Decreased Bile Duct Injury Rate During Laparoscopic Cholecystectomy in the Era of the 80-Hour Resident Workweek

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Background: Considerable concern has been raised about the effects of restricted duty hours on surgical training. However, to our knowledge, the effect of the 80-hour resident workweek on operative outcomes after laparoscopic cholecystectomy has not been well studied.

Objective: To compare the rates of bile duct injury and overall complications after laparoscopic cholecystectomy before and after the institution of the duty-hour restriction.

Design: Retrospective review of patient medical records to determine morbidity and mortality before (January 1, 2000, to June 30, 2003; period 1) and after (July 1, 2003, to June 30, 2006; period 2) implementation of duty hour limitations.

Setting: Major public teaching hospital.

Patients: A total of 2470 patients who had undergone laparoscopic cholecystectomy.

Main Outcome Measures: Bile duct injury and overall complication rates as determined using multivariate analysis.

Results: Overall, 2470 laparoscopic cholecystectomy procedures were performed, including 1353 in period 1 and 1117 in period 2. In period 2, more patients had acute cholecystitis as the indication for surgery (49% vs 35% in period 1, \( P < .001 \)), and a higher percentage of patients were male (22% vs 18%, \( P = .01 \)). The incidence of bile duct injury and total complications decreased in period 2 from 1% to 0.4% (\( P = .04 \)) and from 5% to 2% (\( P < .001 \)), respectively. Mortality was unchanged. Multivariate analysis revealed that period 2 was protective for bile duct injury (odds ratio, 0.31; 95% confidence interval, 0.1-0.96; \( P = .04 \)). For complications, both female sex (odds ratio, 0.62; 95% confidence interval, 0.38-0.9) and surgery during period 2 (odds ratio, 0.46; 95% confidence interval, 0.28-0.75) were protective, whereas older age (odds ratio, 1.03; 95% confidence interval, 1.02-1.05) was associated with complications.

Conclusion: At a major public teaching hospital, the bile duct injury rate and the overall complication rate decreased after implementation of the 80-hour workweek.

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The 80-hour workweek restriction for residency training was instituted on July 1, 2003, because of concerns about patient safety and resident well-being. However, some surgical educators have expressed misgivings about the restricted hours because of more frequent shift changes, decreased patient exposure for residents, interruption in continuity of care, and increased potential for communication breakdown. As a result of these concerns, it has been hypothesized that duty-hour restrictions may lead to paradoxical deterioration in patient care and surgical outcomes at teaching hospitals. For example, we recently demonstrated that trauma outcomes at a busy level I trauma center were unchanged after the institution of the 80-hour workweek. Few articles have evaluated the effects of the 80-hour workweek on the outcomes of laparoscopic cholecystectomy and, more specifically, the rate of bile duct injury. This is an important issue for several reasons. Laparoscopic cholecystectomy is one of the most commonly performed procedures by surgical residents nationwide. Previous studies using simulators have indicated that sleep deprivation has substantial adverse effects on laparoscopic skills in residents. Bile duct injury has a potentially devastating
long-term adverse effect on the patient. Furthermore, despite the less invasive nature of laparoscopic surgery, the rate of bile duct injury is higher for laparoscopic than for open cholecystectomy and is frequently the result of technical error. Our institution is a public teaching hospital in which chief residents under supervision of the attending surgeon frequently serve as teaching residents for junior residents for these surgical procedures. The study objective was to compare the rates of bile duct injury and overall complications after laparoscopic cholecystectomy before and after the institution of the duty-hour restriction.

METHODS

The Department of Surgery, Harbor-UCLA Medical Center, Torrance, California, has a 6-year residency program in general surgery. To comply with the 80-hour workweek, numerous changes were implemented in the residency program before July 2003 that have been described in detail previously. As a result of these changes, the average in-house call requirements for the surgical residents decreased from once every 4.8 nights before duty hour changes to once every 6.4 nights after the changes.

To study the effects of the work hour changes on patient outcomes, we compared the morbidity and mortality for laparoscopic cholecystectomy performed because of benign biliary disease between 2 periods: January 1, 2000, to June 30, 2003 (period 1), and July 1, 2003, to June 30, 2006 (period 2), via a retrospective review of patient medical records. Cholecystectomies performed in conjunction with other abdominal operations or because of nonbiliary disease were excluded from analysis. All patients were operated on and their care managed by surgery residents as the primary surgeons under the supervision of attending surgeons. Our surgery department encourages liberal use of intraoperative cholangiography (IOC), but the final decision to perform IOC was at the discretion of the attending surgeon. Intraoperative cholangiography was attempted routinely in patients with gallstone pancreatitis or suspected common bile duct stones, and when anatomy was unclear. Endoscopic retrograde cholangiopancreatography (ERCP) was performed preoperatively in patients with suspected cholangitis or suspected choledocholithiasis and postoperatively in patients with common bile duct stones seen at IOC. Patient data collected included age, sex, and race/ethnicity; history of diabetes mellitus; indication for cholecystectomy; whether IOC or ERCP was performed; conversion to open cholecystectomy; and complications or death.

STUDY END POINTS

The primary end point of the study was bile duct injury. This included major and minor intraoperative injury to the bile ducts (common bile duct, common hepatic duct, and right and left hepatic ducts) and postoperative bile duct leak including cystic duct stump leak. A major bile duct injury was defined as a complete transaction or any injury that required biliary-enteric bypass. A minor bile duct injury was defined as an incisional injury that was repaired primarily or a bile leak that required a therapeutic postoperative ERCP intervention such as endoscopic sphincterotomy or stent placement. A bile duct leak was defined as bilirubin concentration in the drain exceeding that in the serum or bile duct leakage seen on a nuclear scintigram. The secondary end point included a composite of all postoperative complications including intraoperative bleeding requiring conversion to open cholecystectomy, postoperative bleeding requiring transfusion, pneumonia, wound or urinary tract infection, and death.

STATISTICAL ANALYSIS

Patient data were collected on a spreadsheet (Microsoft Excel; Microsoft Corp, Redmond, Washington) and translated into a native statistical analysis system format using DBMS/Copy (DataFlux Corp, Cary, North Carolina). Descriptive statistics were calculated for all variables. Numerical variables were compared using the nonparametric Wilcoxon rank sum test and are reported as medians with interquartile ranges. Categorical or nominal variables were compared using the $\chi^2$ test or Fisher exact test as appropriate. Statistical comparisons were conducted with subjects separated into periods 1 and 2. In addition, multivariate logistic regression analysis was performed with bile duct injury and any complication as the 2 dependent variables or outcomes of interest. The independent or predictor variables were age, sex, operation period, diabetes mellitus, and acute cholecystitis. The results of the logistic regression models are given as odds ratios for a 1-U change in the predictor variable of interest, with the associated 95% confidence intervals. $P < .05$ was deemed statistically significant; no adjustment was made for multiple comparisons. All statistical comparisons were performed using commercially available statistical software (SAS version 9.1; SAS Institute, Inc, Cary, North Carolina). This study was approved by the institutional review board of the Los Angeles BioMedical Institute at Harbor-UCLA Medical Center.

RESULTS

OVERALL GROUP

A total of 2470 laparoscopic cholecystectomies were performed. The median patient age was 37 years, and 20% of the patients were male. Race/ethnicity included Hispanic (84%), white (5%), African American (5%), Asian (3%), and other (3%) categories. Indications for cholecystectomy included acute cholecystitis (41%), symptomatic choledolithiasis (24%), gallstone pancreatitis (23%), and choledocholithiasis (13%). All procedures were initially begun laparoscopically, with 14% requiring conversion to open cholecystectomy. Intraoperative cholangiography was performed in 74% of patients, and ERCP was performed in 24%. The overall complication rate was 4%, and there was 1 death (mortality rate, 0.04%). The bile duct injury rate was 0.8%, including a major duct injury rate of 0.2%, a minor duct injury rate of 0.3%, and a postoperative bile leak rate of 0.2%. The median length of hospital stay was 5 days.

COMPARISON OF PRE– AND POST–WORK HOUR RESTRICTIONS: DEMOGRAPHIC, CLINICAL, AND OUTCOME DATA

There were 1353 patients in period 1 and 1117 patients in period 2, with a similar median age of 37 years. There was a higher percentage of males in period 2 (22% vs 18%; $P = .01$) and a higher percentage of Hispanic patients (85% vs 82%; $P = .02$). There was a similar incidence of diabetes mellitus in the 2 groups: 8% and 7% in periods 1 and 2, respectively. Acute cholecystitis was the most common indication for laparoscopic cholecystectomy in both groups;
however, more patients in period 2 had acute cholecystitis (49% vs 35%; P < .001). The rate of conversion from laparoscopic to open cholecystectomy increased in period 2 from 13% to 16% (P = .02). Fewer patients underwent IOC in period 2 (from 76% to 70%; P = .001). The use of ERCP was unchanged between the 2 periods. The overall rate of bile duct injury decreased in period 2 compared with period 1 (Table 1). Similarly, the overall complication rate decreased in period 2 (Table 1). Complications in period 1 were intraoperative procedural (19 patients), infectious (14 patients), cardiovascular (7 patients), gastrointestinal (6 patients), respiratory (5 patients), metabolic (1 patient), and neurologic (1 patient). Complications in period 2 were intraoperative procedural (9 patients), infectious (6 patients), cardiovascular (3 patients), gastrointestinal (1 patient), respiratory (2 patients), and neurologic (1 patient). The median length of hospital stay decreased from 6 to 5 days (P < .001).

MANAGEMENT OF BILE DUCT INJURIES

In period 1, of 15 bile duct injuries, 2 were major injuries treated with biliary-enteric bypass and 6 were postoperative bile leaks, of which all but 1 were treated with postoperative ERCP interventions. Seven patients had minor bile duct injuries, of which 5 were treated with primary duct repair and 2 were treated with postoperative ERCP interventions. In contrast, in period 2, of 4 bile duct injuries, 3 were major injuries requiring biliary-enteric bypass. The 1 minor injury was treated with primary repair of the bile duct.

### Table 1. Comparison of Patient Characteristics and Outcomes Associated With Laparoscopic Cholecystectomy During Pre- and Post-80-Hour Resident Workweek Eras

<table>
<thead>
<tr>
<th>Patient Variable</th>
<th>Period 1, January 1, 2000, to June 30, 2003 (n=1353)</th>
<th>Period 2, July 1, 2003, to June 30, 2006 (n=1117)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morbidity, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall complication rate</td>
<td>65 (5)</td>
<td>24 (2)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Bile duct injury, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>15 (0.01)</td>
<td>4 (0.4)</td>
<td>0.04</td>
</tr>
<tr>
<td>Major</td>
<td>2 (0.15)</td>
<td>3 (0.27)</td>
<td>0.80</td>
</tr>
<tr>
<td>Minor</td>
<td>7 (0.52)</td>
<td>1 (0.09)</td>
<td>1.0</td>
</tr>
<tr>
<td>Postoperative bile leak</td>
<td>6 (0.44)</td>
<td>0</td>
<td>0.07</td>
</tr>
<tr>
<td>Mortality, No. (%)</td>
<td>1 (0.07)</td>
<td>0</td>
<td>&gt; .99</td>
</tr>
</tbody>
</table>

### Table 2. Multivariate Analysis of Bile Duct Injury and Complications

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR (95% CI)</th>
<th>P Value</th>
<th>OR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post–work hour era</td>
<td>0.32 (0.10-0.96)</td>
<td>.04</td>
<td>0.46 (0.28-0.75)</td>
<td>.002</td>
</tr>
<tr>
<td>Female sex</td>
<td>0.72 (0.25-2.02)</td>
<td>.05</td>
<td>0.62 (0.38-0.90)</td>
<td>.05</td>
</tr>
<tr>
<td>Age</td>
<td>1.02 (0.10-1.05)</td>
<td>.10</td>
<td>1.03 (1.02-1.05)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Acute cholecystitis</td>
<td>0.671 (0.268-1.679)</td>
<td>.40</td>
<td>1.13 (0.72-1.80)</td>
<td>.60</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1.10 (0.24-5.06)</td>
<td>.90</td>
<td>0.89 (0.46-1.70)</td>
<td>.70</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; OR, odds ratio.

MULTIVARIATE ANALYSIS

At multivariate analysis (Table 2), only surgery during period 2 was inversely associated with bile duct injury. At multivariate analysis of factors associated with overall complications (Table 2), age was associated with an increased risk of complications, whereas female sex and surgery during period 2 were inversely related.

**COMMENT**

The present single-institution study at a major public teaching hospital compared the outcomes of laparoscopic cholecystectomy before and after the institution of the 80-hour resident workweek. The major findings of the study were that the bile duct injury and overall complication rates significantly decreased, from 1.1% to 0.4% (P = .04) and from 5% to 2% (P < .001), respectively, during the era of duty-hour restriction. At multivariate analysis, surgery during period 2 was the only factor associated with decreased risk of bile duct injury. Insofar as overall complications, female sex and surgery during period 2 were associated with a decreased risk of complications, whereas age was associated with an increased risk. At subset analysis, the rates of major bile duct injury were unchanged. The complication rate in period 2 decreased despite there being a higher percentage of patients with acute cholecystitis and a greater percentage of male patients, both of which have been shown to be associated with a higher risk of bile duct injury.10-18

There are several potential explanations for the improved results in period 2. With the advent of resident duty-hour restrictions, many institutions have noted an increase in attending surgeon hours and their involvement in perioperative care.3 This has been observed anecdotally at our institution. Another possible explanation is that difficult cases may have been more often delayed until daytime hours because our hospital is a busy level I trauma center and the operative trauma volume has increased dramatically in recent years. The conversion rate to open cholecystectomy increased from 13% to 16% in period 2, which suggests a lower threshold for conversion when difficult dissection was encountered. Alternatively, the increased conversion rate may simply reflect the greater frequency of acute cholecystitis during period 2. To our knowledge, only 1 other study has evaluated the effects of resident work hours on complications during laparoscopic cholecystectomy. Naylor et al,3 in a study of 275 patients, evaluated...
technical complications of emergency laparoscopic cholecystectomy and found no correlation between complication rates and the imposition of the work hour restrictions. They similarly attributed their improved outcomes to increased attending surgeon involvement and delaying difficult cases until the morning, when well-rested residents were available.

Data for the effect of resident sleep deprivation on patient outcomes and quality of care are conflicting. A survey of US anesthesiologists reported that 61% made fatigue-related errors. In another survey of 225 residents, tiredness was judged the single most important factor contributing to the lack of quality patient care. However, Ellman et al demonstrated that short-term sleep deprivation in thoracic surgery residents did not affect operative efficiency, morbidity, or mortality in cardiac surgical operations. Other recent studies have noted unchanged morbidity and mortality in trauma, general, and vascular surgery patients after the institution of duty-hour restrictions.

The deleterious effects of excessive work hours and sleep deprivation on learning and technical skill also have been investigated. Goldman et al compared videotapes of postcall operations performed by surgical residents after fewer than 2 hours of sleep with videotapes of the same residents performing operations after longer periods of sleep. They found that 30% more operative time was required because of poorly planned maneuvers by sleep-deprived residents. Two simulated laparoscopy studies found that substantially more errors were made and more time was required to perform procedures on mornings after being on call during the night. Taffinder et al determined that surgeons who were awake throughout the night made 20% more errors and took 14% longer to complete tasks than those who had a full night’s sleep.

Risk factors for complications and bile duct injury during laparoscopic cholecystectomy have been well studied. Giger et al evaluated 22,953 patients in the Swiss Association Laparoscopic and Thoracoscopic Database and found several factors to be predictive of a complication in laparoscopic cholecystectomy. These included male sex, heavier body weight, surgeon experience, and prolonged duration of the intervention. Risk factors for bile duct injury during laparoscopic cholecystectomy included male sex, older age, and high degree of severity of disease.

In conclusion, we observed improved outcomes in the era of restricted resident work hours in patients undergoing laparoscopic cholecystectomy. Despite the concerns that work hour restrictions may have deleterious effects on patient care and resident education, these results clearly indicate otherwise. Whether the better-rested resident surgeon leads to better surgical outcomes needs further study.

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Author Contributions: Dr Yaghoubian had full access to all of the data in the study and takes responsibility for the data and the accuracy of the data analysis and the conclusions drawn. Study concept and design: de Virgilio. Acquisition of data: Yaghoubian, Saltmarsh, Rosing, and de Virgilio. Analysis and interpretation of data: Yaghoubian, Lewis, Stabile, and de Virgilio. Drafting of the manuscript: Yaghoubian, Saltmarsh, Rosing, Stabile, and de Virgilio. Critical revision of the manuscript for important intellectual content: Yaghoubian, Lewis, and de Virgilio. Statistical analysis: Yaghoubian, Saltmarsh, Lewis, and de Virgilio. Administrative, technical, and material support: Stabile and de Virgilio. Study supervision: de Virgilio.

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REFERENCES


DISCUSSION

Lawrence W. Way, MD, San Francisco, California: The article shows that many variables affected the results, some of which could not possibly be related to resident work hours. So the question is, What conclusions are firmly supported?

Dr de Virgilio and his colleagues performed a retrospective review of 2470 laparoscopic cholecystectomies from the years 2000 through 2006, recording the incidence of major and minor bile duct injuries and bile leaks after the operations. The patients were divided into two 3-year groups that covered the periods before and after limits had been placed on resident work hours. The objective was to determine whether the changes in work hours affected the rate of operative complications, since it has been shown that sleep deprivation of the magnitude associated with the previous more strenuous schedules is enough to impair the performance of cognitive and procedural tasks.

The results seem to show that the decreased work hours had a positive effect. The rate of bile duct injury decreased from 1.1% in period 1 to 0.4% in period 2. Closer scrutiny, however, shows that the difference is entirely due to a marked reduction in the categories called minor bile duct injuries and cystic duct stump leaks: 13 in the first period and 1 in the second period. Why? There are few specifics about the operations or the complications in the article. It would be nice to have more information about the nature of minor bile duct injuries and their circumstances to make sense of the observation.

Perhaps the biggest obstacle to fully accepting the authors’ conclusion, that “better-rested residents were able to do better surgery,” is that the data might just be an example of correlation without causation: the post-hoc fallacy. It is proven fact, for example, that shark attacks increase proportionate to the sale of ice cream.

Thus, assuming that the change is real, were better work hours the cause? Other than the dates they were performed, there is no additional evidence to support the assumption that the faulty operations were performed by sleep-deprived surgeons. Other possible influences on the basic correlation are numerous. Were the residents who were performing the operations more experienced in period 2 than in period 1? Did increasing knowledge of the cause of bile duct injuries lead to more effective avoidance? Did the problems during period 1 lead to more intense teaching programs or independent study? Did vigilance of the attending surgeons increase after recognizing that complications were too high?

The surgical operations were done under the supervision of attending surgeons, who in laparoscopic cholecystectomy are in a good position to detect injury-prone dissections and intervene to avoid problems. In fact, the low overall rate of injuries in this series is in the range of experienced surgeons, not trainees on the steep part of their learning curves. In other words, whether the operations were done before or after the initiation of workweek restrictions (ie, elimination of sleep deprivation), incipient technical errors of residents should largely be avoided through the time-honored mechanism of supervision. Potential substandard performance from inadequate sleep should be offset by the protection provided by the supervising attendings. One might even ask whether the data should not be expected to reflect the attendings’ performance more than the residents’.

This is an interesting subject, and the authors are exploring it fruitfully and with open minds. The article indicates that they are well aware of the types of questions I have asked, and they have addressed several of them in the “Comment” section.

In closing, I would be interested in their thoughts about the following. First, what were the minor injuries, and why was the effect confined to them and the cystic duct stump leaks? Second, do they believe they have established causation as well as correlation? Third, if they really are measuring the residents’ technical performance when counting the complications, how did the errors sneak through the attending surgeons’ oversight?

Dr de Virgilio: I agree with Dr Way that, with regard to cause and effect, we really cannot say that the duty hour changes themselves are the reason why the outcomes were better. In other words, just the fact that the residents are potentially more awake and alert does not directly result in a decrease in bile duct injury. What we can state, however, is that laparoscopic cholecystectomy in this new era, performed by residents at a county teaching hospital in which the residents are the primary caregivers, is safe and that outcomes in this new era are better. The fears that have been expressed, that patient care would be potentially compromised by duty-hour restrictions, have not proved true, at least with regard to our laparoscopic cholecystectomy outcomes.

One thing that is important to reiterate with our residency program is that we are a busy county hospital and a busy level 1 trauma center, and with the recent closure of an adjacent trauma center, our trauma center has gotten even busier. As a result, the chief residents take on an important role as a teaching assistant. I do feel that we have a unique opportunity at Harbor-UCLA Medical Center to study the effects of duty-hour restrictions because of this reliance on residents. So, in a sense, the study demonstrates that a chief resident serving as teaching assistant can have excellent outcomes, which are, in fact, better than what we have had in the past.

To pinpoint exactly why the outcome is better I do not think is possible given the retrospective nature of the study. I agree with you that when you look at the data, the bile duct injury rate was really a reflection of a decrease in the minor bile duct injury and the cystic duct leakage rates and not in the major bile duct injury. However, I would counter that even more minor injuries can have significant effects on morbidity and do result in additional interventions being required and lengthening of hospital stay, and in our study we did demonstrate that our hospital stay was shortened as well.

Specifically with respect to the definition of a minor bile duct injury, a minor bile duct injury was an injury that was able to be repaired primarily, such as a small ductotomy or laceration, and a major bile duct injury was one that required a biliary-enteric bypass. Regarding why the improvement in total bile duct injury and complications was seen, I suspect it is multifactorial. For one, with the new duty hours, the faculty has by necessity gotten more involved in the care of the patients to fill in the gaps and has a higher presence in the day-to-day management of patients. Another factor, given the increase in trauma we have seen, is that urgent laparoscopic cholecystectomies are less likely done in the middle of the night and are put off for the elective schedule. And certainly we cannot rule out recent heightened awareness of methods of bile duct injury prevention such as the critical view.

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