Effects of the incontinence dish pessary on urethral support and urodynamic parameters

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OBJECTIVE: To evaluate the effects of the incontinence dish pessary (IDP) on urethral mobility and urodynamics.

STUDY DESIGN: Prospective study of women with symptoms of stress incontinence. Q-tip test was performed recording the resting and straining angles with and without an IDP. Changes in resting and straining angles were calculated. Those with evidence of urodynamic stress incontinence had urodynamics with the IDP. Paired t-test was used to compare the difference in Q-tip angles with and without the pessary.

RESULTS: Mean Q-tip straining angle without and with the pessary, respectively, was 57.8 (+19.5) and 34.4 (+29.7). Mean change was 23.5 (+18.5) $P < .00001$. Maximum urethral closure pressure (MUCP) was significantly increased by 19.7 cm H_20 $P < .001$. Overall, 60% of the subjects did not leak with the IDP.

CONCLUSION: The IDP eliminates >60% of USI. The mechanism of action may be a combination of improved UVJ support and increased MUCP.

Key words: incontinence, pessary, Q-tip test, urodynamics

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Urinary incontinence affects up to 13 million adults in the United States with an estimated 1 million new cases diagnosed each year. Of those incontinent sufferers the vast majority, up to 85%, are women.[1] Current treatment modalities for stress incontinence can be globally divided into surgical and nonsurgical options. However, 1 common theme between these approaches is to provide restoration of normal anatomic support at the urethrovesical junction (UVJ). Nonsurgical options are important since many women may opt for an alternative to surgery or may be poor surgical candidates. One nonsurgical option is the use of a pessary. Pessaries have been in use for over 4000 years, with 1 of the first descriptions of a pessary being half of a pomegranate soaked in vinegar.[2] Pessaries historically have been used for pelvic organ prolapse, but since the first description of the pomegranate, pessaries have undergone multiple improvements in both structure and design. One such improvement has been the development of pessaries designed specifically to treat stress incontinence, but unfortunately this treatment modality has been underused. This may be due to a combination of the paucity of data on these particular pessaries, as well as the common belief by up to 88% of general gynecologists that this is an ineffective treatment modality for stress incontinence.[3] The proposed mechanism of action of the incontinence pessary is that it provides mechanical support under the UVJ and prevents descent of the bladder neck during increases in intraabdominal pressure. Several studies have demonstrated efficacy and patient satisfaction in up to 45-55% of those using an incontinence pessary.[4,5] However, the exact mechanism of action of the incontinence pessary has not been studied. The primary aim of this study is to evaluate the effect of the incontinence dish pessary (IDP) (Milex, Chicago, IL) on bladder neck support and to determine whether the Q-tip straining angle is normalized to < 30 degrees with the pessary in place in subjects with proven UVJ hypermobility (> 30 degrees). The secondary aim is to determine the effects of the IDP on urodynamic parameters, most specifically, the maximum urethral closure pressure and uroflowmetry, as well as to determine whether or not the IDP resolves urodynamic stress incontinence.

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MATERIALS AND METHODS

A prospective study of women presenting for evaluation of urinary incontinence and/or pelvic organ prolapse (POP) who have evidence of urethral hypermobility were recruited for the study. This study was approved through our institutional review board (IRB). Nonpregnant women over the age of 18 with symptoms of stress urinary incontinence and urethrovesical junction hypermobility were considered candidates for participation. One study described vaginal length of < 7 cm as a risk factor for unsuccessful pessary fitting; therefore, women with a foreshortened vagina (vaginal length < 6 cm) were excluded.[6] All subjects underwent a detailed pelvic exam, including staging of prolapse using the POP-Q system.[7] A Q-tip test was performed in the standard fashion and the resting and straining angles were recorded. Two independent examiners re-

TABLE 1
Demographic data

	Mean/median	Standard deviation	Range
Age	60.6	± 11.8	35-86
BMI	28.7	± 6.45	19-51
Parity	3	± 2.56	0-13
Race (N)			
White	43	46	
Hispanic	40	42	
Asian	8	8.5	
African American	2	2	
Other	2	2	

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TABLE 2
Distribution of anterior wall defects

Stage	Number (n = 95)	Percent
0	2	2%
1	10	11%
2	54	56%
3	21	23%
4	8	8%

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corded the Q-tip angle simultaneously, and any discrepancy in numbers was resolved by taking an average of the 2. An appropriately sized incontinence dish pessary was then placed transvaginally, and the Q-tip test repeated. The changes in the resting and straining angles with and without the pessary were compared. Those women with evidence of urodynamic stress incontinence had the urodynamic testing repeated with the incontinence dish pessary in place. The results of the urodynamic testing with and without the pessary were compared. Due to the fact that hypermobility needed to be determined as part of the inclusion criteria, the Q-tip test without the pessary was always performed first. In similar fashion, the urodynamic testing was performed initially without the pessary to determine the presence of urodynamic stress incontinence, and, if present, was then repeated with the pessary in place. Urodynamics were performed with the Medtronic Duet (Minneapolis, MN). Methods, definitions, and descriptions conform to the recommended standards set by the International Continence Society.[8]

The primary efficacy endpoint is defined as a Q-tip straining angle normalized to < 30 degrees above the horizontal. We estimated that 50% of patients would correct to a Q-tip straining angle of < 30 degrees, and used this to define a positive response. A power analysis determined the number of patients required would be 93 for an alpha of 0.05 and a power of 80%. Paired *t* tests were used to compare the results with and without the pessary. Logistic regression analysis was performed to determine factors predictive of normalization of the straining Q-tip angle. Descriptive data are presented in means or medians with standard deviation and ranges. The relative risk reduction of incontinence with the pessary in place was calculated.

Results

Ninety-five patients completed the study. Demographic data are outlined in Table 1. The vast majority of subjects (73%) were postmenopausal. Anterior wall defects were identified in 98% of the cohort with 11% stage 1, 57% stage 2, 23% stage 3, and 8% stage 4 (Table 2). Just over 28% (n = 27) had a previous hysterectomy. A total of 18.9% of subjects had prior surgery for incontinence and/or prolapse; 11.3% (n = 11) had undergone prior surgery for incontinence, 3% (n = 3) for prolapse, and 4.1% (n = 4) for both. Mean Q-tip straining angle with and without the pessary, respectively, was 34.4 (+29.7) and 57.8 (+19.5). The mean change was −23.5 (+18.5), $P < .001$. Overall, 49 (51.6%) corrected to a Q-tip angle of < 300.

In looking at factors predictive of Q-tip angle correction, we specifically addressed anterior wall prolapse. Thirty-seven of our subjects had a POP-Q point Aa at < 0. Of those, 84% had correction of their Q-tip angle, while of the remaining 56 whose point Aa was > 0, only 27% had correction of their Q-tip to < 30 degrees. The relative risk of correcting to a Q-tip angle of < 30 degrees was 5.3 (2.64-12.720) for those with point Aa < 0.

Thirty-three subjects had complete urodynamic information. Maximum urethral closure pressure (MUCP) with and without the pessary was 72.6 cm H_2O (±35.1) and 52.9 cm H_2O (±29.5), respectively. The mean difference was significantly increased by 19.7 cm H_2O (±29.5), $P < .001$. Maximum urine flow rate with and without the pessary was 10.2 mL/sec (±3.5) and 14.2 mL/sec (±5.2), respectively, for a mean difference of −4.1 mL/sec (±6.7), $P = .09$. Average flow rate, however, was significantly affected from 5.7 mL/sec without the pessary to 3.7 mL/sec with the pessary for a mean change of −2.0 (±2.2), $P < .017$ (Table 3). Overall, 60% of the subjects did not leak with the pessary in place, while 97% leaked without the pessary. Of those who did not leak with the pessary in place, 63% (12/19) corrected to a Q-tip angle of < 30 degrees. The relative risk of incontinence with the pessary was 0.41 (0.27-0.62 95% confidence intervals).

Multivariate logistic regression analysis was performed looking for factors predictive of correction of the Q-tip with the pessary in place. Point Aa remained highly significant, while higher age was marginally significant in predicting a corrected Q-tip angle. Prior surgery for prolapse, BMI, and parity were not related (Table 4).