD: Standard deviation, df: Degrees of freedom,  $\overline{X}$ : Mean, t: Independent-samples t-test

**Table 5** (Continue). Item analysis of the SQOL-TR questionnaire (factor 3 and factor 4)

Factor	Item no.	Cronbach's α if the item is deleted	Adjusted item total correlation	$\bar{\mathbf{x}}$	SD	t	Analysis
Factor 3.	SQOL-TR_6	0.785	0.730	2.39	0.99	-12.73	df =87 p=0.000
	SQOL-TR_7	0.825	0.644	2.44	1.11	-13.29	
Daily activities	SQOL-TR_8	0.776	0.754	2.40	0.96	-12.86	
	SQOL-TR_10	0.832	0.617	2.53	1.02	-10.73	
	SQOL-TR_15	0.949	0.742	2.78	1.18	-24.96	
	SQOL-TR_16	0.933	0.869	2.96	1.15	-25.36	
Factor 4. Social relationships	SQOL-TR_17	0.932	0.874	3.01	1.18	-30.52	df =78 p=0.000
	SQOL-TR_18	0.932	0.880	3.24	1.07	-20.52	
	SQOL-TR_19	0.937	0.834	3.31	1.03	-17.04	1
	SQOL-TR_20	0.937	0.841	3.28	1.02	-17.82	

SQOL-TR: Turkish version of the Stoma-specific Quality of Life questionnaire, SD: Standard deviation, df: Degrees of freedom,  $\overline{X}$ : Mean, t: Independent-samples t-test

Canadian<sup>31</sup>, and Chinese<sup>32</sup> adaptations reported coefficients of 0.90, 0.86, 0.87, 0.93, and 0.93, respectively. Based on these findings, the SQOL-TR appears to exhibit the highest internal consistency among the culturally adapted versions of the questionnaire.

Although item discriminative power analysis is a commonly used method to evaluate reliability, <sup>37, 38</sup> it was not reported in the original development study or in most adaptation studies. However, the current study included item discriminative power analysis and found that all items in the SQOL-TR significantly differentiated between sub and upper scoring groups. These results support the instrument's ability to detect variation across different levels of perceived QoL, indicating that the items are also reliable at the item level.

# **Limitations and Strengths of the Study**

This research has some limitations. First, this was a single-center study. Second, the psychological state of the patients during the interviews may have influenced the data obtained. The sample consisted of 125 participants, drawn from the 132 patients with ostomies followed up at the study center within 1 year.

Although limited by low survival rates, this sample size is notable compared with previous studies: 182 participants across four European countries in the original development<sup>27</sup>, 251 from 73 centers in Italy<sup>23</sup>, 125 in Spain<sup>29</sup>, 111 in Brazil<sup>30</sup>, and 120 in Canada<sup>31</sup>. Reaching this number in a single center within 1 year reflects a strength of this study.

# Conclusion

The SQOL-TR is a user-friendly, multidimensional, and objective tool for healthcare professionals working with patients with ostomies (Supplementary file). This adaptation confirmed its validity and reliability for individuals with colostomy, ileostomy, or urostomy. It is recommended for use in clinical and multinational studies as a standardized QoL assessment instrument.

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#### **Ethics**

Ethics Committee Approval: Ethical approval was granted by the Hacettepe University Ethics Committee (GO21/1034), along with institutional permission (approval number: 2021/20-02, dated: 05.10.2021). Informed Consent: Informed consent was obtained from all participants, and the study was conducted in accordance with the principles of the Declaration of Helsinki.

#### **Footnotes**

#### **Authorship Contributions**

Surgical and Medical Practices: T.E., S.Ş.A., Ş.Ş., Concept: B.D., T.E., Design: B.D., T.E., Data Collection or Processing: B.D., S.Ş.A., Ş.Ş, Analysis or Interpretation: B.D., Literature Search: B.D., T.E., Writing: B.D., T.E., S.Ş.A., Ş.Ş.

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# **Enhancing Surgical Performance Through Automated** Video Analysis Utilizing Computer Vision and Machine Learning

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#### IIIIIIII ABSTRACT

Aim: Recent advancements in computer vision have enabled the development of automated systems that can assess surgeons' expertise with high accuracy using automated performance metrics (APMs). This study aims to evaluate and enhance surgical performance through the use of APMs.

Method: This is a prospective, quality-control, multicenter international cohort study. The primary outcome is the improvement of APMs extracted from two-dimensional laparoscopic or robotic colorectal procedure video films after feedback to the surgeons. The secondary outcome is the development of new metrics to measure the model's performance beyond simple accuracy. The collaborators will send 2-3 real-world video films of colorectal procedures they have performed. They will then receive feedback on their films, including an APM data analytics report. After the feedback, the collaborators will send 2-3 videos of the same colorectal procedures. Data analysis of APMs comparing pre- and post-feedback operations will

Conclusion: The study will enable efficient training programs within constrained working hours and address heightened ethical considerations regarding patient safety. Moreover, the training of surgeons in low- and middle-income countries will benefit from the results of this study, as they can improve their skills without the need to spend months to years training in developed countries.

Keywords: Automated performance metrics, training, surgery, performance, computer vision

# Introduction

The accurate evaluation of surgical trainees' performance is essential for surgical training (i.e., acquiring surgical skills) and serves as a key component of proficiency-based training (i.e., mastering surgical skills).1 To develop their skills, surgeons must regularly perform procedures under supervision. However, the growing complexity of modern healthcare, restrictions on working hours, and ethical concerns related to patient safety necessitate the development of efficient training programs that protect patients. Such programs should facilitate automated, objective, and data-driven assessments of surgical skills while offering meaningful feedback.2 Recent shifts in surgical training, including self-directed learning and reflective practice, highlight the benefits of repetitive and independent practice, which have been enabled by objective evaluation tools.3

The potential for bias in surgical skill assessment has been widely debated in various studies. 4-6 A data-driven approach can provide an objective evaluation method, minimizing bias in assessing surgical proficiency (see the appendix for further in-depth discussion). Current methods for evaluating technical skills include task-specific checklists, global rating scales,



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and technology-based performance measures. Although observer-based scoring metrics are cost-effective and easily accessible, they are prone to bias and can be time-consuming to implement. In contrast, technology-based performance measures offer a unique opportunity for detailed, automated, and objective assessments,<sup>7</sup> which can be integrated into the digital platforms connected to laparoscopic and robotic workstations.

A systematic review examining the objective assessment of robotic surgical techniques across different specialties<sup>8</sup> has revealed that manual and automated tools, such as the Objective Structured Assessment of Technical Skills and the Global Evaluative Assessment of Robotic Skills, still carry potential subjective bias. However, automated assessment tools, which utilize data from robotic workstations, provide more objective and comprehensive evaluations. The review highlights that a key issue is the lack of a universally accepted standard for assessment, resulting in variability in the focus, application, and effectiveness of existing tools.

Recent advancements in computer vision have enabled the development of automated systems capable of assessing surgeons' expertise with high accuracy using automated performance metrics (APMs). Studies have demonstrated that experts considerably outperform novices in areas such as instrument length, bimanual dexterity, instrument idle time, camera path length, and camera movements. Similar distinctions have also been observed between super experts and experts.8 APMs may offer a more comprehensive and objective evaluation of a surgeon's skills than expert evaluators. However, most studies on APMs (Appendix 1 and Appendix 2) are based on small sample sizes, lack diversity in training datasets, and have no or limited validation datasets. There is a need to investigate the benefits of existing APMs using large, diverse, real-world video datasets. This study aims to enhance the evaluation and improvement of surgical performance in colorectal procedures by using APMs extracted from laparoscopic and robotic surgical video analysis.

# **Materials and Methods**

#### **Designing the Study**

The European Society of Coloproctology (ESCP) has successfully conducted many international prospective audits. 9,10 This study was presented during the annual conference of the ESCP in Thessaloniki at the cohort studies session on Wednesday, September 25, 2024. The study design, including the type of index procedure, the time interval between the index and the next procedure, how many procedures are expected between them, how data can be transferred, and other design-related questions, was then discussed with the audience. The audience then voted on

these issues using the ESCP mobile phone application. The design of this study is based on these discussions and the subsequent voting.

To see this session and the voting, use this link:

https://vimeo.com/escp/review/1033584541/e8a4b81d1d

This is a prospective, randomized, multicenter international cohort study. The participants (surgeons) will be randomly assigned to one of two groups to ensure comparability and minimize selection bias. Group 1 will receive feedback based on video analyses of their performance, and Group 2 will serve as the control group and will not receive feedback. Randomization will be conducted using a computer-generated sequence, with allocation concealed until assignment.

The study will compare the same types of cases performed by the same surgeon over time to monitor whether feedback improves the surgeon's performance.

# **Primary Outcome**

The primary outcome is the improvement of surgical performance, measured by improvement in APMs. APMs will be extracted from two-dimensional laparoscopic or robotic colorectal procedure video films after feedback to the surgeons.

#### **Secondary Outcome**

The secondary outcome is the measurement of the model's performance beyond simple accuracy, including the assessment of APMs using large, diverse, real-world video datasets.

#### **Inclusion and Exclusion Criteria**

The inclusion criteria are two-dimensional, real-world surgical video films recorded during elective laparoscopic or robotic colorectal procedures. Both procedures used for training and those not intended for training will be included.

#### **Selection of the Colorectal Procedures**

The authors' choice of colorectal procedures is a pragmatic one aimed at obtaining a homogeneous group of surgical procedures, enabling knowledge transfer from common to more complex procedures and promoting data efficiency. By selecting different colorectal procedures, the algorithm's applicability in medical practice and the scalability of the networks will be greatly improved.

Only elective curative procedures will be included, as the emergency setting may be affected by multiple factors that could introduce noise into the interpretation. Procedures in which conversion from the original plan (laparoscopic or robotic) to an open procedure occurs will also be included to train the algorithm to recognize non-progression in the surgical procedure.

The following index colorectal procedures will be included:

- Ileo-caecal and ileocolic resections
- Right hemicolectomy and extended right hemicolectomy, as defined in the ESCP 2015 audit<sup>9</sup>

 Left hemicolectomy and sigmoid colon resections, as defined in the ESCP 2017 audit<sup>10,11</sup>

These colorectal procedures are usually performed by supervised trainees and consultant surgeons. The procedures will be included regardless of indication (benign or malignant), provided that they are intended to be curative. There is no need for special adjustment for case mix or surgical complexity, as the surgeon will choose 2-3 video films of a procedure performed by them, followed by 2-3 video films of the same procedure after receiving APM-based feedback.

Appendix 3 shows the clinical report form (CRF) that will be attached to each film. This CRF has been kept simple to ensure basic information is provided for each procedure.

# **Quality Control of the Video Films**

The video data will be recorded in high definition with a resolution of  $1920 \times 1080$  pixels. However,  $1280 \times 720$  pixels will be accepted in centers that cannot provide higher-resolution films.

Unedited video films will undergo quality control checks. Two authors will review the footage for overall quality, including blurriness, lack of focus, loss of fine details, stability, color accuracy, exposure, and clarity.

#### **Phase Definition**

The phase definitions for each laparoscopic or robotic colorectal procedure will follow the recommendations of leading international surgical societies, if available. For procedures with no well-defined phases, at least three expert surgeons will be consulted to define the procedure phases.

#### Preprocessing and De-identification of Surgical Video Data

Data and video files will be uploaded to and stored on a secure server provided by Aalborg University. To comply with data privacy regulations, the data will first be de-identified, with the removal of all metadata. Metadata includes all patient data, the date, time, and location of the operation, as well as information about the operating staff. No off-the-shelf solutions exist for such a setting, so tools tailored for this study will be developed.

# **Annotation of Surgical Video Data**

The annotation process will encompass two key tasks: identification of surgical phases and tool positions. These annotations are critical for subsequent model training and analysis of APMs, and as such, rigorous procedures will be followed to ensure consistency and reliability.

# **Annotator Roles and Tools**

 Surgical phase annotation will be performed by surgical residents in their 4<sup>th</sup> year or higher of clinical training, who possess adequate familiarity with the procedural workflow and phase definitions.  Tool position annotation, which is comparatively more mechanical and less reliant on clinical judgment, will be conducted by trained undergraduate or graduate student assistants.

# Annotations Will Be Conducted Using Established Tools Such as

- V7 (https://www.v7labs.com),
- Computer Vision Annotation Tool (https://www.cvat.ai/)
- Labelbox (https://labelbox.com)

All annotations will be exported and stored in multiple object tracking format,<sup>12</sup> a standard format suitable for downstream analysis and model training.

#### **Annotator Training**

All annotators will undergo a structured training program, including:

- A 2-hour initial training session introducing the annotation platform, guidelines, and tasks
- Annotated examples and a reference manual defining surgical phases and annotation criteria
- A pilot annotation set of 3-5 videos to be annotated during training, followed by a feedback session with an expert reviewer (a board-certified surgeon or senior research fellow)
- Certification, requiring annotators to achieve ≥85% agreement with expert labels on a pilot set before contributing to the main dataset

# Inter-rater Reliability and Adjudication

To ensure consistency:

- A subset of 20% of the videos will be annotated independently by at least two annotators.
- Inter-rater reliability will be calculated using Cohen's kappa for phase annotations and Intersection over Union (IoU) for tool position bounding boxes.
- A minimum acceptable kappa score of 0.75 and IoU ≥0.5 will be enforced, and discrepancies will trigger review.

Although manual annotation inherently carries a degree of subjectivity -particularly in complex tasks such as surgical phase recognition- our protocol is specifically designed to minimize variability. Structured training, expert-reviewed feedback, a certification threshold, and ongoing inter-rater reliability checks help ensure consistency and mitigate annotator bias.

# **Quality Control and Adjudication**

- A surgical expert will review a random sample of 10% of the annotations to validate correctness and completeness.
- If systematic errors or deviations are found, affected annotations will be re-reviewed or corrected.

- A weekly consensus meeting involving annotators and supervising experts will be held to discuss edge cases and update annotation guidelines as needed.
- A detailed annotation logbook will be maintained for each video, documenting the annotator ID, timestamp, tools used, and any issues or anomalies.

These measures will ensure that the dataset used for downstream machine learning (ML) model training is robust, consistent, and clinically reliable.

# Study Stages

# Stage One

A prospective audit will be conducted, in which laparoscopic and robotic real-world video films of colorectal procedures are collected from international collaborating centers. Any consultant or trainee can participate in the study. The collaborators will send 2-3 real-world video films of colorectal procedures that they have performed. The collaborators may choose how many procedures to send for analysis, provided that they submit at least two films of the same procedure.

#### Stage Two

The collaborators will then receive feedback on their films, including an APMs data analytics report. Based on the APMs report, the participating surgeon will receive an objective, data-driven technical assessment of performance adjusted for case difficulty. The confidential, password-protected report will highlight areas for performance improvement. This report will include the types of assessed APMs, their interpretation, and suggestions for improving performance. The report will be generated in a standardized format by the study team after a short pilot assessment.

# **Stage Three**

The collaborators will send 2-3 videos of the same colorectal procedures that they performed in stage one after receiving the data analytics. These follow-up procedures must be performed within 6 months of the first (index) procedure. At least 10 procedures must be performed after the index procedure.

#### Stage Four

Data analysis of APMs will compare pre- and post-feedback operations. The collaborators will receive a detailed feedback report upon request. The confidential, password-protected report will include APMs from the two sets of films collected in stages one and three.

#### **Data Collection**

With a vast network of surgeons in the OpenSourceResearch Collaboration, ESCP, and American Society of Colon and Rectal Surgeons, it is expected that a large, generalizable, and diverse dataset will be obtained, which can be used to train the model.

#### **Statistical Analysis**

The data analysis consists of two parts:

- Extraction of surgical phases and tool tracks
- Computation of APMs from extracted data

#### **Extraction of Surgical Phases and Tool Tracks**

No off-the-shelf solutions for computing APMs exist, so a custom algorithm will be developed. Inspiration can be found in earlier approaches. <sup>13,14</sup> Even so, improved results should be obtainable using more modern transformer-based methods, including action recognition methods, <sup>15</sup> such as ASFormer surgical phase detection; object detection methods, <sup>16</sup> such as DEtection TRansformer<sup>17</sup> for tool detection; and CoTracker<sup>18</sup> for surgical tool tracking.

Fine-tuning of pre-trained algorithms will be leveraged to the fullest possible extent, but substantial amounts of training data must be manually annotated, as outlined in the previous section.

Accuracy will be reported using standard metrics: Mean over Frames<sup>15</sup> for surgical phase detection and Higher Order Tracking Accuracy<sup>19</sup> for tool tracking.

# Computations of Automated Performance Metrics From Extracted Data

Computation of APMs will be performed using custom methods for each metric. All APMs are well-defined by mathematical formulas (Appendix 2), so no ML is required for this stage. It may be interesting to test an ML-based surgeon rater using the raw extracted data and compare its performance with the predefined APMs. However, that exercise is left for future work.

#### **Evaluation**

Apart from using standard evaluation metrics as mentioned above, an important aspect of modeling is out-of-sample validation, which involves partitioning the data into training, validation, and test sets-usually in a 70%:10%:20% split or similar. This project will follow this standard procedure for the computer vision field. If the amount of annotated data is insufficient to allow for such a split, N-fold cross-validation will be performed.

# **Statistical Analysis**

# **Sample Size Calculation**

Assuming a 20% change in APMs, the sample size was calculated as follows:

- Z is the Z-score corresponding to the desired confidence level (for a 95% confidence level, Z≈1.96).
- p is the estimated proportion at baseline (or for the control group).
- E is the margin of error expressed as a proportion (20%=0.2).
- p' is the desired percentage change expressed as a decimal.

The sample size used the given values:

- Population size (N)=1,000
- Confidence level=95% (Z≈1.96)
- Margin of error=20% (0.2)
- Desired percentage change=20% (0.2)

The following formula was used:  $n=(1.96^2 \times p \times [1-p])/(0.2^2 \times [p \times (1+0.2)])$ 

We can assume a conservative estimate of 0.5 for p:

 $n=(1.96^2 \times 0.5 \times [1-0.5]) / (0.2^2 \times [0.5 \times (1+0.2)])$ 

 $n=(3.8416 \times 0.25) / (0.04 \times 0.6)$ 

n≈10.1056 / 0.024

n≈421.0667

Based on this calculation, a sample size of approximately 422 individuals is needed to detect a 20% change in APMs.

Given the lack of prior evidence on which APMs are most responsive to feedback, this study adopts an exploratory approach, assessing multiple performance domains without designating a single primary outcome. A 20% relative improvement in any APM will be considered meaningful in this context.

# **Adjusting for Case Complexity**

To address potential confounders related to case complexity, key patient-level variables that may influence surgical performance will be collected for each patient undergoing surgery. During the analysis phase, statistical methods such as multivariable regression or propensity score matching will be used to adjust for differences in case complexity between groups. This approach will help isolate the effect of feedback on the surgeon's performance, minimizing the risk of confounding due to patient-related factors. It allows for accounting for case complexity while maintaining the integrity of randomization and minimizing bias.

# **Analysis Plan**

This study includes within-subject pre- and post-feedback comparisons for surgical performance, alongside classifier evaluation tasks for tool detection and phase recognition. Analyses will be conducted using SPSS and/or Python statistical libraries (e.g., SciPy, scikit-learn).

#### 1. Descriptive Statistics

 Summary statistics (mean, median, standard deviation, range) will be provided for continuous variables, and frequencies and proportions will be provided for categorical variables.

#### 2. Analysis of APMs

• For pre- vs. post-feedback comparisons within surgeons, paired t-tests (for normally distributed APMs) and Wilcoxon signed-rank tests (for non-parametric data) will be used.

• For comparing multiple time points or groups, repeated measures analysis of variance or linear mixed-effects models will be applied, allowing for both fixed effects (e.g., feedback, session) and random effects (e.g., surgeon ID).

# 3. Evaluation of Classifier Performance (Tool Detection and Phase Recognition)

- Receiver operating characteristic curves and the area under the curve (AUC) will be computed for binary classification tasks, including tool presence detection (whether a specific tool is in use at a given time) and phase classification performance (correct classification of surgical phase per video frame).
- For multi-class phase classification, macro- and micro-averaged AUCs will be reported.
- Precision, recall, F1-score, and confusion matrices will also be presented to provide a comprehensive evaluation of classification performance.

# 4. Handling of Missing or Ambiguous Data

- Incomplete annotations or ambiguous cases will be flagged and excluded from the primary analysis, but they may be included in sensitivity analyses.
- Multiple imputation will be considered if missing data exceeds 5% in any analytic subset.

# 5. Statistical Significance

 A two-sided p-value of <0.05 will be considered statistically significant. Where applicable, 95% confidence intervals will be reported alongside effect sizes.

# **Ethical Considerations**

All data collected will reflect current practice, with no changes made to planned treatment pathways. As such, this study should be registered as an audit of current practice at each participating center. The local team at each site is responsible for ensuring that local audit approval (or equivalent) is obtained. Participating centers will be asked to confirm that they have received formal approval at their sites. Patients' consent to use the videos for research purposes will be obtained, including consent for the de-identified videos to be used in future studies without additional consent.

# **Discussion**

This protocol presents a novel approach to surgical education and performance assessment, utilizing advanced computer vision and ML technologies. By focusing on APMs derived from laparoscopic and robotic surgical videos, the study aims to improve surgical training for trainees and enhance performance for specialists.

This approach is particularly relevant in the context of modern healthcare's evolving complexities, including the need for efficient training programs within constrained working hours and heightened ethical considerations around patient safety. The training of surgeons in low- and middle-income countries (LMICs) will benefit from the results of this study. If improvements in APMs lead to improved performance, surgeons from LMICs can enhance their skills without the need to spend months or years training in developed countries.

Real-world data on surgeons' performance can personalize training in precise and productive ways. Guided by surgical educators, ML models can identify performance qualities not necessarily evident to experienced trainers, potentially leading to more rapid skill acquisition. Automated surgical phase recognition is a foundational step for other applications that can create informative and focused educational material for students and residents.

Challenges such as non-static cameras resulting in abrupt viewpoint changes, inconsistent organs and instruments, variations in illumination, unfocused frames, and the presence of blood and smoke in the surgical field can be addressed through iterative refinement of the models to improve image analysis.

# **Perspectives**

In the future, APMs might be correlated with different postoperative outcomes (functional, oncological, patient-reported outcomes, etc.), opening a new era in surgical research as objective measures are integrated with clinical assessments and patient-reported outcome measures. An artificial intelligence system capable of recognizing surgical phases may be used for numerous tasks, including quality measurement, adverse event recording and analysis, education, statistics, and surgical performance evaluation.<sup>20</sup>

High-volume simulator training based on real procedures will be possible, as anonymized procedures can be transformed into surgical simulators for training and experimentation with innovative modifications to traditional techniques. The efficiency of producing surgical reports is an additional benefit. For hospital administration, operating room scheduling is challenging because pre-operative estimates of procedure duration are often inaccurate. This inaccuracy stems from considerable variability in how procedures unfold. Real-time information about the progress of surgeries is crucial for effectively adjusting the daily operating room schedule. Ideally, this information should be objective, automatically accessible, and available in real time to predict the remaining duration of surgeries. Such data would enable optimal planning and utilization of operating theatre resources, ensuring they are used to their fullest capacity.20

#### **Ethics**

Ethics Committee Approval: Not applicable.

Informed Consent: Not applicable.

#### **Acknowledgement**

Princess Nourah bint Abdulrahman University Researchers Supporting Project number PNURSP2025R54, Princess Nourah bint Abdulrahman University, Riyadh, Saudi Arabia. The OSRC is an international research organization with a particular focus on implementing information technologies and AI in medical research. The role of the OSRC in this project was to recruit researchers and coordinate research work. More information about this organization is available on its website: https://www.osrc.network.

#### **Footnotes**

#### **Authorship Contributions**

Concept: A.E.H., A.M., Design: A.E.H., A.M., H.A., Data Collection or Processing: A.E.H., A.M., Analysis or Interpretation: A.E.H., A.M., Literature Search: A.E.H., M.E., A.M., Writing: A.E.H., M.E., A.M., H.A.

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Appendix 1-3 Link.

https://d2v96fxpocvxx.cloudfront.net/8a9ff4da-541a-42fa-9980-1a9a3ab6d6c5/content-images/54657bfa-ee96-494b-bf09-301400fde7e3.pdf



# Breaking the Silence: Shame, Communication, and **Diagnostic Delay in Proctologic Practice**

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**Keywords:** Colorectal surgery, shame, communication, physicians, patients

# Dear Editor,

Although proctologic disorders are common, some patients delay seeking medical attention for anorectal symptoms due to embarrassment, cultural taboos, privacy concerns, or fear of invasive examinations. This hesitation, while understandable, can lead to worsening disease, more invasive interventions, and an increased psychological burden.<sup>1,2</sup>

Shame and silence around anorectal complaints often hinder timely diagnosis and care. Patients -especially women, younger individuals, and those from conservative backgrounds- may delay enlisting help because they fear judgment or a loss of dignity. Many initially turn to online sources or herbal remedies, which can result in misdiagnosis or missed opportunities for early intervention. Clinician behavior plays a crucial role in shaping this dynamic. A rushed or emotionally distant approach may reinforce a patient's reluctance, whereas clear explanations, respectful language, and open-ended questions help build trust and encourage the disclosure of sensitive symptoms. Practical gestures, such as maintaining privacy or proposing the attendance of a chaperone, can provide additional reassurance. These subtle yet meaningful actions often influence whether a patient engages in care or continues to suffer in silence.<sup>3-6</sup>

Delays are not without consequence. Anal fissures may become chronic, and pilonidal disease can evolve from a simple condition into a complex one or, in rare cases, undergo malignant transformation over time. Rectal bleeding, an early potential sign of colorectal cancer, may be misattributed to benign conditions and therefore overlooked. 5,7,8 These missed opportunities carry implications not only for individual outcomes but also for public health and resource allocation. Particularly in young adults, increasing rates of early-onset colorectal cancer highlight the importance of timely evaluation of anorectal symptoms.9

Efforts to improve communication should be incorporated into clinical training. Educational initiatives that develop emotional intelligence, empathy, and cultural awareness are essential.<sup>10</sup> These skills not only improve patient satisfaction but also contribute to early diagnosis, better compliance, and reduced healthcare costs over time. Embedding such competencies within surgical and outpatient settings could have measurable benefits across multiple domains of care.

A supportive healthcare environment is also key. Patients benefit from knowing their concerns are common and will be taken seriously. Normalizing these conversations helps reduce stigma and encourages early disclosure. Providing accessible, non-judgmental information through clinics or public health campaigns may further support early engagement with care services

Ultimately, improving outcomes in proctologic care requires more than procedural skill. Clinicians must recognize the psychosocial factors that influence care-seeking behaviors. By fostering open communication and building trust, it becomes possible to detect conditions earlier, intervene more effectively, and minimize unnecessary suffering. Recognizing shame and



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silence as clinical challenges allows for a more humane and patient-centered approach to care. To support this shift, we recommend that proctology departments incorporate structured communication skills training into residency and continuing education programs, with an emphasis on empathy, privacy, and stigma reduction.

#### **Footnotes**

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# Laparoscopic Ventral Mesh Rectopexy and Lateral Suspension for Multicompartment Prolapse: A Video Vignette

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#### IIIIIIIII ABSTRACT I

This case report presents the management of a patient with multicompartment pelvic organ prolapse through laparoscopic ventral mesh rectopexy and lateral suspension in a single transabdominal approach. The surgical technique was described in the video. The patient was discharged on postoperative day 3. Obstructed defectation had completely regressed. There were no complaints after 2 years. Prolapse involving more than one compartment can occur concurrently and requires multidisciplinary management.

Keywords: Rectal prolapse, laparoscopic ventral mesh rectopexy, pelvic organ prolapse, obstructed defecation syndrome

#### Introduction

Pelvic floor disorders are a group of conditions caused by the failure of the pelvic floor muscles to properly support the pelvic organs. They can affect the urinary, gynecological, and anorectal organs and require a multidisciplinary approach. Pelvic organ prolapse affects 25% of women, and multicompartment prolapse can be found in 10-55% of patients.¹ Laparoscopic ventral mesh rectopexy (LVMR) is a nerve-sparing technique introduced by Consten et al.² in 2004 for pelvic floor disorders, and its efficacy has been supported by many studies over the past two decades. For apical prolapse, the widely accepted approach is laparoscopic sacrocolpopexy. However, in patients wishing to preserve the uterus, lateral suspension is a safe and effective alternative³ with comparable functional outcomes and a lower risk of complications.⁴

# **Case Report**

A 39-year-old woman presented with complaints of obstructed defecation syndrome, stress incontinence, and vaginal flatulence. The patient had a medical history of three vaginal deliveries and bilateral salpingo-oophorectomy. Informed consent for the use of patient data is obtained from all individuals who present to our university hospital. A copy of this patient's consent form is provided in the appendix. Defecography revealed an Oxford grade 3 rectal prolapse, an anterior rectocele, moderate middle compartment prolapse, and a small cystocele. The pelvic organ prolapse quantification stage was 2. A combined LVMR and lateral suspension were performed, restoring all compartments through a single transabdominal approach (Video 1).



#### Video 1.

Laparoscopic ventral mesh rectopexy and lateral suspension for multicompartment prolapse



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#### **Ethics**

**Informed Consent:** Informed consent for the use of patient data is obtained from all individuals who present to our university hospital.

#### **Footnotes**

#### **Authorship Contributions**

Surgical and Medical Practices: Ç.A., S.K., Y.Y., Concept: Ç.A., S.K., Design: Ç.A., S.K., Data Collection or Processing: Ç.A., Y.Y., Analysis or Interpretation: Ç.A., Literature Search: Ç.A., Y.Y., Writing: Ç.A., Y.Y.

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