

Original Investigation

Complications of Daytime Elective Laparoscopic Cholecystectomies Performed by Surgeons Who Operated the Night Before

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IMPORTANCE The effect of surgeons' disrupted sleep on patient outcomes is not clearly defined.

OBJECTIVE To assess if surgeons operating the night before have more complications of elective surgery performed the next day.

DESIGN, SETTING, AND PARTICIPANTS Population-based, matched, retrospective cohort study using administrative health care databases in Ontario, Canada (2012 population, 13 505 900). Participants were 2078 patients who underwent elective laparoscopic cholecystectomies performed by surgeons who operated the night before, matched with 4 other elective laparoscopic cholecystectomy recipients (n = 8312).

EXPOSURE In total, 94 183 eligible elective laparoscopic cholecystectomies were performed between 2004 and 2011. Of these surgeries, there were 2078 procedures in which 331 different surgeons across 102 community hospitals had operated between midnight and 7 AM the night before. Each "at-risk" surgery was randomly matched with 4 other elective laparoscopic cholecystectomies (n = 8312) performed by the same surgeon, who had no evidence of having operated the night before.

MAIN OUTCOMES AND MEASURES The primary outcome was conversion from a laparoscopic cholecystectomy to open cholecystectomy. Secondary outcomes included evidence of iatrogenic injuries or death. Risks were quantified using generalized estimating equations.

RESULTS No significant association was found in conversion rates to open operations between surgeons when they operated the night before compared with when they did not operate the previous night (46/2031 [2.2%] vs 157/8124 [1.9%]; adjusted odds ratio [OR], 1.18; 95% CI, 0.85-1.64). There was no association between operating the night before vs not operating the night before, and risk of iatrogenic injuries (14/2031 [0.7%] vs 72/8124 [0.9%]; adjusted OR, 0.77; 95% CI, 0.43-1.37) or death ($\leq 5/2031$ [$\leq 0.2\%$] vs 7/8124 [0.1%]).

CONCLUSIONS AND RELEVANCE No significant association was found between operating the night before and not operating the previous night for conversion to open cholecystectomy, risk of iatrogenic complications, or death for elective daytime cholecystectomy. These findings do not support safety concerns related to surgeons operating the night before performing elective surgery.

JAMA. 2013;310(17):1837-1841. doi:10.1001/jama.2013.280372

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Sleep is a biological necessity. Lack of sleep is associated with impaired performance in many situations.^{1,2} To theoretically prevent medical errors, work-hour restrictions on surgeons in training were imposed.^{3,4} There are now proposals for similar work-hour restrictions on practicing surgeons.⁵⁻⁹ Several studies found no association between surgeon sleep deprivation as assessed by operating the night prior to an operation or when surgeons report few hours of sleep and patient outcomes.¹⁰⁻¹³ Prior studies were limited because of small sample sizes and being from single academic institutions. Consequently, there is insufficient evidence to conclude that surgeon performance is compromised by insufficient sleep the night prior to performing surgery.⁴ This study researches the association of operating the night before performing an elective cholecystectomy with complication rates when performed by community-based surgeons in 102 hospitals in Ontario, Canada.

Methods

Study Design and Setting

Residents of the province of Ontario, Canada (2012 population, 13 505 900), have universal access to hospital care and physician services. These encounters are recorded in large population-based health care databases, many of which are held at the Institute for Clinical Evaluative Sciences (ICES). This study used these data sources to conduct a surgeon-matched retrospective multicenter cohort study. This study was approved by the Sunnybrook Health Sciences Centre Research Ethics Board in Toronto, Ontario, Canada. Participant informed consent was not required for this study. The reporting of this study followed guidelines for observational studies (eTable 1 in Supplement).

Data Sources

Surgeon and patient characteristics were ascertained from 5 linked health care administrative databases. Diagnostic and procedural information for all hospitalizations and day procedures are recorded in the Canadian Institute for Health Information's discharge abstract and same-day surgery databases. From 2002 onward, the 10th edition of the Canadian-modified *International Classification of Diseases (ICD-10-CA)* system was used to record all diagnostic codes and the Canadian Classification for Health Interventions was used to record all procedural codes. Health claims for inpatient and outpatient physician services are recorded in the Ontario Health Insurance Plan database, in which claims start the process toward physician reimbursement. The ICES physician database has information on all physicians practicing in Ontario, including their demographics and educational backgrounds. The Registered Persons Database contains vital statistics for all Ontario citizens, including all-cause mortality.

In Ontario, physicians receive payment for procedures performed, and the surgical codes are expected to be highly accurate—similar to other fee-for-service procedure codes. Cholecystectomy fee-for-service billing codes were cross-referenced with laparoscopic cholecystectomy procedure codes from the

hospital record. When the 2 codes did not reconcile, the case was excluded. Databases are complete for all Canadian citizens residing in the province of Ontario. All the variables in the data set are 100% complete, with the exception of rural vs urban hospital status, which is missing in 2.3% of surgeries. All missing values for this variable are assumed to be urban in the analyses of this study. These databases have been used extensively to conduct surgery research, including studies on cholecystectomy.¹⁴⁻¹⁷ All diagnostic and procedure codes used for variable definitions are presented in eTables 2 through 7 in Supplement.

Selection and Matching

All elective daytime laparoscopic cholecystectomies performed by a surgeon on a nonholiday weekday, between April 1, 2004, and March 31, 2011, were identified. Cholecystectomy was studied because it is one of the most frequent surgeries performed in Ontario ($\approx 25\,000$ yearly) and errors attributable to disrupted sleep occur in common and routine tasks.^{18,19} Cholecystectomy is performed by general surgeons who tend to operate at night more often than other types of surgeons. Elective laparoscopic cholecystectomy was defined as having started between the hours of 7 AM and 6 PM. Procedures performed at teaching hospitals were excluded because disruption related to house staff was unknown. At-risk surgeries were defined as those performed by community-based surgeons who had worked the night before, determined by the surgeon billing for a nonelective operation between midnight and 7 AM the previous night. Each at-risk surgery was matched with 4 other laparoscopic cholecystectomies performed by the same surgeon in the same year, when that surgeon had not worked the night before. Matching was conducted without replacement. Each surgeon could have multiple matched sets of procedures.

Surgical Complications

The primary outcome was conversion from a laparoscopic cholecystectomy to open cholecystectomy. Although not always considered a complication, conversion to open cholecystectomy may serve as an aggregate end point for many complications. Patients view conversion to an open procedure as an unwanted outcome. Secondary outcomes were death or evidence of an iatrogenic injury within 30 days of surgery. Each outcome was analyzed separately. The composite outcome of iatrogenic injuries was defined by codes for accidental puncture or laceration and included injury to the bile duct, bowel, or major blood vessel (eTables 2 and 3 in Supplement).

Statistical Analyses

All statistical analyses were performed at the ICES using SAS Statistical Software, version 9.3 (SAS Institute Inc). *P* values for all analyses were 2-sided with a significance threshold of 5%. Baseline characteristics were compared after matching, associated *P* values were calculated using the Cochran *Q* test for binary variables, and repeated-measures analysis of variance was used for continuous variables to account for the 4-to-1 matching. To estimate the association between laparoscopic cholecystectomy performed by a surgeon who operated the night before (yes/no) and each cholecystectomy complication (yes/no), a gen-

eralized estimating equation was used. This analysis accounted for multiple surgeries performed by the same surgeon and controlled for 8 patient and hospital characteristics potentially influencing surgical outcomes: patient age, sex, and history of diabetes, chronic liver disease, acute pancreatitis, morbid obesity, and abdominal surgery; and rural hospital. All patient medical characteristics were identified using administrative health care codes (eTables 4-7 in Supplement) appearing for a patient within 5 years prior to cholecystectomy, except for acute pancreatitis, which was considered as a medical comorbidity if it was present within 1 year prior.

Results

There were 94 183 elective daytime cholecystectomies that met inclusion criteria, of which 2078 were performed by a surgeon who had operated the night before. These at-risk procedures were randomly matched to 8312 procedures performed by the same surgeon in the same year but on days when the surgeon had not operated the night before, resulting in a total sample of 10 390 procedures performed across 102 hospitals by 331 different community-based surgeons.

Surgeon Characteristics

The age (mean [SD]) and sex of the surgeons at the time of cholecystectomy was 48 (10) years, and 56 (16.9%; 95% CI, 12.9%-

20.0%) were women. Most (257/331 [77.6%; 95% CI, 73.2%-82.1%]) were graduates of a Canadian medical school. In this cohort, a given surgeon performed an average of 6 daytime laparoscopic cholecystectomies after operating the night before.

Patient and Hospital Characteristics

Patient and hospital characteristics of the 2 groups of matched cholecystectomies are presented in Table 1. As shown, patient and hospital characteristics for the 2 groups of cholecystectomies were generally well balanced. Patient age (mean [SD]) was 49 (16) years. In the group of surgeons who operated the night before, 73.4% (1526) of surgeries were performed by women and 2.3% (48) of procedures were performed in rural hospitals (those in which a community surgeon operated in a rural community with a population of <10 000 individuals). In the group of surgeons who had not operated the night before, 73.7% (6123) of surgeries were performed by women and 2.6% (216) of procedures were performed in rural hospitals.

The outcomes for the 2 groups of matched cholecystectomies are presented in Table 2. There were 46 of 2031 (2.2%; 95% CI, 1.6%-2.9%) procedures performed by a surgeon who operated the night before, which required conversion to an open procedure. Open conversion occurred in 157 of 8124 (1.9%; 95% CI, 1.6%-2.2%) cases performed without evidence that the surgeon had operated the night before. These rates were not statistically different. Adjustment for patient and hospital factors yielded odds of undergoing a conversion to open

Table 1. Patient and Hospital Characteristics of Daytime Laparoscopic Elective Cholecystectomies Performed by Surgeons Who Did and Did Not Operate the Night Before^a

Characteristics	Surgeon Operated the Night Before		P Value
	Yes (n = 2078)	No (n = 8312)	
Patients			
Age, mean (SD), y	49 (16)	49 (16)	.13
Women	1526 (73.4)	6123 (73.7)	.83
Diabetes	274 (13.2)	1001 (12.0)	.16
Chronic liver disease	131 (6.3)	529 (6.4)	.92
Pancreatitis in previous year	102 (4.9)	328 (3.9)	.05
Morbid obesity	54 (2.6)	282 (3.4)	.07
Abdominal surgery	43 (2.0)	166 (2.0)	.97
Rural hospital ^b	48 (2.3)	216 (2.6)	.72

^a Data are reported as No. (%) unless otherwise indicated.

^b The location of 220 procedures (47 [2.3%] and 178 [2.1%] in each group, respectively) was missing and were assumed to be performed in a nonrural hospital. A rural hospital was defined as a hospital in city with a population of less than 10 000 individuals.

Table 2. Complications of Daytime Laparoscopic Elective Cholecystectomies Performed by Surgeons Who Did and Did Not Operate the Night Before

	Surgeon Operated the Night Before ^a , Events, No. (%) [95% CI]		Unadjusted OR (95% CI)	P Value ^b	Adjusted OR (95% CI) ^c	P Value ^b
	Yes (n = 2031)	No (n = 8124)				
Conversion to open procedure	46 (2.2) [1.6-2.9]	157 (1.9) [1.6-2.2]	1.18 (0.84-1.64)	.34	1.18 (0.85-1.64)	.33
Iatrogenic injuries	14 (0.7) [0.3-1.0]	72 (0.9) [0.7-1.1]	0.78 (0.44-1.38)	.39	0.77 (0.43-1.37)	.37
Death	≤5 ^d (≤0.2)	7 (0.1) [0.0-0.2]	NR ^d	.60	NR ^d	.57

Abbreviations: NR, not reported; OR, odds ratio.

^a Procedures performed by a surgeon who had not operated the night before served as the reference group.

^b Tests used to calculate P values were 2-sided with a significance threshold of less than .05.

^c Adjusted for 8 patient and hospital characteristics (patient age, sex, history of

diabetes, chronic liver disease, acute pancreatitis, morbid obesity, and abdominal surgery; and rural hospital).

^d In accordance with privacy regulations imposed by the Ontario Ministry of Health, event rates, ORs, and 95% CIs for absolute numbers less than or equal to 5 cannot be reported.

cholecystectomy of 1.18 (95% CI, 0.85-1.64; $P = .33$) for surgeons operating when they had performed procedures the night before compared with procedures when they had not operated the night before.

There were 14 of 2031 (0.7%; 95% CI, 0.3%-1.0%) procedures performed by a surgeon who operated the night before that were associated with iatrogenic injuries. Iatrogenic injuries occurred in 72 of 8124 (0.9%; 95% CI, 0.7%-1.1%) cases performed without evidence that the surgeon had operated the night before. These rates were not statistically different. Adjustment for patient and hospital factors yielded odds of experiencing an iatrogenic injury of 0.77 (95% CI, 0.43-1.37; $P = .37$) for surgeons operating when they had performed procedures the night before compared with procedures when they had not operated the night before.

Fewer than 5 ($\leq 0.2\%$) patients died (privacy regulations disallow reporting of absolute numbers ≤ 5) when operated on by surgeons who had operated the night before the procedure. There were 7 of 8124 (0.1%; 95% CI, 0.0%-0.2%) patients who died when operated on by surgeons who had not operated the night before (Table 2).

Discussion

In this population-based, matched study of 331 community surgeons operating in 102 hospitals in Ontario, Canada, there was no evidence that operating the night before was associated with conversion to open cholecystectomy, risk of iatrogenic complications, or death for elective laparoscopic surgery performed the next day.

Results in Relation to Other Studies

Our findings are similar to 4 previous studies of sleep and surgical outcomes. Taken together, research in this area has not shown a relationship between complication rates and surgeon sleep the night before an operation is performed.¹⁰⁻¹³ Observational studies found no association of surgeon sleep deprivation on patient outcomes in cardiac surgery (sleep deprivation defined respectively by operating the night before and hours of sleep the night before).^{10,11} Outcomes are unaffected by trauma surgeons' overnight shifts and operations performed the next day.¹³ When attending surgeons in an academic setting operate the night before, surgical outcomes are not different than when they had not operated the night before.¹²

Strengths and Limitations

This study has several strengths. To the authors' knowledge, this is the first population-based study to examine the association between surgeons operating the night before a major elective sur-

gery and patient outcomes. In contrast with other studies of surgeon sleep and outcomes, academic hospitals were excluded. This was to avoid confounding related to resident trainees' participation in patient care. This study focused on a single, common operation with its associated complications rather than a heterogeneous group of procedures. Prior studies suggest that mundane and monotonous tasks are the most susceptible to the effects of sleep deprivation.^{18,19} Our research protocol, cohort, and outcomes were prespecified, patient characteristics of the 2 comparison groups were well balanced, and matching procedures performed by the same surgeon avoided the confounding influence of surgical expertise or hospital setting. We studied a large number of operations and events, providing good statistical precision. Our large, population-based study of community practices provides high-quality evidence regarding surgical outcomes. It is unlikely that a randomized controlled trial will ever be conducted on the effect of sleep deprivation on surgical outcomes.

There are limitations of our data sources and study. Although Ontario surgeons receive a premium and bill accurately when they operate urgently between 12 AM and 7 AM, the times and length of the overnight procedure and also how fatigued the surgeon truly was when starting elective cases the next day were unknown. It is possible some surgeons cancelled elective daytime procedures when they were too fatigued. Alternatively, some elective procedures may have been performed by surgeons who were sleep deprived for reasons other than operating the night before.

Study Implications

Policies limiting attending surgeon work hours are controversial. Critics suggest such policies reduce continuity in care, increase communication errors, and introduce the potential for a bystander effect (in which one surgeon may expect another to bear the burden for authority and responsibility).²⁰ Restructuring health care delivery to prevent surgeons operating during the day after they operated the previous night would have important cost, staffing, and resource implications.^{21,22} One estimate is that health care costs could increase by more than \$1 million per life saved if all physicians were constrained by work hour restrictions.²¹ In some rural underserved areas, restricting surgeon work hours may not be possible without making care unavailable.

Conclusions

We found no significant association between conversion to an open cholecystectomy, risk of iatrogenic complications, or death for elective daytime laparoscopic cholecystectomies and whether the surgeon had operated the night before. These findings do not support safety concerns related to surgeons operating under these conditions.

ARTICLE INFORMATION

Author Contributions: Dr Vinden and Mr Rangrej 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.
Study concept and design: Nash, Shariff, Jain, Garg, Vinden.

Acquisition of data: Garg, Vinden.
Analysis and interpretation of data: Nash, Rangrej, Shariff, Dixon, Garg, Vinden.
Drafting of the manuscript: Nash, Garg, Vinden.
Critical revision of the manuscript for important intellectual content: Nash, Rangrej, Shariff, Dixon, Jain, Garg, Vinden.
Statistical analysis: Rangrej, Shariff, Dixon.

Obtained funding: Vinden.
Administrative, technical, or material support: Nash, Shariff, Vinden.
Study supervision: Shariff, Jain, Garg, Vinden.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest.

Dr Vinden reports receipt of a grant to his institution from the Division of General Surgery, University of Western Ontario; board membership and receipt of travel and accommodation expenses from the Ontario Association of General Surgeons; board membership and receipt of per diem honorarium and travel expenses from the Ontario Medical Association, Section of General Surgery; provision of expert testimony for the Canadian Medical Protective Association; and receipt of travel accommodations and or meeting expenses from Cancer Care Ontario. Dr Jain reports receipt of a grant to his institution from Baxter Health Care. The other authors report no disclosures.

Funding/Support: The Institute for Clinical Evaluative Sciences (ICES) is a nonprofit research corporation funded by the Ontario Ministry of Health and Long-Term Care. This work was supported by personnel at the ICES Western facility, which receives support from the Academic Medical Organization of Southwestern Ontario, the Lawson Health Research Institute, the Schulich School of Medicine and Dentistry, and multiple departments at Western University. This project was funded by the Division of General Surgery at the London Health Sciences Centre.

Role of the Sponsor: The London Health Sciences Centre did not have any role in the design or conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; or the decision to submit the manuscript for publication.

Disclaimer: The opinions, results, and conclusions are those of the authors and are independent from the funding sources. No endorsement by any of the funding sources is intended or should be inferred.

Additional Contributions: We would like to thank Kathryn Barber, CHIM, Health Information Analyst at London Health Sciences Centre, London, Ontario, who provided input regarding hospital coding procedures. Ms Barber did not receive compensation for her role in this study. We also thank personnel from the ICES Western facility for their support in association with this article. They

were not compensated beyond their regular salaries for their contributions.

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