



Digestive Endoscopy

Early and delayed complications of polypectomy in a community setting: The SPoC prospective multicentre trial



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ABSTRACT

Background: Colonoscopic polypectomy is effective in reducing the incidence of and mortality from colorectal cancer, but is not complication-free.

Aims: To evaluate the incidence of early and delayed polypectomy complications and factors associated with their occurrence in a community setting.

Methods: Web-database collection of patients' and polyp's features in consecutive colonic polypectomies during a 3-month period in 18 endoscopy centres.

Results: Data on 5178 polypectomies in 2692 patients (54.3% males, mean age 59 years) were collected. The majority of the polyps were <10 mm (83.5%). Antithrombotic agents were taken by 22.7% of patients, 57.3% of which withheld them before the procedure. Overall, 5 patients experienced perforations (0.2%) and 114 had bleeding (4.2%); the overall complication rate was 4.4%. Early complications were observed in 87 (3.2%); delayed complications (all major bleedings) occurred in 32 (1.2%). At multivariate analysis polyp size (size >10 mm: OR 4.35, 95% CI 5.53–7.48) and, inversely, right-sided location (OR 0.58, 95% CI 0.36–0.94) were correlated with bleeding events. The use of antithrombotics was associated with 5-fold increased risk of delayed bleeding.

Conclusions: In the community setting, polypectomy was associated with a 1.4% risk of major complications. Polyp size and, inversely, right-sided location were associated with early bleeding; the use of antithrombotics increased the risk of delayed events.

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1. Introduction

Colonoscopy has been shown to decrease colorectal cancer incidence and mortality [1–3] by detecting and removing

precancerous lesions (i.e. adenomas). Although it is generally regarded as a safe procedure, major complications can occur and, in fact, more than 85% of these result from polypectomy [4,5]. An analysis of Canadian administrative data, including over 97,000 colonoscopies, found that polypectomy was associated with a 7-fold increase in the risk of bleeding or perforation [6]. In line with these findings, polypectomy was associated with an 11-fold and 3-fold increased risk of bleeding and perforation in the English National Health Service Bowel Cancer Screening Programme (NHSBCSP) [7].

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¹ See Appendix A.

Although many studies in the literature have explored the incidence and predictors of adverse events associated with polypectomy [7–12], most of them are characterized by significant bias related to retrospective observations from single referral centres and/or a short follow-up, preventing the assessment of delayed complications. Up to now, few population-based studies carried out in community settings have evaluated early and delayed complications of colonoscopy, with particular focus on polypectomy. Aims of the present study were to prospectively evaluate the incidence of early and delayed (30-day) polypectomy complications in a large multicentre community setting and to analyze patient-, polyp-, and procedure-related factors associated with their occurrence.

2. Methods

Overall, 18 endoscopy centres of Lombardy, a Northern Italian region with almost 10 million inhabitants, participated in the study. These units were representative of a large area of the region, located in community hospitals and they all were involved in the colorectal cancer (CRC) screening programme.

A total of 78 endoscopists took part in the study. Data on all polypectomies performed over a 3-month period were prospectively collected, by means of a network platform, without pre-establishing polyp-related exclusion criteria. All colonoscopies were carried out according to the common practice of each centre and endoscopists were given no specific recommendations on procedure techniques and management of antithrombotic agents.

The following information was prospectively recorded in the web-database: patients' demographics (age, gender) and setting (in- or out-patients), ASA (American Society of Anesthesiology)-status, colonoscopy indication (screening, surveillance or symptoms), use of anti-coagulants (vitamin K antagonists, VKAs) or anti-platelet agents (APAs) and their management before the procedure (interruption or not). Regarding polyp data, the number, location, size and morphology, modality of removal, application of prophylactic manoeuvres to prevent perforation (sub-mucosal solution injection to lift the lesion) or bleeding before or after polyp resection (sub-mucosal epinephrine injection, argon plasma coagulation, the use of clips or endo-loops, either alone or in combination), and histology-report were recorded. Only patients undergoing polypectomy were included in the analysis. Patient-related exclusion criteria were represented by pregnancy and incapacity to provide informed consent.

In detail, complications were considered as early, defined as intra-procedural or occurring before discharge from the Endoscopy Unit, or delayed, defined as those occurring after but within 30 days of hospital discharge. The former were recorded by the endoscopists soon after the examination, whereas the latter were assessed through a structured questionnaire that was given to each patient before discharge from the Endoscopy Facility. The questionnaire included questions to identify potential occurrence of complications, need for medical evaluation or hospitalization. The questionnaire was to be returned by mail, fax or via phone call 4 weeks after the polypectomy procedure. Patients who did not return the survey were later contacted by phone.

Moreover, complications were categorized as minor or major, according to their relevance to the clinical outcome. According to previous definitions [6], we considered as major complications any bleeding leading to shock, blood transfusion, hospitalization, surgery, recurrent bleeding after endoscopic haemostasis and any perforation and death. Minor complications involved any bleeding event without the abovementioned major criteria, which could be managed during the same procedures or did not require any further assessment.

The protocol was registered at ClinicalTrials.gov (NCT02007395). It was approved by the local ethics committees

of all participating centres and written informed consent was obtained from all patients undergoing a colonoscopy, before knowing whether they had polyps or not.

2.1. Study end-points

The primary end point of the study was to evaluate the early and late polypectomy complication rates and associated factors, by means of a logistic regression analysis.

Furthermore, data were extrapolated to provide a descriptive analysis of the endoscopists' attitudes towards the polypectomy technique, by focusing on three different scenarios: small (less than 10 mm), large (more than 20 mm) polyps and polypectomy in presence of antithrombotic agents.

2.2. Statistical analysis

Categorical and continuous variables were reported as proportions and as means \pm standard deviation (SD), respectively. For univariate analysis, comparisons for means and proportions were made by the Student *t* or Chi-squared test and Yates correction for continuity as needed.

Due to the paucity of other adverse events, the regression approach was restricted to immediate haemorrhagic complications only. A logistic regression analysis was carried out to assess both patient- and polyp-related risk factors and the risk of immediate post-polypectomy bleeding. A logistic stepwise regression model was used; all parameters with a *P* value <0.2 on univariate analysis were included and those with a *P* value >0.4 were removed, according to an automated stepwise procedure. For all comparisons, the odds ratio (OR) and 95% confidence interval (CI) were given for significant variables. A *P* value <0.05 was considered statistically significant.

3. Results

From June 2013 to August 2013, 78 endoscopists enrolled 3288 patients into the study. Data recorded by endoscopists who performed less than 50 colonoscopies (with or without polypectomy) during the study period ($n=368$, 11.1%) were excluded from the analysis, together with data of examinations whose questionnaire was not returned ($n=229$, 6.9%). So that, we considered for the final analysis data from 50 endoscopists who collected 5178 polypectomies in 2692 patients (54.3% males, mean age 59 ± 12.1 years). Overall 92.7% were outpatients and 95.1% were ASA status 1 or 2. The indications for colonoscopy were screening, surveillance and symptoms in 30.4%, 39.2% and 29.4% of cases, respectively. Overall, 22.7% of patients were receiving antithrombotic agents, although 57.3% of them had withheld the treatment for at least five days before colonoscopy (Table 1). Direct oral coagulants (DOACs) were not available in Italy at the time of the study, so they were not considered; no patient was receiving dual anti-platelet therapy.

Overall, 1448 patients (53.8%) had more than one polyp and the mean number of polyps per patient (MPP) was 1.93. Polyp characteristics are shown in Table 2.

3.1. Complication rates

Overall, 119 polypectomy-related complications occurred in 119 patients, accounting for a cumulative complication rate of 4.4%. Of these, 37 patients (1.4%) experienced a major complication, 5 of which were perforations and 32 delayed bleedings requiring hospitalization (Table 3).

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