GYNECOLOGY

Is vaginal mesh a stimulus of autoimmune disease?

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BACKGROUND: Polypropylene mesh has been used as a means of reinforcing weak tissues in women with pelvic organ prolapse and stress urinary incontinence.

OBJECTIVE: We sought to investigate a potential link between the development of systemic/autoimmune disorders and synthetic polypropylene mesh repairs.

STUDY DESIGN: New York State Department of Health Statewide Planning and Research Cooperative System data were utilized to conduct this retrospective cohort study. Adult women undergoing surgery for pelvic organ prolapse with vaginally implanted mesh from January 2008 through December 2009 in inpatient and ambulatory surgery settings in New York State were identified. Two separate control cohorts were created to compare outcomes, including a screening colonoscopy cohort and a vaginal hysterectomy cohort for benign gynecologic conditions (without pelvic organ prolapse repair or sling). Patients in the mesh cohort were individually matched to the control cohorts based on demographics, comorbidities, and procedure date. The development of systemic/autoimmune disease was determined before and after matching for 1-year, 2-year, 3-year, and entire follow-up (up to 6 years until December 2014) and differences between groups were evaluated.

RESULTS: A total of 2102 patients underwent mesh-based pelvic organ prolapse surgery from January 2008 through December 2009. In the control cohorts, 37,298 patients underwent colonoscopy and 7338 underwent vaginal hysterectomy. When patients were matched based on demographics, comorbidities, and procedure time, mesh-based surgery was not associated with an increased risk of developing autoimmune disease at any of the evaluated time periods.

CONCLUSION: Mesh-based vaginal surgery was not associated with the development of systemic/autoimmune diseases. These data refute claims against mesh as a cause of systemic disease.

Key words: autoimmune disease, prolapse, vaginal mesh

Introduction

Implantation of surgical mesh was introduced into urogynecologic surgery in the 1990s as a means to reinforce weak tissues and, in the case of vaginal mesh kits, provide apical support through an extraperitoneal approach.[1] The US Food and Drug Administration (FDA) approved surgical mesh for use in stress urinary incontinence surgery in 1996 and for use in pelvic organ prolapse (POP) surgery in 2002. Over time, there has been increasing use of mesh-based prolapse repair, with the majority placed via a transvaginal approach.[2-4] Of the reconstructive materials used, synthetic nonabsorbable polypropylene mesh has become the dominant material used in gynecologic surgery. However, in 2011, the FDA issued a safety communication regarding the use of surgical mesh in POP surgery and stated that serious complications associated with surgical mesh for transvaginal repair of POP were no longer considered rare.[5] Known risks of polypropylene mesh placement include vaginal extrusion, mesh erosion, sexual dysfunction, urinary tract injury, and pain.[6]

Apart from the known risks, synthetic mesh has also been placed under scrutiny on consumer World Wide Web sites, with allegations that mesh placement leads to the subsequent development of systemic autoimmune inflammatory disorders (SAID).[7] Overall SAID is a group of rare disorders with a reported prevalence ranging from 3.2-9.4%.[8-10] One theory to explain why this group of rare disorders may greatly affect this population of women is a chronic foreign body response to a mesh implant, which leads to an oxidative process. This oxidation in theory causes degradation of polypropylene, which comprises synthetic mesh.[11] The occurrence of degradation of the polypropylene could then theoretically result in a state of chronic inflammation, leading to the development of SAID.[12] To date, however, the process of mesh degradation has not been confirmed in human beings and remains controversial.[13] Consumer World Wide Web sites, mesh litigation World Wide Web sites, and patient groups have included anecdotal reports from patients who, after undergoing transvaginal mesh repair, were later diagnosed with SAID such as lupus, fibromyalgia, and rheumatoid arthritis.[7] However, the occurrences of SAID may be events unrelated to the preceding mesh placement. To investigate this issue further, we used administrative claims data to conduct a retrospective cohort study with matched controls. We hypothesized that rates of SAID development do not differ between patients who undergo placement of synthetic polypropylene vaginal mesh and those who do not.

Materials and Methods

Data source

We used New York State Department of Health Statewide Planning and Research Cooperative System (SPARCS) data for this study. Established in 1979, SPARCS is an all-age-group, all-payer data set that collects patient and treatment information for every hospital discharge, ambulatory surgery, outpatient service, and emergency department admission in

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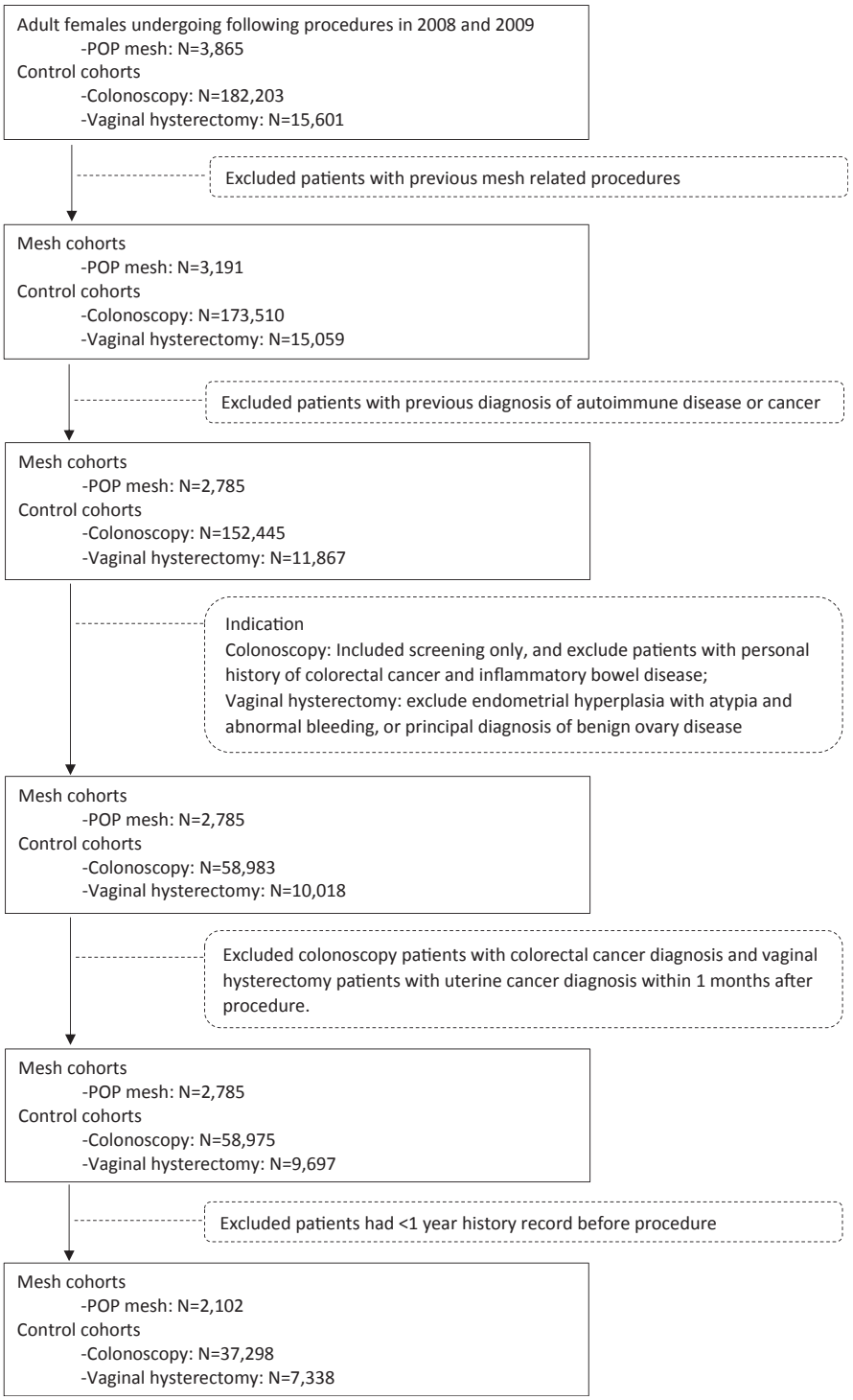
FIGURE
Patient selection process



Flow chart demonstrating how the different patient cohorts were chosen.

POP, pelvic organ prolapse.

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New York State.[14] The data contain patient characteristics, primary and secondary diagnoses and procedures, and length of stay and charges. A unique personal identifier is assigned to every patient and encrypted to allow longitudinal analyses without compromising patient confidentiality.

Study population and follow-up

Adult women (age ≥18 years) undergoing surgeries for POP with vaginal mesh from January 2008 through December 2009 were identified using the *International Classification of Diseases, Ninth Revision, Clinical Modification* procedure codes and *Current Procedural Terminology Coding System, Fourth Edition* codes. For the POP cases, mesh use was identified based on the inclusion of mesh-specific *International Classification of Diseases, Ninth Revision* and *Current Procedural Terminology* codes (insertion of mesh or other prosthesis for repair of pelvic floor defect).

Two control cohorts were selected during the same time period, including women undergoing: (1) screening colonoscopy (nonsurgical cohort); and (2) vaginal hysterectomy for benign gynecologic and urogynecologic conditions. The rationale for including these 2 groups rather than including a third cohort of patients who underwent non-mesh prolapse repair was because a large portion of those patients will also have a mesh sling (which does not include a mesh insertion code and therefore mesh use with sling cannot be calculated). So the third cohort of similarly matched group undergoing colonoscopies was chosen.

Patient histories were queried from the database dating back to 1995 (first year available to us). In mesh and both control cohorts we excluded patients with previous or concomitant SAID diagnosis, cancer diagnosis, or mesh-related procedures (hernia, sling, or prolapse repair). Because there were no mesh-specific codes for prolapse repair prior to 2008, patients who underwent any prolapse repair prior to 2008 were excluded. In the colonoscopy cohort, patients with history

TABLE 1
Patient characteristics and balance before and after matching for pelvic organ prolapse mesh and colonoscopy (female) cohorts

	Before matching			After matching		Balance	
	POP mesh N = 2102	Colonoscopy N = 37,298	*P* value	POP mesh N = 1507	Colonoscopy N = 3014	Difference before	Difference after
Demographics							
Age, y Mean (SD)	61.8 (12.7)	57.0 (12.7)	<.01	60.4 (11.5)	60.4 (11.6)	4.8	0.0
Race/ethnicity			<.01				
Caucasian	1704 (81.9%)	20,218 (56.1%)		1169 (78.1%)	2338 (78.1%)	25.7	0.0
Black	108 (5.2%)	5706 (15.8%)		98 (6.6%)	196 (6.6%)	10.7	0.0
Hispanic	160 (7.7%)	3963 (11.0%)		131 (8.8%)	262 (8.8%)	3.3	0.0
Other	109 (5.2%)	6127 (17.0%)		98 (6.6%)	196 (6.6%)	11.8	0.0
Insurance			<.01				
Medicare	824 (39.2%)	5010 (13.4%)		470 (31.2%)	940 (31.2%)	25.8	0.0
Medicaid	123 (5.9%)	6036 (16.2%)		98 (6.5%)	196 (6.5%)	10.3	0.0
Commercial/other	1155 (54.9%)	26,252 (70.4%)		939 (62.3%)	1878 (62.3%)	15.4	0.0
NY resident	2065 (98.2%)	36,871 (98.9%)	.01	1489 (98.8%)	2978 (98.8%)	0.6	0.0
Comorbidities							
Hypertension	902 (42.9%)	8176 (21.9%)	<.01	584 (38.8%)	975 (32.3%)	21.0	6.4
Diabetes	221 (10.5%)	2819 (7.6%)	<.01	118 (7.8%)	193 (6.4%)	3.0	1.4
Obesity	113 (5.4%)	787 (2.1%)	<.01	52 (3.5%)	52 (1.7%)	3.3	1.7
CAD	115 (5.5%)	707 (1.9%)	<.01	33 (2.2%)	53 (1.8%)	3.6	0.4
CHF	19 (0.9%)	191 (0.5%)	.02	NR		0.4	0.3
PVD	29 (1.4%)	152 (0.4%)	<.01	NR		1.0	0.0
CPD	252 (12.0%)	2072 (5.6%)	<.01	126 (8.4%)	161 (5.3%)	6.4	3.0
Anemia	85 (4.0%)	929 (2.5%)	<.01	27 (1.8%)	50 (1.7%)	1.6	0.1
Renal failure	21 (1.0%)	201 (0.5%)	<.01	NR		0.5	0.0
Depression	161 (7.7%)	1092 (2.9%)	<.01	65 (4.3%)	92 (3.1%)	4.7	1.3

CAD, coronary artery disease; *CHF*, congestive heart failure; *CPD*, chronic pulmonary disease; *NR*, no response; *POP*, pelvic organ prolapse; *PVD*, peripheral vascular disease.
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of colorectal cancer and diagnosis of inflammatory bowel diseases were excluded. In the vaginal hysterectomy cohort, patients with endometrial hyperplasia with atypia, abnormal vaginal bleeding, or a principal diagnosis of benign ovarian tumor or cysts were excluded. We also excluded controls who had a colorectal cancer diagnosis within 1 month after colonoscopy, as well as women with a uterine cancer diagnosis within 1 month after vaginal hysterectomy. To assess comorbidities we further restricted the study population to patients who had at least 1 year's record in SPARCS before the index admission. Detailed patient selection process is depicted in the flow chart (Figure).

Patients were then followed up until the end of the study time period (December 2014). The primary outcomes of interest was the development of SAID at 1 year, 2 years, and during entire follow-up time. Patient characteristics analyzed included age, race (Caucasian and non-Caucasian), insurance status (Medicare, Medicaid, commercial, and other), place of residence (New York State or out-of-state resident), and comorbidities. Relevant comorbidities were identified using algorithms validated by Elixhauser et al,[15] including coronary artery disease, hypertension, congestive heart failure, diabetes, chronic pulmonary disease, obesity, anemia, peripheral vascular disease, renal failure, and depression. An unknown category was created for missing race information for analysis.

Statistical analyses

Individual matching was performed to account for difference in patient characteristics between mesh and control cohorts. Matching ratio was 1:2 for

TABLE 2
Patient characteristics and balance before and after matching for pelvic organ prolapse mesh and vaginal hysterectomy cohorts

	Before matching			After matching		Balance	
	POP mesh N = 2102	Vaginal hysterectomy N = 7338	*P* value	POP mesh N = 1375	Vaginal hysterectomy N = 1375	Difference before	Difference after
Demographics							
Age, y Mean (SD)	61.8 (12.7)	50.4 (12.9)	<.01	59.2 (12.7)	59.1 (12.6)	11.4	0.1
Race/ethnicity			<.01				
Caucasian	1704 (81.9%)	5566 (76.3%)		1102 (80.3%)	1102 (80.3%)	5.6	0.0
Black	108 (5.2%)	510 (7.0%)		73 (5.3%)	73 (5.3%)	1.8	0.0
Hispanic	160 (7.7%)	754 (10.3%)		124 (9.0%)	124 (9.0%)	2.6	0.0
Other	109 (5.2%)	465 (6.4%)		73 (5.3%)	73 (5.3%)	1.1	0.0
Insurance			<.01				
Medicare	824 (39.2%)	1229 (16.7%)		452 (32.9%)	452 (32.9%)	22.5	0.0
Medicaid	123 (5.9%)	930 (12.7%)		93 (6.8%)	93 (6.8%)	6.8	0.0
Commercial/other	1155 (54.9%)	5179 (70.6%)		830 (60.4%)	830 (60.4%)	5.6	0.0
NY resident	2065 (98.2%)	7208 (98.2%)	.97	1353 (98.4%)	1353 (98.4%)	0.0	0.0
Comorbidities							
Hypertension	902 (42.9%)	1981 (27.0%)	<.01	520 (37.8%)	524 (38.1%)	15.9	0.3
Diabetes	221 (10.5%)	542 (7.4%)	<.01	108 (7.9%)	123 (8.9%)	3.1	1.0
Obesity	113 (5.4%)	407 (5.5%)	.76	52 (3.8%)	49 (3.6%)	0.2	0.2
CAD	115 (5.5%)	228 (3.1%)	<.01	42 (3.1%)	69 (5.0%)	2.4	1.9
CHF	19 (0.9%)	35 (0.5%)	.02	NR		0.4	0.6
PVD	29 (1.4%)	45 (0.6%)	<.01	NR		0.8	0.4
CPD	252 (12.0%)	873 (11.9%)	.91	146 (10.6%)	144 (10.5%)	0.1	0.1
Anemia	85 (4.0%)	698 (9.5%)	<.01	33 (2.4%)	64 (4.7%)	5.5	2.3
Renal failure	21 (1.0%)	41 (0.6%)	.03	NR		0.4	0.5
Depression	161 (7.7%)	688 (9.4%)	.02	80 (5.8%)	92 (6.7%)	1.7	0.9

CAD, coronary artery disease; *CHF*, congestive heart failure; *CPD*, chronic pulmonary disease; *POP*, pelvic organ prolapse; *PVD*, peripheral vascular disease.
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mesh and colonoscopy patients and 1:1 for mesh and vaginal hysterectomy patients. Because age and race/ethnicity are important risk factors for SAID,[8] while procedure date and place of residence affect follow-up, exact matching was performed on age category (in 5 years), race/ethnicity, insurance payer, place of residence, and date of procedure (in quarters) to achieve full balance. Patients were also matched by comorbidity status to account for their general health conditions, with at least 7 of the 10 comorbidities being exactly matched for each pair. A total of 1507 POP mesh patients were matched to 3014 colonoscopy patients. The matching of POP mesh patients and vaginal hysterectomy patients yielded 1375 pairs. Baseline characteristics were compared between mesh and control cohorts. Events and percentages were presented for patient demographics and comorbidities. Mean and SD was calculated for age. Differences between groups were assessed using χ^2 tests and Student *t* tests. Balance was assessed by examining differences in baseline variables between mesh and control cohorts before and after matching.

The presence of SAID of interest was determined before and after matching at 1 year, 2 years, 3 years, and the entire follow-up time period after index procedure. Events and percentages in the matched cohort were presented. Differences in outcomes between mesh and control groups were assessed using conditional logistic regression. Univariable analysis and multivariable analysis, further adjusting for age as a continuous variable and each individual comorbidity, were performed. Sample size calculation indicated that to detect a 1% difference in SAID occurrence with

TABLE 3
Entire follow-up of systemic autoimmune/inflammatory disease in mesh and control cohorts after matching

	Matched cohort				
	Mesh cohort	Control cohort	Difference (95% CI)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Cohort	POP mesh	Colonoscopy			
N matched	1507	3014			
SAID	43 (2.9%)	97 (3.2%)	−0.3% (−1.4% to 0.7%)	0.88 (0.61−1.27)	0.91 (0.62−1.34)
Cohort	POP mesh	Vaginal hysterectomy			
N matched	1375	1375			
SAID	39 (2.8%)	46 (3.4%)	−0.6% (−1.8% to 0.8%)	0.85 (0.55−1.30)	0.78 (0.48−1.26)

CI, confidence interval; *OR*, odds ratio; *POP*, pelvic organ prolapse; *SAID*, systemic autoimmune inflammatory disorder.
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alpha of 0.05 and 80% power, 4863 patients were needed in each group. To detect a 1% difference in SAID occurrence with alpha of 0.15 and 60% power, 1772 patients were needed in each group. All analyses were performed using software (SAS v9.3; SAS Institute Inc, Cary, NC).

Results

For the time interval from January 2008 through December 2009, a total of 3865 women underwent POP repairs with vaginally implanted mesh. Of these, 2102 patients did not have previously diagnosed SAID, and were included in the final analysis. The 2 control cohorts without preexisting SAID included 37,298 female patients having screening colonoscopy and 7338 undergoing vaginal hysterectomy.

Mean ages of patients undergoing mesh-based POP surgery, colonoscopy, and vaginal hysterectomy were 61.8, 57.0, and 50.4 years old, respectively (Tables 1 and 2). Most were Caucasian (POP 81.9%, colonoscopy 56.1%, and hysterectomy 76.3%) and had commercial insurance (54.9%, 70.4%, and 70.6%, respectively). When compared to control groups, patients undergoing POP repair were older and more likely to be Caucasian and Medicare beneficiaries. This group of patients was also more likely to have comorbidities at the time of procedure.

The average time between the procedure and end of follow-up was 6 years. A total of 59 (2.8%), 1060 (2.8%), and 235 (3.2%) patients undergoing mesh-based POP surgery, colonoscopy, and vaginal hysterectomy, respectively, were diagnosed with SAID during follow-up until the end of 2014 (Table 3). When patients were individually matched based on demographics, date of procedure, and comorbidities, mesh-based prolapse surgery was not associated with increased risks of developing autoimmune disease over the entire follow-up time period (Table 3), when comparing to either the colonoscopy group (odds ratio, 0.91; 95% confidence interval, 0.62−1.34) or the vaginal hysterectomy group (relative risk, 0.78; 95% confidence interval, 0.48−1.26). No association between mesh surgery and increased risks of SAID was found at any of the measured time points (1-, 2-, and 3-year follow-up) (Table 4).

Comment

We found no relationship between exposures to vaginal mesh and subsequent development of SAID. The unadjusted rates of SAID were higher in both the vaginal hysterectomy group and colonoscopy group. After matching based on patient characteristics and procedure time, there remained no association between exposure to vaginal mesh and SAID up to 6 years.

Vaginal mesh has been used safely for decades, and synthetic slings for stress urinary incontinence are considered the gold standard by the Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction; American Urogynecologic Society; and American Urological Association.[16,17] More recently, vaginally placed kits became popular as a minimally invasive yet durable means to address prolapse through an extraperitoneal vaginal approach. Although efficacious overall, these kits were associated with complications that led to FDA safety communications in 2008[18] and 2011.[5] In fact, since 2011, there has been a significant increase in Internet search activity for terms such as "vaginal mesh,"[19] demonstrating public interest in the topic. The number of litigation claims related to vaginal mesh has also significantly increased. More than 73,000 federal lawsuits have been filed against manufacturers of transvaginal mesh products.[20] Mesh has been placed under additional scrutiny with concerns on consumer World Wide Web sites about the association of mesh and the subsequent development of systemic/autoimmune diseases.[7] There is growing uncertainty among patients regarding the long-term safety of these procedures, which have been associated with high success rates. Further investigation of these long-term outcomes is necessary to be able to adequately counsel patients about the possible risks of the procedures.

Animal models have shown various types of meshes to cause inflammation,

TABLE 4
Follow-up of autoimmune disease in mesh and control cohorts in matched cohorts

	Unadjusted OR (95% CI) Mesh vs control	Adjusted OR (95% CI) Mesh vs control
1-y		
POP mesh vs colonoscopy	0.15 (0.02–1.18)	0.20 (0.03–1.62)
POP mesh vs vaginal hysterectomy	0.17 (0.02–1.38)	0.25 (0.03–2.24)
2-y		
POP mesh vs colonoscopy	0.53 (0.25–1.16)	0.60 (0.27–1.36)
POP mesh vs vaginal hysterectomy	0.70 (0.27–1.84)	0.67 (0.19–2.36)
3-y		
POP mesh vs colonoscopy	1.02 (0.63–1.65)	1.09 (0.65–1.83)
POP mesh vs vaginal hysterectomy	1.35 (0.72–2.53)	1.42 (0.67–2.98)

CI, confidence interval; *OR*, odds ratio; *POP*, pelvic organ prolapse.

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foreign body reaction, and fibrosis.[21] Patient support groups have also maintained that patients with adverse reactions to transvaginal and hernia mesh repairs are reporting subsequent diagnoses of autoimmune disorders such as lupus, fibromyalgia, and rheumatoid arthritis.[22-24]

Interestingly, 41.6% of women in the original mesh cohort were excluded because of preexisting SAID. This attests to the high rate of SAID in this female adult population with prolapse, and so the subsequent rates of SAID development is expected in both mesh and nonmesh cohorts. To date, evidence on the role of polypropylene and onset of SAID is limited with a lack of controlled data from trials or prospective cohort studies. To our knowledge, this is the first population-based study with matching controls to evaluate the association between vaginal mesh and onset of SAID.

There were a few limitations associated with using the New York State cohort data. SPARCS is an administrative database. Clinical variables including severity of POP and volume of mesh placed were not available in administrative data. Clinical and laboratory data for autoimmune disease were also not available. Furthermore, there is the risk of miscoding of procedures and diagnosis of autoimmune disease. We made every attempt to adjust for observed confounding factors when running statistical methods by matching. The paired design to include patients with similar characteristics was likely to balance the unobserved confounding between mesh and control cohorts. We selected our control cohorts carefully such that a history of mesh would have been very unlikely. However, patients who had mesh-related surgery before 1995 or in another state may have been included and their history of mesh use would not be identified. To increase the strength of our data, the study was conducted using data from patients from 2008 through 2009 who underwent an incident vaginal mesh operation. Further, we were unable to adjust for environmental factors as they were not available in administrative data.

Conclusions

Mesh-based vaginal surgery was not associated with the development of systemic autoimmune/inflammatory diseases compared to those undergoing routine screening colonoscopy or vaginal hysterectomy. These findings suggest that the transvaginal implantation of vaginal mesh for POP repair does not appear to be correlated with the development of SAID. ■

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References

1. Iglesia CB, Fenner DE, Brubaker L. The use of mesh in gynecologic surgery. Int Urogynecol J Pelvic Floor Dysfunct 1997;8:105-15.

2. Rogo-Gupta L, Rodriguez LV, Litwin MS, et al. Trends in surgical mesh use for pelvic organ prolapse from 2000 to 2010. Obstet Gynecol 2012;120:1105-15.

3. Jonsson Funk M, Edenfield AL, Pate V, Visco AG, Weidner AC, Wu JM. Trends in use of surgical mesh for pelvic organ prolapse. Am J Obstet Gynecol 2013;208:79.e71-7.

4. Chughtai B, Mao J, Buck J, Kaplan S, Sedrakyan A. Use and risks of surgical mesh for pelvic organ prolapse surgery in women in New York state: population-based cohort study. BMJ 2015;350:h2685.

5. Food and Drug Administration. Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication. Available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm. Accessed August 10, 2016.

6. American Urological Association. AUA position statement on the use of vaginal mesh for the repair of pelvic organ prolapse. Available at: https://www.auanet.org/education/vaginal-mesh-for-pelvic-organ-prolapse.cfm. Accessed August 10, 2016.

7. Akre J. Autoimmune diseases and surgical mesh—causation or correlation? Available at: http://meshmedicaldevicenewsdesk.com/autoimmune-diseases-and-surgical-mesh-causation-or-correlation. August 10, 2016.

8. Cooper GS, Stroehla BC. The epidemiology of autoimmune diseases. Autoimmun Rev 2003;2:119-25.

9. Cooper GS, Bynum ML, Somers EC. Recent insights in the epidemiology of autoimmune diseases: improved prevalence estimates and understanding of clustering of diseases. J Autoimmun 2009;33:197-207.

10. Eaton WW, Rose NR, Kalaydjian A, Pedersen MG, Mortensen PB. Epidemiology of autoimmune diseases in Denmark. J Autoimmun 2007;29:1-9.

11. Ostergard DR. Polypropylene vaginal mesh grafts in gynecology. Obstet Gynecol 2010;116:962-6.

12. Clave A, Yahi H, Hammou JC, Montanari S, Gounon P, Clave H. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. Int Urogynecol J 2010;21:261-70.
13. Ostergard DR. Degradation, infection and heat effects on polypropylene mesh for pelvic implantation: what was known and when it was known. Int Urogynecol J 2011;22:771-4.
14. New York State Department of Health. Statewide Planning and Research Cooperative System (SPARCS). Available at: http://www.health.ny.gov/statistics/sparcs/. Accessed Aug. 19, 2014.
15. Elixhauser A, Steiner C, Harris DR, Coffey RM. Comorbidity measures for use with administrative data. Med Care 1998;36:8-27.
16. Dmochowski RR, Blaivas JM, Gormley EA, et al. Update of AUA guideline on the surgical management of female stress urinary incontinence. J Urol 2010;183:1906-14.
17. Lucas MG, Bosch RJ, Burkhard FC, et al. EAU guidelines on surgical treatment of urinary incontinence. Eur Urol 2012;62:1118-29.
18. Food and Drug Administration. Transvaginal Placement of Surgical Mesh. Available at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm079028.htm. Accessed August 10, 2016.
19. Google. Google trends for "vaginal mesh." Available at: https://www.google.com/trends/explore#q=vaginal%20mesh&cmpt=q&tz=Etc%2FGMT%2B4. Accessed August 11, 2016.
20. Transvaginal Mesh Legal Center. Mesh lawsuits. Available at: http://www.tvmeshlegal.com/. Accessed August 11, 2016.
21. Orenstein SB, Saberski ER, Kreutzer DL, Novitsky YW. Comparative analysis of histopathologic effects of synthetic meshes based on material, weight, and pore size in mice. J Surg Res 2012;176:423-9.
22. Wideman N. The links between surgical mesh complications and the development of autoimmune diseases. Available at: http://meshproblems.weebly.com/linking-the-research-from-fbr-to-implant-materials-to-autoimmune-disease-initiation-or-exacerbation.html. Accessed July 20, 2016.
23. Mesh Medical Device Newsdesk. Autoimmune Diseases and Surgical Mesh-Causation or Correlation? Available at: http://www.meshmedicaldevicenewsdesk.com/autoimmune-diseases-and-surgical-mesh-causation-or-correlation/. Accessed July 20, 2016.
24. Day P. Autoimmune disease: pelvic mesh owners guide. Available at: http://pelvicmeshownersguide.com/category/complications/autoimmune-disease/. Accessed August 11, 2016.

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