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Title (type in CAPITAL LETTERS, leave one blank line before the text) CHANGES IN QUALITY OF LIFE FOLLOWING SURGERY WITH TENSION FREE VAGINAL TAPE (TVT) OR COLPOSUSPENSION FOR PRIMARY GENUINE STRESS INCONTINENCE (GSI)	
<u>Introduction</u>	
<p>Urinary incontinence is a significant problem for up to 10% of the female population, with serious impact on quality of life. Whilst the aim of surgery is to cure stress incontinence and improve quality of life, adverse effects may also result. Quality of life assessment is an essential component of any trial comparing two surgical procedures.</p> <p>As women with urinary incontinence are often otherwise in good health, generic health scores may be unable to detect a clinically relevant change in lower urinary tract symptoms. Thus it is important to include both generic (1) and disease specific questionnaires (2, 3)</p>	
<u>Aims of study</u>	
To assess general health status and quality of life changes within the context of a randomised trial comparing TVT and colposuspension as primary treatments for GSI.	
<u>Methods</u>	
Women were randomised to either TVT (Gynecare, Edinburgh) or colposuspension. SF-36 health status was completed at initial assessment, six weeks and 6 months post operatively. The Bristol female lower urinary tract symptoms (BFLUTS) questionnaire was completed pre operatively and at six months post operatively. In addition patients were questioned about overall satisfaction with the procedure and their time to full recovery.	
<u>Results</u>	
<p>At 6 weeks post-operatively 78% of TVT patients and 60% of colposuspension patients felt well enough to return to normal activities around the house. Of those who worked outside the home, 76% and 41% respectively felt well enough to return to work by 6 weeks. The median time to return to full activity around the house was 2-3 weeks and 4-8 weeks respectively. The median time to return to work was 3-4 weeks and 8-16 weeks respectively.</p> <p>Individual SF-36 scores were combined and transformed to generate eight health dimensions. Each dimension has a potential score ranging from 0 to 100, where higher values indicate better perceived health. At six weeks patients</p>	

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in the TVT group had significantly higher scores for physical function, role limitation due to emotional problems, social functioning, and vitality, than those in the colposuspension group. By 6 months these differences are less apparent between groups. With the exception of pain and general health perception, all scores from the SF-36 improved in both treatment groups from pre-operative to 6 months post-operatively.

The changes reported in symptoms of stress incontinence on the BFLUTS questionnaire are comparable to objective results reported elsewhere by this group. Most other urinary symptoms also improved following surgery, to a similar degree for both procedures. The extent to which urinary symptoms were bothersome also reduced to a similar degree. Symptoms of voiding difficulty were more commonly reported following surgery, but were less bothersome. Pain associated with sexual activity did not change, although incontinence during intercourse and disruption of sex life by urinary symptoms in general were both less commonly reported and less bothersome following both procedures. Responses to questions relating to the impact of urinary symptoms on overall quality of life all indicated marked improvement. The extent of improvement was comparable for both procedures at 6 months.

Overall, 96% of the TVT patients and 94% of the colposuspension patients regarded themselves as satisfied or very satisfied with the results of their surgery at 6 weeks. A similar proportion said that they would recommend the same operation to a friend or relative. The responses to both these questions did not change significantly by 6 months post-operatively.

Conclusions

Patients perceived themselves to have returned to normal activity more rapidly following TVT than colposuspension. This is mirrored in the responses of the generic health status questionnaire (SF-36) at 6 weeks. By 6 months following surgery all patients looked on themselves as being fit for normal activities both around the house and in work. All dimensions of the incontinence specific questionnaire (BFLUTS) and many of those of the generic questionnaire (SF-36) were improved to a similar degree following both procedures by this stage.

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1. BMJ 1993;306(6890):1437-1440.
2. BJU 1996;77(6):805-812.
3. BJOG 1997;104(12):1374-1379.