ORIGINAL RESEARCH

Impact of Invalidation and Trust in Physicians on Health Outcomes in Fibromyalgia Patients

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ABSTRACT

Introduction: Patients with fibromyalgia have reported experiencing discouragement, rejection, suspicion, and stigma during their encounters with health care professionals. The impact of these experiences on health outcomes has not been extensively examined. The aim of this study was to assess fibromyalgia patients' self-reported quality of life (QoL) and pain based on the following: perceptions of physician attitudes, trust in physicians, perceptions of medical professionals, type of treatment, and various demographic variables.

Method: An online survey was advertised in the electronic newsletter of the National Fibromyalgia and Chronic Pain Association and data were collected in February 2013. A new scale was developed to measure patient perceptions of physician attitudes. Patients' trust in physicians, patients' perceptions of medical professionals, and QoL were measured using the following standardized scales: Trust in Physician Scale, Illness Invalidation Inventory (3*I), and Quality of Life Scale-16 (QOLS-16).

Results: The survey resulted in 670 usable responses. The Patient Perceptions of Physician Attitudes Scale showed high internal consistency and convergent validity (Cronbach α = 0.91). Factor analysis of the Trust in Physician scale, 3*I, and QOLS-16 showed a 1-dimensional structure. Invalidation, use of complementary and alternative medicine, income, age, and marital status were significant predictors of QoL (*P* < .001). Trust in physician, income, education, and number of referrals to health care providers were significant predictors of pain (*P* < .001).

Conclusions: Invalidation, trust in physician, and use of complementary medicine can have significant impact on QoL and pain in fibromyalgia. Further research in more representative fibromyalgia samples may help confirm findings.

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ibromyalgia is a chronic pain disorder characterized by the combination of several symptoms. In addition to physical symptoms of pain, fatigue, sleep disturbance, and muscle stiffness, psychological symptoms such as anxiety, depression, and impaired cognition are commonly reported among patients with fibromyalgia.¹ The diagnosis, management, and treatment of fibromyalgia is a challenge for both health care professionals and patients mainly due to an unknown etiology, symptom heterogeneity, symptom overlap, and a lack of objective diagnostic techniques. Very often, there is nonuniformity in symptom experience among patients. Literature has classified fibromyalgia patients into different groups based on the nature and severity of their symptom experience. For example, de Souza et al² classified fibromyalgia patients into 2 subgroups on the basis of presence of psychological distress. Loevinger et al³ classified them into 4 subgroups on the basis of the following: experience of trauma in childhood (eg, physical or sexual abuse), variations of certain physiologic characteristics (eg, cortisol), psychological profiles (eg, depression and anxiety), and severity of pain, fatigue, and disability. Furthermore, diagnosis is complicated by symptom overlap with other disorders such as rheumatoid arthritis, osteoarthritis, systemic lupus erythematosus, psoriatic arthritis, and irritable bowel syndrome.⁴ Another problem with fibromyalgia diagnosis is the invisible nature of its symptoms. The normal appearance of patients without any physically noticeable symptoms has resulted in physicians reporting disbelief in patients' symptom experience.^{5,6} Due to the above-mentioned issues, fibromyalgia is mainly diagnosed by eliminating the possibility of other disorders.⁷ In 1990, the widespread pain and tender point criteria were introduced for the diagnosis of fibromyalgia; however, they were not reported to be very successful.⁸ Patients who did not meet these criteria were also found to have fibromyalgia.9 Some physicians have also reported a lack of confidence in the fibromyalgia diagnostic criteria.¹⁰ Because of these issues, patients have reported invalidation of their symptom experiences from physicians.^{10–13} A model of chronic nonmalignant pain developed by Howell¹⁴ suggested that constant invalidation may serve as a barrier in effective management of pain and its associated symptoms. Constant invalidation from medical professionals may interfere with the shared decision-making process regarding treatments.

To our knowledge, no studies have evaluated the impact of these experiences on the health outcomes of fibromyalgia patients. Therefore, the goal of this study was to analyze the impact of invalidation of fibromyalgia from health care professionals on outcomes associated with the disorder. Though symptoms experienced by fibromyalgia patients may vary, pain is a prominent symptom commonly experienced by most patients.^{1–3} Additionally, quality of life (QoL) in fibromyalgia patients has been reported to be very low compared with most other disorders.¹⁵ Therefore, this study evaluated 2 outcomes: pain and QoL.

- Clinician validation of the fibromyalgia patient's experience of the disease increases the patient's overall quality of life; conversely, invalidation of the patient's experience negatively impacts the patient's overall sense of well-being.
- Development of a therapeutic relationship involving empathy and thoroughness in treatment increases trust in physicians and is related to lower self-reported levels of pain in fibromyalgia patients.
- Since use of complementary and alternative medicine is common in patients with fibromyalgia and is associated with increased patient quality of life, clinicians should assess for such use and possible adverse interactions with prescribed treatments.

METHOD

A web-based, self-selected survey methodology was utilized. Since the study required participation of human subjects, the study protocol was approved by the Institutional Review Board at Duquesne University, Pittsburgh, Pennsylvania.

Sample and Data Collection

The registered members of the National Fibromyalgia and Chronic Pain Association (NFMCPA) were invited to participate in the survey. The study team could not obtain a list of e-mail addresses of the members of NFMCPA. Hence, a nonprobability-based method was used by advertising a hyperlink to the survey in the February 2013 edition of the electronic newsletter of the NFMCPA. The link was active for a period of approximately 3 weeks from February 5, 2013, to February 26, 2013, after which the link was deactivated. The survey was conducted via Qualtrics (http://www.qualtrics. com/).

Survey Instrument and Procedure

The survey instrument consisted of 4 sections.

Initial consent and screening (inclusion criteria). Only adults (\geq 18 years) who provided consent and indicated (self-report) that they had received a diagnosis of fibromyalgia from a health care professional were allowed to proceed through the survey.

Patient opinion of physicians. In this section, respondents were provided with 3 questionnaires.

 Patient Perceptions of Physician Attitudes Scale: No previously validated instrument was available to measure physician-patient interaction in fibromyalgia. For the purpose of this study, the Patient Perceptions of Physician Attitudes Scale was developed from a comprehensive review of literature. The aim of this scale was to quantify the support that patients received from their physicians. This scale had 9 items measured on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree).

- 2. Trust in Physician Scale: This is a validated 11-item instrument with responses measured on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree).^{16,17} An unweighted mean of the responses to the 11 items is transformed on a 0–100 scale, with a higher score indicating higher trust in physicians.^{16,17}
- 3. Illness Invalidation Inventory (3*I): The 3*1 consists of 8 items measured on a 5-point Likert scale ranging from 1 (never) to 5 (very often). An unweighted mean of 5 items in the scale measures discounting (experiences of distrust, admonition, rejection of one's ability to work, poor acknowledgment of fluctuations in symptoms, and offer of unusable advice), and an unweighted mean of the remaining 3 items measures lack of understanding.¹⁸ The final discounting and lack of understanding score ranges from 1 to 5, with higher scores reflecting higher experiences of discounting or lack of understanding. This scale measures discounting and lack of understanding with respect to spouse/partner, family, medical professionals, workplace, and people in social services.¹⁸ The medical professionals section of the 3*I was utilized to attain the objectives in this study. The 3*I was validated previously in fibromyalgia patients.¹⁸

Health outcomes. This section measured 2 health outcomes related to fibromyalgia—QoL and pain.

- 1. Quality of Life Scale-16 (QOLS-16): For measuring QoL, respondents were provided with a generic 16-item scale that was previously validated in fibromyalgia patients.^{19,20} The scale measures satisfaction of respondents on 6 domains: material and physical well-being; relationships with other people; social, community, and civic activities; personal development and fulfillment; recreation; and independence.¹⁹ The composite score of the responses to the 16 items (range, 16–112) represents the QoL of respondents, with higher scores reflecting better QoL.
- 2. Visual analog scale for pain: An 11-point, continuous, visual analog scale ranging from 0 (no pain) to 10 (worst pain) was utilized, and respondents were asked to rate their pain levels at the time of answering the survey.

Demographic and miscellaneous questions. This section asked information specific to demography and other questions such as use of prescription or over-the-counter medications, use of nonpharmacologic or complementary and alternative medicine, time since diagnosis, and number of referrals to health care providers.

Content and face validity of the survey were assessed by researchers and a clinician with expertise in fibromyalgia,

health outcomes, and survey methods. The survey was pilot tested, and only minor wording changes were made before the final survey was deployed. The final survey had 75 items.

Data Analysis

Data were imported into IBMSPSS, version 20.0 (IBM Corporation, Armonk, New York). Descriptive statistics, factor analysis, and multiple regression analysis were performed. All analyses were conducted at a significance level of P < .05.

RESULTS

Sample Description

Over a period of 3 weeks, 950 respondents clicked on the survey link, but the usable sample size for the final analysis was 670. A majority of the survey respondents were women (97%), white (93%), and married (66%) and had at least a college degree (56%). The mean \pm SD age of the survey sample was 54.08 ± 10.99 years. With regard to income, nearly 62% of respondents had an annual income \leq \$50,000. Seventeen percent of the respondents were from the Northeast, 22% from the Midwest, 33% from the South, and 21% from the West. In addition, 7% of the respondents indicated that they lived outside of the United States and were from Argentina, Australia, Canada, Chile, Germany, Great Britain, Italy, New Zealand, Puerto Rico, or South Africa.

Nearly 99% of respondents indicated that they had been diagnosed by a health care professional. The mean \pm SD score on the Trust in Physician Scale was 65.56 ± 20.08 , while the QOLS-16 score was 66.98 ± 18.23 . The QOLS-16 score of this sample was consistent with that reported in previous literature for QoL of patients with fibromyalgia.¹⁹ The mean time since diagnosis was nearly 13 years. The mean ± SD scores for discounting and lack of understanding from medical professionals were 2.64 ± 1.00 and 2.45 ± 0.96 , respectively. According to the score classifications of the 3*I, the respondents in this sample "sometimes" experienced discounting and "never/rarely" experienced lack of understanding from medical professionals.¹⁸ Discounting and lack of understanding were very highly correlated (r = 0.80, P < .001). Nearly 91% of respondents used prescription or over-the-counter medications, and 66% used complementary and alternative medicine to treat their symptoms of fibromyalgia. Table 1 provides the sociodemographic characteristics of the survey sample.

Factor Analysis

An exploratory factor analysis (varimax rotation) of the Patient Perceptions of Physician Attitudes Scale showed a 1-factor structure and was named *perceived physician support* (Table 2). Due to the presence of only 1 factor, a composite score was calculated by summing the individual item scores, with a higher score indicating higher perceived physician support. The mean \pm SD score of the Patient Perceptions of Physician Attitudes Scale for this study sample was 34.81 \pm 7.49, indicating that on a scale of 9 to 45, the patients experienced relatively higher support from physicians (Table 1). The Cronbach α coefficient for this scale was very high (0.91), indicating high reliability. This scale was found to have high correlations with the previously validated Trust in Physician Scale (r=0.85, P<.001).

All of the standardized scales used in this study were tested for factor structure by conducting exploratory factor analysis. The 3*I was previously shown to consist of 2 factors, namely discounting and lack of understanding.¹⁸ These 2 factors were found to be highly correlated in this study. Therefore, an exploratory factor analysis with oblique rotation was performed. The scale was found to consist of 1 factor (Table 3), which explained 67% of the variance in the data. This observation was also supported by the scree plot (Figure 1). This factor was termed invalidation and was calculated as the unweighted mean of the responses to the 8 items, with scores ranging from 1 to 5 and higher scores indicating higher invalidation from medical professionals. The internal consistency of this scale was found to be very high (Cronbach $\alpha = 0.93$). The other standardized scales, Trust in Physician Scale and QOLS-16, were also factor analyzed and consisted of 1-dimensional factor structures. The Cronbach a for the Trust in Physician Scale and QOLS-16 were found to be 0.91 and 0.92, respectively.

Regression Analysis

The next objective was to identify the impact of invalidation and trust in physicians on QoL and pain by conducting multiple regression analyses. Due to the exploratory nature of the study, stepwise regressions were performed. The predictors for these analyses were mean scores of perceived physician support, the Trust in Physician Scale, and invalidation; use of prescription or over-thecounter medications; use of complementary and alternative medicine; years since diagnosis; number of referrals to health care providers; and demographic variables of age, marital status, education, and income. Prior to conducting regression analysis, bivariate correlations were assessed. Due to higher correlation between the scores of perceived physician support and trust in physician, the variable perceived physician support was eliminated from the analyses to avoid issues with multicollinearity. After controlling for age, marital status, and income, invalidation and use of complementary and alternative medicine were found to have a significant impact on QoL ($R^2 = 0.22$; $F_{5.577} = 32.98$; P<.001; Table 4). Similarly, trust in physician, number of referrals to health care providers, income, and education were found to be significantly associated with pain ($R^2 = 0.136$; $F_{4,519}$ = 20.46; *P* < .001; Table 5). After adjusting for income and education, higher trust in physician and fewer referrals to health care providers were found to be associated with lower pain.

DISCUSSION

The main finding in this study suggested that physician attitudes of distrust; suspicion; lack of support for and acknowledgment of fibromyalgia, collectively termed

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647 (96.6)
20 (3.0)
620 (92.5)
13 (1.9)
16 (2.4)
18 (2.69)
49 (7.3)
440 (65.7)
146 (21.8)
34 (5.1)
6 (0.9)
77 (11.5)
207 (31.1)
375 (56.0)
~ /
239 (35.7)
173 (25.8)
107 (16.0)
116 (17.3)
111 (16.6)
148 (22.1)
140 (20.9)
221(33.0)
48 (7.2)
34.81 ± 7.49
65.56 ± 20.08
2.64 ± 1.00
2.45 ± 0.96
66.98 ± 18.23
6.20 ± 2.27
12.79 ± 8.14
NA
36 (5.4)
278 (41.5)
176 (26.3)
71 (10.6)
34 (5.1)
71 (10.6)
608 (90.7)
441 (65.8)

invalidation; and use of complementary and alternative medicine were significantly associated with QoL. Fewer invalidating experiences and use of complementary and alternative medicine were associated with higher QoL. It was also demonstrated that higher trust in physician and fewer referrals to health care providers were significantly associated with less pain.

Since treatment of complex disorders such as fibromyalgia is a subject of debate, this study highlights the importance of considering psychological and psychosocial characteristics of patients.^{5,6,10} Due to the complexity of fibromyalgia symptoms, the process of diagnosis and treatment can be frustrating for both patients and physicians. The results of this study suggest that fibromyalgia patients could benefit from empathy, trust, and recognition of the disorder from physicians. Similarly, inclusion of complementary and alternative medicine treatments may be beneficial in improving the patient outcomes, namely QoL. The demographic characteristics of respondents closely matched those in previous studies that used both probability and nonprobability sampling techniques for conducting surveys in fibromyalgia patients.²¹⁻²³ The characteristics of fibromyalgia such as moderate pain and low QoL were in agreement with previous findings for this population.^{19,21} A new instrument, the Patient Perceptions of Physician Attitudes Scale, was developed to measure experiences of poor acknowledgment that fibromyalgia patients may receive from their physicians. A Cronbach α of 0.91 indicated that the scale had high internal consistency. In addition, it was also found that this scale correlated highly with the Trust in Physician Scale. Perceived physician trust and perceived physician support are closely related constructs. High correlations of the new scale with an existing, previously validated instrument

Table 2. Results of the Exploratory Factor Analysis of the Patient Perceptions of Physician Attitudes Scale Demonstrating the Loadings of Each Item in the Scale With the Factor of Perceived Physician Support

Item ^{a,b}	Mean	SD	h^{2c}	Loadings
My doctor is compassionate	4.02	1.01	0.79	0.89
My doctor understands my feelings on pain	3.84	1.10	0.80	0.89
My doctor admits if he does not know the answer	3.90	1.06	0.44	0.66
My doctor treats fibromyalgia as a real illness	4.17	0.99	0.70	0.84
My doctor takes my concerns seriously	4.06	1.02	0.79	0.89
My doctor tries to avoid me ^e	4.40	0.92	0.56	0.75
My doctor thinks my illness is mostly psychological ^e	4.08	1.04	0.57	0.74
I have experienced the frustration of my doctor while treating me ^e	3.15	1.29	0.21	0.45
I am satisfied with the treatment provided by my doctor	3.55	1.20	0.68	0.82

^aRespondents were asked to rate their agreement with the statements in the scale.

^bOn the 5-point Likert scale, response categories are as follows: 1 = strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, 5 = strongly agree.

*ch*² or communalities indicate the proportion of variance explained by each item in the factor. Values above 0.3 indicate that each item from the scale shares common variance with the other items. ^dLoadings represent correlation of each item with the factor.

^eReversely scored item.

Table 3. Results of the Exploratory Factor Analysis of the Illness Invalidation Inventory (medical professionals) Demonstrating the Loadings of Each Item in the Scale With the Factor of Invalidation

Item ^{a,b}	Mean	SD	h^{2c}	Loadings ^d
Medical professionals find it odd that I can do much more work on	2.70	1.11	0.54	0.73
some days than other days Medical professionals think that I should be tougher	2.57	1.19	0.70	0.84
Medical professionals give me unhelpful advice	2.76	1.13	0.64	0.80
Medical professionals make me feel like I am an exaggerator	2.66	1.24	0.82	0.90
Medical professionals think I can work more than I do	2.52	1.24	0.67	0.82
Medical professionals take me seriously ^e	2.27	0.99	0.73	0.86
Medical professionals understand the consequences of my health problems or illness ^e	2.58	1.09	0.65	0.81
Medical professionals give me a chance to talk about what is on my mind ^e	2.53	1.08	0.63	0.79

^aRespondents were asked to rate their frequency of experience with the statements provided.

^bOn the 5-point Likert scale, response categories are as follows: 1 = never, 2 = seldom, 3 = sometimes, 4 = often, 5 = very often.

^c h² or communalities indicate the proportion of variance explained by each item in the factor. Values above 0.3 indicate that each item from the scale shares common variance with the other items.
^dLoadings represent correlation of each item with the factor.

^eReversely scored item.

confirmed the convergent validity of this scale.²⁴ This new instrument was tested in an online population as opposed to a clinic population. These patients may have different levels of symptom severity.²⁵ We recommend further testing of the new scale in clinic patients to confirm psychometric properties.

The factor structure of all standardized scales utilized in this study was previously based on the responses of outpatient populations.^{17,18,20} The 3*I was previously tested on a European outpatient population with fibromyalgia and rheumatoid arthritis and demonstrated the presence of 2 factors, namely discounting and lack of understanding.¹⁸ To the best of the study team's knowledge, this was the first time the 3*I was tested in a US sample of fibromyalgia patients. The results of the exploratory factor analysis revealed 1 factor, which was named *invalidation* and was scored by taking the unweighted mean of all 8 items in the scale. Future studies should be conducted in clinical samples of fibromyalgia from the United States to confirm the factor structure and other psychometric properties.

This was the first study to quantify the relationship between measures of trust in physician, experiences of invalidation, and health outcomes in fibromyalgia patients. The symptoms of fibromyalgia are very diverse. The primary symptom of pain and the more general concept of QoL were chosen as the main outcomes to be studied. Other outcomes such as fatigue, sleep disturbance, or other psychological symptoms like depression or anxiety were not measured to avoid respondent burden. The study findings demonstrated that invalidation, use of complementary and alternative medicine, age, marital status, and income together had a significant impact on QoL. These findings were consistent with previous studies showing that invalidation may have a detrimental effect on health outcomes in fibromyalgia.^{11,12,26-28} The results indicated that trust in physician, number of referrals to health care providers, income, and education together were significantly associated with pain. After controlling for demographic factors and number of referrals to health care providers, the second regression model showed that higher trust in the physician reduced pain. This relationship could be attributed



Table 4. Results of the Ordinary Least Squares Regression Analyses Demonstrating Association Between Invalidation, Age, Use of Complementary and Alternative Medicine, Marital Status, and Income on Quality of Life of Respondents With Fibromyalgia^a

Regression Model								
				95% C	I for B			
				Lower	Upper			
Variables	Levels	B^b	β ^c	Bound	Bound	P Value		
Intercept	None	64.10		55.48	72.71	<.001		
Invalidation	None	-5.66	-0.31	-7.06	-4.27	<.001		
Age	None	0.19	0.12	0.07	0.302	<.05		
Use of complementary and alternative medicine	Yes No*	3.16	0.09	0.57	5.76	<.05		
Marital status	Married Single/divorced/separated/widowed*	3.64	0.1	0.88	6.39	<.05		
Income	> \$50,000 ≤ \$50,000*	7.33	0.21	4.69	9.96	<.001		
Model Characteristics								
n = 583	$R^2 = 0.22$	Adjusted $R^2 = 0.216$		Adjusted $R^2 = 0.216$		F=32.98		Significance level < .001

^aMultiple linear regression analysis stepwise method. Significance level = .05.

^bB = unstandardized regression coefficient.

 $^{c}\beta$ = standardized regression coefficient.

Symbol: * = reference category.

to a placebo effect of trust, wherein reduced pain is a result of the patients' belief that their physician was participating in improving their health. There was a direct association between pain and number of referrals to other physicians. The model showed that >10 referrals was associated with higher pain. Invalidation was found to be related to lower QoL, but was not shown to impact pain. Constant invalidation of symptoms from health care professionals could have an impact on selfdevelopment, relationships with others, and interaction with society, which are important aspects of QoL. This fact could explain the observed relationship between invalidation and QoL. More than 50% of the respondents in this study used complementary and alternative medicine treatments, which were reported as being effective in improving pain. Other variables such as comorbidities and insurance status were not included in this model, but should be incorporated in future studies.

A major limitation of this study is the use of a nonprobability sampling technique for recruiting respondents, which may have presented problems such as coverage Table 5. Results of the Ordinary Least Squares Regression Analyses Demonstrating Impact of Trust in Physician, Number of Referrals to Health Care Providers, Education, and Income on Pain Levels of Respondents With Fibromyalgia^a

Regression Model						
				95%		
				Lower	Upper	
Variables	Levels	B ^b	β ^c	Bound	Bound	P Value
Intercept	None	8.58		7.80	9.36	<.001
Trust in physician	None	-0.02	-0.15	-0.03	-0.01	<.001
No. of referrals to health care professional	>10 referrals ≤10 referrals*	0.86	0.18	0.47	1.26	<.001
Education	At least some college education ≤High school*	-1.28	-0.19	-1.82	-0.73	<.001
Income	> \$50,000 ≤ \$50,000*	-0.76	-0.17	-1.13	-0.39	<.001
Model Characteristics						
n = 524	$R^2 = 0.136$	Adjusted $R^2 = 0.129$		Adjusted $F = 20.46$ $R^2 = 0.129$		Significance level < .001
^a Multiple linear regression	analysis stepwise method. Significance	e level = .05.				

^bB = unstandardized regression coefficient.

^cβ = standardized regression coefficient.

Symbol: * = reference category.

error, nonresponse bias, and generalizability. Respondents with Internet access could participate in this survey, thus presenting coverage error. Nonresponse bias could not be calculated for this study, as 91% of survey respondents had completed the survey in the first week of posting. Furthermore, sending a follow-up survey was not feasible, as e-mail addresses of the respondents were not known. This made it impossible to identify and differentiate respondents who answered the survey when it was first activated from those who did not respond. The survey captured responses on the basis of interaction of patients with any type of health care professional. Therefore, it was not possible to contrast study results according to different categories of physicians treating fibromyalgia patients. The study data were selfreported. Invalidation was only measured with respect to patient interactions with physicians. Future research should attempt to explore relationships between health outcomes in fibromyalgia patients and invalidation from other sources such as spouse, family, and workplace.

CONCLUSION

Psychosocial factors such as recognition of fibromyalgia and trust in physicians are given little consideration in the literature. These factors may significantly impact health outcomes such as QoL and pain in fibromyalgia patients. The current study supports past research that validation of symptom experiences of fibromyalgia patients is important in improving health outcomes and important in the effective management of the disorder. Complementary and alternative medicine may be associated with increased QoL and reduced pain. Although generalizability is an issue, this study observed an association between invalidation and trust in physicians and health outcomes in fibromyalgia patients. Physicians and other health care professionals should give more consideration to these factors while treating fibromyalgia patients. Replication of similar studies in fibromyalgia samples may help confirm the study findings.

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Lobo et al

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