ELSEVIER

JMIG The Journal of Minimally Invasive Gynecology

Original Article

Impact of the 2014 Food and Drug Administration Warnings Against Power Morcellation

Deirdre A. Lum, MD*, Eric R. Sokol, MD, Jonathan S. Berek, MD, MMS, Jay Schulkin, PhD, Ling Chen, MD, MPH, Cora-Ann McElwain, BA, and Jason D. Wright, MD

From the Department of Obstetrics and Gynecology, Stanford University School of Medicine, Stanford, California (Drs. Lum, Sokol, and Berek), American College of Obstetricians and Gynecologists, Washington, DC (Dr. Schulkin, and Ms. McElwain), and Department of Obstetrics and Gynecology, Columbia University College of Physicians and Surgeons, New York, NY (Drs. Chen and Wright).

ABSTRACT **Study Objective:** To determine whether members of the AAGL Advancing Minimally Invasive Gynecologic Surgery Worldwide (AAGL) and members of the American College of Obstetricians and Gynecologists Collaborative Ambulatory Research Network (ACOG CARN) have changed their clinical practice based on the 2014 Food and Drug Administration (FDA) warnings against power morcellation.

Design: A survey study.

Setting: Participants were invited to complete this online survey (Canadian Task Force classification II-2).

Patients: AAGL and ACOG CARN members.

Interventions: An online anonymous survey with 24 questions regarding demographics and changes to clinical practice during minimally invasive myomectomies and hysterectomies based on the 2014 FDA warnings against power morcellation.

Measurements and Main Results: A total of 615 AAGL members and 54 ACOG CARN members responded (response rates of 8.2% and 60%, respectively). Before the FDA warnings, 85.8% and 86.9%, respectively, were using power morcellation during myomectomies and hysterectomies. After the FDA warnings, 71.1% and 75.8% of respondents reported stopping the use of power morcellation during myomectomies and hysterectomies. The most common reasons cited for discontinuing the use of power morcellation or using it less often were hospital mandate (45.6%), the concern for legal consequences (16.1%), and the April 2014 FDA warning (13.9%). Nearly half of the respondents (45.6%) reported an increase in their rate of laparotomy. Most (80.3%) believed that the 2014 FDA warnings have not led to an improvement in patient outcomes and have led to harming patients (55.1%).

Conclusion: AAGL and ACOG CARN respondents reported decreased use of power morcellation during minimally invasive gynecologic surgery after the 2014 FDA warnings, the most common reason cited being hospital mandate. Rates of laparotomy have increased. Most members surveyed believe that the FDA warnings have not improved patient outcomes. Journal of Minimally Invasive Gynecology (2016) 23, 548–556 © 2016 AAGL. All rights reserved.

Keywords: American College of Obstetricians and Gynecologists; American Association of Gynecologic Laparoscopists; Food and Drug Administration warning; Power morcellation; Survey

Morcellation, the division of tissue into fragments, is commonly used during a minimally invasive hysterectomy or myomectomy to facilitate removal of the uterus or leiomyomas. In 1995, the US Food and Drug Administration (FDA) approved the first power morcellator [1], a medical device that uses electromechanical energy to fragment tissue specimens.

Leiomyomas are the most common pelvic tumor in women, occurring in up to 80% of women by age 50 years [2]. They are a leading indication for hysterectomy, of which nearly half are performed through a minimally invasive approach [3]. The benefits of a minimally invasive approach are well documented and include smaller scars, faster recovery, and fewer complications when compared with an open

The authors declare that they have no conflict of interest.

Corresponding author: Deirdre A. Lum, MD, Division of Gynecology, Department of Obstetrics and Gynecology, Stanford University School of Medicine, 300 Pasteur Drive, HG-332, Stanford, CA, 94305-5317.
E-mail: lumd@stanford.edu

Submitted November 16, 2015. Accepted for publication January 21, 2016.
Available at www.sciencedirect.com and www.jmig.org

1553-4650/$ - see front matter © 2016 AAGL. All rights reserved.
http://dx.doi.org/10.1016/j.jmig.2016.01.019

approach [4–6]. Women undergoing an open hysterectomy have 3 times the risk of mortality compared with those undergoing a laparoscopic hysterectomy [7].

In April and November 2014, the US FDA issued warnings against power morcellation, citing a potential risk of the spread of undiagnosed uterine sarcoma [8,9]. The actual reported incidence of an occult uterine sarcoma is highly variable, ranging from 1 in 350 to 1 in 8,300 [10–14]. There is no preoperative diagnostic test that can reliably detect a uterine sarcoma.

Gynecologic surgeons face the dilemma of balancing the potential risk for seeding an undiagnosed uterine sarcoma associated with performing morcellation and the risk of morbidity associated with performing a laparotomy. The frequency of use for power morcellation among practicing gynecologic surgeons subsequent to the 2014 FDA warnings has not been well described. To assess the prevalence in clinical practice of power morcellation, we surveyed members of the AAGL Advancing Minimally Invasive Gynecologic Surgery Worldwide (AAGL) and the American College of Obstetricians and Gynecologists Collaborative Ambulatory Research Network (ACOG CARN). The objective of our study was to ascertain the frequency of the use of power morcellation among gynecologic surgeons and to assess any change in clinical practice generated by the 2014 FDA warnings.

Methods

AAGL and ACOG CARN members were invited via e-mail to participate in an Internet-based survey of power morcellation use during minimally invasive hysterectomy and myomectomy. A total of 3 e-mails (the maximum allowed by the AAGL) were sent to the mailing list of 7,500 AAGL members, and 5 e-mails were sent to 90 ACOG CARN members (until the response rate was over 50%). The CARN consists of a group of practicing obstetricians and gynecologists who volunteer to participate in survey-based research. The CARN has been described in depth elsewhere [5–17]. The 90 members chosen expressed an interest or experience in surgery.

Survey questions were developed based on the type of questions sent to members of the American Urogynecology Society to assess the impact of the 2011 FDA transvaginal mesh safety update regarding the use of synthetic mesh for pelvic reconstructive surgery [18]. The survey was pilot tested by experts in minimally invasive gynecology before final implementation. Exclusion criteria were members who reported practicing outside of the United States and those not performing gynecologic surgery.

The survey collected basic demographic information including age, sex, type of practice, specialty, fellowship training, number of years in practice (in 5-year increments), and number of total gynecologic cases performed per year (in increments of 50). Respondents who reported performing myomectomies and hysterectomies were asked about their use of power morcellation before and after the FDA warnings. The primary objective of the survey was to assess change in clinical practice after the FDA warnings. Questions were asked regarding preoperative counseling, use of endometrial biopsies, and rates of laparotomy since the FDA warnings. Participants were asked whether their hospital banned power morcellation, their opinions on the accuracy of the FDA's risk estimate of an unsuspected uterine sarcoma, and whether the FDA warnings have yielded an overall improvement in patient outcomes.

Data were reported descriptively. Differences between categoric variables were assessed using chi-square tests. All analyses were performed with SAS version 9.4 (SAS Institute Inc, Cary, NC). All statistical tests were 2-sided. A p value $< .05$ was considered statistically significant.

Results

A total of 615 AAGL members and 54 ACOG CARN members responded to the survey (response rates of 8.2% and 60%, respectively). The demographic characteristics of responders are listed in Table 1. Three hundred eighty-nine AAGL members (64.7%) reported practicing in the United States. Both AAGL and CARN responders represented a wide range of ages, years of practice, and surgical volume. The groups were overall similar in demographics except AAGL responders reported performing more surgical cases per year, were more likely to have fellowship training in minimally invasive gynecologic surgery and were more likely to be in academic medicine than CARN responders.

Fig. 1 summarizes the reported use of power morcellation during myomectomy and hysterectomy before and after the 2014 FDA warnings. Most respondents (55.7%) reported using power morcellation in more than 80% of myomectomies before the FDA warnings, with 71.1% reporting 0% use after the FDA warnings. Similarly, 75.2% of respondents reported using power morcellation in up to 50% of hysterectomies before the FDA warnings, with 75.8% reporting 0% use after the FDA warnings.

Table 2 summarizes the changes in clinical practice since the 2014 FDA warnings. Approximately half of all responders (49.6%) reported that their hospital had banned power morcellation. The majority of responders (88.7%) thought that the FDA risk estimate of an unsuspected sarcoma was too high. Most respondents (79.6%) reported that they stopped using power morcellation or used it less often after the 2014 FDA warnings, using a range of alternate options. The most common reason for stopping or decreasing the use of power morcellation was hospital mandate (45.6%), followed by legal consequences (16.1%), the April 2014 FDA warning (13.9%), the November 2014 FDA warning (10.3%), and patient request (6.4%).

Before the 2014 FDA warnings, approximately half of all responders (49.3%) reported usually or always counseling