BACKGROUND

Glutaraldehyde cross-linked bovine (GAX) collagen was previously the most commonly used and studied bulking agent for treatment of stress urinary incontinence (SUI) until it was discontinued in 2011.1-2

Collagen injection (CI) was criticized for limited efficacy with reported durability ranging from 10 to 19 months and need for repeat injection.3-4

Since 1999, our group started to study the evolution of CI using serial transvaginal 3-dimensional ultrasound (3D US).

AIMS OF THE STUDY

To evaluate the durability of CI using serial 3D US in a cohort of women with sufficient improvement of SUI not requiring additional treatment.

MATERIALS AND METHODS

IRB approved, retrospective review of females undergoing CI from 1999 to 2011 at single tertiary center.

Inclusion Criteria:
  o <3 CI for mixed, primary or recurrent SUI
  o Minimum follow-up 1 year.

Exclusion criteria:
  o Urethral hypermobility
  o Received prior bulking agents elsewhere
  o Injection using different bulking agents
  o Reinjection during the follow-up period
  o CI failures
  o Subsequent anti-incontinence procedures.

Durability assessed in office at 6 weeks and every 6-12 months by history and collagen volume by serial 3D US.

All 3D US performed by same technician.

Mixed model used to determine if there was a significant change in 3D US volume over time to account for between-patient correlation and within-patient correlation.
  o Random effects: patients measured multiple times
  o Fixed effects: time of measurement since last injection and total number of injections.
  o Dependent variable: collagen volume

Two-tailed paired student’s t-test used to analyze continuous variables

RESULTS

Patient Demographics of Durable CI
Mean age (range) 67 (42-90)
Mean BMI (range) 27.2 (18.5-49)
Mean parity (range) 2.3 (0-7)
Prior incontinence surgery (%) 31 (46%)
Mean follow-up from time of last CI 43 months (12-149)
Mean 3DUS/patient 4 (2-11)

Number of CI per Patient

<table>
<thead>
<tr>
<th># of CI</th>
<th># of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>43</td>
</tr>
<tr>
<td>2</td>
<td>21</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

Findings according to duration of CI follow-up

<table>
<thead>
<tr>
<th>F/u (yrs)</th>
<th># of Pts</th>
<th>Mean age (yrs)</th>
<th># of CI</th>
<th>Mean total injected vol (cc)</th>
<th>Mean post-op baseline vol (cc)</th>
<th>Mean last visit vol (cc)</th>
<th>% vol left</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2</td>
<td>21</td>
<td>68</td>
<td>1.4</td>
<td>5.3</td>
<td>3.4</td>
<td>2.9</td>
<td>85%</td>
</tr>
<tr>
<td>&gt;2-5</td>
<td>33</td>
<td>70</td>
<td>1.5</td>
<td>6.2</td>
<td>3.2</td>
<td>2.7</td>
<td>77%</td>
</tr>
<tr>
<td>&gt;5</td>
<td>13</td>
<td>62</td>
<td>1.2</td>
<td>5.5</td>
<td>2.9</td>
<td>2.5</td>
<td>80%</td>
</tr>
</tbody>
</table>

Serial 3D US demonstrates that collagen degrades slowly at mean of 0.11cc/yr from last injection in select patients suggesting that those with a durable response may avoid repeat injections or other SUI treatment longer than previously thought.

3D US appearance did not substantially change and remained easy to assess arguing against the effect of a collagenase degrading it over time.

CONCLUSIONS

- CI results can be stable over time in a subset of patients treated for SUI secondary to intrinsic sphincter deficiency.
- Serial 3D US demonstrated that collagen decreased slowly at 0.11cc/yr from the time of last injection.
- In those with durable CI results, 3D US may have a role to document durability of injectables over time.

REFERENCES