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ORIGINAL ARTICLE

Documenting pessary offer prior to hysterectomy for management of pelvic organ prolapse

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Abstract

Objectives To (1) determine the proportion of hysterectomy cases with documentation of pessary counseling prior to prolapse surgery and (2) identify variables associated with women offered a pessary.

Study design The Michigan Surgical Quality Collaborative (MSQC) is a hysterectomy improvement initiative. Hysterectomies from 2013 to 2015 in which prolapse was the principal diagnosis were included. "Pessary offer" was defined as documentation showing the patient declined, could not tolerate, or failed a pessary trial. Bivariate analyses were used to compare demographics, medical history, surgical route, concomitant procedures (colpopexy or colporrhaphy), and intra- and postoperative complications between women with and without pessary offer. Hierarchical logistic regression was used to determine factors independently associated with pessary offer. Risk-adjusted pessary offer rates by hospital were calculated.

Results The adjusted rate of pessary offer was 25.2%, ranging from 3 to 76% per hospital. Bivariate comparisons showed differences between women with and without pessary offer in age, tobacco use, prior pelvic surgery, insurance status, surgical approach, secondary indication for surgery, concomitant prolapse procedure, teaching hospital status and hospital bed size. In logistic regression, odds of pessary offer increased with age > 55 years (OR 1.45, 95% CI 1.12–1.88, $p = 0.006$), Medicare insurance (OR 1.65, 95% CI 1.30–2.10, $p < 0.0001$), and a concomitant procedure (OR 1.5, 95% CI 1.16–1.93, $p = 0.002$). Postoperative urinary tract infections were more common in patients offered a pessary (6.4% vs. 2.5%, $p < 0.0001$), but other complications were similar.

Conclusions Overall, only one-quarter of hysterectomies for prolapse in MSQC hospitals had documentation of pessary counseling—suggesting an opportunity to improve documentation, counseling regarding pessary use, or both.

Keywords Hysterectomy · Pelvic organ prolapse · Pessary

Introduction

Pelvic organ prolapse is common and affects 3–8% of US women [1, 2]. The primary non-surgical management for prolapse is a pessary as it is reusable, low-risk, and effective in improving symptoms [3–7]. Many women choose conservative management of prolapse when given the option, and there is mounting evidence that pessaries can be used to manage a wide variety of prolapse types while maintaining a low complication rate [4, 6, 8–11]. While treatment choice is generally tailored to the patient's individual preferences and needs, the American Congress of Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) recommend a pessary be offered to all patients with prolapse as an alternative to surgery [12].

Despite these recent recommendations, it is not known how often pessary counseling is performed and documented prior to surgical management of prolapse. Therefore, we sought to (1) determine the prevalence of pessary counseling prior to hysterectomy for prolapse and (2) identify variables independently associated with pessary counseling using data from a statewide surgical improvement collaborative.

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Materials and methods

A retrospective study was performed using hysterectomy data from the Michigan Surgical Quality Collaborative (MSQC), a voluntary statewide quality improvement initiative including 62 academic and community hospitals funded by Blue Cross Blue Shield of Michigan. Gynecologic cases are eligible for inclusion in the MSQC data sample if a hysterectomy was performed for gynecologic indications. Data gathered through MSQC is then used to stimulate hospital-level Quality Improvement strategies by identifying "best performers" and "best practices" in best performing hospitals and distributing this information [13]. Hysterectomy cases are selected using a standardized sampling methodology similar to that used in the National Surgical Quality Improvement Program, where the first 25 cases during an 8-day cycle are abstracted per hospital site [14, 15]. Data are collected by chart review by trained nurse data abstractors using methodology previously described and are validated with site visits, conference calls and internal audits [16, 17]. This study was considered "exempt" by Michigan Medicine's Institutional Review Board (HUM00073978). Hysterectomies with an indication of pelvic organ prolapse performed between 1 January 2013 and 30 April 2015 at MSQC member hospitals were identified. Hospitals with < 20 hysterectomies for prolapse during the study period were excluded to be able to reliably compare hospital sites and identify outliers. Primary and secondary indications for surgery were identified using chart review.

Data available in the MSQC database include perioperative hospital records relevant to the hysterectomy, including the preoperative history and physical, operative note, discharge summary, and postoperative complications within 30 days of surgery. If accessible to the nurse data abstractor, outpatient records from separate medical record systems were also reviewed and the data included. The primary outcome was documentation of pessary counseling prior to surgical management of pelvic organ prolapse. A "pessary offer" was defined as documentation of one of the following three scenarios prior to surgery: (1) pessary offered but patient declined, (2) patient offered and accepted pessary trial but could not be successfully fit with the pessary, or (3) pessary trialed but patient was unsatisfied with pessary use. This final scenario included patients who used a pessary while waiting for surgery to be scheduled.

Demographics, medical comorbidities, insurance status, and hospital characteristics that were available in MSQC and potentially relevant were chosen a priori. These included age, body mass index (BMI), race, tobacco use, American Society of Anesthesiologists (ASA) class ≥3—indicating severe systemic disease [18], insurance status, route of hysterectomy, secondary indications for surgery, concomitant procedures, hospital size, and hospital teaching status. Concurrent (performed by the primary surgeon) and other (performed by a separate surgeon) procedures at the time of hysterectomy for prolapse were identified by chart review and included colpopexy (vaginal or abdominal, with or without laparoscopy) or colporrhaphy (enterocele closure, anterior, or posterior repair). Prior pelvic surgeries were defined as cesarean delivery, oophorectomy, tubal ligation, bladder and low gastrointestinal operations, cystocele, rectocele, or enterocele repair, appendectomy, transplant (i.e., kidney or pancreas), open and laparoscopic procedures, myomectomy, and uterine artery embolization. Other indications for hysterectomy included fibroids, pain, pre-malignancy, abnormal uterine bleeding, and "other"—which included personal history of cancer, family history of cancer, pelvic inflammatory disease, and gender transition and were abstracted from the patient chart.

Intraoperative and postoperative complications within 30 days of hysterectomy were analyzed. "Major complications" included: deep surgical site infection (SSI) or pelvic abscess, vaginal cuff dehiscence, pneumonia, venous thromboembolism, acute renal injury, stroke, unplanned intubation, postoperative cardiac arrest, myocardial infarction, postoperative arrhythmia, sepsis, ureteral obstruction, bladder or ureteral injury, vesico-, uretero-, or recto-vaginal fistula, bowel injury, intestinal obstruction or anastomotic leak, and *Clostridium difficile* infection. "Any complication" included all major complications in addition to superficial SSI, urinary tract infection (UTI), vaginal cuff infection, nerve injury, and blood transfusion.

Demographics, perioperative variables, and 30-day complications were compared between women with and without documentation of a pessary offer prior to surgery using $\chi 2$ tests for categorical variables or Fisher's exact test in the case of small sample sizes or Student's *t* tests for continuous variables. Factors with significant and clinically plausible associations with pessary offer informed by the bivariate analysis were considered in stepwise logistic regression. A multivariable hierarchical logistic regression model including significant patient and hospital factors, which accounted for clustering of cases by hospital, was developed to identify independent factors associated with vaginal pessary offer. Multicollinearity across candidate covariates in the final model were assessed with Spearman rank or Pearson's correlation matrices. Model concordance and fit were assessed with a C-statistic, decile analysis of predicted and observed rates across all cases, and Pearson's residuals to assess potential over-dispersion. Final hospital-specific risk-adjusted pessary offer rates and 95% confidence intervals were calculated using the final model and ranked from lowest to highest offer rates. A caterpillar plot ranking hospitals from lowest to highest adjusted pessary offer rates and hospital-specific 95% confidence intervals was developed with a reference MSQC-observed offer rate to identify potential outlier hospitals within the collaborative. Statistical analyses were performed using SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

A total of 26,514 hysterectomies were performed for all indications during the study period, of which 3138 were performed for pelvic organ prolapse at 62 hospitals. After exclusion of low-volume hospitals with < 20 cases, a total of 3000 hysterectomies for prolapse at 47 hospitals were included in the final analysis. Across MSQC hospitals, there was wide variation in documentation of pessary offer prior to surgery for prolapse, with the rates ranging from 2.9 to 75.8%. The adjusted mean rate of documented pessary counseling was 25.2% (Fig. 1). Of patients who had a documented pessary offer, 59.7% (404/677) declined pessary therapy, and 40.3% (273/677) agreed to trial a pessary but were either unable to be fit or were unsatisfied with the therapy and went on to have surgery.

Table 1 shows comparisons of demographics and perioperative variables between women with and without a pessary offer. Women with versus without documentation of a pessary offer were significantly older and had lower rates of tobacco use. Women with a pessary offer had a lower rate of prior pelvic surgery, but a higher rate of concomitant prolapse procedure at the time of hysterectomy. Differences in pessary offer across insurance types and surgical approach were also observed. Patients with a secondary indication for hysterectomy of "pre-malignancy" had a lower rate of pessary offer. Finally, more documented pessary offers were present in hospitals with > 500 beds and fewer were seen in teaching hospitals. No significant differences were observed regarding BMI, race, or ASA class ≥ 3.

Table 2 shows results for the multivariable logistic regression model. Medicare insurance was the factor most strongly associated with a pessary offer, which increased the odds by 65%. Age > 55 also increased the odds of a pessary offer by 45%. Women with a pessary offer also had 50% higher odds of having concurrent prolapse procedures at the time of hysterectomy for prolapse. The correlation coefficient between age and Medicare status was sufficiently low to include both of them in the model. The C-statistic was 0.83, showing strong concordance.

Comparisons of 30-day complications between women with and without a pessary offer are shown in Table 3. Postoperative UTI rate was higher in women with a pessary offer; this difference was responsible for the higher "any complication" rate in this group as well. No significant differences were seen in major complications.

Comment

In this retrospective study of hysterectomies done for prolapse at hospitals in a statewide surgical improvement collaborate, only one-quarter had documentation of a pessary offer prior to surgery. This suggests opportunity exists for improved pessary counseling, documentation of counseling, or both prior to prolapse surgery in the USA. Furthermore, wide variation exists between MSQC hospitals regarding pessary counseling, with some hospitals documenting a pessary offer in over three quarters of cases and others in only a few percent. Medicare insurance, age > 55, and concomitant prolapse procedures were all associated with higher odds of pessary offer.

This study fills a prior knowledge gap in the literature by providing data regarding preoperative pessary counseling in a surgical cohort of women undergoing hysterectomy for prolapse. In a 1997 survey of AUGS members, 77% reported offering pessaries as a first-line alternative to surgery [19], a rate three times higher than the average documentation rate of MSQC hospitals. This discrepancy may be, in part, related to the specialty of the provider. In the AUGS survey, nearly half of the respondents were urogynecologists. Compared with respondents who identified as gynecologists and urologists, urogynecologists were more apt to use pessaries as first-line therapy. There is additional data showing that higher volume surgeons are more likely to offer

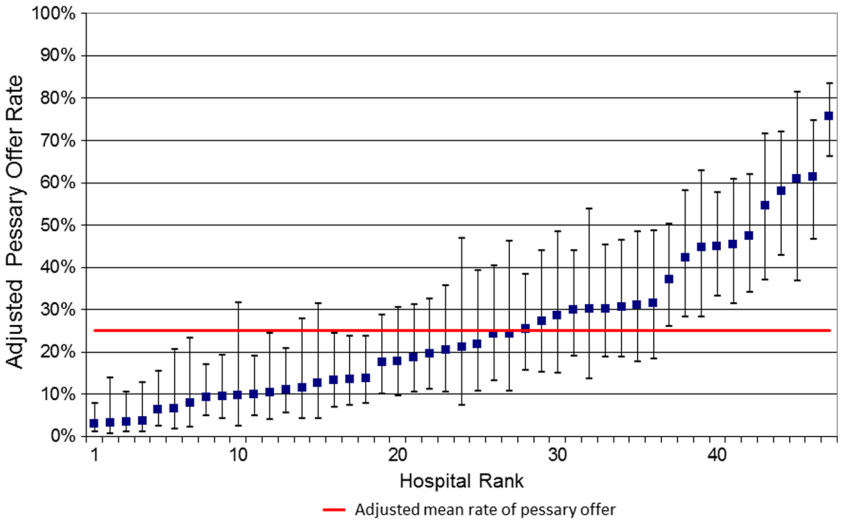

Fig. 1 Michigan Surgical Quality Collaborative hospitals by proportion of hysterectomies for prolapse with a documented pessary offer. Description: Hospitals' rank ordered by the proportion of hysterectomies for prolapse with documentation of a pessary offer prior to surgery. The red line represents the average adjusted rate of pessary offer across all Michigan Surgical Quality Collaborative hospitals

Table 1 Patient, hospital, and surgical characteristics

	Pessary Offered		P value[a]
	Yes N = 677	No N = 2323	
Age, years	61.5 ± 12.4	58.1 ± 12.3	< .0001
Body Mass Index, kg/m^2	28.3 ± 5.7	28.6 ± 7.6	0.45
Race			0.4
White	611 (94.6)	2078 (93.6)	
Non White	35 (5.4)	144 (6.5)	
Tobacco use	71 (10.5)	384 (16.5)	< .0001
ASA Class ≥ 3	149 (22.01)	485 (20.89)	0.52
Prior Pelvic Surgery	270 (39.9)	825/1854 (44.5)	0.04
Insurance			< .0001
Medicare[b]	270 (39.9)	679 (29.2)	
Medicaid	21 (3.1)	145 (6.2)	
Private	324 (47.9)	1363 (58.7)	
Uninsured	1 (0.2)	10 (0.4)	
Other	51 (7.5)	86 (3.7)	
Surgical Approach			< .0001
Abdominal	11 (1.6)	340 (14.6)	
Laparoscopic	21 (3.1)	192 (8.2)	
Robotic	116 (17.2)	599 (25.8)	
Laparoscopic-assisted vaginal	45 (6.7)	222 (9.6)	
Vaginal	482 (71.4)	970 (41.7)	
Additional indications			
Fibroids	46 (6.8)	165 (7.1)	0.86
Pain	101 (14.9)	323 (13.9)	0.53
Pre-malignancy	1 (0.2)	40 (1.7)	0.0005
Abnormal uterine bleeding	83 (12.3)	266 (11.5)	0.59
Other[c]	33 (4.9)	120 (5.2)	0.84
Concomitant Colporrhaphy and/or Colpopexy	512 (75.6)	1527 (65.7)	< .0001
Teaching Hospital	537 (79.3)	1958 (84.3)	0.003
Hospital Bedsize > 500	197 (29.1)	538 (23.2)	0.002

Data presented at mean ± SD or n/N (%)

ASA: American Society of Anesthesiologists

[a] P-values determined using Student's t-test for continuous variables and Chi-square for categorical variables. Fisher's Exact used for small sample sizes

[b] We included women with both Medicare and Medicaid in the Medicare group

[c] Other indications include: personal or family history of cancer, pelvic inflammatory disease, and gender transition

conservative management with a pessary prior to hysterectomy for prolapse [20]. Unfortunately, we do not have information on surgeon specialty or volume in the MSQC data. Surveys from international providers show that a slightly lower (61–69%) number of respondents reported offering a pessary for treatment of prolapse [21, 22]. IUGA members from North America had the highest rate of pessary offer and those from Africa had the lowest, indicating significant regional variation [21]. Furthermore, responses provided on a survey may be incongruent with what actually occurs in clinical practice.

In another study of Medicare beneficiaries, Khan et al. found that 11–13% of women with prolapse had pessary management [23]. However, this study only included women ≥ 65 years with a prolapse diagnosis and determined pessary management via pessary insertion billing data, which would miss women who were offered but who declined a pessary trial. By performing chart review to assess whether a pessary was offered or attempted, our study provides a more robust analysis of pessary counseling specific to women undergoing hysterectomy for prolapse.

Table 2 Multivariable logistic regression for pessary offer

	Unadjusted OR	Adjusted OR	95% CI	P value
Age > 55	1.61	1.45	(1.12-1.88)	0.006
Tobacco Use	0.59	0.762	(0.55-1.05)	0.1
Insurance status				
Private	*ref*	*ref*	*ref*	*ref*
Medicaid	0.61	0.7	(0.41-1.24)	0.23
Medicare[b]	1.64	1.65	(1.30-2.10)	< .0001
All Others	2.5	1.14	(0.63-2.07)	0.66
Uninsured	0.42	0.5	(0.06-4.37)	0.53
Surgical approach				
Abdominal	*ref*	*ref*	*ref*	*ref*
Laparoscopic-assisted vaginal	6.27	1.28	(0.55-3.02)	0.56
Laparoscopic	3.38	0.75	(0.27-2.03)	0.57
Robotic	5.99	1.92	(0.85-4.31)	0.11
Vaginal	15.36	2.03	(0.93-4.45)	0.076
Concurrent or other procedures[a]	1.62	1.5	(1.16-1.93)	0.002
Teaching Hospital	0.72	0.6	(0.23-1.60)	0.3
Bed size > 500	1.36	2.36	(0.95-5.85)	0.06

[a] Concurrent procedures are performed by the same surgeon at the time of hysterectomy, Other procedures are performed by a separate surgeon at the time of hysterectomy

[b] We included women with both Medicare and Medicaid in the Medicare group

Age > 55 years and Medicare insurance were two patient-level factors associated with increased odds of a pessary offer. Prior studies have shown that younger women are more likely to opt for surgical management of prolapse; however, our study suggests that these factors influence physicians' counseling as well [8, 24]. Older women and those with Medicare may have more comorbidities that make them poorer surgical candidates [25–27]; therefore, physicians may be more apt to offer them conservative management. However, in our study cohort, all women ultimately had surgery for prolapse, and the proportion of women with ASA Class ≥ 3 was the same among women with and without a pessary offer. There could be factors or comorbidities that are unmeasured in the MSQC data set that affect these outcomes. Therefore, while severity of comorbidities does not appear to be a significant factor in our study, we cannot account for the appearance of frailty or severity of disease, which may have influenced physician counseling.

Although ACOG states that hysterectomy alone is not considered an acceptable surgical treatment for prolapse [12], this practice is not uncommon. In the current study, 32% (961/3000) of hysterectomies had no concomitant prolapse procedures. This is consistent with prior studies that showed between 27 and 63% of women undergoing surgery for prolapse had an isolated hysterectomy performed [23, 28]. In our study, women with concurrent prolapse procedures at the time of hysterectomy had 50% increased odds of having had a pessary offer. These findings may suggest that surgeons who follow the best practice guideline of performing prolapse procedures at the time of hysterectomy for prolapse are also more likely to follow the best practice guideline of offering a pessary as first-line management of prolapse.

As expected, major complications did not differ between women with and without a pessary offer prior to surgery. However, women with a pessary offer did have a higher prevalence of postoperative UTI. This finding may be explained by the fact that these women also had a higher prevalence of concomitant prolapse procedures at the time of surgery. Prolapse procedures, especially anterior repair, increase the risk of prolonged postoperative catheter use and UTI risk [29].

The main strength of the study is the robust data collection methodology used by MSQC where data are chart abstracted by trained clinical reviewers at each respective hospital. MSQC includes data from all payers at both community and academic hospitals throughout the state of Michigan.

The main limitation of our study is that it does not capture patients who were offered a pessary but did not have it documented in the chart. In the gynecologic portion of MSQC, only hysterectomy is evaluated, and we were therefore unable to assess patients who underwent procedures for prolapse without a hysterectomy. There could have been more than one indication for hysterectomy, and we were unable to identify the primary indication for surgery in this data set. Another limitation is that data abstractors may not have had access to some clinic records in other medical systems, which could therefore have caused us to miss an encounter that included pessary counseling. Additionally, how far back the abstractors looked in the medical

Table 3 Bivariate analysis of intra- and postoperative complications within 30 days of hysterectomy

	Pessary Offered		P value
	Yes N = 677	No N = 2323	
Any complication	60 (8.9)	115 (5.0)	0.0003
Post-op urinary tract infection	43 (6.4)	59 (2.5)	< .0001
Transfusion	5 (0.7)	18 (0.8)	1
Superficial surgical site infection	4 (0.6)	11 (0.5)	0.7565
Vaginal cuff infection	0	1 (0.04)	1
Post-op urinary tract infection	43 (6.4)	59 (2.5)	< .0001
Major complication	10 (1.5)	34 (1.5)	1
Deep surgical site infection	4 (0.56)	13 (0.6)	1
Sepsis	3 (0.4)	11 (0.5)	1
Pelvic abscess	0	5 (0.2)	0.594
Venous thromboembolism	2 (0.3)	5 (0.2)	0.6593
Myocardial Infarction	0	5 (0.2)	0.594
Postop unplanned intubation	1 (0.2)	4 (0.2)	1
Postop arrhythmia	1 (0.2)	4 (0.2)	1
Acute renal injury	1 (0.2)	3 (0.1)	1
Nerve injury	1 (0.2)	2 (0.09)	0.5359
Ureteral obstruction	0	1 (0.04)	1
Bladder/ureteral injury	0	1 (0.04)	1
Intestinal obstruction	0	1 (0.04)	1
Bowel injury	0	1 (0.04)	1
C. difficile	1 (0.2)	0	0.2257
Stroke	0	0	
Pneumonia	0	0	
Vaginal cuff dehiscence	0	0	

record could have varied across sites. Due to the nature of the database, data on prolapse size or POP-Q stage were unavailable. Unfortunately, we do not have information on surgeon age, gender, specialty, or volume in the MSQC data. Our study does not include women who were counseled and successfully managed with a pessary, thereby obviating the need for surgery. Finally, this study only includes women treated in the state of Michigan in the US, and therefore these findings may not be generalizable to women in different states or countries.

In summary, using data from a statewide collaborative, we found that documentation of pessary counseling prior to hysterectomy for prolapse is low and that wide variation exists between hospitals. Opportunity exists to improve pessary counseling and/or documentation of counseling prior to surgery.

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Compliance with ethical standards

Conflicts of interest The authors report no conflict of interest.

Implications and contributions Both ACOG and AUGS recommend offering a pessary as conservative management prior to surgery for pelvic organ prolapse. This study was conducted to assess how often patients are counseled on conservative management options prior to hysterectomy for pelvic organ prolapse. We found that there is wide variation in documentation of pessary offer in Michigan and that a pessary offer is documented in only one-quarter of hysterectomies performed for prolapse. Age > 55 years, Medicare insurance status, and concurrent procedures for prolapse at the time of hysterectomy were associated with increased odds of pessary offer. This study fills a prior knowledge gap in the literature by providing data regarding preoperative pessary counseling in a surgical cohort of women undergoing hysterectomy for prolapse.

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