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TWO-YEAR OUTCOMES AFTER SURGERY FOR STRESS URINARY INCONTINENCE IN OLDER VERSUS YOUNGER WOMEN

Hypothesis / aims of study

There is a relative paucity of information on surgical outcomes in older women. Previous studies looking at risk factors for failure or the effect of age on outcomes for both the Burch colposuspension and fascial sling suggest that cure rates are lower and that there is an increased risk for postoperative storage symptoms, voiding dysfunction, and urinary tract infections in older women [1]. The objective of this study was to determine, in a well characterized randomized cohort, if older women differed from younger women with respect to peri-and postoperative outcomes up to 24 months after undergoing Burch colposuspension or pubovaginal sling for treatment of stress urinary incontinence (SUI).

Study design, materials and methods

Eligibility requirements included a 3 month history of pure or predominant SUI symptoms, a positive standardized urinary stress test, eligibility for both procedures and planned SUI surgery. There was no upper age limit for enrollment. Women were randomized in the operating room to receive a Burch colposuspension or an autologous rectus fascial sling. Abdominal and vaginal approaches for both pelvic prolapse repair and hysterectomy were permitted. Baseline assessment included a medical history, physical examination, urodynamics, and patient symptom surveys. Follow-up data were collected by interview and clinical examination perioperatively, and postoperatively at 6 weeks and 3, 6, 12, 18 and 24 months. Baseline data included age, race, BMI, previous incontinence surgery, number of vaginal deliveries, medication use, menopausal/HRT/smoking status, diabetes, history of frequent urinary tract infections, POPQ stage and Q-tip angle measures. Urge and stress incontinence severity were measured at each visit using a 3-day voiding diary, 24-hour pad test, stress test, the Medical and Epidemiologic Social Aspects of Aging (MESA) questionnaire [2], the Urogenital Distress Inventory (UDI) and Incontinence Impact Questionnaire (IIQ) [3]. Urodynamic data were collected at baseline and 24 months post surgery or at the time of surgical retreatment if that occurred before 24 months. Factors measured included: demonstrable stress incontinence,Valsalva leak point pressures (VLPP's), presence of detrusor overactivity, and voiding dysfunction. Sexual function was characterized using the Pelvic Organ Prolapse and Incontinence Sexual Function Questionnaire (PISQ). Perioperative factors measured were length of hospital stay and adverse events including urinary retention, urinary tract and wound infections. Postoperative measures included: treated and untreated de novo or persistent urge incontinence as measured by MESA, voiding dysfunction, pelvic organ prolapse or subsequent pelvic surgery for any reason after Burch or sling. Overall treatment failure was defined as retreatment for SUI (including behavioural or surgical therapies) at any time and/or self-report of SUI on the MESA questionnaire (response of sometimes or often), and/or positive stress test at the lesser of 300ml or capacity, and/or >15 gram pad weight on 24 hour pad test and/or incontinence episodes on the 3-day bladder diary anytime 6 months after surgery. For factors associated with age we compared women younger than 65 years to those 65 years and older. Perioperative and postoperative events and outcomes were evaluated comparing the two age groups. Bivariate analyses were carried out using cross-classification and the chi-square test for categorical factors and the t-test for comparison of means of continuously measured factors. To further evaluate post-operative outcomes associated with age group, we used multivariable methods to control for treatment group and other covariables. For stress test, a categorical outcome measure, we used multiple logistic regression analysis. For continuous outcome measures, we used least squares regression analysis. For all analyses, we first computed the analysis including age group, treatment group and their interaction. If the interaction effect was not statistically significant we removed it from the analysis. We then added covariates that were found to be significant in bivariate analyses and other variables thought to possibly be clinically significant. A 5% significance level was used. Analyses were performed using SAS Version 9.1 (SAS Institute, Inc. Cary, NC).

Results

655 women were included in analyses of peri-operative events and 554 for 2-year outcomes. Mean age (\pm SD) was 69.7(\pm 3.7) years in the older group and 49.4(\pm 8.2) in the younger group. Older women took slightly longer to resume normal activities [50 versus 42 days, $p=0.05$], but demonstrated no difference in time to resumption of normal voiding [14 versus 11 days, $p=0.42$]. There were no differences in adverse event rates between age groups. Multivariable analyses comparing outcomes between older and younger women are shown in the table:

Outcome	Adjusted Mean Difference (\geq 65 group, <65 group) (95% CI)	p-value
Change in MESA Stress Score	8.4 (2.3, 14.5)	0.007
Change in MESA Urge Score	7.0 (1.8, 12.2)	0.008
	Adjusted odds ratio (\geq 65 group compared to <65 reference group) (95% CI)	p-value
Surgical Retreatment	3.10 (1.34, 6.97)	0.01
Positive Stress Test	3.83 (1.78, 2.87)	<0.001

There were no differences in multivariable analyses for all other 24-month outcomes between the two age groups, including satisfaction with treatment.

Interpretation of results

Older women did not differ from younger women in most perioperative outcomes after undergoing stress incontinence. These outcomes included length of stay, readmissions within 6 weeks, total number of patients with serious adverse events and number of adverse events. However, at 24 months postoperatively, older women were more likely to have a positive stress test, less improvement in subjective assessment of stress and urge incontinence symptoms and a higher odds of surgical retreatment as compared to younger women.

Concluding message

In conclusion, our findings suggest that women 65 years of age and older contemplating surgery for stress urinary incontinence, with or without concomitant prolapse surgery, can expect to do as well as younger women with respect to their surgical experience, voiding function, and patient satisfaction, but may face somewhat lower subjective and objective cure rates. As the number of older women seeking care for this debilitating condition continues to increase, it is imperative that we are able to adequately counsel them with respect to their risks and benefits of surgery, especially with respect to issues of continued symptoms and need for subsequent treatment.

References

1. J Am Geriatr Soc 2007; 55: 1927-1931.
2. J Gerontol 1990; 45:M67-M74.
3. Qual Life Res 1994; 3:291-306.

<i>Specify source of funding or grant</i>	National Institute of Diabetes and Digestive and Kidney Diseases
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	Yes
<i>Specify Name of Public Registry, Registration Number</i>	ClinicalTrials.gov, NCT00064662
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Institutional Review Board
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes