Long-term Detrimental Effect of Bile Duct Injury on Health-Related Quality of Life

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Hypothesis: Long-term quality of life (QOL) in patients undergoing laparoscopic cholecystectomy (LC) incurring bile duct injury (BDI) and repair is comparable to that of patients undergoing uncomplicated LC.

Design: Case comparison study.

Setting: Secondary and tertiary care centers.

Patients: Eighty-six patients incurring BDI during LC between January 1, 1991, and July 31, 2003, were surveyed. Comparison subjects underwent uncomplicated LC during the same period.

Main Outcome Measures: Health-related QOL as assessed by the Karnofsky Performance Scale, Medical Outcomes Study 36-Item Short Form Health Survey (SF-36), and Psychosocial Adjustment to Illness Scale.

Results: Fifty patients with BDI (39 [78%] female; mean±SEM age, 55±2 years) and 74 patients with uncomplicated LC (51 [69%] female, mean±SEM age, 52±2 years) responded. Of the 50 BDI patients, 48 (96%) had no stricture and normal liver function at QOL assessment. The mean±SEM follow-up period to QOL assessment for the BDI and uncomplicated LC groups was 62±6 and 47±3 months, respectively. The mean±SD Karnofsky Performance Scale scores were 77±9 vs 93±8 for the 2 groups, respectively (P<.001). The mean±SD SF-36 physical component scale scores after BDI vs uncomplicated LC were 36±11 vs 47±12, respectively (P<.001), compared with 50±10 for the normal population (P<.001). The mean±SD SF-36 mental component scale scores were 43±14 vs 49±11 for the 2 groups, respectively (P=.02), compared with 50±10 for the normal population (P=.01). Patients with BDI scored poorer on the Psychosocial Adjustment to Illness Scale health care orientation and domestic environment scales (P=.01).

Conclusion: After BDI and repair, there are long-term detrimental effects of BDI on health-related QOL.

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Health-related quality of life (HRQOL) is the extent to which a procedure and disease process impact the physical, psychological, and social aspects of a patient’s life and feelings of well-being. Therefore, to truly assess a patient’s outcome after BDI, one must not only measure the usual objective clinical outcomes but also evaluate the patient’s subjective HRQOL.

This study assessed HRQOL and time to return to work among patients who had BDIs during LC and underwent treatment or repair at secondary and tertiary centers. Outcomes were compared with those of patients who underwent uncomplicated LC (referred to as the LC group), and with the general US population standards for HRQOL.

METHODS

PATIENTS

The institutional review board of the Vanderbilt University Medical Center, Nashville, Tenn, approved the data collection and methodology of this study. Surviving patients who incurred BDIs during LC and who were initially or subsequently treated in the Division of Hepatobiliary Surgery and Liver Transplantation at Vanderbilt University Medical Center were identified as potential participants. Comparison subjects were patients who underwent uncomplicated LC at this institution during the same period. Data were collected retrospectively and included demographic measures, time of referral, level of injury, number and type of treatment, outcomes, return to work, and length of follow-up. Long-term patient outcomes were analyzed by these covariates. The BDIs were graded after review of relevant imaging studies according to Bismuth classification. Patients with limited cystic duct leaks were excluded.

HRQOL ASSESSMENT AND ANALYSIS

Health-related quality of life was assessed with the Karnofsky Performance Scale, Medical Outcomes Study 36-Item Short Form Health Survey (SF-36), and the Psychosocial Adjustment to Illness Scale (PAIS). Questionnaires were either mailed to patients or completed during regularly scheduled follow-up clinic visits. The Karnofsky Performance Scale is an objective, clinician-scored measure of functional performance on which scores range from 0 to 100. Scores of 40 or less represent the poorest level of functioning (“disabled”), of 41 to 80 represent impaired functioning (“unable”), and greater than 80 represent the highest level of functioning (“able”).

Both the SF-36 and the PAIS are subjective, patient-scored surveys of HRQOL. The SF-36 consists of 36 items in 8 subscales: physical functioning, role functioning, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. The physical and mental component summary scales (PCS and MCS, respectively) are then computed as weighted composites of the 8 subscales. Normative data for the general US population are available for the SF-36. Higher scores represent better quality of life.

The PAIS is composed of 46 items, which are scored as 7 domains of psychosocial adjustment to illness: health care orientation, vocational environment, domestic environment, sexual relationships, extended family relationships, social environment, and psychological distress. A global score is also computed. Higher scores represent poorer adjustment to illness.

The HRQOL scores and employment-related outcomes of patients with BDIs were compared with those of patients who had undergone uncomplicated LC. In addition, SF-36 scores were compared with published normative data from the general US population, which were standardized such that PCS and MSC population summary scores averaged 50 with a standard deviation of 10. Patients with BDIs were surveyed concerning whether legal action had been pursued as a result of the injury.

RESULTS

STUDY POPULATION

Eighty-six surviving patients with BDIs were identified as possible participants. All had been treated for BDIs that occurred during LC between January 1, 1991, and July 31, 2003. Of these patients, 50 (58%) completed the SF-36, PAIS, and employment surveys. Of these patients, 39 (78%) were female, the mean ± SEM age was 55 ± 2 years, and the mean ± SEM time of follow-up was 62 ± 6 months (Table 1). Of about 400 patients who underwent uncomplicated LC between January 1, 1991, and July 31, 2003, at our institution, 74 patients completed the survey. Of these patients, 51 (69%) were female, the mean ± SEM age was 52 ± 2 years, and the mean ± SEM follow-up time was 47 ± 3 months.

Nineteen (38%) of the patients with BDIs had their injuries recognized at the time of the initial LC, and a repair was attempted after conversion to an open procedure (Table 2). Of the 16 additional patients (32%) treated postoperatively before referral to our center, 12 were treated endoscopically or radiographically and operatively. Thirteen patients with BDI (26%) required 1 intervention, 25 (50%) required 2 interventions, 10 (20%) required 3 interventions, and 2 (4%) required 4 interventions. Fifteen patients (30%) received their primary treatment and 22 (44%) received later operations at our center. Of those who underwent operative repair at this institution, 35 (95%) required no further intervention.

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Table 1. Characteristics of Patients in the BDI and LC Groups

<table>
<thead>
<tr>
<th></th>
<th>BDI (n = 50)</th>
<th>LC (n = 74)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At LC</td>
<td>50 ± 2</td>
<td>48 ± 2</td>
<td>.47</td>
</tr>
<tr>
<td>At QOL assessment</td>
<td>55 ± 2</td>
<td>52 ± 2</td>
<td>.66</td>
</tr>
<tr>
<td>Sex, No. (%) F</td>
<td>39 (78%)</td>
<td>51 (69%)</td>
<td>.08</td>
</tr>
<tr>
<td>Race, No. (%) white</td>
<td>44 (88%)</td>
<td>67 (91%)</td>
<td>.16</td>
</tr>
<tr>
<td>QOL assessment after LC, mo</td>
<td>62 ± 6</td>
<td>47 ± 3</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Abbreviations: BDI, bile duct injury; LC, uncomplicated laparoscopic cholecystectomy; QOL, quality-of-life.
Data are given as mean ± SEM unless otherwise indicated.
Bile duct injuries are a devastating complication of LC. Despite more than a decade of experience with this procedure, the incidence remains as high as 1.4% in some studies. While more than 85% of these injuries required repair at tertiary referral centers, the remaining patients often require multiple procedures and operations to repair their bile ducts. Occasionally, BDIs necessitate liver transplantation or result in death. There are only limited data describing the psychosocial ramifications of BDIs and repair.

This investigation characterized the long-term HRQOL after bile duct injury and repair, and compared these data with those of patients experiencing uncomplicated LCs. Three validated instruments were used. One of them, the Karnofsky Performance Scale, is one of the oldest instruments for evaluating functional performance. The SF-36 is the most widely used and extensively validated instrument for measuring HRQOL. Finally, the PAIS focuses on psychosocial adjustment to illness. Previous work from our group demonstrated that the PAIS complements the SF-36 by providing unique information relating to attitudes toward and satisfaction with the health care delivery system (via the PAIS health care orientation subscale).

At an average of 5 years after BDI, patients had lower scores on the Karnofsky Performance Scale and all SF-36 measures of HRQOL when compared with patients who underwent uncomplicated LC. The PAIS health care orientation subscale provides evidence that perception of the health care delivery system was negatively affected in patients with BDIs. This is not surpris-

**Table 2. Management and Nature of Injury**

<table>
<thead>
<tr>
<th>No. (%)</th>
<th>Total</th>
<th>50 (100)</th>
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</thead>
<tbody>
<tr>
<td>Injury recognized during LC with attempted repair</td>
<td>19 (38)</td>
<td></td>
</tr>
<tr>
<td>Injury recognized in postoperative period</td>
<td>16 (32)</td>
<td></td>
</tr>
<tr>
<td>Previous attempt at repair before referral to VUMC</td>
<td>15 (30)</td>
<td></td>
</tr>
<tr>
<td>Surgical repair at VUMC</td>
<td>13 (26)</td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:** BDI, bile duct injury; LC, laparoscopic cholecystectomy; LFT, liver function test; QOL, quality-of-life; VUMC, Vanderbilt University Medical Center.

Thirteen (26%) were successfully treated with nonsurgical (endoscopic or radiologic) interventions. At the time of HRQOL assessment, 48 patients in the BDI group (96%) had no radiographic evidence of stricture and normal liver function tests, while 2 (4%) had no stricture but had mildly elevated results of liver function tests.

The level of obstruction or injury to the biliary tree was classified as Bismuth 1 in 9 patients (18%), Bismuth 2 in 11 patients (22%), Bismuth 3 in 4 patients (8%), Bismuth 4 in 22 patients (44%), and Bismuth 5 in 4 patients (8%). The majority of the patients (60%) had a high Bismuth level (3, 4, or 5).

**HRQOL OUTCOMES**

The mean±SEM time after injury or procedure for the BDI and LC groups was 62±6 and 47±3 months, respectively. At these time points, the mean±SD Karnofsky Performance Scale score for patients with BDI was 77±9 vs 93±8 in the LC group (P=.001). Table 3 summarizes the overall and individual domain scores for the SF-36 for the patients with BDIs, patients with uncomplicated LC, and general US population norms. Patients with BDIs had significantly lower scores on all 8 subscales of the SF-36 (P<.01) (Figure 1A). The BDI repair group had lower PCS scores than patients experiencing uncomplicated LC (mean±SD, 36±11 vs 47±12, respectively; P=.001) (Figure 1B). The MCS scores for patients with BDIs were also lower than in the simple LC group (mean±SD, 43±14 vs 49±11, respectively; P=.02).

With higher scores representing poorer psychosocial adjustment, the PAIS global scores trended toward poorer outcomes after BDI than uncomplicated LC (mean±SD, 45±25 vs 33±23; P=.06) (Table 4). Patients with BDIs had significantly poorer scores (both P=.01) on 2 PAIS subscales in comparison with the uncomplicated LC group: the health care orientation (mean±SD, 7±4 vs 5±4, respectively) and the domestic environment (mean±SD, 8±5 vs 5±4, respectively).

Forty-one patients with BDIs (82%) and 73 patients undergoing simple LC (99%) returned to work (P=.03). The median time to return to work was 3 months for the BDI group and 1 week for the LC group (P<.001).

Twenty-two percent of the BDI group reported filing a lawsuit after the injury (Table 5). There were no significant differences in the demographics or clinical management between those who filed a lawsuit and those who did not. Patients who reported filing lawsuits had poorer SF-36 composite scores than those who did not (PCS, 30±5 vs 39±11, P=.04; MCS, 34±13 vs 47±12, P=.02).

Patients in the BDI and LC groups with less than 5 years of follow-up had mean±SD PCS scores of 38±11 and 47±13, respectively (P=.001), while the mean±SD MCS scores for these patients were 45±11 and 51±10 (P<.05). Patients in the BDI and LC groups with 5 years or more of follow-up had PCS scores of 35±10 and 48±12, respectively (P<.001), while the MCS scores for these patients were 40±15 and 45±13 (P=.05). Thus, the relationship between scores in the BDI and LC groups on both the SF-36 PCS and MCS did not change with duration of follow-up (P=.53). The number of repairs, surgical vs nonsurgical repair, level of injury, and duration of treatment to successful repair did not significantly impact the patients' long-term HRQOL.

**COMMENT**

Bile duct injuries are a devastating complication of LC. Despite more than a decade of experience with this procedure, the incidence remains as high as 1.4% in some studies. While more than 85% of these injuries required repair at tertiary referral centers, the remaining patients often require multiple procedures and operations to repair their bile ducts. Occasionally, BDIs necessitate liver transplantation or result in death. There are only limited data describing the psychosocial ramifications of BDIs and repair.
ing in these patients, who were to undergo a relatively simple procedure and ended up having a negative life-altering event.

We were unable to demonstrate a difference in the HRQOL of patients with BDIs that depended on the duration of treatment, level of injury, or type of repair. When we categorized our patients into those with less than 5 years of follow-up and those with 5 years or more of follow-up, our findings were similar. While physical functioning in both groups remained relatively constant de-

Table 3. Quality-of-Life Assessment

<table>
<thead>
<tr>
<th>BDI</th>
<th>LC</th>
<th>P Value, BDI vs LC</th>
<th>Population Norms</th>
<th>P Value, BDI vs Norm</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-36 domain scores</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical functioning</td>
<td>53 ± 29</td>
<td>79 ± 28</td>
<td>&lt;.001</td>
<td>85 ± 23</td>
</tr>
<tr>
<td>Role functioning</td>
<td>39 ± 43</td>
<td>76 ± 40</td>
<td>&lt;.001</td>
<td>81 ± 34</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>53 ± 28</td>
<td>70 ± 27</td>
<td>.006</td>
<td>75 ± 24</td>
</tr>
<tr>
<td>General health</td>
<td>45 ± 25</td>
<td>69 ± 26</td>
<td>&lt;.001</td>
<td>72 ± 20</td>
</tr>
<tr>
<td>Vitality</td>
<td>34 ± 24</td>
<td>57 ± 24</td>
<td>&lt;.001</td>
<td>61 ± 21</td>
</tr>
<tr>
<td>Social functioning</td>
<td>60 ± 31</td>
<td>79 ± 28</td>
<td>.003</td>
<td>84 ± 22</td>
</tr>
<tr>
<td>Role-emotional</td>
<td>51 ± 46</td>
<td>75 ± 38</td>
<td>.008</td>
<td>81 ± 33</td>
</tr>
<tr>
<td>Mental health</td>
<td>62 ± 25</td>
<td>75 ± 19</td>
<td>.007</td>
<td>75 ± 18</td>
</tr>
<tr>
<td>SF-36 component summary scores</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCS</td>
<td>36 ± 11</td>
<td>47 ± 12</td>
<td>&lt;.001</td>
<td>50 ± 10</td>
</tr>
<tr>
<td>MCS</td>
<td>43 ± 14</td>
<td>49 ± 11</td>
<td>.02</td>
<td>50 ± 10</td>
</tr>
</tbody>
</table>

Abbreviations: BDI, bile duct injury; LC, laparoscopic cholecystectomy; MCS, mental component scale; PCS, physical component scale; SF-36, Medical Outcomes Study 36-Item Short Form Health Survey.

* Data are given as mean ± SD unless otherwise indicated.

Figure 1. Scores on the 8 domains (A) and the physical component scale (PCS) and mental component scale (MCS) (B) of the Medical Outcomes Study 36-Item Short Form Health Survey in patients with bile duct injury (BDI), those undergoing uncomplicated laparoscopic cholecystectomy (LC), and general US population norms. Patients with BDI had poorer scores on all 8 domains (asterisks; P < .01) and the PCS (P < .001) and MCS (P < .05). PF indicates physical functioning; RP, role functioning; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role-emotional; and MH, mental health.

Table 4. Quality-of-Life Assessment

<table>
<thead>
<tr>
<th>Karnofsky Performance Score</th>
<th>BDI</th>
<th>LC</th>
<th>P Value, BDI vs LC</th>
</tr>
</thead>
<tbody>
<tr>
<td>77 ± 9</td>
<td>93 ± 8</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>PAIS domain scores</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health care orientation</td>
<td>7 ± 4</td>
<td>5 ± 4</td>
<td>.01</td>
</tr>
<tr>
<td>Domestic environment</td>
<td>8 ± 5</td>
<td>5 ± 4</td>
<td>.01</td>
</tr>
<tr>
<td>Sexual relationships</td>
<td>5 ± 5</td>
<td>5 ± 5</td>
<td>.85</td>
</tr>
<tr>
<td>Extended family relationships</td>
<td>2 ± 2</td>
<td>2 ± 3</td>
<td>.92</td>
</tr>
<tr>
<td>Social environment</td>
<td>6 ± 5</td>
<td>6 ± 5</td>
<td>.41</td>
</tr>
<tr>
<td>Psychological distress</td>
<td>7 ± 5</td>
<td>6 ± 4</td>
<td>.38</td>
</tr>
<tr>
<td>Vocational environment</td>
<td>7 ± 6</td>
<td>5 ± 5</td>
<td>.13</td>
</tr>
<tr>
<td>PAIS global score</td>
<td>45 ± 25</td>
<td>33 ± 23</td>
<td>.06</td>
</tr>
</tbody>
</table>

Abbreviations: BDI, bile duct injury; LC, laparoscopic cholecystectomy; PAIS, Psychosocial Adjustment to Illness Scale.

* Data are given as mean ± SD unless otherwise indicated.

Table 5. SF-36 Component Scores in Patients With BDI Who Did and Did Not File Lawsuits

<table>
<thead>
<tr>
<th>Score, Mean ± SD</th>
<th>Lawsuit (n = 11)</th>
<th>No Lawsuit (n = 39)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCS</td>
<td>30 ± 5</td>
<td>39 ± 11</td>
<td>.04</td>
</tr>
<tr>
<td>MCS</td>
<td>34 ± 13</td>
<td>47 ± 12</td>
<td>.02</td>
</tr>
</tbody>
</table>

Abbreviations: BDI, bile duct injury; MCS, mental component scale; PCS, physical component scale; SF-36, Medical Outcomes Study 36-Item Short Form Health Survey.

We were unable to demonstrate a difference in the HRQOL of patients with BDIs that depended on the duration of treatment, level of injury, or type of repair. When we categorized our patients into those with less than 5 years of follow-up and those with 5 years or more of follow-up, our findings were similar. While physical functioning in both groups remained relatively constant de-
Despite the length of follow-up, their mental functioning worsened with duration of follow-up \((P<.05)\).

We found that less than one fourth of these patients reported filing lawsuits. There were no significant demographic or clinical differences between those who reported filing a lawsuit and those who did not. However, patients who did file a lawsuit reported significantly greater impairment in HRQOL. It was not possible from this analysis to determine a causal direction.

Despite long-term physical and psychosocial impairment, the majority of the patients with BDIs were able to return to work. However, they returned to work almost 3 months later on average than patients who underwent uncomplicated LC.

There are limited comparison data available in the literature addressing quality of life after BDI repair. Boerma and colleagues\(^1\) reported on 106 patients with BDI, 30% of whom were treated endoscopically or radiographically. In their study, the follow-up ranged from about 3 years to 9 years. They demonstrated that scores on the 8 domains of the SF-36 of patients with BDI were significantly different from those of patients with uncomplicated LC and Dutch population norms \((P<.05)\). We studied a similar heterogeneous mix of patients, of whom at least 26% were treated endoscopically or radiographically. Likewise, our patients with BDI scored significantly worse on all 8 subscales of the SF-36 when compared with patients undergoing uncomplicated LC and the general US population norms \((P<.01)\)(Figure 2). Thus, the results of Boerma and coworkers’ study and ours are similar.

Melton and colleagues\(^2\) examined quality of life in 54 patients with BDI, all of whom underwent surgical repair. They used the City of Hope Medical Center Quality of Life Survey, which comprises 3 domains: physical, psychological, and social. They reported that patients with BDI had physical and social quality of life similar to that of patients undergoing uncomplicated LC, but greater impairment in psychological quality of life. In addition, they found that legal activity was associated with worse outcomes.

It is important that we better characterize the clinical outcomes and HRQOL of patients with BDIs. This study adds substantially to the data on quality of life after BDI.

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REFERENCES


**DISCUSSION**

Richard C. Thirlby, MD, Seattle, Wash: Bile duct injuries during cholecystectomies are frequently devastating. Patients are sentenced to a lifetime of blood tests, radiographic studies, and multiple surgical procedures. The surgical literature is filled with large case series from major surgical centers throughout the world reviewing both surgical techniques as well as clinical outcomes. For example, the Mayo Clinic group reviewed their experience with these patients in a paper presented to the 1998 meeting of the Western Surgical Association. Fifty-nine patients underwent operative repair of laparoscopic bile duct injuries. The vast majority were major injuries, so-called type E lesions in the Strasberg classification, or injuries at the bile duct confluence. In the words of Dr Farnell and colleagues at Mayo, “excellent to good long-term results were achieved in 91% of patients. Life-table analysis yielded 95% and 88% chances of stricture-free survival at 2 and 5 years, respectively.” My review of the literature suggests that this 90% success rate is being reproduced in most major referral centers. Today’s study emphasizes that when we read these clinical series, we wonder how patients in these previous series were classified into outcomes groups, or how a good result was determined. In the methods of the Mayo Clinic paper, it was stated that patients were graded as excellent if they were asymptomatic with normal liver function tests or good if they were asymptomatic with mildly abnormal liver function tests. Information was gathered via a detailed questionnaire or a telephone survey. As I reviewed this paper last week with the present study and discussion in mind, the question for my Mayo Clinic friends that became obvious was “Who decided if these patients were asymptomatic?” Or “What were the questions that determined symptoms?”

Increasingly, outcomes studies are focusing on patient-derived data or assessments. Put another way, what is more important: the results of a laboratory test and a physician’s assessment of symptoms, or a patient’s assessment of their health-related quality of life? Obviously, the latter is vitally important. Who cares if the lab tests are normal if the patient feels terrible? Similarly, who cares if the lab tests are abnormal if the patient feels great? Today, Dr Moore and colleagues from Vanderbilt have attempted to answer the key question posed above: “Is health-related quality of life, or HRQOL, affected in patients with bile duct injuries?” Patients with bile duct injuries operated on at Vanderbilt were appropriately age and sex matched with patients undergoing uncomplicated laparoscopic cholecystectomies. The authors found a statistically significant decreased physical component of HRQOL and a nearly significant impaired mental component of HRQOL in the bile duct injury cohort. Their conclusion was that bile duct injury patients, as a group, have impaired HRQOL.

I have several comments and questions. First, a few comments relating to HRQOL research. It is important to emphasize that many factors unrelated to the disease in question affect HRQOL scores. That is, quality of life is not the same as health-related quality of life. Quality of life affects scores on health-related quality-of-life tools. Women and older persons consistently score lower on these self-assessment tools, hence the importance of age and sex matching in the present study. Their control group is certainly more valid than comparisons with the general population. Other quality-of-life factors that are associated with HRQOL scores include social status, marital status, income bracket, and, relevant to the present study, insurance or legal status. For example, divorced women with low incomes score lower on HRQOL tests independent of their disease status. With regard to insurance or legal status, we and others have shown conclusively that patients with workers’ compensation claims do poorly independent of their technical surgical outcome.

I have several questions: first, the difference in scores on the SF-36 was about 10 points. Are you sure that these statistically significant differences are clinically significant? Second, did you attempt to categorize the patients into groups using more traditional physician-derived outcome measures such as laboratory values or radiographic imaging, and if you did, could you correlate those findings to HRQOL scores? In other words, were there many patients with normal labs who had impaired HRQOL? Third, can you give us more detail on the patients involved in lawsuits? Patients involved in lawsuits could be predicted to have poor HRQOL using patient-derived data. Similar to the previous question, were there patients who, when analyzed with physician-derived outcomes such as laboratory values, had good to excellent outcomes but had poor HRQOL? If so, then the conclusions of the manuscript should be changed from “Bile duct injury negatively affects HRQOL.” To “Malpractice lawsuits invalidate HRQOL data independent of clinical outcome,” a conclusion that has even greater clinical significance. In other words, are patients with lawsuits doing poorly because of bile duct injuries, or are they doing poorly because it is in their financial interest to feel sincerely that they are doing poorly? Finally, the percentage of patients who did not respond to your request to fill out the questionnaires was a bit high. Do you have any laboratory or clinical data on these patients to suggest that they were better or worse than the study cohort?

In summary, Dr Moore and coauthors should be congratulated on a significant contribution to the field. In my opinion, patient-derived HRQOL data should trump physician-derived outcome data in most outcomes studies. However, I believe that the lack of traditional physician-derived data such as liver function and radiographic tests seriously compromises the conclusions of the authors. Since the present study addresses a surgical disease that is characterized by very high litigation rates, the authors may be missing the accurate and important point of their data: I would contend that patient-derived HRQOL data may not be valid in patients who have filed lawsuits.

Dr Pinson: To answer the questions about the clinical significance of the 10-point difference on a composite scale, 10 points is 1 SD away from normal. The way the SF-36 is designed, if you are 1 SD away from normal, you are considered to be doing poorly. Furthermore, if you are significantly different from normal, you would not be able to pass for normal. Therefore, we would expect that if patients were considered to be significantly different from normal, they would be significantly different from one another. Finally, the answer is probably only some.

Another way for me to frame this is to provide some comparison data. We have studied quality of life in our group for about 10 years, mostly focusing on transplant patients. If you look at patients who have had transplants—liver, heart, lung,
and kidney—and then look at patients who have had bile duct injuries, these bile duct injury patients are in the same range as the people who have had their transplants. I would submit to you that the people who have had a transplant are pretty good, but they are not normal. Patients before transplant for liver, lung, and heart are about 2 SDs off. I think we would agree the patients waiting for their heart, lung, and liver transplants are in noticeably bad shape and they are aware of this. So that helps us to understand what 2 SDs off means. I hope the comparison helps by saying that these patients are 1 SD off and very much like posttransplant patients.

The second question you brought up has to do with the objective measures of outcomes in these patients. There was no patient here who was currently undergoing any further treatment or having cholangitis. Radiographs of all the patients at the time these quality-of-life studies were performed demonstrated no strictures. Lab values were normal or near normal. You mentioned the Mayo Clinic description. All of our patients would fall into their excellent to good categories. So the HRQOL data provided you today is in a group of patients who are otherwise doing very well by our objective measure.

Your third question had to do with patients who are involved in lawsuits. When we go back and review the 22% who were involved in lawsuits, objectively they had no better or worse outcomes than the rest. The lower scores in the health-related quality of life for patients with lawsuits are the subjective observation; the cause or the direction cannot be assigned by our method of study here. Being involved in a lawsuit is associated with a poorer quality of life, and I am sure you can believe that. We’ve quantified the amount. If you feel that this skews the overall data, then we can take that 22% out. We’ve actually done that and the results aren’t much changed for the remaining 78% of the patients.

As for the question about nonresponders, objectively, there is no difference in that we could find. Again, all the outcomes of all these patients objectively were pretty good, so there is no difference between responders and nonresponders. While I am used to 85% or 90% response rates for previous work in the transplant patients, a 58% response rate is very good for this type of work.

Now your final question was whether there was really any validity to this subjective study. I hope the multiple pieces of data in concert convince you. This includes Karnofsky Performance Score data that demonstrate a score in the 70s, which is quite a ways away from 100 for normal; all of the domains of the SF-36, significantly different; composite physical and mental component scores for the SF-36, significantly different; near significance in a totally different measure of the global PAIS; 2 domains of the PAIS significantly different; a return-to-work rate that is 81% vs 98%; and finally, time off from work of 3 months vs a week. I hope the collection of data convinces you of the validity of work. Dr Thirlby, I do appreciate your very careful evaluation and discussion.

Vic Velanovich, MD, Detroit, Mich: I have 2 questions. Why did you not use a gastrointestinal-specific questionnaire like the GRS or the GIQLI? The 2 scales that you used have some overlap, and sometimes disease-specific instruments give you different information than the generic instruments that you used. The second question I have is with regard to the statistics. Did you do any tests to determine whether the SF-36 scores did in fact follow a gaussian distribution because you used parametric statistical methods? When I’ve used this scale, I find that they generally do not follow a gaussian curve. I have to use non-parametric statistical tests.

Dr Pinson: First of all, you are right, there are 2 major categories of quality-of-life tools: there are generic and then there are disease specific. Some people feel that disease-specific tools are more useful. We, in 10 years of work in transplantation, have found that the generic tools that we used today were actually more helpful to us than some of the disease-specific tools. I cannot answer the question as to whether a disease-specific tool would have been a better choice here. We chose what we chose because we had a lot of experience with it. We did have a gaussian distribution of our data and believe we were safe with the analysis we used.

Jeffrey H. Peters, MD, Los Angeles, Calif: A very interesting paper. I wonder if the dichotomy between the clinical papers and the HRQOL papers isn’t just the comparison of a prevalence set of data, that is, 90% good, 10% bad clinical outcome vs mean data, which all of the HRQOL papers report. I wonder, if you categorized the HRQOL data as good vs bad, would you get a 90:10 relationship?

Dr Pinson: You have to look at our data, at the means and the standard deviations, and then it speaks for itself. But you’re right, there is a proportion of patients who wouldn’t be significantly different from either the population norms or the laparoscopic cholecystectomy norms, and then there is another group of patients who clearly are different. We would have to do that analysis to answer your question.

William R. Fry, MD, Colorado Springs, Colo: I was wondering if you had any data using your analysis on patients who were converted from laparoscopic cholecystectomies to open without bile duct injury, because that seems like that might be a better control group to the patients who go on to having an open procedure for their bile duct repair.

Dr Pinson: That would be interesting, but we didn’t do it.

William P. Schecter, MD, San Francisco, Calif: Perhaps I missed it. Did the number of repairs required affect outcome? Presumably, patients who have multiple operations have more complex anatomic problems, a more prolonged and arduous recovery, and less satisfactory outcome.

Dr Pinson: We looked at both number and duration of treatment, and we were unable to demonstrate a difference. I would like to close by saying that I first considered this paper after I heard the Amsterdam group present in 2000, when they said that the health-related quality of life was reduced after bile duct injury. I said to myself, “We do that kind of work. Our patients are happy. I’m going to go back and do this study and set the record straight.” And now we have done the study, and we turn out to have very similar results to the Amsterdam group.