

Algorithms to identify endoscopy-related adverse events (AEs) in a colorectal cancer screening program population

Levesque, P.; Pouliot, S.; Simard, M.;
Gagnon, R.; Candas, B.; Jobin, G.

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Background

In the context of a colorectal cancer screening program, individuals with a positive FOBT undergo a colonoscopy to confirm the diagnosis;

Colonoscopy is a safe procedure but adverse events (AEs) occasionally occur;

Monitoring AEs is essential for quality assurance in screening program but it raises many challenges:

1. Identifying occurrence of AEs;
2. Reporting and classifying AEs uniformly;
3. Capturing delayed events.

Objectives

- Identify endoscopies performed in a population similar to the one targeted by the colorectal screening program in the province of Québec and establish a list of AEs possibly related to endoscopies;
- Select the most significant AEs that could be monitored in a colorectal screening population;
- Describe the development of algorithms that exploit medico-administrative databases to classify AEs according to their level of severity and the likelihood of relationship with endoscopy.

Approach

- Retrospective cohort study using medico-administrative databases;
- Bleeding, perforation, cardiovascular events and deaths following endoscopies performed during a 4 year-period were extracted from databases;
- To attribute severity level, we looked if AEs required hospitalization and/or some specific medical procedures;
- To establish likelihood of relationship, the delays between AEs and endoscopies were analysed over a 30 day period. For this period, daily frequencies of AEs were also considered;
- Specific severity levels and relationship were combined to retain clinically significant AEs.

Study population

645 451 endoscopies between January 1, 2000 and December 31, 2004
(n=446 299 individuals)

Inclusion criteria :

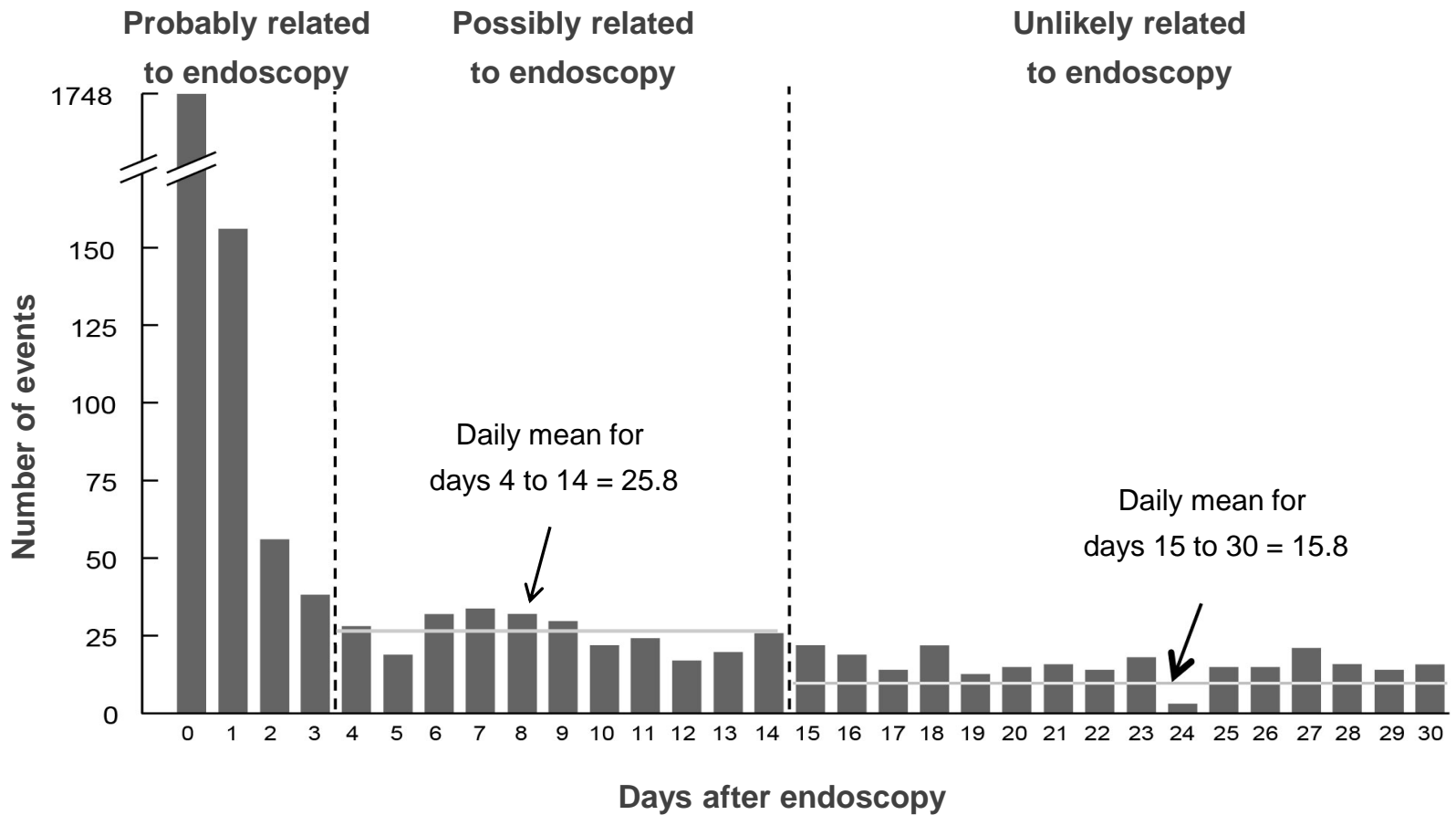
- Aged between 50-74 years;
- No history of colorectal cancer;
- No endoscopy, abdominal surgery or surgical repair within 90 days preceding the initial endoscopy;
- No other previous abdominal surgery on the same day;
- Endoscopies for which the indication was not the presence of a bleeding

256 500 endoscopies used in our study
(n=210 353 individuals)

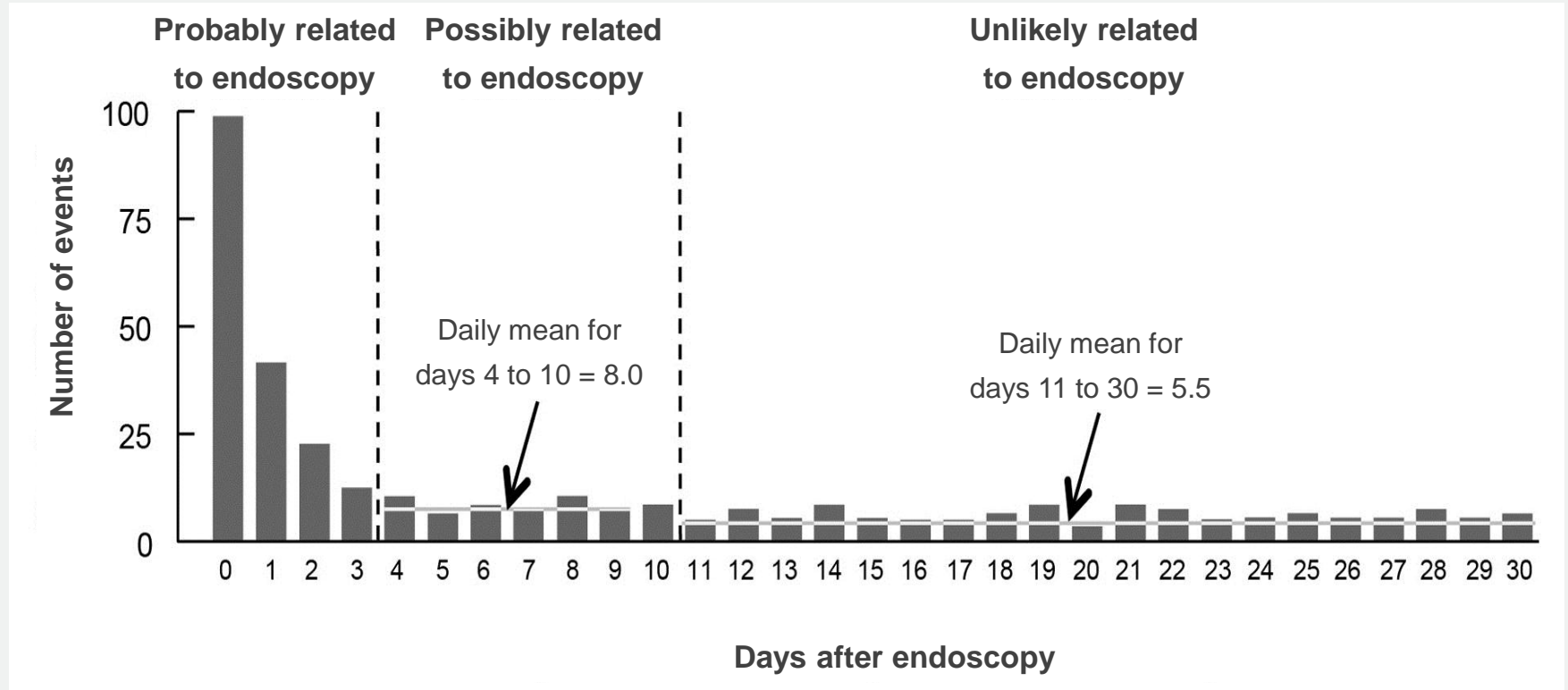
Definition of severity level for AEs

Adverse events	Severity			
	High	Moderate	Low	
			Category A	Category B
Bleeding				
Hospitalisation	Yes	Yes	Yes	No
Endoscopy	Yes	Yes	No	Yes
Medical procedure	Yes	No	No	Yes
Perforation				
Hospitalisation	Yes	Yes	No low category	
Endoscopy	Yes	Yes		
Medical procedure	Yes	No		
Cardiovascular events				
Hospitalisation	Yes	No moderate category	No low category	
Endoscopy	No			
Medical procedure	No			

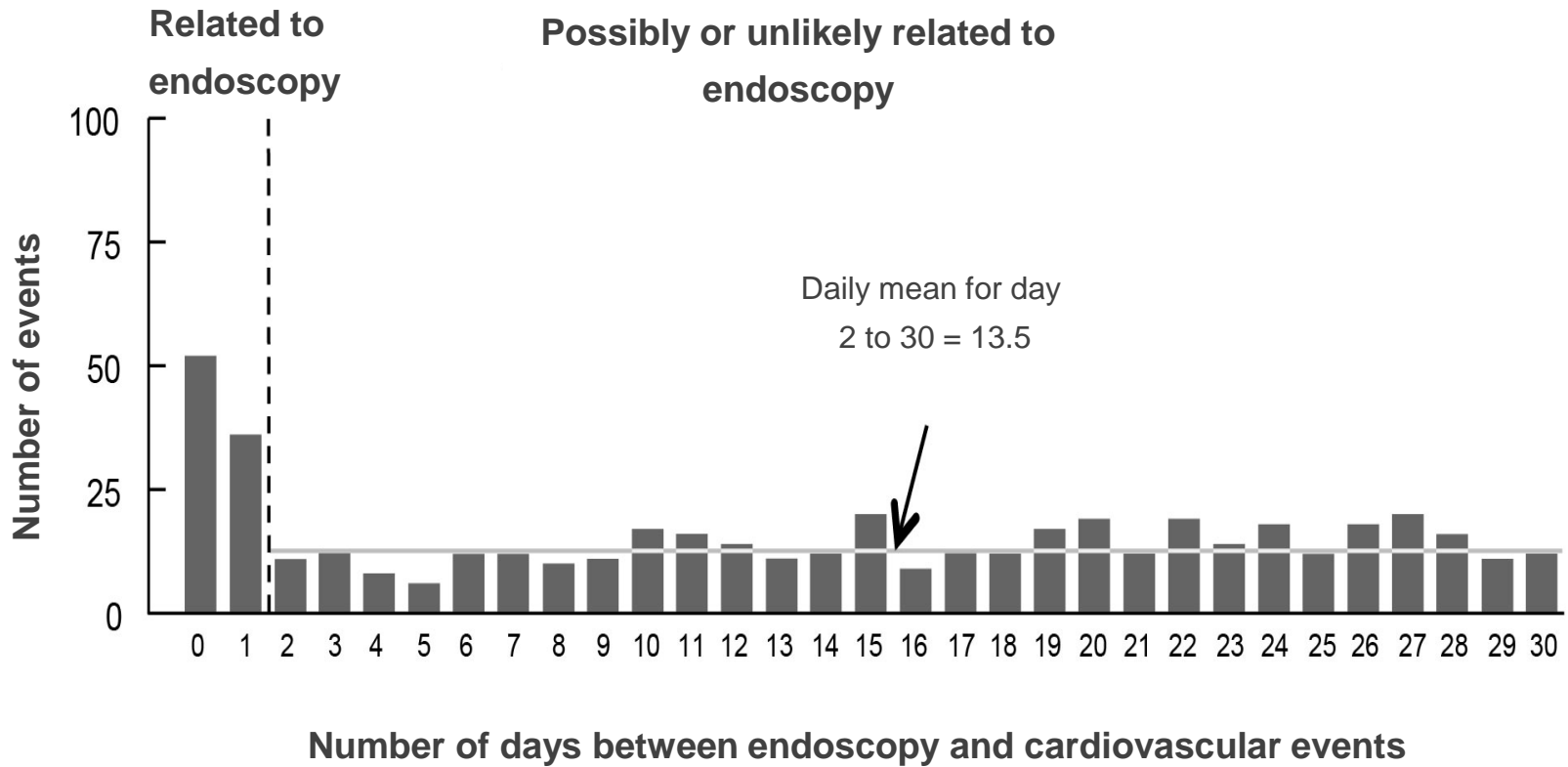
Likelihood of relationship between bleeding and endoscopies



Likelihood of relationship between perforation and endoscopies



Likelihood of relationship between cardiovascular event and endoscopies



Summary of likelihood of relationship between AEs and endoscopies

AEs	Delays between endoscopy and AEs (days)		
	Probably related to endoscopy	Possibly related to endoscopy	Unlikely related to endoscopy
Bleeding	0-3	4-14	15-30
Perforation	0-3	4-10	11-30
Cardiovascular events	0-1	2-30	---

Likelihood of relationship between death and endoscopies

Likelihood of relationship	Criteria		
	AEs before death		Delay between endoscopy and death
Possibly related	High severity cardiovascular events probably related to endoscopy	AND	7 days after endoscopy
	High severity perforation probably or possibly related to endoscopy	AND	11 days after endoscopy
	No AEs	---	Within 30 days (for codes K92.2,K65.0 ,K65.8 ,K65.9)
Unrelated	Perforation unlikely related endoscopy	AND	Between day 11 th and 30 th
	High severity cardiovascular events possibly or unlikely related to endoscopy	AND	Between day 2 nd and 30 th
	AEs other than bleeding, perforation and cardiovascular events	AND	Within 30 days

Clinically significant AEs

Likelihood of the relationship between endoscopy and AEs	Level of severity		
	High	Moderate	Low
Colorectal bleeding			
Probably related to endoscopy	Significant AEs	Significant AEs	Not significant AEs
Possibly related to endoscopy	Significant AEs	Significant AEs	Not significant AEs
Unlikely related to endoscopy	Not significant AEs	Not significant AEs	Not significant AEs
Colorectal perforation			
Probably related to endoscopy	Significant AEs	Not significant AEs	---
Possibly related to endoscopy	Significant AEs	Not significant AEs	---
Unlikely related to endoscopy	Not significant AEs	Not significant AEs	---
Cardiovascular events			
Probably related to endoscopy	Significant AEs	---	---
Possibly related to endoscopy	---	---	---
Unlikely related to endoscopy	---	---	---

Conclusion

This study is the first to define the likelihood of relationship between AEs and endoscopies;

Combining severity level and relationship is a new approach that improve the identification of AEs specific to endoscopy;

Our study demonstrate the feasibility of estimating AEs through medico-administrative databases;

Once validated against medical records, theses algorithms could be used to estimate AEs for the Québec colorectal screening program.