



Published in final edited form as:

*Female Pelvic Med Reconstr Surg.* 2013 ; 19(3): 142–147. doi:10.1097/SPV.0b013e31827e857c.

## PATTERNS OF PESSARY CARE AND OUTCOMES FOR MEDICARE BENEFICIARIES WITH PELVIC ORGAN PROLAPSE

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### Abstract

**Objectives**—Using a national dataset, we sought to assess patterns of pessary care in older women with pelvic organ prolapse (POP) and subsequent outcomes, including rates of complications and surgical treatment of POP.

**Methods**—Public Use Files from the United States Centers for Medicare and Medicaid Services were obtained for a 5% random national sample of beneficiaries from 1999 to 2000. Diagnostic and procedural codes (ICD-9-CM and CPT-4) were used to identify women with pelvic organ prolapse (POP) and those treated with pessary. Individual subjects were followed longitudinally for nine years. Across this duration, patient care and outcomes (e.g., return clinic visits, repeat pessary placements, complications, and rate of surgical treatment of prolapse) were assessed.

**Results**—Of 34,782 women diagnosed with POP, 4,019 (11.6%) were treated with a pessary. In the initial three months after pessary placement, 40% underwent a follow-up visit with the provider who had placed the pessary, and through nine years after the initial fitting, 69% had such a visit. During this period, 3% of subjects developed vesicovaginal or rectovaginal fistulas, and 5% had a mechanical genitourinary device complication. Twelve percent of women underwent surgery for POP by one year; with 24% by nine years.

**Conclusions**—Pessary can be effectively used for management of POP in older women. Despite this, a low percentage of Medicare beneficiaries undergo pessary fitting. Lack of continuity of care results in a small, but unacceptable rate of vaginal fistulas.

### Keywords

pelvic organ prolapse; Medicare; pessary; Public Use Files

## INTRODUCTION

Pelvic organ prolapse (POP) is a common medical condition that negatively impacts quality of life for many women<sup>1</sup>. Pelvic floor disorders, including POP, urinary incontinence, and fecal incontinence, affect almost a quarter of the adult female population in the United States<sup>1</sup>. This incidence increases to almost 50% among women over the age of eighty. The United States Census Bureau projects that the number of women 65 years old and over will double and exceed 40 million by the year 2030<sup>2</sup>. With the aging United States population, there has been a renewed interest in the use of non-surgical treatments for POP. A survey distributed to members of the American Urogynecologic Society in 2000 showed that 77% of respondents offered pessaries to their patients as a first-line therapy for POP<sup>3</sup>. The majority of women with symptomatic POP choose a pessary over surgery as their initial treatment<sup>4</sup>.

Pessaries have been used to treat POP since the beginning of recorded medical history. Hippocrates suggested the use of half of a pomegranate for “womb prolapse” in the fifth century BC. Despite the evolution of various other treatments for POP through the centuries, pessaries remain a viable and practical option. There are very few contraindications to their use, which allows clinicians to offer pessaries to almost all patients presenting with prolapse<sup>5,6</sup>.

Even though pessary is a low risk, minimally invasive treatment option for POP, complications can occur with its use. Most are mild, such as odor or discharge; however, complications associated with high morbidity, such as fistulas, pessary impaction, vaginal fibrosis with stricture, and enterocele rupture with vaginal evisceration, have been reported<sup>7-11</sup>.

Despite being a first line therapy for many patients, there are currently no clear guidelines on the management of women with pessaries. This study used a national dataset to identify patterns of pessary care and subsequent safety and effectiveness outcomes, including rates of complications and pessary discontinuation requiring definitive prolapse surgery.

## MATERIALS AND METHODS

Upon review of the protocol for this retrospective analysis of de-identified, longitudinal patient data, an exemption was obtained from the Institutional Review Board at the University of California, Los Angeles. Women with the diagnosis of pelvic organ prolapse in 1999-2000 were identified from a 5% national random sample of Medicare beneficiaries from the Public Use Files provided by the Centers for Medicare and Medicaid Services (CMS). Subjects were selected to be in the 5% beneficiary sample on the basis of the last two digits of their Medicare Health Insurance Claim number. Medical care and outcomes were identified on the basis of diagnosis and procedure codes according to the International Classification of Disease, 9th edition, Clinical Modification (ICD-9-CM) system or of procedure codes according to the Current Procedural Terminology, 4th edition (CPT-4) system. Subjects receiving a pessary were identified if they had a code for pessary placement (57160) during the two-year index period 1999-2000. Individual de-identified subjects were each longitudinally tracked for nine years, through 2009. Follow-up clinic visits (99211-99215), and repeat pessary placements (51760) were used to identify and measure follow-up (Appendix 1). The non-specific nature of the 99211-99215 codes does not guarantee that patients underwent a pelvic exam at the time of these visits; therefore, we specifically analyzed follow-up by provider type.

Because the 57160 code is used for fitting of a new pessary, repeat pessary exchanges were considered to have occurred if a follow-up clinic visit took place, which might artificially

inflate the presumed rate of follow up that includes pessary care. The “vaginal irrigation after pessary” code was encountered infrequently, but was considered to indicate a follow up pessary visit as well. To further increase accuracy, repeat follow-up clinic visit were determined for specific specialties as well as for the same provider who placed the initial pessary. Pessary changes were evaluated quarterly for the first two years and annually thereafter. The rates of complications and outcomes, identified by ICD-9 and CPT-4 codes, including mechanical device complications and the rate of surgery for pelvic organ prolapse, were determined within the same time interval (Appendix 2). Demographic and clinical characteristics, including co-morbidities and complication rates were obtained from an analytical file created by linking encrypted beneficiary identification numbers from three Medicare Standard Analytic Files representing hospital inpatient, hospital outpatient, and physician-supplier part B care<sup>12,13</sup>. ICD-9-CM codes were used to calculate Charlson scores to measure co-morbidity. The Charlson score is an index measurement totaling scores from nineteen weighted co-morbidities to predict the likelihood of one-year mortality for a patient. A higher score indicates greater co-morbidity<sup>14</sup>. All descriptive analyses were conducted using SAS version 9.2 (SAS Institute, Inc., Cary, North Carolina).

## RESULTS

Of 34,782 women diagnosed with POP in 1999-2000, 4,019 (11.6%) were treated with a pessary. Twenty four percent underwent surgery for POP (about half of which had the surgery in the first year). Majority of the POP surgery was reconstructive with only 3% rate of an obliterative procedure (colpocleisis). Apical repair was the most commonly performed prolapse repair performed. The second most common procedure was a combined anterior and posterior colporrhaphy, followed by an anterior colporrhaphy alone.

The majority of pessary recipients were Caucasian (94%). Main co-morbidities identified in this cohort were diabetes (10%), congestive heart failure (9%), malignancy (7%), chronic respiratory disease (5%), dementia (3%), renal disease (2%), and cerebrovascular disease (3%). However, most women (95%) had a Charlson score less than or equal to three (Table 1). The all-cause mortality rate through nine years was 30.4%.

The prevalence of prolapse treatment with pessaries appeared to be uniform throughout United States with a slightly higher rate of 15% in the Northeastern region of the country. Among pessary users, rates of placement progressively increased with age from 4.9% in women age 65 to 69 to 24.7% in the group 85 and over. The vast majority of pessaries were placed by gynecologists (84%), 3.8% by a provider in a multi-specialty or group practice, 3.5% by urologists, and 3% by an internist or family practitioner (Table 2).

In the initial three months after pessary placement, 40% underwent a follow-up visit with the provider who had placed the pessary, and through nine years after the procedure, 69% had such a visit. Overall rate of follow up (by any provider, and therefore not specific to pessary follow-up) was 84% in the first three months and 98% at nine years (Table 3).

In the ensuing nine years following pessary placement, 3% of subjects developed vesicovaginal or rectovaginal fistulas, 5% had a mechanical genitourinary device complication. Other complications associated with pessary use, include 19% urinary tract infections and 6% vaginitis diagnosed within the first three months after initial pessary placement. Vaginitis was documented in 35% of patients through the nine years follow-up. Over time, a large percentage of women acquired a diagnosis of (or treatment for) urinary retention. Rates of dyspareunia also increased over time (Table 4).

## DISCUSSION

Pessaries offer a low morbidity, minimally invasive treatment option for women with symptomatic POP while achieving comparable rates of success when compared to surgical outcomes<sup>6,15</sup>. They are cited as being a preferred first line treatment option for POP by both health care providers and patients and often serve as definitive treatment for those who are poor surgical candidates<sup>3,4</sup>. Our study confirms that pessaries represent an appropriate treatment choice for many older women. The mortality rate of 30.4% at nine years exceeded the rate of surgical repair during that time (24%) in this cohort. But despite these and contrary to the results of surveys and polls, our study highlights a low utilization of pessaries in women aged 65 years and older. In our analysis of over 34,000 women with POP, only 11.6% were identified as being treated with a pessary. The ICD-9 codes for POP do not currently have modifiers, thus not allowing to ascertain severity of prolapse or degree of symptoms. Thus, it is possible that a low rate of pessary utilization in our study is partially due to the inclusion of asymptomatic patients with diagnosis of POP who did not require treatment. The total number of randomly sampled Medicare beneficiaries from which we drew our cohort was 825,000. Thus our study population of 34,782 women with diagnosis of POP represents 4.2%. Recently published epidemiological studies have shown a 7% prevalence of POP at or distal to the hymen in general population of women with median age of 42 years (18-83)<sup>16</sup>. Several studies have now shown that symptoms due to POP develop when the leading edge is at or distal to the hymen<sup>17-18</sup>. Age is a known risk factor for POP progression<sup>19</sup>. Given the limitations of the data available to us, we are unable to deduce a precise reason for low utilization of pessary in treatment of POP; however we do not believe that patients with asymptomatic POP represented a significant enough portion of our cohort to account for it. Further, our data points to a possibility that the number of women with symptomatic POP prolapse is likely under-diagnosed among Medicare beneficiaries in the real-world.

Pessaries have been a viable treatment for POP for centuries<sup>20</sup>; still no clear guidelines for pessary fitting, follow-up, or management exist to date. We found that the majority of women, treated with a pessary, had a subsequent follow-up visit either with the same provider and/or a gynecologist. However, a significant minority appeared not to have continuity of care. The sequelae of this lack of continuity of care may include an unacceptable rate of vaginal fistula formation. Though the diagnoses of fistula may result from inflammatory bowel disease, abdomino-pelvic surgery, malignancy, radiation treatment, it seems plausible that at least some of these fistulae were likely related to a forgotten pessary.

Proposed protocols for pessary follow-up usually come from the pessary manufacturer; some suggest follow-up every 4 to 6 weeks, which can be very burdensome and costly to patients. Variables in management to consider include timing to follow-up after the initial fitting, the frequency of follow-ups thereafter, use of hormone replacement therapy in post-menopausal women, the type of pessary to be placed, and additional conservative options for unsuccessful pessary trials. Published reports on the length of follow-up after the initial pessary fitting vary from 1 to 3 weeks to assess for successful fitting<sup>12, 13, 21-23</sup>. Subsequent follow-up intervals also vary greatly in the literature, from every three months to annually for those who are able to perform self-care<sup>12, 21-25</sup> to 1-3 months for those who are not<sup>24</sup>. We recently developed quality-of-care indicators for POP management, and, using the RAND appropriateness method<sup>26-27</sup>, it was determined that patients with a pessary should have a pelvic examination by a physician at least once every six months (unpublished data).

The strength of our study lies in the fact that claims data allow for analysis of a large sample of patients with a broad geographic distribution. Long-term follow-up is another invaluable

aspect of archival data. Both the large sample size and nine-year longitudinal follow-up allowed us to determine the risk of rare complications related to pessary use, as well as rates of conversion to surgical management of prolapse over time.

The limitations of our research are inherent in the study design, with accuracy of the data dependent on proper coding by the providers. Our analyses were further limited by a paucity of clinical details, such as severity of prolapse or degree of symptoms and inability to know with certainty if complications of interest were directly caused by the pessary use. The biggest limitation in assessing the frequency of follow-up lies in the fact that the CPT-4 procedure code for pessary fitting (57160) applies to fittings of a new pessary per Medicare rules and regulations. As reimbursement for services was dependent on appropriate coding, providers were incentivized to accurately report their services through the available codes. However, lack of a pessary exchange/cleaning code may preclude an accurate assessment of pessary follow-up care using these national claims data sets. Electronic health records conceivably could provide more information, however the sample sizes available to date are relatively small. Also, as the Medicare data we analyzed were limited to patients 65 year old and older, no information is available on those younger than 65.

This study provides real-world evidence of pessary utilization for management of POP among elderly Americans. Its effectiveness is suggested by the relatively modest subsequent surgery rate, while the low rates of complications confirm the safety of the procedure. Future analyses should identify whether the low pessary placement rate and lack of continuity of care in this population still exist. Large prospective are warranted to further examine outcomes of pessary use. Based on the data from such trials, clear guidelines on frequency of follow-up after pessary placement can be determined. Optimal pessary management protocols will balance timing and frequency of follow-up, while minimizing pessary-related complications and taking into consideration patient burden, cost, and access.

**Acknowledgments**

Funded by a National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Patient-Oriented Research Career Development Award (1 K23 DK080227, JTA) and an American Recovery and Reinvestment Act (ARRA) Supplement (5K23DK080227, JTA)

**Appendix 1: ICD-9 & CPT-4 Codes Used to Determine Rates of Pessary Placement 342 and Follow-up, as well as Surgery for POP**

CODES	CPT-4 PROCEDURE	ICD-9 PROCEDURE	OTHER
<b>Pessary Fitting</b>	57160, 57150, 57415		HCPCS OUTPATIENT SUPPLY CODES: A4561/A4562
<b>Follow-Up Visits</b>	99211-99215		
<b>Definitive Prolapse Surgery Codes</b>	45560, 56800, 56810, 57120, 57240, 57250, 57260, 57265, 57267, 57268, 57270, 57280, 57282, 57283, 57284, 57285, 57289, 57423, 57425, 58150, 58152, 58180, 58260, 58267, 58270, 58280, 58290, 58292, 58293, 58294, 58400, 58410, 58541, 58570, 58543, 58571	17.4, 68.3, 68.31, 68.39, 68.5, 68.51, 68.59, 69.22, 70.50, 70.51, 70.52, 70.53, 70.54, 70.55, 70.62, 70.64, 70.77, 70.78, 70.8, 70.92, 70.93	

## Appendix 2: ICD-9 and CPT-4 Codes Used to Identify Complications 373 Associated with 374 Pessary Use

	ICD-9 DIAGNOSIS	CPT-4 PROCEDURE	ICD-9 PROCEDURE
<b>Surgical</b>	553.21, 569.83, 593.3, 596.6, 596.9, 902.5, 902.50-902.59, 902.8, 902.81-902.89, 902.9, 997.5, 998.2, 998.3, 998.8, 998.0	49000, 50392, 50780, 51800, 51860, 57200, 57210, 52332, 57200, 58520	54.11, 55.02, 56.74, 57.81, 70.71
<b>Bleeding</b>	285.9, 569.3, 569.4, 596.7, 599.7, 624.5, 665.7, 997.2, 998.1, 998.10, 998.12, 999.80, 999.2	36430	99.00
<b>Infection/Inflammation</b>	590.10, 590.80, 590.9, 595, 595.0, 595.3, 595.89, 595.9, 597.0, 599.0, 780.6, 616.10, 616.11, 616.8, 616.81, 616.89, 616.9, 958.3, 998.5, 998.51, 998.59	51080	
<b>Pain</b>	625, 625.1, 635.7, 625.8, 625.9, 789.9		
<b>Retention</b>	596.0, 599.6, 788.2, 788.21, 788.29, 788.38, 788.62	51040, 51701, 52270, 52281, 52285, 53620, 53660/53661/53665	57.1, 57.94, 58.0, 58.6
<b>Mechanical Device</b>	996.3, 996.30, 996.39, 996.6, 996.64, 996.65, 996.69, 996.76	57295, 57296, 57426, 57287	58.5
<b>Fistula</b>	565.1, 596.1, 596.2, 599.1, 619, 998.6	51900, 51920, 51925, 57300, 57305, 57307, 57308, 57310, 57311, 57320, 57330	57.84, 58.43
<b>Urodynamics</b>		51725, 51726, 51727, 51728, 51729, 51736, 51741, 51772, 51784, 51785, 51795, 51797	89.22, 89.24, 89.25
<b>Medical/Non-urollogic</b>	402.01, 402.11, 402.91, 410, 410.0, 410.00, 410.01, 410.02, 410.1, 410.10, 410.11, 410.12, 410.2, 410.20, 410.21, 410.22, 410.3, 410.30, 410.31, 410.32, 410.4, 410.40, 410.41, 410.42, 410.5, 410.50, 410.51, 410.52, 410.6, 410.60, 410.61, 410.62, 410.7, 410.70, 410.71, 410.72, 410.8, 410.80, 410.81, 410.82, 410.9, 410.90, 410.91, 410.92, 427.5, 428, 428.0, 428.1, 428.2, 428.20, 428.21, 428.22, 428.23, 428.3, 428.30, 428.31, 428.32, 428.33, 428.4, 428.40, 428.41, 428.42, 428.43, 428.9, 785.51, 997.1, 415.1, 466, 466.0, 466.1, 480, 480.0, 480.1, 480.2, 480.3, 480.8, 480.9, 481, 482, 482.1-482.9, 483, 483.0, 483.1, 483.8, 485, 486, 507.0, 511, 511.0, 511.1, 511.8, 511.9, 518.0, 518.4, 518.5, 518.81, 518.82, 799.1, 997.3, 433, 433.0, 433.00, 433.01, 433.1, 433.10, 433.11, 433.2,		

	ICD-9 DIAGNOSIS	CPT-4 PROCEDURE	ICD-9 PROCEDURE
	433.20, 433.21, 433.3, 433.30, 433.21, 433.8, 433.80, 433.81 433.9, 433.90, 433.91, 434, 434.0, 434.00, 434.01, 434.1, 434.10, 434.11, 434.9, 434.90, 434.91, 436, 437, 437.0-437.9, 444.2, 444.22, 444.81, 451.1, 451.2, 451.81, 451.9, 453.8, 560.1, 560.8, 560.81, 560.89, 560.9, 997.4, 584, 584.5, 584.6, 584.7, 584.8, 584.9, 586, 785.5, 785.50, 785.52, 785.59, 995.0, 995.4, 998.0, 999.4, 798, 798.1, 798.2, 798.2		

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**Table 1**

## Demographic and Clinical Characteristics of the Cohort

<b>Demographics of Pessary Users</b>	<b>N</b>	<b>%</b>
All	4019	100
<b>Race/Ethnicity</b>		
Unknown	13	0.32
White	3772	93.85
Black	140	3.48
Other	39	0.97
Asian	17	0.42
Hispanic	37	0.92
North American Native	1	0.02
<b>Age</b>		
65-69	531	13.21
70-74	826	20.55
75-79	1105	27.49
80-84	869	21.62
85+	688	17.12
<b>Charlson Score</b>		
0	2434	60.56
1	620	15.43
2	578	14.38
3	202	5.03
4	101	2.51
5+	84	2.09
<b>Region of residence</b>		
Northeast	1178	29.31
Midwest	924	22.99
South	1416	35.23
West	489	12.17
Other/Unkown	12	0.3

**Table 2**

Proportion of pessaries placed by different medical specialties

Specialty	%
16 Obstetrics/Gynecology	83.99
70 Multi-specialty Clinic or Group Practice	3.77
34 Urology	3.49
08 Family Practice	2.04
50 Nurse Practitioner	0.88
01 General Practice	0.76
11 Internal Medicine	0.73
02 General Surgery	0.58
98 Gynecological Oncology	0.58

**Table 3**

Follow-up of women fitted with pessaries during the index period

	Quarter 1 (1st 3 months)	6 months	9 months	1 year	2 years	4 years	5 years	9 years
57160 Repeat Pessary fitting	25%	32%	37%	39%	45%	50%	52%	55%
57150 Vag irrigation after pessary	2%	3%	3%	4%	5%	7%	7%	8%
A4561/A4562 Outpatient pessary	0%	0%	0%	0%	1%	4%	5%	7%
99211-99215 Follow-up visit (any specialty)	85%	94%	96%	97%	98%	98%	98%	98%
Any follow-up with same provider (cumulative)	<b>39.9%</b>	50.7%	56.3%	60.1%	65.3%	67.8%	68.3%	68.8%
% patients with follow-up visits with same provider	39.9%	30.5%	27.2%	26.8%	18.8%	22.3%	17.7%	5.6%
Any follow-up visit (99211x)	84%	93%	95%	96%	98%	98%	98%	98%
general	4%	5%	5%	6%	7%	9%	10%	11%
family	17%	23%	25%	27%	33%	40%	42%	48%
internal	30%	39%	44%	47%	53%	62%	64%	69%
gynecology	41%	54%	60%	65%	73%	78%	79%	81%
urology	6%	8%	10%	11%	14%	18%	20%	24%

**Table 4**  
Cumulative Outcomes of Pessary Placement, Complications and Definitive Surgery Rates

	Quarter 1 (1st 3 months)	6 months	9 months	1 year	2 years	4 years	5 years	9 years
<b>Overall Surgery for Prolapse</b>	5%	8%	10%	12%	15%	20%	21%	24%
Colpocleisis	0%	1%	1%	1%	2%	2%	2%	3%
Anterior	2%	2%	3%	3%	4%	6%	6%	8%
Anterior & posterior	2%	4%	5%	6%	8%	10%	11%	12%
Anterior & posterior & apical	1%	1%	1%	2%	2%	3%	3%	3%
Posterior	1%	2%	2%	3%	3%	4%	5%	5%
Apical	4%	6%	7%	8%	11%	14%	15%	18%
Mesh insertion	0%	0%	0%	0%	0%	0%	0%	1%
<b>Complications</b>								
UTI	19%	30%	38%	44%	58%	73%	77%	86%
Vaginitis	6%	9%	12%	14%	20%	27%	29%	35%
Dyspareunia	8%	12%	15%	17%	24%	32%	34%	41%
Retention of urine	2%	4%	5%	6%	8%	12%	13%	18%
Mechanical Complication of Device, implant, & graft (996.3-996.76)	0%	1%	1%	1%	2%	3%	3%	5%
Fistula (599.1, 619)	0%	0%	0%	0%	1%	1%	2%	3%