

Robotic Colonoscopy: Comparative Analysis of Costs Compared to Painless Conventional Colonoscopy

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Research

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Abstract

Background

Among the various causes of death, colorectal carcinoma represents the second highest cause in frequency both in men and in women. A colorectal cancer is diagnosed every 3.5 minutes and a person dies of colorectal cancer every 9 minutes. In 2018, in Italy were recorded around 51.000 new cases, with a mortality rate of over 18.000 deaths. There is clear evidence demonstrating that the identification and treatment of cancer at an early stage positively influence the reduction in mortality. Colonoscopy is the most effective technique used to identify and remove polyps, thus avoiding the costs related to surgical treatment and hospitalization.

The purpose of this study is to evaluate the costs of the system Endotics for robotic colonoscopy as an alternative to conventional diagnostic colonoscopy performed under anaesthesia at the University Hospital of Pisa.

Methods

The cost analysis was developed according to the Budget Impact Analysis method application, an essential and complementary part of the Health Technology Assessment evaluation, which has the main purpose of assessing the financial sustainability of new health technology, estimating the consequences of its use and diffusion in a specific context characterized by the limited availability of resources. The observation period covered a time interval of 3 months, during which an average of 43 colonoscopic procedures per day was performed and mapped and a total of 23 colonoscopes were used.

Results

Overall, the work done has allowed identifying the cost of a conventional painless diagnostic colonoscopy performed in our institution which amounts to € 426.25. The valuation of the costs of the robotic colonoscopy amounted overall to € 441.25.

Conclusions

The ideal procedure to diagnose a colon disease should be safe, well-tolerated, possibly non-invasive, with high diagnostic accuracy and, not least, cost-effectiveness. The results of this study suggest that in the University Hospital of Pisa the costs related to robotic colonoscopy performed with the Endotics system are superimposable to those of conventional painless colonoscopy, reducing the overall risk associated with the colonoscopic procedure maintaining a high diagnostic accuracy with a greater tolerability by the patient, thus pushing the colonoscopy towards "the ideal procedure".

Background

Among the various causes of death, colorectal carcinoma (CRC) represents the second highest cause in frequency both in men (10.4%) and in women (12.4%). A CRC is diagnosed every 3.5 minutes and a person dies of CRC every 9 minutes [1]. Only in 2018, in Italy were recorded around 51,000 new cases of colorectal cancer, with a mortality rate of over 18,000 deaths [2]. The CRC is a disease characterized by the development of malignant cells in the epithelium of the large intestine. These malignant cells can invade the surrounding tissues locally or they can spread throughout the body. About one person in every 25 is likely to have, within his lifetime, a diagnosis of CRC [3]. There is clear evidence demonstrating that the identification and treatment of cancer at an early stage positively influence the reduction in mortality for CRC, especially when the removal of adenomatous polyps, precursors of the disease, is involved. In fact, the identification and removal of adenomas interrupt their progression towards malignancy, resulting in an outstanding 76-90% reduction in the incidence of the neoplasm [4]. Currently, colonoscopy is the most effective technique used to identify and remove polyps, thus avoiding the costs related to surgical treatment and hospitalization of the patient. CRC-related surgical and hospital costs fluctuate between € 15.40 (\$ 16.72) [5] and € 21.28 (\$ 23.11) [6] per patient. The costs related to the treatment of the disease are not limited to those mentioned above, but also include the procedure of investigation, diagnosis and Colonoscopy examination with all the phases related to the procedure, which are not insignificant costs and are often unknown. A 2014 study shows that the average cost for a single colonoscopy procedure in the US in 2010 was € 1.98 (\$ 2.15) for the population not covered in public welfare programs (Medicare) and € 986

(\$ 1,071) in the Medicare population [7]. In Italy, just for screening purposes, are performed approximately 120,000 colonoscopies every year [8], with a theoretical cost equivalent to about € 118 Million (\$ 128,520,000), costs calculated based on the data referred to in the American article of the Medicare population. The purpose of this study is to evaluate the costs of the system Endotics for robotic colonoscopy (once Endoscopy Srl, Peccioli (Pisa), Italy) [9, 10, 11] as an alternative to conventional diagnostic colonoscopy performed under anaesthesia at the University Hospital of Pisa (AOUP).

Methods

The cost analysis was developed according to the of Budget Impact Analysis (BIA) method application, an essential and complementary part of the Health Technology Assessment (HTA) evaluation, which has the main purpose of assessing the financial sustainability of new health technology, estimating the consequences of its use and diffusion in a specific context characterized by the limited availability of resources [12]. The BIA provides contextualizing of the data that gain significance by using the parameters related to the prospecting chosen for the analysis; Hence, the point of view adopted in this work was related to a public hospital perspective, consequently, the costs recorded were the direct health costs, that is, those that most influence the budget of a public hospital. The economic analysis relating to conventional painless diagnostic colonoscopy was divided into three cost detection phases: endoscopy reprocessing costs, anaesthesiologic costs and colonoscopic examination costs (Table 1).

Table 1. Conventional painless colonoscopy step.

Conventional painless colonoscopy step
Reprocessing step
Personal Protective Equipment (PPE) for reprocessing personnel
Bedside pre-cleaning
Leak testing
Manual cleaning
Visual inspection, cleaning verification and re-cleaning 20% of endoscopes
High-level disinfection (HLD) in Automated Endoscope Reprocessor (AER)
Drying end storage
Anaesthesia step
Pre-anaesthesia advice
Patient acceptance: delivery of questionnaires and assistance in filling in the questionnaires, entry of patient data and booking of the examination
Analysis of examinations completed by the anaesthetist
Anaesthesiologic advice
Pre-anaesthesia examinations
Personnel present during the anaesthesia procedure
Medical Devices
Drugs
Maintenance
Device amortization
Colonoscopy procedure step
Personnel present during the colonoscopy procedure
Medical Devices
Device amortization for one procedure
Device maintenance for one procedure
Ordinary maintenance
Extraordinary maintenance

The detection of the phases was carried out utilizing analytical records of the colonoscopy examinations carried out in the Endoscopic Ambulatory Service of the University Hospital of Pisa, through the use of the "Bill of Materials" (BOM), a cost detection tool adopted in our institution since 2011 and already widely used for the analysis of other costs. The evaluated macro-steps, summarized in Table 1, are derived from the synthesis of the analysis of all the micro-steps identifiable in the various phases. In this regard, in relation to the reprocessing of endoscopes, the recordings were made following the steps recommended by the guidelines for the correct execution of the procedure [13, 14] and on the example of the work published by Ofstead et al. [15]. The observation period covered a time interval of 3 months (September - November 2018), during which an average of 43 examinations per day was performed and mapped and a total of 23 colonoscopes were used. To economically evaluate the processes, materials and times referred to the various steps examined, reference was made to the costs sustained by the hospital in 2018, obtained by contacting the relevant hospital structures directly.

The economic evaluation of the robotic colonoscopy was performed according to the same method described above, with the difference that the only section to be mapped for the robotic colonoscopy was only the colonoscopy procedure, as the patient undergoing colonoscopy with the system Endotics it does not require anaesthesia and the procedure involves the use of a disposable sterile probe that does not require reprocessing. The macrosteps analysed are shown in Table 2.

Table 2. Robotic Colonoscopy procedure step.

Robotic colonoscopy procedure step
Personnel present during the colonoscopy procedure
Medical Devices
Device amortization for one procedure

Results

From the evaluation carried out it was found that the cost of the reprocessing of a single colonoscope in our institution is € 70.74, a value that falls within the range of costs reported in the Ofstead study. The data relating to the costs of reprocessing macro-steps are shown in detail in Table 3; in the section, the leaking test costs have been reported as € 0.00, given that this test is automatically carried out by the endoscopes sterilising machines and therefore inserted in the high-level disinfection (HLD) section, this section was higher than the highest value identified in the American analysis range.

Table 3. Reprocessing Step costs.

Reprocessing Step costs				
Step	Ofstead Minimum cost *	Ofstead Maximum cost *	AOUP cost	AOUP vs Ofstead
Reprocessing	€ 43.54	€ 132.34	€ 70.74	↔
PPE for reprocessing personnel	€ 4.36	€ 15.33	€ 5.05	↔
Bedside pre-cleaning	€ 3.84	€ 16.50	€ 7.13	↔
Leak testing	€ 2.27	€ 5.28	€ 0.00	↓
Manual cleaning	€ 9.59	€ 31.99	€ 18.48	↔
Visual inspection, cleaning verification and re-cleaning 20% of endoscopes	€ 12.60	€ 42.84	€ 11.88	↓
High Level Disinfection (HLD) in Autometad Endoscope Reprocessors (AER)	€ 9.26	€ 14.84	€ 24.31	↑
Drying end storage	€ 1.62	€ 5.56	€ 3.89	↔

*October 2018 exchange rate: 1 USD = 0.86166 Euro.

↔ in the range

↓below range

↑above range

The anaesthesiology phase is the one that has contributed the most to the valorization of the cost of the conventional pain-free colonoscopy, with a value of € 223.37 per patient treated (Table 4); the main expenditure item, in this case, was represented by

the cost of the healthcare personnel. The cost analysis of a colonoscopy phase showed an expense of € 132.14 for colonoscopy (Table 4); once more the main cost entry was the one attributed to the staff.

Table 4. Anaesthesia and conventional colonoscopy procedure step costs.

Anaesthesia and conventional colonoscopy procedure step costs	
Step	AOUP cost
Anaesthesia	€ 223.37
Pre-procedural consultancy	€ 27.42
Pre-procedural exams	€ 13.60
Staff present during the sedation procedure	€ 84.75
Medical Devices	€ 11.21
drugs	€ 2.62
Depreciation equipment	€ 3.30
Staff present in the awakening room	€ 80.47
Conventional painless colonoscopy	€ 132.14
Staff by procedure	€ 87.64
Medical Devices for procedure	€ 0.11
Amortization of equipment by the procedure	€ 35.45
Maintenance of equipment app by the procedure	€ 8.94

Overall, the work done has allowed identifying the cost of a conventional painless diagnostic colonoscopy performed in our institution which amounts to € 426.25. The valuation of the costs of the robotic colonoscopy amounted overall to € 441.25 (Table 5).

Table 5. Robotic colonoscopy step costs.

Robotic colonoscopy step costs	
Step	AOUP cost
Robotic colonoscopy	€ 441.25
Staff on procedure	€ 38.86
Endotics probe	€ 391.00
Endotics workstation rental fees per one procedure	€ 11.28
Medical Devices to procedure	€ 0.11
Depreciation of equipment and procedure	€ 0.00

The main expense item, in this case, was represented by the Endotics system and specifically by the disposable Endotics probe. It should be noted that the cost of the probe is related to the number of annual colonoscopies planned by the hospital centre; a substantial increase in the volume of annual procedure performed with the robotic technology could result in a further reduction in the cost of the medical devices. The workstation, monitor, controller parts of the system, which are multiuse, are provided through annual rental agreement; assuming the use of two workstations and considering the number of annual procedures programmed by the hospital, the rental fee of the device for each procedure amounts to € 11.28 (Table 5).

The comparison between the costs of robotic colonoscopy and those of painless conventional colonoscopy are shown in Figure 1.

Figure 1. Robotic Colonoscopy Costs vs Conventional Painless Colonoscopy Costs.

Legend:

//// Robotic Colonoscopy

|||| Conventional Painless Colonoscopy

Discussion

The ideal procedure to diagnose a colon disease should be safe, well-tolerated, possibly non-invasive, with high diagnostic accuracy and, not least, cost-effectiveness [16]. Despite at present colonoscopy performed with multiuse endoscopes with multipurpose is an examination performed routinely, the real cost associated with the procedure is not truly known. They are, in fact, very few papers published on the subject and these include the aforementioned study of Ofstead, which, however, provides partial data as it relates to the only phase of reprocessing of the tools and a recent analysis conducted by Larsen [17]. In this latter paper the authors found that the cost per colonoscopy including the purchasing, maintaining and reprocessing cost of the endoscopes, is within a range from € 173.72 (\$ 188.64) to € 461.52 (\$ 501.16) respectively for centres that perform at least 3,000 procedures and centres that perform 1,000 per year. The authors have analysed also the costs related to the development of post-procedural infections in patients undergoing traditional colonoscopy; in this case, an additional cost of € 18.53 (\$ 20.12) and € 42.84 (\$ 46.52) respectively are added to the previously reported values [17] rising the cost of colonoscopy without anaesthesia to € 192.25 (\$ 208.76) and € 504.36 (\$ 547.68). Furthermore, with regard to clinical efficacy, despite limited scientific evidence comparing conventional and robotic colonoscopy using the Endotics System, the most recent study about Endotics System reports 93.1% success of robotic colonoscopy in reaching the caecum in patients with a history of failure of conventional colonoscopy.

In just 7 subjects (6.9%) the exam was not completed; nevertheless, in 5 cases out of 7 it was possible to surpass the segment of the colon reached by traditional colonoscopy and in 2 cases the same intestinal tract was at least reached [9]. Furthermore, a relevant factor highlighted by the scientific evidence currently available is represented by the high level of tolerability of the robotic procedure by the patients. In 2010 a study of 71 patients undergoing colonoscopy with either techniques, reported the administration of midazolam and meperidine in 19.7% of patients treated with conventional colonoscopy, while no sedation was required when subjected to the procedure with the robotic system [10]. Potentially, this can be considered a predictive index of greater adherence to the diagnosis by the patient, whereas in Italy 20% of patients with Fecal Occult Blood Test (FOBT) positive do not undergo the subsequent colonoscopy [8]. A further positive element concerning robotic colonoscopy is represented by the data, recorded in normal clinical practice, related to the short learning curve necessary for the correct use of the medical devices; it is, however, necessary additional ad-hoc studies to confirm the significance of this figure. Despite conventional colonoscopy is currently the gold standard among the methods available for the screening of colorectal cancer [18], there are various risks factors associated to this type of procedure, ranging from cardiopulmonary complications [19, 20], the perforation of the colon [21, 22], to the risks associated with anaesthesia in painless conventional colonoscopy, especially if performed on paediatric patients or with comorbidities [23, 24]. Besides, the fact that anaesthesia is not required in robotic colonoscopy, determines a series of social-organizational and also economic advantages related to the patient: greater autonomy of the subject being examined, lack of influence of the procedure on the patient's driving ability, hence giving the possibility to the patient to come to examination unaccompanied, the ability to take important decisions or sign contracts within 24 hours of the procedure [25]; these are all elements that influence the indirect costs related to the evaluation of technology, which have not been the subject of this study, but which nevertheless have an important role on the overall analysis of the study. Another important aspect is represented by the disinfection process to which conventional colonoscopes are subjected between each use; the risk of infection related to the reprocessing phase is well known [26, 27]. The Emergency Care Research Institute (ECRI), in its latest release on the 10 greatest risks associated with the use of health technologies of 2018, shows in the

second position, the risk of contamination related to the failure of the reprocessing. According to the document, the areas that require attention include especially the cleaning step, performed manually, and the conservation of the instrument after the disinfection [26]. Finally, among the problems related to conventional colonoscopy, the literature also reports a high prevalence of musculoskeletal disorders, in particular in the upper limb district, related to the endoscopists personal ability and in relation to the number of tests performed [28, 29, 30, 31].

Conclusions

On the basis of the scientific evidence mentioned above, with Endotics robotic colonoscopy, there is a reduction in the overall risk associated with the colonoscopic procedure, due to the absence of anaesthesia and related risks and the use of the disposable probe that eliminates the risk of infection introduced by the reprocessing phases, while maintaining, compared to the conventional procedure, a comparable level of diagnostic accuracy [10] and greater tolerability of the procedure by the patient [10, 31], thus pushing the colonoscopy towards "the ideal procedure". In the last year, the high number of robotic colonoscopies programmed from the hospital lead to the lowering of the sale price of single-use robotic colonoscope compared to the price of the prices, further reducing the cost gap between the two methodologies. Overall, the results of this study suggest that in the University Hospital of Pisa the costs related to robotic colonoscopy performed with the Endotics system are superimposable to those of conventional painless colonoscopy. In the near future, it would be interesting to extend the study done, also to the costs mentioned above of the evaluation of the indirect costs associated with both procedures.

Abbreviations

AER Automated Endoscope Reprocessor

AOUP Azienda Ospedaliero Universitaria Pisana

BIA Budget Impact Analysis

BOM Bill Of Material

CRC Colorectal Cancer

ECRI Emergency Care Research Institute

FOBT Faecal Occult Blood Test

HLD High Level Disinfection

HTA Health Technology Assessment

PPE Personal Protective Equipment

Declarations

Ethics approval and consent to participate: not applicable.

Consent for publication: not applicable.

Availability of data and materials: the datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests: the authors declare that they have no competing interests.

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Authors' contributions: the cost analysis presented in this study involves two main cost areas: costs associated with the number of human resources and the time taken to execute processes; costs relating to disposable consumables, amortization costs for multi-use materials, and maintenance costs.

RS has worked on the acquisition of cost data related to the second area described, on the analysis and interpretation of all cost items and has contributed substantially to the drafting of the article. ET has personally performed most of the colonoscopic procedures and has been responsible for the collection, integrity and interpretation of the data for the first cost area and has contributed to the revision of the article. CL has taken care of the acquisition of data related to the timing of all processes and sub-processes that have allowed to identify the items pertaining to the first area of cost. DM has designed and followed all the phases of the study, defining the methodology and interpreting its development and final results, also performing the critical review of the article.

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Figures

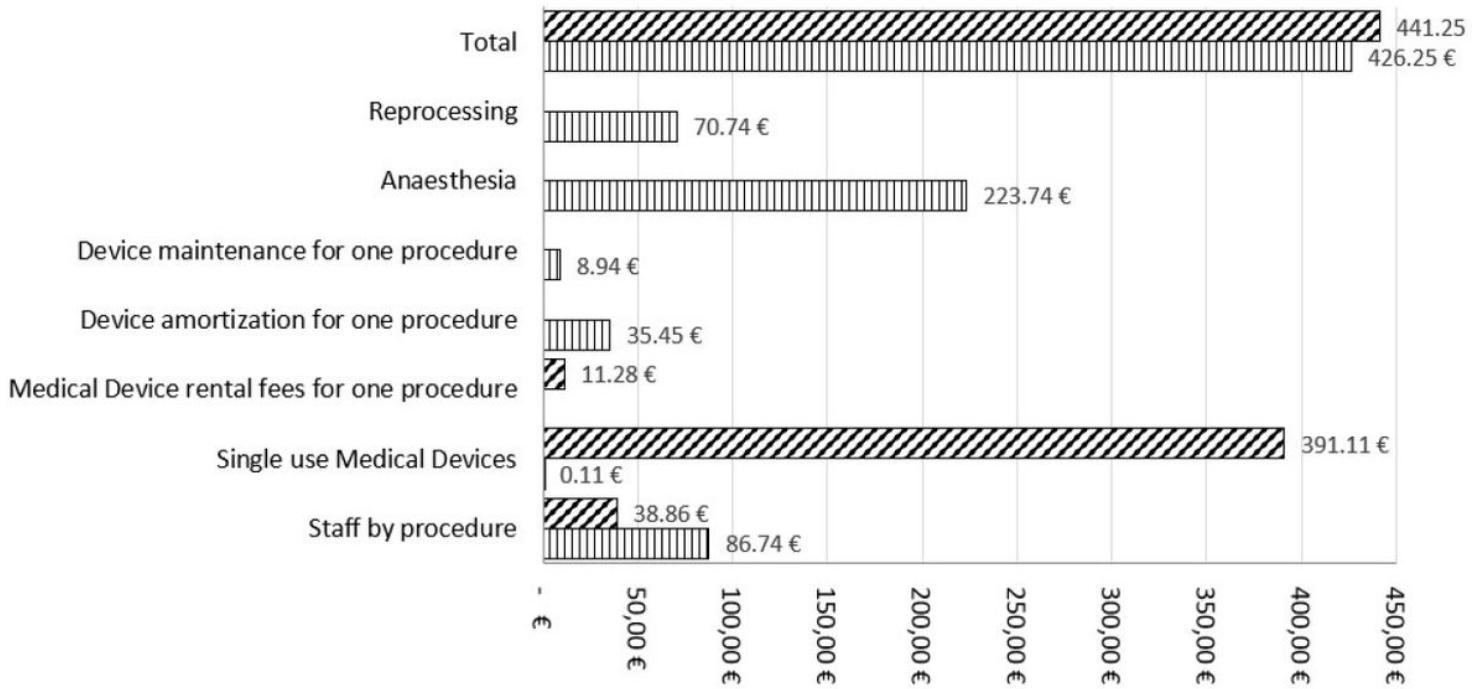


Figure 1

Robotic Colonoscopy Costs vs Conventional Painless Colonoscopy Costs. Legend: //// Robotic Colonoscopy ||||| Conventional Painless Colonoscopy

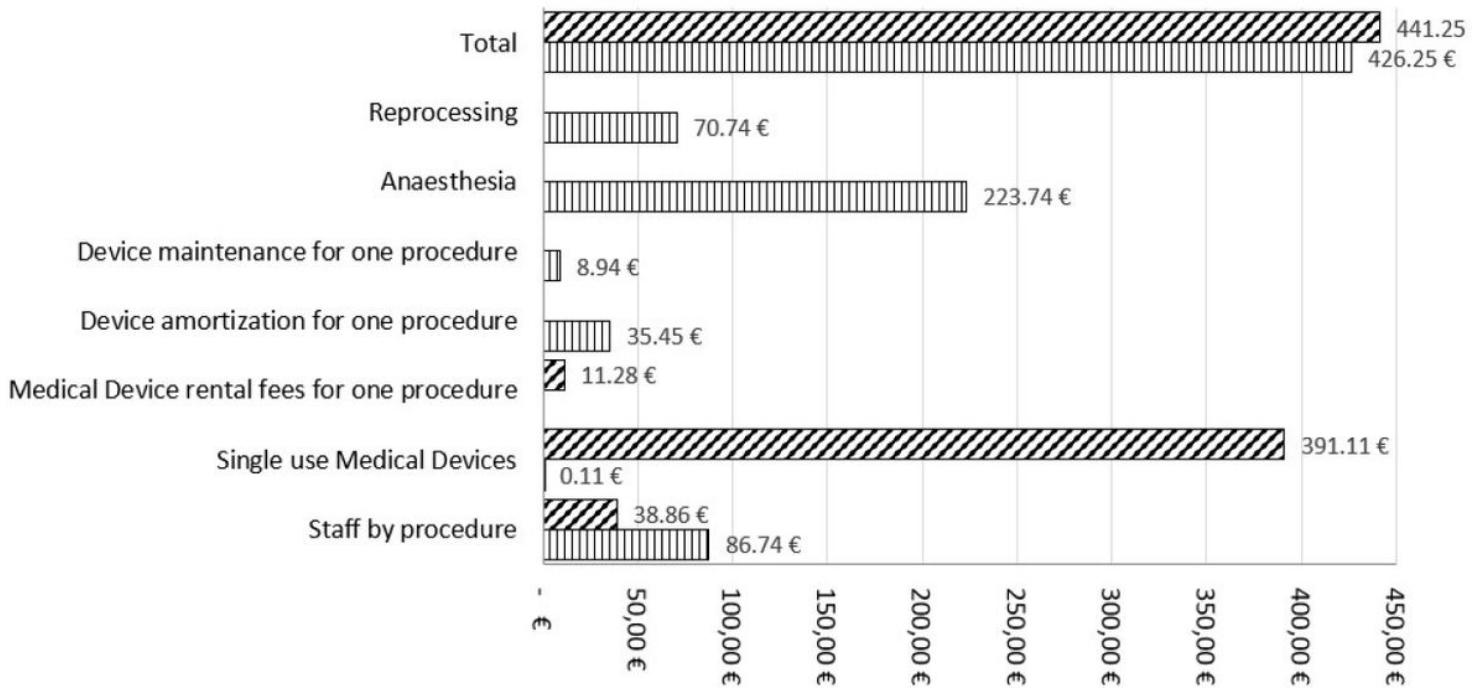


Figure 1

Robotic Colonoscopy Costs vs Conventional Painless Colonoscopy Costs. Legend: //// Robotic Colonoscopy ||||| Conventional Painless Colonoscopy