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REDEFINING THE SUCCESS RATE OF BULKING AGENTS: ROLE OF COMPOSITE ENDPOINTS

Hypothesis / aims of study

To assess outcome measures following bulking agents for stress urinary incontinence by using composite endpoints.

Bulking agents may be used for the treatment of stress urinary incontinence in a specific cohort of patients; women who have had radiotherapy, or elderly, unfit for surgery or have intrinsic sphincter deficiency are suitable candidates. Traditionally assessment of outcome of continence procedures has been based on objective and subjective cure rates. However it is unclear which of these measures, are the best methods to assess success rates of these procedures. Composite endpoints are based on a combination of multiple measures of outcomes. The use of composite endpoints has the potential to assess standardised patient-centred outcomes. In this study we defined a composite endpoint for periurethral bulking agents based on multiple objective measures and lack of complications. We then compared it with the difference in Quality of Life scores with pre and post treatment change in the King's Health Questionnaire (KHQ) (3).

Study design, materials and methods

Women undergoing bulking agent procedures performed using polydimethylsiloxane (Macroplastique) between January 2006 and June 2008 were eligible for inclusion in this retrospective study. All women had the procedure performed under local anaesthesia in the outpatient setting using a minimally invasive implantation system. Assessments were made preoperatively and 6 months after the procedure. Health related quality of life was assessed using the King's health Questionnaire. Objective outcome was assessed by cystometry, videocystourethrography (VCU), and pressure flow studies. Subjective outcome was assessed during the consultation based on how satisfied the woman was with the outcome of the surgery. The 'composite endpoint' required the absence of urodynamic stress incontinence (USI), de novo detrusor overactivity (DO) and voiding difficulties. Pre and post-treatment differences were compared using the Wilcoxon signed rank test, and the Mann-Whitney U test using SPSS version 15.0.

Results

Complete data including preoperative and 6 months postoperative urodynamics and quality of life evaluation were available for 20 women who were included in the analysis. The mean age at the time of surgery was 71 years (range 50–83 years).

The majority of the women who underwent these procedures had had previous unsuccessful continence surgeries; radiotherapy; excessive abdominal or retropubic surgery; a fixed scarred urethra or co-morbidities posing an anaesthetic risk. Most women had (7/20) undergone at least one previous continence procedure like colposuspension, sub-urethral or trans-obturator tapes or bulking agents. One of them had undergone 6 such unsuccessful procedures.

Objective cure of stress incontinence was observed in 75% (15/20) of women and subjective cure in 80% (16/20). There was a 5.0% (1/20) incidence of de novo detrusor overactivity and 20% (4/20) incidence of voiding difficulties at 6 months. Using the composite endpoint 12 (60%) women were treatment 'successes' and 8 (40%) who had USI, DO or voiding difficulties were treatment 'failures'. Overall there was a greater improvement in QoL scores in those with composite success group when compared to those with composite failure. This achieved statistical significance only for the role limitations domain (p=0.047). There is no significant difference between the objective and subjective cure rates. But QoL measured by the total KHQ scores significantly improved in all the women who underwent surgery (p=0.001) (Table 1). This did not differ in those groups where success was measured objectively, subjectively or using the composite endpoint.

Table 1: Difference in mean KHQ scores before and after surgery

	Total KHQ	General Health Perception	Incontinence Impact	Role Limitations	Physical Limitations	Social Limitations	Physical Relationship	Emotions	Sleep Energy	Severity Measures
1	542	48	85	71	72	46	13	64	65	74
2	306	52	57	27	28	27	11	33	30	38

1: Preoperative
2: 6 months after operation

Interpretation of results

Establishing the most appropriate treatment endpoint to assess success of treatment for stress incontinence requires further investigation. Unfortunately, the quality of life scores did not reflect the high (75%) objective and (80%) subjective cure rate. It is also unclear from this study whether composite clinical endpoints based on objective cure are a valid method of defining success of peri-urethral bulking agents.

Concluding message

This group of patients seem to have different expectation from their treatment as most of them have significant improvement in their quality of life even with minimal improvement in their symptoms.

References

1. Am J Obstet Gynecol. 2007 Dec;197(6):647
2. BJOG. 2004 Jun;111(6):605-12
3. BJU Int. 2007 Jan;99(1):101-6

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Was informed consent obtained from the patients?	**No**