Original Article

Medico-Legal Cases Involving Cardiologists and Cardiac Test Underuse or Overuse

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ABSTRACT

Background: Evidence-based campaigns are available to support appropriate diagnostic testing in cardiology, but medico-legal concerns can impede implementation.

Methods: We conducted a retrospective descriptive analysis of medico-legal cases (civil legal, regulatory authority, hospital matters) involving cardiologists in Canada. For eligibility, cases must have closed at the Canadian Medical Protective Association between January 1, 2009 and December 31, 2018. We defined test underuse and overuse using criticisms in the medico-legal record from peer experts, regulatory authorities, or hospitals. We used a contributing factors framework and descriptive statistics for analysis.

RESULTS: The underuse and overuse of screening or diagnostic tests can pose risks to patient safety. In 1998, an Institute of Medicine national roundtable acknowledged these risks in the context of health care quality in the United States. They de-duced test underuse and overuse (Supplemental Appendix S1) as care that would have produced a favourable outcome for a patient, and overuse as care with the potential for harm that exceeded the possible benefit. Increasingly over time, countries around the world have acknowledged the importance of physicians reducing these practices and yet, there remains evidence that cardiac diagnostic tests are being underused and overused in Canada.

The Canadian Cardiovascular Society’s clinical practice guidelines and Choosing Wisely Canada’s clinical guidelines are evidence-based campaigns to support appropriate screening and diagnostic testing in cardiology, but medico-legal concerns can impede implementation. Pitfalls in clinical decision-making, such as cognitive biases or lack of knowledge, could lead to diagnostic errors and test underuse. Conversely, lack of knowledge or incidental findings might trigger a cardiology workup and test overuse. The fear of litigation is cited as another reason for test overuse. In a recent Canadian survey, a sample of cardiologists and cardiology residents expressed concern that if they ordered fewer tests, in accordance with Choosing Wisely Canada’s list of Five Things Physicians and Patients Should Question for cardiology—a list dedicated to addressing cardiac diagnostic test overuse (Supplemental Appendix S1)—they would increase their medico-legal risk. To date, however, very little information has been published about medico-legal matters involving cardiologists in Canada.

Medico-legal data can shed light on these issues by informing cardiologists about the frequency of complaints in their specialty area and the factors that contribute to a complaint. With a contextualized understanding of risk, cardiologists might be able to mitigate some of their medico-legal concerns. The aim of this study was to understand the medico-legal issues faced by cardiologists with respect to

RESUMÉ

Contexte : Même s’il existe des campagnes fondées sur des données probantes visant à promouvoir le recours aux tests diagnostiques appropriés en cardiologie, il arrive que des préoccupations d’ordre médico-légal nuisent à la réalisation de ces tests.

Méthodologie : Nous avons réalisé une analyse descriptive rétrospective des affaires médico-légaux (poursuites au civil et plaintes déposées auprès d’organismes de réglementation et d’hôpitaux) touchant des cardiologues au Canada. Ont été retenus pour l’analyse les dossiers clos à l’Association canadienne de protection médicale entre le 1er janvier 2009 et le 31 décembre 2018. La sous-utilisation et la surutilisation de tests ont été définies à partir des...
Results: From 2009 to 2018, the Canadian Medical Protective Association closed 60,598 cases with 368 (0.6%) involving a cardiologist. Within those cases, there was no criticism of cardiac diagnostic test overuse and 15 cases (4.1%) with criticism of underuse (tests not ordered, not expedited, delayed). In 12 of 15 cases of underuse (80.0%), the patient experienced severe harm or death. Of 8 civil legal cases, 6 were decided in favour of the plaintiff (75.0%) and 2 were dismissed by consent before proceeding to trial (25.0%). Decisions on regulatory authority matters did not favour the cardiologist (7 of 7 cases). In all cases of underuse, there was need for focused testing to investigate new or worsening symptoms. The most common contributing factors included clinical decision-making, situational awareness, and communication with teams and patients.

Conclusions: Medico-legal cases involving cardiologists and the overuse or underuse of cardiac diagnostic tests were extremely rare in Canada, despite the potential for harm. The criticisms of cardiac diagnostic test underuse related to issues with diagnosing symptomatic patients.

cardiac diagnostic testing. Our specific objectives were: (1) to measure the frequency of medico-legal cases involving cardiologists in Canada that related to the underuse or overuse of cardiac diagnostic tests; and (2) to identify the contributing factors in these cases.

Methods
We conducted a retrospective descriptive analysis of closed medico-legal cases. The Canadian ethics review panel of the Advarra (formerly Chesapeake) institutional review board, based in Aurora, Ontario and comprised of Canadian members, reviewed and approved the study in compliance with Canada’s Tri-Council policy statement on the ethical conduct for research involving humans. This review body was chosen because the principal investigator (L.A.C.) and other staff conducting the research (H.K.N., E.M.W., J.J.) were full-time employees of the Canadian Medical Protective Association (CMPA) and the CMPA funded the research in full.

Data repository and medico-legal coding
The CMPA is a national, not for profit mutual defense organization for physicians, and a provider of medico-legal and patient safety education. The CMPA currently maintains a national repository of coded medico-legal data, which was the basis for our study. The CMPA secures the confidentiality of medico-legal data through measures such as encryption, firewalls, limited file access, and researcher confidentiality agreements. Data shared for research purposes is deidentified and anonymized. Each medico-legal matter, or “case,” in the repository represents a complaint against a physician in Canada in the form of a civil legal action or complaint to a regulatory authority (college) or hospital. All cases are brought forward voluntarily to the CMPA by physicians seeking medico-legal advice and/or support. As of December 31, 2018, the CMPA had 99,708 physician members (estimated as > 95% of Canadian physicians) of whom 1793 self-identified as cardiologists when obtaining membership with the CMPA.

For each case involving a patient, a nurse-analyst reviewed the medico-legal record and then coded clinical details and factors that might have contributed to each case. These methods were described previously.19 Analysts used the Canadian Classification of Health Interventions20 to code interventions (defined in Supplemental Table S1). They coded patient harm using a classification system on the basis of the American Society for Healthcare Risk Management’s “Healthcare Associated Preventable Harm Classification”21 (Supplemental Table S2). Additionally, analysts used an in-house coding framework19 to assign patient safety indicators and contributing factor codes (provider, team, system) on the basis of peer expert, college, or hospital criticisms (defined in Supplemental Table S1) in the medico-legal case. Analysts conducted quality assurance reviews of their coding, electronically and in a group format, on a weekly basis to reduce miscategorization.

Eligibility
For inclusion in our study, cases must have involved a physician named in the medico-legal matter who self-reported cardiology as their specialty when obtaining membership with the CMPA. Additionally, cases must have closed (defined in
Supplemental Table S1) by the CMPA between January 1, 2009 and December 31, 2018 inclusive. The 10-year interval reflected relatively recent medicine while providing a reasonable number of cases for analysis. We included civil legal, college, and hospital cases, and all clinical settings in and out of hospital. We excluded class actions/global settlements and cases involving pregnant patients (because patient to case ratios were >1), legal actions that were threatened but not pursued, and duplicate cases. When there were duplicate cases, we included only the most serious case type (in order of decreasing severity: legal then college then hospital).

Subgroups

For the purpose of this study, we did not appraise diagnostic test underuse or overuse in each case. Rather, we appraised the criticisms and complaints of underuse and overuse as documented in the medico-legal record. Therefore, our definition of test underuse was the failure to perform a cardiac screening or diagnostic test when it was clinically indicated, according to peer expert, college, or hospital criticisms in the medico-legal record (the Supplemental Methods S1 lists the cardiac tests in our medico-legal cases). Our definition of test overuse was performing a cardiac screening or diagnostic test that was not clinically indicated, or did not provide clinically relevant diagnostic information, according to peer expert, college, or hospital criticisms in the medico-legal record. Discordant patient complaints were cases in which a patient or family complained of cardiac test underuse or overuse, but there was no criticism of this by peer experts, colleges, or hospitals; these complaints were of secondary interest. Supplemental Figure S1 shows our classification scheme. To identify these 3 subgroups, we applied the extraction methodology described in Supplemental Methods S2.

Variables

We extracted the following variables from the CMPA repository: date and province for underuse or overuse; medico-legal case characteristics; patient sex and age; patient harm (Supplemental Table S2); clinical setting; number of physicians named per case; type of cardiac tests; and contributing factors. A nurse-researcher (E.M.W.) identified cardiac risk factors, cardiac conditions, and clinical outcomes by manual review of medical analyst summaries. The same nurse-researcher also derived the variables described in Supplemental Methods S3.

Data analysis

We calculated frequencies and proportions to describe case characteristics, patients, physicians, and diagnostic tests. To summarize contributing factor themes, we used frequencies and a spectrum display. For context, we also determined the total number of CMPA members who self-identified as a cardiologist when obtaining membership, as well as the number of cases that closed during the study period. For discordant patient complaints, we determined only the frequency, date, and province of underuse or overuse. We used the CMPA’s in-house data analysis tool and SAS statistical software utility, version 9.4 for statistical analyses.

Results

From 2009 to 2018, the CMPA closed 60,598 medico-legal cases and of those, 368 (0.6%) involved a cardiologist. The cardiologists in these cases practiced in 9 Canadian provinces, with the highest proportion (196 cases; 53.3%) in Ontario. Overall, there were 31 cases involving cardiologists and the underuse or overuse of cardiac diagnostic tests (8.4% of 368 cardiologist cases): 0 cases with criticism of test overuse, 15 cases with criticism of test underuse, and 16 discordant patient complaints. We describe these cases in the following sections.

Of 368 cardiologist cases, we found no criticisms of cardiac diagnostic test overuse by peer experts, colleges, or hospitals. There were, however, 15 cases with criticisms of diagnostic test underuse (4.1%). These criticisms related to diagnostic tests such as echocardiograms, coronary angiograms, and stress tests performed between 1994 and 2016 that involved cardiologists in 3 Canadian provinces, mostly in Ontario (11 of 15; 73.3%). When there was criticism of diagnostic test underuse, the case types were civil legal cases or college matters (8 and 7 cases, respectively). Civil legal cases were usually decided in favour of the plaintiff (6 of 8; 75.0%); others were dismissed by consent before proceeding to trial (2 of 8; 25.0%). There were no college matters decided in favour of the cardiologist (7 of 7 unfavourable).

Across 15 cases with criticism of diagnostic test underuse, patients were typically older (45 years or older) and had cardiac risk factors: 14 patients had at least 1 documented cardiac risk factor, 5 had a documented valve disorder, and 3 underwent a cardiac procedure in the previous 3 months. Most patients (12 of 15) died or experienced severe harm (Table 1).

The most common clinical location for cardiac diagnostic test underuse was a cardiologist’s office (6 of 15); most patient encounters were in a large population region of Canada (12 of 15; Table 2). Approximately one-half of the 17 physicians involved (52.9%) were 15-29 years post graduation from a medical degree (Table 2). Comparatively, as of February 2020 at the CMPA, 40.9% of all cardiologist members were 15-29 years post graduation (22.1% were <15 years and 36.7% were 30 years or more post graduation, respectively).

Of 15 cases with criticism of cardiac diagnostic test underuse, 7 involved delayed tests or tests not expedited, and 8 involved tests not ordered. These diagnostic tests were usually noninvasive, such as echocardiography (Table 3). In all 15 cases, there was a need for focused diagnostic testing to investigate new or worsening symptoms. Documented physical exam findings were cited as a clinical indication for cardiac diagnostic testing in 9 cases. No case involved the underuse of cardiac screening or preoperative tests.

The factors most frequently associated with cardiac diagnostic test underuse were a cardiologist’s inadequate clinical decision-making and lost situational awareness (Figure 1A). As an example of the latter, patients in 3 cases presented repeatedly with similar or worsening health concerns. In 1 case, patient factors might have contributed to diagnostic test underuse because the patient had atypical symptoms. In 6 of 15 cases (40.0%), criticisms of physicians were compounded with criticisms of communication or health care systems (eg, in 4 cases [26.7%], the lack of resources or inadequate office systems was noted in the medico-legal record). Figure 1B provides the specific
Table 1. Patient characteristics in medico-legal cases involving cardiologists and criticisms of cardiac diagnostic test underuse, CMPA closed cases, 2009-2018 (n = 15 patients)

| Characteristic                          | n (%)     |
|----------------------------------------|-----------|
| Self-reported sex                      |           |
| Male                                    | 10 (66.7) |
| Female                                  | 5 (33.3)  |
| Age, years                              |           |
| 0-18                                    | 0 (0)     |
| 19-44                                   | 3 (20.0)  |
| 45-64                                   | 6 (40.0)  |
| 65 or older                             | 6 (40.0)  |
| Cardiac risk factors<sup>1</sup>        |           |
| Hypertension                            | 6 (40.0)  |
| Diabetes mellitus                       | 5 (33.3)  |
| Coronary artery disease<sup>1</sup>     | 4 (26.7)  |
| Smoking                                 | 4 (26.7)  |
| Hyperlipidemia                          | 2 (13.3)  |
| Family history of heart disease         | 1 (6.7)   |
| Obesity                                 | 1 (6.7)   |
| None                                    | 1 (6.7)   |
| Other cardiac conditions                |           |
| Heart valve disorder<sup>1</sup>        | 5 (33.3)  |
| Arrital fibrillation                    | 0 (0)     |
| Heart failure                           | 0 (0)     |
| Peripheral vascular disease             | 0 (0)     |
| None                                    | 10 (66.7) |
| Patient harm<sup>1</sup>                |           |
| Death                                   | 11 (73.3) |
| Severe                                  | 1 (6.7)   |
| Moderate                                | 1 (6.7)   |
| Mild                                    | 1 (6.7)   |
| Asymptomatic                            | 1 (6.7)   |
| Patient clinical outcome                |           |
| Cause of death, n = 11                  |           |
| Unknown cause                           | 5 (33.3)  |
| Aortic dissection                       | 3 (20.0)  |
| Arrhythmia                              | 1 (6.7)   |
| Cardiac tamponade                       | 1 (6.7)   |
| Severe aortic stenosis                  | 1 (6.7)   |
| Discharge diagnosis, survivors n = 4    |           |
| Arhythmia                               | 1 (6.7)   |
| Thrombosed cardiac stent                | 1 (6.7)   |
| Myocardial infarction                   | 1 (6.7)   |
| Vascular injury                         | 1 (6.7)   |

Table 2. Health care locations and physicians named in medico-legal cases with criticism of cardiac diagnostic test underuse<sup>4</sup>; CMPA closed cases, 2009-2018 (n = 15 cases)

| Characteristic                          | n (%)     |
|----------------------------------------|-----------|
| Clinical location                      |           |
| Doctor’s office                         | 6 (40.0)  |
| Emergency department                   | 4 (26.7)  |
| Other hospital location                | 5 (33.3)  |
| Geographic location<sup>1</sup>         |           |
| Large population region                 | 12 (80.0) |
| Medium or small population region       | 3 (20.0)  |
| Number of physicians per case           |           |
| 1                                      | 13 (86.7) |
| >1                                     | 2 (13.3)  |
| Physician years since graduation, n = 17 physicians<sup>1</sup> | | |
| <15                                    | 4 (25.3)  |
| 15-29                                  | 9 (52.9)  |
| 30 or more                             | 4 (25.3)  |

CMPPA, Canadian Medical Protective Association.<sup>4</sup> Criticisms by peer experts or colleges in the medico-legal case.<sup>1</sup> Geographic locations in which there was test underuse by a cardiologist; locations were classified using Statistics Canada definitions for small, medium, and large population regions.<sup>11</sup>

Discussion
In this study, we aimed to understand the medico-legal issues faced by cardiologists with respect to diagnostic testing. In the past 10 years, medico-legal cases associated with cardiac diagnostic testing were rare for the cardiologists in our data set; we identified this issue or allegation in 31 of 368 eligible closed cases at the CMPA (8.4%). Although 15 cases included criticism of diagnostic test underuse by peer experts or colleges, these cases were also rare (4.1%), and all featured the need for focused diagnostic testing in patients with new or worsening symptoms. Often, the criticisms in these cases coincided with other criticisms related to situational awareness, communication, or health care systems. In contrast, Choosing Wisely Canada’s list of Five Things Physicians and Patients Should Question aims to reduce low-value cardiac diagnostic testing in specific subgroups of asymptomatic patients. The findings of our study were therefore unrelated to Choosing Wisely Canada recommendations. Moreover, across 10 years of medico-legal data, we found no peer expert criticisms of cardiac diagnostic test overuse despite high testing volumes. For example, there were more than 530,000 coronary angiograms performed in the province of Ontario alone over 10 recent years (Supplemental Fig. S2).

There are several possible reasons we did not detect cardiac diagnostic test overuse, including detection bias and reporting bias. It might be that peer experts and colleges did not comment on the appropriateness of diagnostic testing unless it related causally to the harm. It might also be that patients did not complain unless they viewed diagnostic testing as the proximal cause of their experience; for instance, the medico-
legal literature describes (invasive) cardiac catheterizations that were not indicated or contraindicated as a source of medico-legal complaints.\textsuperscript{23} Our extraction methodology might have also contributed to our findings. Although we extracted cases of cardiac diagnostic test underuse using contributing factor codes, we extracted cases of overuse using codes and a word search, which might have missed cases. It is also possible that our findings under-represent certain case types in the CMPA data repository. Although physician members report the a large proportion of civil legal cases to the CMPA, they report a smaller but not quantifiable percentage of all college and hospital complaints in Canada. Clearly, the nature of our data restricted us from addressing all consequences of test overuse, such as the burden on patients who receive a false positive test result, and the resource burden on health care systems.

"Importantly, our findings do not diminish the problem of overuse in health care," nor do they reflect an absence of cardiac diagnostic test overuse. From April 1, 2008 to March 31, 2018, coronary angiograms were performed with increasing frequency in Ontario (23.0\% higher in 2017-2018 than in 2008-2009; Supplemental Fig. S2). Although an aging population and rising cardiac morbidity rates likely contributed to this increase,\textsuperscript{24} research suggests that a variety of cardiac diagnostic tests are being overused.\textsuperscript{6,8} and those tests, in turn, might have led to referrals. In the example provided (Supplemental Fig. S2), approximately 42\% of the coronary angiograms in Ontario were ordered by noncardiologists. Depending on the nature of the referral and accompanying testing, cardiologists might have believed they were obligated to respond and possibly ordered further, invasive testing for which they questioned the clinical indication. The inherent nature of our medico-legal data did not allow us to capture these complexities in test-ordering.

Still, our study provides important insights into cardiac diagnostic test underuse in the context of diagnostic error in patients with symptoms. Medico-legal studies in the United States have shown diagnostic error to be a leading complaint against cardiologists.\textsuperscript{7} They have also identified specific cardiac tests misinterpreted by cardiologists\textsuperscript{8} or not performed in a timely manner\textsuperscript{23,29} and cardiac conditions that were misdiagnosed.\textsuperscript{25,28,29} In a contributing factors analysis, Oetgen et al. noted “communication between providers” as the top medical issue for paid claims involving cardiologists, followed by “problem with history or examination,” and “premature discharge,” which we also identified, albeit among a small sample of cases. Most cases of underuse in our study (73.3\%) were in Ontario, Canada’s most populous province, likely reflecting the high number of cardiologists practicing there. These findings suggest an opportunity for medical education for cardiologists on mitigating the risks of diagnostic error.

There were important limitations of our study, described previously\textsuperscript{19} and in the preceding paragraphs. A key distinction, because of the nature of our data, was our inability to study the full complexity of decision-making around test-ordering; rather, we focused on medico-legal criticisms of care. Our data were also limited for estimating the frequency of patient safety incidents in Canada. Medico-legal cases represent a small proportion of patient safety incidents overall because many factors influence a patient and/or family decision to file a complaint, and physicians report voluntarily to the CMPA. It is also possible, because of our inclusion criteria, that we excluded cases involving physicians who practiced cardiology but did not report it as their specialty with the CMPA. Furthermore, our closed case analysis might not completely reflect the most current issues facing cardiologists because of the lag time between a patient encounter and a medico-legal case closure. Because data were not collected for research purposes, the clinical information was also limited. Additionally, the retrospective, descriptive nature of our study meant that we could not show causation between the physician, patient, or test characteristics and medico-legal risk—only associations. As in other medico-legal studies, our contributing factors analysis was prone to hindsight and outcome bias.\textsuperscript{30} Finally, our definitions of test underuse and overuse might not be generalizable to other studies because they reflect the individual and context-specific opinions of peer experts, colleges, and hospitals, respectively.

In conclusion, using a physician-focused, national repository of medico-legal cases—the largest of its kind in the world—we found no cases of cardiac diagnostic test overuse. This finding, however, does not diminish the problem of overuse in health care," nor does it suggest that overuse is less common or less risky than underuse. Rather it suggests an extremely low medico-legal risk from diagnostic test overuse by cardiologists in Canada. Although there were criticisms of cardiac diagnostic test underuse by peer experts and colleges, these criticisms were also extremely rare, and the clinical scenarios were unrelated to Choosing Wisely Canada recommendations on when not to test. Instead, the cases highlighted issues with diagnosing symptomatic patients. Overall, test-ordering did not appear to be a major driver of medico-legal complaints. Still, our findings might not fully address cardiologists’ medico-legal concerns about evidence-based campaigns to promote appropriate diagnostic testing. Future studies that aim to understand the relationships between cardiac diagnostic test-ordering, Choosing Wisely Canada recommendations, patient harm, and “near misses” for a medico-legal complaint, in a broader sample of physicians, would complement our findings.
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Supplementary Material

To access the supplementary material accompanying this article, visit CJC Open at https://www.cjcopen.ca/ and at https://doi.org/10.1016/j.cjco.2020.11.018.