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Title (type in CAPITAL LETTERS, leave one blank line before the text)	<p>RESPONSIVENESS OF THE BRISTOL FEMALE LOWER URINARY TRACT SYMPTOMS QUESTIONNAIRE (BFLUTS-Q) TO SURGICAL INTERVENTION IN A RANDOMISED CONTROLLED TRIAL</p> <p><u>Aims of Study:</u> The BFLUTS-Q is a direct descendent of the ICS questionnaire used in the ICS-'BPH' study, with sections on LUTS and their bother, impact of LUTS on quality of life (QoL) and on sexual function. As incontinence is more of a problem in the female patient than the male, the BFLUTS-Q has a greater emphasis on quantifying the frequency and extent of urinary incontinence in women, compared to the ICSmale questionnaire which is more orientated towards voiding symptoms</p> <p>The excellent psychometric validation data of the male questionnaire was mirrored by the BFLUTS-Q during its initial testing to establish content, construct and criterion validity (1). The BFLUTS-Q has subsequently performed well in a large community survey of more than 2000 women, with overall item completion levels of 95% (2).</p> <p>As the final part of validation, the aim of this study is to assess the responsiveness of the BFLUTS-Q after surgical treatment of genuine stress incontinence (GSI).</p> <p><u>Methods:</u> The data used in this study is derived from a randomised controlled trial (RCT) in which open colposuspension is being compared to the transvaginal tape (TVT) procedure. 316 women (mean age 50.4, range 23 to 79 years) gave fully informed consent to enter the trial, were randomised to one or other treatment, and had surgery performed. Each woman completed the BFLUTS-Q and had full urodynamics including leak point pressure measurements, prior to treatment, and 6 months after treatment.</p> <p>Only a selection of the most relevant data can be presented here. Responses have been dichotomised and the chi square test applied to test for statistically significant changes in the distribution of responses when pre and post-operative data is compared</p>

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Results: 310 women were followed up as per protocol. The table shows the marked changes in selected LUTS and QoL items. All changes are highly significant ($p < 0.001$ for all). Furthermore, the bother of each symptom was also significantly changed following surgery ($p < 0.001$ for all).

Item	Pre-operative (%)	Post-operative (%)
LUTS items		
Micturition 9 times per day or more	51.1	27.4
Rushing to the toilet to urinate	95.0	76.8
Urinary leakage before reaching a toilet	95.4	56.3
Urinary leakage once per week or more	99.7	52.1
Urinary leakage during physical activity	100.0	36.7
The need to change underclothes or wear protection	95.4	28.4
Urinary leakage during sleep	45.6	16.1
Reduced strength of urinary stream	38.0	63.4
Bladder not emptied properly after urination	76.6	56.1
Urinary leakage during sexual intercourse	60.8	21.9
QoL items		
Reduced fluid intake	72.5	42.3
Sex life spoiled by urinary symptoms	67.5	38.2
Urinary symptoms interfere with physical activity	93.7	24.8
Overall, urinary symptoms interfere with life	96.1	32.0
Not happy about spending life with symptoms	99.7	27.8

Conclusions: Both colposuspension (3) and TVT (4) have been shown to be highly effective in treating GSI and hence pooled results can be used to judge the responsiveness of the BFLUTS-Q. All data items related to storage symptoms, including incontinence, show clear change when pre-operative data is compared to post-operative data. Marked differences were also seen in pad usage/need to change clothing because of leakage. The data changes presented are to be expected from effective intervention used by competent surgeons and therefore the responsiveness of the BFLUTS-Q to symptoms and their bother is good. The QoL data also shows marked alterations after surgery, demonstrating good responsiveness for the questions in this section of the BFLUTS-Q. Data in this area is not so readily available from the literature, as there have been few RCTs in the surgical treatment of GSI. In conclusion, the BFLUTS-Q shows excellent responsiveness for symptoms, their bother, and the impact of symptoms on QoL, in a RCT of surgical treatment for GSI.

References: 1. B J Urol. 1996, 77: 805-812.

2. B J Gen Pract. 1999, 49: 897-900.

3. Incontinence, Pub. Health Publication Ltd 1999, p. 644-645.

4. Neurourol. Urodyn 1999, 18: 300-301.

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