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The Quality of Care Provided to Women with Urinary Incontinence in Two Clinical Settings

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Abstract

Purpose—Our aim was to test the feasibility of a set of quality-of-care indicators for urinary incontinence (UI) and, at the same time, measure the care provided to women with UI in two different clinical settings.

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Dr. Anger: Investigator for ASTORA Women's Health LLC, investigator and expert witness for Boston Scientific Corporation; Dr. Alas: Investigator for Pfizer, Inc.; Dr. Litwin has nothing to disclose; Dr. Chu has nothing to disclose; Ms. Bresee has nothing to disclose; Ms. Roth has nothing to disclose; Ms. Rashid has nothing to disclose; Dr. Shekelle has nothing to disclose; and Dr. Wenger has nothing to disclose.

Materials and Methods—This was a pilot test of a set of quality-of-care indicators (QIs). This was a pilot test of a set of quality-of-care indicators (QIs). Twenty QIs were previously developed using the RAND Appropriateness method. These QIs were used to measure care received for 137 women with a urinary incontinence (UI) diagnosis in a 120-physician hospital-based multi-specialty medical group (MSG). We also performed an abstraction of 146 patient records from primary care offices in Southern California. These charts were previously used as part of the Assessing Care of Vulnerable Elders Project (ACOVE). As a post-hoc secondary analysis, the two populations were compared with respect to quality, as measured by compliance with the QIs.

Results—In the ACOVE population, 37.7% of patients with UI underwent a pelvic examination, versus 97.8% in the MSG. Only 15.6% of cases in the MSG and 14.2% in ACOVE (p=0.86) had documentation that pelvic floor exercises were offered. Relatively few women with a body mass index (BMI) of >25 were counseled about weight loss in either population (20.9% MSG vs. 26.1% ACOVE, p=0.76). For women undergoing sling surgery, documentation of counseling about risks was lacking, and only 9.3% of eligible cases (MSG only) had documentation of the risks of mesh.

Conclusions—QIs are a feasible means to measure the care provided to women with UI. Care varied by population studied, yet deficiencies in care were prevalent in both patient populations studied.

Keywords

Urology; Incontinence; Health Services Research; Quality Assessment

INTRODUCTION

As medical costs have risen, the need to decrease costs of health care while improving the quality of the care has made the investigation of appropriate effectiveness of medical and surgical interventions a priority in health services research.[1,2,3] To that aim, quality-of-care indicators (QIs) have been developed to investigate the quality of care for various diseases.[4–6.] Unlike clinical guidelines, which measure optimal care, quality indicators outline the minimum care appropriate for a patient with a specific condition. If an element of care, as measured by a quality indicator, is not performed, then such care would be considered inadequate.[7]

Urinary incontinence (UI), has been defined by the International Continence Society as “the complaint of any involuntary leakage of urine.”[8] Approximately 11% of all women will undergo surgery for UI or pelvic organ prolapse by the age of 80, and of these, 29% will require a re-operation for recurrence of symptoms.[9–10] As part of the Assessing Care of Vulnerable Elders (ACOVE) project at RAND, QIs were developed for community-dwelling adults 65 years or older.[11] QIs specifically designed for vulnerable community-dwelling adults with UI were used to assess the records of 372 randomly selected patients enrolled in two senior managed care plans who were identified to be at risk for functional decline.[12] A pelvic examination was performed in only 20% of women, only 50% of patients received medical treatment for incontinence, and only 13% were prescribed behavioral intervention, despite its proven effectiveness.[12]

While these findings from ACOVE identified poor quality of care for UI in older patients, there remains a lack of data in women more likely to undergo surgical procedures for UI, including younger women and older women with relatively good health. The objective in this study was to use our recently developed QIs to test their feasibility and, at the same time, measure the care provided to women with UI in two different clinical settings.

MATERIALS AND METHODS

QI Development

Building on ACOVE, we previously developed and validated a set of 27 process-based QIs to measure the care provided to women with UI in both generalist and specialist settings.[13] Briefly, we developed and ranked a set of QIs that address prevention, screening, diagnosis, workup, and both non-surgical and surgical management (Appendix 1). These QIs were developed using the UCLA-RAND Appropriateness (Delphi) method, a widely used method for synthesizing evidence and expert judgment to produce QIs.[14–16] A panel of nine experts from the fields of urogynecology, urology, and internal medicine then ranked the validity and feasibility of the proposed QIs on a nine point scale, with 1 representing “definitely not valid”, and 9 representing “definitely valid”.[12] We then convened an in-person panel and moderated discussions regarding the advantages and disadvantages of each QI, after which each panelist re-ranked the validity of each QI (Appendix 1). Although the panel ranked QIs on feasibility, it was validity scores that determined inclusion in the final set of indicators. The true test of feasibility is if 1) the QI is identifiable in the medical record, and 2) this recorded information is likely to be reliable.

Study Populations

We performed a pilot test of these candidate QIs to determine the feasibility by performing an abstraction of records in two different health care systems. First, we abstracted 146 de-identified patient charts previously used in ACOVE from primary care offices caring for older adults (age 65 and over) at risk of functional decline with a diagnosis of UI in the Southern California area[7,11,12]. Patients were previously identified as a vulnerable elder by a vulnerable elders survey, which asked about self-rated health, limitations in physical function, age group, and functional disabilities. These records did include the notes of any specialists seen and any related procedure or operative notes. Therefore, the care measured included that of all the doctors treating the patient. As long as the necessary care was given to the patient, it did not matter which provider gave the care to the patient.

For our second population, we reviewed 287 charts from all adult women diagnosed with UI and treated between April 2010 and September 2011 from a 120-physician hospital-based multi-specialty group in Los Angeles. In addition to primary care providers, this multi-specialty group (MSG) had three fellowship-trained female pelvic medicine specialists (two urologists and one urogynecologist), six general gynecologists, and two urologists who provided the care to the patients in the cohort. For this population a retrospective chart abstraction of electronic health records was performed by trained nurses with experience in chart abstraction and quality assessment. This time frame marked the first 18-month period after the launching of a new hospital-based electronic health system (Epic Systems

Corporation, Verona WI)). From this set, 137 cases were identified as having documented new or worsening symptoms of UI of any kind in the medical record (vs. stable/prevalent UI, improving UI or UI attributable to infection), and were included in the study. We applied our proposed QIs to measure compliance with the indicators in both settings. As a *post-hoc* secondary analysis, we also assessed variation in care between the two clinical settings.

Outcome Measures

Our primary outcome measures were compliance with our set of QIs and aggregate scores. Compliance with a QI was defined as at least one provider documenting the delivery of the indicated care to the patient. As described by McGlynn et al,, the number of times a patient was counted in the denominator was dependent on the number of providers who saw the patient and could have performed the specified process[16]. A passing score was given if at least one of the patient's providers delivered the indicated care. In order to produce aggregate scores, we divided all encounters in which recommended care was given by the number of times patients were eligible for specific indicators over a 6-month time period. Aggregate scores were reported as a percentage.

Statistical Analysis

The proportion of recommended care received was calculated as a score from 0 to 100% for each QI. Data are presented as counts and percentages, or means and standard deviations (SD). In our *post-hoc* secondary analysis, tests for significant differences in the proportion of cases receiving appropriate care across groups were performed by way of a Fisher's exact test. Group means were tested for significant differences by way of a Student's t-test, after confirming data met assumptions required for parametric analysis. Differences were considered statistically different where $p < 0.05$. As a quality control measure, 10% of all cases were randomly selected and re-abstracted to measure inter-rater reliability which was determined to be 95.6%. All analysis was performed using SAS v9.2 software.

RESULTS

All quality indicators studied were found to be feasible in both populations, as they were all identifiable in the medical records at least once in both the populations examined. However, there was variation in care identified within and between the different populations (Table 1).

Diagnosis/Workup

63.4% of ACOVE patients had documentation of an attempt to differentiate stress versus urge incontinence, versus 96.4% in the multi-specialty group (MSG, $p<0.001$). Additionally, fewer ACOVE patients had documentation of an assessment for severity of symptoms (75.2% MSG vs. 47.3% ACOVE, $p<0.001$). Neither cohort consistently had documentation of previous pharmaceutical therapies (66.4% MSG vs. 76.3% ACOVE, $p=0.141$) or an assessment of fluid intake (76.3% MSG vs. 55.7% ACOVE, $p=0.117$). In ACOVE, only 37.7% of patients with UI underwent a pelvic exam, versus 97.8% in the MSG ($p<0.001$). Of patients presenting with new or worsening stress urinary incontinence (SUI), only 50.0% of ACOVE received a urinalysis to screen for microhematuria or urinary tract infection, compared with 78.8% of the MSG ($p<0.001$).

General Management

Offering pelvic floor muscle training for UI was documented in only 15.6% of MSG patients and 14.2% of ACOVE patients (p = 0.86). Only a small percentage of women with a body mass index of >25 had documentation of counseling of weight loss as a continence improvement strategy (20.9% MSG vs. 26.1% ACOVE, p = 0.76). A small percentage of providers used anticholinergic medication inappropriately for SUI (1% MSG vs. 11.1% ACOVE, p=0.020).

SUI Management

For women undergoing surgery for SUI, a higher percentage of MSG patients received a pre-operative post void residual assessment (83.0% MSG vs. 50.0% ACOVE, p=0.168). The panel voted that cystoscopy should *not* be performed prior to an incontinence procedure (which includes an intra-operative cystoscopy). Consistent with this, the majority of women did not receive an unnecessary diagnostic cystoscopy before surgery (96.9% MSG vs. 94.4% ACOVE, p=0.613). An intra-operative cystoscopy was performed in most cases in the MSG (95.5% MSG vs. 25.0% ACOVE, p<0.001). These results were limited; however, as only four ACOVE patients received retropubic sling surgery (vs. bulking agents). Only about half of patients in both cohorts had a documented pre-operative Valsalva stress test (57.5% MSG vs 50.5% ACOVE, p=0.999).

Documentation of counseling about specific risks of each procedure type was lacking in both groups (63.8% MSG vs. 75% ACOVE, p=0.99). Even among specialists who treat UI, there was an absence of documentation of informed consent for sling surgery for stress urinary incontinence that specifically addressed mesh-related complications (only 9.3% of eligible cases, MSG only). Post-operative follow-up to assess the efficacy or side effects of intervention by three months was lacking in both groups (69.8% MSG vs. 58.3% ACOVE, p=0.221).

UUI Management

For UUI, there was insufficient use of behavioral modification in both groups, either as initial therapy (69.6% MSG vs. 20.4% ACOVE, p <0.001) or in combination with anticholinergic therapy (58.8% MSG vs. 29% ACOVE, p =0.065) but this was worse in the ACOVE population.

Aggregate Scores

Aggregate scores were categorized by the type of care received: general, SUI, UUI, and overall care (Table 2). Overall, the MSG achieved a higher aggregate score (73.9+/−12.0 MSG vs. 52.1+/−18.9 ACOVE, p<0.001), and a higher score in the specific categories of general care (71.1+/− 14.6 MSG vs. 54.2+/−20.5 ACOVE, p<0.001) and UUI care (73.1+/−34.6 MSG vs. 39.3+/−33.1 ACOVE, p<0.001). SUI care, however, was similar in both populations (79.5+/−14.4 MSG vs. 73.9+/−18.5 ACOVE, p=0.069).

DISCUSSION

In both study populations, the QIs helped to identify areas of suboptimal care. The specific quality issues varied by clinical setting. The ACOVE population included vulnerable elders, who likely had many medical issues that had to be prioritized over UI. Therefore, very few patients underwent second-line therapies, with only 4 undergoing a surgical procedure for SUI. The MSG, conversely, may have represented the other extreme, in which patients were referred to an on-site specialist early and frequently, often before beginning conservative therapy. Unfortunately, our chart abstraction to assess compliance with the QIs did not include collection of demographic data, prohibiting us from making specific conclusions about patient characteristics that may have influenced care.

A pelvic and perineal examination and stress testing are recommended by the International Continence Society (ICS) as part of the initial evaluation of women with UI.[17,18] While a pelvic exam is indicated for all patients presenting with UI, the increased incidence of pelvic organ prolapse amongst the elderly makes it an even more critical component of diagnosis. Urinalysis, which is indicated for all patients presenting with new incontinence, was likewise not used consistently in either population. These represent easy targets for improvement of care for UI, as they are easily obtained, and have the potential to provide diagnostic information and earlier treatment.

A Valsalva stress test prior to operative treatment for SUI is a means to document the presence of SUI. However, this was recorded in only half of patients. A pre-operative post-void residual (PVR) evaluation is recommended as well, as procedures for SUI place patients at increased risk of post-operative urinary retention.[19] A PVR of >30% before surgery may present an even higher risk of post-operative urinary retention due to concomitant bladder outlet obstruction or detrusor underactivity.[17]

Both the MSG and ACOVE populations were highly compliant with the negative indicators, which were indicators that, if performed, are of no proven benefit to the patient but increase cost and even risk to the patient. The ICS recommends that uroflow be reserved for patients with symptoms suggestive of urinary voiding dysfunction and that pre-operative urodynamics be performed only on patients with complicated, refractory, or recurring UI.[17] Medicare data has shown that nearly 25% of women age 65 and over undergo cystoscopy prior to a sling procedure, often unnecessarily.[20] In line with these recommendations, there were zero uroflow studies, very few urodynamic studies, and very few pre-operative cystoscopies performed in both study settings. It should be noted that compliance with the negative indicators might not always be knowledge-based, but rather may be consistent with these providers failing to do the right thing. Hence some of these practices may have been compliant with the negative indicators by “luck”, rather than by knowledge-based decisionmaking.

Needle suspension procedures[21], anterior colporrhaphy[22] and the Kelly plication procedure[23] have been shown to produce suboptimal outcomes compared to other incontinence procedures. Fortunately very few of these procedures were performed in either cohort. However, three-month follow-up rates after surgery for SUI were low in both groups,

ranging from one-half to two-thirds. It is unclear whether newly asymptomatic patients felt no need to return for further care, or whether patients obtained their post-operative care elsewhere.

Both patient populations had insufficient documentation of first-line, non-invasive management options. Despite Level I evidence recommending the use of pelvic floor muscle training (PFMT) for women with UI[17]; fewer than 1 in 6 women had documented counseling regarding it. Although PFMT does not have high absolute cure rates, it is related to significant improvements in symptoms and perceived quality of life,[24–26] and should be utilized as a non-invasive, first-line treatment. Similarly, despite studies showing a correlation between weight loss and improvement of incontinence frequency,[27] only 1 in 4 overweight women had documented evidence of weight loss counseling. Counseling about behavior modification for UUI was also insufficiently documented in both groups. Of note, these findings may be due to both a deficit of counseling as well as a failure to document counseling that did occur.

Documentation regarding counseling about complications of mesh was recorded in fewer than 1 in 10 MSG patients (there were no synthetic sling procedures performed in the ACOVE cohort). After a safety notification concerning vaginal mesh for the treatment of pelvic organ prolapse was released by the FDA in 2011,[28] there has been considerable media and legal attention to the complications of synthetic mesh used in both prolapse and stress incontinence surgery.[29] Given the litigious nature of surgery involving vaginal mesh, pre-operative discussion and documentation of the major risks and benefits associated with surgical procedures using mesh is essential.

CONCLUSIONS

This study provides novel data on the quality of care provided to women with UI in varied clinical settings. The set of QIs we developed were found to be both valid and feasible, and also identified variation in care. These findings serve as preliminary data for interventions to improve the quality of care provided to women with UI.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Incidence of appropriate care given in MSG vs. ACOVE

		# cases meeting criteria/# cases eligible (%)		
	UI	**MSG**	**ACOVE**	**p-value**
Assessment of stress and urge symptoms	1a	132/137 (96.4%)	59/93 (63.4%)	<0.001
Assessment for previous pharmaceutical treatment	1b	91/137 (66.4%)	71/93 (76.3%)	0.141
Assessment of severity	1d	103/137 (75.2%)	44/93 (47.3%)	<0.001
	1a+b+d	326/411 (79.3%) SD 29.6%	174/279 (62.4%) SD 30.0%	<0.001
Assessment of recent pelvic exam	2	134/137 (97.8%)	55/146 (37.7%)	<0.001
Urinalysis for SUI	3	108/137 (78.8%)	73/146 (50.0%)	<0.001
No uroflow for SUI without signs of voiding dysfunction	4	137/137 (100%)	146/146 (100%)	n/a
No urodynamic testing for new UUI without neurologic disease or voiding dysfunction	5	21/28 (75.0%)	21/24 (87.5%)	0.309
Offering of pelvic floor muscle training for new/worsening UI	6	20/128 (15.6%)	17/120 (14.2%)	0.859
Weight loss counseling for overweight women (BMI>25)	7	9/43 (20.9%)	6/23 (26.1%)	0.760
Anticholinergic therapy not offered for SUI without symptoms of overactive bladder	8	95/96 (99.0%)	32/36 (88.9%)	0.020
Preoperative counseling about risks of mesh	9	4/43 (9.3%)	0/0 (0%)	n/a
Preoperative PVR prior to SUI surgery	10	39/47 (83.0%)	2/4 (50.0%)	0.168
No diagnostic cystoscopy for SUI and no other urologic diagnosis or prior incontinence surgery	11	93/96 (96.9%)	34/36 (94.4%)	0.613
Preoperative stress test prior to SUI surgery	12	24/47(57.5%)	2/4 (50.5%)	0.999
No Kelly plication, anterior colporrhaphy or needle suspension for SUI	13	94/96 (97.9%)	34/36 (94.4%)	0.299
Risk counseling for SUI procedures	14	30/47 (63.8%)	3/4 (75.0%)	0.999
Intraoperative cystoscopy during sling surgery for SUI	15	42/44 (95.5%)	¼ (25.0%)	<0.001
Reevaluation within 3 months of initiation of intervention for SUI	16	67/96 (69.8%)	21/36 (58.3%)	0.221
Assessment of fluid intake for UUI	17	61/80 (76.3%)	34/61 (55.7%)	0.117
Behavioral modification counseling, including fluid restriction and bladder training, for UUI/OAB	18	55/79 (69.6%)	11/54 (20.4%)	<0.001
Behavioral modification counseling for women with UUI/OAB being treated with anticholinergic medications	19	10/17 (58.8%)	9/31 (29.0%)	0.065
Counseling about urinary retention and UTI risks prior to Botox injections	20	0/1 (0%)	0/0	n/a

Table 2

Overall aggregate scores

Indicator	MSG		ACOVE		p-value
	N	Mean % (SD)	N	Mean % (SD)	
General care	137	71.7 (14.6)	146	54.2 (20.5)	<0.001
SUI	96	79.5 (14.4)	36	73.9 (18.5)	0.069
UUI	80	73.1 (34.6)	61	39.3 (33.1)	<0.001
Total	137	73.9 (12.0)	146	52.1 (18.9)	<0.001