

IMAGING FINDINGS OF CROSSLINKED VINYL DIMETHYL POLYDIMETHYLSILOXANE USED AS PARAURETHRAL INJECTABLE FOR FEMALE STRESS URINARY INCONTINENCE

Hypothesis / aims of study

Primary objective of this study was to develop a tool to assess the positioning of urethral bulking agents after implantation using computed tomography (CT). Using this tool we retrospectively analyzed the correlation between the findings on CT and the patient reported outcome on stress urinary incontinence (SUI) after treatment with crosslinked vinyl dimethyl polydimethylsiloxane (VDPDMS), (Urolastic[®], Urogyn BV, Nijmegen, The Netherlands).

Study design, materials and methods

We retrospectively analyzed the charts of all patients in our tertiary referral centre that underwent CT scanning after blind paraurethral injections with VDPDMS. We chose this injectable because it is clearly visible on CT, but difficult to visualize using ultrasound. Treatment with VDPDMS usually consisted of 4 midurethral injections with 0.6-1.2cc of material in an outpatient setting under local anesthesia. Low-dose CT-scans without contrast agent were in most cases performed after treatment to confirm the position of the implanted material or in some patients because of other medical reasons.

A senior radiologist experienced in urological procedures assessed all CT's. Assessment took place following a predefined schedule, partially based on the method used by Hedge et al. (2013) [1]. First, possible scattering of the material (i.e. a non-spherical implant), injection in a lymph- or bloodvessel and presence of VDPDMS >15 mm from the urethra were listed. Second, the plane and the angle of the plane in which most material was present around the urethra were defined. Subsequently the length of the urethra was measured. If the plane with the most material was located in the middle third of the urethra, we considered it to be midurethral. The distance of the most proximal part of the implants to the urethrovesical junction was furthermore measured.

To assess whether the VDPDMS was distributed equally around the urethra, we calculated the surface of the plane occupied by VDPDMS within a radius of 15mm from the center of the urethra, in four quadrants. If over 50% of the surface was occupied in all four quadrants, we considered the material to be circumferentially distributed. Finally the volume of the bulking agent was measured. The calculations on the images were made with commercially available software from TeraRecon (Foster City, California, USA).

The imaging findings were thereafter compared with the percentage of subjective improvement experienced by the patients.

Results

Ten female patients were included who underwent a CT-scan 1-6 months after treatment. Three patients reported no improvement, 4 patients had 20-70% improvement and 3 had 100% subjective improvement of their SUI (table 1).

Table 1: patient characteristics

	Radboudumc (N=10)
Age (median, years)	63.4 (10.5; 48.0-77.0)*
Previous Treatments (median)	2.5 (5.0; 0-13)
Injected volume (median, milliliters)	3.2 (1.3; 1.2-4.4)
Subjective improvement (median)	37.5% (100; 0-100)

* (interquartile range (IQR), range)

In 7 out of 10 patients (70%) the material was scattered in one or more positions. Scattering occurred only once at the 2 o'clock position, in the other positions this was observed in 3-5 cases. In almost all patients (9/10) the injected material seemed to follow the structure of small blood or lymph vessels or endopelvic fascia in at least one of the 4 positions. An example of such can be found in figure 2.

Figure 2: VDPDMS following an anatomical structure



Measuring the exact length of the urethra was challenging, because the meatus in the vaginal vestibulum is hard to distinguish on CT. Despite this fact, the longest urethra's had the highest percentage of success, with all 4 urethra's >32mm having a subjective success rate of 70-100%.

The distance of the most proximal implant to the bladderneck was 0 mm in 3 out of 10 patients (30%). In another 3 this distance was short: 3-6 mm. Positioning of VDPDMS at the urethrovesical junction was not correlated to clinical failure.

There was no significant correlation between the age of the patient, the volume injected or midurethral position and the chance of clinical success. In none of the 10 patients the material was distributed circumferentially using this assessment tool. Half of the documented injected volume could be traced using volume measurements.

Interpretation of results

This is -to our knowledge- the first study after the imaging findings of urethral bulking agents on CT. It shows us that CT is a feasible way to visualize VDPDMS after implantation, as it gives clear interpretable pictures with relatively low costs. Using our assessment schedule we found that the distribution of VDPDMS is more heterogeneous than expected. We are able to describe the anatomical position and form of the bulking agents. Volume measurements are however impossible. We considered this to be due to the spreading of the material. Smaller particles or longitudinal implants can't be traced with the software we used.

For VDPDMS this study found that clinical success can still be achieved with non-circumferentially distributed material at the urethrovesical junction, so a possible correlation between position and clinical outcome will be by no means "absolute". The major drawback of this study is the low number of patients we included. It was therefore impossible to find significant correlations between study parameters and clinical outcome. Therefore the clinical usefulness for urethral bulking agents of this tool cannot be confirmed.

Other literature on the (ultrasound) imaging of different bulking agents (bovine collagen) shows that correlations can be found and may lead to clinically useful recommendations[2]. It seems therefore important to expand our knowledge about CT-imaging of urethral bulking agents to possibly give recommendations on the optimal volume, position and distribution.

Concluding message

CT is a good way to visualize VDPDMS after implantation and using the assessment schedule we can systematically describe the aspects of it. There appears to be a large heterogeneity in the position and form of the deposits of VDPDMS. This does however not necessarily influence the clinical outcome.

A long urethra might be a factor positively influencing the chance of success after treatment. No significant correlation was found between any of the investigated parameters and clinical success in this small study. Future research with larger numbers of patients and possibly multiple observers should be performed to determine which CT findings significantly influence or predict the outcome of urethral bulk procedures on stress urinary incontinence in women.

References

1. Hegde A, Smith AL, Aguilar VC, Davila GW. Three-dimensional endovaginal ultrasound examination following injection of Macroplastique for stress urinary incontinence: outcomes based on location and periurethral distribution of the bulking agent. International urogynecology journal. 2013;24(7):1151-9.
2. Defreitas GA, Wilson TS, Zimmern PE, Forte TB. Three-dimensional ultrasonography: an objective outcome tool to assess collagen distribution in women with stress urinary incontinence. Urology. 2003;62(2):232-6.

Disclosures

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