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AN OPEN CLINICAL EVALUATION OF PERMACOL™ INJECTION AS NEW URETHRAL BULKING AGENT
AN UPDATED 12 MONTH FOLLOW-UP

Hypothesis / aims of study

To evaluate the efficacy of a new urethral bulking agent, Permacol™ Injection in the treatment of stress urinary incontinence.

Study design, materials and methods

Permacol™ Injection (Tissue Science Laboratories plc, "TSL" Aldershot UK) is a sterile saline suspension of acellular crosslinked porcine collagen matrix. Permacol™ Injection is fully approved for permanent implantation into humans carrying the Class III CE Mark. During the manufacturing process the natural three dimensional architecture of the collagen remains intact, Permacol™ Injection is not reconstituted collagen. A prospective open study was undertaken on 32 female patients aged between 18 and 90 years who were listed for a urethral bulking agent (UBA) to treat stress urinary incontinence. The patients received one treatment with Permacol™ Injection. Those who were no better after one treatment could be reinjected after a minimum follow up period of one month. Patients were recruited from three UK hospitals after urodynamic studies to exclude idiopathic detrusor overactivity. Clinical examination and evaluation were carried out prior to treatment, and 1, 6 and 12 months after surgery. Both transurethral (n=21) and periurethral (n=11) routes of injection were used depending on the surgeon's preferred method. The inclusion criteria permitted previous incontinence procedures including UBA injections and suburethral slings. Treatment success for individual patients was defined as an improvement (decrease) in Incontinence Grade from baseline. The following criteria was used to assess the patient's treatment success: Incontinence Grade Stamey (1979)[1], Patient diary, Quality of Life Questionnaire, pad test, uroflowmetry and cystocopy.

Results

Twelve months after treatment 63% of patients (n=21) were improved by at least 1 incontinence grade. 33% (n=11) of patients improved by 2 grades and 30% (n=10) by 1 grade. Eight patients (25%) were completely dry (grade 0). Each patient had an average of 1.1 treatments. Twenty nine patients received one treatment. Three patients received two treatments. The mean and median injection volumes were 6.8ml and 6.0ml respectively per treatment. The volume injected per treatment ranged from 2.5ml to 12ml.

Interpretation of results

Permacol™ Injection produced a good to excellent result in 63% of patients after twelve months. The procedure is simple to perform and easy to inject requiring no special delivery system or sensitivity test. It is a low risk procedure, which can be used as a first line treatment in the elderly and infirm and also in patients whose lifestyle does not permit lengthy convalescent periods. The majority of patients (88%) received one injection treatment only. Patients who are no better can go on to more invasive incontinence procedures.

Concluding message

Permacol™ Injection is a safe and efficacious treatment for stress urinary incontinence, which continues to perform twelve months post treatment

References

(1) Stamey T. Urinary incontinence in the Female. Cambells Urology 4th Edition, Philadelphia W B Saunders Company 2272-2293, 1979.

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