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Causes and Outcomes of Medicolegal Proceedings Following Gastrointestinal Endoscopy in Canada

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Short Title: Legal Implications Endoscopy Canada

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Abstract

Background and Aims: Endoscopic procedures are frequently performed in Canada but can be associated with potential complications and medicolegal implications. This study aimed to identify potential medicolegal cases in Canada relating to upper and lower endoscopy as well as advanced endoscopic procedures.

Methods: Westlaw Canada was searched for any cases regarding upper and lower endoscopy and advanced endoscopic procedures from inception to December 31, 2020. Cases were classified by type of case, procedure performed, patient and defendant demographics, outcome, and alleged reason for litigation/complaint.

Results: 29 civil cases and 9 board and tribunal decisions for upper and lower endoscopy and 3 advanced endoscopic procedure cases were analyzed. The most frequent defendant specialities were family physician, general surgery, and gastroenterology. The plaintiff was successful in 12 cases involving upper or lower endoscopy with an average award of $243,934 (2021 CDN). The most alleged reasons for litigation were procedural error or negligence (n=19). The plaintiff was successful in 1 advanced endoscopic procedure case with an award of $153,031.72.

Conclusion: Medicolegal cases regarding gastrointestinal endoscopy in Canada occur infrequently. Endoscopy should be performed by skilled providers with appropriate informed consent from the patient, and careful consideration of whether procedures are indicated are key for endoscopic providers.

Keywords: colonoscopy; litigation; ERCP; lawsuit; EGD
Introduction

Endoscopic evaluation of the upper and lower gastrointestinal tracts through esophagogastroduodenoscopy (EGD), sigmoidoscopy and colonoscopy is a critical diagnostic and therapeutic tool for management of gastrointestinal disease typically performed by gastroenterologists and surgeons in Canada. Data suggest that at least 1.6 million upper and lower endoscopies are performed annually in Canada¹, while 21.6 million upper and lower endoscopies were performed in 2019 in the United States². Advanced procedures such as endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasound (EUS) afford the additional ability to investigate and manage non-luminal conditions such as pancreaticobiliary disease³,⁴. Although generally safe, luminal endoscopy is associated with several rare but potentially serious adverse events (AEs), including bleeding and perforation, with further risks associated with advanced endoscopy procedures⁵–⁸. These AEs can lead to patient morbidity and mortality and can therefore potentially lead to complaints and/or medicolegal action against providers.

Two recent studies assessed litigation patterns associated with colon cancer screening⁹ and colonoscopy¹⁰ in the United States. In both analyses, among the key identified reasons associated with litigation were delays in diagnosis and delays in treatment. To date, there have been no reports assessing medicolegal outcomes of endoscopy in Canada. Therefore, we aimed to identify causes and outcomes of medicolegal proceedings and regulatory board proceedings associated with the performance of endoscopic procedures in Canada.
Methods:

Westlaw Canada was searched from inception (1803) until December 31, 2020, to identify any potential medicolegal cases and regulatory board cases involving endoscopic procedures in Canada. Westlaw Canada is a legal database providing complete coverage of reported decisions from 1977 to present day, unreported court decisions from 1986 to present day, decisions in Carswell Law Reports, and decisions predating these periods from law report series and is felt to cover every reported case in Canada since 1803\textsuperscript{11} including cases prior to Canada becoming independent in 1867. All cases reported in the 10 provinces and 3 territories are covered by this database; reporting of court decisions is obligatory.

Our Boolean search strategy was designed with the aid of a legal librarian (KO-S) and consisted of the following terms: a) for upper and lower endoscopy: "colon cancer" OR "colorectal cancer" OR "colonoscopy" OR "polypectomy" OR "colectomy" OR "colostomy" OR "ileocolonoscopy" OR "sigmoidoscopy" OR "gastroscopy" OR "esophagogastroscopy" OR "esophagastroduodenoscopy" OR "enteroscopy" OR "endoscopy". To analyze advanced endoscopic procedures, the Boolean search strategy was “endoscopic retrograde cholangiopancreatography” OR “ERCP” OR “endoscopic ultrasound” OR “EUS”.

Cases were included for analysis if they were related to performing an endoscopic procedure or not ordering an endoscopic procedure when indicated. Exclusion criteria included not being related to medicolegal action (e.g., labour tribunal) or if endoscopy was not a significant factor for the medicolegal action (e.g., predominantly related to a surgical complication).

Cases were reviewed by two individuals independently (SM, SEC) and case details were extracted using a standardized form. Duplicates, appeals of decisions made by a lower court, and
interlocutory decisions (orders made by a court prior to the final disposition of a case) were removed. Disagreements regarding inclusion of cases were all resolved by consensus. Cases in Westlaw are distinguished between those in the traditional court system and those in the parallel administrative tribunal system (also referred to as boards and commissions). A key difference is that decision makers in tribunals usually have specialized knowledge of the topic whereas judges in the court system have a more general knowledge about many topics of the law. Tribunal decisions can subsequently be reviewed in court.

Details extracted included: the type of case (criminal, civil, administrative), type(s) of endoscopic procedure performed, patient age and sex, year, province, defendant specialty(ies), sex(es), outcome of the case, the alleged reason for litigation, and the settlement amount (for civil suits). For cases in the court system (criminal, civil), the alleged reasons for medicolegal action were classified according to the following themes: delay in diagnosis, delay in treatment, procedural error/negligence, lack of informed consent, unnecessary procedure, medication error, misinterpretation of test/imaging, failure to order investigations/testing, death, and other. Cases were permitted to have more than one alleged reason for medicolegal action. For cases reviewed by administrative boards or tribunals (i.e., a professional regulatory body), the alleged reasons were classified into the following themes: failure to meet the standard of practice of care, performing acts or practices that would be considered disgraceful, dishonourable, or unprofessional by other colleagues, and practicing medicine in a non-competent manner. Civil and cost awards were converted to 2021 Canadian dollars using the Bank of Canada Inflation Calculator. Although our study is not a traditional medical systematic review, we conducted it based on the principles of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.
Results:

Case Identification

Upper and Lower Endoscopy

A total of 736 court cases and 750 board and tribunal decisions across Canada were initially identified by the electronic search strategy for upper and lower endoscopy. After initial screening, a total of 54 cases and 16 board and tribunal decisions were identified for detailed review and data extraction. Accounting for multiple published proceedings, interlocutory rulings of cases with decisions, and appeals of decisions, there were a total of 32 unique cases and 9 board and tribunal decisions included in the final analysis. A summary of the case review can be found in Figure 1.

Advanced Endoscopy

For advanced endoscopy, a total of 29 court cases and 15 board and tribunal decisions were identified on the initial search strategy. Eleven cases and three board and tribunal decisions were identified for detailed review. Accounting for appeals, interlocutory rulings and cases that were predominantly based on surgical complications, the final analysis consisted of three cases; no relevant board and tribunal decisions were identified. A summary of the case review can be found in Figure 2.

Cases

Upper and Lower Endoscopy

There was a total of three criminal cases and 29 civil cases analyzed for upper and lower endoscopy. For the civil cases, most plaintiffs were male (n=16); 3 cases did not report the
plaintiff’s sex. Cases were distributed throughout the country, with the majority being from Ontario (n=14). Of the 29 cases, there were 45 male defendants, 5 female defendants and 4 organizations (average of 1.86 defendants per case). The most frequent defendant specialties were family physician (n=15), general surgery (n=12), and gastroenterologist (n=10) with colonoscopy being the most common procedure involved with litigation (Table 1). In 12 cases, the plaintiff was successful with an average award of $243,934 (2021 CDN); there were 15 verdicts in favour of the defendant, one settlement and 1 case was an interlocutory ruling with no subsequent published verdict suggestive that the case was settled or discontinued. The most common alleged reasons for litigation were procedural error or negligence (e.g., perforation, fall post endoscopy, inappropriate cleaning strategies) (n=19) with 15 cases reporting more than one reason for litigation (average of 1.6 reasons/case) [Figure 3 and Figure 4]. For cases involving family physicians, the most common alleged reasons for litigation were delays in diagnosis, failure to order diagnostic tests, and failure to appropriately refer, with only one case associated with procedural error or negligence. Conversely, for cases involving gastroenterologists and general surgeons, 14 cases were associated with procedural error or negligence.

Two of the three criminal cases involved accusations of alleged sexual assault with one involving the endoscopist and one by an assistant (n=2); in both cases, the defendant was acquitted. The third case involved an appeal of fraudulent billing of procedures that were not performed; this conviction was upheld.

Advanced Endoscopy

Of the three relevant cases identified, all involved ERCP and all plaintiffs were female. One case had a plaintiff verdict, one had a defense verdict and one case with published
interlocutory rulings, but no subsequent published verdict had proceedings suggesting that the

case was settled or discontinued. The alleged reasons for suit included procedural error or

negligence (1/3), failure to refer and/or order diagnostic tests (3/3), death (1/3) and lack of

informed consent. A total of 7 men, 1 woman and one organization were named through the

three cases; 4 were gastroenterologists, 4 were general surgeons. In the one case with a plaintiff

verdict, the gastroenterologist defendant had a verdict of $153,031.72 against him.

Board and Tribunal Decisions

All the board and tribunal decisions analyzed were Ontario based; 8 were proceedings by

the College of Physicians and Surgeons of Ontario in which all physicians were found guilty of

the charges while one was a Human Rights Commissions of Ontario proceeding where the

physician was found not guilty.

In the College of Physicians and Surgeons of Ontario regulatory proceedings, 7/8 were

male with physician specialties including family medicine (3), gastroenterology (1), surgery (2)

and anesthesia (2). The average age of implicated physicians was 68 (n=5). Key reasons for

complaints included failure to meet the standard of practice (5/8), conduct that would be

considered to be disgraceful, dishonourable or unprofessional (5/8), and incompetent practice

(5/8). Most physicians received public reprimands (6/8), five either agreed to never practice

medicine again or had their license revoked, two were suspended (3 and 5 months) and one

required a practice reassessment. Average costs awarded against the physician were $21,913.93

2021 CDN.
**Discussion:**

In our study, we performed the first comprehensive analysis of medicolegal outcomes of gastrointestinal endoscopic procedures in Canada and ultimately identified 32 cases and 9 board/tribunal decisions. Approximately 41% of the civil cases led to a plaintiff verdict, with most defendants being family physicians. All the board/tribunal decisions originated from Ontario with all 8 physicians charged by the College of Physicians of Surgeons of Ontario being found guilty. It is notable that despite how frequently endoscopy is performed in Canada, the number of cases is very low.

In our study, the most common theme for civil litigation was procedural error or negligence, with 19 cases involving this theme linked with the defendant specialities of general surgery and gastroenterology. Given the invasive nature of endoscopic procedures and the risk of complications, it is not surprising that procedural error/negligence was a common reason for litigation. To try and help reduce the risk of error, it is important for all providers to remain up-to-date regarding quality indicators and guidelines for endoscopy to ensure that they are performing to the expected standard and so that informed consent can take place in the most effective manner. As examples, audit and feedback of colonoscopy quality indicators and brief educational courses have both been shown to be associated with improvements in colonoscopy quality.

Interestingly, in a previous study assessing 305 colonoscopy cases from 1980-2017 in the United States, litigation was most commonly associated with delays in treatment and/or diagnosis (e.g., delays in performing endoscopy); however, 44% still involved procedural error or negligence. The rate of litigation in our series is about 10% of previously published US series although there is limited data in the US on medicolegal actions dealing with upper
endoscopy. Although there may be many factors for this difference in litigation patterns, one important factor may be the availability of endoscopy; in Canada, our single-payer system dictates that endoscopy resources are significantly more limited as compared to the United States, and so some element of delay may be expected. Nonetheless, the significant rate of procedural error or negligence being associated with litigation highlights the importance of providers being adequately trained and performing procedures skillfully, acknowledging that AEs can and will arise with endoscopy.

In this analysis, there were very few physicians-in-training involved in litigation; all the board/tribunal complaints involved staff physicians. The involvement of residents with medicolegal claims is becoming more recognized and is of growing research interest\textsuperscript{21,22}. Notably, the frequency of calls for medicolegal advice to the Canadian Medical Protective Agency from trainees (the primary provider of medical claims insurance) has been increasing at a higher rate than other groups\textsuperscript{23}. Given this, trainees are an important group to target for formal training in post-graduate programs; unfortunately, medicolegal education in the post-graduate setting is limited\textsuperscript{24–26}. Currently in Canada, maintenance of certification programs by either the College of Family Physicians of Canada or the Royal College of Physicians and Surgeons of Canada do not mandate continuing medical education in procedural skills for practitioners who perform medical procedures. Furthermore, there is no national standard for the granting and renewal of endoscopy privileges for providers in Canada; instead, local standards are applied by individual hospitals and/or health authorities. Endoscopist speciality has been associated with colonoscopy quality indicators and outcomes, with the best outcomes associated with the performance of colonoscopy by gastroenterologists\textsuperscript{27}; this may be linked to differences in training models. As such,
potentially adding procedural skills to the maintenance of certification program with consideration of speciality-specific strategies as well as developing an updated national standard for endoscopy accreditation (as current recommendations are dated)\(^{27}\) may lead to reducing the risk of procedural AEs and eliminating the postal code lottery of care\(^{28}\).

In general, evaluation of medicolegal actions in Canada has been limited and only more recently have data emerged specifically assessing outcomes in surgical specialties\(^{29,30}\), anesthesia\(^{31}\) and cardiology\(^{32}\) using claims-based data from a single medical insurance claims provider. Although Westlaw has been used more frequently in the United States\(^{9,33-35}\), to our knowledge, there is only one other Canadian medicolegal study that employed Westlaw Canada\(^{36}\); nonetheless, given its comprehensive database, we feel it is a valuable source for research. Further research into medicolegal outcomes is important for providers to understand risk factors associated with litigation and to help with continuous practice improvement. As well, with the consideration of organizational, team and system factors, medicolegal data may help with patient safety research and quality improvement overall\(^{37}\). This is especially true in advanced endoscopy, where AEs are more common and where human factors play an increasingly recognized role\(^ {38}\).

Our study has several unique strengths. Ours is the first study to comprehensively analyze the medicolegal implications of all forms of gastrointestinal endoscopy in Canada including all published court cases and administrative tribunals. Key themes for litigation were extracted to allow for all providers who perform endoscopy to reflect on their own practices and potentially make changes if required.

There are some limitations to this study which are inherent to the database used. Cases identified are only those that have proceeded to court or a tribunal; as such, there are many cases
that are dismissed or settled prior to reaching this stage that would not be captured by published
decisions. As such, the cases analyzed in this study reflect only the minority of cases, but the
themes identified are likely able to be extrapolated. Although Westlaw is the most
comprehensive database of administrative tribunals, not all regulatory bodies publish their
decisions readily. Only four of the provincial physician regulatory bodies (Colleges)
systematically publish their decisions with Ontario having started publishing cases the earliest.
However, as Ontario is the largest province in Canada and the general principles of physician
regulation are similar, we feel that likely the themes identified in the cases can be extrapolated to
the rest of the country.

In conclusion, medicolegal action following endoscopy is uncommon in Canada despite
the measurable rates of adverse events associated with endoscopic procedures. Endoscopy should
be always performed by skilled providers and should include an appropriate informed consent
process in addition to careful consideration and documentation of why the procedure is indicated.
Table 1: Characteristics of Evaluated Cases.

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of Cases (n=29)</th>
<th>Cases with Plaintiff Verdicts (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases by location (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>British Columbia</td>
<td>3 (10.3)</td>
<td>1 (8.3)</td>
</tr>
<tr>
<td>Alberta</td>
<td>6 (20.6)</td>
<td>3 (25)</td>
</tr>
<tr>
<td>Saskatchewan</td>
<td>1 (3.4)</td>
<td></td>
</tr>
<tr>
<td>Ontario</td>
<td>14 (48.3)</td>
<td>7 (58.3)</td>
</tr>
<tr>
<td>Quebec</td>
<td>3 (10.3)</td>
<td>1 (8.3)</td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>1 (3.4)</td>
<td></td>
</tr>
<tr>
<td>Newfoundland</td>
<td>1 (3.4)</td>
<td></td>
</tr>
<tr>
<td>Number female plaintiffs (%)</td>
<td>16 (55.2)</td>
<td>4 (33.3)</td>
</tr>
<tr>
<td>Procedure Type (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper endoscopy</td>
<td>9 (31.0)</td>
<td>5 (41.7)</td>
</tr>
<tr>
<td>Sigmoidoscopy</td>
<td>3 (10.3)</td>
<td>3 (25)</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>15 (51.7)</td>
<td>4 (33.5)</td>
</tr>
<tr>
<td>Upper endoscopy/colonoscopy</td>
<td>2 (6.9)</td>
<td></td>
</tr>
<tr>
<td>Defendants Named</td>
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</tr>
<tr>
<td>Male</td>
<td>45</td>
<td>20</td>
</tr>
<tr>
<td>Female</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Organization</td>
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<tr>
<td>Defendant Speciality</td>
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<td>Family Medicine</td>
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<tr>
<td>Specialty</td>
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<td>Number 2</td>
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<td>-------------------</td>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td>General Surgery</td>
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<td>4</td>
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<tr>
<td>Gastroenterology</td>
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<tr>
<td>Radiology</td>
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<td>1</td>
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<tr>
<td>Anesthesia</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
<td>4</td>
</tr>
</tbody>
</table>
Figure Legends

Figure 1: PRISMA Flowsheet for Upper and Lower Endoscopy Cases
Figure 2: PRISMA Flowsheet for Advanced Endoscopy Cases
Figure 3: Alleged Reasons for Litigation for Upper and Lower Endoscopy
Figure 4: Alleged Reasons for Litigation for Successful Plaintiff Cases


Records identified and screened from Westlaw Canada:
Cases (n=736)
Board and Tribunal Decisions (n=750)

Records excluded for lack of relevance:
Cases (n=682)
Board and Tribunal Decisions (n=734)

Records selected for detailed review:
Cases (n=54)
Board and Tribunal Decisions (n=16)

Records excluded:
Cases (n=22)
Interlocutory motion = 7
Appeal = 7
Not relevant = 7
Duplicate = 1

Board and Tribunal Decisions (n=7)
Not related to endoscopy = 5
Appeal = 1
Follow-up to original decision = 1

Final analysis:
Cases (n=32)
Board and Tribunal Decisions (n = 9)
Records identified and screened from Westlaw Canada:
Cases (n=29)
Board and Tribunal Decisions (n=15)

Records excluded for lack of relevance:
Cases (n=18)
Board and Tribunal Decisions (n=12)

Records selected for detailed review:
Cases (n=11)
Board and Tribunal Decisions (n=3)

Records excluded:
Cases (n=8)
Interlocutory motion = 2
Appeal = 2
Not relevant = 4
Board and Tribunal Decisions (n=3)
Not related to endoscopy = 3

Final analysis:
Cases (n=3)