The PESSRI study: symptom relief outcomes of a randomized crossover trial of the ring and Gellhorn pessaries

Geoffrey W. Cundiff, MD; Cindy L. Amundsen, MD; Alfred E. Bent, MD; Kimberly W. Coates, MD; Joseph I. Schaffer, MD; Kris Strohbehn, MD; Victoria L. Handa, MD

OBJECTIVE: The aim of this randomized crossover trial was to compare symptom relief and change in life impact for women using the ring with support and Gellhorn pessaries.

STUDY DESIGN: Subjects were randomized to use each pessary for 3 months. Outcome data included a visual analog satisfaction score, and quality of life questionnaires. Analysis included student's t-test, Wilcoxan Signed–rank test and logistical regression.

RESULTS: Subjects were primarily white, parous, postmenopausal women with a mean age of 61. The median POPQ stage was III. We enrolled 134 subjects and collected 3-month data on 94 ring and 99 Gellhorn subjects. There were statistically and clinically significant improvements in the majority of the PFDI and many PFIQ scales with both pessaries, but no clinically significant differences between the two pessaries.

CONCLUSIONS: The ring with support and Gellhorn pessaries are effective and equivalent in relieving symptoms of protrusion and voiding dysfunction.

Key Words: Ring pessary, Gellhorn pessary, pelvic organ prolapse

Cundiff GN, Amundsen CL, Bent AE, et al. The PESSRI study: symptom relief outcomes of a randomized crossover trial of the ring and Gellhorn pessaries. Am J Obstet Gynecol 2007;196:405.e1-405.e8.

Introduction

Pelvic organ prolapse (POP); Table 1 summarizes the abbreviated terms in the paper) is a common condition among women, with prevalence estimates from 4.3 to 8.3% for symptomatic POP.[1,2] and an anticipated increase as the population ages.[3] The impact of POP on quality of life can be deduced from the estimated 11.1% lifetime risk for having surgery for POP or urinary incontinence before the age of 80.[4] On a continuum of disease, surgical treatment likely reflects the severe end of the spectrum and undoubtedly a sizable proportion of affected women seek non-surgical treatments. Non-surgical treatments include expectant management, pelvic muscle exercises, and pessaries. Unfortunately, counseling patients on treatment is hindered by the lack of evidence to compare treatment options. The quantity and quality of evidence on surgical intervention is gradually improving, but there remains a paucity of information on non-surgical modalities. Although pelvic muscle exercises have proven efficacy for urinary and fecal incontinence, there is minimal evidence to support pelvic muscle exercises as a treatment for POP.[5] The evidence for the efficacy of pessaries, only slightly better, is limited to level II and III data.[6-10] Most studies focus on outcomes related to successful fitting and continued use with minimal data on symptom relief or patient satisfaction, and none based on validated outcome measures.

In spite of limited evidence to define optimal use, pessaries are commonly used by those who treat POP.[11,12] Moreover, there are clearly defined differences of opinion regarding their use, as revealed by a survey of the American Urogynecologic Society (AUGS; Table 1) members on pessary use. The majority of respondents to this survey (77%) reported offering pessaries as a first-line therapy, although a subset of AUGS members reserved them for patients who declined or were not candidates for surgery. Some physicians tailor the type of pessary to the patient, based on various clinical parameters, while others use the same type of pessary for all women with POP. In both groups, the ring and Gellhorn pessaries were the most commonly used pessaries.

In 1999, the National Institutes of Health held a terminology workshop for researchers in female pelvic floor disorders with the goals of establishing a standardized terminology in research related to female pelvic floor disorders, as well as setting a minimal data set for theses studies.[13] The report lamented the deficiencies of the literature for describing outcomes of interventions for pelvic floor disorders, including POP. Major methodological flaws cited included; failure to control for confounding by random assignment, variability in duration of follow-up, poor external validity, inadequate power to detect clinically important differences, and marked variability in outcome assessment. Outcome assessment was specifically criticized for lack of blinding, for the use of non-validated and non-standardized outcome measures, and for failure to obtain patients'

From the Departments of Gynecology and Obstetrics, Johns Hopkins School of Medicine, Baltimore, MD (Drs Cundiff and Handa); Duke University Medical Center, Durham, NC (Dr Amundsen); Dalhousie University School of Medicine, Halifax, NS, Canada (Dr Bent); Austin, TX (Dr Coates); Department of Obstetrics and Gynecology, University of Texas Southwestern Medical Center, Dallas, TX (Dr Schaffer); and Dartmouth-Hitchcock Medical Center, Lebanon, NH (Dr Strohbehn).

Correspondence and Reprints: Geoffrey Cundiff, M.D., 1081 Burrard St, Vancouver, BC V6Z 1Y6 Canada, Phone (604)806-8166, Fax (604)875-2987 geoff.cundiff@gmail.com

0002-9378/$32.00

doi: 10.1016/j.ajog.2007.02.018

TABLE 1
Alphabetical summary of abbreviated terms

AUGS	American Urogynecologic Society
Clinical significance	Changes in pre and post intervention outcome parameters that are statistically significant and equal greater than half the standard deviation of the pre-intervention score.[18]
CONSORT	Consolidated Standards of Reporting Trials: A checklist and a flow diagram showing ideal reporting of a randomized control trial.[14]
CRADI	Colorectal-Anal Distress Inventory: One of three scales of the Pelvic Floor Distress Inventory. The CRADI scale focuses on colorectal symptoms. It has 17 items with 4 subscales (obstruction, incontinence, pain/irritation, rectal prolapse).[17]
CRAIQ	Colorectal-Anal Impact Questionnaire: One of three scales of the Pelvic Floor Impact Questionnaire. The CRAIQ scale is designed to assess life impact in women with colorectal and anal symptoms and prolapse.[17]
HRQOL	Health-related quality of life
IIQ	Incontinence Impact Questionnaire: One of three scales of the Pelvic Floor Impact Questionnaire. The IIQ scale is designed to assess life impact of urinary incontinence symptoms.[17]
PFDI	Pelvic Floor Distress Inventory: Health related quality of life instrument, designed to assess the presence and bother of symptoms in women with Pelvic Floor Dysfunction. The PFDI has 46 questions using a Likert scale and has 3 scales: the CRADI, POPDI, and UDI.[17]
PFIQ	Pelvic Floor Impact Questionnaire: Health related quality of life instrument, designed to assess the life impact of pelvic floor symptoms in women with pelvic floor disorders. The PFIQ has a parallel structure to the PFDI with 3 Scales: CRAIQ (31 items), POPIQ (31 items), and IIQ (31 items); each with 4 subscales: travel, social, emotional, physical.[17]
POP	Pelvic Organ Prolapse
POPDI	Pelvic Organ Prolapse Distress Inventory: One of three scales of the Pelvic Floor Distress Inventory. The POPDI scale focuses on prolapse symptoms. It consists of 16 questions regarding symptoms of POP with 3 subscales (General, Anterior, Posterior).[17]
POPIQ	Pelvic Organ Prolapse Impact Questionnaire: One of three scales of the Pelvic Floor Impact Questionnaire. The POPIQ scale is designed to assess life impact of pelvic organ prolapse symptoms.[17]
POP-Q	Pelvic Organ Prolapse Quantification: An internationally adopted system for quantifying and staging pelvic organ prolapse. POP Staging includes stages 0, I, II, III, IV, V.[15]
SFQ	Sexual Function Questionnaire (validated but not published)
UDI	Urinary Distress Inventory: One of three scales of the Pelvic Floor Distress Inventory (also published independently). The UDI scale focuses on urinary symptoms. It consists of 29 questions regarding symptoms of the urinary tract with 3 subscales (Obstructive/Discomfort, Irritatitve, and Stress).[17]
UIQ	Urinary Impact Questionnaire: One of three scales of the Pelvic Floor Impact Questionnaire. (also published independently). The UIQ scale is designed to assess life impact of urinary symptoms. A questionnaire designed to assess life impact of urinary symptoms.[17]
VAS	Visual Analog Scale: Used to assess subject satisfaction at each follow-up using a 10 cm scale. 0=no satisfaction; 10 = complete satisfaction

views through the use of valid and reliable clinometric questionnaires. These observations hold true today with respect to the literature on pessaries used for POP. This study was undertaken to help address these shortcomings. We sought to design a study that would meet the Consolidated Standards of Reporting Trials standards and use health-related quality of life (HRQOL; Table 1) instruments to define optimal pessary use, by describing the efficacy of the two most commonly used pessaries, the ring with support and Gellhorn pessary, for relieving symptoms attributed to POP.

Materials and Methods

The study was a multi-centered randomized crossover trial, to compare the ring pessary with support to the Gellhorn pessary in women with symptomatic pelvic organ prolapse. Each of the six participating sites obtained Institutional Review Board approval and all subjects provided signed informed consent before participation. We drew subjects from the clinical practices at each site, enrolling women presenting with symptomatic pelvic organ prolapse (stage II or greater by Pelvic Organ Prolapse Quantification (POP-Q; Table 1) staging, who expressed interest in non-surgical treatment. Women were excluded for pregnancy, prior pessary use, and vaginal narrowing or agglutination on exam that was felt to compromise pessary use. Figure 1 presents the Consolidated Standards of Reporting Trials (CONSORT; Table 1)

diagram summarizing the flow of subjects in the study.[14]

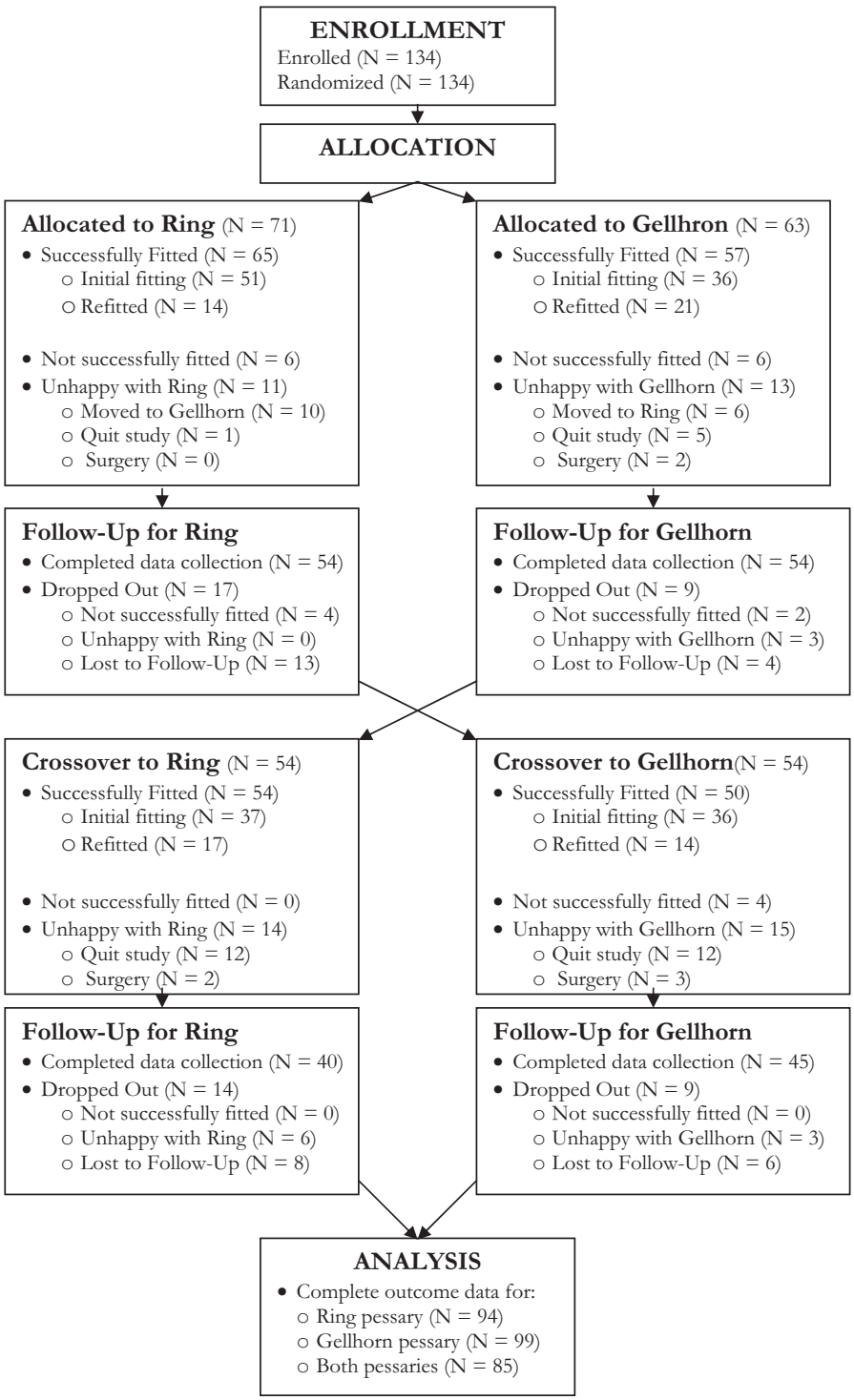
Following enrollment, randomization assigned subjects to one of two groups that differed in the sequence of pessary use, and subjects were assigned to the two groups with equal probability. Randomization used computer-generated random numbers in permuted blocks of variable size (6-10), allocated by sealed opaque envelopes. While masking of subjects and clinicians was not feasible, we coded data collection to permit blinding during analysis.

Following randomization and initial data collection, we fitted subjects with the first pessary. Those who were successfully fitted were asked to wear the pessary for 3 months with interval data collection at 1, 6, and 12 weeks. Subjects could discontinue pessary use at anytime during the 3-month period for any reason, although for subjects who did not complete the 3-month intervention we accelerated data collection. We then fitted the subject with the second pessary and the sequence repeated.

Patients returned 1-week post-pessary fitting for a vaginal exam and refitting if necessary. At this visit, we attempted pessary teaching, including removal, replacement, and cleaning. To ensure subject safety, subjects also returned 6 weeks after pessary fitting for a vaginal exam and assessment of adverse events. After completing the data collection for both pessary types, we allowed subjects to choose further treatment, as they desired. They returned at 1 year for the final data collection regarding continuation of pessary use or subsequent surgery.

We collected anatomical and clinometric data at study enrollment and following 3 months of pessary use, or sooner if the subject declined further pessary use prior to 3 months. The anatomical assessment included POP-Q staging[15], pelvic muscle grading[16], assessment for perineal descent, perineal reflexes, assessment for atrophy and erosions, and a wet prep. Questionnaires completed by subjects at baseline and follow-up included: Pelvic Floor Distress Inventory (PFDI; Table 1) and Pelvic Floor Impact Questionnaires (PFIQ; Table 1);[17] and a validated but unpublished

FIGURE 1
Consort Diagram



Sexual Function Questionnaire (SFQ; Table 1) [personal communication, Barber]. The PFDI is a 43-question pelvic floor dysfunction specific quality of life instrument that uses a Likert scale to provide both a symptom survey and bother scale. It includes three scales: the Urinary Distress Inventory (UDI; Table 1), Pelvic Organ Prolapse Distress Inventory (POPDI; Table 1) and Colorectal Distress Inventory (CRADI; Table 1) focused on urinary symptoms, prolapse

symptoms, colorectal symptoms respectively. Within each scale there are subscales that focus on specific categories of symptoms. Higher scores represent more bother. The PFIQ is an impact questionnaire with a parallel structure providing for three impact scales; the Urinary Impact Questionnaire (UIQ; Table 1), the Pelvic Organ Prolapse Impact Questionnaire (POPIQ; Table 1) and the Colorectal Impact Questionnaire (CRAIQ; Table 1). Each of the scales of the PFIQ have 4 subscales; travel, social, emotional, and physical subscales. Higher scores represent more impact. We defined clinically significant changes in the PFDI and PFIQ scores based on a change of greater than half the standard deviation of the pre-intervention score. This approach is based on the recommendations of Sloan and colleagues, who propose this as a conservative estimate of an effect size that is clinically meaningful when using quality of life questionnaires (Table 1).[18] In addition to the PFDI and PFIQ, we assessed patient satisfaction at each follow-up, using a visual analog scale (VAS; Table 1) with a 10cm linear continuum in which 0 represents no satisfaction and 10 represents complete satisfaction.

Given the absence of prior studies addressing the effectiveness of pessaries in alleviating symptoms associated with pelvic organ prolapse, we used descriptive data from a survey of the American Urogynecologic Society on pessary use, to calculate study sample size.[12] In this survey, the majority of respondents (97%) were of the opinion that pessaries are effective in relieving prolapse associated symptoms. Responses about specific support defects varied from 60–87% with a mean value of 75%. Assuming a difference in symptom relief between the two pessaries of 50 and 75%, and figuring a probability for an alpha error of 5% and beta error of 20%, power analysis revealed a necessary study size of 130 with 65 in each group.

Analysis of differences in patient satisfaction used a paired student's *t*-test. We analyzed differences in the PFDI and PFIQ scale scores, both before and after pessary use, and between interventions, using the Wilcoxan Signed-rank test, due to non-normal distributions. To compare changes in the PFDI and PFIQ scale scores with VAS scores, we used the student's *t*-test. Two-way analysis was used throughout. We used linear regression analysis to look for associations between changes in PFDI scale scores and independent variables, including age, estrogen status, prior hysterectomy, pelvic muscle strength, size of the genital hiatus, and specific support defects.

RESULTS

The study enrolled 134 subjects with 71 initially randomized to the ring pessary and 63 to the Gellhorn pessary. The population had a mean age of 61 (30-89) and was primarily comprised of parous (median = 3, range = 0-11) postmenopausal women (82%) with 26% on estrogen replacement therapy. Half of subjects (67) had a chronic disease that might impact pessary use, including 42 (31%) with arthritis, 25 (19%) with peripheral vascular disease, 18 (13%) with pulmonary disease, 15 (11%) with diabetes mellitus, and 5 (3%) with connective tissue disease. Additionally, 14 (10%) reported major depression. Most subjects (80%) described their lifestyle as active with 13% reporting heavy lifting. Prior surgeries included hysterectomy (45%), incontinence surgery (10%), and prolapse surgery (9%). The median POPQ stage was III, including 48% with stage II, 42% with stage III, and 10% with stage IV. Anterior prolapse predominated in 51%, apical prolapse in 34%, posterior prolapse in 10%, and no site predominated in 5%. Fourteen percent had perineal descent. Table 2 lists baseline characteristics by allocation group, showing no significant differences between groups.

Figure 1 provides specifics on subject dropout and continuation. Of the 134 subjects randomized and allocated, 108 subjects completed data collection for the first pessary trial. Fifty-four women were allocated to the ring first, although 13 completed data collection before 3 months; 2 because they could not be properly fitted, and 11 because they were unhappy with the ring pessary. Similarly, 54 subjects were allocated to the Gellhorn first and completed data collection, although 14 completed data collection before 3 months; 4 because they could not be properly fitted, and 10 because they were unhappy with the Gellhorn pessary. The 108 subjects that completed data collection for the first pessary trial included 54 who crossed over to the ring pessary and 54 who crossed over to the Gellhorn pessary. Of those that used the ring second, 40 completed data collection, although 8 completed data collection before 3 months because they were unhappy with the ring. Similarly, of those that used the Gellhorn second, 45 completed data collection, although 16 completed data collection prior to 3 months; 4 because they could not be properly fitted and 12 because they were unhappy with the Gellhorn. With both pessary trials taken together, there were 94 subjects with complete data for the ring pessary, 99 with complete data for the Gellhorn pessary, and 85 with complete data for both pessaries.

Forty-nine subjects did not complete data collection for one of the pessary trials. This included 31 who quit the ring pessary (4 could not be fitted, another 6 were unhappy with the ring and quit, including 2 who had surgery, and 21 were lost to follow-up). Additionally, 18 quit the Gellhorn pessary (2 could not be fitted, another 6 were unhappy with the Gellhorn and quit, including 2 who had surgery, and 10 were lost to follow-up). Subjects who would not wear a pessary for 3 months tended to be younger (57 v. 66 years, $P = 0.0004$) and were less apt to be white ($P = 0.006$). Eleven subjects could not be fitted with at least one of the pessaries, including 6 (4%) that could not be fitted with the ring pessary, 10 (8%) that could not be fitted with the Gellhorn pessary, and 5 (4%) that were not successfully fitted with either pessary. Successful pessary fitting required a refitting in 28% for the ring pessary and 33% for the Gellhorn pessary.

There were no significant differences in the pretreatment scores for the PFDI scales between the randomization groups ($P = 0.37$. for UDI, $P = 0.38$ for POPDI, and $P = 0.50$ for CRADI), suggesting that the two groups were similar with respect to POP symptoms. Similarly, there were no significant differ-

TABLE 2
Baseline characteristics of subjects, by initial allocation group

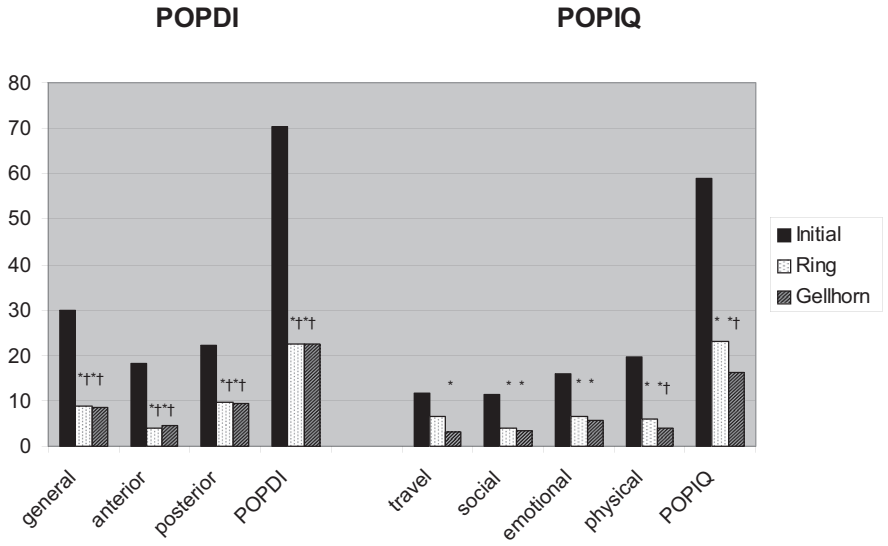
		Ring → Gellhorn N = 71	Gellhorn → Ring N = 63	*P*-value
Age (years)	Mean ± SD	60.4 ± 15.113.5	61.5 ± 13.6	0.54
Race*	White/Caucasian	47 (66%)	39 (62%)	
	Black/African American	12 (17%)	8 (13%)	
	Other	12 (17%)	16 (25%)	
Hispanic*		12 (17%)	15 (24%)	0.22
Chronic Disease		38 (54%)	29 (46%)	0.39
Major Depression		4 (6%)	10 (16%)	0.06
Lifestyle*	Sedentary	13 (18%)	14 (22%)	0.57
	Active	46 (65%)	44 (70%)	0.53
	Active with heavy lifting	12 (17%)	5 (8%)	0.23
Smoking	Never	52 (73%)	49 (78%)	0.54
	Past	8 (11%)	4 (6%)	0.32
	Present	11 (16%)	10 (16%)	0.95
Total Previous Births	Median, range	3 (0-8)	3 (1-11)	
Previous Vaginal Births	Median, range	3 (0-8)	3 (1-11)	
Previous Cesarean Births	Median, range	0 (0-2)	0 (0-1)	
Estrogen status	Premenopausal	12 (17%)	12 (19%)	0.75
	Postmenopausal	59 (83%)	51 (81%)	0.75
	Estrogen therapy	19 (27%)	16 (25%)	0.85
Prior pelvic muscle exercises		18 (25%)	19 (30%)	0.53
Prior Hysterectomy		26 (37%)	33 (52%)	0.07
Prior Surgery for Incontinence		8 (11%)	6 (10%)	0.74
Prior Surgery for Prolapse		5 (7%)	7 (11%)	0.41
Nonambulatory		8 (11%)	7 (11%)	0.98
BMI > 25		3 (4%)	0	0.10
POP-Q Stage***	Stage II	36 (51%)	30 (48%)	0.72
	Stage III	29 (41%)	25 (40%)	0.89
	Stage IV	6 (8%)	8 (12%)	0.24
Predominant compartment	Anterior	35 (49%)	34 (54%)	0.59
	Apical	24 (34%)	21 (33%)	0.95
	Posterior	7 (10%)	6 (10%)	0.94
Pelvic muscle strength	Median (range)	2 (0-9)	4 (0-9)	0.61

* Self-reported by the subject

ences in the pretreatment scores of the PFIQ scales between the randomization groups ($P = 0.88$ for UIQ, $P = 0.30$ for POPIQ, and $P = 0.79$ for CRAIQ).

Following both pessaries, there was a statistically significant change in the majority of the PFDI and PFIQ scale scores. Figure 2 presents the change in the POPDI and POPIQ scores. Both the POPDI and POPIQ scales and subscales had statistically significant changes for both pessaries, although there were no significant differences in terms of improvement in POPDI ($P = 0.99$) or POPIQ ($P = 0.29$) between the ring and Gellhorn pessaries. Using Sloan and colleagues' recommendations for judging clinical significance of patient reported data,[18] the POPDI and all of its subscales were clinically significant for both pessaries. However, the only clinical significance for the POPIQ was the physi-

FIGURE 2
Changes in the POPDI and POPIQ, by pessary type



*Statistical significance ($P < .05$).
†Clinical significance.

cal subscale and the total POPIQ score for the Gellhorn pessary.

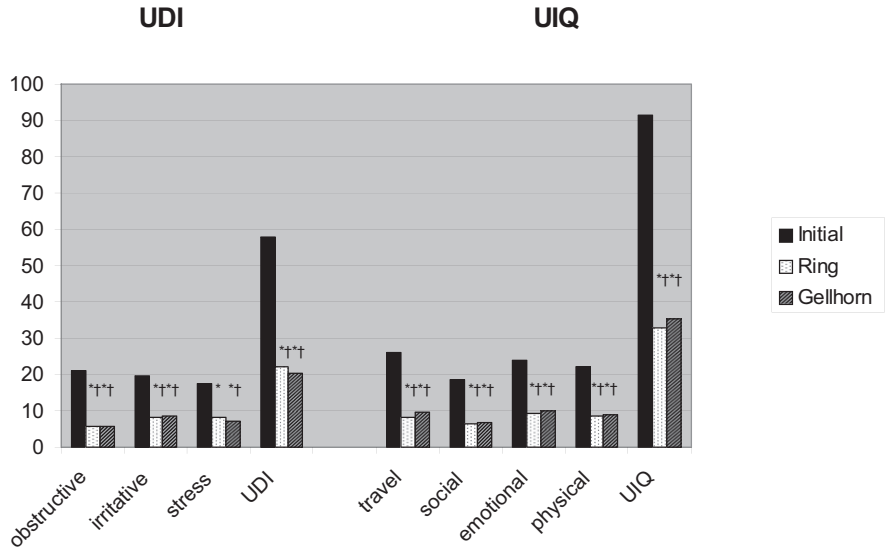
The UDI and UIQ scales and subscales also showed statistically significant and clinically significant improvements, with the exception of the stress subscale for the ring pessary (Figure 3). The improvements in these scales were not different between the two pessaries (UDI; $P = 0.62$, UIQ; $P = 0.74$).

While the CRADI and CRAIQ scale scores all showed statistically significant improvements, with no differences between the two pessaries (CRADI; $P = 0.91$, CRAIQ; $P = 0.29$), only the total CRADI score and the obstructive and irritative subscales reached the level of clinical significance (Figure 4).

Based on bimodal distributions of the VAS scores for both pessaries, we dichotomized the VAS scores into high satisfaction (≥8) and low satisfaction (<8). Table 3 presents the change in PFDI and PFIQ scores by satisfaction category for both pessaries. For both pessaries there was a larger improvement in all scales of the PFDI for those with high satisfaction than those with low satisfaction, although this difference only reached statistical significance for the Gellhorn pessary. Similarly, the PFIQ scales had a larger improvement in the satisfied cohort for both pessaries, although it only reached clinical significance in the UIQ for the Gellhorn pessary.

For the Gelhorn pessary there was an association between stage, and change in POPDI scores, but not UDI or CRADI scores. Higher stage associated with more improvement in these scales. Anterior predominant and apical predominant prolapse were also associated with the change in POPDI scores for the Gelhorn pessary, although these variables dropped out when controlled for stage. There was also a direct association of prior surgery for incontinence or prolapse, and Latin ethnicity with change in all scales of the PFDI, including the POPDI, UDI, and CRADI. Posterior predominant prolapse was associated with improvement in CRADI scores for both pessaries.

FIGURE 3
Changes in the UDI and UIQ, by pessary type



*Statistical significance ($P < .05$).
†Clinical significance.

Comment

Increasingly, expert opinion recommends pessaries as first-line therapy for POP[19] and this seems to reflect common practice. For example in a survey of practitioners focused on pelvic floor dysfunction, 98% of responders reported using pessaries in their practice, including 77% who used them as first line therapy for pelvic organ prolapse.[12] The literature on pessary use to date has focused primarily on successful pessary fitting and continuation rates.[6,7,8] Shortcomings include the absence of outcomes data for symptom relief and a lack of information about differences in efficacy for different types of pessaries. This investigation ad-

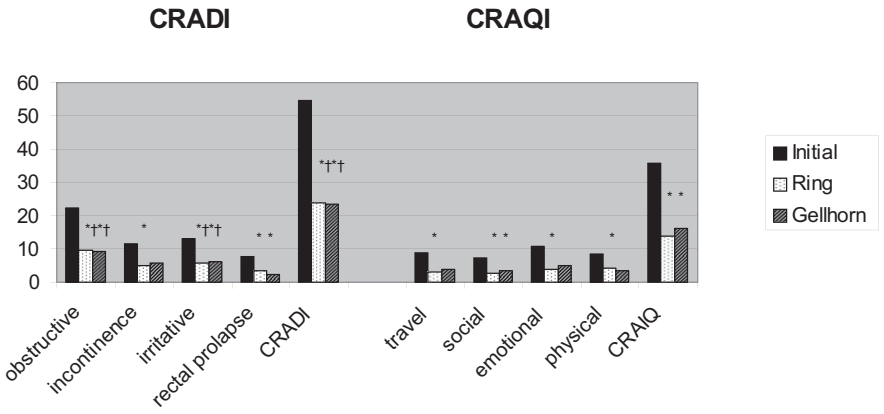
dresses these knowledge gaps. We chose to study the ring with support and Gellhorn pessaries to maximize external validity, as previous data suggest that while most physicians tailor the choice of pessary to the patient, the two most commonly used pessaries are the ring with support and Gellhorn varieties.[12] Our study is comparable to prior investigations with respect to rates of successful pessary fitting (92%) and continuation (60% for the first 3-month trial and 57% for the second).[6,7,8]

While our data showed statistically significant improvements in the majority of the PFDI subscales, we chose to consider clinically significant changes based on a change of greater than half the standard deviation of the pre-intervention score. This approach is based on the recommendations of Sloan and colleagues, who proposes this as a conservative estimate of an effect size that is clinically meaningful when using quality of life questionnaires.[18] Even using this strict criterion, both pessaries relieved symptoms commonly attributed to pelvic organ prolapse. This was most notable in the POPDI scale, although it was also true for the obstructive and irritative subscales of the UDI and the obstructive and irritative subscales of the CRADI.

Overall, symptoms commonly attributed to POP do not appear to have linear associations with POP severity. The protrusion symptoms (POPDI scale) seem to have the highest correlations with POP severity.[20] Urinary incontinence symptoms (UDI Scale) tend to be inversely related to POP severity, a relationship that has been hypothesized to result from urethral obstruction in more severe POP. This relationship would tend to decrease the magnitude of improvement in incontinence symptoms by lowering the pre-intervention score. This may explain why pessaries, which are commonly used for urinary incontinence, failed to show a clinically significant change in the UDI stress subscale in this trial. Symptoms related to defecatory dysfunction (CRADI scale) have been reported to have the weakest correlation with POP, presumably reflecting the breadth of the differential diagnosis for these symptoms.[20] Nevertheless, improvements in the CRADI score following pessary use in this study were associated with posterior predominant prolapse. This parallels the relief of obstructive colorectal symptoms reported in some surgical series for posterior prolapse and contradicts common preconceptions that pessaries are less effective for posterior predominant prolapse.[12]

Both pessaries provided relief of prolapse associated symptoms, yet only the Gellhorn pessary provided clinically significant improvements in the impact score for pelvic organ prolapse (POPIQ). Moreover, while high satisfaction with the Gellhorn was associated with symptom improvement, this was not the case for the ring with support. This suggests that high satisfaction with the ring with support is driven by something else. Other factors commonly used in tailoring the type of pessary, including the predominant POP, weak pelvic floor musculature, and size of the genital hiatus, did not associate with symptom relief in our study, although prior surgery for incontinence or prolapse appeared to

FIGURE 4
Changes in the CRADI and CRAIQ, by pessary type



*Statistical significance ($P < .05$).
†Clinical significance.

TABLE 3
Comparison of changes in PFDI and PFIQ scores by satisfaction group

	Ring			Gellhorn		
	Low (n = 44)	High (n = 90)	*P*	Low (n = 52)	High (n = 82)	*P*
ΔUDI	−21.7	−42.64	0.029	−17.83	−50.01	.001
ΔPOPDI	−40.3	−51.65	0.25	−27.42	−60.62	0.001
ΔCRADI	−22.61	−34.67	0.26	−16.36	−40.49	0.012
ΔUIQ	−46.55	−64.48	0.33	−25.64	−75.56	0.006
ΔPOPQI	−31.19	−38.07	0.68	−34.75	−47.59	0.38
ΔCRAQI	−24.13	−20.74	0.79	−10.65	−25.56	0.17

confer some benefit for predicting symptom relief.

In counseling patients about pessaries, it seems reasonable to anticipate the relief of symptoms related to pelvic organ prolapse, including protrusion symptoms, and symptoms related to urinary and defecatory obstruction. Patients with more severe stages of POP and those with prior pelvic floor surgery might anticipate a better response. In choosing a pessary for a patient, the ring with support and Gellhorn pessaries appear to be equivalent in relieving prolapse associated symptoms. ■

ACKNOWLEDGEMENTS

The design of this study was facilitated by the American Urogynecologic Society's Research Retreat for Multi-Centered Studies, August 1997. The study was also supported by an unrestricted grant from Milex Inc, which was limited to providing pessaries for the study.

REFERENCES

1. Tegerstedt G, Maehle-Schmidt M, Nyren O, Hammarstrom M. Prevalence of symptomatic pelvic organ prolapse in a Swedish population. Int Urogynecol J Pelvic Floor Dysfunct 2005;16:497-503.

2. Woodman PJ, Swift SE, O'boyle AL, Valley MT, Bland DR, Kahn MA, Schaffer JI. Prevalence of severe pelvic organ prolapse in relation to job description and socioeconomic status: a multicenter cross-sectional study. Int Urogynecol J Pelvic Floor Dysfunct 2005;1-6.

3. Luber KM, Boero S, Choe JY. The demographics of pelvic floor disorders: current observations and future projections. Am J Obstet Gynecol 2001;184:1496-501; discussion 1501-3.

4. Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol 1997;89:501-6.

5. Thakar R, Stanton S. Management of genital prolapse. BMJ 2004;324:1258-62.

6. Sulak PJ, Kuehl TJ, Shull BL. Vaginal pessaries and their use in pelvic relaxation. J Reprod Med 1993;38:919-23.

7. Clemons JL, Aguilar VC, Tillinghast TA, Jackson ND, Myers DL. Risk factors associated with an unsuccessful pessary fitting trial in women with pelvic organ prolapse. Am J Obstet Gynecol 2004;190:345-50.

8. Clemons JL, Aguilar VC, Tillinghast TA, Jackson ND, Myers DL. Patient satisfaction and changes in prolapse and urinary symptoms in women who were fitted successfully with a pessary for pelvic organ prolapse. Am J Obstet Gynecol 2004;190:1025-9.

9. Mutone MF, Terry C, Hale DS, Benson JT. Factors which influence the short-term success of pessary management of pelvic organ prolapse. Am J Obstet Gynecol 2005;193:89-94.

10. Hanson LA, Schulz JA, Flood CG, Cooley B, Tam F. Vaginal pessaries in managing women with pelvic organ prolapse and urinary incontinence: patient characteristics and factors contributing to success. Int Urogynecol J Pelvic Floor Dysfunct 2005.

11. Pott-Grinstein E, Newcomer JR. Gynecologists' patterns of prescribing pessaries. J Reprod Med 2001;46:205-8.

12. Cundiff GW, Weidner AC, Visco AG, Bump RC, Addison WA. A survey of pessary use by members of the American Urogynecologic Society. Obstet Gynecol 2000;95:931-5.

13. Weber AM, Abrams P, Brubaker L, Cundiff GW, Gary Davis G, Dmochowski RR, Fischer J, Hull T, Nygaard I, Weidner AC. The standardization of terminology for researchers in female pelvic floor disorders. Int Urogyn J 2001;12:178-86.

14. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. Lancet 2001;357:1191-4.

15. Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JO, Klarskov P, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 1996;175:10-7.

16. Brink C, Wells T, Sampselle CM, Tallie ER, Mayer R. A digital test for pelvic muscle strength in women with urinary incontinence. Nurs Res 1994;43:352-6.

17. Barber MD, Kuchibhatla MN, Pieper CF, Bump RC. Psychometric evaluation of 2 comprehensive condition-specific quality of life instruments for women with pelvic floor disorders. Am J Obstet Gynecol 2001;185:1388-95.

18. Sloan JA, Cella D, Hays RD. Clinical significance of patient-reported questionnaire data: another step towards consensus. J Clin Epid 2005;58:1217-9.

19. Weber AM, Richter HE. Pelvic organ prolapse. Obstet Gynecol 2005;106:615-34.

20. Ellerkmann RM, Cundiff GW, Melick CF, Nihira MA, Leffler K, Bent AE. Correlation of symptoms with location and severity of pelvic organ prolapse. Am J Obstet Gynecol 2001;185:1332-8.