



# Complications in colonoscopy: analysis of 7-year physician-reported adverse events

Yaron Niv<sup>a</sup>, Yael Gershtansky<sup>b</sup>, Ron S. Kenett<sup>c</sup>, Yossi Tal<sup>b</sup> and Shlomo Birkenfeld<sup>d</sup>

**Introduction** The number of malpractice claims against physicians and health institutes in Israel is increasing continuously, as in the rest of the Western world. This trend became a serious financial burden.

**Aim** In this study we analyzed reports of gastroenterologists on colonoscopy adverse events to the medical malpractice insurer, as well as complaint/demand for compensation from patients represented by lawyers, between 1 January 2000 and 31 December 2006.

**Methods** All the reports of physicians associated with colonoscopy adverse events from health institutes covered by Madanes Insurance Group were analyzed and summarized using a specially designed questionnaire. Clinical and epidemiological details about the patients, procedures, and adverse events were coded into an excel sheet, discussed, and evaluated.

**Results** One hundred and two cases of colonoscopy adverse events were reported. There were 48 cases of men (47.1%) and the average age was  $69.9 \pm 12.90$  years. In this period of time 252 064 colonoscopies were performed by the institutes in the sampling frame, and the number of adverse

events was on average 4.0 (between 2.8 and 6.2) for 10 000 colonoscopies. The difference between the years was not statistically significant. Perforation occurred in one of 2864 procedures, bleeding in one of 29 007 procedures, and respiratory complications in one of 50 412 procedures.

**Conclusion** This is the first study in Israel based on physicians' reports of colonoscopic adverse events. The picture is optimistic, as the rate of complications is low, and the data encourage early detection and reporting. *Eur J Gastroenterol Hepatol* 00:000–000 © 2011 Wolters Kluwer Health | Lippincott Williams & Wilkins.

European Journal of Gastroenterology & Hepatology 2011, 00:000–000

**Keywords:** adverse events, bleeding, colonoscopy, perforation, sedation

<sup>a</sup>Department of Gastroenterology, Rabin Medical Center, Tel Aviv University, <sup>b</sup>Medical Risk Management, The Madanes Group, <sup>c</sup>The KPA Group, University of Torino, Italy and <sup>d</sup>Clalit Health Services, Tel Aviv District, Israel

Correspondence to Professor Yaron Niv, MD, FACP, AGAF, Department of Gastroenterology, Rabin Medical Center, Beilinson Hospital, 39 Jabotinski Street, Petach Tikva 49100, Israel  
Tel: +972 3 9377237; fax: +972 3 9210313; e-mail: yniv@clalit.org.il

Received 7 February 2011 Accepted 22 March 2011

## Introduction

More than 60% of the Israeli population has health insurance at Clalit Health Services (CHS). The physicians of CHS, in the community and in hospital have professional insurance at the same company. The number of malpractice claims against physicians and health institutes is increasing continuously in Israel, as in the rest of the Western world, and becomes a serious financial burden. Health economics became critically unstable, and risk management strategy for decreasing claims, and reducing losses became an integral part of every health program in Israel. It was recently reported that 93 and 98% of American and Japanese physicians, respectively, practice defensive medicine, such as assurance behavior, and avoidance behavior [1,2].

As a part of their risk management policy health providers in Israel are required to report immediately any adverse event or complication in patients' treatment. Such reporting provides an opportunity to prepare an adequate defense against potential legal claims, and drive lessons learned to prevent recurrence. It is not rare that caregivers are reluctant to report errors, facing a self

image or ego conflict. Persuasive efforts by health organizations, claiming that early reports are for the physician's own benefit, have the potential to overcome this problem. Regular reporting rates increase systematically, but are still far from fully representing the actual extent of adverse events.

In this study we analyzed complications of colonoscopy reported by the insured institutions, adverse events, claims, and complaints to the risk management authority, between 1 January 2000 and 31 December 2006.

## Methods

The researchers reviewed and coded during several work sessions all the reports of physicians associated with colonoscopy adverse events or complications in health institutes covered by Madanes Insurance Company between 1 January 2000 and 31 December 2006. Clinical and epidemiological details about the patients, procedure, and adverse event were ascertained, discussed, and evaluated by the researchers. The process was based on a specially designed questionnaire covering the relevant and available data.

Date, time of the day and place of the colonoscopy, background diseases and operations, medications, indication, additional procedure such as dilatation, biopsy and polypectomy, completeness of informed consent, treatment with anticoagulant or antiplatelets adhesion agent, adverse events and the time of diagnosis, treatment of complication and outcome, were all thoroughly discussed and coded.

Outcome was evaluated according to three categories: complete recovery, death, and residual damage. Patients, who underwent operations as the result of the complication, were classified in the 'residual damage' category even though completely recovered. This is more of a legal term than medical term, as every scar on the abdominal wall recognized as 'damage'. The number of colonoscopies performed to members of CHS in Israel, between 2000 and 2006, was extracted from the CHS database, for each year of the study. The incidence of colonoscopic adverse events was separately calculated for members of CHS, according to the database for the corresponding period of time.

A Quantum value ( $Q$ ) in New Israeli Shekels (NIS) represents the economic loss from an adverse event, actual or potential, in cases that were evaluated as malpractice. The  $Q$  value was calculated for each case by the medical insurance team who assigned  $Q=0$  (no damage and/or no responsibility), or  $Q$  greater than 0 (responsibility accompanied by damage). Parameters that determine the value of  $Q$  are: severity of damage, pain and suffering, decrease in the ability to work and have salary (in relationship to income and family status), need of help for daily activity, potential changes in housing or relocation, life expectancy, expenses in the particular case, and experience with similar cases in the past.

The statistical analysis was performed using SPSS version 13 (IBM, USA) and MINIAB 15.2 (KPA, Israel). The results are expressed as mean  $\pm$  standard deviation, and  $P$  value of less than 0.05 is considered significant. Kaplan–Meier curves and Wilcoxon nonparametric tests were used to determine differences in age distributions by outcome, anticoagulant treatment, time to detect, and urgency of procedure.

## Results

One hundred and two cases of colonoscopy adverse events were reported to Madanes Insurance Group between 1 January 2000 and 31 December 2006, 73 cases (71.6%) occurred at CHS facilities. Clinical and demographic data of the cases are presented in Table 1. There were 48 (47.1%) cases of men and the average age was  $69.9 \pm 12.90$  years, range 29–90 years, median 71 years. Seventy-five patients (73.5%) were 65 years or older. Eighty-two events (80.4%) were reported voluntarily by

the staff (primary report), and 20 (19.6%) were reported after complaints and claims for compensation (secondary report) or claims in court (tertiary report). Most of the procedures were for diagnostic reasons, and performed on an elective basis. Polypectomy was performed in 38 (37.2%) procedures. More than 50% of the cases had two or more chronic background diseases, have undergone two or more operations, and were regularly treated with two or more medications, including aspirin (20.6%), Coumadin, or Clexan (3.9%).

Distribution of 73 colonoscopic adverse events along 7 years period for CHS members is presented in Table 2. In this period of time 252 064 colonoscopies were performed by the institutes concerned. The number of adverse events per year was between 2.0 and 4.3 for 10 000 colonoscopies. The difference between the years is not statistically significant and could be incidental. Perforation occurred in one of 2864 procedures, bleeding in one of 29 007 procedures, and respiratory complications in one of 50 412 procedures.

Distribution of the procedures along the week working days was similar: 15.7% minimum, and 21.6% maximum, on Monday and Wednesday, respectively. Sixty-two (60.8%) events happened in the morning, and 22

**Table 1 Demographic and clinical data of the reported cases [N=102 (100%)]**

Parameter	n	Percentage
Sex		
Men	48	47.05
Women	54	52.95
Age		
Average $\pm$ SD (years)	69.9 $\pm$ 12.90	
Median (years)	71	
Range (years)	29–90	
> 65 years	75	73.53
Referral center		
Hospital	90	88.24
Community unit	12	11.76
Indication for colonoscopy		
Symptoms	65	63.72
Screening high-risk population	28	27.45
Iron deficiency anemia	9	8.83
State of urgency		
Elective	96	94.12
Urgent	6	5.88
Procedure characteristics		
Diagnostic (with or without biopsy)	62	60.78
Polypectomy	38	37.26
Stent insertion	1	0.98
Argon plasma coagulation	1	0.98
Preparation quality		
Good or fair	48	47.06
Poor or unknown	54	52.94
Record of two or more chronic diseases	53	51.96
Record of two or more operations	55	53.92
Record of two or more medications	63	61.76
Anticoagulant or antiplatelet therapy		
None	62	60.78
Aspirin	21	20.59
Coumadin	3	2.94
Clexan	1	0.98
Unknown	15	14.71

**Table 2 Distribution of 73 colonoscopic adverse events along 7-year period, for Clalit Health Services members**

Year	Number of adverse events	Number of colonoscopies performed	Number of adverse events per 10 000 procedures
2000	9	20 819	4.3
2001	9	24 937	3.6
2002	8	31 341	2.6
2003	12	37 157	3.2
2004	13	43 117	3.0
2005	10	50 254	2.0
2006	12	44 439	2.7
Total	73	252 064	2.9

**Table 3 Adverse events in colonoscopies, [N=102 (100%)]**

Parameter	n	Percentage
Complication		
Perforation	88 <sup>a</sup>	86.27
Bleeding	9	8.83
Cardiovascular and respiratory event	5	4.90
Site in the colon (bleeding or perforation)	97	100.00
Rectum	6	6.19
Recto-sigmoid junction	4	4.12
Sigmoid colon	27	27.84
Splenic flexure	2	2.06
Ascending colon	4	4.12
Cecum	2	2.06
Anastomosis	1	1.03
Diverticle	2	2.06
Unknown	49	50.52
Time detected		
Immediately	66	64.70
Within 24 h	24	23.53
More than 24 h	10	9.80
Unknown	2	1.97
Treatment		
Operation	83	81.37
Hospitalization and conservative treatment	16	15.69
Ambulatory treatment	2	1.96
Unknown	1	0.98
Outcome		
Residual damage	73	71.57
Complete healing	20	19.61
Death	8	7.84
Unknown	1	0.98

<sup>a</sup>For CHS the numbers are 63 perforations, seven cases of bleeding, and three cases of cardiovascular and respiratory events.

(21.6%) in the afternoon. As we did not have data on the number of procedures performed by day or by shift we could not evaluate the difference statistically. Informed consent was properly filled and signed in 73 (71.6%) cases, and partially filled in eight (7.8%) additional cases. The informed consent form could not be found in the insurance company file or in the patient's file in 21 (20.6%) cases.

Description of adverse events and clinical outcome is presented in Table 3. There were 88 perforations, 86.2% of the adverse events. The sigmoid colon was the most vulnerable site for complication (27.8% of the cases, or 56% of the known site cases). Most of the cases were detected and reported immediately or within 24 h. Eighty-three patients were operated on (81.3%), and 99 patients required hospitalization. There were eight

**Table 4 Claims and legal status for 16 July 2010**

Parameters	N	Percentage
Claim in court	2	1.96
Compromise agreement (in and out of court)	10	9.80
Limitation	29	28.43
Demand for compensation	12	11.76
Adverse events (primary reports)	49	48.05

(7.8%) mortality cases, and 73 patients had residual damage, of whom mild in 50 (68.4%).

The status of legal claims is presented in Table 4. Half of the cases reported by the staff involved no legal activity. Only minority of the cases came to court, 10 achieved compromise agreements, and 12 are engaged in ongoing negotiations.

The assigned *Q* value was zero in 39 (38.2%) cases, and 100 000 NIS or more in 13 (12.7%) cases; with mean of 43 609 ± 91 650, median of 25 000, and range of 0 to 750 000 NIS.

Age distribution by outcome showed significant differences ( $P < 0.001$ ) with a median age of full recovery of 63 years, a death median age of 79 years, and a median age for residual damage of 73 years (Fig. 1). Figures 2–4 present survival curves by age distribution and anticoagulant, time of detection and urgency of procedure. Only urgency of procedure shows significant impact with the median age of elective procedure being 71 years (mean 69 years), urgent procedures with median age 71 years (mean 75 years), and semi elective as 83 years (mean 83 years).

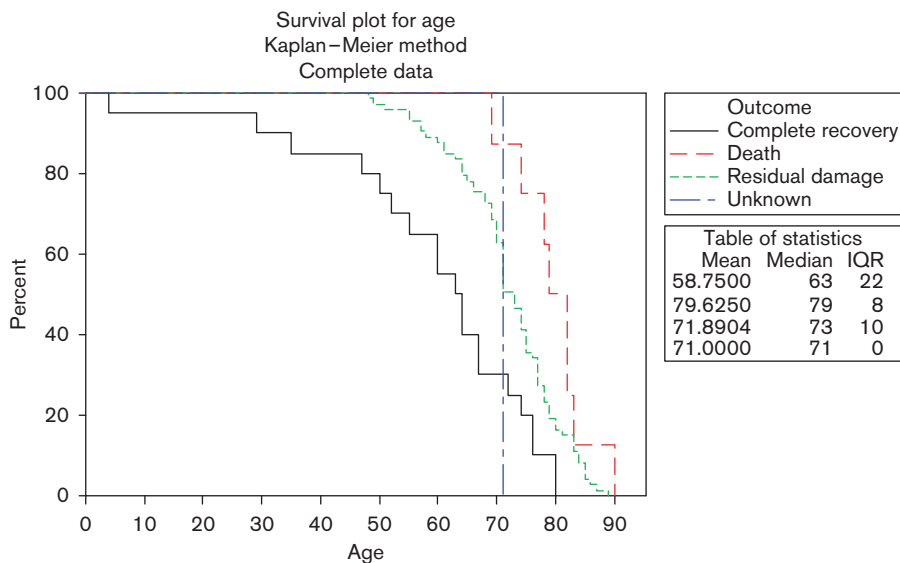
## Discussion

Reporting adverse events and complications is a part of daily routine work in Israeli healthcare system, encouraged by the health organizations and the insurance companies, but not supported by objective measures [3]. With sensational mass media coverage on medical malpractice cases, economic considerations and intrinsic drives to improve patient safety, physicians have begun to focus on risk management activities. Another aspect of the reporting is the need of insurers to prepare for potential claims by assigning the *Q* value, collecting specific data, and debriefing selected events to decrease probability of recurrences.

Described adverse events and complications of colonoscopy included perforation, bleeding, sedation-associated cardiovascular and respiratory problems, preparation-related hypovolemia, electrolyte disturbances, phosphate nephropathy, and missing lesions or misinterpreting them. There are also rarely described adverse events as a consequence of colonoscopy such as appendicitis, diverticulitis, acute colitis, or relapse of ulcerative colitis [4].

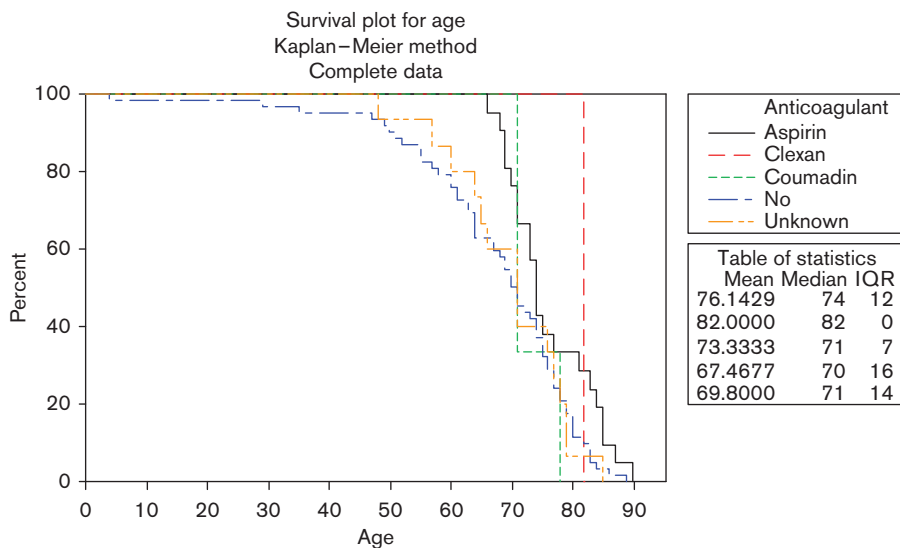
The manner in which the incident is managed has important consequences for the affected patients'

Fig. 1



Survival plot of age distribution and outcome of colonoscopy. IQR, interquartile range.

Fig. 2



Survival plot of age distribution and anticoagulant treatment. IQR, interquartile range.

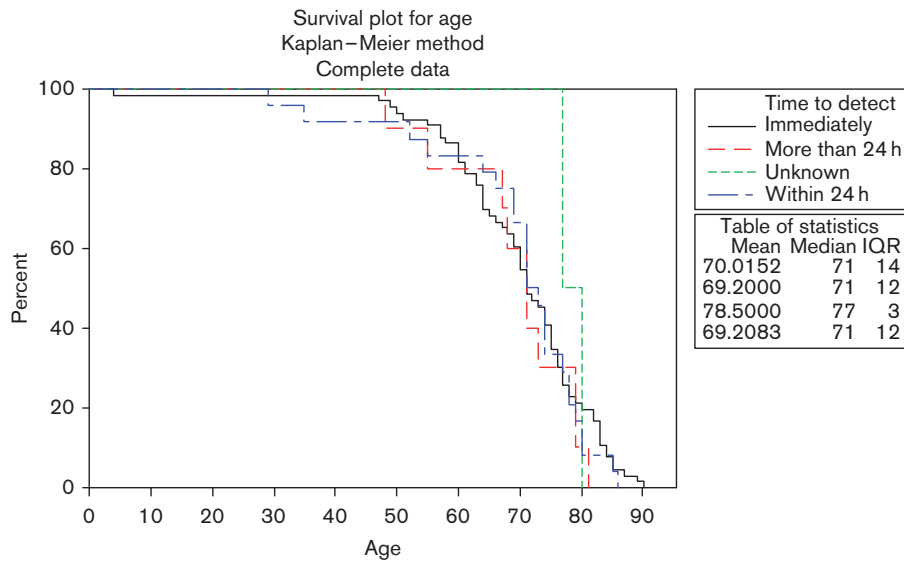
decision to take legal action [5,6]. Complete disclosure of adverse event or near misses to the patients and family members may prevent lawsuits, but this strategy is not always practiced because of shame, embarrassment, fear of losing trust, and lack of training [7-9].

The predominant complication of colonoscopy is perforation. The incidence of colonic perforation ranges from 0.016 to 0.2% following diagnostic colonoscopies and could be up to 5% following interventions [10]. In Israel,

we found a perforation rate of diagnostic and interventional colonoscopies to be 0.058% [11].

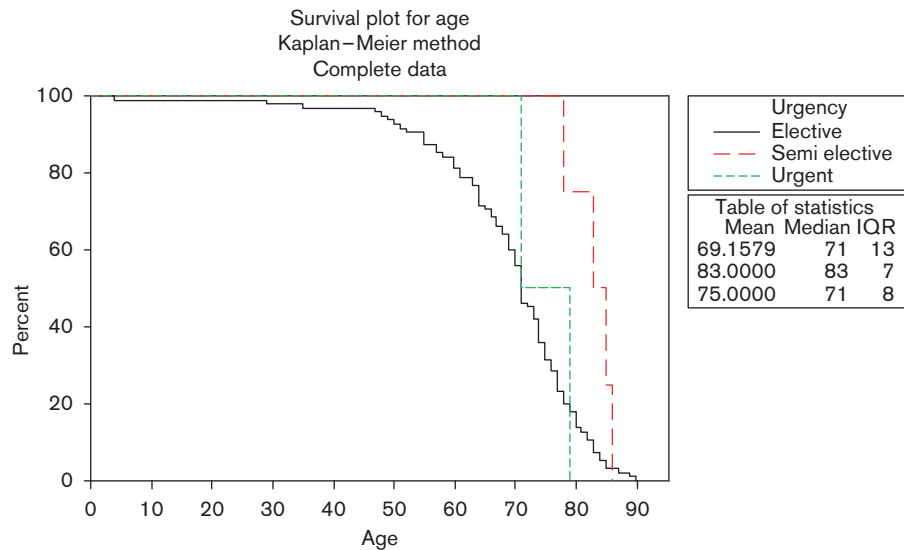
In this study we described 102 cases of adverse events during colonoscopy reported to the Madanes Insurance Group in 7 years. Not surprisingly most of the cases were of elderly patients with a background of chronic diseases, with no change in age distribution over the 7 years period. The main adverse event was perforation, especially in the sigmoid colon. The rate of perforation was well within

Fig. 3



Survival plot of age distribution and time to detect the complication. IQR, interquartile range.

Fig. 4



Survival plot of age distribution and urgency of the procedure. IQR, interquartile range.

accepted range described in the literature, and most of them happened in diagnostic procedures. The rarity of respiratory and cardiovascular complication, most probably due to sedation, is outstanding. Only five cases were reported, thus a ratio of 1:50 412 procedures could be calculated. The clinical outcome was not so favorable. There were eight cases of mortality, and 83 patients underwent operation. Seventy-three patients left with residual damage.

Most of the complications were diagnosed early, 64.7% immediately after the procedure, and additional 23.5% within 24 h. In 39 cases the *Q* value was zero, and no further legal evaluation should be performed, whereas in 13 cases the *Q* value was 100 000 and higher, and these cases were evaluated thoroughly for potential litigations and financial compensation. Almost 90% of adverse events were reported from hospitals, even though the numbers of performed colonoscopies are very similar in

community units and hospitals. This finding may be due to referral of more serious cases undergo colonoscopy in hospital rather than in community units. We did not find any similar study about gastroenterologists' colonoscopic adverse events reports and this finding should be confirmed and further investigated.

It was not possible to adequately estimate the true rate of adverse events according to these voluntary reports, and there might be far more cases than reported. Milch *et al.* [12] analyzed 92 547 reports from 26 acute care hospitals and found a wide reporting rate difference across hospitals, 9–95 reports per 1000 inpatient days (median = 35). Thus, reporting should be improved. Vincent *et al.* [5] described four main reasons for litigation: concern with standard of care, the need for explanation, compensation, and accountability.

Reporting adverse events is an essential component in preparation of staff and organization that should have to account for their actions. In a survey of teaching hospitals, Kaldjian *et al.* [13] demonstrated that most faculty and resident physicians are inclined to report harm-causing hypothetical errors, but only a minority has actually reported an error. Bleeding is more common than perforation after polypectomy [4], but bleeding that in more than 90% stopped spontaneously, is seldom reported.

In another report, Medicare claims were used to assess the rate of serious gastrointestinal events after colonoscopy [4]. The results based on 53 220 colonoscopies, are very similar to ours: rates of adverse events increased with age and comorbid conditions. Perforation happened in 6.2 cases per 10 000, twice that in our cohort. Kern [14] investigated 99 malpractice cases tried in the US, federal and state civil court system, involving 103 allegations of malpractice over a 21-year period. There were 44 cases of misdiagnosis, 25 cases of iatrogenic colon injury, and 16 cases of medical complications. In eight (8%) cases lack of informed consent was the reason for litigation. This series is different from our cohort, in which misdiagnosis was not part of it.

Despite the effort placed by the insurance companies there is still underreporting of complications and adverse events and the reported complications probably represent the tip of the iceberg. It is likely impossible to know how many patients had immediate bleeding during the procedure which was treated by clips and injection. In addition, respiratory problems (desaturation, need for bagging, etc) occur quite often, but as they are not 'perceived' by the patient or are not 'severe' enough are not routinely reported.

Informed consent was properly filled and signed in only 73 (71.6%) cases. This was a surprising finding, as physicians, patients, and legal authorities imply great importance to understanding and accepting procedure risks, according to Israeli law.

Our study is limited by being retrospective and by the lack of essential data from the patients' files and source documents. It was not feasible to compare statistically the rate of adverse events in the morning and afternoon shifts as we had no data on the global colonoscopies amount performed in these shifts separately. In addition, the follow-up is too short to evaluate the legal outcome of this cohort. We do not have information about 49 of 102 patients that still can sue or file a complaint.

In conclusion, this is the first study in Israel about physicians' reports of colonoscopic adverse events. The picture is optimistic, as the rate of complications is low, and the data encourage early detection and report.

### What is current knowledge?

The number of malpractice claims against physicians and health institutes in Israel is increasing continuously, as in the rest of the Western world. There is a serious financial burden on the Health Organizations due to malpractice claims. As a part of their risk management policy, health providers in Israel are required to report immediately any adverse event or complication in patients' treatment.

### What is new here?

This is the first study in Israel based on physicians' reports of colonoscopic adverse events. Perforation occurred in one of 2864 procedures, bleeding in one of 29 007 procedures, and respiratory complications in one of 50 412 procedures.

### Acknowledgements

Authors' contribution: Yaron Niv: study concept and design, acquisition of data, analysis and interpretation of data, drafting of the manuscript; Yael Gershtansky: study concept and design, acquisition of data, analysis and interpretation of data; Yossi Tal: study concept and design, acquisition of data, analysis and interpretation of data, statistical analysis; Ron Kenett: analysis and interpretation of data, statistical analysis; Shlomo Birkenfeld: study concept and design, acquisition of data, analysis and interpretation of data. The authors had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of interest: none declared.

### References

- 1 Studdert DM, Mello MM, Sage WM, DesRoches CM, Peugh J, Zapert K, Brennan TA. Defensive medicine among high-risk specialist physicians in a volatile malpractice environment. *JAMA* 2005; **293**:2609–2617.
- 2 Hiyama T, Yoshihara M, Tanaka S, Urabe Y, Ikegami Y, Fukuhara T, Chayama K. Defensive medicine practices among gastroenterologists in Japan. *World J Gastroenterol* 2006; **12**:7671–7675.
- 3 Glassman PA, Rolph JE, Peterson LP, Bradley MA, Kravitz RL. Physicians' personal malpractice experience is not related to defensive clinical practices. *J Health Polit Policy Law* 1996; **21**:219–241.
- 4 Warren JL, Klabunde CN, Mariotto AB, Meekins A, Topor M, Brown ML, Ransohoff DF. Adverse events after outpatients colonoscopy in the Medicare population. *Ann Intern Med* 2009; **150**:849–857.

- 5 Vincent C, Young M, Phillips A. Why people sue doctors? A study of patients and relatives taking legal action. *Lancet* 1994; **343**: 1609–1613.
- 6 Wu AW. Handling hospital errors: is disclosure the best defense? *Ann Intern Med* 1999; **131**:970–972.
- 7 Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. *JAMA* 2003; **289**:1001–1007.
- 8 Hingorani M, Wong T, Vafidis G. Patients' and doctors' attitudes to amount of information given after unintended injury during treatment: cross sectional, questionnaire survey. *BMJ* 1999; **318**:640–641.
- 9 Kaldjian LC, Jones EW, Wu BJ, Forman-Hoffman VL, Levi BH, Rosenthal GE. Reporting medical errors to improve patient safety: a survey of physicians in teaching hospitals. *Arch Intern Med* 2008; **168**:40–46.
- 10 Lohsiriwat V. Colonoscopic perforation: incidence, risk factors, management and outcome. *World J Gastroenterol* 2010; **16**:425–430.
- 11 Tulchinsky H, Madhala-Givon O, Wasserberg N, Lelcuk S, Niv Y. Incidence and management of colonoscopic perforations: 8 years' experience. *World J Gastroenterol* 2006; **12**:4211–4213.
- 12 Milch CE, Salem DN, Pauker SG, Lundquist TG, Kumar S, Chen J. Voluntary electronic reporting of medical errors and adverse events. An analysis of 92547 reports from 26 acute care hospitals. *J Gen Intern Med* 2006; **21**:165–170.
- 13 Kaldjian LC, Jones EW, Wu BJ, Forman-Hoffman VL, Levi BH, Rosenthal GE. Reporting medical errors to improve patient safety. *Arch Intern Med* 2008; **168**:40–46.
- 14 Kern KA. Medical malpractice involving colon and rectal disease: a 20-year review of United States civil court litigation. *Dis Colon Rectum* 1993; **36**:531–539.

AUTHOR QUERY FORM

**LIPPINCOTT  
WILLIAMS AND WILKINS**

**JOURNAL NAME: MEG**

**ARTICLE NO: 201446**

**QUERIES AND / OR REMARKS**

QUERY NO.	Details Required	Author's Response
	No queries	