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No increased risk of carcinogenesis with mesh-based hernia repairs

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ABSTRACT

Background: The use of synthetic mesh has been placed under considerable scrutiny. We sought to evaluate whether there is a link between placement of synthetic polypropylene mesh for hernia repair and a subsequent cancer diagnosis.

Methods: Adult men undergoing mesh-based hernia repair from January 2008–December 2009 in New York State were identified and followed through December 2014. Control cohorts of men undergoing cholecystectomy and total knee replacement were control cohorts.

Results: 1894 patients undergoing hernia repair, 912 patients in the cholecystectomy control cohort, and 1099 in the TKA control cohort with a cancer diagnosis. In the matched analyses of mesh-based hernia repair and cholecystectomy patients 6.5% vs. 7.1% developed cancer. In the matched analysis of hernia patients and TKA patients, 9.3% vs. 9.1% developed cancer. No association between mesh-based hernia surgery and increased risk of cancer was found.

Conclusions: Mesh-based hernia repair was not associated with an increased risk of subsequent development of cancer in men.

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1. Introduction

Each year over 800,000 hernia repairs are performed in the United States.^{1,2} Surgical mesh has been used to reinforce weak tissues by creating the development of scar tissue, stimulated by a foreign body reaction.³ There are a myriad of mesh types currently available, with the specific type used based on the provider's preference. The most popular types of mesh commercially available are synthetic non-absorbable polypropylene meshes.⁴

In response to a number of reported complications for polypropylene mesh in both men and women, the Food and Drug Administration (FDA) began analyzing scientific reports of adverse events since 2011. The most commonly reported complications associated with mesh-based hernia repair are adhesions, injury to adjacent organs, pain (0.7–43.3%),^{5,6} hernia recurrence (0.5–15%),⁷ infection (0.1–0.2%),⁸ mesh migration,⁹ mesh shrinkage and bowel obstruction.³ Mesh complications leading to repeat surgery has

been well documented in large scale real world investigations.^{10,11}

The use of synthetic mesh has been also placed under considerable scrutiny on a number of consumer websites. Concerns related to systemic diseases and cancer are linked to theories suggesting that mesh degrades under an oxidative process and release of free radicals,¹² leading to a state of chronic inflammation, which could later induce carcinogenesis.^{13,14} We conducted a large cohort study utilizing statewide all-inclusive data to determine if there is a potential link between placement of synthetic polypropylene mesh for hernia repair and a subsequent cancer diagnosis.

2. Materials and methods

2.1. Data source

We used the all-age-group, all payer New York State Department of Health Statewide Planning and Research Cooperative System (SPARCS) data for the present study. SPARCS collects records for every hospital discharge, ambulatory surgery, outpatient service and emergency department admission in New York State,¹⁴

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containing 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. This study was approved by the Weill Cornell Medical College Institutional Review Board.

2.2. Study population and follow-up

Adult male patients undergoing hernia surgery with mesh between January 2008 and December 2009 were identified using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure codes and Current Procedural Terminology Coding System, Fourth Edition (CPT-4) codes (See Appendix Table 1). Patients undergoing inguinal hernia repair in our cohort were assumed to have undergone the repair with mesh due to the universal adoption of mesh for inguinal herniorrhaphy.^{3,15–17} Two control cohorts of men undergoing procedures during the same time period were selected. The first control cohort included men undergoing cholecystectomy for cholecystitis or cholelithiasis. The second control cohort included men undergoing primary knee arthroplasty (TKA) for osteoarthritis. Both groups were chosen because these are two benign conditions that affect males with no immediate increase in cancer development. Further, the two conditions afflict men about the same age as those undergoing hernia repair. These two control groups were chosen to help define baseline rates of cancers among men. Although there are other procedures with larger amounts of mesh used, the number were too small or had comorbidities that may confound results.

Patients' histories were collected from the inception of the database (1995). In mesh and control cohorts we excluded men with a previous cancer diagnosis or mesh related procedures (hernia). In the cholecystectomy cohort, patients with a diagnosis of gallbladder, liver or pancreatic cancer within one month after surgery were excluded. Patients with less than one year's record in SPARCS before index admission were also excluded. The detailed patient selection process is depicted in a flow chart (Fig. 1).

The end of the study follow-up time was December of 2014 (last date of available data). Our primary outcome was the cancer incidence at one year, two years and three years, and during entire follow-up time through December of 2014 (See Appendix Table 2 for cancer diagnosis codes). Our goal was to identify if there was an immediate public health risk with exposure to polypropylene mesh, thus the short-term follow-up. Patient characteristics included age, race (white and non-white), insurance status (Medicare, Medicaid, Commercial and other), place of residence (New York State or out-of-state resident) and comorbidities. Relevant comorbidities (coronary artery disease, hypertension, congestive heart failure, diabetes, chronic pulmonary disease, obesity, anemia, peripheral vascular disease, renal failure, and depression) were identified using algorithms validated by Elixhauser et al.¹⁸ An unknown category was created for missing race information.

2.3. Statistical analyses

Individual 1:1 exact matching was performed to account for difference in patient characteristics between hernia and control cohorts. Matching was performed based on age category (in 5 year increments), race/ethnicity, insurance payor, place of residence, and date of procedure (in quarters) to achieve full balance. Patients were also matched by individual comorbidities to account for their general health conditions.

Baseline characteristics before and after matching were

compared between mesh and control cohorts. Events and percentages were presented for patient demographics and comorbidities. Mean and standard deviation (SD) were calculated for age. Differences between groups were assessed using Chi-square and Student's *t* tests. Balance was assessed by examining differences in baseline variables between mesh and control cohorts before and after matching.

The incidence of the cancer of interest was determined before and after matching at one year, two years, three years, and the entire follow-up time period after the index procedure. Events and percentages in the matched cohort were compared differences in outcomes between mesh and control groups were assessed using conditional logistic regression. Univariate and multivariate analyses adjusting for age as a continuous variable and each individual comorbidity were performed. All analyses were performed using SAS v9.3 (SAS Institute Inc., Cary, NC).

3. Results

For the study period from January 2008 to December 2009, a total of 53,409 men underwent mesh-based hernia repair. Of these, 27,425 met inclusion criteria and were included in the final analysis. The control cohort included 13,339 men who underwent cholecystectomy and 11,435 men undergoing TKA who did not have a previous or concurrent cancer diagnosis.

The average age of patients undergoing mesh-based hernia repair, cholecystectomy and TKA were 56.9, 55.1, and 65.4 years, respectively (Tables 1 and 2). Most patients were Caucasian in all groups (hernia: 74.8%, cholecystectomy: 75.9%, TKA: 85.0%). Patients undergoing hernia repair were less likely to have comorbidities at the time of procedure compared with cholecystectomy and TKA patients. After matching, patient characteristics were balanced between hernia and control groups.

The average time of follow-up was six years (range 5–7 years). When hernia patients were compared to cholecystectomy and TKA patients, mesh-based hernia repair was not associated with an increased risk of cancer at one, two and three years (Table 3), with or without further adjustment of age and comorbidities. During the entire follow-up time period, there was also no difference between hernia and control cohorts in cancer incidence after matching and further adjusting for age and comorbidities (Hernia vs. Cholecystectomy Odds Ratio (OR) 0.90, 95% CI 0.79–1.03; Hernia vs. TKA OR 1.03, 95% CI 0.90–1.17).

4. Discussion

Mesh-based hernia repair has been the dominant method of hernia repair since 1998.¹⁹ Furthermore, it is widely accepted as the gold standard over basic suture repairs.¹⁶ The host response with fibrosis provides strength and support to weak tissue. Despite this, patient advocate groups have made claims that the fibrotic response may be long standing and have a systemic response to hernia mesh, a reaction that may lead to carcinogenesis.^{20,21}

Consumer websites have questioned the long-term safety of mesh on health outcomes. This may be based on the theory that an immune reaction causes the mesh material to degrade oxidatively.¹² This would then lead to a chronic state of inflammation, release of free radicals, and the subsequent development of cancer.¹³ Although mesh induces foreign body reaction, a fibrotic response, and scar formation which gives it its strength, we found no evidence for the risk of malignancy.

Our previous work has demonstrated higher rates of complications in women with the use of mesh.^{10,17} Given this finding and possible concern over long-term systemic effects, we have also looked for systemic effects of mesh in both men and women and

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