Utility of the short form (SF)-36 health related quality of life questionnaire as a measure of outcome among contraceptive users

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Abstract

Background: Health related quality of life tools have been utilized in assessing many medical conditions; however, there has been minimal use in reproductive health research locally.
Objectives: To evaluate the utility of the short form (SF)-36 health survey questionnaires among contraceptive users.
Methodology: This was a cross sectional study which formed part a longitudinal observation study conducted over a 6-month period at the Aga Khan University Hospital and the Family Health Options clinics in Nairobi, Kenya among users of depot medroxyprogesterone acetate for contraception. The main outcome measures were the eight scales within the SF 36 health profile. Kline's criterion of 0.4 was used to test for inter scale correlations while the internal consistency was measured by the Cronbach's alpha using the Nunnally's criterion of 0.7.
Results: The SF-36 questionnaire was administered to 107 consenting clients. The mean scores for the eight scale SF-36 questionnaire were: physical functioning 81.4 (SD 22.4), social functioning 77.3 (SD 19.4), role limitation attributed to physical problem 81.6 (SD 31.6), role functioning attributed to emotional problems 76.3 (SD 35.5), energy and fatigue 66.9 (SD 16.4), mental health 71.4 (SD 17.5), general health 74.1 (SD 14.5) and pain 79.7 (SD 22.1). The SF-36 questionnaire satisfied rigorous psychometric criteria for reliability and internal consistency for 6 of the 8 scales. The item scale correlation persistently exceeded 0.4 for all variables.
Conclusion: These results provide support for use of SF-36 and other medical outcome survey tools as potential measures of quality of life among contraceptive users in the local population.

Keywords: Health related quality of life, contraceptives, depot-medroxyprogesterone acetate, RAND SF-36

Introduction

Emphasis in contraceptive research has been on the burden of gynaecological and other related medical complications associated with the various methods, with little attention on their effect on the Quality of Life (QoL). However, the personal burden of illness cannot be described fully by measures of disease status alone. Psychosocial factors such as apprehension, functional impairment, difficulty in fulfilling personal and family responsibilities, financial burden and diminished cognition must also be encompassed (1). Some lifestyle choices such as contraception may have effects on daily life and life satisfaction besides providing the desired effects of fertility control. Information on QoL associated with the use of contraceptives is critical in comprehensive counseling prior to initiation of any method.

Health Related Quality of Life (HRQL) ranges from negatively valued aspects of life, including death to the more positively valued aspects such as role function and happiness (2). It is not only important in measuring the impact of chronic disease but also the effects of long term interventions and health related choices such as contraception (3). Many validated tools exist that could effectively assess QoL and changes over a period of time. The Medical Outcomes Survey (MOS) group has developed generic quality of life instruments that have been used in over 4,000 publications and have been translated into 50 languages (4). These tools have been subject to criterion and construct validity and have been found to be

reproducible. The tools have also been found to be reliable in assessing change in QoL over time in different study populations (4-8). Their utility has been mainly in other disciplines of medicine and aspects of healthcare with minimal use in contraceptive research. However, the existing information on the use of the short form-36 (SF-36) health survey in other study settings provide strong evidence of its clinical validity as a measure of a patient's perceived health (8).

We conducted a longitudinal observation study using the SF-36 to measure quality of life changes among users of Depot Medroxyprogesterone Acetate (DMPA) for contraception over a 6 month period. The findings of this study are reported elsewhere (9). Before adopting the SF-36 questionnaire, it was tested for validity and reliability in the local population. As much as the validity of this tool is well established very little QoL research has been undertaken locally using the instrument. Our main aim was therefore to establish whether the questionnaire could be used reliably and effectively in a local population.

Materials and methods

A cross sectional study was carried out at the Aga Khan University Hospital, Nairobi and the Family Health Options clinics at Nairobi West. The study was conducted for a period of 6 months starting from December 2008 to May 2009. This was part of a longitudinal study that sought to determine the quality of life changes among users of Depot Medroxyprogesterone Acetate (DMPA) for contraception (9). In this cross sectional study the aim was to establish whether SF-36 is a reliable tool that could be adopted locally for assessing the effects of contraceptives on quality of life. The SF-36 questionnaire is a generic quality of life tool that contains 36 questions covering mental and physical aspects of quality of life. The specific components assessed in this tool include; social functioning (2 items), physical functioning (10 items), role limitations-physical (4 items), role limitation-emotional (3 items), energy and fatigue (4 items), mental health (5 items), pain (2 items) and general health (5 items). Sample questionnaires are available for free downloading at http://www.rand.org/health/survey_tools (4).

Details on the recruitment of participants, sampling procedure, eligibility criteria and data management are reported elsewhere (9). However in summary, all women who opted for DMPA were approached by a family planning provider for recruitment into the study. Eligibility was ascertained and those who met the criteria and agreed to participate had a brief description of the study read to them and an informed consent obtained. The socio-demographic data were captured and a brief clinical history taken. The SF-36 was then introduced to the client for self administration. The questionnaires were to be completed within the clinic. Upon returning the questionnaire, it was checked for completeness and difficulties encountered during completion were ascertained. Assistance was provided as desired. The total time taken to fill the questionnaire was also recorded and any comments on the exercise recorded. Consecutive sampling technique was used. Estimates of sample size were derived from the SF-36 health survey manual by Ware (10). A sample size of 105 was estimated as sufficient for the study with a power of 80%, alpha value of 0.05 and an inter-temporal correlation between scores of 0.60.

To be eligible a participant had to be aged between 18 and 49 years, willing to give written consent and had to fulfil the WHO-Medical Eligibility Criteria for the DMPA. One was excluded if they had been using DMPA within the previous 12 months at the time of recruitment, or did not meet the WHO Medical Eligibility Criteria for DMPA. Women with any chronic illness including mental conditions, those with menstrual abnormalities or less than 6 month post partum were excluded. Upon collection, data were entered into the statistical software spreadsheet. Qualitative data were captured in a word processor and reported without alteration. Incomplete SF-36 forms were excluded from the final analysis. Scoring for the SF-36 was performed using the research and development corporation; USA [RAND]-36-item health survey technique (11). The participants were also asked to rank the ease of completion of the questionnaire on a Likert scale of 1 to 5 with 1 being very difficult , 2 difficult, 3 average, 4 easy and 5 very easy. The total time taken to complete the questionnaire was also recorded.

Data analysis was performed using the SPSS® software version 15 and STATA® version 10. A statistical test with a p value of < 0.05 was considered significant. Descriptive statistics were used with 95% confidence intervals (CI) where applicable. Kline's criterion of 0.4 was used to test for inter scale correlations while the internal consistency was measured by the Cronbach's alpha using the Nunnally's criterion of 0.7 (12, 13). Sub-analysis was done using multivariate logistic regression models to cater for probable confounders like age, level of education, marital status and prior contraceptive use.

Qualitative data were analyzed for content. Responses were categorized and quantified. Comments and quotes were cited in the manuscript as they appeared in the questionnaires. Institutional ethical and research committee approvals were sought prior to commencing the study.

Results

A total of 107 eligible women were recruited into the study.

Socio- demographic characteristics

The participants had a mean age of 30.7 years (SD 5.5). The average family size was 1.7 (SD 1.1), with the desired size being 2.7 children (SD 1.1). The mean age of first pregnancy was 22.4 years (SD 8.4); 10.3% of the respondents were nulliparous. The other socio-demographic characteristics are presented in Table 1.

Table 1: Socio-demographic characteristics

Characteristics	Frequency	Percentage	95% CI
Level of education	**(n=107)**		
Primary	3	2.8	0.0-6.0
Secondary	18	16.8	9.8-24.0
Tertiary*	49	45.8	36.2-55.4
University	37	34.6	25.4-43.7
Marital Status	**(n=107)**		
Single	7	6.5	1.8-11.3
Married	99	92.5	87.5-97.6
Widowed	1	0.9	0.0-2.8
Occupation	**(n=107)**		
Student	3	2.8	0.0-6.0
Formal employment	67	62.6	53.3-71.9
Informal sector	21	19.6	12.0-27.3
Unemployed	16	15.0	8.1-21.8

*Tertiary includes any education beyond secondary but excluding university education.

Contraceptive history

Majority of the participants (72%; 95% CI 47.2 to 62.2) were contraceptive naive. Table 2 presents the different methods the women had used 12 months prior to choosing DMPA.

Table 2: Prior contraceptive use

Contraceptive method	Frequency	Percentage	95%CI
None	56	72.0	47.2 – 62.2
Combined oral pills	17	15.9	8.8 – 22.9
Natural billing method	3	28.0	0.0 – 6.0
Progesterone only pills	11	10.3	10.4 – 16.1
IUCD*	7	6.5	1.8 - 11.3
Implants	4	3.7	0.0 – 7.4
Barrier	6	5.6	1.2 – 10.0
Other†	3	2.8	0.0 – 4.5
Total	**107**	**100**	

*IUCD: Intrauterine contraceptive device
†other included Chinese pills, traditional methods and herbs.

Reasons for choosing DMPA

The reasons for opting to use DMPA varied as shown in Table 3 with 72% (95% CI 65.3-80.6) choosing it for convenience {i.e. ease of administration, confidentiality and the 3 monthly intervals}

Table 3: Reasons for choosing DMPA

Reason	Frequency	Percent	95% CI
Convenience	77	72.0	63.3-80.6
Efficacy	4	3.7	0.0-7.4
Lack of preferred method	7	6.5	1.8-11.3
Medical advice	11	10.3	4.4-16.1
Peer advice	2	1.9	0.0-4.5
Trial of method	4	3.7	0.0-7.4
None	2	1.9	0.0-4.5
Total	**107**	**100**	

Reliability of the data collection tools

The reliability and internal consistency of the SF-36 are presented in Table 4.

Table 4: Internal consistency of RAND SF-36 and MOS health profile

RAND SF-36 scales	No of items	Cronbach's alpha	Mean(SD)	Item scale correlation
Physical functioning	10	0.89	82.63(25.00)	0.44
Social functioning	2	0.56	77.61(2.30)	0.39
Role limitation/physical	4	0.83	82.79(5.74)	0.55
Role limitation emotional	3	0.79	76.83(4.47)	0.55
Energy/fatigue	4	0.62	67.2(7.43)	0.29
Mental health	5	0.75	71.39(10.04)	0.38
Pain	2	0.73	79.05(3.29)	0.57
General health	5	0.85	73.95(14.72)	0.43
MOS-Sexuality scale				
Sexual functioning	4	0.87	70.31(5.04)	0.63

Completion of the SF-36 questionnaire

The average score for ease of completion of the SF-36 was 4.6 out of a scale with a maximum possible value of 5 (very easy). It took a participant an average of 7.4 minutes to complete the 40 items and other data that were sought on the questionnaire.

Below are some of the comments of the participants on the SF-36 questionnaire.

'...i found this a very unique way of evaluating the quality of my life…very simple yet am told informative....'

'..it did not take me long to complete the questionnaire and the questions were actually relevant to what I do and how I feel..'

'…Could we be evaluating our life more often with such tools after receiving treatment from you people…?'

'…I would like to know how the quality of my life changed even after this survey is over…'

'…very easy to complete, not time consuming as I had initially thought…'

Discussion

In this study the RAND SF-36 was found to be reliable with a Cronbach's alpha exceeding 0.7 in six of the eight components tested. The inter-item correlation was also consistently above the Kline's criteria of 0.4 (12,13). The tool was found easy to administer and complete by the study participants. This compares to findings from similar studies in various fields assessing the quality of life using this tool, where it has been reported by respondents to be easy to comprehend and complete (2,6). However, minimal use of this tool in our local population made it difficult to determine a comparison group even though the mean and standard deviations of the different SF-36 components derived from our cohort were comparable to the standards found among populations elsewhere (14,15).

The study was restricted to an urban population with a high level of education and presumably a higher socioeconomic status in a country where more than 80% of the reproductive health population is rural. One may therefore argue that the findings may not be representative of contraceptive users in the country. It would therefore be incorrect to apply these findings to the entire Kenyan population. However, the Kenya Demographic and Health Surveys (KDHS) 2009 showed that majority (53%) of the contraceptive users were married women in urban areas. Furthermore modern methods use was generally higher in urban (47%) than in rural areas and more than 60% of the contraceptive users had at least some secondary level of education (16). Similar characteristics could be said of our study population. These results could therefore remain relevant to the Kenyan modern contraceptive users.

DMPA was chosen because it is the most preferred contraceptive hence reflecting a larger proportion of contraceptive users. Restriction to one method ensured uniformity of the outcomes since different contraceptive users could have different characteristics. Despite these limitations, the results of this study demonstrate the simplicity with which health related quality of life tools such as the SF36 could be incorporated into contraceptive service evaluation and research. Caution may however need to be exercised while interpreting the results from such studies as it has been demonstrated that these tools sometimes produces different results from those of primary efficacy outcomes (17).

We recommend further testing and piloting of these tools in different populations of contraceptives users especially rural and if found desirable then the SF36 and any reliable health related quality of life assessment tools could be incorporated into family planning/contraceptive programming.

Conflict of interest

None

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