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The Journal of Minimally Invasive Gynecology

Review Article

Safety of Minimally Invasive Tissue Extraction in Myoma Management: A Systematic Review

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ABSTRACT **Objective:** This review seeks to establish the incidence of adverse outcomes associated with minimally invasive tissue extraction at the time of surgical procedures for myomas.

Data Sources: Articles published in the following databases without date restrictions: PubMed, EMBASE, Web of Science, Cochrane Database of Systematic Reviews and Trials. Search was conducted on March 25, 2020.

Methods of Study Selection: Included studies evaluated minimally invasive surgical procedures for uterine myomas involving morcellation. This review did not consider studies of nonuterine tissue morcellation, studies involving uterine procedures other than hysterectomy or myomectomy, studies involving morcellation of known malignancies, nor studies concerning hysteroscopic myomectomy. A total of 695 studies were reviewed, with 185 studies included for analysis.

Tabulation, Integration, and Results: The following variables were extracted: patient demographics, study type, morcellation technique, and adverse outcome category. Adverse outcomes included prolonged operative time, morcellation time, blood loss, direct injury from a morcellator, dissemination of tissue (benign or malignant), and disruption of the pathologic specimen.

Conclusion: Complications related to morcellation are rare; however, there is a great need for higher quality studies to evaluate associated adverse outcomes. Journal of Minimally Invasive Gynecology (2021) 28, 619−643. © 2020 AAGL. All rights reserved.

Keywords: Morcellation; Hysterectomy; Myomectomy; Fibroid

The first "electric cutting device" for tissue removal from the abdominal cavity was introduced in 1993 [1]. Thereafter, a widely used method for tissue extraction at the time of minimally invasive hysterectomy or myomectomy involved the use of a laparoscopic electromechanical or a power morcellator. These devices employ rapidly spinning blades or energy application to cut myomas into fragments that are removed through small incisions. The practice of uterine tissue power morcellation was publicly called into question in April 2014, when the Food and Drug Administration (FDA) issued a safety communication discouraging its use owing to concerns about tissue dissemination and upstaging in cases of occult uterine malignancy [2]. Even in the absence of malignancy, there is concern about the potential for dissemination of benign pathology, with consequences including iatrogenic implantation of endometriosis or disseminated peritoneal leiomyomatosis. The drive to change practice in an evidence-based fashion after this safety communication has incited a new period of investigation and innovation within the field of minimally invasive gynecology [3−6].

It is well established that women undergoing hysterectomy and myomectomy for the management of myoma-related symptoms by means of a minimally invasive approach have shorter hospital stays and less perioperative morbidity [7]. Yet, it is unavoidable that to remove enlarged uterine tissue or myomas without a laparotomy, the specimen must be cut into tissue fragments and removed through small incisions. Even before the FDA safety communication, there had been several reports of benign and malignant cell dispersion in the peritoneal cavity with uncontained

Jon I. Einarsson is a consultant for Hologic and Arthrex. The other authors declare that they have no conflict of interest.

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Submitted July 30, 2020, Revised August 28, 2020, Accepted for publication September 8, 2020.
Available at www.sciencedirect.com and www.jmig.org

1553-4650/$ — see front matter
https://doi.org/10.1016/j.jmig.2020.09.013

morcellation [8]. Concerns were also raised about direct tissue injury from the morcellation process, as well as disruption of pathologic examination of morcellated specimens [9−11]. Subsequently, many practices have adapted to contain the tissue extraction process within a surgical containment bag, and some have discontinued the use of power morcellation in favor of manual morcellation [6,12,13].

The practice of morcellation, with or without the use of the power morcellator, remains controversial. Previously published, well-designed reviews have examined questions regarding the incidence of sarcoma in presumed benign myoma disease and the impact of morcellation of uterine malignancy on overall survival [14,15]. This systematic review aims to describe adverse outcomes related to tissue extraction at the time of surgery for uterine myomas, with the goal of providing evidence-based clinical guidance. A comparison was made with existing data on complications that occur with a laparotomy, as this is the alternative procedural approach for patients with myoma burden.

Methodology

We conducted a literature review to search for all published articles reporting on morcellation-related adverse outcomes at the time of or after a hysterectomy or a myomectomy. This review considered all studies that involved human subjects who underwent a minimally invasive surgical procedure for uterine myomas. Tissue extraction techniques extracted from article review included uncontained morcellation through the abdominal wall, contained abdominal wall/vaginal morcellation, and uncontained vaginal/transcervical morcellation. The term laparoscopic in this study encompasses both traditional laparoscopies, laparoscopic-assisted procedures and robot-assisted laparoscopic procedures.

The primary outcome of interest was incidence of tissue extraction (morcellation)−related adverse outcomes, defined as dissemination of malignant tissue, dissemination of benign tissue, prolonged operation time, additional time required for morcellation, estimated blood loss, direct trauma from morcellation, and impaired pathologic review secondary to morcellation. We considered all study types focused on morcellation and morcellation-related complications, including case reports. No limitations were made in regard to year of publication or language of publication.

This review did not consider studies of extraction of tissues other than myomas/uterine tissue, studies involving uterine procedures other than hysterectomy or myomectomy, studies involving cases of morcellation of known malignancies, and studies concerning hysteroscopic myomectomy. The work was registered with PROSPERO, the international prospective registrar of systematic reviews.

Search Strategy

Search criteria were developed in conjunction with a medical librarian (J.C.) to find articles pertaining to uterine tissue extraction. Final search criteria are available in Supplemental Appendix 1. Articles published in the following databases were searched without date restrictions: PubMed, EMBASE, Web of Science, and Cochrane Database of Systematic Reviews and Trials. All articles were uploaded, stored, and managed in Covidence [16]. Articles published through March 2020 were included.

A full title and abstract screening were performed independently by 2 reviewers (A.C. and K.P.). Discrepancies in reviewer selections were resolved by a third reviewer (S.L.C.). Reference lists of the articles collected were searched for additional relevant articles for inclusion. A full-text screening was then independently undertaken by 2 reviewers (A.C. and K.P.) to determine relevance, and again, any discrepancies were resolved by the third reviewer (S.L.C.). Once a final set of articles were identified according to the inclusion and exclusion criteria, full-text articles were reviewed in detail, and data elements extracted. Selection details available in Fig. 1.

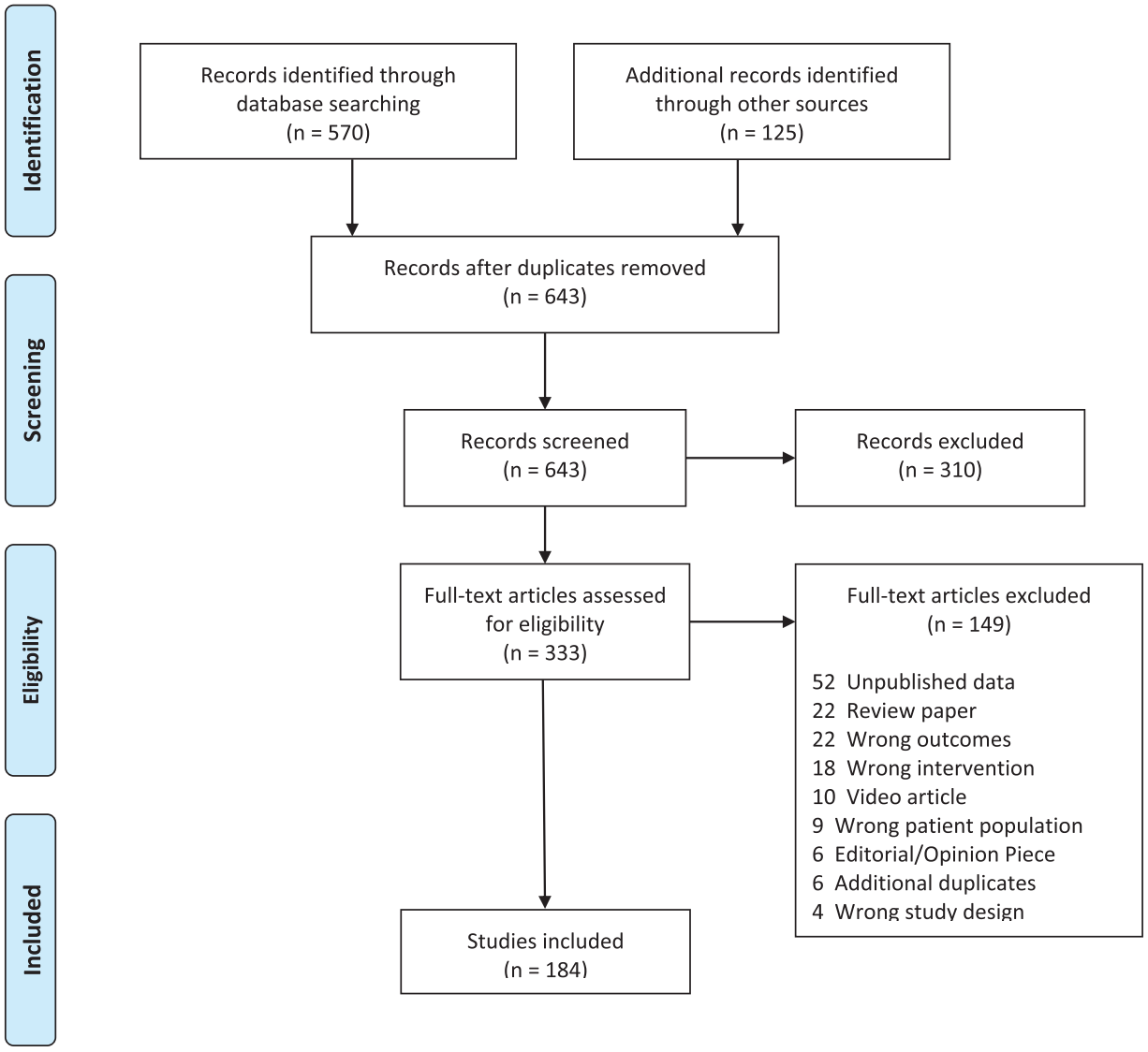
Data Extraction

Articles selected for inclusion in the study were carefully reviewed by protocol authors, and appropriate data were extracted. Variables extracted from the data included operating room time (expressed as mean or median), morcellation time (expressed as mean or median), procedure blood loss (expressed as mean or median), inadvertent morcellation or dissemination of malignant tissue (expressed as number, percent), dissemination of benign tissue (expressed as number, percent), direct trauma from morcellator or morcellation procedure (expressed as number, percent), impaired pathologic specimen reviews (expressed as number, percent), and loss of extraction bag integrity (expressed as number, percent). For studies that reported a mean or median morcellation time and uterine weight, we calculated a morcellation rate expressed in grams per minute. In addition, data were collected on the study type, total enrollment, surgery type, morcellation route (transabdominal, transvaginal), morcellation containment, and use of power morcellation. Intraoperative and postoperative complications not explicitly related to morcellation were not reported. In studies comparing a morcellation group and a nonmorcellation group, only the morcellation group data were extracted. Thus, no data reported in this review concern abdominal procedures, hysteroscopic procedures, or minimally invasive procedures not requiring morcellation.

Case reports and small cases series (5 or fewer subjects) were also included in the review but are reported separately because of the inability to extract the same quantitative data points as the remainder of the included studies. Data collected from cases reports and small case series included complication type, presenting symptoms, initial surgical procedure, interval between surgical procedure and presentation, morcellation route (transabdominal, transvaginal),

Fig. 1

Article selection strategy.



morcellation containment, use of power morcellation, and management of complication.

Quality Assessment

Studies meeting the inclusion criteria were grouped by study type (clinical trials, cohort studies, case-control studies, case series and case reports). Studies were then assessed independently for methodological validity and risk of bias by 2 reviewers (A.C. & K.P.). Quality assessment was based on Cochrane Risk of Bias Assessment for randomized controlled trials (RCTs) and Risk of Bias Assessment in Non-randomized Studies-Intervention for case series, cohort, and case-control studies [17,18]. The registered proposal had included a plan to use the Newcastle-Ottowa Scale for evaluation of nonrandomized studies, but the decision was made to replace this with the Risk of Bias Assessment in Non-randomized Studies-Intervention tool to allow for assessment of cases series. No objective quality assessment was made of cases reports and small case series (5 or fewer subjects).

Randomized trials were rated as low risk of bias, some concerns for bias, or high risk of bias on the basis of description of randomization, blinding, and data reporting. Nonrandomized studies were rated on the risk of bias as low, moderate, serious, or critical in regard to risk of confounding, participant selection, intervention definition, and data reporting. All disagreements that arose between the initial reviewers were resolved with the assistance of the third reviewer. Given the overall low quality of data

available on this subject, no studies were excluded on the basis of the risk of bias. Full quality assessment data are available in Supplemental Appendix 2.

Statistical Analysis

Data for continuous outcomes were directly extracted from published data presented as mean and standard deviation or median and range. Data for categoric variables were also directly extracted from published data presented as the number of events and the percent. No meta-analysis was performed. Descriptive statistics were calculated in Microsoft Excel 2018.

Results

A total of 696 studies were identified for review on the basis of the aforementioned search strategy. Fig. 1 provides a flow diagram of the search strategy. On manual review of titles and abstracts, 52 duplicates studies and 310 irrelevant studies were removed. A total of 332 studies underwent a full-text assessment for eligibility, with an additional 149 articles excluded. Ultimately, 184 studies met our inclusion criteria. Data were extracted separately for case reports and small cases series (5 or fewer participants), reported in Supplemental Appendix 3.

Loss of Bag Integrity

We identified 20 studies that evaluated containment bags for leaking or damage after contained morcellation of myomas and uterine tissue. These data consisted of 1 RCT, 1 case-control study, 5 pilot studies, 3 prospective cohorts, 8 retrospective cohorts, and 1 cohort study in which a prospective cohort and retrospective cohort were compared [3,19−34]. Data are presented in Table 1. Studies evaluated a total of 1009 patients who underwent in-bag morcellation. Only studies that explicitly described checking bags for integrity at the end of the procedure were included. A total of 7 studies included patients undergoing hysterectomy, 8 studies evaluated patients undergoing myomectomy, and the remainder included a combination of both procedures. Power morcellation was used in 12 studies. Morcellation occurred by means of abdominal route in 17 studies and vaginal route in 3 studies. Rates of bag damage or leakage ranged from 0% to 40.6%. Of the 20 studies, 13 (65%) reported no loss of bag integrity.

Disruption of Pathologic Specimens by Morcellation

We identified 11 studies meeting our criteria that addressed morcellation's disruption of pathologic specimens leading to difficultly with pathologic interpretation. Data are presented in Table 2. These data include 1 case series, 1 retrospective cohort, and 8 case reports [11,35−42]. In the case series by Bean et al [35], 514 patients underwent laparoscopic myomectomy with abdominal power morcellation, both contained and noncontained. In this study, there was 1 case of possible error in interpretation of pathologic specimen. Two patients in this study had pathology return as uterine smooth muscle tumors of undetermined malignant potential (STUMP). One patient went on to have a total abdominal hysterectomy with pathology notable only for benign myomas and adenomyosis. The other patient, wishing to preserve fertility, underwent serial imaging without further surgical intervention.

In the study by Rivard et al [11], hysterectomy specimens were morcellated after intact extraction and sent to a blinded pathologist to review. Specimens underwent a routine pathologic evaluation before morcellation. Among 5 specimens known to contain endometrial carcinoma, 4 were correctly identified as endometrial carcinoma, and 1 grade 1A malignancy was misdiagnosed as benign. The stage could not be determined in the morcellated specimens. Among the known benign specimens, 2 were misclassified as complex atypical hyperplasia. In addition, 8 case reports raised concerns about impaired pathologic review, wherein pathology was reported to be benign at the time of morcellation, but patients later went on to be diagnosed with a malignancy. This included 6 cases of metastatic leiomyosarcoma, 1 case of undifferentiated adenocarcinoma, and 1 case of metastatic endometrioid adenocarcinoma [36−42].

Morcellation and Dissemination of Malignant Tissue

A total of 56 studies addressed the complication of morcellation of malignant tissue, with or without dissemination. It is important to note that this is not a comprehensive review of all studies addressing the incidence of sarcoma in patients presumed to have benign myomas nor is it a review of survival outcomes of patients who have had a malignancy morcellated because these have been the topics of separate high-caliber systematic reviews [14,15]. Rather, Table 3 summarizes studies in which morcellation was reported on malignant tissue. It is not intended to make a comprehensive statement on the incidence of uterine sarcoma because it does not account for cases performed by or converted to laparotomy.

The studies meeting inclusion criteria included 2 cases series, 1 prospective cohort, 39 retrospective cohorts, 1 cohort study in which a prospective cohort and retrospective cohort were compared, and 13 case reports [10,24,29,31,33−84]. Many of these studies have also reported on aberrant pathologic diagnoses, including cellular leiomyomas, atypical leiomyomas, STUMP tumors, endometrial hyperplasia, cervical carcinoma in situ, and serous tubal intraepithelial carcinomas; these findings are reported in Table 3 but are not included in the calculated incidences of malignancy. The included studies represent a total of 139 740 patients undergoing morcellation. Six studies were designed such that an incidence could not be reported, as was the case for the case reports. Among

Table 1

Bag integrity

Author	Year	Study type	Patients enrolled	Type of surgery	Morcellation route	Contained in extraction bag	Morcellationtype	Outcomesn, %	Risk of bias
Anapolski et al [19]	2016	Pilot	10	Hysterectomy	Abdominal	Yes	Power	0, 0	Critical
Aoki et al [20]	2016	Pilot	12	Hysterectomy Myomectomy	Abdominal	Yes	Power	0, 0	Serious
Boza et al [21]	2019	Retrospective cohort	31	Myomectomy	Vaginal	Yes	Manual	3, 9.7	Moderate
Cohen et al [22]	2016	Prospective cohort	76	Hysterectomy Myomectomy	Abdominal	Yes	Power	7, 9.2	Critical
Cohen et al [23]	2019	Prospective cohort	36	Hysterectomy	Abdominal	Yes	Manual	3, 8.3	Moderate
			32	Hysterectomy	Vaginal	Yes	Manual	13, 40.6	
Devassy et al [24]	2019	Case-control	239	Hysterectomy Myomectomy	Abdominal	Yes	Power	0, 0	Critical
Einarsson et al [3]	2014	Pilot	15	Hysterectomy Myomectomy	Abdominal	Yes	Power	0, 0	Critical
Emery et al [25]	2019	Prospective cohort	32	Myomectomy	Abdominal	Yes	Power	3, 10	Critical
Hong et al [26]	2020	Retrospective cohort	165	Hysterectomy Myomectomy	Abdominal	Yes	Manual	22, 13.3	Critical
Paul et al [27]	2016	Pilot	10	Myomectomy	Abdominal	Yes	Power	0	Critical
Rimbach and Schempershofe [28]	2017	Retrospective cohort	49	Hysterectomy	Abdominal	Yes	Power	3, 6.1	Moderate
Serur et al [29]	2016	Retrospective cohort	43	Hysterectomy	Vaginal	Yes	Manual	0, 0	Critical
Solima et al [164]	2015	Pilot	12	Hysterectomy	Vaginal	Yes	Manual	4, 33.3	Critical
Takeda et al [184]	2016	Retrospective cohort	26	Myomectomy	Abdominal	Yes	Manual	0,0	Critical
Takeda et al [30]	2018	Retrospective cohort	24	Myomectomy	Abdominal	Yes	Manual	0,0	Critical
Vargas et al [31]	2015	Cohort (prospective and retrospective)	36	Hysterectomy Myomectomy	Abdominal	Yes	Power	0,0	Serious
Venturella et al [32]	2016	RCT	53	Myomectomy	Abdominal	Yes	Both	0, 0	High
Winner et al [33]	2015	Retrospective cohort	51	Hysterectomy	Abdominal	Yes	Power	0, 0	Serious
Won et al [34]	2018	Retrospective cohort	27	Myomectomy	Abdominal	Yes	Power	0, 0	Serious

RCT = randomized controlled trial.

Table 2

Pathology

Author	Year	Study type	Patients enrolled	Type of surgery	Morcellation route	Extraction bag used	Morcellation type	Outcomes n, %	Outcome description	Risk of bias
Bean et al [35]	2017	Retrospective cohort	514	Myomectomy	Abdominal	Both	Power	1, 0.19	Pathology from myomectomy returned as STUMP. Patient underwent a TAH, final pathology without evidence of malignancy.	Critical
Rivard et al [11]	2012	Case series	5 benign specimens 5 known endometrial carcinomas	Hysterectomy	N/A specimens morcellated after intact removal	N/A specimens morcellated after intact removal	Manual	Benign specimens 2, 40 Endometrial carcinomas: 1, 20	Benign: mistakenly classified at complex atypical hyperplasia. Endometrial carcinomas: mistakenly called benign.	Critical

N/A = not applicable; STUMP = smooth muscle tumors of undetermined malignant potential; TAH = total abdominal hysterectomy.

studies reporting an incidence of morcellated malignancies, 9 studies reported no observations of malignancy, though it is likely that many were underpowered to detect this rare outcome. Among the studies reporting malignancies, 32 described incidence, ranging from 0.05% to 9.8%. Study or cohort size ranged from 26 patients to 36 470 patients. Six of these studies reported the use of contained morcellation, 9 reported no containment, 3 reported both contained and uncontained morcellation, and 16 made no comment on containment. Power morcellation has been reported in 17 studies/cohorts, manual morcellation in 4 cohorts, a combination of methods in 3 cohorts, and extraction technique was not reported in 8 studies. Of these studies, 17 studies/cohorts examined patients undergoing hysterectomy, 7 addressed patients undergoing myomectomy, 1 with patients having vaginal hysterectomies, and 7 included patients undergoing a combination of procedures.

In terms of malignancies reported, there were 54 leiomyosarcomas, 75 endometrial stromal sarcomas, 6 uterine sarcomas not otherwise specified (NOS), 3 carcinosarcomas, 20 endometrial adenocarcinomas, 4 myometrial malignancies NOS, 126 uterine malignancies NOS, 4 ovarian cancers, 1 cervical adenocarcinoma, 1 cervical squamous cell carcinoma, 1 embryonal rhabdomyosarcoma, 1 metastatic gastrointestinal tumor, and 52 malignancies listed as “other.” Nonmalignant aberrant pathology included 386 cases of endometrial hyperplasia, 57 of STUMPs, 15 of atypical leiomyoma, 2 of cellular leiomyomas, 1 of cervical carcinoma in situ, 1 of ovarian borderline tumor, and 1 of serous tubal intraepithelial carcinoma. The 13 case reports describe 3 adenocarcinomas, 8 leiomyosarcomas, and 2 endometrial stromal sarcomas. Of the case reports, 46% were published before 2014, whereas the most of the cohorts were published after the FDA communication.

Morcellation and Dissemination of Benign Tissue

There were 16 studies that evaluated the sequalae of dissemination benign tissue (15 retrospective cohorts and 1 case-control) in addition to 45 case reports and 13 small case series [30,35,46,63,65,67−69,76,79,84−144]. Of the larger studies, which included 21 629 women, 9 studies reported on incidence of parasitic myomas, 3 on leiomyomatosis, 3 on morcellation related endometriosis, 1 on a pelvic adenomyoma and 2 evaluated the abdomen with washings for uterine cells after morcellation. Results are presented in Table 4. Just 2 of these studies reported use of contained morcellation, and 1 used containment in 1% of the cases (the bag was not used in the patient who developed a complication) [35]. The other study specifically looked for uterine cells in pelvic washings after contained morcellation, which they found in 20 of 24 women (83%) who underwent a myomectomy with contained manual morcellation. A similar study evaluated postmorcellation washings after myomectomies with uncontained power morcellation and found uterine cells in the washings of 6 of

Table 3

Morcellation of malignant tissue

Author	Year	Study type	Patients enrolled	Type of surgery	Morcellation route	Contained extraction	Morcellation type	Outcomes n, %	Outcomes description	Risk of bias
Bean et al [35]	2017	Retrospective cohort	514	Myomectomy	Abdominal	Both	Power	1, 0.2	1 leiomyosarcoma	Critical
Bojahr et al [44]	2015	Retrospective cohort	10 731	Hysterectomy	Abdominal	No	Power	13, 0.13	4 endometrial stromal sarcomas 2 leiomyosarcomas 8 endometrial cancers	Critical
Brown et al [45]	2015	Retrospective cohort	778	Hysterectomy	Abdominal	Yes	Power	3, 0.39	2 endometrioid adenocarcinomas 1 endometrial stromal sarcoma 16 endometrial hyperplasias	Critical
Chin et al [43]	2015	Retrospective cohort	3013	Myomectomy	Abdominal	No	Not reported	3, 0.10	1 atypical leiomyoma 1 cellular leiomyoma 1 endometrial stromal sarcoma 2 leiomyosarcomas 2 STUMPs	Critical
Devassy et al [24]	2019	Retrospective cohort	239	Hysterectomy Myomectomy	Abdominal	Yes	Power	3, 1.3	2 endometrial carcinomas 1 uterine leiosarcoma	Critical
Ehdaivand et al [46]	2014	Retrospective cohort	352	Hysterectomy Myomectomy	Not reported	Not reported	Not reported	3, 0.9	1 endometrial adenocarcinoma 1 endometrial stromal sarcoma 1 sex cord stromal	Critical
Graebe et al [47]	2015	Retrospective cohort	1361	Hysterectomy	Not reported	Not reported	Power	10, 0.73	3 endometrial adenocarcinomas 1 serous carcinoma 3 endometrial stromal sarcomas 3 leiomyosarcomas	Critical
Graziano et al [48]	2015	Retrospective cohort	365	Hysterectomy	Transcervical	No	Power	1, 0.27	1 endometrial stromal sarcoma	Critical
Günthert et al [49]	2015	Retrospective cohort	442	Hysterectomy	Vaginal	No	Manual	1, 0.23	1 leiomyosarcoma	Critical
			61	Hysterectomy	Vaginal	Yes	Manual	6, 9.8	6 leiomyosarcomas	
			3	Hysterectomy	Abdominal	Yes	Manual	0, 0		
Hagemann et al [50]	2011	Retrospective cohort	101	Hysterectomy	Not reported	Not reported	Not reported	0, 0		Critical
Hill et al [51]	2014		63	Hysterectomy	Not reported	Not reported	Not reported	2, 3.2		Critical

Table 3

Continued

Author	Year	Study type	Patients enrolled	Type of surgery	Morcellation route	Contained extraction	Morcellation type	Outcomes n, %	Outcomes description	Risk of bias
		Retrospective cohort							2 endometrial adenocarcinomas	
Kundu et al [52]	2017	Retrospective cohort	254	Hysterectomy	Not reported	Not reported	Not reported	0, 0		Critical
			26	Vaginal					hysterectomy	Not reported
Not reported	Not	reported	1, 3.8	1					leiomyosarcoma	
			195	Myomectomy	Not reported	Not reported	Not reported	0, 0		
Lieng et al [53]	2015	Retrospective cohort	1846	Hysterectomy					Myomectomy	Not reported
Not reported		Power	1, 0.05	1					leiomyosarcoma	Critical
Malzoni et al [54]	2006	Retrospective cohort	982	Myomectomy	Not reported	Not reported	Power	1, 0.1	1 leiomyosarcoma	Critical
Meurs et al [55]	2017	Retrospective cohort	297	Hysterectomy					Myomectomy	Abdominal & Vaginal
Both	Both	1, 0.34	1 endometrial						adenocarcinoma	Moderate
Mori et al [56]	2018	Retrospective cohort	281	Hysterectomy	Not reported	Yes	Power	1, 0.36	1 leiomyosarcoma	Serious
									2 complex hyperplasias	
									1 STUMP	
Mowers et al [57]	2015	Case series	8	Hysterectomy					Myomectomy	Abdominal
Both	Both	n/a	2 endometrial stromal	sarcomas	Critical					
									7 STUMPs	
Multinu et al [58]	2019	Retrospective Cohort	3759	Vaginal converted to robotic	Not reported	Not reported	Not reported	1 (% of cases morcellated not reported)	1 endometrial stromal sarcoma	Critical
Naumann and Brown [10]	2015	Case series	51	Hysterectomy					Myomectomy	Not reported
Not reported		Power	27	5 sarcomas	Critical					
									22 malignancy NOS	
Pados et al [59]	2017	Retrospective cohort	1216	Myomectomy	Not reported	Not reported	Not reported	0, 0	7 atypical leiomyomas	Critical
Paul et al [27]	2016	Retrospective cohort	1781	Hysterectomy	Vaginal	No	Manual	5, 0.28	3 leiomyosarcomas	Critical

Table 3

Continued

Author	Year	Study type	Patients enrolled	Type of surgery	Morcellation route	Contained extraction	Morcellation type	Outcomes n, %	Outcomes description	Risk of bias
			897	Myomectomy	Abdominal	No	Power	3, 0.33	2 endometrial stromal sarcomas 2 leiomyosarcomas 1 endometrial stromal sarcoma	
Rechberger et al [61]	2016	Retrospective cohort	426	Hysterectomy	Abdominal	No	Power	4, 0.9	3 endometrial adenocarcinomas 1 ovarian cancer	Critical
Rosenblatt et al [62]	2010	Retrospective Cohort	51	Hysterectomy	Transcervical	No	Power	0, 0		Critical
Seidman et al [63]	2012	Retrospective cohort	1091	Hysterectomy Myomectomy	Not reported	Not reported	Power	2, 0.18	1 endometrial stromal sarcoma 3 STUMPs 1 leiomyosarcoma 1 cellular leiomyoma 6 atypical leiomyomas	Critical
Serur et al [29]	2016	Retrospective cohort	104	Hysterectomy	Abdominal and vaginal	Both	Manual	2, 1.9	1 uterine sarcoma 1 endometrial adenocarcinoma	Critical
Shim et al [64]	2018	Retrospective cohort	456	Hysterectomy Myomectomy	Not reported	Not reported	Power	1, 0.2	1 atypical leiomyoma	Critical
Sinha et al [65]	2008	Retrospective cohort	505	Myomectomy	Abdominal	No	Manual	2	2 leiomyosarcomas	Critical
Sinha et al [66]	2019	Retrospective cohort	128	Hysterectomy	Abdominal and vaginal	Both	Manual	0, 0		Critical
Smits et al [67]	2016	Retrospective cohort	186	Hysterectomy	Abdominal	No	Power	0, 0		Critical
Tan et al [68]	2015	Retrospective cohort	734	Hysterectomy Myomectomy	Not reported	Not reported	Both	3, 0.41	2 leiomyosarcomas 1 endometrial adenocarcinoma 1 STIC	Critical
Tan-Kim et al [69]	2015	Retrospective cohort	941	Hysterectomy	Not reported	Not reported	Power	6, 0.6	3 leiomyosarcomas 3 endometrial stromal sarcomas	Moderate
Tchartchian et al [70]	2019	Retrospective cohort	1461	Hysterectomy Myomectomy	Abdominal	No	Not reported	2, 0.14	2 endometrial cancers 1 cervical cancer in situ	Critical
Theben et al [71]	2013		1584	Hysterectomy	Not reported	Not reported	Not reported	4, 0.25	2 leiomyosarcomas	Critical

Table 3

Continued

Author	Year	Study type	Patients enrolled	Type of surgery	Morcellation route	Contained extraction	Morcellation type	Outcomes n, %	Outcomes description	Risk of bias
		Retrospective cohort								
									2 endometrial adenocarcinomas	
Vargas et al [31]	2015	Cohort (prospective and retrospective)	36	Hysterectomy	Abdominal	Yes	Power	0, 0		Serious
				Myomectomy						
			49	Hysterectomy	Abdominal	No	Power	0, 0		
				Myomectomy						
Weng et al [72]	2018	Prospective cohort	30	Hysterectomy	Abdominal	Yes	Manual	1	1 endometrial adenocarcinoma	Critical
Winner et al [33]	2015	Retrospective cohort	101	Hysterectomy	Abdominal	No	Power	1, 0.99	1 leiomyosarcoma	Serious
			51	Hysterectomy	Abdominal	Yes	Power	0, 0		
Won et al [34]	2018	Retrospective cohort	27	Myomectomy	Abdominal	Yes	Power	0, 0		Serious
			31	Myomectomy	Abdominal	No	Manual	0, 0		
Wright et al [73]	2014	Retrospective cohort	36470	Hysterectomy	Not reported	Not reported	Not reported	99, 0.27	99 uterine cancer NOS	Moderate
									26 other GYN malignancy	
									39 uterine neoplasms of uncertain malignant potential	
									368 endometrial hyperplasias	
Yang et al [74]	2017	Retrospective cohort	33723	Myomectomy	Not reported	Not reported	Power	62, 0.18	38 endometrial stromal sarcomas	Critical
									13 leiomyosarcomas	
									3 carcinosarcomas	
									5 leiomyomas with undetermined malignant potential	
									4 other NOS	
Yuk et al [75]	2018	Retrospective cohort	22613	Myomectomy	Not reported	Not reported	Not reported	18, 0.08	8 endometrial malignancy NOS	Moderate
									4 myometrial malignancy NOS	
									6 uterine malignancy NOS	
Zhang et al [76]	2019	Retrospective cohort	5154	Hysterectomy	Not reported	Not reported	Power	19, 0.36	3 endometrial adenocarcinomas	Critical
									2 endometrial stromal sarcomas	
									2 leiomyosarcomas	

Table 3

Continued

Author	Year	Study type	Patients enrolled	Type of surgery	Morcellation route	Contained extraction	Morcellation type	Outcomes n, %	Outcomes description	Risk of bias
									1 uterine papillary serous adenocarcinoma 1 cervical adenocarcinoma 1 cervical squamous cell carcinoma 1 embryonal rhabdomyosarcoma 3 endometrial stromal sarcomas 2 leiomyosarcomas 1 metastatic GI adenocarcinoma 1 ovarian serous borderline 1 ovarian papillary serous adenocarcinoma	
Zhang et al [77]	2015	Retrospective cohort	3068	Myomectomy	Not reported	Not reported	Power	5, 0.2	5 endometrial stromal sarcomas	Critical
Zhang et al [78]	2016	Retrospective cohort	1104	Hysterectomy	Abdominal & vaginal	Not reported	Both	7, 0.63	6 endometrial stromal sarcomas 1 leiomyosarcoma	Critical

GI = gastrointestinal; GYN = gynecologic; NOS = not otherwise specified; STIC = serous tubal intraepithelial carcinoma; STUMP = smooth muscle tumors of undetermined malignant potential.

Table 4

Dissemination of benign tissue

Author	Year	Study type	Patients enrolled	Type of surgery	Morcellation route	Contained extraction	Morcellation type	Outcomes n, %	Outcome type	Risk of bias
Bean et al [35]	2017	Retrospective cohort	514	Myomectomy	Abdominal	Both	Power	1, 0.2	Parasitic myoma	Critical
Donnez et al [85]	2007	Retrospective cohort	1405	Hysterectomy	Abdominal	No	Power	8, .57	Pelvic adenomyotic masses	Critical
Ehdaivand et al [46]	2014	Retrospective cohort	352	Hysterectomy Myomectomy	Not reported	Not reported	Not reported	1, 0.3	Parasitic myomas	Critical
Kho et al [86]	2009	Retrospective cohort	6	Myomectomy	Not reported	Not reported	Not reported	6, n/a	Parasitic myomas	Critical
Koninckx et al [87]	2000	Retrospective cohort	10	Hysterectomy	Abdominal	No	Manual	2, 20	Umbilical endometriosis	Critical
Leren et al [88]	2012	Retrospective cohort	2470	Hysterectomy Myomectomy	Abdominal	No	Power	3, 0.12	Parasitic myomas	Critical
Lu et al [89]	2016	Retrospective cohort	8000	Hysterectomy Myomectomy	Not reported	Not reported	Power	6, 0.07 5 parasitic leiomyomas 1 leiomyomatosis		Critical
Schuster et al [90]	2012	Case control	217	Hysterectomy	Abdominal	No	Power	3, 1.4	New diagnosis of endometriosis after hysterectomy	Serious
Seidman et al [63]	2012	Retrospective cohort	1091	Not reported	Not reported	Not reported	Power	1	Disseminated peritoneal leiomyomatosis	Critical
Sinha et al [65]	2008	Retrospective cohort	505	Myomectomy	Abdominal	No	Manual	1	Parasitic myomas requiring surgical excision	Critical
Smits et al [67]	2016	Retrospective cohort	186	Hysterectomy	Abdominal	No	Power	1, 0.5	Parasitic myomas	Critical
Takeda et al [30]	2018	Retrospective cohort	24	Myomectomy	Abdominal	Yes	Manual	20, 83.3	Myoma cells identified in washing fluid	Critical
Tan et al [68]	2015	Retrospective cohort	734	Hysterectomy Myomectomy	Not reported	Not reported	Both	2, 0.27	Leiomyomatosis	Critical
Tan-Kim et al [69]	2015	Retrospective cohort	941	Hysterectomy	Not reported	Not reported	Power	4, 0.4	Parasitic myomas	Moderate
Toubia et al [91]	2016	Prospective cohort	20	Myomectomy	Abdominal	No	Power	6, 30	Smooth muscle cells identified on cytologic evaluation of peritoneal washings after morcellation	Critical
Zhang et al [76]	2019	Retrospective cohort	5154	Hysterectomy	Not reported	Not reported	Power	57, 1.1 11, 0.2	New diagnosis of endometriosis after hysterectomy Parasitic myomas	Critical

N/A = not applicable.

20 (30%) women. The remainder of studies that were designed in a manner to report incidences all had benign tissue dissemination incidences less than 2%.

A total of 89 cases of benign sequala from morcellation have been reported in case reports and small case series. Most have been reports of parasitic myomas (52%) and disseminated peritoneal leiomyomatosis (32%). Other case reports included new diagnosis endometriosis after supracervical hysterectomy (n = 2), port site endometriosis (n = 4), port site adenoma (n = 1), vaginal cuff endometriosis (n = 1), retained myomas after index surgery (n = 5), and mass with precancer or STUMP tumors (n = 3). Most of these patients (86%) were treated surgically by laparotomy, with 5% requiring a bowel resection.

Direct Trauma from Morcellation

A total of 20 studies were found that addressed intraoperative morcellation-related trauma (Table 5). They consisted of 2 cases series, 1 pilot study, 4 RCTs, 1 prospective cohort, and 12 retrospective cohorts [9,10,19,29,32,34,44,59,61,62,145−154]. Only studies that expressly stated that intraoperative injuries were or were not related to the use of the power morcellator or the manual morcellation were included. Studies reporting on this outcome included 14 553 women. Of the 20 studies, 16 studies including 13 812 women reported no morcellation-related injuries. The use of power morcellation was reported in 16 studies.

Two studies, both case series, evaluated morcellator injury as a primary outcome. Both used the Manufacturer and User Facility Device Experience database, a database of medical device reports including adverse events submitted to FDA. The study by Milad and Milad [9] comprised all morcellator injuries (including nongynecologic procedures) from 1993 to 2013. This publication was an update on an earlier publication from 2003, which was excluded from the present study. The work by Naumann and Brown [10] reported on morcellator injuries between 2004 and 2014 but was restricted to only gynecologic procedures. Given the likely significant overlap in the reported complications between the 2 studies, we chose to report only data from the study by Naumann and Brown [10], which did include 2 patients who underwent solely oophorectomy but could not be excluded from the reporting on the basis of the way the data were presented. Naumann and Brown [10] reported 51 organ injuries related to morcellators in gynecologic procedures over this 9-year period including 18 bowel injuries, 17 vascular injuries, 7 skin/abdominal wall, 4 ureter, 3 decreased heart rate, 1 fallopian tube, 1 omentum, 1 bladder, 1 hernia, and 1 retained tissue [10].

In addition, 2 retrospective cohort studies evaluated morcellator-related injury as a secondary outcome. Rechberger et al [61]reported 1 morcellator-related small bowel injury in a study of 426 women undergoing uncontained abdominal power morcellation. In the study by Bogani et al [147], comparing 100 women undergoing uncontained abdominal power morcellation vs contained vaginal manual morcellation at the time of myomectomy, they reported a patient with postoperative day 1 bleeding from the trocar site used for morcellation that required suturing at the bedside.

Morcellation Time

A total of 3208 patients were included in 32 studies that reported on the outcome of morcellation time (Table 6). These included 2 case-controls, 5 pilot studies, 4 prospective cohorts, 13 retrospective cohorts, and 6 randomized trials [4,19−29,32,62,91,145−148,152,154−165]. Eleven studies evaluated laparoscopic hysterectomies, 13 evaluated myomectomies, 2 studies compared laparoscopic with vaginal hysterectomies, and the remainder evaluated both laparoscopic hysterectomies and myomectomies. Twelve studies compared morcellation technique, 4 compared different types of power morcellators, and 1 compared cases considered high vs low difficultly level.

When evaluating by morcellation technique, the most commonly reported technique was uncontained abdominal power morcellation; this was evaluated in 13 studies. Studies reporting means had values between 4.8 and 26 minutes, medians were between 4 and 10 minutes, and ranges encompassed morcellation times between 0.5 and 90 minutes. Mean and median morcellation rates ranged between 4.8 and 64.3 grams per minute for power morcellation. Seven studies evaluated morcellation time among procedures using contained abdominal power morcellation, with means between 9 and 37 minutes, medians between 2 and 10 minutes, and ranges between 1.4 and 50 minutes. Three studies evaluated uncontained abdominal manual morcellation with morcellation times ranging between 1.5 and 240 minutes and rates between 5.2 and 66.1 grams per minute. Contained abdominal manual morcellation was evaluated by 6 studies, with mean morcellation times between 9.5 and 18.9 minutes. Uncontained vaginal manual morcellation was evaluated in 5 studies with ranges between 3 and 8 minutes. Finally, contained vaginal manual morcellation was reported in 3 studies, with ranges between 3 and 30 minutes. An additional 4 studies had a different type of morcellation, a combination of multiple types, or did not report their morcellation technique in detail.

Among studies that compared morcellation techniques, the findings were mixed. Four studies compared uncontained abdominal power morcellation with contained abdominal manual morcellation; 2 reported significantly faster times with uncontained power morcellation, 1 reported significantly faster times with contained manual morcellation, and 1 study found no difference. One study examined the same morcellation techniques, with the exception of the manual morcellation being uncontained, and found the power morcellation to be significantly faster. Four studies compared uncontained abdominal power morcellation with vaginal manual morcellation (1 contained, 3

Table 5

Morcellator injury

Author	Year	Study type	Patients enrolled	Type of surgery	Morcellation route	Extraction bag used	Morcellation type	Outcomes n, %	Outcome description	Risk of bias
Agrawal et al [145]	2016	Retrospective cohort	232	Laparoscopic & vaginal hysterectomy	Abdominal & vaginal	No	Power	0, 0		Critical
Anapolski et al [19]	2016	Pilot	10	Hysterectomy	Abdominal	Yes	Power	0, 0		Critical
Bogani et al [147]	2014	Retrospective cohort	50	Myomectomy	Abdominal	No	Power	1, 0.5	Bleeding from morcellator trocar site POD 1, repaired at bedside.	Moderate
			50	Myomectomy	Vaginal	No	Manual	0, 0		
Bojahr et al [44]	2015	Retrospective cohort	10 731	Hysterectomy	Abdominal	No	Power	0, 0		Critical
Brucker et al [148]	2007	RCT	20	Hysterectomy	Abdominal	No	Power	0, 0		High
			28	Hysterectomy	Abdominal	No	Power	0, 0		
Clark Donat et al [149]	2015	Retrospective cohort	320	Hysterectomy	Vaginal	Yes	Manual	0, 0		Critical
Ghezzi et al [150]	2018	Retrospective cohort	316	Myomectomy	Vaginal	No	Manual	0, 0		Critical
Martínez-Zamora et al [146]	2009	RCT	15	Hysterectomy Myomectomy	Not reported	Not reported	Power	0, 0		High
			14	Hysterectomy Myomectomy	Not reported	Not reported	Power	0, 0		
Milad amd Milad [9]	2014	Case series	55*	Hysterectomy Myomectomy	Not reported	Not reported	Power	52	22 bowel 18 vascular system 4 genitourinary 4 other	Critical
Morgan-Ortiz et al [151]	2015	Retrospective cohort	65	Myomectomy	Abdominal	No	Power	0, 0		Critical
Naumann and Brown [10]	2015	Case series	215	Hysterectomy Myomectomy	Not reported	Not reported	Power	51	18 bowel 17 vascular 7 skin or abdominal wall 4 ureter 3 decreased heart rates 1 fallopian tube 1 omentum	Critical

Table 5

Continued

Author	Year	Study type	Patients enrolled	Type of surgery	Morcellation route	Extraction bag used	Morcellation type	Outcomes n, %	Outcome description	Risk of bias
									1 bladder 1 hernia 1 retained tissue	
Pados et al [59]	2017	Retrospective cohort	1216	Myomectomy	Not reported	Not reported	Not reported	0, 0		Critical
Rechberger et al [61]	2016	Retrospective cohort	426	Hysterectomy	Abdominal	No	Power	1, 0.2	1 small bowel	Critical
Rosenblatt et al [62]	2010	Retrospective cohort	51	Hysterectomy	Transcervical	No	Power	0, 0		Critical
Serur et al [29]	2016	Retrospective cohort	104	Hysterectomy	Abdominal & vaginal	Both	Manual	0, 0		Critical
Venturella et al [32]	2016	RCT	53	Myomectomy	Abdominal	Yes	Manual	0, 0		High
			51	Myomectomy	Abdominal	No	Power	0, 0		
Won et al [34]	2018	Retrospective cohort	58	Myomectomy	Abdominal	Both	Both	0, 0		Serious
Yang et al [152]	2019	Retrospective cohort	428	Myomectomy	Abdominal	Both	Both	0, 0		Serious
Zhang et al [153]	2011	Prospective cohort	26	Myomectomy	Abdominal	No	Power	0		Critical
Zullo et al [154]	2010	RCT	74	Hysterectomy Myomectomy	Abdominal	No	Power	0		High

POD = postoperative day; RCT = randomized controlled trial.

Table 6

Morcellation time

Author	Year	Study type	Grouping category	Patients enrolled	Type of surgery	Morcellation route	Contained in extraction bag	Morcellation type	Outcomes, min	Rate g/min	Data units	Risk of bias
Agrawal et al [145]	2016	Retrospective cohort		232	Laparoscopic and vaginal hysterectomy	Abdominal and vaginal	No	Both	35, 15.1		n, % of procedures with morcellation time < 10 min	Critical
Amemiya et al [155]	2017	Retrospective cohort	Morcellation technique	*45*	Myomectomy	Abdominal	Yes	Manual	18.1 ± 25.6 (1−172)	9.3	Mean ± SD, (range)	Critical
				29	Myomectomy	Abdominal	No	Power	28.37 ± 19.7 (6−69)	7.8	Mean ± SD, (range)	
Anapolski et al [19]	2016	Pilot		10	Hysterectomy	Abdominal	Yes	Power	10.5 (3−28)	18.2	Mean (range)	Critical
Aoki et al [20]	2016	Pilot		12	Hysterectomy Myomectomy	Abdominal	Yes	Power	37 (19−66)	20.3	Mean (range)	Critical
Bogani et al [147]	2014	Retrospective cohort	Morcellation technique	50	Myomectomy	Abdominal	No	Power	7 (3−35)	17.1	Median (range)	Moderate
				50	Myomectomy	Vaginal	Yes	Manual	5 (3−30)	24.0	Median (range)	
Boza et al [21]	2019	Retrospective cohort	Morcellation technique	31	Myomectomy	Abdominal	Yes	Power	10 (3−15)	10.5	Median (range)	Moderate
				31	Myomectomy	Vaginal	No	Manual	17 (14−42)	7.1	Median (range)	
Brucker et al [148]	2007	RCT	Morcellator type	20	Hysterectomy	Abdominal	No	Power	10 (2−45)	14.7	Median (range)	High
				28	Hysterectomy	Abdominal	No	Power	4 (0.5−12)	28.8	Median (range)	
Campagna et al [156]	2017	RCT	Morcellator type	50	Hysterectomy	Abdominal	Yes	Power	4.10(2.4−4.6)	30.5	Median (range)	High
				50	Hysterectomy	Abdominal	Yes	Power	2.1 (1.4−3.3)	64.3	Median (range)	
Carter and McCarus	1997	Case control	Morcellation technique	14	Myomectomy	Abdominal	No	Manual	79 (20-240)	5.2	Mean (range)	Moderate
				14	Myomectomy	Abdominal	No	Power	26 (3−90)	6.2	Mean (range)	
Chang et al [158]	2018	Retrospective cohort		190	Hysterectomy	Abdominal	No	Manual	8 (1.5−90)	38.9	Mean (range)	Critical
Chong et al [159]	2016	Retrospective cohort	Surgical procedure	16	Hysterectomy	Abdominal	Yes	Manual	9.6 ± 8.1	34.9	Mean ± SD	Critical
				50	Myomectomy	Abdominal	Yes	Manual	10.7 ± 10.8	23.5	Mean ± SD	
Cohen et al [22]	2016	Prospective cohort		76	Hysterectomy Myomectomy	Abdominal	Yes	Power	30.2 ± 22.4	11.9	Mean ± SD	Critical
Cohen et al [23]	2019	Prospective cohort	Morcellation technique	36	Hysterectomy	Abdominal	Yes	Manual	22.5 ± 7.8	31.1	Mean ± SD	Moderate
				32	Hysterectomy	Vaginal	Yes	Manual	18.7 ± 11.3	24.9	Mean ± SD	

Table 6

Continued

Author	Year	Study type	Grouping category	Patients enrolled	Type of surgery	Morcellation route	Contained in extraction bag	Morcellation type	Outcomes, min	Rate g/min	Data units	Risk of bias
De Grandi et al [160]	2000	pilot		70	Hysterectomy Myomectomy	Vaginal	No	Manual	3−14		Range	Critical
Devassy et al [24]	2019	Retrospective cohort		239	Hysterectomy Myomectomy	Abdominal	Yes	Power	12.7	35.1	Mean	Critical
Emery et al [25]	2019	Prospective cohort		32	Myomectomy	Abdominal	Yes	Power	9 ± 6	10.6	Mean ± SD	Critical
Frascà et al [161]	2018	RCT	Morcellation technique	34	Myomectomy	Abdominal	Yes	Manual	9.5 ± 5.1		Mean ± SD	High
				38	Myomectomy	Abdominal	No	Power	6.2 ± 7.7		Mean ± SD	
Hong et al [26]	2017	Retrospective cohort		40	Hysterectomy	Abdominal	No	Manual	13.2 ± 11.2		Mean ± SD	Critical
Lee et al [162]	2016	Case control	Morcellation technique	64	Myomectomy	Abdominal	No	Power	14.9 ± 8.4	13.7	Mean ± SD	Moderate
				128	Myomectomy	Vaginal	No	Power	20.1 ± 7.4	10.0	Mean ± SD	
Martínez-Zamora et al [146]	2009	RCT	Morcellator type	15	Hysterectomy Myomectomy	Not reported	Not reported	Power	14 (2−17)	28.0	Median (range)	High
				14	Hysterectomy Myomectomy	Not reported	Not reported	Power	11 (2−17)	40.4	Median (range)	
Nazah et al [163]	2003	RCT	Morcellation technique	14	Laparoscopic and vaginal hysterectomy	Vaginal	No	Manual	25 (12−80)	14.0	Median (range)	High
				16	Laparoscopic and vaginal hysterectomy	Vaginal	No	Manual	28 (44−75)	11.6	Median (range)	
Paul et al [27]	2016	Pilot		10	Myomectomy	Abdominal	Yes	Power	24.8 (10−50)	8.7	Mean (range)	Critical
Rimbach and Schempershofe [28]	2017	Cohort		49	Hysterectomy	Abdominal	Yes	Power	12.1 (9, 2−54; 7.2 −17.1)	14.1	Mean (median, range; 95% CI)	Moderate
Rosenblatt et al [62]	2010	Retrospective cohort		51	Hysterectomy	Transcervical	No	Power	12.8 ± 14.4	9.7	Mean ± SD	Critical
Serur et al [29]	2016	Retrospective cohort	Morcellation technique	104	Hysterectomy	Abdominal	Both	Manual	14.8 (4.5−21.6)	54.5	Median (range)	Critical
				105	Hysterectomy	Vaginal	Both	Manual	11.7 (5.2−16.8)	64.4	Median (range)	
Solima et al [164]	2015	Pilot		12	Hysterectomy	Vaginal	Yes	Manual	5.6 (5; 4−19)	66.1	Mean (median; range)	Critical
Toubia et al [91]	2016	Prospective cohort		20	Myomectomy	Abdominal	No	Power	16 (2−36)	17.7	Median (range)	Critical

Table 6

Continued

Author	Year	Study type	Grouping category	Patients enrolled	Type of surgery	Morcellation route	Contained in extraction bag	Morcellation type	Outcomes, min	Rate g/min	Data units	Risk of bias
Venturella et al [32]	2016	RCT	Morcellation type	53	Myomectomy	Abdominal	Yes	Manual	16.2 ± 8.1	20.8	Mean ± SD	High
				51	Myomectomy	Abdominal	No	Power	14.4 ± 7 .8	21.7	Mean ± SD	
Wang et al [165]	2006	Prospective cohort	Morcellation type	32	Myomectomy	Abdominal	No	Power	15 (5−35)	11.7	Median (range)	Critical
				46	Myomectomy	Vaginal	No	Manual	20 (10−60)	7.5	Median (range)	
Wang et al [2014]	2014	Retrospective cohort	Morcellation type	335	Myomectomy	Vaginal	No	Manual	13 (5−60)	7.7	Median (range)	Moderate
				81	Myomectomy	Abdominal	No	Power	10 (3−90)	18.9	Median (range)	
Yang et al [152]	2019	Retrospective cohort	Myomectomy technique and morcellation type	248	Myomectomy	Abdominal	No	Power	25.8 ± 9.3	4.8	Mean ± SD	Serious
				180	Myomectomy	Abdominal	Yes	Manual	18.9 ± 10.1	6.4	Mean ± SD	
Zullo et al [154]	2010	RCT	Morcellator type	37	Myomectomy	Abdominal	No	Power	4.8 ± 2.6; 3.9−5.6	30.0	Mean ± SD; 95% CI	High
				37	Hysterectomy	Abdominal	No	Power	8.5 ± 2.5; 7.1−9.8	26.0	Mean ± SD; 95% CI	

RCT = randomized controlled trial; SD = standard deviation.

uncontained), and all concluded that uncontained abdominal power morcellation was significantly faster. This was true in a study comparing uncontained abdominal power morcellation with vaginal power morcellation as well. One study compared contained manual morcellation by means of the abdominal and vaginal routes and found no difference in morcellation times.

Intraoperative Blood Loss

In total, 55 studies reported on estimated blood loss at the time of a surgery with morcellation (Supplemental Appendix 4). Of those, 25 studies included patients undergoing laparoscopic hysterectomy, 49 included patients undergoing myomectomy, 8 studies included both patients undergoing hysterectomy and patients undergoing myomectomy, and 4 studies included both laparoscopic and vaginal hysterectomies. Studies included 3 case-controls, 4 pilot studies, 6 RCTs, 13 prospective cohorts, 25 retrospective cohorts, and 4 cohort studies with both prospective and retrospective components [3,4,19,21−23,25,27,29,31,33,34,55,65,67,72,90,91,149−159,163,165−188].

In the studies that included data of blood loss in laparoscopic hysterectomies with morcellation, the mean blood loss ranged from 95 to 387 mL, the median blood loss ranged from 17 to 200 mL, and the reported ranges had a minimum of 0 mL and a maximum of 2000 mL. This is in comparison to the Cochrane Review of Surgical Approach to Hysterectomy for benign disease, which reported the median range of estimated blood loss for abdominal hysterectomies to be 238 to 650 mL. Similarly, recently published randomized trials including patients undergoing abdominal hysterectomy for uterine myomas estimated the blood loss to be 466 ± 205 mL and the median to be 480 mL (350−700 mL) [189,190].

In the studies and cohorts within studies examining myomectomies, the mean blood loss ranged from 32 to 341 mL, the median blood loss ranged from 15 to 250 mL, and ranges had a minimum of 0 mL and maximum of 2000 mL. This is in reference to recently published RCTs evaluating blood loss in abdominal myomectomy, which quoted mean blood loss at 692 ± 90 mL and 469 ± 75 mL. [191,192]

Operative Time

In total, 71 studies reported on total operative time during a procedure with morcellation (Supplemental Appendix 5). Thirty studies included patients undergoing laparoscopic hysterectomy, 60 included data on patients undergoing myomectomy, 12 studies included data on patients undergoing hysterectomy and myomectomy, 4 studies included both laparoscopic and vaginal hysterectomies, and 1 study included only patients undergoing vaginal hysterectomy [20−23,25,28,29,31,32,48,54,55,62,66,67,91,145,149−151,155,156,158,161,162,164,167,168,170−179,181−187,193−198]. Studies included data on 2 case-controls, 7 pilot studies, 11 RCTs, 14 prospective cohorts, 34 retrospective cohorts, and 4 cohort studies with both prospective and retrospective components.

In the studies reporting data on laparoscopic hysterectomies with morcellation, the mean operative time ranged from 46 to 224 minutes, the median operative time ranged from 40 to 131 minutes, and the ranges had a minimum of 15 minutes and a maximum of 391 minutes. This is in comparison to the Cochrane Review of Surgical Approach to Hysterectomy for benign disease, which reported the mean range operative time for abdominal hysterectomies to be 58 to 133 minutes. In this study, when compared with laparoscopic hysterectomies, the mean difference between operative time between laparoscopic and abdominal was 33.5, 95% CI, 14.82−52.08, with abdominal procedures being faster.

In the studies reporting data on myomectomies, the mean operative time ranged from 57 to 210 minutes, the median operative time ranged from 60 to 188 minutes, and the ranges had a minimum of 15 minutes and a maximum of 360 minutes. This is in contrast to recently published RCTs evaluating blood loss in abdominal myomectomy, which quoted a mean operative time at 111 ± 4 minutes (range 65−170 minutes) and 49 ± 10 minutes (range 30−64 minutes) [191,192].

Discussion

Main Findings

The current study comprehensively summarizes the reported adverse outcomes associated with tissue extraction at the time of minimally invasive surgical procedures for uterine myomas. A total of 184 studies evaluating the safety of morcellation as a primary or secondary outcome were included. The first article meeting inclusion criteria was published in 1994. The adverse outcomes evaluated included loss of bag integrity, morcellation or dissemination of malignant tissue, dissemination of benign tissue, impaired pathologic review, direct injury from the morcellation process, morcellation time, operative time, and procedure blood loss. Overwhelmingly, despite multiple adaptions in the practice of morcellation since the FDA warning in 2014, the quality of data on the subject remains poor.

In regard to bag integrity, most studies reporting on this outcome reported no breaches in bag integrity, but other studies reported rates as high as 40%. Current trends have moved toward the use of containment bags in morcellation procedures, and it does seem that this is a reasonable strategy to contain uterine tissue with morcellation [3,58]. However, questions still remain regarding if this strategy is useful in myomectomies in which myoma cells appear to escape into the peritoneum as a result of the surgical procedure itself [21,23,25,26]. More research into bag integrity

and strategies to minimize bag damage during contained morcellation are needed.

In this study, we also reported on the incidence of disseminated benign and malignant tissue as a result of morcellation. In both instances, the outcomes of these rare events can be devastating. The incidence of morcellated and disseminated uterine malignancies among the 32 included studies ranged from 0.05% to 9.8%. It is important to note that this does not represent the true incidence of sarcoma in women with suspected myomas or the specific impacts on patient survival, as has been investigated elsewhere [14,15]. An important finding in the studies evaluating sequala of disseminated benign tissue is that none reported the use of a containment bag. It is possible that many of the tragic outcomes highlighted among the case reports (laparotomy, bowel resection, sepsis, etc.) may be avoided with the judicious use of contained tissue extraction techniques, although long-term follow-up and better outcomes reporting are required to confirm this hypothesis.

Other outcomes of interest included direct morcellation-related trauma and impaired pathologic specimen review. Although widely quoted as an adverse outcome of morcellation, there is a paucity of data on the subject of impaired pathologic review. The most highly quoted study on the topic involved a review of only 10 specimens, leaving room for additional studies on the topic to make a significant impact on our understanding of how morcellated specimens are interpreted. In addition, very few studies have addressed issues of direct morcellation trauma. In the studies by Milad and Milad [9] and Naumann and Brown [10] using the Manufacturer and User Facility Device Experience database, it seems that, though rare, such events do occur [9,10]. These events should be reported in a comprehensive complication registry when they occur to better understand the magnitude of this issue.

Finally, we reported on operative characteristics in studies involving morcellation, including morcellation time, operative time, and procedural blood loss. It has been well established in the surgical literature that longer operative times are predictive of postoperative complications, and such an association has been seen in laparoscopic hysterectomies lasting longer than 240 minutes [199]. Although there was a wide range in operative and morcellation times reported, only the upper range of procedures approached 240 minutes or longer. This in no way proves a lack of risk associated with longer laparoscopic procedures requiring morcellation, compared with relatively shorter abdominal procedures, but such risk is hard to quantify. This is especially true when weighed against the other advantages of minimally invasive procedures. The mean and median blood loss ranges reviewed in this study are less than would be expected for the comparable abdominal procedures The need for morcellation likely does not contribute significantly to operative bleeding unless a vascular injury occurs during morcellation or unrecognized bleeding takes place while the morcellation is being performed.

Strengths and Limitations

This is the largest work evaluating morcellation specific adverse outcomes at the time of gynecologic procedures. The search was designed by a library services professional to maximize detection of applicable studies. A large number of studies were reviewed for inclusion, and their quality was assessed rigorously. In addition, our results blend case report data with larger studies, an important feature for a topic in which so much of the reporting has been done by case report. However, the present work is limited by the overall low quality of available data on the topic and challenges with reporting incidence if the size of the at-risk population is not known.

Conclusion

The history of gynecologic tissue extraction was forever affected by the FDA warning issued in 2014 [2]. Despite the changing landscape around morcellation for gynecologic procedures, the quality of research remains poor, with inadequate descriptions of the morcellation technique and few attempts to control for confounders in nonrandomized studies. To employ evidence-based tissue extraction practices, it is necessary to elevate the level of available evidence.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.jmig.2020.09.013.

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