ONTARIO HEALTH TECHNOLOGY ASSESSMENT SERIES

Robotic-Assisted Surgery for Rectal Cancer AN EXPEDITED SUMMARY OF THE CLINICAL EVIDENCE

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Key Messages

What Is This Expedited Summary of the Clinical Evidence About?

Rectal cancer is a disease in which cancer cells form in the rectum, which has the primary function of temporarily storing feces, controlling defecation, and maintaining continence. Surgery is the most common treatment for rectal cancer.

Surgical approaches for rectal cancer include open rectal cancer surgery (an invasive procedure that involves a large surgical incision), laparoscopic rectal cancer surgery (a minimally invasive procedure that involves several smaller incisions and the use of smaller surgical tools), and robotic-assisted rectal cancer surgery (a minimally invasive procedure that involves the use of a robotic system operated by the surgeon).

We examined published systematic reviews, meta-analyses, randomized controlled trials, and grey literature to determine what is known about the effectiveness and safety of robotic-assisted rectal cancer surgery compared with the laparoscopic and open approaches.

What Did This Expedited Summary of the Clinical Evidence Find?

Compared with laparoscopic rectal cancer surgery, robotic-assisted rectal cancer surgery may result in similar overall survival and similar rates of conversion (i.e., when a robotic-assisted or laparoscopic procedure is switched to an open procedure), blood transfusion, and readmission; reduced blood loss; shorter length of stay; and improved quality of life. Compared with open rectal cancer surgery, robotic-assisted rectal cancer surgery may result in similar overall survival, reduced blood loss, and shorter length of stay.



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Abstract

Background

Rectal cancer is a disease in which cancer cells form in the rectum, which has the primary function of temporarily storing feces, controlling defecation, and maintaining continence. Surgery is the most common treatment for rectal cancer; surgical approaches include open, laparoscopic, and robotic assisted. We conducted an expedited summary of the clinical evidence for robotic-assisted surgery for rectal cancer, which included an evaluation of effectiveness and safety.

Methods

We performed a systematic literature search of the clinical evidence to retrieve systematic reviews and randomized controlled trials (RCTs). We assessed the risk of bias in the included systematic reviews using AMSTAR 2 (A Measurement Tool to Assess Systematic Reviews, version 2), and we assessed the risk of bias in the included RCT using the Cochrane Risk-of-Bias Tool for Randomized Trials, version 1. We reported the quality of the body of evidence as evaluated in the included systematic reviews according to the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) Working Group criteria if it was evaluated.

Results

We included 14 studies in the clinical evidence review (12 systematic reviews and 1 RCT on roboticassisted vs. laparoscopic rectal cancer surgery and 1 systematic review on robotic-assisted vs. open rectal cancer surgery). Compared with laparoscopic rectal cancer surgery, robotic-assisted rectal cancer surgery may result in similar overall survival; similar rates of conversion, blood transfusion, and readmission; reduced blood loss; shorter length of stay; and improved quality of life. Compared with open rectal cancer surgery, robotic-assisted rectal cancer surgery may result in similar overall survival, reduced blood loss, and shorter length of stay.

Conclusions

Robotic-assisted rectal cancer surgery may result in similar or improved clinical outcomes compared with laparoscopic and open rectal cancer surgery.

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Objective

This expedited summary of the clinical evidence evaluates the effectiveness and safety of roboticassisted surgery for rectal cancer.

Background

Health Condition

Rectal cancer is a disease in which cancer cells form in the rectum, which, in an adult, makes up about the last 6 inches of the large bowel and connects the colon to the anus. Its purpose is to temporarily store feces, control defecation, and maintain continence.

Rectal cancer is often grouped with colon cancer, referred to collectively as colorectal cancer. Rectal cancer may be found during colorectal cancer screening or based on suspected symptoms. Signs and symptoms of rectal cancer may include change in bowel habits, rectal bleeding, blood in the stool, abdominal pain, narrow stool, fatigue, and unexplainable weight loss.¹ Risk factors for rectal cancer include age, family history, smoking, eating processed meats, and obesity.

Tests to diagnose and stage rectal cancer may include colonoscopy, biopsy, computed tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography (PET).² The stages of rectal cancer range from 0 (limited to the rectum lining) to 4 (advanced cancer that has spread to other areas of the body).³

Clinical Need and Population of Interest

According to a 2022 report on cancer statistics from Ontario Health (Cancer Care Ontario), colorectal cancer accounted for about 11% of all newly diagnosed cases of cancer in Ontario, making it the third most common cancer after breast and lung cancer.⁴ Colorectal cancer also represented 11% of all cancer deaths and is the second leading cause of death from cancer after lung cancer. About 1 in 15 people in Ontario are expected to develop colorectal cancer in their lifetime.

Rectal cancer is the second most common cancer in the large intestine after proximal colon cancer.⁵ According to US data from 2013 to 2019, the 5-year survival rate is about 90% for localized rectal cancer, about 74% for regional rectal cancer, and about 18% for distant rectal cancer.⁶

Current Treatment Options

Prognosis and treatment for rectal cancer depend on many factors, including tumour location, size, and stage; overall health; and personal preferences regarding treatment.⁷ Treatments for rectal cancer include surgery, chemotherapy, radiation therapy, targeted drug therapy, and immunotherapy.

Surgery is the most common treatment for all stages of rectal cancer. Types of rectal cancer surgery include transanal local excision (the removal of small cancers from inside the rectum), low anterior

resection or proctectomy (the removal of all or part of the rectum), and abdominoperineal resection (the removal of the rectum, anus, part of the colon, and nearby tissue and lymph nodes).⁸

Chemotherapy or radiation therapy may be used as the primary treatment for advanced rectal cancer or if surgery is not an option.⁸ Radiation therapy and/or chemotherapy may also be used before surgery to reduce tumour size or after surgery to destroy remaining cancer cells and reduce the chance of cancer recurrence.

Health Technology Under Review

Robotic surgical systems are typically composed of 3 integrated elements: a surgeon console, a patient side cart with interactive robotic arms connected to the surgical instruments, and a video tower, which consists of a high-definition 3-dimensional vision system. The most commonly used robotic surgical system worldwide is Intuitive Surgical's da Vinci Surgical System; however, other systems are available, including the Hugo RAS system (Medtronic), the Senhance Surgical System (Asensus), and the hinotori Surgical Robot System (Medicaroid).

The benefits of robotic-assisted surgery include improved ergonomics for surgeons, better visualization owing to 3-dimensional imaging, elimination of physiologic tremors, improved dexterity owing to the flexible surgical instruments, and improved ability to navigate narrow spaces such as the pelvis.⁹ However, limitations may include loss of haptic feedback, longer surgical procedure times, increased cost, and decreased accessibility.

Regulatory Information

Four robotic surgical systems are currently licensed by Health Canada (Table 1).

Table 1: Robotic Surgical Systems Licensed by Health Canada

Robotic surgical system	Manufacturer (location)	Device class	Licence number	Date of first issue
Da Vinci Si Surgical System	Intuitive Surgical, Inc. (Sunnyvale, CA)	IV	81353	December 3, 2009
Da Vinci Xi Surgical System	Intuitive Surgical, Inc. (Sunnyvale, CA)	IV	97378	July 27, 2016
Da Vinci X Surgical System	Intuitive Surgical, Inc. (Sunnyvale, CA)	IV	103348	July 26, 2019
Hugo RAS System	Medtronic (Minneapolis, MN)	111	107066	December 3, 2021

Several versions of the da Vinci Surgical System have been introduced: the da Vinci Si was launched in 2009, the da Vinci Xi in 2014, and the da Vinci X in 2017. The Hugo RAS system was launched in 2021.

The various versions of the da Vinci Surgical System have been approved by the US Food and Drug Administration (FDA) and have received the Conformité Européenne (CE) mark in Europe. The Hugo RAS System received the CE mark in March 2022. However, at the time of writing, the Hugo RAS System has not been approved by the FDA.

Expedited Summary of the Clinical Evidence

Research Question

What are the effectiveness and safety of robotic-assisted surgery compared with open or laparoscopic surgery for the treatment of rectal cancer?

Methods

Appendix 1 provides the full methods for the expedited summary of the clinical evidence, and Appendix 2 provides our literature search strategy.

Results

Clinical Literature Search

The database search of the clinical literature yielded 247 citations published between January 1, 2019, and November 7, 2023, including grey literature searches and after duplicates were removed. We identified no additional eligible studies from other sources or from database alerts (monitored until January 15, 2024). In total, we identified 14 studies (12 systematic reviews and 1 randomized controlled trial [RCT] on robotic-assisted vs. laparoscopic rectal cancer surgery and 1 systematic review on robotic-assisted vs. open rectal cancer surgery) that met our inclusion criteria. There was a high degree of overlap for the primary RCTs included in the systematic reviews and less overlap for the included comparative observational studies. Appendix 3 provides a list of selected studies excluded after full-text review. Appendix 4, Figure A1, presents the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA)¹⁰ flow diagram for the clinical literature search. Appendix 5 provides a summary of the characteristics of the included systematic reviews (Table A1) and RCT (Table A2).

Risk of Bias in the Included Studies

We assessed the risk of bias of the included systematic reviews using AMSTAR 2 (A Measurement Tool to Assess Systematic Reviews, version 2)¹¹ and found that the included systematic reviews were of low to moderate quality (Appendix 6, Table A3). Most systematic reviews did not assess publication bias or state conflicts of interest, and none included a list of excluded studies. All systematic reviews assessed the risk of bias in the included primary studies using a validated tool. In the primary comparative observational studies, risk of bias was reported as generally ranging from low to moderate; for the primary RCTs, risk of bias was reported to be higher.

We assessed the risk of bias of the included RCT using the Cochrane Risk-of-Bias Tool for Randomized Trials¹² as generally low (Appendix 6, Table A4). However, it should be noted the RCT was ended prematurely because of difficulty recruiting participants, resulting in an underpowered study with reliability concerns.

Robotic-Assisted Versus Laparoscopic Rectal Cancer Surgery

Twelve systematic reviews compared robotic-assisted versus laparoscopic rectal cancer surgery.¹³⁻²⁴ Most systematic reviews broadly included any type of rectal cancer and any type of rectal cancer surgery. Limited information was provided on the patient characteristics and surgical procedures of the primary studies. The longest follow-up for an outcome of interest was 5 years; this was for overall survival. We found no systematic reviews that evaluated positive margin rate, recovery time, or time to return to normal activity.

Overall Survival

Seven systematic reviews evaluated overall survival for robotic-assisted and laparoscopic rectal cancer surgery (Table 2).^{13,15-20} In general, overall survival was found to be similar between groups.

Only 1 systematic review assessed the quality of the body of evidence reported in the included studies according to the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) Working Group criteria.¹⁵ This review found the certainty of evidence for 3-year overall survival to be low.

The RCT found no mortality in either the robotic or laparoscopic group within 30 days post-surgery.²⁵

Table 2: Robotic-Assisted vs. Laparoscopic Rectal Cancer Surgery—Overall Survival

Author, year	Procedure	N, included studies N, total participants	Results ^a
Flynn et al, 2023 ¹³	Not specified	13 studies Robotic: 2,050 Laparoscopic: 2,044	3-year overall survival, robotic vs. laparoscopic RR 0.79 (95% CI: 0.65 to 0.97), $P = .023$
Khajeh et al, 2023 ¹⁵	Not specified	14 studies Robotic: 1,578 Laparoscopic: 1,487	90-day mortality, laparoscopic vs. robotic All study types: OR 1.13 (95% CI: 0.30 to 4.20) RCTs only: OR 1.23 (95% CI: 0.29 to 5.18) Prospective observational studies only: OR 0.74 (95% CI: 0.03 to 18.61)
Liu et al, 2021 ¹⁶	Not specified	5 studies Robotic: 943 Laparoscopic: 1,138	Mortality, robotic vs. laparoscopic RR 0.75 (95% CI: 0.34 to 1.62), P = .46
Ryan et al, 2021 ¹⁷	Total mesorectal excision	30 studies Robotic: 388 Laparoscopic: 3,072	Overall survival, laparoscopic vs. robotic HR 1.0 (95% Crl: 0.65 to 1.7)
Safiejko et al, 2021 ¹⁸	Resection surgery	42 studies Robotic: 3,858 Laparoscopic: 5,408	Survival to hospital discharge or 30-day overall survival, robotic vs. laparoscopic 99.6% vs. 98.8%; OR 2.10 (95% CI: 1.00 to 4.43), P = .05 1-year overall survival, robotic vs. laparoscopic 100% vs. 90.3%; OR 10.68 (95% CI: 0.56 to 204.84), P = .12 3-year overall survival, robotic vs. laparoscopic 86.3% vs. 87.1%; OR 1.02 (95% CI: 0.56 to 1.83), P = .96 5-year overall survival, robotic vs. laparoscopic 85.6% vs. 87.6%; OR 0.87 (95% CI: 0.61 to 1.23), P = .43
Seow et al, 2023 ¹⁹	Total mesorectal excision	32 studies Robotic: 479 Laparoscopic: 3,289	3-year overall survival, robotic vs. laparoscopic (GRADE: Low) HR 1.1 (95% Crl: 0.72 to 1.5) Perioperative mortality within 30 days, robotic vs. laparoscopic (GRADE: Low) RR 0.44 (95% Crl: 0.035 to 4.6)

	-	N, included studies	
Author, year	Procedure	N, total participants	Results ^a
Tang et al, 2021 ²⁰	Not specified	7 studies	Perioperative mortality, robotic vs. laparoscopic
		Robotic: 507	OR 0.79 (95% CI: 0.15 to 4.12), P = .78
		Laparoscopic: 516	

Abbreviations: CI, confidence interval; CrI, credible interval; GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; HR, hazard ratio; OR, odds ratio; RCT, randomized controlled trial; RR, risk ratio.

 $^{\mathrm{a}}\!\textit{P}\text{-values}$ presented only when reported in the included studies.

Conversion Rate

Six systematic reviews evaluated conversion rate (i.e., the rate at which a robotic-assisted or laparoscopic procedure is switched to an open procedure) (Table 3).^{13,15,18-21} In general, conversion rate was found to be statistically significantly lower in the robotic group.

The RCT found conversion rate to be similar between the robotic and laparoscopic groups (0.7% vs. 1.4%, respectively, P = .534).²⁵

	-	=	
		N, included studies	
Author, year	Procedure	N, total participants	Results ^a
Flynn et al, 202313	Not specified	50 studies	Robotic vs. laparoscopic
		Robotic: 4,809	OR 0.34, <i>P</i> < 0.001
		Laparoscopic: 5,636	
Khajeh et al,	Not specified	17 studies	Laparoscopic vs. robotic
202315		Robotic: 1,760	All study types: OR 3.13 (95% CI: 1.87 to 5.21)
		Laparoscopic: 1,679	RCTs only: OR 2.35 (95% CI: 1.46 to 3.77)
			Prospective observational studies only: OR 3.36 (95% CI: 1.11 to 10.18)
Safiejko et al,	Resection surgery	42 studies	Robotic vs. laparoscopic
2021 ¹⁸		Robotic: 3,858	2.6% vs. 7.3%
		Laparoscopic: 5,408	OR 0.35 (95% CI: 0.26 to 0.46), P < .001
Seow et al, 2023 ¹⁹	Total mesorectal	32 studies	Laparoscopic vs. robotic (GRADE: Low)
	excision	Robotic: 479	RR 0.23 (95% Crl: 0.034 to 0.70)
		Laparoscopic: 3,289	
Tang et al, 2021 ²⁰	Not specified	7 studies	Robotic vs. laparoscopic
		Robotic: 507	OR 0.61 (95% CI: 0.35 to 1.07), P = .08
		Laparoscopic: 516	
Yao et al, 2023 ²⁶	Surgeries for mid-	8 studies	Robotic vs. laparoscopic
	to low rectal cancer	Robotic: 1,350	MD 0.49 (95% CI 0.29 to 0.84), P = .009
		Laparoscopic: 1330	

Table 3: Robotic-Assisted vs. Laparoscopic Rectal Cancer Surgery—Conversion Rate

Abbreviations: CI, confidence interval; CrI, credible interval; GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; OR, odds ratio; RCT, randomized controlled trial; RR, risk ratio.

^a*P*-values presented only when reported in the included studies.

Reoperation Rate

Eight systematic reviews^{13,15-18,20-22} evaluated reoperation rate, but only 1¹³ noted the time period for reoperation (Table 4). In general, reoperation rate was found to be similar between the robotic and laparoscopic groups.

• •		N, included studies	- - - -
Author, year	Procedure	N, total participants	Results ^a
Flynn et al, 2023 ¹³	Not specified	50 studies	90-day reoperation rate, robotic vs. laparoscopic
		Robotic: 4,809	OR 0.93 (95% CI: 0.69 to 1.26), P = .595
		Laparoscopic: 5,636	
Khajeh et al,	Not specified	12 studies	Reoperation rate, laparoscopic vs. robotic
202315		Robotic: 1,324	All study types: OR 1.69 (95% CI: 1.10 to 2.62)
		Laparoscopic: 1,290	RCTs only: OR 1.82 (95% CI: 1.10 to 3.02)
			Prospective observational studies only: OR 1.28 (95% CI: 0.46 to 3.51)
Liu et al, 2021 ¹⁶	Not specified	5 studies	Reoperation rate, robotic vs. laparoscopic
		Robotic: 478	RR 0.85 (95% CI: 0.46 to 1.54), P = .58
		Laparoscopic: 541	
Ryan et al, 2021 ¹⁷	Total mesorectal excision	30 studies	Reoperation rate, laparoscopic vs. robotic
		Robotic: 388	RR 0.32 (95% Crl: 0.039 to 1.6)
		Laparoscopic: 3,072	
Safiejko et al,	Resection surgery	42 studies	Reoperation rate, robotic vs. laparoscopic
2021 ¹⁸		Robotic: 3,858	6.3% vs. 7.1%; OR 0.87 (95% CI: 0.61 to 1.25), P = .46
		Laparoscopic: 5,408	
Tang et al, 2021 ²⁰	Not specified	7 studies	Unscheduled reoperation rate, robotic vs. laparoscopic
		Robotic: 507	OR 0.91 (95% CI: 0.26 to 3.20), P = .89
		Laparoscopic: 516	
Wang et al, 2020 ²²	Not specified	17 studies	Reoperation rate, robotic vs. laparoscopic
		Robotic: 1,554	OR 0.53 (95% CI: 0.27 to 1.04), P =.07
		Laparoscopic: 1,639	
Yao et al, 2023 ²¹	Surgery for mid- to	8 studies	Reoperation rate, robotic vs. laparoscopic
	low rectal cancer	Robotic: 1,350	MD 0.71 (95% CI: 0.40 to 1.25), <i>P</i> = .23
		Laparoscopic: 1,330	· · · · · ·

Table 4: Robotic-Assisted vs. Laparoscopic Rectal Cancer Surgery—Reoperation Rate

Abbreviations: CI, confidence interval; CrI: credible interval; OR, odds ratio; RCT, randomized controlled trial; RR, risk ratio. ^a*P*-values presented only when reported in the included studies.

Transfusion Rate and Estimated Blood Loss

Only 2 systematic reviews evaluated transfusion rate, which was found to be similar between groups (Table 5).^{17,18} Seven systematic reviews evaluated estimated blood loss and found similar or less estimated blood loss in the robotic group.^{13,15,18,20-23} Limited information was provided on the surgical techniques used in the included studies.

The RCT found estimated blood loss to be similar between the robotic and laparoscopic groups (mean $118.0 \pm 151.5 \text{ mL vs.} 112.3 \pm 162.0 \text{ mL}$, respectively, *P* = .756).²⁵

Table 5: Robotic-Assisted vs. Laparoscopic Rectal Cancer Surgery—Transfusion Rate and Estimated Blood Loss

Author, year	Procedure	N, included studies N, total participants	Results ^a
Flynn et al, 2023 ¹³	Not specified	50 studies Robotic: 4,809 Laparoscopic: 5,636	Estimated blood loss (mL), robotic vs. laparoscopic SMD -0.12 (95% CI: -0.32 to 0.43), P < .001
Khajeh et al, 2023 ¹⁵	Not specified	9 studies Robotic: 1,196 Laparoscopic: 1,347	<i>Estimated blood loss (mL), laparoscopic vs. robotic</i> All study types: MD 20.47 (95% CI: 7.57 to 33.36) RCTs only: MD 18.48 (95% CI: 5.51 to 31.45) Prospective observational studies only: MD 390.66 (95% CI: –302.59 to 1083.91)
Ryan et al, 2021 ¹⁷	Total mesorectal excision	30 studies Robotic: 388 Laparoscopic: 3,072	Tranfusion rate, laparoscopic vs. robotic RR 0.87 (95% Crl: 0.28 to 2.7)
Safiejko et al, 2021 ¹⁸	Resection surgery	42 studies Robotic: 3,858 Laparoscopic: 5,408	Transfusion rate, robotic vs. laparoscopic 3.7% vs. 2.1% Estimated blood loss (mL), robotic vs. laparoscopic 224 ± 327.6 vs. 210.7 ± 305.2 MD –0.94 (95% Cl: –30.11 to 28.22), P < .001
Tang et al, 2021 ²⁰	Not specified	7 studies Robotic: 507 Laparoscopic: 516	Bleeding, robotic vs. laparoscopic OR 0.89 (95% Cl: 0.27 to 2.97), P = .85
Wang et al, 2020 ²²	Not specified	17 studies Robotic: 1,554 Laparoscopic: 1,639	Estimated blood loss (mL), robotic vs. laparoscopic MD –0.08 (95% Cl –0.31, 0.15), P = < .0001
Yao et al, 2023 ²¹	Surgeries for mid- to low rectal cancer	8 studies Robotic: 1,350 Laparoscopic: 1,330	Estimated blood loss (mL), robotic vs. laparoscopic MD –15.72 (95% Cl: –23.18 to – 8.26), P < .0001
Zhang et al, 2021 ²³	Intersphincteric resection	5 studies Robotic: 273 Laparoscopic: 237	Estimated blood loss (mL), robotic vs. laparoscopic MD -23.31 (95% Cl: -41.98 to -4.64), P = .01

Abbreviations: CI, confidence interval; CI, credible interval; MD, mean difference; OR, odds ratio; RCT, randomized controlled trial; RR, risk ratio; SMD, standardized mean difference.

^a*P*-values presented only when reported in the included studies.

Length of Stay and Readmission Rate

Seven systematic reviews reported on length of stay, and all found that length of stay was significantly shorter for the robotic approach (Table 6).^{16-19,21-23} None of the systematic reviews mentioned length of stay for readmission, but four reported on readmission rate, ^{16,18,21,22} which was found to be similar between groups.

The RCT found length of stay to be similar between the robotic and laparoscopic groups (median [interquartile range] 8 [7–10] vs. 8 [6–10], respectively, P = .895).²⁵

Table 6: Robotic-Assisted vs. Laparoscopic Rectal Cancer Surgery—Length of Stay and Readmission Rate

Author war	Drocoduro	N, included studies	Desulted
Author, year	Procedure	N, total participants	Results ^a
Flynn et al, 2023 ¹³	Not specified	50 studies	Length of stay (days), robotic vs. laparoscopic
2023-5		Robotic: 4,809	SMD 0.22 (95% CI: 0.33 to 0.11), <i>P</i> < 0.001
		Laparoscopic: 5,636	
Khajeh et al,	Not specified	18 studies	Length of stay (days), laparoscopic vs. robotic (GRADE: Low)
202315		Robotic: 1,937	All study types: MD 0.00 (95% Cl: –0.55 to 0.54)
		Laparoscopic: 3,008	RCTs only: MD 0.26 (95% CI: -0.33 to 0.86)
			Prospective observational studies only: MD –1.18 (95% CI: –2.86 to 0.50)
Liu et al, 2021 ¹⁶	Not specified	4 studies	Readmisison rate, robotic vs. laparoscopic
		Robotic: 2,730	RR 1.17 (95% CI: 0.75 to 1.83), P = .48
		Laparoscopic: 5,502	
Ryan et al,	Total mesorectal	30 studies	Length of stay (days), laparoscopic vs. robotic
202117	excision	Robotic: 388	MD 0.16 (95% Crl: -1.5 to 1.9)
		Laparoscopic: 3,072	
Safiejko et al,	Resection surgery	42 studies	Length of stay (days), robotic vs. laparoscopic
2021 ¹⁸		Robotic: 3,858	8.0 ± 5.3 vs. 9.5 ± 10.0; MD -2.01 (95% CI: -2.90 to -1.11), P < .001
		Laparoscopic: 5,408	Readmission rate, robotic vs. laparoscopic
			Robotic vs. laparoscopic: 10.3% vs. 9.8%; OR 1.14 (95% CI: 0.82 to 1.60), <i>P</i> = .44
Seow et al,	Total mesorectal excision	32 studies	Length of stay (days), robotic vs. laparoscopic and open (GRADE: Low)
2023 ¹⁹		Robotic: 479	Laparoscopic: MD 1.7 (95% Crl: - 1.1 to 4.4)
		Laparoscopic: 3,289	Open: MD 3.3 (95% Crl: 0.12 to 6.0)
Wang et al,	Not specified	17 studies	Readmission rate, robotic vs. laparoscopic
2020 ²²		Robotic: 1,554	OR 0.80 (95% CI: 0.48 to 1.34), P = .40
		Laparoscopic: 1,639	
Yao et al, 2023 ²¹	Surgeries for mid- to	8 studies	Length of stay (days), robotic vs. laparoscopic
	low rectal cancer	Robotic: 1,350	MD – 0.97 (95% Cl: – 1.11 to – 0.83), <i>P</i> < .00001
		Laparoscopic: 1,330	Readmission rate, robotic vs. laparoscopic
			MD 0.95 (95% CI: 0.56 to 1.63), <i>P</i> = .86
Zhang et al,	Intersphincteric	5 studies	Length of stay (days), robotic vs. laparoscopic
2021 ²³	resection	Robotic: 273	MD –1.52 (95% CI: –2.10 to –0.94), <i>P</i> < .00001
		Laparoscopic: 237	

Abbreviations: CI, confidence interval; CrI, credible interval; GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; MD, mean difference; OR, odds ratio; RCT, randomized controlled trial; RR, risk ratio; SMD, standardized mean difference. ^a*P*-values presented only when reported in the included studies.

Health-Related Quality of Life and Patient Functioning

Four systematic reviews evaluated quality of life (Table 7).^{14,17,24,26} Yang and Zhou evaluated urinary and sexual function using the International Prostate Symptom Score (IPSS), the International Index of Erectile Function (IIEF), and the Female Sexual Function Index (FSFI).²⁶ The IPSS is used to measure the severity of lower urinary tract symptoms, with higher scores indicating more severe symptoms. The IIEF assesses erectile function over the preceding four weeks, with higher scores indicating mild or no

erectile dysfunction. The FSFI assesses female sexual function, with higher scores indicating greater levels of sexual functioning. Yang and Zhou found significantly improved urinary and sexual function among those in the robotic group.²⁶ However, Ryan et al found no significant difference between groups for sexual dysfunction.¹⁷

Martins et al²⁴ specifically evaluated quality of life using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30), which assesses the quality of life of people with cancer. A higher score represents a higher response level (i.e., higher global quality of life, higher level of functioning, higher level of symptoms). The authors reported that physical functioning was superior among those in the robotic group but found no significant difference between groups in global quality of life, nausea and vomiting, pain, fatigue, or psychosocial subdomains (i.e., emotional, cognitive, role, and social functioning).

Flynn et al¹⁴ found that those in the robotic group reported either similar or slightly better scores for sexual function, urinary function, and some dimensions of quality of life compared with those in the laparoscopic group but found no significant difference for bowel function between groups. In contrast to the other systematic reviews, the primary studies included by Flynn et al used a variety of questionnaires to assess outcomes.

In the RCT, at 6 months post-surgery, global health status was found to be significantly impaired compared with the baseline period for both groups, but both groups had recovered by 12 months post-surgery.²⁵

In the RCT over the course of 24 months, no significant differences were found between groups for global health status (EORTC QLQ-C30 score; P = .518), anal sphincter function (Wexner score; P = .450), female sexual score (FSFI score; P = .354), or urinary function (IPSS score; P = .404).²⁵ Also over 24 months, male sexual function was not significantly different between groups compared with baseline (IIEF-5 score; P = .190). However, IIEF-5 scores at 24 months were significantly higher for the robotic group than for the laparoscopic group (8.1 vs. 4.6, P = .010). Also at 24 months, anal sphincter function scores remained significantly higher than at baseline for both groups (robotic: 3.3 vs. 8.4, P < .001; laparoscopic: 3.6 vs. 7.7, P < .001), indicating that normal function had not recovered by 24 months in either group.

Neither the included systematic reviews^{14,17,24,26} nor the RCT²⁵ specifically evaluated low anterior resection syndrome (a collection of symptoms or issues people may experience after resection or removal of the rectum, including frequency, urgency, incontinence, and constipation).

Table 7: Robotic-Assisted vs. Laparoscopic Rectal Cancer Surgery—Health-RelatedQuality of Life and Patient Functioning

		N, included studies	
Author, year	Procedure	N, total participants	Results ^a
Flynn et al, 2022 ¹⁴	Not specified	14 studies Robotic: 462 Laparoscopic: 470	 Male sexual function, robotic vs. laparoscopic (11 studies)^b 12 mo: OR 0.51 (95% CI: 0.28 to 0.95), P = .043 7 studies found significantly better scores in the robotic group 3 studies found a faster return to baseline in the robotic group but no significant difference between groups at 12 mo 3 studies found a significantly lower rate of sexual dysfunction at 1 y in the robotic group Female sexual function, robotic vs. laparoscopic (3 studies)^c Only 1 study found significantly better results at 12 mo for the robotic group 1 study found that at 6 mo, compared with preoperative scores, scores
			for the robotic group were comparable ($P = 0.181$), but scores for the laparoscopic group were significantly worse ($P = 0.0154$)
			Overall sexual function, robotic vs. laparoscopic (2 studies) ^d
			No significant difference between groups Urinary function, robotic vs. laparoscopic (11 studies) ^e
			 IPSS at 12 mo: MD 0.26 (95% CI: 0.47 to 0.05), P = .016 6 studies found significantly better scores in the robotic group 2 studies found short-term results favouring the robotic group but no diference between groups at later follow-ups
			Bowel function, robotic vs. laparoscopic (3 studies) ^g
			No significant difference between groups
			 Quality of life, robotic vs. laparoscopic (3 studies)^a No significant difference between groups for global quality of life 1 study found significantly better pain and insomnia levels in the robotic group but significantly better social functioning in the laparoscopic group 1 study found significantly better role function, cognitive function, and emotion scores in the robotic group
Martins et al,	Not specified	7 studies	Global EORTC QLQ-C30 score, robotic vs. laparoscopic
2023 ²⁴		Robotic: 429	MD -0.43 (95% CI: -3.49 to 2.62)
		Laparoscopic: 440	EORTC QLQ-C30 functioning scale scores, robotic vs. laparoscopic
			Physical functioning: MD 1.92 (95% CI: 0.97 to 2.87)
			Role functioning: MD -3.99 (95% CI: -8.19 to 0.21)
			Emotional functioning: MD 1.22 (95% CI: -0.58 to 3.01)
			Cognitive functioning: MD 0.18 (95% CI: -1.04 to 1.40)
			EORTC QLQ-C30 symptom scale scores, robotic vs. laparoscopic
			Fatigue: MD – 0.81 (95% CI: –4.13 to 2.52)
			Nausea and vomiting: MD –0.58 (95% CI: –1.33 to 0.16)
			Generalized pain: MD –0.58 (95% Cl: –3.63 to 2.47)
Ryan et al, 2021 ¹⁷	Total mesorectal excision	30 studies Robotic: 388 Laparoscopic: 3,072	Sexual dysfunction, robotic vs. laparoscopic RR 0.72 (95% CrI: 0.39 to 1.5)

	-	N, included studies	-
Author, year	Procedure	N, total participants	Results ^a
Yang and Zhou,	Not specified	11 studies	Change in IPSS score from baseline, robotic vs. laparoscopic
2023 ²⁶		Robotic: 790	3 mo: WMD -1.21 (95% CI: - 1.8 to -0.62)
		Laparoscopic: 888	6 mo: WMD – 1.13 (95% Cl: –1.74 to – 0.52)
			12 mo: WMD –0.93 (95% Cl: –1.59 to – 0.26)
			Change in IIEF score from baseline, robotic vs. laparoscopic
			3 mo: WMD 3.36 (95% Cl: 1.28 to 5.44)
			Change in FSFI score from baseline, robotic vs. laparoscopic
			3 mo: WMD 1.31 (95% CI: 0.87 to 1.76)
			6 mo: WMD 2.36 (95% CI: 1.93 to 2.79)
			12 mo: WMD 1.67 (95% Cl: 0.41 to 2.93)

Abbreviations: CI, confidence interval; CrI, credible interval; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FSFI, Female Sexual Function Index; IIEF, International Index of Erectile Function; IPSS, International Prostate Symptom Score; MD, mean difference; OR, odds ratio; RR, risk ratio; WMD, weighted mean difference.

^a*P*-values presented only when reported in the included studies.

^b8 studies used IIEF or a modified IIEF; 3 studies used other questionnaires.

^cAll 3 studies used FSFI or a modified FSFI.

^d1 study used IIEF and FSFI; the other study used another questionnaire.

^e8 studies used IPSS or a modified IPSS; 3 studies used other questionnaires.

^f1 study used the Wexner score (also known as the Cleveland Clinic Fecal Incontinence Severity Scoring System [CCIS]) to assess fecal incontinence (a higher score indicates a greater level of incontinence); 2 studies used other questionnaires.

^g2 studies used the EORTC QLQ-C30; 1 study used other questionnaires.

Robotic-Assisted Versus Open Rectal Cancer Surgery

One systematic review by Khajeh et al,¹⁵ which included 4 studies (2 RCTs and 2 prospective observational studies), compared robotic-assisted rectal cancer surgery (N = 265) with open rectal cancer surgery (N = 982). This systematic review reported a subgroup analysis based on study design (RCTs vs. prospective observational studies) but reported only on overall survival, estimated blood loss, and length of stay.

Overall Survival

Overall survival was reported only in 1 primary study (N, robotic: 65; N, open: 55) included in the systematic review by Khajeh et al.¹⁵ One-year overall survival for both groups was 98%. At 3 years, overall survival was 93% for those in the open group and 87% for those in the robotic group. Confidence intervals, standard errors, and *P*-values were not reported for either time period. Perioperative mortality was not reported.

Estimated Blood Loss

Transfusion rate was not reported.¹⁵ However, for all study types, estimated blood loss was found to be statistically significantly lower in the robotic group compared with the open group (Table 8).

		N, included studies	
Author, year	Procedure	N, total participants	Results
	Not specified	1 study	All study types: MD 156.63 (95% CI: 62.36 to 250.91), P = .001
202315		Robotic: 315	RCTs only: MD 161.36 (95% CI: 8.61 to 314.11), P < .00001
		Open: 268	Prospective observational studies only: MD 149.37 (95% CI: 5.99 to 292.74), <i>P</i> < .00001

Table 8: Robotic-Assisted vs. Open Rectal Cancer Surgery—Estimated Blood Loss

Abbreviations: CI, confidence interval; MD, mean difference; RCT, randomized controlled trial.

Length of Stay

For all study types, length of stay was found to be statistically significantly lower in the robotic group (Table 9).¹⁵

Table 9: Robotic-Assisted vs. Open Rectal Cancer Surgery—Length of Stay

Author, year	Procedure	N, included studies N, total participants	Results
Khajeh et al, 2023 ¹⁵	Not specified	1 study Robotic: 315	All study types: MD 2.51 (95% Cl: 0.35 to 4.67), <i>P</i> = .02 RCTs only: MD 3.21 (95% Cl: –1.19 to 7.61), <i>P</i> < .00001
		Open: 268	Prospective observational studies only: MD 2.19 (95% CI: 1.20 to 3.18), $P < .0001$

Abbreviations: CI, confidence interval; MD, mean difference; RCT, randomized controlled trial.

Ongoing Studies

We found 3 ongoing studies (2 prospective observational studies and 1 RCT) that have potential relevance to our research question (Appendix 7, Table A5).

Discussion

Our expedited summary of the clinical evidence summarizes the most recent systematic reviews and RCTs on robotic-assisted rectal cancer surgery compared with laparoscopic or open rectal cancer surgery. However, our findings are limited to what was reported in the systematic reviews. Twelve of the 13 included systematic reviews compared robotic-assisted with laparoscopic rectal cancer surgery; just 1 systematic review compared robotic-assisted with open rectal cancer surgery. In the primary comparative observational studies, risk of bias was reported as generally ranging from low to moderate; for the primary RCTs, risk of bias was reported to be higher. There was a high degree of overlap for the primary RCTs included in the systematic reviews and less overlap for the included comparative observational studies. Based on the findings of the included systematic reviews, robotic-assisted rectal cancer surgery may result in similar or improved outcomes compared with the laparoscopic approach and may result in reduced blood loss and shorter length of stay compared with the open approach.

However, the included RCT found no significant differences in outcomes between the robotic and laparoscopic groups, but these findings should be interpreted with caution because the study was underpowered owing to difficulty recruiting participants, which negatively affects the reliability of the results.

Potential differences in patient population, intervention, comparator, and outcomes between studies may limit comparability and generalizability. Most systematic reviews did not comment on the patient characteristics of the primary studies or whether there may have been differences between groups. Clinical heterogeneity may exist between primary studies (e.g., cancer severity, patient comorbidities) and thus may have affected the appropriateness of meta-analysis.

In addition, none of the included systematic reviews specifically evaluated potential subpopulations of interest, particularly those with a narrow pelvis and those with a high body mass index (BMI). Narrow pelvis and high BMI may pose surgical challenges, and other studies have suggested that the robotic-assisted approach may benefit these subpopulations. For example, a systematic review on robotic-assisted colorectal cancer resection for people with obesity found a higher rate of conversion to laparotomy (open abdominal surgery) for those with obesity compared with those without obesity (odds ratio [OR] 1.99 [95% CI: 1.54 to 2.56], P < .001).²⁷ Blood loss and length of stay were found not to be significantly different between those with and without obesity.

Most included systematic reviews did not report the type of surgical system used within the primary studies. Although the most widely used robotic surgical system is the da Vinci Surgical System, there are 3 versions of this system currently in use (the da Vinci Si, X, and Xi), and other systems are also used in Ontario (i.e., the Hugo RAS System) and available internationally.

Most included systematic reviews also broadly included rectal cancer surgery and included different surgical techniques or procedures (e.g., anterior resection, total mesorectal excision).

The included systematic reviews did not assess the impact of surgeons' experience with robotic or laparoscopic surgical approaches. However, other studies have found that conversion and complication rates may be lower for the robotic approach compared with the laparoscopic approach for experienced laparoscopic surgeons.²⁸ There may also be a short learning curve as surgeons transition from the laparoscopic to the robotic approach.²⁹

The time point at which reoperation and readmission rates were assessed was unclear in some of the included systematic reviews. Not all primary studies used the outcome definition or score or consistently reported results from the same time point, which made meta-analysis difficult within the systematic reviews. Meta-analysis was also sometimes conducted despite high statistical heterogeneity, and only 2 systematic reviews¹⁵ evaluated the certainty of the evidence using the GRADE criteria.

We did not find any systematic reviews that assessed the impact of the uptake of robotic-assisted rectal cancer surgery on the number of open procedures performed. However, a cross-sectional study from the United States found that the proportion of rectal cancer surgeries performed using the robotic approach increased from 15% (95% CI: 13% to 16%) in 2018 to 22% (95% CI: 20% to 24%) in 2020.³⁰

Conclusions

We examined the peer-reviewed published and grey literature to determine what is known about the effectiveness and safety of robotic-assisted rectal cancer surgery compared with the laparoscopic and open approaches and found the following.

• We identified 12 systematic reviews and 1 RCT that compared robotic-assisted versus laparoscopic rectal cancer surgery

- Compared with laparoscopic rectal cancer surgery, robotic-assisted rectal cancer surgery may result in the following:
 - Similar overall survival, conversion rate, transfusion rate, and readmission rate
 - Reduced blood loss
 - Shorter length of stay
 - o Improved health-related quality of life or patient functioning
- We identified 1 systematic review comparing robotic-assisted versus open rectal cancer surgery
- Compared with open rectal cancer surgery, robotic-assisted rectal cancer surgery may result in the following:
 - Similar overall survival
 - Reduced blood loss
 - Shorter length of stay
- None the included systematic reviews specifically evaluated potential subpopulations of interest (e.g., those with a narrow pelvis, those with a high body mass index)
- None of the included systematic reviews evaluated positive margin rate, recovery time, or time to return to normal activity

Abbreviations

AMSTAR 2: A Measurement Tool to Assess Systematic Reviews, version 2

BMI: body mass index

CE: Conformité Européenne

CI: confidence interval

Crl: credible interval

CT: computed tomography

EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire

FDA: US Food and Drug Administration

FSFI: Female Sexual Function Index

GRADE: Grading of Recommendations Assessment, Development, and Evaluation

HR: hazard ratio

IIEF: International Index of Erectile Function

IPSS: International Prostate Symptom Score

MD: mean difference

MRI: magnetic resonance imaging

NR: not reported

OR: odds ratio

PET: positron emission tomography

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-analyses

RCT: randomized controlled trial

RR: risk ratio

SMD: standardized mean difference

WMD: weighted mean difference

Appendices

Appendix 1: Evidence Methods

Clinical Literature Search

We performed a clinical literature search on November 7, 2023, to retrieve studies published from January 1, 2019, until the search date. We focused on studies published within the last 5 years to capture the most recent literature on the topic. We used the Ovid interface in the following databases: MEDLINE, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews.

A medical librarian developed the search strategies using controlled vocabulary (e.g., Medical Subject Headings) and relevant keywords. Methodological filters were used to limit retrieval to systematic reviews, meta-analyses, health technology assessments, and randomized controlled trials. The final search strategy was peer-reviewed using the PRESS Checklist.³¹

We created database auto-alerts in MEDLINE and monitored them until January 15, 2024. We also performed a targeted grey literature search of the International HTA Database, the websites of health technology assessment organizations and regulatory agencies, and clinical trial and systematic review registries following a standard list of sites developed internally. See Appendix 2 for our literature search strategy, including all search terms.

Eligibility Criteria

Studies

Inclusion Criteria

- English-language full-text publications
- Studies published between January 1, 2019, and November 7, 2023
- Systematic reviews and meta-analyses with a literature search date of 2020 or later, that follow PRISMA reporting guidelines, and that report a risk-of-bias assessment for all included primary studies
- Randomized controlled trials (RCTs) not included in any included systematic reviews or metaanalyses

Exclusion Criteria

- Animal and in vitro studies
- Nonsystematic reviews, narrative reviews, abstracts, editorials, letters, case reports, and commentaries

Participants

Inclusion Criteria

- Adults with rectal cancer
 - Subpopulations of interest: elevated body mass index (BMI), narrow male pelvis, very low rectal cancer, rectal sigmoid cancer, distal rectal cancer, locally advanced rectal cancer

Exclusion Criteria

• Adults with colorectal cancer

Interventions

Inclusion Criteria

 Robotic-assisted rectal cancer surgery (e.g., anterior resection, abdominal perineal resection, proctectomy, coloanal or intracorporeal anastomosis, total or transanal mesorectal excision, intersphincteric resection)

Exclusion Criteria

Robotic-assisted surgery for other indications

Comparators

Inclusion Criteria

• Rectal cancer surgery using an open or laparoscopic approach

Exclusion Criteria

 Comparisons of robotic-assisted rectal cancer surgery using different surgical systems or surgical techniques

Outcome Measures

- Overall survival
- Positive margin rate
- Conversion rate
- Reoperation rate
- Transfusion rate and estimated blood loss
- Length of stay (including readmission and follow-up visits)
- Recovery time or time to return to normal activity

- Health-related quality of life (e.g., experience of low anterior resection syndrome, patient functioning)
- Impact of uptake of robotic-assisted rectal cancer surgery on the number of open rectal cancer surgeries performed

Literature Screening

A single reviewer screened titles and abstracts using Covidence³² and obtained the full texts of studies that appeared eligible for review according to the inclusion criteria. The same reviewer then examined the full-text articles and selected studies eligible for inclusion. The reviewer also examined reference lists for any additional relevant studies not identified through the search.

Data Extraction

We extracted relevant data on study characteristics and risk-of-bias items using a data form to collect information on the following:

- Source (e.g., citation information, study type)
- Methods (e.g., study design, study duration and years, participant allocation, allocation sequence concealment, blinding, reporting of missing data, reporting of outcomes, whether the study compared two or more groups)
- Outcomes (e.g., outcomes measured, number of participants for each outcome, number of participants missing for each outcome, outcome definition and source of information, unit of measurement, upper and lower limits [for scales], time points at which the outcomes were assessed)

Critical Appraisal of Evidence

We assessed risk of bias using AMSTAR 2 (A Measurement Tool to Assess Systematic Reviews, version 2)¹¹ for systematic reviews and the Cochrane Risk-of-Bias Tool for Randomized Trials, version 1,¹² for the included RCT (Appendix 6).

We reported the quality of the body of evidence as evaluated in the included systematic reviews according to the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) Working Group criteria³³ if it was evaluated. The body of evidence was assessed based on the following considerations: risk of bias, inconsistency, indirectness, imprecision, and publication bias. The overall rating reflects the systematic review authors' assessment of the certainty of the evidence.

Appendix 2: Literature Search Strategy

Literature Search

Search date: November 7, 2023

Databases searched: Ovid MEDLINE, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials

Database segments: EBM Reviews - Cochrane Central Register of Controlled Trials <September 2023> EBM Reviews - Cochrane Database of Systematic Reviews <2005 to November 1, 2023> Ovid MEDLINE(R) ALL <1946 to November 06, 2023>

Search strategy:

1 Robotic Surgical Procedures/ 17447

2 Surgery, Computer-Assisted/ 21377

3 Video-Assisted Surgery/2483

4 Robotics/ 29123

5 (((procedur* or surg* or techni* or excis*) adj5 (robot* or comput* assist*)) or (robot* adj3 assist*) or remote* surg*).ti,ab,kf. 45154

6 (da vinci* or davinci or hugo* or versius* or ottava*).ti,ab,kf. 6645

7 or/1-6 85005

8 Rectal Neoplasms/ 51029

9 ((rectal* or rectum* or rectosigmoid* or recto sigmoid* or rectalsigmoid*) adj3 (cancer* or neoplas* or tumo?r or carcinoma* or adenocarcinoma* or carcinogen* or malignan* or metasta* or oncolog*)).ti,ab,kf. 49580

10 Proctectomy/ 1619

11 (proctectom* or anterior resection* or APR or TME or ((abdominoperineal* or abdomino perineal* or abdominal* perineal* or intersphincteric* or inter* sphincteric* or rectum* or rectal* or mesorectal* or meso rectal* or rectosigmoid* or recto sigmoid* or rectalsigmoid*) adj3 (surg* or operat* or procedure* or excision* or resection* or re section* or recision* or dissection* or anastomo*))).ti,ab,kf. 49418

12 or/8-11 97648

13 7 and 12 2053

14 (robot* adj3 (anterior resection* or proctectom* or APR or TME or ((abdominoperineal* or abdomino perineal* or abdominal perineal* or intersphincteric* or inter* sphincteric* or rectum* or rectal* or mesorectal* or mesorectal* or rectosigmoid* or recto sigmoid* or rectalsigmoid*) adj3 (surg* or procedure* or operat* or excision* or resection* or re section* or recision* or dissection* or anastomo*)))).ti,ab,kf. 1054

15 13 or 14 2084

16 (Systematic Reviews or Meta Analysis).pt. 189330

17 Systematic Review/ or Systematic Reviews as Topic/ or Meta-Analysis/ or exp Meta-Analysis as Topic/ or exp Technology Assessment, Biomedical/ 370596

18 ((systematic* or methodologic*) adj3 (review* or overview*)).ti,ab,kf. 344301

19 (meta analy* or metaanaly* or met analy* or metanaly* or meta review* or metareview* or health technolog* assess* or HTA or HTAs or (technolog* adj (assessment* or overview* or appraisal*))).ti,ab,kf. 315226

20 (evidence adj2 (review* or overview* or synthes#s)).ti,ab,kf. 50289

21 (review of reviews or overview of reviews).ti,ab,kf. 1267

22 umbrella review*.ti,ab,kf. 1680

23 GRADE Approach/ 116

24 ((pool* adj3 analy*) or published studies or published literature or hand search* or handsearch* or manual search* or ((database* or systematic*) adj2 search*) or reference list* or bibliograph* or relevant journals or data synthes* or data extraction* or data abstraction*).ti,ab,kf. 307364

25 (medline or pubmed or medlars or embase or cinahl or web of science or ovid or ebsco* or scopus).ab. 359179

26 cochrane.ti,ab,kf. 154578

27 (meta regress* or metaregress*).ti,ab,kf. 15670

```
28 (((integrative or collaborative or quantitative) adj3 (review* or overview* or synthes*)) or (research adj3 overview*)).ti,ab,kf. 19714
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29 (cochrane or (health adj2 technology assessment) or evidence report or systematic review*).jw.
 39764

30 ((comparative adj3 (efficacy or effectiveness)) or relative effectiveness or ((indirect or indirect treatment or mixed-treatment) adj comparison*)).ti,ab,kf. 33427

31 or/16-30 837857 15 and 31 32 213 33 15 use coch 1 34 32 use medall.cctr 212 35 or/33-34 213 36 exp Animals/ not Humans/ 5171182 37 35 not 36 213 38 limit 37 to english language 204 limit 38 to yr="2019 -Current" 39 122 40 Clinical Trials as Topic/ 238361 41 controlled clinical trials as topic/ 6087 42 exp Randomized Controlled Trials as Topic/ 209627 43 controlled clinical trial.pt. 95446 44 randomized controlled trial.pt. 602616 45 Pragmatic Clinical Trial.pt. 2268 46 Random Allocation/ 130401 47 Single-Blind Method/ 57690 48 Double-Blind Method/ 331742 49 Placebos/ 61413 50 trial.ti. 709067 51 (random* or sham or placebo* or RCT*1).ti,ab,kf. 2934182 52 ((singl* or doubl*) adj (blind* or dumm* or mask*)).ti,ab,kf. 519375 53 ((tripl* or trebl*) adj (blind* or dumm* or mask*)).ti,ab,kf. 4440 54 or/40-53 3539353 55 15 and 54 379 56 15 use cctr 176 57 55 use medall,coch 255 58 or/56-57 431

59	exp Animals/ n	ot Humans/	5171182
60	58 not 59	431	
61	limit 60 to engl	ish language	405
62	limit 61 to yr="	2019 -Current"	199
63	39 or 62	272	
64	63 use medall	196	
65	63 use cctr	75	
66	63 use coch	1	
67	remove duplica	ites from 63	251

Grey Literature Search

Performed: November 7-9, 2023

Websites searched:

Alberta Health Evidence Reviews, Alberta Health Services, BC Health Technology Assessments, Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et en services sociaux (INESSS), Institute of Health Economics (IHE), Ontario Health Technology Assessment Committee (OHTAC), McGill University Health Centre Health Technology Assessment Unit, Centre Hospitalier de l'Universite de Quebec-Universite Laval, Contextualized Health Research Synthesis Program of Newfoundland (CHRSP), Health Canada Medical Device Database, Health Technology Assessment Database, Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Centers, Centers for Medicare and Medicaid Services Technology Assessments, U.S. Dept of Veteran Affairs, Institute for Clinical and Economic Review, Oregon Health Authority, Washington State Health Care Authority Health Technology Assessment Findings, National Institute for Health and Care Excellence (NICE), NHS England, Healthcare Improvement Scotland, and Health Technology Wales.

robot, robot-assisted surgery, robotic assisted surgery, robotics, rectal, rectal cancer, rectal neoplasms, mesorectal, proctectomy, proctectomies, da vinci, davinci, rectale, proctectomie, chirurgie robotique

Clinical results (included in PRISMA): 1

Appendix 3: Selected Excluded Studies

For transparency, we provide a list of studies that met our literature search criteria (published between January 1, 2019, and November 7, 2023) but had a literature search date of 2019 or earlier and were thus excluded:

- Bilgin IA, Bas M, Aytac E, Benlice C, Esen E, Kirbiyik E, et al. Operative and long-term oncological outcomes in patients undergoing robotic versus laparoscopic surgery for rectal cancer. Int J Med Robot. 2020;16(6):1-10.
- Butterworth JW, Butterworth WA, Meyer J, Giacobino C, Buchs N, Ris F, et al. A systematic review and meta-analysis of robotic-assisted transabdominal total mesorectal excision and transanal total mesorectal excision: which approach offers optimal short-term outcomes for mid-to-low rectal adenocarcinoma? Tech Coloproctol. 2021;25(11):1183-98.
- Conticchio M, Papagni V, Notarnicola M, Delvecchio A, Riccelli U, Ammendola M, et al. Laparoscopic vs. open mesorectal excision for rectal cancer: are these approaches still comparable? A systematic review and meta-analysis. PLoS One. 2020;15(7):e0235887.
- Eltair M, Hajibandeh S, Hajibandeh S, Nuno A, Abdullah KH, Alkaili-Alyamani A, et al. Meta-analysis and trial sequential analysis of robotic versus laparoscopic total mesorectal excision in management of rectal cancer. Int J Colorectal Dis. 2020;35(8):1423-38.
- Gavriilidis P, Wheeler J, Spinelli A, de'Angelis N, Simopoulos C, Di Saverio S. Robotic vs laparoscopic total mesorectal excision for rectal cancers: has a paradigm change occurred? A systematic review by updated meta-analysis. Colorectal Dis. 2020;22(11):1506-17.
- Grass JK, Chen CC, Melling N, Lingala B, Kemper M, Scognamiglio P, et al. Robotic rectal resection preserves anorectal function: systematic review and meta-analysis. Int J Med Robot. 2021;17(6):e2329.
- Grass JK, Perez DR, Izbicki JR, Reeh M. Systematic review analysis of robotic and transanal approaches in TME surgery - a systematic review of the current literature in regard to challenges in rectal cancer surgery. Eur J Surg Oncol. 2019;45(4):498-509.
- Guo Y, Guo Y, Luo Y, Song X, Zhao H, Li L. Comparison of pathologic outcomes of robotic and open resections for rectal cancer: a systematic review and meta-analysis. PLoS One. 2021;16(1):e0245154.
- Han C, Yan P, Jing W, Li M, Du B, Si M, et al. Clinical, pathological, and oncologic outcomes of robotic-assisted versus laparoscopic proctectomy for rectal cancer: a meta-analysis of randomized controlled studies. Asian J Surg. 2020;43(9):880-90.
- Hoshino N, Sakamoto T, Hida K, Sakai Y. Robotic versus laparoscopic surgery for rectal cancer: an overview of systematic reviews with quality assessment of current evidence. Surg Today. 2019;49(7):556-70.
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- Huang YJ, Kang YN, Huang YM, Wu AT, Wang W, Wei PL. Effects of laparoscopic vs robotic-assisted mesorectal excision for rectal cancer: an update systematic review and meta-analysis of randomized controlled trials. Asian J Surg. 2019;42(6):657-66.
- Kowalewski KF, Seifert L, Ali S, Schmidt MW, Seide S, Haney C, et al. Functional outcomes after laparoscopic versus robotic-assisted rectal resection: a systematic review and meta-analysis. Surg Endosc. 2021;35(1):81-95.
- Lam J, Tam MS, Retting RL, McLemore EC. Robotic versus laparoscopic surgery for rectal cancer: a comprehensive review of oncological outcomes. Perm J. 2021;25(12):14.
- Liao G, Zhao Z, Deng H, Li X. Comparison of pathological outcomes between robotic rectal cancer surgery and laparoscopic rectal cancer surgery: a meta-analysis based on seven randomized controlled trials. Int J Med Robot. 2019;15(5):e2027.
- Liu C, Li X, Wang Q. Postoperative complications observed with robotic versus laparoscopic surgery for the treatment of rectal cancer: an updated meta-analysis of recently published studies. Medicine. 2021;100(36):e27158.
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Appendix 4: PRISMA Flow Diagram

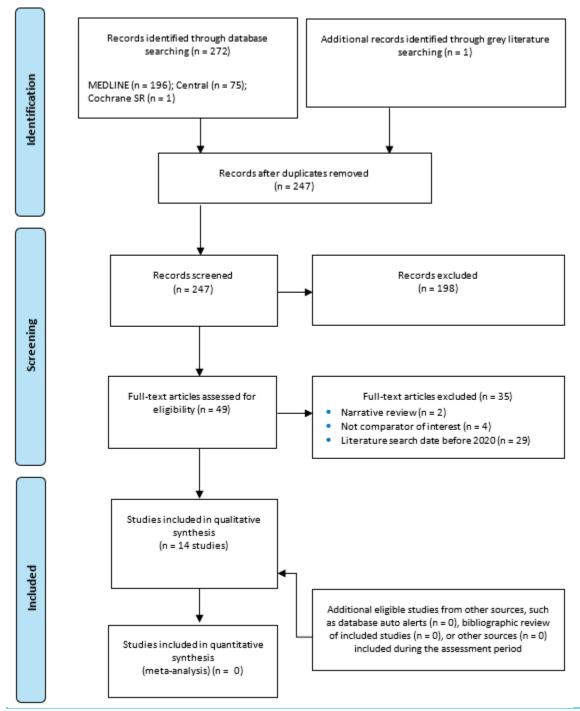


Figure A1: PRISMA Flow Diagram – Clinical Search Strategy

PRISMA flow diagram showing the clinical search strategy. The database search of the clinical literature yielded 247 citations published between January 1, 2019, and November 7, 2023, including grey literature searches and after duplicates were removed. We screened the abstracts of the 247 identified studies and excluded 198. We assessed the full text of 49 articles and excluded a further 35. In the end, we included 14 articles in the qualitative synthesis.

Abbreviation: PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses. Source: Adapted from Page et al.¹⁰

Appendix 5: Summary of Included Studies

Table A1: Characteristics of the Included Systematic Reviews

Author, year	Search date		N, included studies			
Country	Literature searched	Study details	N, total participants	Risk of bias	Outcomes of interest	
Flynn et al, 2022 ¹⁴ United States	Up to February 3, 2021 Medline, PubMed, Embase, Cochrane library, Clinical Trials Register, grey literature, manual abstract searches from selected colorectal conferences, reference lists	Inclusion criteria: comparison of medium- and long-term (> 3 mo after surgery) functional outcomes between groups, English or Spanish language Exclusion criteria: no comparative data on ≥ 1 functional outcomes, reporting only immediate postoperative and short-term (< 3 mo) functional outcomes, reason to suspect possible overlap with another included article, included data from a national database	14 studies (2 RCT, 12 observational) Robotic: NR Laparoscopic: NR	RCTs: Cochrane RoB, Jadad scale Nonrandomized studies: NOS, ROBINS-I Included primary studies generally had low to moderate risk of bias	Functional: sexual function, urinary function, bowel function, quality of life	
Flynn et al, 2023 ¹³ United States	Up to February 8, 2021 Medline, Embase, Cochrane databases, reference lists	Inclusion criteria: comparison of laparoscopic vs. robotic TME (namely anterior resection or abdominoperineal resection) in adults with ≥ 1 outcome of interest, English language Exclusion criteria: case reports, case series, trials published only in abstract form	50 studies (3 RCT, 3 prospective cohort, 31 retrospective cohort, 13 case- matched) Robotic: 4,809 Laparoscopic: 5,636	RCTs: Jadad scale Nonrandomized studies: NOS Included primary studies generally had low to moderate risk of bias	Operation time, blood loss, conversion rate, length of stay, unplanned readmission, pathological and oncological outcomes (number of LNs harvested, CRM < 1 mm or incomplete TME graded by pathologist as involving the muscularis propria or intramesorectal plane), survival	
Khajeh et al, 2023 ¹⁵ Germany	Up to October 2022 Medline, Web of Science, CENTRAL, reference lists	Population: adults with rectal cancer undergoing elective rectal resection Intervention: robotic-assisted rectal cancer surgery Comparator: open or laparoscopic rectal resection Study design: RCT, prospective observational Exclusion criteria: data unsuitable for meta- analysis, retrospective studies, review articles, studies using cadavers or animals, studies that reported similar data on the same patient population	26 studies (15 RCT, 11 prospective observational) Robotic: 5,348 Laparoscopic: 1,574	RCTs: Cochrane RoB 2 Nonrandomized studies: ROBINS-I Included primary studies generally had some concerns or high concerns for risk of bias	Intraoperative outcomes (intraoperative complications, conversion rate, blood loss, operation time), postoperative surgical outcomes (histopathological outcomes, postoperative pain, postoperative complications, reoperation rate, length of stay, mortality up to 90 d), survival, cost	

Author, year Country	Search date Literature searched	Study details	N, included studies N, total participants	Risk of bias	Outcomes of interest
Liu et al, 2021 ¹⁶ China	Search date not specified CENTRAL, Medline, Embase, Google Scholar, Web of Science, ClinicalTrials.gov	Inclusion criteria: comparison of robotic vs. laparoscopic rectal cancer surgery, published after 2015, reported postoperative complications, dichotomous data, English language Exclusion criteria: studies not comparing robotic vs. laparoscopic, published before or during 2015, non-English language, postoperative outcomes not reported, studies repeatedly found in different search databases	15 studies (2 RCT, 13 observational) Robotic: 9,178 Laparoscopic: 13,566	RCTs: Cochrane RoB Observational studies: NOS Included primary studies generally had moderate risk of bias	Postoperative outcomes (overall complications, wound complications, anastomotic leak, anastomotic bleeding, stoma-related complication, postoperative ileus, intra-abdominal access, urinary retention, enterocolitis, urinary tract infection, readmission, reoperation, mortality)
Martins et al, 2023 ²⁴ United States	Up to February 20, 2022 Medline, Embase, Scopus, CENTRAL, manual searching, reference lists, grey literature	Study design: observational or interventional clinical studies reporting original data Population: adults with rectal cancer Intervention: robotic-assisted rectal cancer surgery Comparator: laparoscopic rectal cancer surgery Exclusion criteria: studies not administering a complete QoL tool, studies reporting QALYs	7 studies (2 RCT, 4 prospective cohort, 1 retrospective cohort) Robotic: 429 Laparoscopic: 440	RCTs: Cochrane RoB 2 Nonrandomized studies: ROBINS-I Included primary studies generally had low risk of bias	Quality of life
Ryan et al, 2021 ¹⁷ Ireland	Up to January 1, 2020 Medline/PubMed, Embase, CENTRAL, Scopus, reference lists, ClinicalTrials.gov	Inclusion criteria: people with rectal cancer, comparison of TME modalities, reported surgical and clinical outcomes of interest, clear research methodology and participant randomization, have the longest follow-up or largest sample size when 2 or more studies were reported by the same institution, English language Exclusion criteria: did not meet inclusion criteria, non-English language	36 articles (30 trials with 6 updates) Robotic: 388 Laparoscopic: 3,072 Open: 2,207	NR	Primary: recurrence, development of distant metastasis, DFS, OS Secondary: pathological outcomes, intraoperative outcomes, patient recovery from surgery, short- to medium-term morbidity

Author, year Country	Search date Literature searched	Study details	N, included studies N, total participants	Risk of bias	Outcomes of interest
Safiejko et al, 2021 ¹⁸ Poland	Up to November 10, 2021 PubMed, Cochrane library, Web of Science, Scopus, Google Scholar, reference lists	Population: adults diagnosed with rectal cancer and treated with rectal cancer surgery Intervention: robotic-assisted rectal cancer surgery Comparator: laparoscopic or open rectal cancer surgery Outcomes: detailed information on survival or mortality Study design: RCTs, English language Exclusion criteria: no comparator, reviews, conference articles, editorials, letters, duplicate publications	41 studies Robotic: 3,858 Laparoscopic: 5,408	RCTs: Cochrane RoB 2 Nonrandomized studies: ROBINS-I Included primary studies generally had low to moderate risk of bias	Survival, DFS, length of stay, adverse events
Seow et al, 2023 ¹⁹ Australia	Up to September 2020 Medline, Embase, CINAHL, CDSR, CENTRAL, DARE, WHO Registry Network, reference lists	Inclusion criteria: RCTs of adults (age > 16 y) with rectal tumours stage ≤ 4 (≤ T4), direct comparison of ≥ 2 surgical approaches, RCTs evaluating efficacy based on ≥ 1 surgical and/or clinical outcome, English language Exclusion criteria: nonrandomized studies, participant age ≤ 16 y, rectal cancers grade ≥ T4, studies with operations other than colorectal resection, trials published only as abstracts, non-English language	47 articles consisting of 32 RCTs Robotic: 216 Laparoscopic: 3,289 Open: 2,167	Cochrane RoB 2 Comparison-adjusted funnel plot for publication bias Included primary studies generally had low to moderate risk of bias	Primary: rate of clear/negative CRM, rate of complete mesorectal excision Secondary: complete mesorectal excision, distance to distal margin, total LNs retrieved, conversion rate, incidence of anastomotic leakage, operating time, rates of diverting ileostomy and permanent colostomy, incidence of perioperative mortality, postoperative complications, locoregional recurrence, 3- or 5-y DFS and OS, length of stay, bowel function, bladder function, sexual function

Author, year	Search date		N, included studies		
Country	Literature searched	Study details	N, total participants	Risk of bias	Outcomes of interest
Tang et al, 2021 ²⁰ China	Up to April 2020 PubMed, Embase, Cochrane library, CNKI, Wanfang Data Knowledge Service Platform, CBMdisc, reference lists	Population: adults with primary rectal cancer Intervention: robotic-assisted rectal cancer surgery Comparator: laparoscopic rectal cancer surgery Study design: RCT, English or Chinese language	7 studies (all RCT) Robotic: 507 Laparoscopic: 516	Cochrane RoB, Jadad scale Included primary studies generally had low risk of bias	Primary: postoperative complications within 30 d (overall and severe postoperative complications, anastomotic leakage, surgical site infection, bleeding, ileus, urinary complications, respiratory complications
					Secondary: conversion rate, TME completeness, number of harvested LNs, proximal margin, distal margin, unscheduled reoperation, perioperative mortality
China	Up to April 2020 PubMed, Embase, Cochrane library, Web of Science, reference lists	Inclusion criteria: people with histologically diagnosed rectal cancer, comparative studies of robotic vs. laparoscopic rectal cancer surgery (RCTs and non-RCTs), studies that clearly reported grade of postoperative	17 studies (1 RCT, 3 prospective cohort, 13 retrospective cohort) Robotic: 2,168	RCTs: Cochrane RoB Nonrandomized studies: NOS Included primary studies generally had low to moderate	Postoperative complications within 30 d Primary: C-D grade III, IV, V, III to V (severe complications)
		complications based on C-D classification, most recent studies or those with larger sample sizes were selected if studies reported on same study population	Laparoscopic: 3,328	risk of bias	Secondary: C-D grade I, I, I- II (minor complications), overall complications, individual complications,
		Exclusion criteria: case reports, letters comments, conference proceedings, review articles, meta-analyses, abstracts only, studies that reported postoperative complications without C-D classification, studies including combined resection or Hartmann procedure, non-English language			reoperation, readmission
Yang and Zhou, 2023 ²⁶ China	Up to November 4, 2021 PubMed, Embase, CNKI, Wanfang, Cochrane library	Inclusion criteria: clinical studies comparing robotic-assisted with laparoscopic rectal cancer surgery; primary endpoints of IPSS, IIEF, FSFI	11 studies (2 RCT, 2 propensity-matched, 2 prospective cohort, 5 retrospective cohort)	NOS	Primary: IPSS Secondary: IIEF, FSFI
		Exclusion criteria: letters, editorials, noncomparative studies, duplicate studies, nonhuman studies	Robotic: NR Laparoscopic: NR		

Author, year	Search date		N, included studies		
Country	Literature searched	Study details	N, total participants	Risk of bias	Outcomes of interest
Yao et al, 2023 ²¹ China	Up to July 2023 PubMed, Embase, Cochrane, Web of Science	Inclusion criteria: studies comparing robotic- assisted with laparoscopic rectal cancer surgery, tumour in the mid- to low part of the rectum, RCTs, cohort studies, case-control studies, the higher-quality study for authors or institutions reporting more than 1 study, sufficient data can be extracted Exclusion criteria: high rectal cancer or not rectal cancer, overlapping data, data could not be extracted, conference abstracts, case reports, reviews, comments	8 studies (3 RCT, 5 retrospective cohort) Robotic: 1,350 Laparoscopic: 1,330	NOS	Estimated blood loss, number of LNs dissected, operation time, time to first flatus, time to first fluid test, length of hospital stay, complications
Zhang et al, 2021 ²³ China	Up to July 2021 PubMed, Embase, Cochrane library, Web of Science	Inclusion criteria: people histologically diagnosed with low rectal cancer; robotic- assisted rectal cancer surgery (experimental group) vs. laparoscopic rectal cancer surgery (control group); studies with data on feasibility, safety, clinical efficacy, short-term oncological outcomes; any language Exclusion criteria: duplicate articles, review articles, comments, correspondence, meta- analyses, irrelevant topics, case reports, unable to extract data on people with low rectal cancer, overlapping data	5 studies (all retrospective cohort) Robotic: 273 Laparoscopic: 237	NOS	Intraoperative blood loss, operative time, number of LNs retrieved, CRM, distal resection margin, conversion rate, time to first flatus, time to resume regular diet, length of hospital stay, complications

Abbreviations: CBMdisc, China Biology Medicine disc; CNKI, China National Knowledge Infrastructure; Cochrane RoB, Cochrane Risk-of-Bias Tool for Randomized Trials; CRM, circumferential resection margin; DFS, disease-free survival; FSFI, Female Sexual Function Index; IIEF, International Index of Erectile Function; IPSS, International Prostate Symptom Score; LN, lymph node; NOS, Newcastle– Ottawa Scale; NR, not reported; OS, overall survival; QALY, quality-adjusted life-year; RCT, randomized controlled trial; ROBINS-I, Risk of Bias in Non-randomised Studies – of Interventions; TME, total mesorectal excision.

Table A2: Characteristics of the Included Randomized Controlled Trial

Author, year	N	Study details	Age (y), mean ± SD	Male, n (%)	Follow-up
Park et al, 2023 ²⁵	Robotic: 151 Laparoscopic: 144	Inclusion criteria: Adult (≥ 18 y) with newly diagnosed middle or low rectal cancers without systemic metastases, rectal adenocarcinoma located < 10 cm from the anal verge Exclusion criteria: did not give informed consent; tumours invading adjacent organs (cT4b); severe concomitant diseases that might limit protocol compliance or completion; presented with an acute surgical emergency, including intestinal perforation or obstruction; history of any other malignancy	Robotic: 65.5 ± 11.4 Laparoscopic: 67.2 ± 10.1 <i>P</i> = .170	Robotic: 97 (64.2%) Laparoscopic: 99 (68.8%) P = .412	2γ

Appendix 6: Critical Appraisal of Clinical Evidence

Table A3: Risk of Bias in the Included Systematic Reviews (AMSTAR 2)

Item Description	Flynn et al, 2022 ¹⁴	Flynn et al, 2023 ¹³	Khajeh et al, 2023 ¹⁵	Liu et al, 2021 ¹⁶	Martins et al, 2023 ²⁴	Ryan et al, 2021 ¹⁷	Safiejko et al, 2021 ¹⁸	Seow et al, 2023 ¹⁹	Tang et al, 2021 ²⁰	Wang et al, 2020 ²²	Yang and Zhou, 2023 ²⁶	Yao et al, 2023 ²¹	Zhang et al, 2021 ²³
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	No	No	Partial yes	Partial yes	No	No	Partial yes	No	No	No	Partial yes	No	No
3. Did the review authors explain their selection of the study designs for inclusion in the review?	No	No	No	No	No	No	No	No	Yes	No	No	No	No
4. Did the review authors use a comprehensive literature search strategy?	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes
5. Did the review authors perform study selection in duplicate?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
6. Did the review authors perform data extraction in duplicate?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
7. Did the review authors provide a list of excluded studies and justify the exclusions?	No	No	No	No	No	No	No	No	No	No	No	No	No
8. Did the review authors describe the included studies in adequate detail?	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes

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Item Description	Flynn et al, 2022 ¹⁴	Flynn et al, 2023 ¹³	Khajeh et al, 2023 ¹⁵	Liu et al, 2021 ¹⁶	Martins et al, 2023 ²⁴	Ryan et al, 2021 ¹⁷	Safiejko et al, 2021 ¹⁸	Seow et al, 2023 ¹⁹	Tang et al, 2021 ²⁰	Wang et al, 2020 ²²	Yang and Zhou, 2023 ²⁶	Yao et al, 2023 ²¹	Zhang et al, 2021 ²³
9. Did the review authors use a satisfactory technique for assessing the risk of bias in individual studies that were included in the review?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
10. Did the review authors report on the sources of funding for the studies included in the review?	No	No	No	No	No	No	No	No	No	No	No	No	No
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	Yes	No meta- analysis conducted	No	Yes	No meta- analysis conducted	Yes	No	Yes	No	Yes	No	Yes	No
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	No	No meta- analysis conducted	Yes	No	No meta- analysis conducted		No	No	No	No	No	No	No
13. Did the review authors account for risk of bias in individual studies when interpreting/ discussing the results of the review?	Yes	Yes	Yes	No	No	No	Yes	Yes	No	No	No	Yes	No
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	No	No	Yes	No	Yes	No	No	No	No	No	No	No	No
15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	No	No meta- analysis conducted	Yes	No	No meta- analysis conducted	Yes	Yes	No	Yes	Yes	No	No	No

Item Description	Flynn et al, 2022 ¹⁴	Flynn et al, 2023 ¹³	Khajeh et al, 2023 ¹⁵	Liu et al, 2021 ¹⁶	Martins et al, 2023 ²⁴	Ryan et al, 2021 ¹⁷	Safiejko et al, 2021 ¹⁸	Seow et al, 2023 ¹⁹	Tang et al, 2021 ²⁰	Wang et al, 2020 ²²	Yang and Zhou, 2023 ²⁶	Yao et al, 2023 ²¹	Zhang et al, 2021 ²³
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes
Overall	Low	Low	Moderate	Low	Moderate	Low	Moderate	Low	Low	Low	Low	Low	Low

Note: for further details on AMSTAR scoring, see Shea et al.¹¹

Abbreviations: AMSTAR, A Measurement Tool to Assess Systematic Reviews, version 2; PICO, population, intervention, comparator, outcome.

Table A4: Risk of Bias in the Included Randomized Controlled Trial (Cochrane Risk-of-Bias Tool)

Author, year	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Incomplete outcome data	Selective reporting	Other bias
Park et al, 2023 ²⁵	Low	Low	Low	Low	Low	Highª

Note: The possible risk-of-bias levels are low, high, and unclear. For further details on the Cochrane Risk-of-Bias Tool, see Higgins et al.¹²

^aThe RCT was ended prematurely owing to difficulty recruiting participants.

Appendix 7: Ongoing Studies

Table A5: Robotic-Assisted vs. Laparoscopic or Open Rectal Cancer Surgery—Ongoing Studies

ClinicalTrials.gov ID	Title	Comparator(s)	Country	Study design	Enrolment	Anticipated completion date
NCT04404673	Urinary and Sexual Dysfunctions Evaluation After Rectal Resection (EURECA)	Laparoscopic, open	Italy	Prospective observational	Estimated: 1,172	February 2024
NCT03574493	Rectal Surgery Evaluation Trial (RESET)	Laparoscopic, open	France	Prospective observational	Actual: 1,098	December 2024
NCT06105203	RATME vs LATME in Middle and Low Rectal Cancer	Laparoscopic	China	RCT	Estimated: 1,026	January 2026

Abbreviations: RCT, randomized controlled trial; LATME, laparoscopic total mesorectal excision; RATME, robotic-assisted total mesorectal excision.

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About Us

We are an agency created by the Government of Ontario to connect, coordinate, and modernize our province's health care system. We work with partners, providers, and patients to make the health system more efficient so everyone in Ontario has an opportunity for better health and well-being.

For more information about Ontario Health, visit OntarioHealth.ca.

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Ontario Health is committed to advancing equity, inclusion and diversity and addressing racism in the health care system. As part of this work, Ontario Health has developed an <u>Equity</u>, <u>Inclusion</u>, <u>Diversity</u> and <u>Anti-Racism Framework</u>, which builds on existing legislated commitments and relationships and recognizes the need for an intersectional approach.

Unlike the notion of equality, equity is not about sameness of treatment. It denotes fairness and justice in process and in results. Equitable outcomes often require differential treatment and resource redistribution to achieve a level playing field among all individuals and communities. This requires recognizing and addressing barriers to opportunities for all to thrive in our society.

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