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Measuring outcomes of importance to women with stress urinary incontinence

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Abstract

Objective: To provide evidence on outcomes of importance to women who have stress urinary incontinence (SUI). The secondary aim was to identify additional outcomes that ought to be collected in future primary studies or in systematic reviews of the literature.

Design: Questionnaire survey of a cohort of women with SUI.

Setting: UK.

Sample: 188 women with SUI.

Methods: Areas of importance to women who suffer from SUI were assessed using a patient generated index (PGI). In addition to the PGI, the questionnaire included the King's Health Questionnaire (KHQ) and the EuroQol- 5D (EQ-5D).

Main Outcome Measures: PGI, EQ-5D, and the King's Health Questionnaire.

Results: In total, 38 different areas were reported by respondents on the PGI. PGI and EQ-5D scores were positively correlated and significant. Correlations between the seven domains of the KHQ and PGI were all negative but only two were statistically significant: personal relationships and severity measures.

Conclusion: The PGI succeeded in capturing a diverse range of outcomes of importance to women suffering with SUI. Given the limited correlation between the

KHQ domains and the PGI and, in addition, that the areas mentioned in the PGI were not found to map well to the EQ-5D, the PGI in this instance may be capturing concerns of women who suffer from SUI which are not captured by quality of life measures such as the EQ-5D.

Introduction

Stress urinary incontinence (SUI) is the most common type of incontinence, especially in middle aged-women. It is defined as involuntary leak or loss of urine caused by sneezing, exercising, lifting or physical activity (Abrams et al 2002). Studies investigating the prevalence of SUI in women are hampered by differing definitions of SUI, and social factors such as the limited recourse to health care due to embarrassment. Indeed, only 15% of women identified as suffering from SUI consult a health professional (Shaw et al, 2006; 2001), suggesting that those presenting for help represent the 'tip of the iceberg' of a common condition. Embarrassment associated with urinary incontinence may cause withdrawal from social situations and reduces quality of life (Hunskar and Vinsnes 1991). Many women with SUI show symptoms of depression and introverted behaviour, together with dysfunctional interpersonal relationships (Norton et al, 1988). Furthermore, SUI may lead to withdrawal from regular physical activities and thus impair women's general health (Nygaard et al 1990).

The aim of this survey was to provide evidence on outcomes of importance to women who have SUI. Much of the available literature focuses on clinical outcomes which as a result may have limited relevance to women with SUI. The purpose of this work was to prospectively survey women with SUI to provide information on outcomes of

importance to them; a secondary aim was to identify additional outcomes that ought to be collected in future primary studies or define relevant outcomes for systematic reviews of the literature.

Methods

In order to assess the areas of importance to women who suffer from SUI, a questionnaire was designed. A patient generated index (PGI) (Ruta et al, 1994) was employed to allow respondents to state and evaluate the areas of their life affected by SUI. In addition to the PGI, the questionnaire included the Kings Health Questionnaire (KHQ) (Kelleher et al, 1997), the EQ-5D and questions relating to socioeconomic and demographic information.

The Questionnaire

The PGI is an individualised patient-reported health instrument which allows the respondent to select, weight, and rate the importance of a particular health outcome (Martin et al, 2006). The PGI was designed with the aim of producing a valid measure of outcome that reflected areas of importance to patients' lives (Ruta et al 1994). The PGI involves the respondent deciding what factors are important to them. Examples of the types of factors that may be important are included to provide guidance. The aim of the PGI is therefore to capture the diverse range of concerns or priorities of respondents. Using the PGI, respondents can vary the weight they attach to these concerns or priorities, which provide researchers with an insight into the respondent's viewpoint. An overall score for the PGI for each respondent can then be

calculated by multiplying the rating for each health area by the proportion of points allocated to that particular area.

The PGI is completed in three stages: in the first stage respondents are asked to identify up to five areas of their life that are affected by their SUI. Respondents are given a list of outcomes to act as prompts to help them think about which areas of their life are affected by their condition. Respondents can then choose from these options or provide their own examples. In addition to the five boxes, there is a sixth box which enables respondents to rate all other areas of their life affected by their SUI. Possible examples of the factors to include on the PGI were drawn from three sources. The first of these was the King's Health Questionnaire, which was used to generate a list of outcomes under the broad headings of: Role limitations; Physical limitations; Social limitations; Personal relationships and Emotions. These outcomes were supplemented from Cochrane reviews of non-surgical treatments (Hay-Smith and Dumoulin 2006; Brazzelli et al 2007; Mariappan et al 2007; Bezerra et al 2007). Finally, a general literature search was also conducted although this did not provide further additions to the 17 different outcomes identified from the KHQ and the Cochrane reviews. These outcomes were then narrowed down to those considered most relevant by members of the project team.

In stage two of the PGI, respondents were asked to score each area listed in stage one of the PGI on a scale ranging from 0 to 6. The score given in stage two was intended to reflect how the individual was affected by their SUI in the past month. A score of 0 would signify that the effect on their life was as bad as it could possibly be and a score of 6 would correspond to an effect that was as good as it could possibly be.

Finally, in stage 3, respondents were asked to ‘spend’ 10 points to indicate the relative importance of each of the areas mentioned in stage one. Respondents were requested to spend more points on areas that were the most important to them.

As noted above, in addition to the PGI, the questionnaire also contained the Kings Health Questionnaire (KHQ) and the EQ-5D. The KHQ is a condition specific questionnaire which aims to assess the impact of urinary incontinence on an individual’s quality of life. It contains questions set in nine domains relating to: general health perception, incontinence impact, role limitations, physical limitations, social limitations, personal relationships, emotions, sleep and energy, and severity. With the exception of the final part of the questionnaire (severity measures) scores can be calculated for each domain (0 – 100). The higher the score the worse off an individual feels they are and the lower they perceive their quality of life to be.

The EQ-5D is a standardised instrument for use as a measure of health outcome. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status (<http://www.euroqol.org/>.) The EQ-5D has five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) that can be converted into a utility score.

Sample

The Bladder & Bowel Foundation (formerly InContact and the Continence Foundation) is a national charity that provides information and support to people with bladder and bowel problems, representing the interests of people with continence

problems with the aim of ensuring they have access to the latest information and services available (<http://www.bladderandbowelfoundation.org/>). In 2006 a survey conducted by InContact was completed by 755 people affected by bladder and bowel problems (Buckley, Wagg, Winder 2007). Of these, 188 women with SUI gave consent for future contact about relevant research and formed the sample for the current study. In July 2007 these women were sent questionnaires for the current study by InContact. Given that this is a self selected sample of women suffering from SUI and not a random sample of the population, it is not known how representative this sample is of the wider population.

Ethical issues

The 2006 survey in which the participants were originally identified was a service evaluation in which InContact surveyed people who had previously been in touch with the charity and as such no ethical approval was necessary. The 2006 survey materials contained an explicit assurance that confidentiality would be maintained and that identifiable data would not be passed on to third parties. Respondents were asked if they were willing to be contacted in the future for research purposes. For this study questionnaires were sent in July 2007 to 188 women with SUI who gave their consent for further contact relating to research. The questionnaires were returned directly to the charity and after screening only anonymous data were subsequently forwarded to the authors in accordance with the Medical Research Council's guidance on the use of personal information in medical research and the Data Protection Act 1998 (HMSO, 1998; Medical Research Council, 2000).

Results

In total, 105 out of 188 respondents (55.9%) completed and returned the questionnaire. Table 1 shows the areas of an individual's life that they reported to be affected by their SUI and the frequency that the area was mentioned within the sample as a whole. Thirty-eight different areas were reported by respondents.

Out of 105 respondents, 73 answered the PGI correctly, 9 respondents made mistakes in the PGI and 23 respondents did not fully complete it (Table 2). Of the 73 respondents who correctly completed the questionnaire, 61 answered the PGI with no mistakes (all sections were completed satisfactorily), the remaining 12 respondents made a small error in completion of the PGI. This small error always occurred in section three of the PGI, where respondents had to spend 10 points, these respondents did in fact spend ten points, however they missed out spending points in area 6 (all other areas of their life affected by SUI) and totalled to ten in box 6. [An example of the PGI used can be seen in Appendix 1.](#)

Table 3 shows the demographic information of the sample as a whole and for those individuals who correctly completed and incorrectly completed the PGI. The mean age for the sample as a whole was 57 (range 28 to 89). As can be seen in Table 3, those respondents who correctly completed the PGI were on average younger than those who incorrectly completed the PGI. In addition, those who correctly completed the PGI appear to be better educated and in higher income groups.

In addition to listing the outcomes of importance to women who suffer from SUI, the PGI can also be calculated into a score of overall quality of life. The score ranges from 0 to 6, with 0 reflecting a very low quality of life ("it's as bad as it could

possibly be”) and 6 reflecting a very high quality of life (“it’s as high as it could possibly be”) An example of the PGI and the method used to calculate the score is given in Table 4. For the respondents who successfully completed the PGI the mean score was 2.4 (SD 1.4, range 0-6). 101 of 105 returned questionnaires had a fully completed EQ-5D. Scores on the EQ-5D ranged from -0.17 to 1. The mean EQ-5D score was 0.598 (SD 0.339). Correlation between the mean PGI score and the mean EQ-5D was, as expected, positive and significant.

Scores (out of 100) for each domain in the KHQ can be seen in Table 5. The higher the score, the worse off an individual feels. In addition to the domains of the KHQ, it also contains a section detailing the respondent’s bladder problems and how much they affect the individual’s life.

Correlations of the PGI and seven domains of the KHQ were also performed. We would expect to find a negative correlation between the PGI and KHQ. All correlations were negative, however only two were significant: personal relationships (P=0.004) and severity measures (P=0.003).

In addition, correlations of the EQ-5D score and the domains of the KHQ were also performed. We found all seven of the KHQ domains to be significantly (negatively) correlated with the EQ-5D. This result is to be expected since many of the EQ-5D and KHQ domains are similar.

Discussion

The PGI has been used to quantify the effect of SUI on the quality of patients' lives for the first time. The respondents are a self-selected sample of women who had previously been in touch with a patient support charity and who may be considered to be active help-seekers. However, there is no reason to suspect that their experience of SUI and the relative perceived impact of SUI on various aspects of their lives are different from the wider population of women affected. Nearly 70% of respondents successfully completed the questionnaire, a further 9% attempted the PGI but made mistakes in its completion, and 22% failed to fully complete the PGI; the majority of these respondents completed stage 1 of the PGI but failed to complete stage 2 or 3. Those respondents who successfully completed the questionnaire were found to be younger, in higher income groups and have a higher level of education. For the PGI to be used as a valid and reliable measure of outcomes of importance to women with SUI and to be able to accurately quantify the effect of SUI on their lives the response rate and successful completion of the PGI would need to be improved. Of the respondents, 31% of respondents had difficulty in completing the questionnaire and there was also a low response rate to the survey in general (55.9%).

In order to improve this response rate and successful completion alterations could be made to the layout of the PGI to make it more user-friendly. An alternative would be to use the questionnaire as the basis for setting a patient's goals for treatment in a clinical or research setting: achieving those goals could then be used as a measure of patient satisfaction.

In stage 1 of the PGI, 38 different areas of an individual's life affected by SUI were reported. The most frequently mentioned areas were going out or socialising, with

14% of all respondents listing this as one of the areas of their life affected by their condition. Thirteen percent of respondents mentioned personal hygiene and 11% mentioned the effect their condition has on their sleep. Shopping (8%), depression (8%), physical activity (6%), work (6%), anxiety (6%), travel (4%), household tasks (2%), personal (1%) and sexual relationships (2%) were all also listed as areas of their life affected by SUI.

The PGI, or instruments like it, have been criticised in the past, with some authors questioning whether they reflect the patient's view point or, conversely, whether they are simply reflecting the views of the researchers who designed the questionnaire (Tully and Cantrill, 2000). In this survey, whilst we did find a varied response in the number of outcomes listed by respondents, the majority of these did in fact come from the prompt list provided in the PGI. Of the 10 most mentioned areas, eight of these were from the prompt list. Other studies have found similar associations between the prompt list and final outcomes listed by respondents. However, it is unclear whether this association is due to the most relevant examples being selected from the prompt list, or due to respondents being unwilling or unable to think of their own examples because the prompt list is already comprehensive (Russell and Macduff, 1998).

We correlated the mean PGI score and the mean EQ-5D scores. This correlation was, as expected, found to be positive and significant. In addition to this, correlations of the KHQ and the PGI were performed. Although all correlations of the PGI and KHQ were of the expected sign (negative), only two were found to be statistically significant. Given that the PGI outcomes and the domains of the KHQ do not correlate well, and that many of the aspects respondents mentioned in the PGI list of

outcomes do not map very well on to the dimensions of the EQ-5D this might suggest that generic measures, like the EQ-5D, may not be a very good reflection of the preferences of people with incontinence. The PGI in this instance may therefore be capturing concerns of women who suffer from SUI which are not adequately captured by generic instruments such as the EQ-5D. This is of particular interest in the context of health technology appraisals, where EQ-5D has become the accepted standard for calculation of Quality Adjusted Life Year indices for use in determination of cost effectiveness (NICE 2008).

Conclusion

Much of the available literature on SUI focuses on doctor-selected clinical outcomes. Given the undoubted social and personal impact of SUI, these outcomes may as a result have limited relevance to the women who suffer this condition. The aim of this survey was therefore to provide evidence on outcomes of importance to women who have SUI. This is the first attempt to use the PGI in this area. In total, 48 different areas of an individual's life affected by SUI were mentioned, the most common of these being: going out or socialising; personal hygiene; sleep disruption; the effect on daily activities such as shopping; depression; physical activity; work; anxiety; travel; household tasks; and personal and sexual relationships. The PGI succeeded in capturing a diverse range of outcomes of importance to women suffering from SUI. However, it must be noted that some respondents did have difficulty in completing the PGI.

Finally, the PGI was not found to correlate well with the domains of the KHQ, in addition, many of the aspects respondents mentioned in the PGI list of outcomes were not found to map well on to the dimensions of the EQ-5D suggesting that generic measures, like the EQ-5D, may not be a very good reflection of the preferences of people with incontinence. We conclude that the PGI in this instance may therefore be capturing concerns of women who suffer from SUI which are not adequately captured by generic instruments such as the EQ-5D.

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Ethics approval: No ethical approval was necessary. The sample was surveyed by a charity to whom they had already given consent to be contacted for research purposes. Questionnaires were returned to the charity. Only anonymous data were supplied to the authors by the charity. Ethical approval for the study was provided by InContact. The 2006 survey in which the participants were originally identified was a service evaluation in which InContact surveyed people who had previously been in touch with the charity and as such no ethical approval was necessary.

Disclosure of Interests: Brian Buckley is a Cochrane Fellow at the Department of General Practice, National University of Ireland, Galway, and is the Chair of the Board of Trustees of the Bladder & Bowel Foundation.

Contribution to Authorship: All authors contributed to the design of the study, interpretation of data and writing of the manuscript.

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Table 1 Area of life affected by SUI

	Responses		Percent of Cases
	N	Percent	N
Going out/socialising*	58	14%	60%
Personal hygiene*	53	13%	55%
Sleep*	47	11%	49%
Shopping*	33	8%	34%
Depression*	32	8%	33%
Physical activity	30	7%	31%
Work*	24	6%	25%
Anxiety*	24	6%	25%
Travel	18	4%	19%
Going on holiday/staying away from home	12	3%	13%
Lack of public toilets	11	3%	12%
Household tasks	10	2%	10%
Sexual relationships	10	2%	10%
Need to use products/pads	8	2%	8%
Personal relationships	7	2%	7%
Sneezing/coughing/laughing	7	2%	7%
Affecting choice of clothes	6	1%	6%
Infections/skin irritations	4	<1%	4%
Family activities	4	<1%	4%
Loss of independence	3	<1%	3%
Time spent at Doctors/hospital	3	<1%	3%
Bladder controlling life	2	<1%	2%
Limiting liquid intake	2	<1%	2%

Embarrassment	2	<1%	2%
Affecting confidence	1	<1%	1%
Travelling on public transport	1	<1%	1%
Continually going to toilet when not necessary	1	<1%	1%
Being housebound	1	<1%	1%
Feeling cold	1	<1%	1%
Body image	1	<1%	1%
Feeling unfeminine	1	<1%	1%
Worry about leaving wet stains	1	<1%	1%
It annoys me	1	<1%	1%
Public queues	1	<1%	1%
Long term effect it is having on me	1	<1%	1%
Failure	1	<1%	1%
Inability to study/write	1	<1%	1%
Activities outside the home	1	<1%	1%
Total	424	100.0%	441%

*Areas provided in prompt list in the PGI

Table 2 **PGI responses**

	Frequency	Percent		
PGI answered correctly	73	69.5	PGI correct	61
Mistake in PGI	9	8.6	PGI put total in box sixth	12
PGI not fully completed	23	21.9		
Total	105	100.0		

Notes:

PGI completed correctly = those respondents who had fully completed PGI (Outcomes, scores and points) it includes those who mistakenly totalled their points in box 6, but points summed to 10

Mistake in PGI = those respondents who fully completed the PGI but who did not sum to 10

PGI not fully completed = not all sections of the PGI were completed

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Table 3 Demographic and socioeconomic information

Variable	Total sample	Correct PGI	Incorrect PGI
N	105	73	32
Mean age of respondents (range)	56.90 (28 – 89)	55.16 (28 – 89)	60.84 (37 – 87)
Age ranges (%):			
25 – 34	3 (2)	3 (4)	-
35 – 44	15 (14)	11 (15)	4 (13)
45 – 54	39 (37)	28 (38)	11 (35)
55 – 64	21 (20)	15 (21)	6 (19)
65 – 74	8 (8)	6 (8)	2 (6)
75 +	19 (18)	10 (14)	9 (28)
Income (valid %):			
<£6000	10 (11)	7 (11)	3 (11)
£6,001 - £10,000	16 (17)	12 (19)	4 (15)
£10,001 - £15,000	20 (22)	11 (17)	9 (33)
£15,001 - £20,000	13 (14)	9 (14)	4 (15)
£20,001 - £25,000	5 (5)	3 (5)	2 (7)
£25,001 - £30,000	10 (11)	7 (11)	3 (11)
£30,001 - £35,000	8 (9)	6 (9)	2 (7)
£35,001 +	10 (11)	10 (15)	-
Education (%):			
None	2 (2)	1 (1)	1 (3)
Secondary school	39 (37)	22 (30)	17 (53)
College	29 (28)	21 (29)	8 (25)
University	35 (33)	29 (40)	6 (19)

Table 4 **Example of PGI scoring**

Part 1: List areas of life affected by urinary incontinence	Part 2: score (0-6)	Part 3: Spend your 10 points	Final PGI score
1. Interrupted sleep	1	3	0.3
2. Affects my social life	6	1	0.6
3. Affects my work	3	2	0.6
4. Personal relationships	2	2	0.4
5. It makes me feel depressed	4	1	0.4
6. All other areas of your life affected by your urinary incontinence	5	1	0.5
Total			2.8

Notes:

$$[1*3/10] + [6*1/10] + [3*2/10] + [2*2/10] + [4*1/10] + [5*1/10] = 2.8$$

Table 5 **KHQ – descriptive statistics**

	N	Minimum	Maximum	Mean	Std. Deviation
KHQ scores for role limitation	101	0.00	100.00	53.30	30.64
KHQ physical limitation scores	100	0.00	100.00	61.83	30.09
KHQ social limitation	95	0.00	100.00	45.61	30.98
KHQ score for personal relationships	73	0.00	100.00	37.90	35.92
KHQ score for emotions	98	0.00	100.00	60.32	31.67
sleep energy	100	0.00	100.00	60.67	31.02
severity measures	98	6.67	100.00	68.50	22.55

Appendix 1: Please complete the questionnaire to tell us how your life is currently affected by your **urinary incontinence and its treatment** and how you would like to see it improve.

PART 1: List Areas	PART 2: Score Areas	PART 3: Spend Points
<p>In this part we would like you to think of the 5 most important areas of your life affected by your urinary incontinence and its treatment and write these in the boxes below.</p> <p>If you cannot think of 5 areas then just fill as many boxes as you want. Some examples are shown below.</p> <p>Work; Household tasks e.g. shopping); Social activities; Feeling depressed/Anxious; Personal hygiene; Affecting your sleep</p>	<p>Please score each area you listed in Part 1. The score should show how badly you were affected by your urinary incontinence over the <u>last month</u>. Give each area a score by circling the number.</p> <p>In the same way, we would like you to rate "All other areas of your life affected by your urinary incontinence not listed above."</p> <p>By this we mean all other aspects of life affected by your urinary incontinence and not included in the list you gave.</p>	<p>We want you to "spend" 10 points to show which areas of your life you feel are most important to your overall quality of life.</p> <p>Spend more points on areas you feel are most important to you and less on areas that you feel are not so important. You don't have to spend points on an area. You can't spend more than 10 points in total.</p>
	<p>As bad as could possibly be As good as could possibly be</p> <p>Please circle one number on each line</p>	
<input style="width: 100%;" type="text"/>	→ 0 1 2 3 4 5 6 →	<input style="width: 100%;" type="text"/>
<input style="width: 100%;" type="text"/>	→ 0 1 2 3 4 5 6 →	<input style="width: 100%;" type="text"/>
<input style="width: 100%;" type="text"/>	→ 0 1 2 3 4 5 6 →	<input style="width: 100%;" type="text"/>
<input style="width: 100%;" type="text"/>	→ 0 1 2 3 4 5 6 →	<input style="width: 100%;" type="text"/>
<input style="width: 100%;" type="text"/>	→ 0 1 2 3 4 5 6 →	<input style="width: 100%;" type="text"/>
<input style="width: 100%;" type="text"/> All other areas of your life affected by your stress urinary incontinence	→ 0 1 2 3 4 5 6 →	<input style="width: 100%;" type="text"/>
		<p>↑</p> <p>Total number of points that you spend must add up to 10</p> <p>↓</p> <p>Total = 10</p>