FATIGUE AS A MAJOR PREDICTOR OF QUALITY OF LIFE IN WOMEN WITH AUTOIMMUNE LIVER DISEASE
The Case of Primary Biliary Cirrhosis

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Objectives. Fatigue is a nearly universal symptom of many chronic diseases, yet it is often poorly understood and underappreciated as a factor in quality of life (QOL). Generally, clinicians have relied on subjective measures of fatigue, if they consider it at all. This study uses well-validated instruments to examine fatigue as a predictor of QOL in women with primary biliary cirrhosis (PBC), an autoimmune, chronic liver disease.

Methods. Eighty-one women with PBC completed a survey that included measures of fatigue (Fatigue Impact Scale) and QOL (SF-36) as well as demographic variables (age, education) and medical information (symptoms, stage of illness, time since diagnosis). QOL results for the sample were compared with those of a nationally normed U.S. population. Bivariate and multivariate analyses were conducted to identify contributors to variation in QOL.

Results. Compared with national norms, QOL for this PBC population was significantly impaired. When all variables with bivariate significance in relation to QOL were included in multivariate analyses, results showed fatigue to be the primary predictor of QOL, including all 8 QOL scales and the 2 summary scales. Regression results, dominated by fatigue, explain 25–59% of the variance in QOL.

Conclusions. Fatigue has profound effects on every aspect of life for women with PBC—physical, social, emotional, and psychological. The results lead to recommendations for health care providers to assess fatigue in their patients with PBC and to take steps, where warranted, to mitigate its effects.

Liver disease is the 7th leading cause of death among Americans 25–64 years of age (Minino, 2004). One chronic liver condition, called primary biliary cirrhosis (PBC), is found predominantly in people aged 40–65; 90% are women. PBC is a rare autoimmune disease in which the body attacks the cells lining the liver’s bile ducts, causing inflammation and destruction. The cause of PBC is thought to be related to viral, environmental, and/or genetic causes (National Institutes of Health [NIH], 2005; Selmi et al., 2004). Liver transplantation is the only current solution for treating end-stage PBC, although women with PBC may live for years with the disease before requiring transplantation.

Autoimmune disorders, including PBC, rank among the top 10 causes of death of U.S. women in every age group under 65. The NIH report asserts that “autoimmune diseases . . . represent a significant physical, emotional, social, and fiscal burden to the country’s health care system” (NIH, 2005). These diseases are generally poorly recognized and not well researched. As a result, women who experience the symptoms of autoimmune disease are often misdiag-
nosed and must fight for recognition that they have a “real” disease (Dumit, 2006; Richman, Jason, Taylor, & Jahn, 2000).

Contributing to the misdiagnosis of PBC and other autoimmune diseases is that a major symptom—fatigue—is operating in a disease that targets women predominantly. Women who report fatigue are too often not taken seriously (Dumit, 2006).

As demonstrated by studies in Canada, The Netherlands, and the United Kingdom (Goldblatt et al., 2002; Huet, Deslauriers, Tran, Faucher, & Charbonneau, 2000; Newton, Bhala, Burt, & Jones, 2006; Prince, James, Holland, & Jones, 2000; Witt-Sullivan et al., 1990), among others, fatigue is a highly prevalent symptom among people with PBC. One study, for example, showed that fatigue is greater in persons who have PBC than in matched community controls or in persons with autoimmune hepatitis (Goldblatt et al., 2002).

Fatigue in general, and specifically in relationship to chronic liver disease, remains poorly understood. Until recently, fatigue has not been measured with psychometric precision, perhaps recognized as a subjective report but lacking clinical validation (Jones, 2004). In addition, there is little evidence for an association between fatigue and histologic markers of liver disease (Huet et al., 2000; Miller, Hiller, & Shaw, 2001; Jones, 1995). As a study argues, fatigue in people with PBC is not well studied because it is difficult to get society to appreciate that fatigue is a “real” symptom, and because it is difficult to quantify (Goldblatt et al., 2002). Yet fatigue may be the most disabling symptom experienced by persons with chronic liver disease.

Although some studies have addressed quality of life (QOL) in chronic liver disease, there has been a paucity of such research for people with PBC (Martin, Sheridan, & Younossi, 2002; Rannard, Buck, Jones, James, & Jacoby, 2004). Yet, QOL has been shown to be significantly compromised in people with cholestatic liver disease (Younossi, Kiwi, Boparai, Price, & Guyatt, 2000), and in people with liver disease who are awaiting transplant (Gross et al., 1999).

We know that fatigue is common in many chronic illnesses, yet we have little information about the relationship of fatigue to overall QOL or to the various dimensions of QOL among people with PBC, other autoimmune diseases, or other chronic liver diseases. A few recent studies suggest there is a relationship; however, the researchers did not use validated measures of fatigue (Newton et al., 2006; Poupon, Chretien, Chazouilleres, Poupon, & Chwalow, 2004). Stanca et al. (2005) used the Fatigue Impact Scale (FIS) and found correlations between fatigue and dimensions of QOL as measured by the Mayo version of the NIDDK-QA, but they also found fatigue to be less prevalent than seen in other PBC studies. A recent effort to develop a PBC-specific QOL measure incorporated fatigue as 1 of 6 domains (Jacoby et al., 2005). Yet, arguably, locating fatigue as an outcome may confound understanding its role as a predictor (Newton et al., 2006).

The aims of this paper are to examine QOL in women with PBC, comparing their results with national norms; to assess the relationship of fatigue to QOL, using widely accepted and well-validated measures; and to consider the relative impact of fatigue on QOL when other important factors—symptoms and stage of disease—are taken into account. Our key hypothesis is that fatigue is a significant predictor of QOL, and when considered in multivariate analyses, fatigue will remain a strong explanatory factor.

Methods

In the current study, participants are women with PBC who attended the biannual conference of the PBCers Organization, held in Biloxi, Mississippi, in May, 2003. Permission for the study was obtained from the Institutional Review Board of Lehigh University, with protocol number 03-118, and the Board of Directors of the PBCers Organization, an Internet-based organization with >2,400 members worldwide (www.pbcers.org/).

We distributed the survey at the time that attendees picked up their registration materials when they arrived at the conference. They were given a consent form and a questionnaire (in a separate packet from registration) and were asked to complete them if they were willing, and to return them to a box in the registration area before the end of the conference. The authors were available to answer questions if needed.

The survey included demographic items (age, education), self-reports of stage of illness (histologic stage ranging from 1 to 4 as determined by liver biopsy, with stage 4 indicating the presence of cirrhosis), and years since diagnosis, as well as the FIS (Fisk et al., 1994), and the SF-36 QOL instrument (Ware & Dewey, 2000). We also listed possible symptoms of PBC and asked if the participant had experienced any of them in the past 60 days. This time frame was used to optimize inclusion of information on infrequent events such as bleeding. The symptoms listed were ascites (fluid in abdomen, which can become infected), bleeding problems, encephalopathy (confusion and cognitive dysfunction caused by toxic substances entering the brain), fatigue, itching, liver cancer, osteoporosis, varices (swollen vessels in the esophagus), and leg swelling. We used total symptoms to characterize, in an approximate way, the severity of living with PBC.

The FIS has 40 items distributed across 3 scales: 10 cognitive items, 10 physical items, and 20 social items. Subjects were asked to indicate on a 5-point Likert
scale (from 0 for “no problem” to 4 for “extreme problem”) the extent to which fatigue had caused problems for them in the past 30 days. This instrument is designed such that total FIS is the sum of the 3 scales. It has been validated with diseases associated with fatigue (chronic fatigue syndrome and multiple sclerosis) and not associated with fatigue (hypertension; Fisk et al., 1994); it has also been validated specifically with people who have PBC (Prince et al., 2000). When analysis called for a comparison of FIS with total symptoms, we omitted the self-report of fatigue from the list of symptoms.

The SF-36 is a measure that has been widely used with studies of illness, including liver disease (Rannard et al., 2004; Unal et al., 2001; Bravata, Olkin, Barnato, Keeffe, & Owens, 1999). It has 8 scales (Physical Functioning, Role—Physical, Body Pain, General Health, Vitality, Social Functioning, Role—Emotional, and Mental Health) as well as 2 summary measures (Physical Component Summary and Mental Component Summary). Results, with higher scores indicating better QOL, can be compared to U.S. national norms established separately by gender and age.

We scored SF-36 QOL data using the standard protocol (Ware et al., 2000). We then compared results against national normed data for women in the 55–64 age group, the closest to the mean for this sample of women with PBC, using a Pascal program developed by one of the authors (L.M.S.) to examine the comparisons statistically. All other analyses—frequencies, Pearson correlations, t-tests, and stepwise linear regression—were carried out in SPSS.

Results

Description of the Sample

Of the approximately 100 people with PBC who attended the conference in Biloxi, 81 women completed the survey. Table 1 describes this group. On average, the group members knew of their diagnosis for 6.24 years, with a range of <1 to 27 years. Most participants (61.3%) were in their 40s or 50s, and 41.8% had graduated college or gone on to postgraduate education. They were approximately evenly divided between the early stages (1–2) and later stages (3–4) of PBC.

Symptoms

Participants reported a range of 0–8 major symptoms, with a mean of 3.01. Most frequent were fatigue (84.0%) and pruritus (itching; 56.8%), followed by osteoporosis (33.3%), leg swelling (28.4%), bleeding problems (27.2%), encephalopathy (18.5%), ascites (13.6%), varices (9.1%), and liver cancer (2.5%).

Quality of Life

Table 2 provides the SF-36 results for the PBC sample and for normed data from the most comparable U.S. population group (women 55–64; Ware et al., 2000). Scale scores for the PBC sample ranged from 37.15 for General Health to 45.40 for Mental Health. The summary scores showed poorer QOL for the Physical Component Summary (38.61) than for the Mental Component Summary (44.38). When compared with national norms, the women in the PBC sample are significantly lower in QOL across all scales and summary scores.

Bivariate Analyses

We examined relationships between the 8 SF-36 scales and 2 summary measures on the one hand and the variables we expected to influence variations in QOL on the other: fatigue (as measured by the FIS scales and FIS-Total), stage of illness (1–4), years since diagnosis, age, education, and Total Symptoms (Table 3). Years since diagnosis and educational level were not associated with SF-36 scales or summary components.
The multiple regressions (Table 4) show that fatigue is a significant predictor of all SF-36 scales and both summary measures. The percentage of the variance in QOL explained in these equations ranges from 25–59%. In most cases, the FIS-P, representing limitations in physical activity owing specifically to fatigue, is the best predictor. In the case of the Mental Component Summary, Role—Emotional, and Mental Health, FIS-S is the relevant predictor. Thus the inability to participate in social activities as a result of fatigue is the most important contributor to poor QOL in the arena of mental health. FIS-C only appears in the equation with Physical Functioning as the dependent variable, and surprisingly in a positive direction (more cognitive impairment owing to fatigue is associated with better physical functioning after controls for the other variables). Stage of illness was a significant predictor only for the Vitality scale. Age contributed positively to General Health and Social Functioning, and total number of symptoms did not predict any SF-36 scales.

### Discussion and Conclusions

With population changes showing an increase in older adults as well as an increase in prevalence of autoimmune disorders (NIH, 2005), both phenomena disproportionately affecting women, the issue of chronic illness and its impact on QOL is vital to an understanding of women's well-being. Chronic illness disproportionately affects women, and the impact on QOL is vital to understanding women's well-being.

### Table 3. Correlations of Fatigue Impact Score (FIS), Stage, Total Symptoms, and Age With Quality of Life (SF-36) and Scales

<table>
<thead>
<tr>
<th>Quality of Life</th>
<th>FIS—Cognitive</th>
<th>FIS—Physical</th>
<th>FIS—Social</th>
<th>FIS—Total</th>
<th>Stage</th>
<th>Total Symptoms</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>-.401***</td>
<td>-.664***</td>
<td>-.503***</td>
<td>-544***</td>
<td>-.146</td>
<td>-.437***</td>
<td>-.095</td>
</tr>
<tr>
<td>Role—physical</td>
<td>-.602***</td>
<td>-.679***</td>
<td>-.664***</td>
<td>-.686***</td>
<td>-.334**</td>
<td>-.362**</td>
<td>.103</td>
</tr>
<tr>
<td>Body pain</td>
<td>-.477***</td>
<td>-.663***</td>
<td>-.576***</td>
<td>-.598***</td>
<td>-.319*</td>
<td>-.374**</td>
<td>.273</td>
</tr>
<tr>
<td>General health</td>
<td>-.585***</td>
<td>-.717***</td>
<td>-.676***</td>
<td>-.693***</td>
<td>-.396**</td>
<td>-.318**</td>
<td>.183</td>
</tr>
<tr>
<td>Vitality</td>
<td>-.565***</td>
<td>-.717***</td>
<td>-.676***</td>
<td>-.693***</td>
<td>-.396**</td>
<td>-.318**</td>
<td>.183</td>
</tr>
<tr>
<td>Social functioning</td>
<td>-.613***</td>
<td>-.726***</td>
<td>-.728***</td>
<td>-.735***</td>
<td>-.270*</td>
<td>-.395***</td>
<td>.245</td>
</tr>
<tr>
<td>Role—emotional</td>
<td>-.473***</td>
<td>-.498***</td>
<td>-.524***</td>
<td>-.531***</td>
<td>-.197</td>
<td>-.369**</td>
<td>.125</td>
</tr>
<tr>
<td>Mental health</td>
<td>-.501***</td>
<td>-.520***</td>
<td>-.626***</td>
<td>-.598***</td>
<td>-.165</td>
<td>-.259*</td>
<td>.087</td>
</tr>
<tr>
<td>Physical component summary</td>
<td>-.461***</td>
<td>-.707***</td>
<td>-.548***</td>
<td>-.594***</td>
<td>-.268*</td>
<td>-.372**</td>
<td>.046</td>
</tr>
<tr>
<td>Mental component summary</td>
<td>-.550***</td>
<td>-.563***</td>
<td>-.661***</td>
<td>-.644***</td>
<td>-.257*</td>
<td>-.309**</td>
<td>.238</td>
</tr>
</tbody>
</table>

*p < .05; **p < .01; ***p < .001.

### Table 2. Quality of Life (SF-36) Scales, Means, Standard Deviations, and Ranges, Comparing People With PBC With U.S. Norms

<table>
<thead>
<tr>
<th>S-F 36 Scale</th>
<th>PBC Sample (n = 81)</th>
<th>National Norms, Females (55–64 (n = 647)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>40.22 10.19 14.94–57.03</td>
<td>46.26 11.07 14–58</td>
<td>4.67 &lt;.0001</td>
</tr>
<tr>
<td>Role—physical</td>
<td>39.34 11.23 17.67–56.85</td>
<td>47.78 10.98 17–57</td>
<td>6.51 &lt;.0001</td>
</tr>
<tr>
<td>Body pain</td>
<td>42.23 9.45 28.31–45.21</td>
<td>47.73 11.09 19–63</td>
<td>4.27 &lt;.0001</td>
</tr>
<tr>
<td>General health</td>
<td>37.15 10.15 18.61–62.47</td>
<td>48.98 10.93 18–64</td>
<td>9.25 &lt;.0001</td>
</tr>
<tr>
<td>Vitality</td>
<td>41.36 10.31 20.87–61.46</td>
<td>50.16 10.90 20–71</td>
<td>6.89 &lt;.0001</td>
</tr>
<tr>
<td>Social functioning</td>
<td>41.63 12.09 13.22–56.85</td>
<td>49.31 11.07 13–57</td>
<td>5.82 &lt;.0001</td>
</tr>
<tr>
<td>Role—emotional</td>
<td>42.01 13.04 9.23–55.88</td>
<td>49.16 11.06 9–56</td>
<td>5.37 &lt;.0001</td>
</tr>
<tr>
<td>Mental health</td>
<td>45.40 10.65 16.22–64.09</td>
<td>50.19 10.75 10–65</td>
<td>3.78 .0002</td>
</tr>
<tr>
<td>Mental component summary</td>
<td>44.38 11.29 16.47–62.19</td>
<td>50.95 10.70 9–70</td>
<td>5.18 &lt;.0001</td>
</tr>
</tbody>
</table>
illness affects both physical and emotional well-being (Morewitz, 2007). PBC, a relatively rare autoimmune disorder affecting primarily women in their middle years, is emblematic of challenges facing many women.

QOL, as measured by the SF-36, is compromised in all 8 domains for women with PBC compared with national norms for a comparable age group. Fatigue explains a large portion of this deficit in QOL; Total Symptoms is not a factor nor is stage of illness, except in predicting the Vitality scale of the SF-36.

Because fatigue frequently has been dismissed—considered too subjective, not associated with clinical markers of disease, and perhaps discounted as a woman’s “complaint”—this symptom has been too often neither understood nor appreciated. Indeed, it has often been ignored, with notable exceptions in the case of PBC (Bergasa, 2004; Newton et al., 2006). Medical professionals have been found to downplay conditions such as chronic fatigue syndrome and fibromyalgia, which are predominantly found in women (Asbring & Narvanen 2003). Richman et al. (2000) and Jones (2004) add that physicians may be reluctant to pay attention to fatigue because of the lack of treatments to ameliorate it. The current study demonstrates that fatigue has profound effects on every aspect of life—social, psychological, emotional, and physical—even more than the specific physical markers represented by stage of illness and symptoms. Thus, it is crucial that fatigue in people with PBC, as well as in other chronic diseases that are typified by fatigue, be acknowledged and assessed, and efforts made to alleviate it.

Although there is broad consensus that fatigue is a common symptom of PBC, researchers continue to examine fatigue only as an outcome, even including a domain for fatigue in a recent PBC-specific instrument (Jacoby et al., 2005). This view may lead to or reinforce the expectation that treatment of fatigue requires focus on something else, such as changes in laboratory results. Because such clinical markers appear to be unrelated, the frustration with treatment of fatigue may be reinforced.

A recent study raised a question about whether U.S. persons with PBC might have less fatigue than previously observed in non-U.S. PBC populations (Stanca et al., 2005). In this Biloxi study, however, levels of fatigue are comparable with the non-U.S. results for people with PBC. Also, because this study used the SF-36, QOL in women with PBC relative to national norms can be demonstrated. Given the correlation between fatigue and QOL, the diminished QOL compared with a nationally normed population provides concurrent validity for the diminished fatigue findings.

This study is subject to 3 limitations. First, because these findings are based on a convenience sample of those who attended a conference for persons with PBC, they may be biased in certain ways. For instance, arguably, people with PBC who attend a conference may be less fatigued than their counterparts who are not well enough to travel. On the other hand, persons who are more ill may be more motivated to attend a conference that features expert speakers. To clarify how typical this sample is (or is not), we compared descriptive data on fatigue and FIS scores in this population with that available from other studies.

The proportion of people in this study reporting fatigue as a symptom (80%) is comparable with the average (78%) from 4 major studies that recruited participants with PBC (Cauch-Dudek, Abbey, Stewart, & Heathcote, 1998; Huet et al., 2000; Wanless, Heathcote, & Cauch, 1993; Witt-Sullivan et al., 1990). These

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Table 4. Multiple Regression: Quality of Life (SF-36) Summary Scores and Scales, With Fatigue Impact Scale (FIS) Subscales (Physical, Social, Cognitive), Stage of Illness, Total Symptoms,* and Age as Independent Variables

<table>
<thead>
<tr>
<th>Quality of Life: Dependent Variable</th>
<th>ANOVA</th>
<th>Adjusted R²</th>
<th>Significant Predictors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Beta</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>F = 35.42; p = .000</td>
<td>.466</td>
<td>FIS-P: -.887</td>
</tr>
<tr>
<td>Role—physical</td>
<td>F = 67.54; p = .000</td>
<td>.457</td>
<td>FIS-C: .278</td>
</tr>
<tr>
<td>Body pain</td>
<td>F = 62.63; p = .000</td>
<td>.438</td>
<td>FIS-P: -.681</td>
</tr>
<tr>
<td>General health</td>
<td>F = 30.83; p = .000</td>
<td>.433</td>
<td>FIS-P: -.667</td>
</tr>
<tr>
<td>Vitality</td>
<td>F = 49.89; p = .000</td>
<td>.556</td>
<td>FIS-P: -.615</td>
</tr>
<tr>
<td>Social functioning</td>
<td>F = 56.63; p = .000</td>
<td>.585</td>
<td>age: .204</td>
</tr>
<tr>
<td>Role—emotional</td>
<td>F = 27.49; p = .002</td>
<td>.251</td>
<td>FIS-S: -.510</td>
</tr>
<tr>
<td>Mental health</td>
<td>F = 47.27; p = .000</td>
<td>.372</td>
<td>FIS-S: -.617</td>
</tr>
<tr>
<td>Physical component summary</td>
<td>F = 5.96; p = .000</td>
<td>.493</td>
<td>FIS-P: -.707</td>
</tr>
<tr>
<td>Mental component summary</td>
<td>F = 56.04; p = .000</td>
<td>.417</td>
<td>FIS-S: -.651</td>
</tr>
</tbody>
</table>

*Total symptoms did not predict any aspect of QOL.
studies found frequencies of fatigue at 68%, 76%, 81%, and 85%, respectively.

The mean score for the total FIS in the current study was 67.44, similar to the 59.6 found in a clinic sample of 116 people with PBC (based on 1.49 average scale score, which we converted into 59.6 when computed for all 40 items; Huet et al., 2000). Another comparison of the FIS is based on the median, which was 66.5 for this study, midway between the FIS reports of 2 other studies, one that used the FIS with a community-based sample of 136 people with PBC in northern England and reported a median score of 40 (Goldblatt et al., 2002) and another with a sample of 58 people with PBC recruited through a hospital clinic and a PBC organization, reporting a median of 78.0 (Prince et al., 2000). Thus, the current sample has similar proportion of participants with the fatigue symptom as other studies that reported on this condition, and mean and median FIS scores similar to or within the range reported by other studies.

A second limitation is the small size of the current sample. It is possible that a larger population is needed to ascertain additional relationships that were not apparent here. For research involving a rare disease such as PBC, however, this sample of 81 is larger than that used in many other studies and has been adequate to support these analyses in all instances. Third, this study did not consider other factors that also may be relevant to QOL. For instance, medication side effects, depression, and other comorbidities may confound both fatigue and QOL, but were not examined in this study. Also, socioeconomic status and health insurance may be important factors to examine, especially if they impact eligibility for transplant.

Three implications follow from findings of fatigue as a strong predictor of QOL in women with PBC. First, physicians may consider adding a precise and valid measure of fatigue as part of their pretransplant evaluations. This would support long-term evaluation and management. The FIS has several advantages compared with usual evaluation methods: 1) Fatigue is a nearly universal symptom of PBC, so that the FIS instrument would be a specific test for many patients; 2) The FIS score is independent of what can be determined by liver function tests and, thus, provides a multiple measure for evaluation; 3) Use of the FIS does not require acute life-threatening symptoms such as ascites or encephalopathy before instruments are sufficiently sensitive to observe the event; and 4) the FIS is a self-administered, brief paper-and-pencil instrument that can be readily completed during the office visit. As such, the FIS is low cost and potentially high benefit.

Second, the health care team can intervene to treat the ongoing fatigue. The team may refer persons with PBC to occupational and physical therapists who can teach them healthier ways to adapt to fatigue-induced limitations. Rather than withdrawal from events involving physical efforts, occupational therapists may assist persons with PBC to find alternative ways to carry out at least some activities of daily living. Similarly, referrals to physical therapists may provide training to remediate the loss of muscle strength that often accompanies PBC and the adaptations to living with PBC.

Longitudinal studies with regular assessments of fatigue and QOL in people with PBC are needed to identify better the course of this disease and its disabling effects. For instance, a recent follow-up study by Jones et al. (2006) of 136 people with PBC who were assessed in 2000 identified 28 who had subsequently died, and revealed that those with higher levels of fatigue in 2000 were more likely to die in the subsequent years.

Until recent years, fatigue was an acceptable criterion for transplantation for PBC in the United States, and it remains so in some other countries. Longitudinal study with well-validated instruments would allow evidence-based decision making when allocation committees review policies and procedures. The role of fatigue in other autoimmune disorders and chronic ailments, particularly those targeting women, also should receive much greater attention.

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