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Effect of pessary use on hydronephrosis in women with advanced pelvic organ prolapse: a self-selected interventional trial

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Abstract

Introduction and hypothesis—The purpose of this study was to determine the proportion of women who demonstrate improvement in hydronephrosis after pessary placement for advanced pelvic organ prolapse (POP).

Methods—This was a planned subset analysis of a prospective study on the prevalence of hydronephrosis in women with advanced POP. Women with anterior or apical POP 1 cm past the hymenal remnant were enrolled and screened for hydronephrosis. All were offered expectant management, pessary placement or surgery. Participants self-selecting pessary placement were compared with those with expectant management during the study period. A follow-up ultrasound scan was performed after >3 weeks of treatment. The proportions of participants demonstrating cure/improvement were compared using Fisher's exact test.

Results—Of 180 participants enrolled, 55 had hydronephrosis for a prevalence of 30.6% (95% CI 24.3–37.6%). Of those with hydronephrosis, 39 (70.8%) chose pessary placement while 16 (30.2%) declined. A follow-up ultrasound scan was performed in 89% of participants at a median of 77 days (interquartile range 49–99 days). Intention-to-treat analysis showed no difference in improvement or resolution of hydronephrosis between women who accepted and those who declined pessary placement ($p = 0.43$). However, of 22 women successfully using a pessary, 77.3% showed improvement or cure, compared with 29.6% of 27 women not using a pessary ($p = 0.003$).

Conclusions—Successful pessary use improved hydronephrosis in over 75% of women with advanced POP. Approximately 39% of women with prolapse did not comply with pessary use and did not demonstrate hydronephrosis improvement.

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Compliance with ethical standards

Conflicts of interest None.

Keywords

Epidemiology; Obstructive uropathy; Screening

Introduction

Pelvic organ prolapse (POP) is known to be associated with hydronephrosis [1–5]. The prevalence of hydronephrosis in women with POP has been reported to range from 5% to 55, with more severe prolapse associated with more hydronephrosis [6–11]. Several case studies have shown that hydronephrosis may improve or resolve after surgical correction of prolapse. To date, there have been no studies looking specifically at whether nonsurgical treatments for prolapse may have an effect on prolapse-associated hydronephrosis. The objective of this study was to determine the proportion of women who may expect improvement or resolution of hydronephrosis after pessary placement for advanced POP.

Materials and methods

This was a planned subset analysis of a prospective cohort study of women referred to Los Angeles County (LAC) + University of Southern California (USC) Medical Center for symptomatic POP between November 2010 and May 2013. The inclusion criteria for this subset analysis were: women aged 18 years or more presenting for care with advanced POP in the apical or anterior compartments, measured by POP-Q examination (defined as Aa, Ba, or C point $>+1$) [12] and who screened positive for hydronephrosis on initial ultrasound scan. The exclusion criteria were: inability to give informed consent, prior pelvic surgery, known intrinsic renal disease, and Foley catheterization or pessary treatment in the preceding 12 months. The Institutional Review Board at the University of Southern California approved this protocol.

Basic demographic data including age, self-reported race and ethnicity, gravidity, parity, menopausal status, medical comorbidities, and prior surgery were recorded. Physical examination findings, including assessment of POP by the standardized POP-Q examination [12], systolic blood pressure, diastolic blood pressure, and body mass index were recorded. All women were offered trial of a pessary. Women who accepted pessary use were fitted with a pessary in the clinic; multiple pessary fittings were allowed as long as the patient indicated she wished to continue fitting attempts. All POP-Q examinations and pessary fittings were performed by a urogynecology fellow or attending physician. If the patient had a renal ultrasound scan or computed tomography scan within 3 months of enrollment, the images were reviewed and considered as screening for hydronephrosis. The remaining participants were screened with a transabdominal renal ultrasound scan using an Acuson S2000 machine with a 6C2 or a 4C2 curvilinear probe (Siemens, Mountain View, CA) or a S-Women's Health machine (Sonosite, Bothell, WA) with a 5–2 MHz transducer performed in the lateral decubitus position with an empty bladder. All ultrasound scans were performed by a trained technician under the supervision of an attending radiologist. All images were reviewed for adequacy and diagnosis by an attending radiologist who was blinded to the treatment group. Ultrasound findings were categorized as normal, mild, moderate or severe

according to the following definitions: mild was defined as blunting of minor calyces with minimal calyceal separation; moderate was defined as any distention of the minor and majorcalyceal systems, renal pelvis or ureters; severe was defined as severe pelvicalyceal and ureteric distention or thinning of the renal parenchyma [11].

All participants were scheduled for a follow-up visit at 3 to 12 weeks as clinically indicated. Participants fitted with a pessary were scheduled for a follow-up visit at 2 weeks and again at 6 and 12 weeks. The type of pessary placed was left to the discretion of the treating physician. Pessary use was considered successful if the woman used the pessary at least until the first follow-up visit. A repeat ultrasound scan was performed in all participants with hydronephrosis at their scheduled follow-up visit between 3 and 12 weeks. Cure or resolution of hydronephrosis was defined as a change from any degree of hydronephrosis to no hydronephrosis. Improvement in hydronephrosis was defined as a change from any degree of hydronephrosis to any less severe degree of hydronephrosis (e.g. severe to moderate or severe to mild). Worsening of hydronephrosis was defined as a change from any degree of hydronephrosis to any more severe degree of hydronephrosis (e.g. mild to moderate or mild to severe).

Statistical considerations

In order to detect resolution of hydronephrosis in a clinically significant proportion (50%) of participants with reduction of prolapse using a two-sided paired Student's t test, with $\beta = 0.8$ and $\alpha = 0.05$, a total of 33 participants with hydronephrosis were required. Expecting a 15% dropout rate, the target recruitment was for 38 participants with hydronephrosis. When discordant levels of hydronephrosis were found between kidneys in the same individual, the hydronephrosis was classified as the more severe finding. For comparisons between groups, the chi-squared test, independent samples t test, Wilcoxon rank sum test, Kruskal-Wallis test and ANOVA were used as appropriate. All analyses were performed using SAS v 9.3.

Results

A total of 206 women were approached for inclusion, and 181 were screened. Images from one woman were not saved for review, and that woman was excluded. Of the 180 remaining participants, 55 had at least mild hydronephrosis and are the subject of this report, and of these 55, 27 (49%) had mild, 22 (40%) had moderate, and 6 (10.9%) had severe hydronephrosis. The overall prevalence of hydronephrosis in the study population was 30.5% (95% CI 24.3%–37.6%). In the study cohort of 55 women, 39 agreed to a trial of pessary, while 16 declined. The demographics of those who accepted a pessary trial and those who declined are shown in Table 1.

The study flow diagram is shown in Fig. 1. Of 39 women desiring a pessary, 34 (87.2%) had a successful initial fitting and went home with a pessary in situ. The most commonly used pessary was the donut (41%) followed by the ring with support (29%) and the Gellhorn (17.6%). Of women who went home with a pessary in situ, 9 (25%) had discontinued the pessary prior to the initial follow-up visit. Five women did not return for follow-up and 1 woman had interval surgery before her first follow-up visit and all 6 were excluded from analysis.

A follow-up ultrasound scan was performed in 49 of 55 participants (89%) at a median of 77 days (interquartile range 49–99 days). Among participants who initially self-selected to a trial of pessary treatment (intention-to-treat analysis), 55.5% demonstrated improvement in the degree of hydronephrosis (mild to none, moderate to mild, severe to moderate or severe to mild) and 44.4% demonstrated complete resolution of their hydronephrosis. This was not statistically significantly different from women who declined a pessary trial (Table 2). Among the participants who were successfully using their pessary at the time of their follow-up ultrasound scan, there was a statistically significant difference in the follow-up scan compared with the scans in women who were not using a pessary (either by initial choice or because of discontinuation); improvement in hydronephrosis was seen in 77.3% and resolution was seen in 59.1% (Table 3). Participants with moderate or severe hydronephrosis were significantly more likely to show an improvement with pessary use ($p = 0.01$), while participants with mild hydronephrosis did not show significant improvement with pessary use ($p = 0.37$). Among the six participants with severe hydronephrosis, complete resolution was demonstrated in the two participants using a pessary, while no change was seen in the degree of hydronephrosis in the four participants who did not use a pessary.

Discussion

Successful pessary use improved prolapse-associated hydronephrosis in 77.3% of women at a median of 77 days. While this is less than the surgical cure rate of 95% reported by Shuk et al. [10], it nevertheless demonstrates that nonsurgical treatment of prolapse may resolve hydronephrosis in the majority of patients. Of the women who were not using a pessary, because they declined, could not be fitted or decided to discontinue pessary use, 29.6% showed improvement in hydronephrosis. This may represent test–retest variation in the ultrasound diagnosis of hydronephrosis or it may represent the dynamic nature of hydronephrosis. In the majority of women who showed improvement, the improvement was by one grade (e.g. moderate to mild, or severe to moderate). This variation is expected given that test–retest reliability and interobserver reliability in the diagnosis of hydronephrosis by ultrasonography are only fair [13].

It is clear that successful pessary use can improve patient symptoms of prolapse and improve quality of life measures [14, 15]. However, this is the largest study to show that pessary use can successfully improve prolapse-associated hydronephrosis. Unfortunately, a significant proportion of women can either not be fitted with a pessary or will discontinue pessary use. In the current study, the nonplacement/discontinuation rate was 38.8%, which is higher than the rates of 16–37% reported in the literature [16–19]. This discontinuation rate may represent a bias specific to our patient population. Patients who are found to have hydronephrosis refractory to pessary placement should be evaluated further to determine whether additional interventions are warranted.

The strengths of the study include the large sample size, the use of a control group, blinding of the ultrasound scan interpretation and strict criteria for ultrasound definitions of the severity of hydronephrosis. The weaknesses include the high discontinuation rate of pessary

use, lack of data on the effect of pessary use on symptoms of renal disease, and the fact that the study was a self-selected interventional trial, which may have introduces selection bias.

Women with advanced POP and hydronephrosis who desire to avoid surgical intervention can be counseled that pessary use improves hydronephrosis in the majority of women.

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Fig. 1.
Flow diagram of study participation

Table 1

Demographics of those who accepted and those who declined a pessary trial

	Accepted pessary (N = 39)	Declined pessary (N = 16)	p value
Age (years), mean ± SD	61.0 ± 7.6	57.1 ± 11.7	0.23 ^a
BMI (kg/m ²), mean ± SD	28.7 ± 3.9	29.2 ± 5.3	0.76 ^a
Race, N (%)			
Caucasian	5%	2%	1.0 ^b
Asian	2%	0%	
Other	32%	14%	
Ethnicity, N (%)			
Hispanic	34 (87.2)	15 (93.7)	0.66 ^b
Non-Hispanic	5 (12.8)	1 (6.3)	
Postmenopausal, N (%)	32/36 (88.9)	11/15 (73.3)	0.21 ^b
Parity, median (range)	4 (0–15)	3.5 (2–6)	0.37 ^c
Presence of, N (%)			
Hypertension	11 (28.2)	1 (6.3)	0.15 ^b
Diabetes mellitus	9 (23.1)	3 (18.7)	1.0 ^b
Smoking, N	0	0	n/a
POP-Q examination, median (range)			
gh	5 (3 to 8)	5 (4 to 7)	0.5 ^c
pb	3.25 (2 to 5)	3 (2 to 5)	0.34 ^c
tvI	9 (5 to 11)	8 (6 to 10)	0.023 ^c
C	3.5 (–5 to 11)	5 (–3 to +8)	0.78 ^c
D	–2 (–7 to 11)	–1 (–5 to 6)	0.92 ^c
Aa	3 (–1 to 3)	3 (0 to 3)	0.6 ^c
Ba	5 (0 to 11)	5 (3 to 8)	0.67 ^c

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	Accepted pessary (N = 39)	Declined pessary (N = 16)	p value
Ap	0 (-2 to 3)	-0.5 (-2 to 3)	0.38 ^c
Bp	0 (-2 to 9)	-0.5 (-2 to 8)	0.37 ^c

^aStudent's T test

^bFisher's exact test

^cWilcoxon rank sum test

Table 2

Improvement in hydronephrosis among those who accepted and those who did not accept a pessary trial (intention-to-treat analysis)

	Agreed to use (<i>N</i> = 36)	Did not agree to use (<i>N</i> = 13)	<i>p</i> value ^{<i>a</i>}
Cure	16 (44.4)	4 (30.8)	0.43
Improved	4 (11.1)	1 (7.7)	
No change	16 (44.4)	7 (53.8)	
Worse	0	1 (7.7)	

The values presented are number (%) of women

^{*a*} Fisher's exact test

Table 3

Improvement in hydronephrosis among those who successfully used and those who did not successfully use a pessary

	Successfully used (<i>N</i> = 22)	Did not use (<i>N</i> = 27)	<i>p</i> value ^{<i>a</i>}
Cure	13 (59.1)	7 (25.9)	0.0034
Improved	4 (18.2)	1 (3.7)	
No change	5 (22.7)	18 (66.7)	
Worse	0	1 (3.7)	

The values presented are number (%) of women

^{*a*}Fisher's exact test