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The Myeloma Patient Outcome Scale is the first quality of life tool developed for clinical use and validated in patients with follicular lymphoma

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Abstract

Objectives: The development of novel agents and an ageing population has led to an increasing number of patients with follicular lymphoma (FL) living longer with their disease. Health-related quality of life (HRQOL) is a priority for patients and should guide clinical decisions. The Myeloma Patient Outcome Scale (MyPOS), originally developed for myeloma, was validated in a cross-sectional survey recruiting 124 FL patients.

Methods: Content and construct validity, structural validity using confirmatory factor analyses, reliability and acceptability were evaluated.

Results: Three subscales were indicated: symptoms and function, emotional response, and healthcare support. MyPOS symptom and function scores were higher (worse) in participants with poorer ECOG performance status ($F=26.2$, $P<.000$) and discriminated between patients on and off treatment. Good convergent and discriminant validity in comparison to the EORTC-QLQ-C30 and FACT-Lym were demonstrated. Internal consistency was good; α coefficient 0.70-0.95 for the total MyPOS score and subscales.

Conclusion: The MyPOS is valid, reliable and acceptable, and can be used to support clinical care of FL patients. This is the first measurement tool developed specially for use in clinical practice that has been validated for use in people with FL. Further longitudinal validation is now required to support its use in outcome measurement.

KEYWORDS
factor analysis, Follicular lymphoma, non-Hodgkin lymphoma, psychometrics, quality of life, questionnaire validation

1 | INTRODUCTION

In Europe 93 500 new cases of non-Hodgkin's lymphoma (NHL) were diagnosed in 2012, making it the 11th most common cancer. Today 250 000 people are living with NHL in Europe up to 5 years after being diagnosed.[1] Follicular lymphoma (FL) is the most common indolent form of NHL, accounting for 20% of all NHL in the USA and Western Europe.[2,3] FL is more common in women, median age at diagnosis is 65 years old and incidence increases with age.[2] As populations in Western Europe and the United States increasingly age, and advances in treatment continue to improve survival, healthcare systems face growing numbers of people with FL needing long-term care.

FL remains incurable despite considerable improvements in treatment options over the last four decades. The disease trajectory is characterised by patterns of remission and relapse and is without a defined optimal management strategy.[4] Active monitoring for patients with low disease burden is a common strategy but is associated with anxiety as patients anticipate inevitable progression of the disease.[5] Moreover,

because of the increase in survival, long-term effects of therapy accumulate, among them toxicity-related symptoms, persistent fatigue, depression and anxiety.[5-11] These long-term effects have been shown in a recent systematic review to impact all dimensions of health-related quality of life (HRQOL) even at more than 5 years post-diagnosis.[10]

Despite these long-term effects, research on HRQOL in NHL and FL patients is lacking. Only four studies so far have specifically focused on FL patients, documenting the effect of different modes of treatment on return to work and emotional well-being.[8,11-13] Two systematic reviews of HRQOL in NHL present overall results for this group of haematological cancer patients.[10,14] Both conclude that the paucity of evidence is caused in part by a lack of disease-specific HRQOL measures. Indeed, prior to 2013 no HRQOL measure was validated for use in NHL. The Functional Assessment of Cancer Therapy—Lymphoma (FACT-Lym)[15] is the only questionnaire available, however, its validation study does not identify the proportion of FL in the sample. A further NHL-specific module of the European Organisation for Research and the Treatment of Cancer (EORTC) is currently being developed.[16] Moreover, as HRQOL and other patient-reported outcome measures are increasingly used in the clinical care of oncology patients,[17-19] a different type of measure, suitable for routine clinical use, is needed. Measures developed for clinical use differ from HRQOL measures developed for use in research by a special focus on content and face validity, acceptability and interpretability.[20]

The Myeloma Patient Outcome Scale (MyPOS) is such a measure, designed using extensive patient interviews, it is brief and suitable for use in clinical practice for measuring myeloma-specific HRQOL.[21] Given the comparability of disease trajectories (ranging from relatively indolent forms of FL and myeloma-spectrum diseases to relapsed/refractory stages) and treatment-related side effects,[11,13,22,23] suitability of MyPOS for use in FL is plausible. The objectives of this study are to test the construct and structural validity, examine the content validity and acceptability, and evaluate the reliability of MyPOS in FL patients.

2 | METHODS

2.1 | Setting and population

Between June and August 2013, patients with FL and myeloma were recruited for a self-completion, cross-sectional survey from outpatient clinics and inpatient wards in 13 hospital trusts in England, including a mix of tertiary and district general hospitals (see Acknowledgements for list of collaborators). In this paper, we focus on validation results for the sample of FL patients. Full details about the methods are reported in the validation study with myeloma patients.[24]

Patients were included if they were 18 years or older, had a confirmed histological diagnosis of FL, were aware of their diagnosis, and could give written informed consent. Patients were excluded if they were too unwell, symptomatic or distressed to take part (as judged by the clinical team), had severe neutropenia, or were unable to understand written or spoken English.

Research Ethics Committee approval was granted by the South East London REC-3 (ref 10/H0808/133) and local approvals were obtained from each Research & Development department of all participating sites. All participants gave written consent to take part and participation was voluntary. Completed questionnaires were screened for clinically important issues and where necessary the participant's consent was sought to feed such issues back to the clinical team.

2.2 | Procedure

Consecutive (all available) patients seen on wards or in outpatient clinics at participating sites were screened by clinical teams for eligibility and if eligible offered the opportunity to participate in the survey by research staff. Participants were given the choice to complete the questionnaire at the point of recruitment or at a later date and to return the survey by post. Demographic and clinical data were extracted from medical records by research nurses at recruitment.

2.3 | Study measures

Questionnaire booklets contained MyPOS alongside two further measures for validation purposes; FACT-LYM and EORTC-QLQ-C30. The latter two measures were chosen for testing convergent and divergent construct validity. They represent the only lymphoma-specific HRQOL questionnaire and the EORTC's core cancer questionnaire, which has been validated in lymphoma.[25]

The MyPOS is a 30-item questionnaire, a myeloma-specific version of the Palliative Care Outcome Scale (http://pos-pal.org/). The questionnaire starts with an open question "*What are your main problems or concerns at the moment?*". This is followed by 27 structured items on a 5-point Likert scale. There is one further open question designed to pick up problems not covered in the structured items "*Please list any other symptoms not mentioned above, and tick one box to show how they have affected you over the past week*". The MyPOS was developed through qualitative investigation of the issues most important to the HRQOL of people with myeloma.[24] It was initially validated in a sample of 380 patients. Factor analysis confirmed three subscales; (i) symptoms and function (14 items covering physical symptoms and functional impairments); (ii) emotional response (eight items describing the emotional impact of the disease); and (iii) healthcare support (five items on information needs and satisfaction with healthcare).[24] The MyPOS is a valid and reliable tool for use in the routine clinical care of myeloma patients.[24] For validation, the total MyPOS score (formed by summing the scores of the 27 structured items), and subscale scores (formed by summing the item scores within each subscale) were used for analyses. Higher scores represent worse HRQOL.

The FACT-LYM includes the Functional Assessment of Cancer Therapy—General (FACT-G) and fifteen additional disease-specific items. Overall it contains 42 questions, each on a 5-point Likert scale, and can be combined into five well-being subscales: (i) physical (seven items); (ii) social/family (seven items); (iii) emotional (six items); (iv) functional (seven items); and (v) lymphoma-specific additional concerns (15 items, covering symptoms, patient concerns about symptoms, emotional problems and future care plans). The validity and reliability of the FACT-LYM was tested in patients with NHL, with preliminary tests

confirming its good internal consistency and a full validation study showing its validity and sensitivity to change.[26,27] For convergent and divergent validity testing, only the individual subscales of the FACT-LYM were used. Higher scores represent better functioning.

The EORTC-QLQ-C30 has 30 items on a 4-point scale, combined into five subscales (i) physical; (ii) role; (iii) cognitive; (iv) emotional; and (v) social functioning. In addition, two 7-point items form a global health status scale. All subscale scores were transformed to a 0-100 scale following the recommended method.[28] High scores on functional sub-scales and the global scale represent better functioning, whereas high scores on symptom scales represent a worse symptom burden and poor HRQOL. Its validation status in NHL is not well supported, the only psychometric study having been conducted in a Greek sample of 80 NHL patients.[25]

Clinical characteristics included date of diagnosis, the stage of disease at diagnosis,[29] current treatment phase ((i) active monitoring/observation; (ii) on active treatment; (iii) on maintenance treatment; (iv) progressive/palliative disease), number of lines of treatment (including the current treatment), and Eastern Cooperative Oncology Group performance status (ECOG PS).[30]

2.4 | Statistical analysis

The recruitment target was 111 participants, for detecting differences in MyPOS symptom and function subscale scores according to performance status, in a one-way ANOVA with small effects (0.03) and 80% power. Data was double-entered into an SPSS database. All analyses were completed in SPSS v 22.0,[31] and in AMOS v. 22.0.[32]

The following psychometric properties were tested:

1. Construct validity: structural validity (factor analysis). Confirmatory factor analysis (CFA) was used to test the retention of the three-factor model (symptom and function, emotional response, and healthcare support) previously established for MyPOS in patients with myeloma.[24] The question about sex (item 6 on the MyPOS) was excluded from analyses due to a large proportion of missing data. Item parcelling, using the median score across four items related to gastro-intestinal symptoms (diarrhoea, constipation, nausea and vomiting) was also used to increase the participant to item ratio, in line with the recommend 5:1 ratio.[33,34] Factorability of the matrix was tested using Bartlett's test of sphericity, seeking a large significant value indicating the MyPOS matrix was significantly different from a matrix with no correlations.[35] Given our small sample size, factorability was further confirmed in SPSS using the Kaiser-Meyer-Olkin Measure of Sampling Adequacy (MSA), applying Kaiser's criteria for 'good factor-analytic' of MSA≥0.80.[36] Initial CFA was carried out on the simplest uni-dimensional model, loading all items onto one factor. Different three-factor solutions were tested in contrast to this model. Three goodness-of-fit indices were used to compare models: Chi-square, Comparative Fit Index (CFI), and the Root mean square error of approximation (RMSEA). Because of the known limitation of the Chi-square χ^2 statistic with its sensitivity to sample size, the supplementary index; ratio of χ^2 to degrees of freedom (χ^2/df) was used. A ratio of <2 is considered to reflect good model fit.[37] The CFI ranges from 0 to 1 and compares the model against the null model; a value >0.95 is considered representative of good fit.[38] For the RMSEA, 0.08 represents a reasonable fit.[39] Factor loadings of items on predicted factors were considered acceptable when above 0.30.[40] Communalities (sum of the squared factor loadings) provide an estimation of the proportion of total variance explained for each item by the final model.

2. Construct validity, known group comparisons. It was hypothesised that: (i) MyPOS symptom and function subscale scores would be higher (representing worse QoL) in patients with poorer ECOG performance status; and; (ii) that the MyPOS symptom and function subscale scores would be higher in patients receiving active treatment compared to those on observation, maintenance or palliative treatment. To account for non-normally distributed data, parametric (ANOVA) and non-parametric (Kruksal Wallis) tests were run in parallel. Post hoc, pair-wise T-tests, with Bonferroni adjustment, were used to explore differences in means between each group.

3. Construct validity, convergent and divergent validity. A priori hypotheses about the nature of correlations between the MyPOS total score, MyPOS subscale scores and subscales from the EORTC-QLQ-C30 and FACT-LYM were specified, using Pearson product-moment correlation coefficients with missing data excluded pairwise. Strong and moderate correlations were predefined as >0.70 and >0.50, respectively. It was hypothesised that: (i) MyPOS total scores would have a strong to moderate negative correlation with the EORTC-QLQ-C30 Global Health Status scale; (ii) MyPOS symptoms and function subscale would have a strong to moderate negative correlation with the EORTC-QLQ-C30 Physical, Role, Cognitive and Social subscales, and the FACT-LYM Physical, Functional and Additional Social Well-being subscales; (iii) MyPOS emotional response subscale would have a strong to moderate negative correlation with the EORTC-QLQ-C30 Emotional subscale, and the FACT-LYM Emotional and Additional Well-Being subscales; and (iv) MyPOS healthcare support subscale would not correlate strongly with any of the EORTC-QLQ-C30 or FACT-LYM subscales as these measures do not contain items on satisfaction.

4. Content validity. Content analysis of the MyPOS open questions was used to assess comprehensiveness of the structured items.[41] Responses to the opening question "*What are your main problems or concerns at the moment?*", and to the second open question "*Please list any other symptoms not mentioned above, and tick one box to show how they have affected you over the past week*" were analysed to identify symptoms or problems not covered in the MyPOS structured items.

5. Acceptability and floor/ceiling effects. Acceptability was assessed by the proportion of missing data for each MyPOS item. Floor and ceiling effects were considered present if more than 15% achieved the lowest or highest score.[42]

6. Internal consistency. Cronbach's α was determined for MyPOS total scores and MyPOS subscales separately. A α coefficient in the

range 0.70-0.95 was considered desirable to indicate good internal consistency without redundancy of items.[41]

3 | RESULTS

148 patients with FL were screened by clinical teams, seven were ineligible, 12 declined to participate and five withdrew from the study. Sample characteristics are shown in Table 1, and reasons for non-participation in Fig. S1.

Median age was 66 years old (range: 27-94). Sixty-two percent of respondents were women. Most participants (75.8%) were married or partnered, White British (91.1%) ethnic origin, not working or retired (75.0%), and not educated beyond college level (79.8%). Forty-four percent were managed on active monitoring; 40.3% were receiving active or maintenance treatment; and 16.1% were palliative. Sixty-eight per cent had ECOG PS 0; 23.4% had ECOG PS 1; 5.6% ECOG PS 2; 3.2% ECOG PS 3; and no participant had ECOG PS 4. Median time from diagnosis was 34 months (IQ range: 25-84) at the time of questionnaire completion.

3.1 | Structural validity: Confirmatory factor analysis (CFA)

Bartlett's test of sphericity (χ^2=1525.0, P<.001) and the MSA (0.848) indicated good factorability. Results from the model fit statistics for the three models tested with CFA are presented in Table 2. An iterative improvement in model fit is indicated with each new model. The final model falls short of demonstrating good fit; χ^2/df=2.385, CFI=0.774 and RMSEA=0.109 (90% confidence interval: 0.097-0.121), despite item parcelling increasing the participant to item ratio from 4.5 to 5.1

All items load above 0.30 on the factors predicted (Table 3). 'Tingling in hands and/or feet' was close to the lower threshold, with a loading of 0.314, suggesting a weaker correlation between this item and other items on the subscale. Eigenvalue estimates report 54.9% of the total variance explained by the three factors.

3.2 | Construct validity

The first hypothesis of higher MyPOS symptom and function scores in participants with poorer ECOG performance status was confirmed (F=26.17, P<.000). The second hypothesis, poorer MyPOS symptom and function scores in those on active treatment versus those on maintenance, active monitoring and palliative treatment, was also confirmed (F=4.16, P=.008). Figure 1 displays results for the parametric tests for 120 participants who had complete data for the MyPOS symptom and function subscale. Results were confirmed in a sensitivity analysis using non-parametric tests.

Post-hoc, pair-wise comparisons of the subscale means confirmed significant differences between participants on (i) active treatment and maintenance treatment (P=.023); and (ii) active treatment and active monitoring (P=.010), but non-significant differences between; (iii) active treatment and progressive/palliative disease (P=.891).

TABLE 1 Sample characteristics for cross sectional survey (n=124)

Age, n, %	
<65	55 (44.4)
≥65	69 (55.6)
Median age, range	66 (27-94)
Gender, n, %	
Male	47 (37.9)
Female	77 (62.1)
Marital status, n, %	
Single, divorced or separated	16 (12.9)
Married or partnered	94 (75.8)
Widowed	14 (11.3)
Ethnicity, n, %	
White British	113 (91.1)
White other	8 (6.5)
Black	2 (1.6)
Other	1 (0.8)
Highest education level, n, %	
Primary school	5 (4.0)
Secondary school	54 (43.5)
College/technical qualification	40 (32.3)
University first degree	18 (14.5)
Not known	7 (5.6)
Occupation status, n, %	
Working or studying	31 (25.0)
Not working or retired	18 (14.5)
Retired	75 (60.5)
ECOG performance status, n, % (abbreviated descriptions)	
0 - Fully active without restriction	84 (67.7)
1 - Restricted in physically strenuous activity but ambulatory	29 (23.4)
2 - Ambulatory but unable to do work activities, Up>50% of waking hours	7 (5.6)
3 - Limited self-care, confined to bed/chair>50% of waking hours	4 (3.2)
4 - Disabled. Cannot carry on any self-care. Totally confined to bed/chair	0 (0)
Stage at diagnosis, n, %	
I Single lymph node group	17 (13.7)
II Multiple lymph node groups on same side of diaphragm	13 (10.5)
III Multiple lymph node groups on both sides of diaphragm	33 (26.6)
IV Multiple extranodal sites or lymph nodes and extranodal disease	42 (33.9)
Missing	19 (15.3)
Treatment status, n, %	
Active treatment	19 (15.3)
Maintenance treatment	31 (25.0)
	(Continues)

TABLE 1 (Continued)

Active monitoring	54 (43.5)
Palliative phase	20 (16.1)
Months since diagnosis, n, %	
0-12	29 (23.4)
13-24	18 (14.5)
25-36	19 (15.3)
37-48	6 (4.8)
>48	52 (41.9)
Median months since diagnosis, range	34 (1-328)
No. of lines of treatment including current, n, %	
0	15 (12.1)
1	48 (38.7)
2	37 (29.8)
3	14 (11.3)
More than 3	9 (7.3)
Missing	1 (0.8)

3.3 | Convergent and divergent validity

All, apart from one, of the hypotheses were confirmed within the predefined limits (for Pearson correlations see Table S2). MyPOS total scores correlated negatively with the EORTC-QLQ-C30 Global Health Status scale ($r=-.723$, $P<.01$); MyPOS Symptom & Function scores correlated negatively with EORTC-QLQ-C30 Physical function ($r=-.791$, $P<.01$), Role function ($r=-.838$, $P<.01$), Cognitive function ($r=-.584$, $P<.01$), and Social function ($r=-.634$, $P<.01$). MyPOS Emotional response scores correlated negatively with scores on FACT-LYM Emotional well-being ($r=-.762$, $P<.01$), Additional concerns ($r=-.729$, $P<.01$), and EORTC-QLQ-C30 Emotional function ($r=-.753$, $P<.01$). Scores on the MyPOS Healthcare support subscale showed no correlation with scores across the subscales from FACT-LYM and EORTC-QLQ-C30 QLQ-C30, apart from a correlation with the FACT-LYM Additional Concerns scores exceeding the 0.50 threshold ($r=-.518$, $P<.01$).

3.4 | Content validity

Eighty-eight (80%) participants recorded some free text about their main problems or concerns at the beginning of the MyPOS questionnaire. In total, 148 main problems or concerns were reported (Tables S4a-S4c), with 112 (76%) of these being covered by a subsequent MyPOS item. Of the 36 (24%) main problems and concerns not covered by a MyPOS item, only weight loss was reported multiple times, three separate participants citing it as a main problem or concern.

After grouping, the largest number of concerns (59 (40%)) were about participants worry for their disease or treatment, for example "*always wondering when the lymphoma will become active again*" and "*worried about having chemo again*", captured by MyPOS items 17, 18, 21, 22, and to some extent by items 26 and 27.

A total of 44 additional symptoms were recorded after the symptom list on the questionnaire (Table S5). The majority (35) were unique symptoms recorded only once. Four were about sweating, two of these specifically about night sweats, a further two about problems sleeping, and three referred to swelling in the legs, feet or ankles.

3.5 | Acceptability

Ten out of 27 MyPOS items had missing data; most (9) of these were missed by just one or two participants (see Table S1). By far the highest rate of missing data was observed for the question about sex; 13 (10.5%) respondents selected 'rather not say' on this item. The proportion of missing data overall was low, 0.7% (23 missing responses out of a possible 3348). Participants used the full range of responses (0-4) in 19 out of 27 items. For the questions about shortness of breath, vomiting, mouth problems, worry about infections, coping with illness, and the three items about healthcare support, participants used the lower four responses (0-3) only. Floor effects are evident for all 27 items; the proportion of answers in the lowest category ranged from 23.4% to 91.9%. Ceiling effects were not present for any item.

3.6 | Reliability

The MyPOS total and subscale scores showed good internal consistency within the 0.70-0.95 desired range (Table 3).

4 | DISCUSSION

Together with survival, improved HRQOL is a priority for haematological cancer patients.[8,13,43,44] Patient-reported monitoring of HRQOL

TABLE 2 Model fit index (n=118)

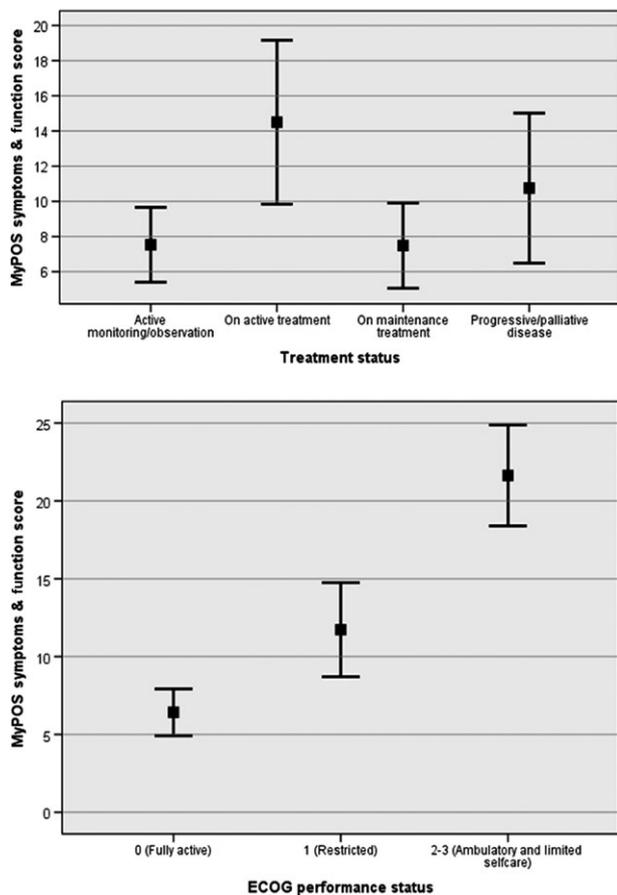|	One factor (no sex; n=118)	Three factor (no sex; n=118)	Three factor (no sex; gastro parcel; n=118)
No. of items	26	26	23
Chi-square	968.266	710.963	541.477
df	299	296	227
P-value	.000	.000	.000
Chi-square/*df*	3.238	2.402	2.385
Comparative fit index (CFI)	0.567	0.732	0.774
Root mean squared error of approximation (RMSEA) [90% CI]	0.138 [0.129-148]	0.109 [0.099-0.120]	0.109 [0.097-0.121]

FIGURE 1 Known group comparisons showing MyPOS symptoms and function subscale scores (mean and 95% CI) by treatment status and ECOG performance status (n=120)

facilitates clinician-patient communication about how patients perceive their physical and emotional symptoms, offering the optimal avenue to support patients and effect outcomes.[18,20] A recent randomised control trial of 766 patients with advanced solid tumours has confirmed the clinical benefits associated with patients self-reporting of symptoms during cancer care, including; 'fewer ED visits, fewer hospitalisations, longer duration of palliative chemotherapy and superior quality-adjusted survival'.[17]

The chronic nature of MM, indolent NHL, and other conditions including, chronic lymphocytic leukaemia (CLL) and chronic myeloid leukaemia (CML), expose patients to the risk of long-term and accumulated effects of toxicity and adverse psychological effects associated with the pattern of disease relapse and remittance.[10,23] Routine monitoring of HRQOL may be particularly beneficial in the care of these patients, helping to support palliation of symptoms and minimise the cumulative negative effects of treatment and disease on HRQOL.[14,23] Of critical importance to greater integration of HRQOL in the clinical care of haematological cancer patients is the availability of valid and reliable tools, sensitive to specific disease-related outcomes, yet brief, and acceptable to patients and clinicians.[15]

This is the first study to demonstrate the validity and reliability of a HRQOL measure for use in patients with FL as a distinct patient group. Although the MyPOS was originally developed for

use in patients with myeloma, similarities between the two diseases and a lack of FL-specific tools, led us to validate the MyPOS in FL. Fatigue, pain, constipation, peripheral neuropathy, dyspnoea, sleep problems, sexual dysfunction, reduced physical and social functioning, and financial problems are common across both patient groups.[11,13,23] The successful validation of MyPOS in FL supports further development and validation of the tool for use in other indolent NHL conditions and chronic haematological malignancies such as CLL and CML.

Sensitivity to the individualistic nature of QOL is supported in the MyPOS through the inclusion of open text questions. This provides an opportunity for clinicians to discover what matters most to patients, helping to support patient centred care.[20] Analysis of the free text recorded by patients established good content validity for MyPOS. Patient's 'main problems and concerns' were comprehensively covered. Worry about disease or treatment was prominent, reaffirming the importance of comprehensively capturing these issues in the MyPOS.[13,23] Weight-loss, problems sleeping, sweating and lower limb swelling are identified as potential areas for extending the symptom list, and should be explored in further qualitative interviews with FL patients.

Despite less than good overall model fit for the final model in the factor analysis, the individual item factor loadings, and the improvement in model fit from the unidimensional to the final model, suggest the three factor model established for MyPOS;[24] (i) symptoms and function; (ii) emotional response; (iii) healthcare support, holds for use in FL patients. Model fit, and lower loading of the item about tinging in hands and feet, which has relatively high prevalence in this sample, comparable to that of pain, warrant further exploration in a larger sample. The aligning of items on symptoms and function further supports the theoretical model underpinning the development of the MyPOS, namely the importance of capturing the indirect effect of physical problems on functioning and HRQOL.[21,24]

MyPOS performs well as a tool for differentiating between patient groups. In line with existing evidence, patients with lower performance status and those on active treatment had worse symptoms and function.[11,13] Total MyPOS and MyPOS subscale scores also behaved as expected against existing validated measures, the FACT-LYM and EORTC-QLQ-C30. Lack of correlation between the MyPOS healthcare support subscale further supports recognition of these factors as a separate domain within overall HRQOL.

Qualitative evidence supporting the development of MyPOS highlighted the importance patients place on issues pertaining to satisfaction with healthcare staff and information needs.[21] Two questions in the original FACT-G measures,[45] and four in the earlier myeloma-specific version of the EORTC; the MY24,[46] related to these issues have since been removed after observing that most patients respond positively. We have similarly observed floor effects for the five items on the MyPOS healthcare support subscale, however, given the importance of these issues in routine clinical care, these items are retained in the MyPOS and further strengthen its use as a clinical tool.

The three dimension model is further supported by the demonstration of good internal consistency with no suggestion of redundancy of items.[41]

TABLE 3 Confirmatory factor analysis (Model 3): standardised estimates for item factor loadings and communalities (n=118)

Cronbach's α	Symptoms & Function subscale .871	Emotional response subscale .867	Healthcare support subscale .749	Squared multiple correlations (Communalities)
Items (abbreviated wording used)				
01. Pain	.623			.388
02. Fatigue or lack of energy	.630			.398
03. Shortness of breath	.479			.229
04-07. Gastro Parcel	.510			.260
08. Mouth problems	.471			.222
09. Poor mobility	.737			.543
10. Tingling in hands or feet	.314			.098
11. Difficulty remembering	.557			.311
12. Usual activities	.846			.717
13. Hobbies and leisure	.847			.717
14. Quality time with friends	.702			.493
16. Feeling depressed		.760		.577
17. Anxious about illness		.818		.669
18. Worry about infections		.561		.314
19. Worry about appearance		.651		.424
20. Worry about finance		.534		.285
21. Worry illness get worse		.816		.666
22. Able to cope with illness		.769		.591
23. Advice if needed			.710	.504
24. Good knowledge & skill			.890	.792
25. Show care & respect			.826	.682
26. Info about illness			.564	.318
27. Info about future			.457	.208

4.1 | Methodological limitations

This study is limited by its cross-sectional design. Validity and reliability, including longitudinal and inter-rater reliability have been established for the generic Palliative Care Outcome Scale from which the MyPOS is derived,[47] and work is currently underway to evaluate the test-retest reliability and responsiveness of MyPOS in detecting clinically important differences in myeloma patients over time.[48] This longitudinal analysis will strengthen our understanding of how to most effectively use MyPOS to improve patient care. Nevertheless, further disease-specific longitudinal validation of MyPOS in FL patients is needed to support the clinical use of this tool in measuring patient outcomes.

We did not seek access to records to compare our sample to the demographic and clinical characteristics of the wider group of patients registered at participating sites. Consecutive recruitment was used to maximise representativeness, and age and gender distributions reflected those in the wider FL population in the UK.[2] However, performance status and length of illness in our sample suggest that the very sickest patients, perhaps because they were non-ambulatory and confined to their homes, were excluded from our sampling frame. This is reflected in the presence of floor effects in many items. Further investigation of the acceptability of the MyPOS in a less-well population of FL patients would be beneficial. Moreover, given the original purpose of this tool, for use with myeloma patients, further qualitative work involving in-depth cognitive interviews with FL patients to evaluate comprehensiveness of the MyPOS items in covering main symptoms and problems in this population is needed.

The MyPOS has previously been demonstrated to be brief, with myeloma patients taking on average (mean) 7 minutes 19 seconds to complete the measure. Information on time taken to complete the MyPOS was recorded by research nurses for only 6 FL patients in this sample and is therefore not reported, this is an omission and should be prioritised in future studies.

Finally, we acknowledge that the confirmatory factor analysis was limited by a small participant to item ratio. Of main concern is that the structural validity of the item concerning worry about sex life has not been established, and the overall fit of the model fell short of pre-defined thresholds for 'good fit', therefore further factor analysis with a larger sample is required.

5 | CONCLUSION

MyPOS, a measure originally developed for use with myeloma patients, is a brief, valid, reliable and acceptable tool for assessing the HRQOL of patients with FL in a clinical setting. Longitudinal validation is now needed to establish test-retest reliability and responsiveness of the measure to clinical changes over time, to further support the use of the MyPOS in the routine clinical care of FL patients. Furthermore, this work supports the case for validating the MyPOS in similar indolent NHL conditions and other chronic haematological malignancies including CLL and CML.

AUTHORS' CONTRIBUTION

IJH, SAS, SD and PME won funding for the project and contributed to the conception, design and conduct of the study, with IJH acting as senior researcher. TRO and CR contributed to the study design, collected the data and co-ordinated the study. CR and JMD planned and conducted the data analysis. JMD prepared the manuscript with all other authors providing comments and critical revisions. The final manuscript was approved by all authors prior to submission.

CONFLICT OF INTEREST

The authors have no competing interests.

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SUPPORTING INFORMATION

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