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Colorectal Endoscopy-Related Adverse Events in the Province of Quebec: a Retrospective Study

Sophie Pouliot, Institut national de santé publique

Marc Simard, Pascale Levesque, Roxanne Gagnon,

Bernard Candas, Gilles Jobin

ARCC, May 28th, Montréal

Institut national de santé publique Québec

Background

- The Quebec colorectal cancer screening program (PQDCCR) is planning to use colonoscopy as a diagnostic procedure following a positive immunochemical fecal occult blood test ($FOBT_i$);
- This procedure occasionally induced adverse events (AEs);
- Previous studies have depicted the rates of AEs in other Canadian provinces* but no one reported data for the province of Québec.

*Singh, H. *and al.*, 2009; Rabeneck, L. *and al.*, 2008; Misra, T. *and al.*, 2004

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Objectives

Our aim was:

1. to determine the rate of colorectal endoscopy-related adverse events (AEs) occurring in a population similar to the one targeted by the PQDCCR and;
2. to identify patients and endoscopies' characteristics associated to the most acute AEs.

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Approach

- This retrospective study used medico-administrative databases to identify colorectal endoscopy-related bleeding, perforation, cardiovascular events and death that occurred in the province of Quebec from 2000 to 2004.
- Algorithms previously developed by our team were used to classify major AEs according to their severity level and their relationship to endoscopy.
- Association between patients and endoscopies' characteristics and AEs have been evaluated using univariate analyses.

Study population (1)

The study population includes average risk individuals, aged from 50 to 74 years old, who were selected to correspond to the PQDCCR audience.

- Inclusion criteria :
  - Undergone an outpatient endoscopy in the province of Quebec between April 1st, 2000 and December 1st, 2004;
  - Aged between 50-74 years;
  - No history of colorectal cancer;
  - No endoscopy, abdominal surgery or surgical repair within 90 days prior to the endoscopy;
  - No previous abdominal surgery the same day;
  - Endoscopies for which the indication was NOT the presence of a bleeding.

Study population (2)

- A total of 256 500 endoscopies were performed on 210 353 individuals between April 1st, 2000 and December 1st, 2004 in the province of Québec among patients, without an history of colorectal cancer, who underwent an outpatient endoscopy.

Clinically significant AEs

Table 1. Significant AEs in a colorectal screening population according to their level of severity and likelihood of relationship with endoscopy

Relation between endoscopy and AEs (day)	Level of severity		
	High (n)	**Moderate (n)**	**Low (n)**
Bleeding			
Probably related (1-3)	10	63	1576
Possibly related (4-14)	24	56	151
Unlikely related (15-30)	1	14	135
Perforation			
Probably related (0-3)	80	93	---
Possibly related (4-10)	26	30	---
Unlikely related (11-30)	37	75	---
Cardiovascular events			
Probably related (0-1)	88	---	---
Possibly related or unlikely related (2-30)	395	---	---

Rate of AEs for long colonoscopies

Variables	Number of endoscopies	Bleedings'rate (n)	Perforations'rate (n)	Cardiovascular events'rate (n)
Gender				
Female	95 949	5.21 (50)	3.86 (37)	2.92 (28)
Male	87 954	11.71 (103)	3.07 (27)	3.41 (30)
Age				
50-59 years	81 515	6.75 (55)	1.96 (16)	0.98 (8)
60-69 years	72 659	9.36 (68)	4.27 (31)	3.72 (27)
70-74 years	29 729	10.09 (30)	5.72 (17)	7.74 (23)
Physician specialty				
Surgeon	63 575	8.02 (51)	5.35 (34)	3.15 (20)
Gastroenterologist	111 706	8.95 (100)	2.51 (28)	3.13 (35)
Internist	7 840	1.28 (1)	2.55 (2)	383 (3)
Other	5	0.00 (0)	0.00 (0)	0.00 (0)
Unspecified	777	12.87 (1)	0.00 (0)	0.00 (0)
Annual volume of endoscopy∞				
0-149	13 634	11.00 (15)	5.13 (7)	4.40 (6)
150-299	32 265	6.51 (21)	6.82 (22)	3.10 (10)
300-999	121 697	8.79 (107)	2.71 (33)	3.29 (40)
1000 and +	16 307	6.13 (10)	1.23 (2)	1.23 (2)
TOTAL	**183 903**	**8.32 (153)**	**3.48 (64)**	**3.15 (58)**

Variables correlated to the rate of AEs

Variables	Bleedings'rate	Perforations'rate	Cardiovascular events'rate
Gender			
Female Male	++		
Age			
50-59 years 60-69 years 70-74 years	+	++	++
Annual volume of endoscopy			
0-149 150-299 300-999 1000 and +		++	
Manipulation	++	++	

The symbols "+" indicate a significant difference. One "+" refers to a p value between 0,01 and 0,05 while "++" refer to a p value inferior to 0,01.

Rate of deaths (1)

- Deaths could not be directly linked to endoscopy using medico-administrative databases. To overcome this difficulty, we used prior endoscopy-related AEs to identify possibly-related deaths following cardiovascular events and perforations.
- Criteria to identify the deaths possibly related to endoscopy have been defined on the basis of 1) the delay between endoscopy and death; 2) the occurrence of an AE between endoscopy and death.
- The rate of deaths possibly related to colorectal endoscopy is of 0.51/10 000 (all types of endoscopies combined) for a total of 13 deaths among 210 353 individuals.
- It is 0.38/10 000 for long colonoscopies only.

Rate of deaths (2)

- Among deaths preceded by an AE in the study population (n=13), 9 occurred in the 70-74 years old group (i.e. 69.2%).
- Endoscopies performed in this age group account for only 16.6% of all endoscopies, which means that the rate of death is particularly high among the oldest individuals.
  - 70-74 years - 1.64 / 10 000
  - 60-69 years - 0.03 / 10 000
  - 50-59 years - 0.09 / 10 000.

Study results against screening program standards

- Looking at long colonoscopies:

	Targets	Results of the study	
Bleeding	< 1/100[1]	0.08/ 100	
Perforation	< 1/2000[2]	0.7/ 2 000	
Cardiovascular events	≤ 1/1000[3]	0.3/ 1000	
Deaths	0[4]	0.38/ 10 000	

1. PQDCCR standards for a bleeding following a polypectomy.
2. PQDCCR standards based on U.S. Multi Society Task Force on Colorectal Cancer, CPAC and Cancer Care Ontario
3. PQDCCR standards referring especially to cardiac arrhythmia which term refers to various heart disorders related to, at least, eight different medico-administrative codes.
4. Standard adopted by the National Bowel Cancer Screening Program Quality Working Group of Australia is of 1/10 000. In this regard, results of the study respect the standard.

Conclusion

- Our study is the first to report rate of endoscopy-related AEs for the province of Québec.
- Endoscopies performed in Québec generate an equivalent rate of AEs than those reported in a similar canadian study and our results respect most of the screening program standards. We can state that the PQDCCR is being implemented in a favorable context.
- Clinically significant AEs selected in the study occurred in a delay of 14 days following endoscopy.
- Our study establish a baseline to reassess the rate of AEs with respect to each variables (i.e. age, gender, volume, etc.) periodically and systematically.

Acknowledgements

- To the Québec Ministry of Health and Social services for its financial support.