

BMJ Open Cost analysis of the use of digital rectoscopy versus flexible sigmoidoscopy in rectal cancer patients undergoing watch and wait

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ABSTRACT

Introduction and objective Organ preservation strategies for rectal cancer following neoadjuvant treatment require intensive endoscopic monitoring to detect early luminal recurrence. This is termed 'Watch and Wait' (WAW). Standard protocols commonly mandate flexible sigmoidoscopy every 3–4 months for 2 years. Digital proctoscopy with the LumenEye device has been shown to be a safe alternative that can be performed in an outpatient setting without the need for sedation and with less staffing requirements. The study objective is to evaluate the economic implications of using digital proctoscopy compared with flexible sigmoidoscopy for patients with rectal cancer managed under a WAW protocol.

Setting and design The study was conducted in a secondary care National Health Service (NHS) setting. A cost comparison analysis was performed over a 2 year time horizon (seven procedures per patient). 177 procedures on rectal cancer patients undergoing WAW with digital proctoscopy between August 2023 and November 2024 were included. The control group, that is, flexible sigmoidoscopy was modelled. The base case was flexible sigmoidoscopy without sedation. Scenarios using sedation were also evaluated. Costs were categorised into fixed and variable costs. A one-way sensitivity analysis, probabilistic sensitivity analysis and What-If scenarios were also performed.

Outcome measures and results The primary outcome was the minimum cost difference between the two procedures. The secondary outcome measure was the robustness of the cost differences. Over 2 years, the total cost per patient was £768.92 (95% CI £656.6 to £900.7) for digital proctoscopy compared with £1,588.15 (95% CI £1458.1 to £1725.2) for flexible sigmoidoscopy without sedation. The absolute minimum cost saving per patient is £820.23 (95% CI £648.7 to £985.1). Cost savings increased to £848.94 (95% CI £677.20 to £1013.83) to £935.62 (95% CI £761.02 to £1103.08) when sedation was used in flexible sigmoidoscopy procedures. Personnel costs during the procedure and recovery phase were the dominant cost drivers for flexible sigmoidoscopy. Probabilistic sensitivity analysis and What-If scenarios confirmed the robustness of the findings, with flexible sigmoidoscopy remaining more costly.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study uses real-world resource utilisation data and contemporary UK unit costs.
- ⇒ Costs were disaggregated into fixed and variable components.
- ⇒ Key drivers were explored using one-way sensitivity analyses while probabilistic sensitivity analysis and What-If scenarios demonstrated the robustness of the findings and model structure.
- ⇒ The analysis was conducted over a clinically relevant 2 year horizon, enhancing the practical relevance of the results for service planning.
- ⇒ Some cost estimates were derived from local NHS data and may vary across institutions depending on staffing models, throughput and procurement contracts. This, in addition to inflationary pressures and rapid changes in staffing and consumable costs may limit the temporal generalisability of the absolute cost estimates. Structural variability across institutions internationally may further limit generalisability.

Conclusion Digital proctoscopy with the LumenEye device is a cost-saving alternative to flexible sigmoidoscopy for patients with rectal cancer on a WAW protocol. Our findings support the integration of digital proctoscopy into WAW pathways as a cost-efficient alternative within resource-constrained healthcare systems. Endoscopy service pressures are also likely to be alleviated.

INTRODUCTION

Although surgery remains the gold standard curative modality for rectal cancer, there has been an increasing shift towards organ preservation with neoadjuvant chemoradiotherapy in selected patients. This strategy is termed 'Watch and Wait (WAW)'.¹ A key part of the WAW strategy is enhanced clinical evaluation of the rectum to detect luminal recurrence early as in a proportion of patients with an initial complete clinical and radiological response, it will recur and require surgical

Table 1 Resource use items and associated costs, uncertainty ranges and distributional assumptions used in the cost comparison, one way sensitivity analysis (OWSA), probabilistic sensitivity analysis (PSA) and What-If scenarios

Resource item	Unit cost (£)	OWSA low (-20%)	OWSA high (+20%)	PSA distribution	Additional notes and references for cost information sources
Variable costs					
1. Personnel - Procedure					
Specialist Colorectal Surgeon (Associate Specialist grade) – digital proctoscopy	£21.27	£17.02	£25.52	Gamma: CV 15%	Note: 100 clinics, 4 hours per clinic Reference: NHS Employers: Consultant Contracts ²⁰
Consultant surgeon or gastroenterologist – flexible sigmoidoscopy*	£31.90	£25.52	£38.28	Gamma: CV 15%	Note: 100 sessions, 4 hours per session Reference: NHS Employers: Consultant Contracts ²⁰
Endoscopy Staff nurse (Band 5)*	£48.00	£38.40	£57.60	Gamma: CV 10%	Note: Average 40 min per procedure Reference: NHS Employers, Agenda for change. ²¹
Healthcare Assistant (Band 4)	£40.00	£32.00	£48.00	Gamma: CV 10%	Note: Average 30 min per procedure. Reference: Unit Costs of Health and Social Care 2024: Manual ²²
Medical secretary	£11.48	£9.18	£13.78	Gamma: CV 10%	Note: Average 10 min per procedure. Reference: Unit Costs of Health and Social Care 2024: Manual ²²
Receptionist	£11.48	£9.18	£13.78	Gamma: CV 10%	Note: Average 10 min per procedure. Reference: Unit Costs of Health and Social Care 2024: Manual ²²
Personnel – Recovery*					
Endoscopy staff nurse (Band 5)	£48.00	£38.40	£57.60	Gamma: CV 10%	Note: Average 30 min per procedure Reference: NHS Employers, Agenda for change. ²¹
Healthcare Assistant (Band 4)	£40.00	£32.00	£48.00	Gamma: CV 10%	Note: Average 30 min per procedure. Reference: Unit Costs of Health and Social Care 2024: Manual ²²
2. Consumables					
Digital proctoscopy consumable	£39.00	£31.20	£46.80	Gamma: CV 20%	SurgEase LumenEye Brochure ²³
Inco pad	£0.23	£0.18	£0.27	Gamma: CV 10%	Note: 25 units per pack at £5.68 Reference: E-procurement Local Database
Optilube	£0.36	£0.29	£0.43	Gamma: CV 10%	Note: 1/10 box per procedure, box at £3.56 Reference: E-procurement Local Database
Scope washing and decontamination*	£20.46	£16.37	£24.55	Gamma: CV 10%	Reference: E-procurement Local Database
Enema kit	£18.09	£14.47	£21.71	Gamma: CV 10%	Reference: E-procurement Local Database
Biopsy forceps	£3.80	£3.04	£4.56	Gamma: CV 10%	Reference: E-procurement Local Database

Continued

Table 1 Continued

Resource item	Unit cost (£)	OWSA low (-20%)	OWSA high (+20%)	PSA distribution	Additional notes and references for cost information sources
Biopsy sample pots	£0.36	£0.29	£0.43	Gamma: CV 10%	Note: 25 units at £9.0 Reference: E-procurement Local Database
3. Medications					
Eutectic Mixture of Local Anaesthetics (EMLA) 5%	£17.00	£13.60	£20.40	Gamma: CV 10%	Reference: British National Formulary ⁵
Instillagel	£2.20	£1.76	£2.64	Gamma: CV 10%	Reference: British National Formulary ⁵
Sedation: Scenario 2: Penthrox only*	£22.15	£17.72	£26.58	Gamma: CV 5%	Reference: British National Formulary ⁵
Sedation: Scenario 3: Midazolam*	£7.34	£5.87	£8.81	Gamma: CV 5%	Reference: British National Formulary ⁵
Sedation: Scenario 4: Penthrox and Midazolam*	£29.49	£23.59	£35.39	Gamma: CV 5%	Reference: British National Formulary ⁵
Fixed costs					
Service and Amortisation					
Digital proctoscopy (LumenEye) service	£3.33	£2.67	£4.00	Gamma: CV 10%	Note: 600 procedures per year at £2000 per year ²³
Digital proctoscopy (LumenEye) device	£5.36	£4.29	£6.43	Gamma: CV 10%	Amortised for 7 years as capital medical equipment. 600 procedures per year at £22 500 per unit Reference: Assets in Action ²⁴
Flexible sigmoidoscope*	£27.35	£21.88	£32.82	Gamma: CV 10%	Amortised for 10 years as capital medical equipment. 400 procedures at £54 708 per unit. 2 units required per session. Reference: Assets in Action ²⁴
Endoscopic Stack*	£21.25	£17.00	£25.50	Gamma: CV 10%	Amortised for 10 years as capital medical equipment. 400 procedures per year at £85 000 per unit. Reference: Assets in Action ²⁴
Proportion Parameters for PSA and assumption testing					
Biopsy rate	12.4%	5%	30%!	Beta (22.155)	Observed. See methodology section
Enema use rate for Digital proctoscopy	80.8%	0%!	100%!	Beta (143.34)	Observed. See methodology section
Sedation rate for flexible sigmoidoscopy	56.3%	30%!	80%!	Beta (99.6,77.4)	Department records. See methodology section
*=Unit cost for Flexible sigmoidoscopy only. Low/High values is +/-20% of the base case for unit costs. != plausible clinical range used in 'What-If' scenarios instead of +/-20%. CV is the co-efficient of variation used to parameterise the gamma distribution in PSA. Beta is (successes + 0.5, failures + 0.5). CV, coefficient of variance; NHS, National Health Service.					

resection. Identifying these patients in a timely fashion is critical for good outcomes. However, there is no standardised protocol for this enhanced evaluation of the rectum. Most institutions report performing flexible sigmoidoscopy every 3–4 months for the first 2 years.^{1–3} This has resulted in an increased demand on endoscopy services, which may not have the capacity to cope.

LumenEye is a novel digital rigid proctoscope capable of visualising the rectum, capturing high-definition videos and images and performing biopsies if required. Furthermore, fewer personnel are required to perform digital proctoscopy with this device, compared with flexible sigmoidoscopy, and sedation is not required. We hypothesise that using digital proctoscopy in this cohort

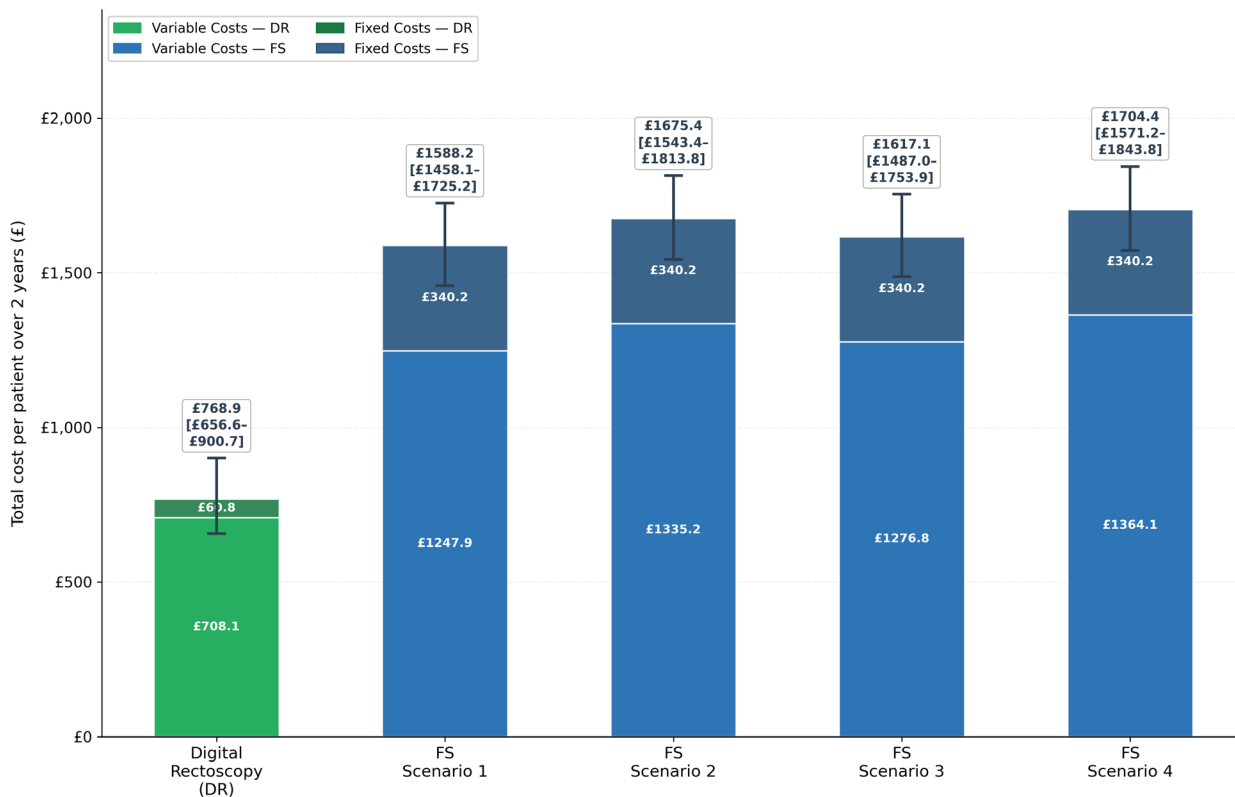


Figure 1 Total cost per patient over 2 years of Watch and Wait (WAW) protocol. FS: flexible sigmoidoscopy. DR: digital proctoscopy. Scenario 1 is no sedation used, Scenario 2 is Pentrox only, Scenario 3 is Midazolam 2 mg in 2 ml and Scenario 4 is Pentrox and Midazolam 2 mg in 2 ml. Error bars=95% credible intervals from probabilistic sensitivity analysis.

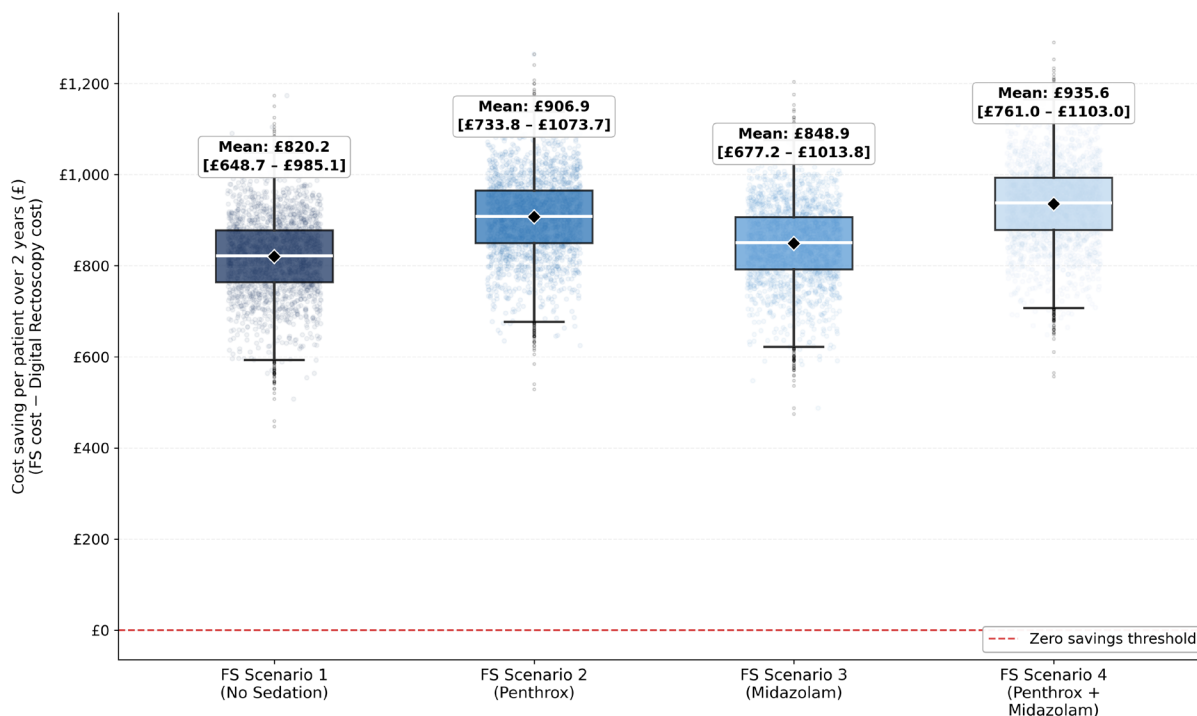


Figure 2 Cost savings per patient with digital proctoscopy compared with flexible sigmoidoscopy (FS) over 2 years of the Watch and Wait (WAW) protocol. Box plots show the median (white line), mean (diamond), interquartile range (box) and 5th to 95th percentile (whiskers) from the probabilistic sensitivity analysis. Scenario 1 is no sedation used, Scenario 2 is Pentrox only, Scenario 3 is Midazolam 2 mg in 2 ml and Scenario 4 is Pentrox and Midazolam 2 mg in 2 ml.

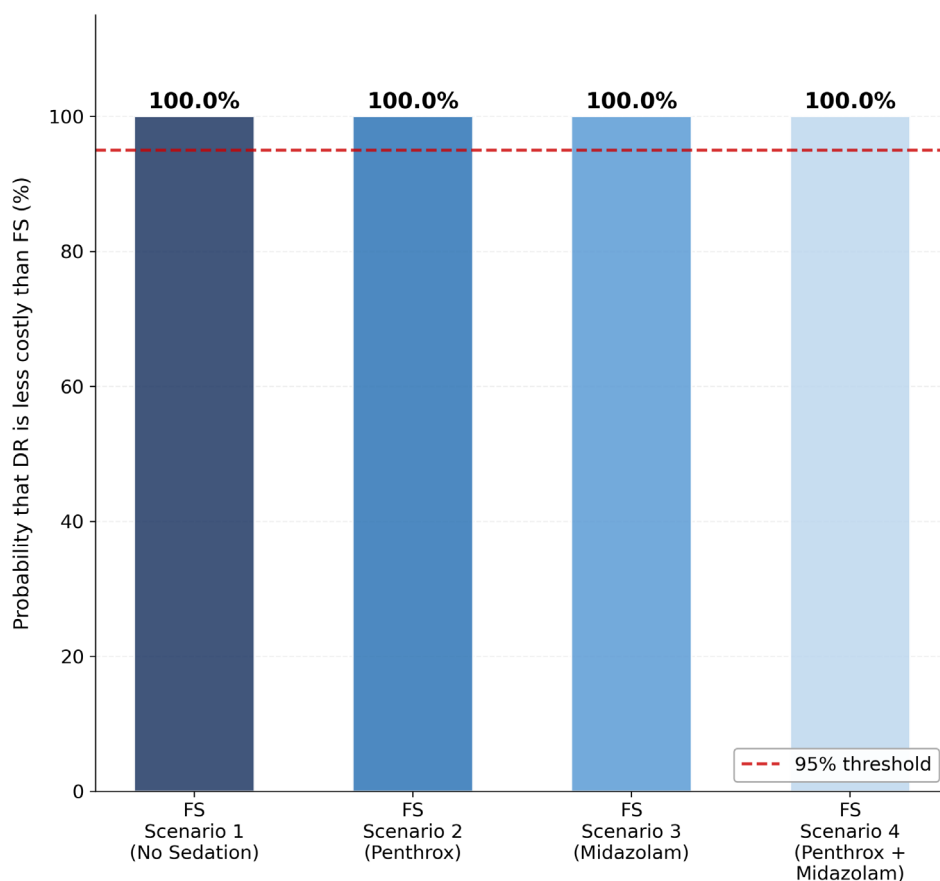


Figure 3 Proportion of 10000 Monte Carlo simulations in which digital proctoscopy (DR) total cost was lower than each flexible sigmoidoscopy (FS) scenario. Scenario 1 is no sedation used, Scenario 2 is Pentrox only, Scenario 3 is Midazolam 2 mg in 2 ml and Scenario 4 is Pentrox and Midazolam 2 mg in 2 ml.

of patients, instead of flexible sigmoidoscopy, would not only improve the demand on Endoscopy services but save costs in an already struggling National Health Service (NHS).

At our trust, we offer digital proctoscopy (with LumenEye) evaluation of the rectum every 3 months for 2 years to patients with rectal cancer who achieve clinical and radiological complete response and are being managed under the WAW pathway. Our protocol is available in online supplemental appendix 1. We have established a digital proctoscopy clinic run by a single Specialist Colorectal Surgeon (Associate specialist grade) who is independent in Lower Gastrointestinal Endoscopy and is part of the Colorectal Multidisciplinary Team (MDT). This surgeon performs the procedure in the presence of/with the assistance of a single Healthcare assistant and also ensures compliance with the rest of the WAW protocol. Patients ideally receive an enema prior to the procedure in the outpatient department. Sedation is not required and therefore there is no post-procedure recovery. We have previously shown that using digital proctoscopy with the LumenEye device in this cohort of patients is safe.⁴

The primary aim of this economic evaluation is to determine if digital proctoscopy is more cost effective

than flexible endoscopy in patients with rectal cancer undergoing WAW.

PATIENTS AND METHODS

Groups compared

- Those undergoing digital proctoscopy: These patients have been previously reported on.⁴ In summary, between August 2023 and November 2024, 177 digital proctoscopy procedures using the LumenEye device were performed on patients with rectal cancer on the WAW pathway, as per the protocol (online supplemental appendix 1), to monitor for local recurrence. These patients had a mean age of 69.47 ± 12.41 (33-93). 67.2% were male and 32.8% were female. 80.8% (143/177) had an enema prior to the procedure. All procedures were performed in the outpatient clinic by the SAS surgeon with one assistant (Band 4 healthcare assistant). These patients are checked in by the receptionist on arrival. The clinics run twice a week. On average, eight digital proctoscopy procedures are performed in a half-day clinic session. The time spent per patient was deduced by interview process, for example, 30 minutes per procedure

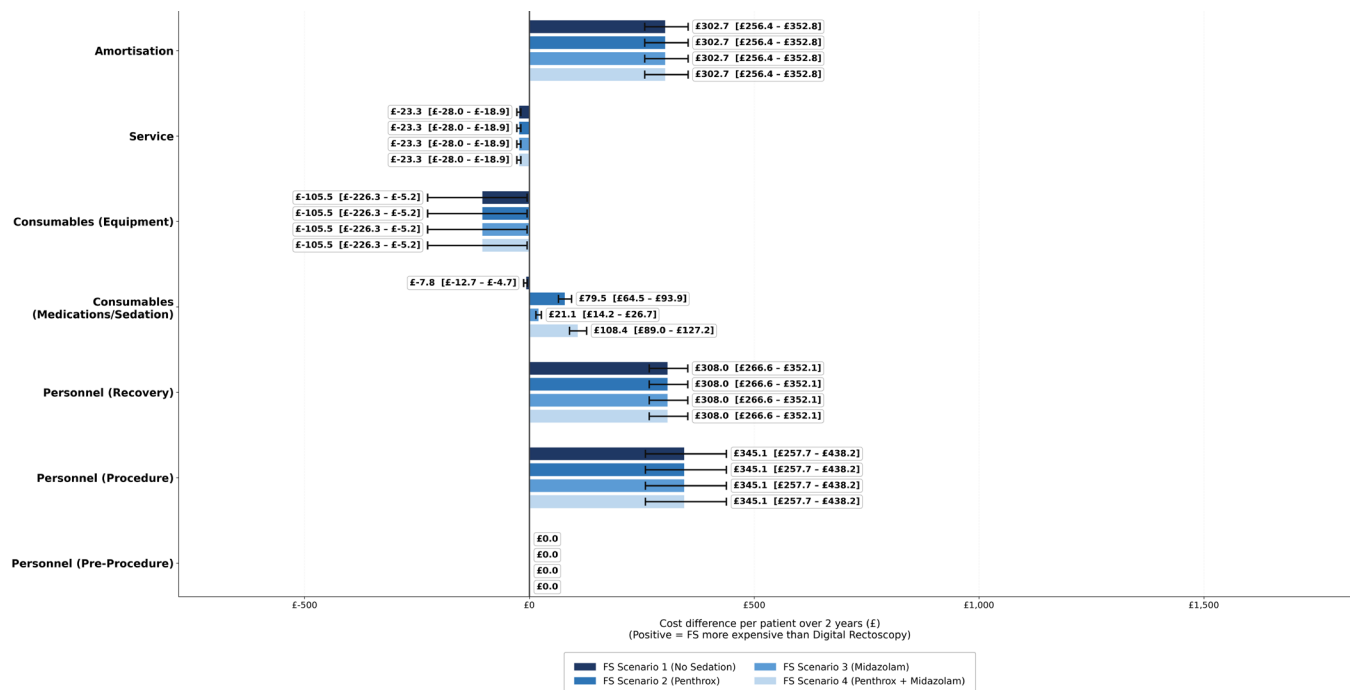


Figure 4 Cost component differences between flexible sigmoidoscopy (FS) compared with digital proctoscopy (DR) over 2 years of Watch and Wait (WAW) protocol as per the probabilistic sensitivity analysis. Bars show base case mean cost difference. Error bars=95% credible intervals. Positive values indicate that DR is cheaper than FS. Negative values indicate that DR is more expensive than FS. Scenario 1 is no sedation used, Scenario 2 is Pentrox only, Scenario 3 is Midazolam 2 mg in 2 mls and Scenario 4 is Pentrox and Midazolam 2 mg in 2 ml.

for the healthcare assistant/clinical support worker and 10 minutes for the receptionist. There is no post-procedure recovery. 12.4% (22/177) required a biopsy for signs of potential local recurrence. 20.3% (36/177) experienced pain, with eight requiring topical 5% Eutectic Mixture of Local Anaesthetics and 28 requiring Instillagel. All patients had Optilube assisted per rectal digitation as standard prior to any rectal instrumentation. There were three occurrences of minor bleeding not requiring any further intervention. There were no occurrences of infection or perforation. There was one episode of missed local recurrence detected 3 months later on flexible sigmoidoscopy. Patients were followed up for a mean of 217.3 days (Range: 93–478).

2. Those undergoing flexible sigmoidoscopy:

Prior to the establishment of this clinic, these patients would have undergone 3-monthly flexible sigmoidoscopy in the endoscopy department, with those requiring biopsy also receiving this in the endoscopy suite. Therefore, analysing an independent sample was unnecessary. We modelled the same cohort under flexible sigmoidoscopy conditions, that is, 100% would be checked in by a receptionist on arrival, 100% would have received a pre-procedure enema, and 100% would receive optilube assisted per rectal digitation. In our endoscopy department, 56.3% of patients receive conscious sedation with either Midazolam 2 mg or Entonox/Pentrox. Modelling the flexible sigmoidoscopy arm to the digital proctoscopy arm and standard NHS endoscopy practice in this way makes the model comparable and

generalisable. The procedures for WAW patients with rectal cancer were performed by a colorectal surgeon or a gastroenterologist. There are two assistants per procedure (one nurse and one healthcare assistant). Post-procedure, patients will proceed to recovery, which is manned by one nurse and one healthcare assistant. Endoscopy nurses are usually band 5 and healthcare assistants are band 4. The time spent per procedure was deduced by interview process, for example, 40 min for the endoscopy nurse and 10 min for the receptionist.

Costs and resources used

Costs are from the perspective of the NHS in the UK and for the years 2022–2024. Costs are expressed in Great British pounds (£). Costs were calculated as a product of the resource use quantity and unit costs of the respective resource use component. Costs are divided into variable and fixed costs. Variable costs for both groups include personnel costs (procedure and recovery) and consumables (equipment and medications) used. Fixed costs for both groups include administration costs, service and amortisation costs. An overview of unit costs and cost information sources can be found in [table 1](#).

Assumptions regarding costs made include

1. Each clinic or endoscopy list is one PA of the clinician's time. This is costed at 12 661.60 per annum. In 1 year, there are 100 digital proctoscopy and flexible sigmoidoscopy lists with 600 and 400 procedures performed, respectively.

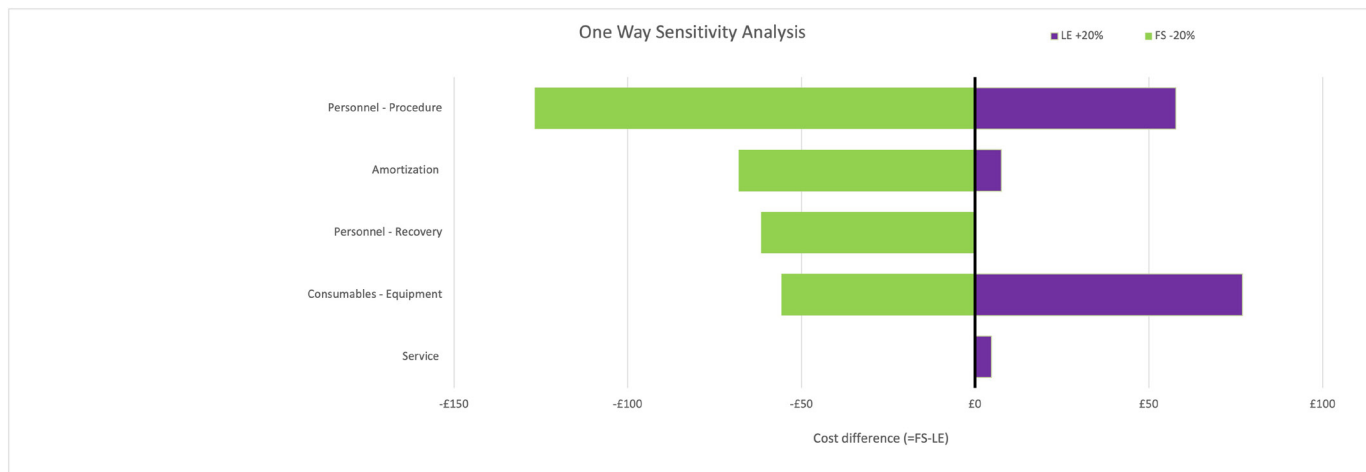


Figure 5 Tornado Diagram depicting the one-way sensitivity analysis. FS, flexible sigmoidoscopy; LE, LumenEye.

- The proportion of patients that had biopsies on digital proctoscopy would be the same if they underwent flexible sigmoidoscopy.
- Fixed building costs to run a digital proctoscopy clinic and a flexible sigmoidoscopy list are equal and therefore not included in the analysis.
- For each patient requiring sedation with Midazolam, only one cannula is placed. Placement of a single cannula requires a single 18 Gauge Safety Draw up needle, Blue Nitrile gloves, Disposable button tourniquet, 22 Gauge BBraun Vasofix Cannula, 3M Tegaderm Peripheral Intravenous dressing, Alcohol Chlorhexidine 2% Skin wipes, two BD Emerald 10mL syringes and two 10mL 0.9% Sodium Chloride flush. This cost has been obtained from the British National Formulary⁵ and is included in the sedation scenario cost.

Statistics

Analysis and reporting are in keeping with the NICE guidance on health technology evaluations⁶ and Consolidated Health Economic Evaluation Reporting Standards (CHEERS) 2022⁷, respectively. A cost-comparison analysis is performed as digital proctoscopy with LumenEye provides similar health benefits (procedure tolerance, complications and missed pathology rates) to flexible sigmoidoscopy in these patients.^{4 8 9} The sensitivity and specificity for the detection of rectal cancer has been shown to be 100% and 100%, respectively, with LumenEye digital proctoscopy.⁹

The primary outcome is the cost difference between the two procedures per patient, over a 2 year horizon. The hypothesis is that digital proctoscopy will be cheaper. A probabilistic sensitivity analysis (PSA) and one way sensitivity analysis (OWSA) are performed to determine the robustness of this cost difference and the primary cost drivers respectively. As per the WAW protocol (online supplemental appendix 1), patients have digital proctoscopy (traditionally Flexible Sigmoidoscopy) every 3 months for 2 years, with the 1 year procedure being a

colonoscopy. All costs per patient are therefore extrapolated to seven procedures over 2 years.⁴

Cost calculations and sensitivity analyses were performed in RStudio (Version 11403). The base case is digital proctoscopy compared with flexible sigmoidoscopy without sedation. Different sedation strategies were assessed including penthrox only (sedation scenario 2), midazolam only (sedation scenario 3) and a combination of both (sedation scenario 4). PSA was performed to simultaneously quantify uncertainty across all parameters. The PSA was conducted using Monte Carlo simulation (10 000 iterations). Cost inputs were assigned gamma distributions, which is the conventional approach for costs in health economic models.¹⁰ The gamma distribution was parameterised from the mean and coefficients of variance (CV). The different CV reflect the varying levels of uncertainty across resource items. Lower CVs (5%) were applied to medications with stable national pricing while higher CVs (10–20%) were used for personnel and specialised consumables where greater variation in pay band ranges, resource use or procurement price variation is known. Proportions (biopsy rate, enema use and sedation rate) were assigned beta distributions. Beta distributions were parameterised from observed event counts or departmental records. Uncertainty ranges and distribution is summarised in table 1. In each simulation, all parameters were sampled simultaneously from their assigned distributions over the 2 year horizon. The 2.5th and 97.5th percentiles of the resulting distributions constitute the 95% credible intervals (95% CI). The probability that digital proctoscopy is less costly than each flexible sigmoidoscopy scenario was calculated as the proportion of simulations in which digital proctoscopy total cost was lower.⁵ Cost drivers (procedure personnel costs, consumable costs and amortisation costs) will be varied by 20% in the OWSA (table 1).

Key assumptions on which the model is based were analysed using “What-If scenarios” to determine structural sensitivity. Clinically plausible ranges were tested

Table 2 Assumption testing to determine structural sensitivity

	Description	Total cost per procedure over 2 years	Cost difference vs FS base case
What-If 1: Low throughput	DR throughput reduced to 400 procedures/year (matching FS).	£1,084.59	-£503.56
What-If 2: DR High Biopsy Rate	Observed biopsy rate (12.4%) increased to 30%.	£775.21	-£812.94
What-If 3: DR High Enema use Rate	Observed enema use rate (80.8%) for DR increased to 100%	£793.00	-£795.15
What-If 4: FS Low Sedation Rate	Observed sedation rate (56.3%) for FS decreased to 30%*.	£1547.41	-£778.49

DR, digital proctoscopy; FS, flexible sigmoidoscopy.

here. What-If scenario 1 looked at decreasing digital proctoscopy throughput to 400 procedures per year (from 600/year). This is equivalent to the flexible sigmoidoscopy throughput. What-If scenario 2 looked at increasing biopsy rates for digital proctoscopy from 12.4% to 30%. What-If scenario 3 looked at increasing enema usage for digital proctoscopy from 80.8% to 100%. What-If scenario 4 looked at decreasing sedation usage for flexible sigmoidoscopy from 56.3% to 30%. A weighted average approach for the sedation costings was used here based on the sedation scenarios that is, cost of sedation per procedure over 2 years is (30% x average cost of sedation scenarios 2–4) + (70% x cost of Flexible Sigmoidoscopy without sedation).

RESULTS

Over a 2year WAW period comprising seven procedures, the total cost per patient was substantially lower for digital proctoscopy compared with flexible sigmoidoscopy, irrespective of sedation strategy. The total cost per patient was £768.92 (95% CI £656.6 to £900.7) for digital proctoscopy, £1,588.15 (95% CI £1458.1 to £1725.2) for flexible sigmoidoscopy without sedation, £1,675.44 (95% CI £1543.4 to £1813.8) for flexible sigmoidoscopy with pentrox, £1,617.08 (95% CI £1487.0 to £1753.9) for flexible sigmoidoscopy with midazolam and £1,704.37 (95% CI £1571.2 to £1843.8) for flexible sigmoidoscopy with pentrox and midazolam (figure 1). Our base case is flexible sigmoidoscopy without sedation (Scenario 1) compared with digital proctoscopy. The absolute cost difference is £820.23 (95% CI £648.7 to £985.1). This equates to flexible sigmoidoscopy being at least 2.07 times (95% CI 1.62 times to 2.63 times) more costly than digital proctoscopy over the 2year horizon (figure 1). Mean cost savings increase with varying sedation scenarios (figure 2). Digital proctoscopy remains less expensive than all flexible sigmoidoscopy scenarios in all 10000 Monte Carlo iterations (probability=1.0) (figure 3). The cost advantage of digital proctoscopy is extremely robust to parameter uncertainty.

The higher costs associated with flexible sigmoidoscopy are driven by personnel costs required to perform

the procedure and in the recovery period (figure 4). Per patient over 2 years, flexible sigmoidoscopy procedure personnel costs are £345.10 (95% CI: £257.7-£438.2) more expensive than digital proctoscopy. Per patient over 2 years, flexible sigmoidoscopy recovery personnel costs are £308.00 (95% CI £266.6 to £352.1), more expensive than digital proctoscopy. Digital proctoscopy costs exceeded flexible sigmoidoscopy costs in equipment related consumable costs and service costs. The cost difference per patient is £105.46 (95% CI £5.2 to 226.3) and £23.33 (95% CI £18.9 to 28.0), respectively, over the 2year horizon (figure 4). One-way sensitivity analysis performed by varying cost factors for both flexible sigmoidoscopy without sedation and digital proctoscopy by +/-20% showed no sign reversal and confirmed personnel costs as the main cost driver (figure 5).

The four What-If scenarios have shown that even when the model is stressed, digital proctoscopy remains dominant or cheaper than flexible sigmoidoscopy (table 2). Break-even analysis for throughput suggests that the digital proctoscopy clinic would need to be 77.5% less efficient, that is, a minimum of 180 procedures per year or 1.8 procedures per half day list, is required to achieve cost parity with flexible sigmoidoscopy.

DISCUSSION

This is the first economic evaluation comparing digital proctoscopy (LumenEye) with standard flexible sigmoidoscopy for patients with rectal cancer managed under the WAW strategy. Using an NHS perspective, we demonstrate that digital proctoscopy is associated with substantial cost savings over a 2year period (exceeding £800 per patient) in this population. These findings are particularly relevant in the context of increasing utilisation of WAW protocols (20% of rectal cancer patients are achieving a complete response post neoadjuvant treatment),¹¹ where patients undergo flexible sigmoidoscopy at least every 3–4 months for the first 2 years to monitor for local recurrence. In addition, due to concerns around stoma formation and decreased quality of life as a result of surgery, patients are increasingly declining curative surgery for the option of

WAW.¹² As WAW strategies are increasingly adopted internationally,^{13–15} the cumulative resource implications for endoscopy services are substantial, and alternative modalities warrant careful economic evaluation.

The principal driver of higher costs associated with flexible sigmoidoscopy was personnel-related expenditure, both during the procedure and in the post-procedure recovery phase. In contrast, digital proctoscopy clinics can be run with less staff and without the requirement for sedation. These structural differences translate into large and consistent cost differences, which remained robust in PSA. Furthermore, What-If analyses have shown that stressing the clinical and operational assumptions in favour of flexible sigmoidoscopy still favours digital proctoscopy as being cheaper. This robustness strengthens the internal validity of the findings and supports generalisability of the cost advantage of digital proctoscopy within similar NHS settings. Furthermore, this has important implications for service delivery. Beyond the substantial resource implications that WAW pathways put on endoscopy services, these departments are already under sustained pressure from workforce shortages and procedural backlogs.¹⁶ The ability to safely and cost-effectively perform rectal monitoring for local recurrence in an outpatient clinic setting represents a potentially transformative shift in resource utilisation. While digital proctoscopy incurred higher equipment-related consumable and service costs, these were modest when compared with the savings generated through reduced staffing requirements. When viewed holistically, the redistribution of costs away from personnel-intensive endoscopy suites towards streamlined outpatient monitoring may offer both economic and operational advantages such as the reallocation of endoscopy capacity to higher complexity diagnostic and therapeutic procedures. This could help endoscopy services better meet policy-driven early diagnosis expectations – such as those articulated in the NHS Long Term Plan¹⁷ – and support the UK government's 5 year commitment to reducing backlogs.^{18 19} In addition, this evaluation is grounded in real-world clinical practice. Real-world safety and tolerability data were incorporated into the costing model including the observed rates of biopsy, analgesic use, minor bleeding and absence of serious adverse events such as perforation or infection. Although we have previously reported one missed detection of local recurrence that was detected on flexible sigmoidoscopy, 3 months after a digital proctoscopy procedure, this does not negate the overall safety profile observed.⁴ The inclusion of these real-world adverse event rates strengthens the credibility of the economic analysis and avoids reliance on idealised assumptions.

The ability to perform the surveillance in a dedicated specialist colorectal clinic also allows for the same specialist clinician to perform all the subsequent procedures. It also allows for the same clinician to monitor and report the outcomes of the 3-monthly MRI and annual CT CAP scan results directly to the patient resulting in

enhanced patient satisfaction (results to be published). This is not possible in the endoscopy setting.

Our study does have several limitations. First, this was a cost-comparison analysis. A cost-effectiveness analysis incorporating quality-adjusted life years was not performed. Although this was appropriate given that digital proctoscopy with LumenEye and flexible sigmoidoscopy provide similar clinical information for rectal assessment within the WAW pathway, differences in patient experience or preference were not valued. Second, some cost estimates were derived from local NHS data and may vary across institutions depending on staffing models, throughput and procurement contracts which may limit external validity. Third, although costs were expressed in contemporary prices, inflationary pressures and rapid changes in staffing and consumable costs within the NHS may limit the temporal generalisability of the absolute cost estimates. Nevertheless, the relative cost differences observed are unlikely to be eliminated by inflation alone, as procedural personnel costs remain the dominant driver. Fourth, the flexible sigmoidoscopy comparator was modelled rather than derived from a matched cohort, although assumptions regarding sedation rates, staffing, post-procedure recovery and consumable use were based on standard departmental practice in the UK or mirrored from the digital proctoscopy cohort. Standard departmental practice in the UK may differ from other countries internationally. Finally, it must be mentioned that LumenEye is the only commercially available proctoscope with biopsy and recording capabilities that we are aware of. Costing for consumables is specific to this device and may vary if other devices are used.

Despite these limitations, this study provides timely and policy-relevant evidence supporting the economic viability of digital proctoscopy as a monitoring tool for rectal cancer patients undergoing WAW protocols. In an era of constrained healthcare resources and increasing cancer survivorship, innovations that maintain clinical safety while reducing demand on high-cost services are urgently needed. Future research should explore patient-reported outcomes and the scalability of digital proctoscopy-based monitoring for these patients across different healthcare systems.

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