Predictive factors for colonoscopy complications

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A B S T R A C T

Objective: To determine factors predicting complications caused by colonoscopy.

Design: Prospective cohort study.

Setting: A private hospital in Hong Kong.

Patients: All patients undergoing colonoscopy in the Endoscopy Centre of the Hong Kong Sanatorium & Hospital from 1 June 2011 to 31 May 2012 were included. Immediate complications were those that were recorded by nurses during and up to the day after the examination, while delayed complications were gathered 30 days after the procedure by way of consented telephone interview by trained student nurses. Data were presented as frequency and percentage for categorical variables. Logistic regression was used to fit models for immediate and systemic complications with related factors.

Results: A total of 6196 patients (mean age, 53.7 years; standard deviation, 12.7 years; 3143 women) were enrolled and 3657 telephone interviews were completed. The incidence of immediate complications was 15.3 per 1000 procedures (95% confidence interval, 12.3-18.4); 50.5% were colonoscopy-related, including one perforation and other minor presentations. Being female (odds ratio$_{adjusted}$=1.6), use of monitored anaesthetic care (odds ratio$_{adjusted}$=1.8), inadequate bowel preparation (odds ratio$_{adjusted}$=3.5), and incomplete colonoscopy (odds ratio$_{adjusted}$=4.5) were predictors of risk for all immediate complications (all predictors had P<0.05 by logistic regression). The incidence of delayed complications was 1.6 per 1000 procedures (95% confidence interval, 0.3-3.0), which comprised five post-polypectomy bleeds and one post-polypectomy inflammation. The overall incidence of complications was 17.8 per 1000 procedures (95% confidence interval, 13.5-22.1). The incidences of complications were among the lower ranges across studies worldwide.

Conclusion: Inadequate bowel preparation and incomplete colonoscopy were identified as factors that increased the risk for colonoscopy-related complications. Colonoscopy-related complications occurred as often as systemic complications, showing the importance of monitoring.

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New knowledge added by this study

- The risks of local and systemic complications of colonoscopy are of paramount importance.

Implications for clinical practice or policy

- Enforcing bowel preparation and post-polypectomy care may reduce the risk of delayed complications.

Introduction

Colonoscopy is an efficient, invasive, and commonly used diagnostic tool with promising therapeutic capacity. Common colonoscopy-related complications include prolonged pain and distension, and rarely draw medical attention or lead to hospitalisation. Severe complications, including bleeding and perforation, are potentially life-threatening and require urgent management. Although death is uncommon, occurring in no more than 3 per 10 000 procedures, the incidence of post-polypectomy bleeding and perforation ranges from 1.6 to 14.8 and 0.2 to 1.0 per 1000 procedures, respectively.[1-6] It is difficult to accurately benchmark direct colonoscopy-related complications due to the different outcome measure definitions used in studies. For example, some studies include immediate complications only, while others extend the complication period to 7 or 30 days, and some studies include an extensive list of complications while others include only bleeding and perforation.[1,2,5,7-10] Furthermore, the efficacy and

結腸鏡檢查併發症的預測因素

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目的：分析因結腸鏡檢查而出現併發症的風險因素。

設計：前瞻性隊列研究。

安排：香港一所私家醫院。

患者：是次研究包括2011年6月1日至2012年5月31日期間在香港養和醫院內窺鏡中心進行結腸鏡檢查的病人。即時併發症是指那些於檢查後即時發生並由護士記錄的狀況，而延遲併發症則是指發生於檢查後30日內透過受訓護士學生以電話訪問形式取得資料的病例。類別變數的數據會以頻率及百分比表示，而與即時及延遲併發症相關的因素會以邏輯迴歸模型來分析。

結果：研究期間替6196名病人進行結腸鏡檢查（病人平均年齡53.7歲，標準差12.7歲；其中有3143名女性），並完成3657個電話訪問。即時併發症發生率為每1000個檢查中有15.3個（95%置信區間，12.3至18.4個）；其中50.5%與結腸鏡檢查相關，包括穿孔一例和其他較輕微事故。而女性（調整後的比值比=1.6）、接受監測麻醉護理（調整後的比值比=1.8）、腸道準備不足（調整後的比值比=3.5）以及未能完成的腸鏡檢查（調整後的比值比=4.5）均是所有即時併發症風險的預測因素（邏輯迴歸：所有P<0.05）。延遲併發症的發生率為每1000個檢查中有1.6個（95%置信區間，0.3至3.0個），其中包括5個瘜肉切除後出血及1個瘜肉切除後炎症。併發症的總發生率為每1000個檢查中有17.8個（95%置信區間，13.5至22.1個）。與各地研究指標相比，本研究的併發症發生率相對較低。

結論：結果指出腸道準備不足及未能完成的腸鏡檢查增加與結腸鏡檢查相關併發症的風險。結腸鏡檢查相關併發症與全身併發症的發生率相若，這正揭示了謹慎監察的重要性。

safety of the procedure vary across clinical settings and the targeted populations. With no available local data, consensus for complication incidence remains inconclusive.

Intravenous sedation is routinely used during colonoscopy to minimise the discomfort and pain associated with the procedure. Endoscopists are equipped to give sedatives and to monitor their side-effects, but anaesthetists are often invited to provide monitored anaesthetic care (MAC) when the patient is considered to be at high risk for complications, for instance, older patients and those with multiple co-morbidities are particularly vulnerable to complications. Systemic complications vary from prolonged drowsiness to fatal events such as cardiovascular or cerebrovascular events. Cardiovascular events following sedation, such as hypotension and myocardial infarction, during colonoscopy have been reported to range from 0.1 to 59.1 per 1000 procedures. Cerebrovascular events such as stroke range from 0.1 to 1.3 per 1000 procedures.[3,6,10] The outcome variables are highly heterogeneous, for example, Nelson et al's study[3] included myocardial infarction, vasovagal event, and arrhythmia in the cardiovascular incidents, while Ma et al's study[10] recorded hypotension only.[10] Some endoscopists opted to study complications related to the use of carbon dioxide (CO_2) insufflation and absence of sedative use.[11-13] This study aimed to record all complications systematically and to determine the relevant risk factors.

Methods

This prospective study collected data for all colonoscopies done from 1 June 2011 to 31 May 2012 at the Endoscopy Centre of the Hong Kong Sanatorium & Hospital (HKSH), which is a private hospital in Hong Kong. Prior to colonoscopy, patients were invited to give their written consent for their participation in the study, including for the 30-day follow-up telephone interview. The Hospital Management Committee involving the Research Ethics Committee of the HKSH approved the study.

The complications were recorded by nurses on a standard form during and immediately after the procedure. The standard audit forms for immediate and delayed colonoscopy complications were designed by a research doctor, with the most common complications based on literature review.

The immediate complications audit form included patients' demographics, use of sedation/analgesic/antispasmodic, use of MAC, gross indications for colonoscopy (therapeutic or diagnostic), type of therapeutic procedures performed such as polypectomy, the reason for incomplete colonoscopy (caecum intubation failure), quality of bowel preparation (adequate – good/adequate or not – fair/poor, which was rated by the endoscopist), and the use of CO_2 insufflation. Complication data were divided into systemic and colonoscopy-related complications. For systemic complications, we captured data for nausea/vomiting, hypotension (systolic blood pressure <100 mm Hg), bradycardia/tachycardia (heart rate <50 to >100 beats/min), vasovagal fainting, and other cardiovascular or cerebrovascular events. For colonoscopy-related complications, data for perforation, persistent pain/discomfort, abdominal distension, and haemorrhage were gathered.

Delayed complications were defined as the above events happening from the day after the initial colonoscopy to the 30th day that required readmission or admission to other hospitals. For those readmissions, we automatically inspected the records for the reasons and interventions if the readmissions were complication-related. Otherwise, trained student nurses or a research doctor telephoned all consented participants to interview for the 30-day complications using the delayed complication audit form. A participant was declared lost to follow-up after three telephone attempts. The student nurses were trained by senior nurses and the research doctor with standard instructions.

Data analysis was performed by the Statistical Package for the Social Sciences (Windows version 14.0; SPSS Inc, Chicago [IL], US). Descriptive statistics (mean, percentage, incidence, and/or 95% confidence interval [CI]) were used to display the characteristics of the sample. For those complications with zero events, only 95% CIs were given.[14] Backward logistic regression analyses were performed to draw prediction models for immediate complications, including colonoscopy-related complications or systemic complications, and overall complications, including immediate and delayed complications, from the sample; entering variables were chosen from age, sex (male or female), use of MAC (yes or no), sufficiency of bowel preparation (adequate or not), and completion of colonoscopy (yes or no) according to the results of the univariate analyses by Pearson Chi squared tests of all potential independent variables, with a significance level set at 10%; variable inclusion in the iteration was set at $P<0.1$ for backward logistic regression analyses. Returning coefficients of the variables were interpreted as adjusted odds ratio ($OR_{adjusted}$) with 95% CI provided. All significance levels were set at two-sided $\alpha=0.05$.

Results

A total of 6196 colonoscopies (3143 women; mean age 53.7 years; standard deviation, 12.7 years) were done during the study period. Most patients were aged between 45 and 64 years, were in-patients, had undergone diagnostic colonoscopy, and received intravenous sedation (60.5%, 70.5%, 53.0%, and 99.4% respectively; Table 1). The data for immediate complications were complete, while the 30-day follow-up was completed for 3657 procedures (803 were lost to follow-up and 1736 refused; compliance rate 59.0%; Table 2).

Of the 6196 colonoscopies, 2912 were therapeutic with 99.7% dedicated to polypectomy (Table 1). There were 73 (1.2%) cases of incomplete colonoscopy, 18 (24.7%) of which were due to inadequate preparation. Other reasons for incomplete colonoscopy were tumour obstruction (15 of 73; 20.5%) and intention of sigmoidoscopy or stent insertion (26 of 73; 35.6%). A total of 149 patients were readmitted within 30 days after the procedure, of which six (4.0%) were related to complications. The other reasons were cancer, gastro-intestinal disease, or cardiac events (Table 2).

Systemic complications

Regarding the choice of sedation, midazolam and pethidine were the most used at 81.5% and 82.0%, respectively, while 15.9% of patients underwent MAC. Immediate complications reported included hypotension, vasovagal fainting, and nausea/vomiting, or a combination (6.1, 0.6, 0.3, and 0.5

TABLE 1. Demographic characteristics, sedation, and colonoscopy data (n=6196)

Characteristics	No. (%) of patients
Sex (male)	3053 (49.3)
Age (years)	
<45	1374 (22.2)
45-64	3751 (60.5)
≥65	1071 (17.3)
In-patient	4370 (70.5)
Monitored anaesthetic care	987 (15.9)
Induction	
None	17 (0.3)
Analgesics	19 (0.3)
Sedatives	957 (15.4)
Analgesics + sedatives	5189 (83.7)
Sedatives + antispasmodics/muscle relaxant	3 (0.1)
All	11 (0.2)
Procedure	
Diagnostic	3284 (53.0)
Therapeutic	2912 (47.0)
Therapeutic procedure (n=2912)	
Polypectomy	2903 (99.7)
Others*	9 (0.3)
Carbon dioxide insufflation	674 (10.9)
Inadequate bowel preparation	161 (2.6)
Incomplete colonoscopy	73 (1.2)

* Haemorrhoid banding (n=1), haemostasis (n=2), stent insertion (n=6)

TABLE 2. Thirty-day follow-up, readmission, and mortality

	No. (%) of patients
30-Day follow-up (n=6196)	
Completed*	3657 (59.0)
Lost to follow-up	803 (13.0)
Refused follow-up	1736 (28.0)
Readmission (n=3657)	
No	3508 (95.9)
Yes	149 (4.1)
Cause of readmission (n=149)	
Complication-related	6 (4.0)
Non-complication–related	143 (96.0)
Intermittent abdominal pain	3 (2.0)
Colorectal cancer	32 (21.5)
Colorectal diseases	14 (9.4)
Non-colorectal diseases	94 (63.1)
Complication-related mortality	0

* Including either telephone interview or readmission record inspection

per 1000 procedures, respectively; Table 3). There were no severe cardiovascular events such as heartbeat irregularity or myocardial infarction or cerebrovascular events such as stroke. Furthermore, none of the patients reported delayed systemic complications in the 30-day follow-up.

Modelling to study the potential risk factors showed that being female, use of MAC, and inadequate bowel preparation were the significant independent predictors for systemic immediate complications ($OR_{adjusted}$=2.0, 2.6, and 3.7, respectively; all were P<0.05; Table 4).

Colonoscopy-related complications

Immediate colonoscopy-related complications were recorded for 48 patients (7.7 per 1000 procedures), including extensive pain/discomfort, abdominal distension, and perforation (Table 3). The only perforation was at the sigmoid-rectal junction and was due to adhesion, which might be related to previous abdominal surgery (total hysterectomy and bilateral salpingo-oophorectomy was done 10 years previously). In the 30-day follow-up, six patients reported complication-related readmissions, five of whom were for bleeding after discharge from hospital and one was for inflammation; all were caused by polypectomy.

Modelling was done to formulate a predictive algorithm for significant independent risk factors and outcome events (Table 4). Inadequate bowel preparation and incomplete colonoscopy were the significant predictors for immediate colonoscopy-related complications ($OR_{adjusted}$=3.5 and 6.2, respectively; both were P<0.05) and for all immediate complications ($OR_{adjusted}$=3.5 and 4.5, respectively; both were P<0.05). In the model for all immediate complications, being female and use of MAC were also predictors ($OR_{adjusted}$=1.6 and 1.8, respectively; all were P<0.05).

A predictive model was also done for overall complications, including all immediate and delayed complications among those who completed follow-up at 30 days. The effect of previous significant predictors was transient in that they did not predict the overall complications occurring in the 30-day post-colonoscopy period. Monitored anaesthetic care was the only predictor during the 30-day period ($OR_{adjusted}$=2.0; P=0.019).

TABLE 3. Incidence of overall complications (per 1000 procedures) and their interventions

	Total No. of complications (No. per 1000, 95% confidence interval)		
	Immediate (n=6196)	**Delayed (n=3657)**	**Overall (n=3657)**
All cause	95 (15.3, 12.3-18.4)	6 (1.6, 0.3-3.0)	65 (17.8, 13.5-22.1)
Systemic complications	47 (7.6, 5.4-9.7)	0 (<0.8)	32 (8.8, 5.7-11.8)
Hypotension	38	-	-
Vasovagal fainting	4	-	-
Nausea/vomiting	2	-	-
Hypotension + vasovagal fainting	2	-	-
Hypotension + nausea/vomiting	1	-	-
Colonoscopy-related complications	48 (7.7, 5.6-9.9)	6 (1.6, 0.3-3.0)	33 (9.0, 6.0-12.1)
Pain	5	-	-
Abdominal distension	36	-	-
Perforation	1	-	-
Pain + abdominal distension	6	-	-
Bleeding*	-	5	-
Inflammation*	-	1	-
Intervention		No. (%)	
Observation	94 (98.9)	3 (50.0)	-
Surgical operation†	1 (1.1)	-	-
Colonoscopic haemostasis + blood transfusion	-	1 (16.7)	-
Blood transfusion	-	1 (16.7)	-
Intravenous antibiotics	-	1 (16.7)	-

* Related to post-polypectomy complications

† Surgical operation was performed to repair the perforation of rectosigmoid colon

TABLE 4. Multivariate analysis of risk predictors for complications by different models

Predictor	Adjusted odds ratios	95% Confidence interval	P value
Immediate complications			
Colonoscopy-related complications			
Inadequate bowel preparation	3.5	1.3-9.3	0.013
Incomplete colonoscopy	6.2	2.1-18.5	0.001
Systemic complications			
Female sex	2.0	1.1-3.7	0.024
Monitored anaesthetic care	2.6	1.4-4.8	0.003
Inadequate bowel preparation	3.7	1.3-10.6	0.013
All complications			
Female sex	1.6	1.0-2.4	0.031
Monitored anaesthetic care	1.8	1.1-2.9	0.012
Inadequate bowel preparation	3.5	1.7-7.3	0.001
Incomplete colonoscopy	4.5	1.8-11.0	0.001
Overall complications (n=3657)			
Monitored anaesthetic care	2.0	1.1-3.5	0.019

Discussion

Significance of this study

Inadequate bowel preparation and incomplete colonoscopy were identified as risk factors for colonoscopy-related complications. Other complications were mostly hypotension and abdominal distension. No myocardial infarction, transient ischaemic attack, or death relating to colonoscopy was reported.

Contribution of individual characteristics to the complications

Colonoscopy is rarely a complication-free procedure, but a good understanding of the possible complications can help to minimise them. While experienced endoscopists, diagnostic procedures, and young patients are protective factors for colonoscopy complications, trainee endoscopists, therapeutic procedures, advanced age, female sex, obesity, co-morbidity, anticoagulant use, and previous abdominal surgery are risk factors for complications.[3,5,6,10,15-17] The relatively low incidence of complications recorded in this study could be attributed to the fact that more than half of the procedures were diagnostic, thus reducing the potential for polypectomy-associated complications.

Other events—such as abdominal pain and distension, hypotension, vasovagal fainting, and nausea/vomiting—accounted for 98.9% of all immediate complications; these events were mostly reported by women (60.6%; $OR_{adjusted}$=1.6; Table 4). This result is consistent with the literature.[17] This effect could possibly be explained by different perceptions of somato-sensation, which could be traced back to the socio-emotional cultivation and cultural expectation of the different sexes.[18]

Hidden factors that may contribute to complications

Despite the sex effect, use of MAC, inadequate bowel preparation, and incomplete colonoscopy were all related to immediate complications. The use of MAC, in particular, requires more interpretation because it has not been found to be a risk factor in other studies and its use ought not be a cause of complications. However, MAC is designed for patients who are vulnerable to the complications of sedation and the procedure, especially those with co-morbidities and who are at an advanced age. In this study, co-morbidity was not reviewed, but patients who underwent MAC were significantly older than those who did not (mean age, 56.1 vs 53.3 years; P<0.001, *t* test) which may be partly contributory. However, age was not significantly associated with any of the complications after adjustment for other factors. Age might have a greater impact if co-morbidity was also considered and this may be an area for further study.

Inadequate bowel preparation, in which faeces obscure the inner lining of the colon, impedes the vision and heightens the risk for complications. Likewise, incomplete colonoscopy due to inadequate bowel preparation or unbearable discomfort inevitably increases the risk for complications. These results are consistent with other studies.[2,3,10]

A large proportion (59%) of the study population completed the study. Per protocol

univariate analyses showed that use of MAC was the sole significant factor related to overall complications (Table 4).

Other factors

Sedation-free colonoscopy is a feasible alternative that could reduce the risk of systemic complications; use of CO_2 insufflation might increase its tolerability while maintaining visibility. In this study, a sedation-free procedure was performed in only 36 patients, with no complications; CO_2 insufflation was done for 647 (10.9%) patients instead of gas (room air), with only minor complications encountered (two patients reported abdominal distension and seven reported hypotension/vasovagal fainting). Insufflation with CO_2 could be adopted more widely because it is non-explosive, absorbable, and does not affect the mucosal blood flow, thus minimising discomfort and the risk of colonic ischaemia. According to Bretthauer et al,[19] CO_2 insufflation leads to quicker recovery, and less pain and complications. These advantages are supported by other studies including local research.[11,19,20] These factors might inspire greater use of CO_2 insufflation and minimise use of sedation for selected patients.[12,13,21]

Inadequate bowel preparation not only hampers completion of the procedure, but also increases the risk for complications. As evidenced from the prediction models, inadequate bowel preparation significantly increases the occurrence of complications. In addition to implementing the current standardised bowel preparation protocol, enforcement of patient education, compliance, and early admission for monitored bowel preparation might help to further suppress the rate for inadequate bowel preparation.

Limitations

Many of the patients were lost to contact by telephone. In this study, we assumed that the pattern of missing patients was random and was not affected by whether or not the patients had complications. However, self-selection bias might exist. If patients without complications were more likely to be lost to contact, the rate of delayed complications would be overestimated. However, the rate of delayed complications would be underestimated if the patients had been admitted to other hospitals or had died.

Endoscopist experience, and patient characteristics of co-morbidities and severe symptoms before the procedure were not recorded for analysis in this study. These are potential risk factors for complications.

In view of the importance of monitoring the complications of colonoscopy, further study might include the missing variables of co-morbidity, endoscopist experience, symptoms at presentation and oxygen level, and explore factors such as the influence of body mass index and medical history, sedation dose, indication for colonoscopy, use of laxatives and compliance, and post-colonoscopy diagnosis/pathology that might help to minimise the variance on prediction of complications.

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