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FACTORS INFLUENCING PARTICIPATION RESEARCH IN UROGYNAECOLOGY: COMPARISON OF PATIENTS FROM THE USA AND UK

Hypothesis / aims of study

In order for clinical research to be successful, patients must be willing to take part. There is sparse literature on factors influencing participation in urogynaecology research, and most has focussed on participants' reasons for participating. It might be expected that patient demographics, including previous treatment, exposure to research, and symptom severity will have an influence. We have previously explored this issue by developing and validating a questionnaire (the bladder clinic questionnaire, BCQ), and surveying a cohort of patients attending gynaecology outpatient clinics in a large UK teaching hospital(1). Here we present data using the same instrument from a sample of women attending a clinic in the USA, and compare and contrast the findings.

Study design, materials and methods

The Bladder Clinic Questionnaire (BCQ) is in two parts. Part 1 addresses participation in surgical trials and provided four discrete research scenarios: a study of a standard operation vs new operation; two new operations; a standard operation versus drug treatment; a standard operation versus alternative medicine (eg acupuncture). Part 2 addresses drug trials and provided four similar scenarios: standard drug versus new drug; two new drugs; standard drug versus an operation; and a standard drug versus alternative medicine. A five point Likert scale response ("I definitely would"; "I probably would"; "I'm not sure": "I probably would not"; "I definitely would not") is included for each item, and responses are collapsed ("any yes"; "not sure"; "any no") for analysis, giving a BCQ score from 0 to 16. The BCQ and the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) were given to all women attending a urogynaecology clinic in a large US teaching hospital to obtain an initial sample of 200 responses. Relevant demographic details about the participants were collected. Institutional review board approval was obtained. Relationship between overall BCQ score, ICIQ-SF and demographic data were compared in univariate analyses or correlations as appropriate. Responses to each question were compared by Chi square and ICIQ score for each response to a given question was compared using Kruskall Wallis test. Findings for US women were also compared to the data obtained from a UK cohort of women(1) to identify differences and similarities. Data are presented as median [range], number (%). Differences in proportions are presented with 95% confidence intervals.

Results

200 questionnaires were returned, but only 156 (78%) included full demographic data for analysis. The median BCQ score was 10 [0-16], compared to 11 [0-16] for UK women (p=0.004), and median ICIQ score was 9 [0-20] compared to 9 [0-21] for UK women (ns)(1). There was no relationship between total BCQ score and any demographic variable tested.

Responses to individual questions differed from each other ($p<0.001$ typically), providing reassurance that the BCQ was recording good quality data. ICIQ score was higher in women willing to participate in two of the eight scenarios provided: new operation versus new operation (p=0.055), and standard tablets versus new tablets (p=0.016). This was in contrast to UK women, where ICIQ score was higher in women willing to participate in three scenarios(1): standard operation versus new operation (p=0.019); new operation versus new operation (p=0.018); comparing two new tablets (p=0.048). Willingness to participate was recorded by between 26.3% and 53.2% of women and was highest for a study comparing a standard drug to a new drug . Willingness was lowest for trials involving surgical comparisons (Table 1). Women from the USA were generally less enthusiastic in their responses than women from the UK, with willingness to participate being lower in over half the scenarios (Table 2). These differences were most pronounced in the scenarios involving surgical interventions, with differences between 15.3% and 28.9%.

Table 1. Willingness to participate for US women

Intervention	**Willing to participate (%)**	**Difference (%) [95%CI]**
Standard operation vs new operation	36.5	--
New operation vs new operation	28.2	8.3 [-2.1, 18.7]
Standard operation vs drug treatment	32.7	3.8 [-6.7, 14.4]
Standard operation vs alternative medicine	41.0	-4.5 [-15.3, 6.3]
Standard drug vs new drug	53.2	--
New drug vs new drug	41.0	12.2 [1.1,23.3]
Standard drug vs an operation	26.3	26.9 [16.1,37.8]
Standard drug vs alternative medicine	46.2	7.1[-4.0, 18.1]

Table 2. Comparison of willingness to participate between US and UK women

Intervention	*UK women*	*US women*	Difference (%) [95%CI]
Standard operation vs new operation	55.1	36.5	28.9 [8.2, 28.9]
New operation vs new operation	43.5	28.2	15.3 [5.2, 25.3]
Standard operation vs drug treatment	42.0	32.7	9.3 [-0.8, 19.4]
Standard operation vs alternative medicine	40.6	41.0	-0.4 [-10.7, 9.8]
Standard drug vs new drug	59.4	53.2	6.2 [-4.1, 16.5]
New drug vs new drug	49.3	41.0	8.2 [-2.1,18.6]
Standard drug vs an operation	50.7	26.3	24.4 [14.3, 34.6]
Standard drug vs alternative medicine	44.9	46.2	-1.2 [-11.6, 9.1]

Interpretation of results

The BCQ data demonstrate that for US women, willingness to participate in research was not influenced by demographic factors, but does depend on the type of research. Similar results were obtained from women in the UK, but there were differences in the types of surgery which US women were most willing to consider. Trials involving surgical comparisons appeared to be less acceptable. A higher ICIQ score was not a major influence for US women, being associated with greater willingness to participate in only two of the eight scenarios offered. Interestingly, a different pattern of responses was found for women in the UK, and UK women were generally more favourably disposed to participation in all study types.

Concluding message

The BCQ is a useful tool for assessing the views of women about willingness to participate in research, at least in theory. Our data have shown that trials of different intervention are regarded differently, with surgical interventions being unfavoured. Furthermore, there appear to be differences between women of different nationalities. These data reinforce the work of ourselves and others that specific, targeted pilot work is required to assess likely recruitment to trials which are in design and development.

References

1. Bakali E, Mayne CJ, Tincello DG. Factors influencing participation in urogynaecology research studies. Int Urogynaecol J 2009;20 Suppl 2:S143-4.

Specify source of funding or grant	**None**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**University of Chicago Institutional Review Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**