



## Colonoscopy-Associated Perforation: Systematic Review and Meta-Analysis of Incidence and Risk Factors

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### Editor's Note

Perforations of the colon associated with colonoscopy were addressed in an article in the December 2006 issue of the *Pennsylvania Patient Safety Advisory*. At that time, the analysts noted 125 to 152 perforations reported to the Pennsylvania Patient Safety Authority for a one-year period in Pennsylvania. Since then, the number of reports mentioning perforation with colonoscopy has not changed greatly. The number for the most recent year is estimated to be in the range of 140 to 170. The Authority publishes this meta-analysis to provide facilities with benchmarks to assess their perforation rates for screening and for diagnostic colonoscopies. Facilities that would like to improve their perforation rates may wish to reference a June 2008 *Advisory* article, "Colon Perforations Complicating Colonoscopies: What is the Best Known Evidence for Prevention?"

### INTRODUCTION

Colonoscopy is a standard method of screening for colorectal cancer, the second leading cause of cancer death in the United States.<sup>1</sup> In the United States in 2009, an estimated 146,970 new cases of colon or rectal cancer were diagnosed, and 49,920 individuals died.<sup>2</sup> Worldwide in 2008, an estimated 695,000 people died from colon or rectal cancer.<sup>3</sup> Early detection of lesions by screening has been shown to reduce mortality from colorectal cancer.<sup>4,5</sup>

Colonoscopy has advantages over other colorectal cancer screening methods: it allows for examination of the entire length of the colon, has high diagnostic sensitivity, and enables the endoscopist to immediately biopsy or remove discovered polyps or other suspicious lesions. However, colonoscopy can result in bowel perforation, a rare but serious and potentially fatal adverse event. Because a range of perforation rates has been reported in the medical literature, the actual risk is unclear.<sup>6</sup> Furthermore, risk factors, especially modifiable ones, have not been well defined. The authors' research group has previously found very little published literature on the prevention of perforation or the identification of modifiable risk factors.<sup>7</sup> These deficiencies complicate estimating risk for an individual patient, assessing whether the perforation rate of a particular provider or center is aberrant, and determining cost-effectiveness.

Although previous reviews have addressed this topic,<sup>8,9</sup> to the authors' knowledge, this is the first published full-text review to systematically investigate perforation risk factors and summarize perforation incidence using a meta-analytic method in patients not selected for any particular characteristics. The authors also performed a systematic qualitative literature review to report risk factors identified in primary literature.

### METHODS

The authors searched 12 databases for clinical studies and reference lists published from January 1, 1990, through June 16, 2010, and hand-searched the results. Databases searched, controlled vocabulary terms, and search strategy are shown in Table 1.

The authors included in their study English-language full-length studies published between January 1, 1990, and June 16, 2010, that assessed patients undergoing conventional colonoscopy and reported original data collected since January 1, 1990, from objective records (i.e., patient record charts, databases, or prospective clinical studies, not recall-based surveys or questionnaires).

The authors compiled the original studies' results into a meta-analysis in order to generate an overall summary estimate of perforation incidence, investigate reasons for differences in findings among studies, and assess the robustness of the authors' own findings. (For further details, see "Methods Summary" on the Authority website.)

### ABSTRACT

Colonoscopy is an important tool for colorectal cancer screening and diagnosis, but reports of the incidence of perforation, a serious complication, vary widely, and risk factors have not been clearly identified. Using meta-analysis and a qualitative literature review, the authors systematically assessed the incidence of and risk factors for colonoscopy-associated perforation. Data on 966,172 screening and diagnostic colonoscopies from 38 original studies was combined in random-effects meta-analysis. The overall perforation incidence was 91 (95% CI: 77 to 104) per 100,000 colonoscopies. Screening colonoscopy had a lower incidence rate (41 [95% CI: 8 to 75] per 100,000 colonoscopies) than diagnostic colonoscopy and studies with mixed indications for colonoscopy (102 [95% CI: 86 to 118] per 100,000 colonoscopies). No other risk factor was identified by this meta-analysis. Published evidence suggests advanced age, polypectomy/biopsy, previous abdominal surgery, gastrointestinal comorbidities, and hemodialysis may be associated with increased risk. Despite the widespread use of colonoscopy and the seriousness of bowel perforation, information on risk factors, especially modifiable risk factors, is limited. (*Pa Patient Saf Advis* 2012 Mar;9[1]:5-10.)

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**RESULTS**

The searches identified 535 citations, of which most were excluded, most frequently due to lack of relevance to colonoscopy-associated perforation or for reporting data collected prior to 1990. The authors included 38 clinical studies that addressed perforation incidence, of which 16 also reported risk factors (see Figure 1). The 38 studies were published between 1998 and June 16, 2010, and reported on a total of 966,172 colonoscopies (for a list of all included studies and a summary of their characteristics, see Table 2 on the Authority website). Fifteen studies were conducted in the United States; the rest were conducted in Israel, Canada, Europe, or Asia. Only 11 studies collected perforation data prospectively. Duration of follow-up was periprocedural.

Many studies did not report basic demographic characteristics or clinical information. Where reported, most studies examined perforation rates in asymptomatic patients undergoing screening colonoscopy or colonoscopy for diagnostic or therapeutic reasons, but two studies limited enrollment to either screening or follow-up of another screening method (e.g., fecal occult blood test),<sup>10,11</sup> and one only examined patients with acute diverticulitis.<sup>12</sup> The authors of this meta-analysis did not limit inclusion by patient age, but only two studies focused on pediatric patients.<sup>13,14</sup>

Few characteristics of the clinicians providing colonoscopy services, such as board certification or experience, were reported. For the most part, gastroenterologists provided colonoscopy services, though sometimes colorectal surgeons, general surgeons, coloproctologists, hepatologists, or medical or surgical trainees performed colonoscopies. Providers were affiliated with a variety of healthcare settings, including university hospitals, general hospitals, and ambulatory centers.

Table 1. Search Strategy

**Databases Searched**

Cumulative Index to Nursing and Allied Health Literature, Cochrane Central Register of Controlled Trials, Embase, Excerpta Medica database, MEDLINE, PreMEDLINE, Cochrane Database of Systematic Reviews, Cochrane Database of Methodology, Health Technology Assessment Database, Healthcare Standards Directory, National Guideline Clearinghouse, and National Health Service Economic Evaluation Database

**Terms Searched**

A combination of controlled vocabulary terms and text words, including but not limited to: adverse, colonoscop\*, complication\*, etiology, harm\*, hazard\*, iatrogenic, intestine perforation, perforat\*, prevention and control, and risk

**SEARCH STRATEGY (OVID FORMAT, PARALLEL STRATEGIES CREATED FOR OTHER DATABASES)**

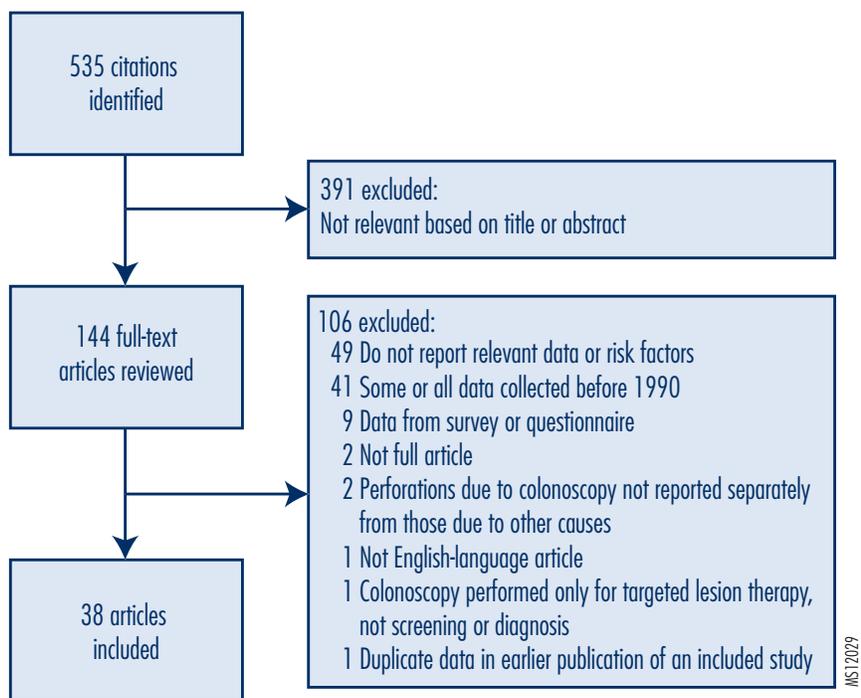
| Set Number | Concept                   | Search Statement  |
|------------|---------------------------|---|
| 1          | Colonoscopy               | Colonoscopy/ or colonoscope   |
| 2          | Perforation               | Exp intestine perforation/ or intestine perforation/ or perforate   |
| 3          | Combine sets              | 1 and 2   |
| 4          | Eliminate overlap         | Remove duplicates from 3  |
| 5          | Limit by publication type | 4 not (letter/ or editorial/ or news/ or comment/ or note/ or conference paper)/ or (letter or editorial or news or comment).pt.) |
| 6          | Risk                      | 5 and (exp risk/ or risk\$.ti. or proportional hazards models/ or proportional hazards model/)                                    |
| 7          | Etiology                  | 5 and (etiology or et.fs.)  |
| 8          | Prevention                | 5 and pc.fs.  |
| 9          | Complication              | 5 and (ae.fs. or co.fs.)  |
| 10         | Iatrogenic disease        | 5 and (iatrogenic disease/ or iatrogenic.ti,ab.)  |
| 11         | Combine sets              | or/6-10   |

Colonoscopy procedures were also poorly described. Most studies did not report methods of bowel preparation, type of colonoscope used, or polypectomy methods or frequency. Most healthcare providers administered conscious sedation for anesthesia to most or all patients; however, one study reported only 10% of patients requested anesthesia,<sup>11</sup> and one study reported administration of anesthesia to less than 5% of patients.<sup>15</sup>

Databases used in some retrospective assessments included single-hospital data-

bases, third-party payer reimbursement databases, and the Medicare Surveillance Epidemiology and End Results database. Two studies collected data on randomized samples of patients,<sup>16,17</sup> the others collected data from a consecutive series. The number of patients enrolled or records examined varied widely, from 21<sup>18</sup> to 277,434.<sup>19</sup> Some studies had so few patients that they were probably underpowered to detect a rare event (e.g., perforation). Since the authors planned to conduct a meta-analysis, studies meeting inclusion criteria were analyzed regardless

Figure 1. Study Selection Process



of the number of patients enrolled. After running the analysis again to include only studies with at least 10,000 records, the authors did not find a significant difference in summary rate. Most studies did not report how they diagnosed or searched databases for perforation. Of those that did, several database reviews used International Classification of Diseases codes to identify perforations,<sup>10,16,17,19,20,21</sup> and two studies reviewed only cases of perforation requiring operative intervention.<sup>22,23</sup>

Following the combination of all data, statistics indicated large differences among the study findings ( $I^2 = 99.7\%$ ). The all-studies summary estimate of perforation incidence was 91 (95% CI: 77 to 104) per 100,000 colonoscopies (Figure 2). The incidence did not substantially change when additional analyses (i.e., cumulative and influence analyses) were conducted, suggesting that no single study has undue influence over the summary effect size, and that the overall perforation rate is not

very likely to change appreciably with the publication of additional studies.

Statistical investigation (i.e., meta-regression) showed that perforation rates were lower in asymptomatic patients undergoing screening than in symptomatic patients or groups of mixed-indication patients. However, these factors did not explain a significant proportion of the differences in results among studies, including when other factors were taken into consideration. The perforation incidence among asymptomatic individuals seeking screening was 41 (95% CI: 8 to 75) per 100,000 colonoscopies. The remaining studies, which enrolled symptomatic and mixed populations (i.e., both symptomatic and asymptomatic patients) had an incidence of 102 (95% CI: 86 to 118) perforations per 100,000 colonoscopies. Even with the clinical groups considered separately, large differences in perforation incidence rates remained. Additional statistical tests (e.g., sensitivity analyses) suggest the rate is stable among studies

enrolling symptomatic and mixed-indication groups of patients, but appears less stable (and therefore more likely to change with the publication of additional studies) in studies with asymptomatic patients.

Additional analyses did not indicate that perforation incidence was significantly related to the following factors: country where the study occurred, number of patients, publication date or first or median year of data collection, or whether data was collected prospectively or retrospectively. No other potential factors could be investigated due to sparse reporting.

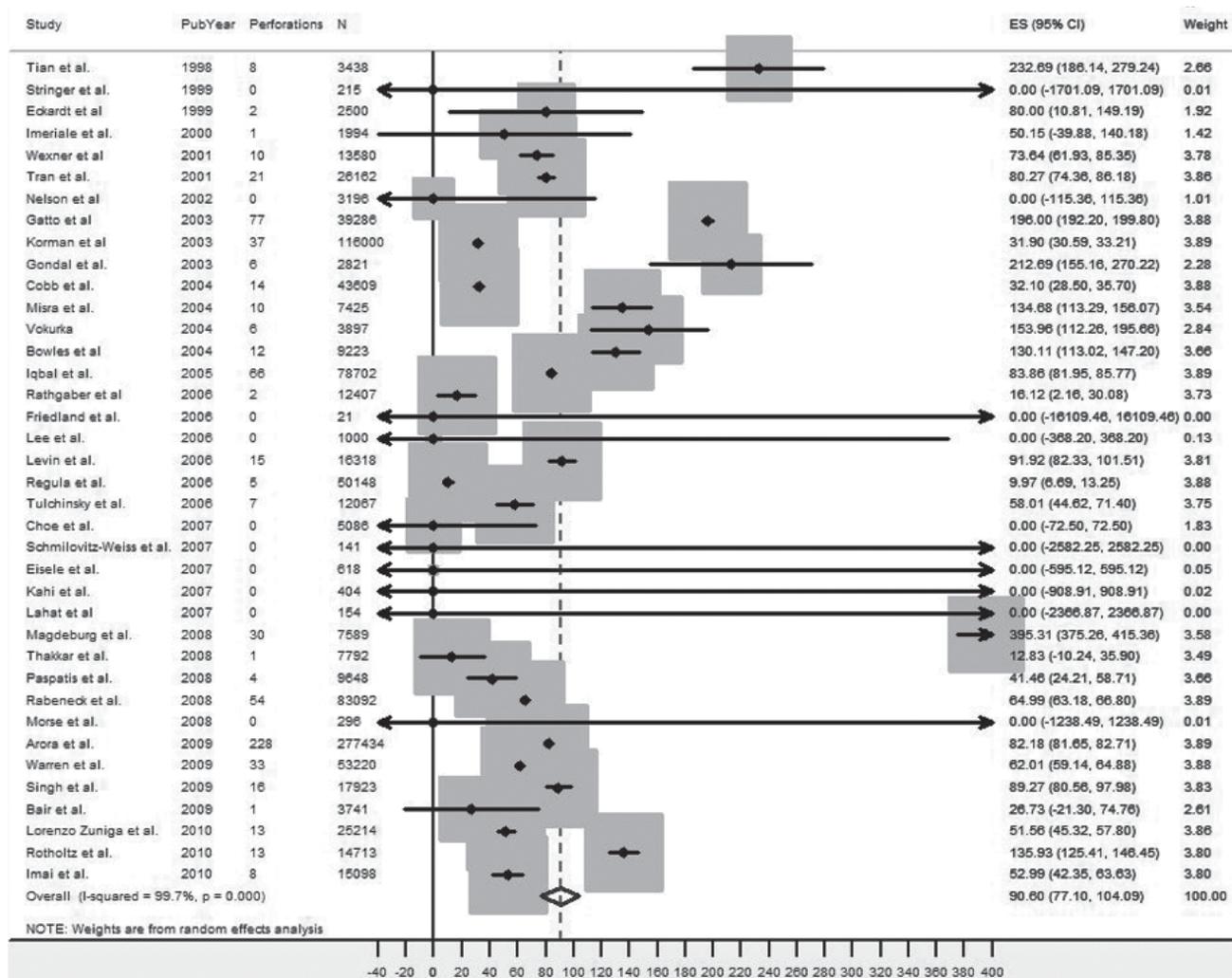
### Literature Review of Published Risk Factors

Reviewing findings from original studies is useful because it provides findings from patient-level investigations of the data, whereas data was only available for study-level analysis in the above meta-analysis. All factors in the original studies identified as risk factors for perforation (or identified as not being risk factors) are reported in the following text.

**Patient characteristics.** Older age was investigated as a risk factor and found to be associated with perforation in six studies, Tian et al.,<sup>24</sup> Gatto et al.,<sup>16</sup> Levin et al.,<sup>10</sup> Korman et al.,<sup>25</sup> Rabeneck et al.,<sup>21</sup> and Arora et al.,<sup>19</sup> but not in the two most recently published studies, Imai et al.<sup>26</sup> and Rotholz et al.<sup>23</sup> Findings regarding sex were inconsistent in five studies: Gatto et al.<sup>16</sup> and Arora et al.<sup>19</sup> reported that sex was not associated with perforation; Korman et al.<sup>25</sup> and Paspatis et al.<sup>27</sup> found that women were more likely to suffer perforation; and Rabeneck et al.<sup>21</sup> found women had lower rates. Gatto et al.<sup>16</sup> and Arora et al.<sup>19</sup> found that race was not associated with perforation.

Number of comorbidities was identified as a risk factor by Gatto et al.,<sup>16</sup> and higher comorbidity indexes were associated with perforation in Rabeneck et al.<sup>21</sup> and Arora et al.<sup>19</sup> Diverticulitis or diverticular disease was associated with perforation in two

Figure 2. Incidence of Perforation per 100,000 Colonoscopies



studies, Tian et al.<sup>24</sup> and Korman et al.<sup>25</sup> Previous abdominal surgery was identified as a risk factor by both Tian et al.<sup>24</sup> and Korman et al.<sup>25</sup> Arora et al.<sup>19</sup> found an increased risk in the presence of obstruction; however, Misra et al.<sup>20</sup> did not find an association between the reason for colonoscopy and perforation. Imai et al. found that patients on hemodialysis regimens had a statistically significant increase in occurrence of perforation.<sup>26</sup>

**Provider characteristics.** Wexner et al.<sup>28</sup> found that practitioner experience was not associated with perforation, but Rabeneck et al.<sup>21</sup> and Lorenzo-Zuniga et al.<sup>29</sup> found

that greater annual caseload was associated with lower rates of perforation. Cobb et al. reported that the rate of perforation was higher for general surgeons than gastroenterologists, although only 1 of the 14 perforations in the study occurred when a surgeon performed the colonoscopy, and that surgeon was a resident.<sup>30</sup> This difference was not found to be statistically significant ( $P = 0.353$ ). Arora et al. found that surgeons had higher perforation rates than gastroenterologists but did not find this was true once other factors were taken into account.<sup>19</sup> Primary care practitioners had lower rates than gastroenterologists in

that study.<sup>19</sup> Rabeneck et al.<sup>21</sup> did not find any association between provider characteristics and perforation.

**Procedural factors.** Bowles et al.,<sup>31</sup> Vokurka,<sup>32</sup> and Rabeneck et al.<sup>21</sup> found that polypectomy/biopsy was associated with an increased perforation rate, but Arora et al.<sup>19</sup> did not. Cobb et al. found that four out of six colonoscopies in adults for whom colonoscopy was attempted with a pediatric colonoscope resulted in perforation, and that both cases of perforation that appeared to be due to overinsufflation in the entire series were associated with pediatric colonoscope

use.<sup>30</sup> However, the difficulties that led to the selection of the pediatric colonoscope may have been the underlying risk factor for perforation rather than the colonoscope itself. Rabeneck et al. did not find a difference in rate between hospital and clinics.<sup>21</sup>

**Methodological factors.** Gatto et al.<sup>16</sup> and Arora et al.<sup>19</sup> did not find a significant association between year of data collection and perforation rate, though both observed a trend toward decreased rates over time.

## DISCUSSION

The perforation incidence among asymptomatic patients undergoing colonoscopy for screening was 41 (95% CI: 8 to 75) per 100,000 colonoscopies, which is significantly lower than the rate in the rest of the studies combined, which was 102 (95% CI: 86 to 118) per 100,000 colonoscopies. Summary estimates subgrouped by indication should be more useful for modeling decisions or cost analyses; however, since sensitivity analyses suggest the incidence of perforation among screening studies may be subject to change with the publication of additional data, literature for the application should be monitored.

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Several potential sources of bias may affect this data. The authors included data from any country but limited inclusion to English-language studies. Most of the data for the meta-analysis was from studies from the United States, Western Europe, and Canada. Only one study was from Central or South America and none were from Africa. As for any meta-analysis, the possibility that publication bias has affected these numbers cannot be ruled out. Since about 90% of the data came from retrospective studies, it is possible that these could be underestimations due to the mode of data collection, although meta-regression does not suggest prospectively and retrospectively collected data significantly differs. None of the other methodological factors investigated as potential quality indicators were associated with perforation rate either.

Although reporting was too limited to enable thorough investigation, no modifiable risk factors for perforation were identified, limiting the authors' ability to inform clinical practice. Findings from the individual studies using patient-level data were also few and sometimes conflicting.

Identifying factors associated with an increased risk of perforation, especially modifiable risk factors, is desirable for

improving the overall safety of colonoscopy. Although the risk of perforation to any individual is not high, minimizing the perforation rate is important as a greater number of individuals can be expected to seek colonoscopy for screening, diagnostic, and therapeutic purposes. Improving the safety of colonoscopy might improve patient compliance with colorectal cancer screening, reportedly only about 60% in 2006,<sup>33</sup> and would improve the cost-effectiveness of colonoscopy by reducing iatrogenic morbidity. The need for reliable information on the identification of risk factors is particularly pressing as the number of individuals undergoing colorectal cancer screening can be expected to increase. To identify means for reducing colonoscopy-associated perforation, prospective study of risk factors is warranted. Such studies could be integrated with clinical care.

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