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A case-control study comparing the Dermatology Life Quality Index (DLQI) ratings of patients undergoing leprosy treatment, people cured of leprosy, and controls in Vietnam

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Summary

Background: Leprosy is a neuro-cutaneous disease caused by the pathogen *Mycobacterium leprae*. The Dermatology Life Quality Index (DLQI) has been used in studying the quality of life (QOL) of people with leprosy. However, the DLQI has not been used to evaluate the QOL of people cured of leprosy in Vietnam.

Objectives: To evaluate the QOL of people being treated for leprosy (Group A), people cured of leprosy (Group B), and controls (Group C), in Ho Chi Minh City, Vietnam and the surrounding province.

Methods: 102 (34 matched sets) adult participants were enrolled using a consecutive sampling technique. Groups B and C were matched to patients receiving leprosy treatment (Group A). Participants were interviewed, collating background characteristics, self-rated disability and stigma, and the validated Vietnamese DLQI.

Results: The sample's median age was 41; each group had 28 men and six women. For the DLQI, Groups A & B had significantly higher (lower QOL) scores than Group C for multiple subdomain scores, including symptoms & feelings (A vs C, $p = 0{\cdot}0004$; B vs C, $p = 0{\cdot}001$), work & school (A vs C, $p = 0{\cdot}003$; B vs C, $p = 0{\cdot}006$), and the total DLQI score (A vs C, $p = 0{\cdot}0009$; B vs C, $p = 0{\cdot}0025$).

Conclusion: The DLQI results shed greater light on the QOL disparity related to leprosy. Clinically, the mean total DLQI scores from both Groups A & B suggest that

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their skin condition has a 'small effect' on their life. The results highlight the fact that the burden of leprosy on QOL does not necessarily fully disappear once a person is cured of leprosy.

Introduction

Leprosy is an infectious disease caused by the bacterium *Mycobacterium leprae*.[1] Although, still thought of as a biblical disease, leprosy, which has affected the human race for well over two thousand years,[2,3] continues to have around 250,000 new cases detected per year worldwide.[4] Leprosy is characterised by skin and neurological involvement, which when left untreated can progress to cause significant physical disability.[5,6] Leprosy exerts a substantial impact on the psychological wellbeing of patients and is often associated with stigma.[6–9] In Vietnam, although great progress has been made, leprosy continues to be associated with 'deep-seated medical and social problems'.[10]

Assessing quality of life (QOL) using questionnaires gives quantifiable information regarding how patients with an experience of leprosy rate their daily lives. Although no validated QOL index is specific for leprosy, the Dermatology Life Quality Index (DLQI) has been used in previous studies on leprosy.[8,9,11–15] The DLQI asks 10 specific questions about the impact of dermatological disease on QOL, which are subdivided into the following sub-domains: symptoms & feelings, daily activities, leisure, work & school, prolonged relationships, and treatment.[16,17]

The primary aim was to assess and evaluate the QOL of people being treated for leprosy (Group A), people cured of leprosy (Group B), and controls (Group C), in Vietnam. There are currently no published studies that have investigated these groups of people in Vietnam.

Material and Methods

METHOD

One hundred and two (34 matched sets) adult participants were enrolled using a consecutive sampling technique from August 2012 – January 2013. Patients receiving treatment or having completing leprosy treatment within the previous 3 months (multi drug therapy (MDT)) (Group A), were enrolled from Ho Chi Minh City, Vietnam and the surrounding province of Đong Nai. People cured of leprosy (Group B) and controls (Group C) were matched to Group A patients by gender, age (within 4 years) and area. All patients undergoing leprosy treatment in the two areas were approached and enrolled into group A, if they consented. The hospital had the information on the patients cured of leprosy, since they are still under review by the hospital team. Those that matched group A participants on the basis of age, gender and area were approached at follow up, and enrolled into group B. Controls were selected from the family and friends of groups A and B on the basis of their age, gender and area.

Written, informed consent was obtained from all participants, and participants understood that taking part was entirely voluntary. All participants were interviewed by medical staff owing to the low levels of literacy present among many of the participants. The medical staff were trained to fill in the questionnaires and where possible were kept consistent throughout the study. The interviewer completed a proforma (available from the authors on request) that

collated background characteristics (such as age, gender, health rating, education level, marital and employment status), self-rated disability and stigma assessment. Notably for the ratings of health, responses were scaled on a 5-point balanced Likert scale (very poor, poor, neither poor nor good, good, very good). Similarly, satisfaction with present living conditions was scaled on a 5-point balanced Likert scale (from very satisfied, satisfied, neutral, dissatisfied, very dissatisfied). The proforma had been developed in English and translated by a native Vietnamese speaker, giving both the Vietnamese translation with the original English for each question. Finally, the validated Vietnamese (VN) DLQI instrument was used with permission.

Clinically, based on hospital records the patients' leprosy type was recorded via the WHO classification. These were paucibacillary (PB), clinically classified ≤ 5 skin lesions or multibacillary (MB), which has ≥ 6 skin lesions.[18] The data was then collated and entered into a spreadsheet ready for analysis. The DLQI total and sub-domain scores were transformed into fractions. According to the instructions for the DLQI, the questionnaires were excluded from the analysis if they were missing a certain amount of the content, this occurred three times (one in each group) for the DLQI.

MATERIALS

The Vietnamese DLQI was used directly from the copyright owner with permission. This has been validated and details on the validation method can be obtained from: http://sites.cardiff.ac.uk/dermatology/files/2014/07/DLQI-Vietnamese-TransInfo.pdf.

STATISTICAL ANALYSIS

The *p* values are reported as 2-talied, 0·05 was taken as the alpha level and 0·2 taken as the beta level (80% power). Owing to non-normality as tested with the Shapiro-Wilk test, the DLQI data was analysed with Kruskal–Wallis one-way analysis of variance test and the chi^2 test determined differences in categorical background variables. The Kruskal–Wallis test determined differences in continuous background variables. When significant results occurred with the Kruskal-Wallis test, the Wilcoxon signed-rank test was used as a post-test in order to determine the relationship between the Groups and the levels of significance; 95% confidence intervals for this data are presented. Cronbach's alpha was used to determine the internal consistency of the DLQI. Software R (version 2.15.2) was used for statistical analysis.

ELIGIBILITY

The general eligibility criteria were that patients were 18 or over and able to give informed consent. Group A consisted of patients with leprosy who were still on treatment or who had completed treatment in the last 3 months. Group B was made up of patients with a history of leprosy who had completed treatment more than 3 months ago. Group C, were the control group and were selected from the family and friends of groups A and B. Exclusion criteria for all groups were people with conditions that might affect capacity such as dementia and people with medical problems that could significantly affect QOL such as a stroke. Specifically, for Group C we excluded people who were full time carers on the basis that this would affect QOL and would be unlikely to represent the general population.

Details of ethics approval: The Director of the Ho Chi Minh City Health Department gave the study clearance. The ethics board of the Bệnh Viện Da Liễu, Ho Chi Minh City granted approval in August 2012. The hospital gave a token of appreciation after each interview was conducted.

Results

The background characteristics of the three groups are summarized in Table 1. The three groups were matched for age and gender but not education level for which a higher proportion of patients with tertiary education were in group C ($p = 0{\cdot}0002$). The median age (with range in brackets) of each group was 41 (21–61), 40·5 (22–61), and 42 (25–59) for Groups A, B and C respectively ($p = 0{\cdot}97$). Each group had six women and 28 men. There was no significant difference in the type of leprosy (MB or PB) between the two groups A and B ($p = 0{\cdot}12$). The differences in self-rated physical disability was statistically significant, with the proportions of each group with physical disability being 37·5% for A, 30% for B and 9% for Group C ($p = 0{\cdot}02$). There was no evidence of a significant difference between the three groups in the other background variables such as marital status ($p = 0{\cdot}14$), employment status ($p = 0{\cdot}59$), self-rated stigma assessment (p = 0·36) and the proportions of other medical conditions ($p = 0{\cdot}88$).

There were significant differences in health rating on a 5-point Likert scale (very poor, to very good) between the three groups ($p = 0{\cdot}0002$). A significantly smaller proportion of participants in Group A rated their health as very good to good (6%) as opposed to that of group B (24%) and C (35%). There was a strong trend towards significance with satisfaction with present living conditions and Group ($p = 0{\cdot}0507$), with a higher proportion of participants reporting as very satisfied or satisfied in groups B (56%) and C (68%) than that in A (35%) on the 5-point Likert scale.

The DLQI results are summarised in Tables 2 & 3. Of the six sub-domain scores of the DLQI, symptoms & feelings ($p = 0{\cdot}0015$), leisure ($p = 0{\cdot}04$) and work & school ($p = 0{\cdot}012$) were statistically significant. Further analysis using the Wilcoxon signed-rank tests as a post-test for the subdomains symptoms & feelings and work & school demonstrated that both A and B were significantly different from C (symptoms & feelings A vs C, $p = 0{\cdot}0004$, B vs C $p = 0{\cdot}001$; work & school A vs C, $p = 0{\cdot}003$, B vs C, $p = 0{\cdot}006$). For the leisure subdomain only group A versus group C was significant ($p = 0{\cdot}01$). For the total score on the DLQI, the difference between the three groups was significant ($p = 0{\cdot}0025$), further analysis again with Wilcoxon signed-rank tests showed that both A versus C ($p = 0{\cdot}0009$) and B versus C ($p = 0{\cdot}0025$) were significant. No scores were significantly different between groups A and B.

In terms of proportions of different scores in the DLQI, 6% of group A, 9% of group B and 0% of Group C participants scored $\geq 11/30$, this score denotes that there was 'very large effect on the patient's life' according to the clinically devised DLQI scoring method (see Table 3).[19] We can see that the majority of participants scored 0-1/30, with 64% in group A, 76% in group B and 91% in group C, meaning any skin disease that they might be experiencing is causing 'no effect at all on the patient's life'. Overall, there was no significant difference between all the proportions ($p = 0{\cdot}092$).

Cronbach's alpha was calculated for internal consistency, the DLQI's alpha was 0·78 which is a very respectable score considering the score needs to $>0{\cdot}7$ to be acceptable.

Table 1. A comparison of background characteristics between Groups A, B, & C

	Group A	Group B	Group C	
Domain	Frequency (%)	Frequency (%)	Frequency (%)	*p*-value
Gender				
Male	28 (82)	28 (82)	28 (82)	1·0
Female	6 (18)	6 (18)	6 (18)	
Education				
None	7 (21)	1 (3)	1 (3)	0·0002
Primary	9 (26)	13 (38)	4 (12)	
Secondary	10 (29)	13 (38)	6 (18)	
Tertiary	8 (24)	7 (21)	23 (68)	
Leprosy type				
MB	20 (59)	26 (76)	NA	0·12
PB	14 (41)	8 (24)	NA	
Marital status				
Divorced	0 (0)	1 (3)	0 (0)	0·14
Married	21 (62)	27 (79)	28 (82)	
Single/separated	12 (35)	5 (15)	6 (18)	
Widowed	1 (3)	1 (3)	0 (0)	
Employment status				
Employed	26 (76)	28 (82)	31 (91)	0·59
Retired	2 (6)	2 (6)	1 (3)	
Unemployed	6 (18)	4 (12)	2 (6)	
Student	0 (0)	0 (0)	0 (0)	
Physical disability				
No	20 (62·5)	21 (70)	31 (91)	0·02
Yes	12 (37·5)	9 (30)	3 (9)	
Missing (not analysed)	2	4	0	
Health				
Very good	0 (0)	1 (3)	0 (0)	0·0002
Good	2 (6)	7 (21)	12 (35)	
Neither poor nor good	19 (56)	23 (68)	20 (59)	
Poor	13 (38)	3 (9)	1 (3)	
Very poor	0 (0)	0 (0)	1 (3)	
Other medical conditions				
No	24 (71)	25 (76)	25 (76)	0·88
Yes	10 (29)	8 (24)	8 (24)	
Missing (not analysed)	0	1	1	
Satisfaction with present living conditions				
Very satisfied	0 (0)	3 (9)	1 (3)	0·0507
Satisfied	12 (35)	16 (47)	22 (65)	
Neutral	15 (44)	12 (35)	10 (29)	
Dissatisfied	7 (21)	3 (9)	1 (3)	
Very dissatisfied	0 (0)	0 (0)	0 (0)	
Perceived stigma				
No	33 (97)	30 (88)	32 (97)	0·36
Yes	1 (3)	4 (12)	1 (3)	
Missing (not analysed)	0	0	1	

Legend: The background variables data shown for each of the Groups A, B, & C. Analysis used the chi^2 test to determine if there was a significant difference in proportions. $p < 0{\cdot}05$ was taken as statistically significant.

Table 2. The DLQI subdomain scores and total scores between Groups A, B, & C

DLQI Domain	Group A		Group B		Group C		*p*-value	Post-comparisons for DLQI (Wilcoxon tests)
	Median (range, min 0 – max 1)	Mean	Median (range, min 0 – max 1)	Mean	Median (range, min 0 – max 1)	Mean		
33 DLQIs analysed per group, 1 per group not analysed due to lack of data								
Symptoms & feelings	0 (0–0·50)	0·14	0 (0–0·67)	0·14	0 (0–0·33)	0·02	**0·0015**	**A v B:** W = 567·0, $p = 0·75$ **A v C:** W = 756·0, $p =$ **0·0004** **B v C:** W = 725·0, $p =$ **0·001**
Daily activities	0 (0–0·50)	0·05	0 (0–0·50)	0·04	0 (0–0·17)	0·01	0·14	
Leisure	0 (0–0·83)	0·07	0 (0–0·50)	0·03	0 (0–0)	0	**0·04**	**A v B:** W = 593·5, $p = 0·29$ **A v C:** W = 643·5, $\boldsymbol{p = 0·01}$ **B v C:** W = 594·0, $p = 0·08$
Work & school	0 (0–1)	0·19	0 (0–1)	0·17	0 (0–0)	0	**0·012**	**A v B:** W = 559·5, $p = 0·79$ **A v C:** W = 676·5, $\boldsymbol{p = 0·003}$ **B v C:** W = 660·0, $\boldsymbol{p = 0·006}$
Prolonged relationships	0 (0–0·50)	0·03	0 (0–0·50)	0·03	0 (0–0·17)	0·01	0·52	
Treatment	0 (0–0·67)	0·04	0 (0–0·67)	0·04	0 (0–0·33)	0·01	0·53	
Total	0 (0–0·53)	0·08	0 (0–0·53)	0·07	0 (0–0·13)	0·01	**0·0025**	**A v B:** W = 576·5, p = 0·65 **A v C:** W = 747·5, $\boldsymbol{p = 0·0009}$ **B v C:** W = 726·0, $\boldsymbol{p = 0·0025}$

Legend: The fractionalised 6 DLQI subdomain scores and total score between Groups A, B, & C. The scores for the subdomains and total score were analysed using the Kruskal–Wallis one-way analysis of variance test since the data was nonparametric. The medians, means and *p*-values are presented. Wilcoxon signed-rank test was used as a post-test in order to determine the relationship between the Groups and the levels of significance. Although the medians for data presented in the table are 0, the Wilcoxon test compares the shift in distribution between each group, not the medians. $p < 0·05$ was taken as statistically significant.

Table 3. Stratification of the proportions of the different raw total DLQI scores between Groups A, B, & C. 33 DLQIs analysed per group, 1 per group not scored due to lack of data

	Group A	Group B	Group C		
Raw total Score	Frequency (%)	Frequency (%)	Frequency (%)	Meaning	Significance
0–1	21 (64)	25 (76)	30 (91)	'no effect at all on patient's life'	$chi^2 = 10{\cdot}68$,
2–5	6 (18)	4 (12)	3 (9)	'small effect on patient's life'	df = 6,
6–10	4 (12)	1 (3)	0 (0)	'moderate effect on patient's life'	p-value = 0·092
11–20	2 (6)	3 (9)	0 (0)	'very large effect on patient's life'	
21–30	0 (0)	0 (0)	0 (0)	'extremely large effect on patient's life'	

Legend: Stratification of the proportions of the different raw total DLQI scores between Groups A, B, & C using the clinically devised DLQI scoring method by Hongbo *et al*. (2005). The chi^2 test determined if there was a statistically significant difference in proportions. $p < 0{\cdot}05$ was taken as statistically significant.

Discussion

Our study highlights that people affected by leprosy tend to have acquired a lower education level, have worse self-rated health, and a higher chance of physical disability than controls (Table 1). These findings are supported by the literature.[9,13] There was a strong trend towards a significant difference regarding satisfaction with present living conditions between the groups. Factors that were not significant between the groups included martial status, employment, and perceived stigma (Table 1). Employment status is interesting since most of the participants in Group A (people with active leprosy or < 3 months since completing treatment) were in employment (76%) whilst being treated for leprosy. Furthermore, it appears that they maintain their employment following MDT treatment, with 82% of the participants in Group B (people > 3 months since completing treatment) continuing to work (Table 1). This is contrasted in a study from China by An *et al.,* where none of the 64 patients in the study who had leprosy were employed.[13] That said, in their study they only included people with the most severe form of leprosy, lepromatous leprosy. In another study from Brazil, which included people with all the forms of leprosy, the number in employment was 42·6% (95/223).[7] Although the sequelae of leprosy still give rise to social problems in Vietnam, it is very positive to note that for most people employment is continued – what that 'employment' constitutes is another question.[10]

Moving on, looking at stigma more specifically, we hypothesized that it was likely that people affected by leprosy might report higher levels of stigma than those that did not. The stigma associated with leprosy is widely known and interventions to reduce the stigma associated with leprosy have been reported.[20–23] However, in this study, participants in Group A reported the least stigma (3%) as did group C (3%). In Group B, 12% of participants perceived they were stigmatised ($p = 0{\cdot}36$). These results were much lower than anticipated for group A and B. Despite Group B participants reporting the highest perceived stigma, it was still a relatively small proportion. More generally, another reason for the relatively low prevalence of perceived stigma, is the translation of 'stigma' into Vietnamese for the interviews. This might have changed its meaning slightly since it translates to a word similar to 'discrimination'. Another possibility is response bias arising from being interviewed rather than completing the questionnaire individually.

In this study we measured QOL using the DLQI. The DLQI has been used in Brazil in mixed and also PB type leprosy populations as well as in people with lepromatous leprosy in China.[11–13,15] We believe we are the first to evaluate the QOL of patients being treated for leprosy alongside those who are cured of leprosy in Vietnam, with a matched control population. There was a significant difference in the DLQI total scores and subdomain scores of symptoms & feelings and work & school between Groups A & B in comparison to Group C at post-test (Table 2). Furthermore at post-testing, for Group A, there was a significant difference in the leisure subdomain score compared to Group C (Table 2).

However, the study did not demonstrate is any significant difference in DLQI total scores or the subdomains between those who are cured of leprosy (Group B) and those who still have the disease or have recently finished treatment (< 3 months) (Group A) (Table 2). This suggests that the burden of leprosy on QOL continues to be a problem even once the leprosy has been fully treated, which was not anticipated. This finding is echoed by another study, which highlighted that over a third of peopled who were cured of leprosy, still had restricted social participation following competition of multidrug therapy.[7]

While this study is particularly interesting and gives quantifiable evidence of the disparity of QOL with those with an experience of leprosy, it is not without its limitations. One might question the use of the DLQI in this research, since it may be considered that there would be a high prevalence of skin disease affecting QOL in group A because skin disease is a manifestation of leprosy; on the other hand, there would presumably be a lower prevalence in the general population (group C). However, it is important to remember that there is a high prevalence of skin disease in the general population.[24] In the UK it was estimated that 55% (95% CI, 49·6–61·3%) of the general population had a skin condition, however, the prevalence in Vietnam remains undetermined.[24] In this study we were identifying whether the skin disease affecting people with leprosy causes greater disruption to QOL than the possible skin diseases in the control group (the general population). Furthermore, it is interesting that there are similar DLQI scores in Groups A and B (no significant differences) since group B participants should have been treated for leprosy and therefore the burden of the skin disease, which would affect QOL. The means of the DLQI total score were 2·4/30 for Group A and 2·1/30 for Group B and 0·3/30 for Group C. This suggests that on average for groups A and B there is a 'small effect on patient's life' from their skin disease according to the clinically devised DLQI scoring method (Table 3).[19] For group C there is 'no effect at all on patient's life' from their skin disease, possibly since the vast majority do not have cutaneous problems (Table 3). Furthermore, the majority of cases in all groups (64% A, 76% B and 91% C) had DLQI total raw scores of 0-1/30 (the medians were 0) suggesting that in people in groups A and B, by and large they do not suffer any deficit in QOL from any skin disease that they might have (Table 3). These results are similar to Bottene *et al.* (2012), in which 63% of 49 patients with PB leprosy scored on the DLQI as 'no effect at all on patient's life'. As the authors allude to, the reason for this could be due to the early identification of these cases, which means their leprosy is being treated before the skin disease becomes a problem. On the same topic of the DLQI, we may also have a similar problem as reported in another study, since the DQLI's question nine asks about sex life.[13] This is a culturally sensitive question and because the participants were being interviewed, they may not have answered it reliably.[13]

More generally, for Group A, we recruited patients receiving treatment or patients who had completed treatment in the last 3 months. The reason for this was because there were not sufficient patients on active MDT from the regions we sampled. We extended the range of

Group A participants by allowing people who had completed their treatment in the last 3 months, to be eligible. This is a potential source of bias, since some patients in Group A have completed treatment for leprosy and thus may have a higher QOL. We were willing to accept this risk since if bias occurred we hypothesised it would tend to make our results more conservative.

To conclude, the results presented by this study highlight the problems faced by those affected by leprosy. Clinically, Groups A & B's mean total DLQI scores suggest that their skin condition has a 'small effect' on their life. Whilst further work evaluating the quality of life of people with leprosy is vital, in particular it is essential to look at those who are cured of leprosy. This is important since the burden of leprosy on QOL as measured by the DLQI does not appear to necessarily fully resolve once a person is cured of leprosy.

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