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THREE-DIMENSIONAL ULTRASOUND (3DUS) TO ASSESS OBJECTIVE LONG-TERM DURABILITY OF PERIURETHRAL COLLAGEN IN WOMEN WITH STRESS URINARY INCONTINENCE (SUI)

Hypothesis / aims of study

1. To investigate the natural history of injected periurethral collagen over time using serial 3DUS of the urethra as an objective measure.
2. To correlate objective 3DUS findings with subjective outcome measures.

Study design, materials and methods

After institutional review board approval, retrospective chart review was performed for all patients who underwent transurethral periurethral collagen injection (PCI) between 2/99 – 7/03 and were followed by 3DUS. All PCI were performed by a single surgeon. Inclusion criteria were (i) diagnosis of SUI due to intrinsic sphincteric deficiency without urethral hypermobility based on history, symptom and quality of life (QOL) questionnaires (Urogenital Distress Inventory (UDI) question 3 (SUI) and a global QOL visual analog scale (0-10, 10 = worst)), physical exam, multichannel urodynamics with differential Valsalva leak point pressure (VLPP) determinations, and voiding cystourethrography (VCUG) with lateral views at rest and straining, (ii) follow-up with ≥ 2 serial 3DUS studies over ≥ 1 year and (iii) no subsequent PCI. Outcome measures included periurethral collagen volume and configuration, UDI question 3 and QOL scores, and need for additional interventions. Urethral 3DUS was performed at routine intervals or as indicated by clinical circumstances after a baseline study usually performed at 1-4 months after PCI. A single technician (MF) performed all 3DUS (Voluson 530D US machine, Medison America, Cypress, CA, with 7.5-Mhz transvaginal 3D probe placed beneath the urethral meatus); no statistically significant intraobserver variability was detected comparing repeated volume measurements performed in a blinded fashion. A Wilcoxon signed ranks test was used to compare pre- and post-PCI questionnaire and QOL scores.

Results

Of 56 patients who underwent PCI with 3DUS follow-up during the accrual period, 19 had follow-up of ≥ 1 year (mean 2.2, range 1-4.6) after most recent (if > 1 injection) PCI; these patients comprised the study group. Of these 19, 10 had follow-up beyond 2 years (mean 2.8, range 2-4.6). Mean age was 62 (44-77) and questionnaire analysis revealed a mean UDI question 3 score of 2.7 $\pm$ 0.5 and quality of life (QOL) score of 7.8 $\pm$ 2.5. Urodynamic studies revealed a mean VLPP of 49 $\pm$ 24 cmH_2O. Total number of PCI per patient was, on average, 1.9 (1-4) with a mean total injected volume of 10 cc (5-24). Mean 3DUS collagen volumes were not statistically different at baseline (2.5 $\pm$ 1.9 cc) compared to last follow-up (2.5 $\pm$ 1.8 cc) ($p = 0.98$). Figure 1 illustrates stable serial collagen volumes measured over time for each patient. Mean volume retention rate was 112 $\pm$ 53% of the baseline volume. Periurethral configuration was circumferential or horseshoe-shaped in 68% and asymmetric in 32% (figure 2). Post-injection UDI 3 and QOL scores were significantly improved compared to baseline evaluations with means of 1.4 $\pm$ 1.0 ($p=0.01$) and 3.2 $\pm$ 3.1 ($p=0.007$), respectively. At last follow-up, 17 patients continued to experience improvement in continence, while only 2 patients proceeded to additional procedures, a pubovaginal sling (1) and 2nd PCI (1).

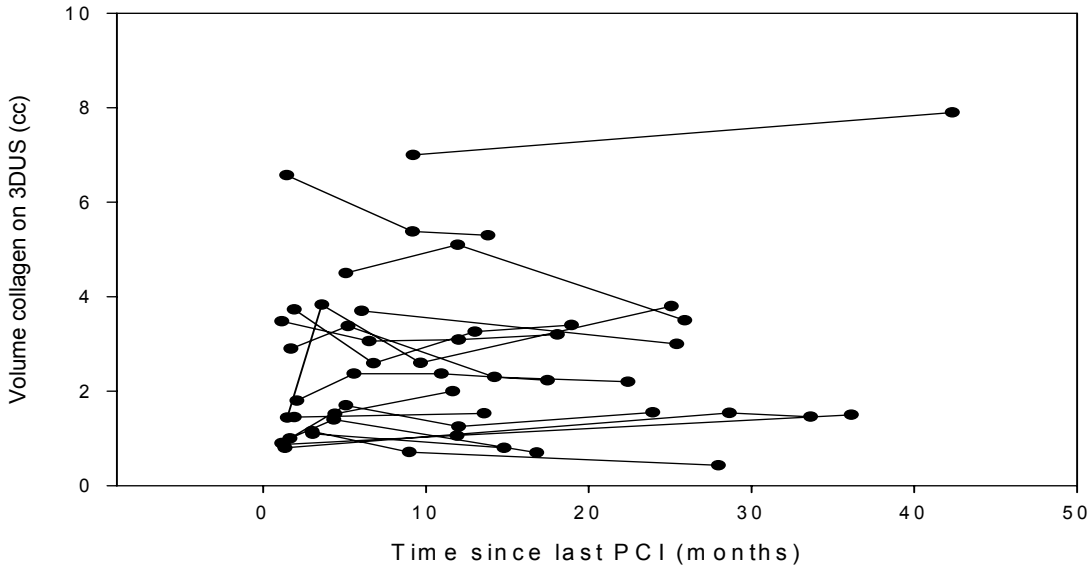

Figure 1: Serial collagen volume on 3DUS in patients with at least 1 year follow-up after most recent PCI. Each line represents a single patient and each point represents a single 3DUS measurement.

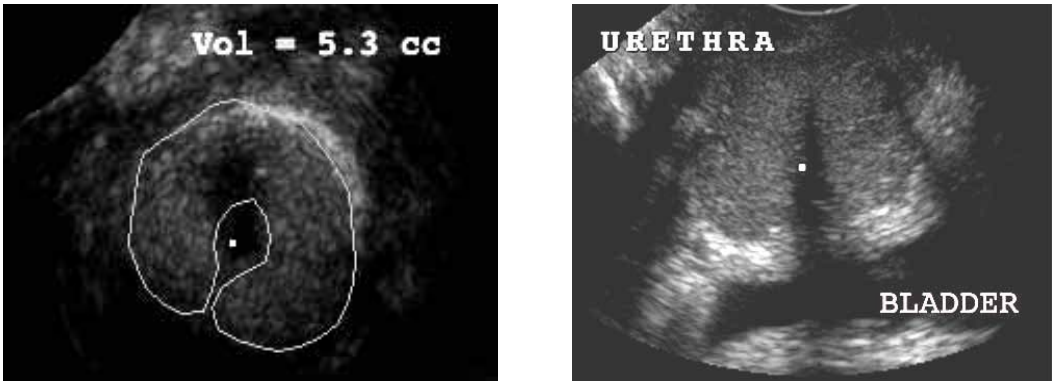

Figure 2: Circumferential periurethral collagen configuration on 3DUS views in the axial (left) and longitudinal (right) planes through the urethra and bladder. The white dot represents the level of the mid-urethra. Collagen volume measured = 5.3 cc.

Interpretation of results

Serial imaging to demonstrate the natural history of collagen in periurethral tissues has never been reported. It has been assumed that collagen volume declines over time and failure requiring repeat injections is inevitable. In these patients with SUI due to ISD, significantly improved clinical outcome post-PCI based on questionnaire analysis of symptoms and QOL were associated with objective evidence of stable periurethral collagen volume on 3DUS over time. The trend toward a circumferential distribution may be of significance in predicting an optimal clinical outcome and, therefore, may represent a technical endpoint.

Concluding message

This is the first study to demonstrate stable, persistent volumes of periurethral collagen on serial 3D ultrasound imaging associated with improved continence and quality of life based on questionnaire analysis. This new knowledge should allow the clinician to better define technical success and, thereby, provide an objective therapeutic endpoint which may be incorporated into a treatment algorithm for managing stress incontinence.