

AN OPEN CLINICAL EVALUATION OF PERMACOL™ INJECTION: A NEW URETHRAL BULKING AGENT

Aims of Study

To evaluate the efficacy of a new urethral bulking agent, Permacol™ Injection, in the treatment of stress urinary incontinence. Permacol™ Injection (Tissue Science Laboratories plc, 'TSL' Aldershot UK) is a sterile saline suspension of acellular cross-linked 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.

Methods

A prospective open study was undertaken on 33 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=24) and periurethral (n=9) 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 were used to assess the patient's treatment success: Incontinence Grade Stamey (1979)², Patient diary, Quality of Life Questionnaire, pad test, uroflowmetry & cystometry.

Results

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

Conclusions

Permacol™ Injection produced a good to excellent result in 63% of patients after 6 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. This study also illustrates the benefits of Permacol™ Injection as an adjunct to previous incontinence surgery.

References

- (1) Harper C.L. Permacol™: clinical experience with a new biomaterial Hospital Medicine, February 2001, Vol.62 No.2
- (2) Stamey T . Urinary Incontinence in the Female. Cambells Urology 4th Edition, Philadelphia W B Saunders Company 2272-2293, 1979.