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Original Research

Feasibility of myomatous tissue extraction in laparoscopic surgery by contained in – bag morcellation: A retrospective single arm study

Rajesh Devassy[a], Cristina Cezar[b,*], Harald Krentel[b], Hugo Christian Verhoeven[b], Rohan Devassy[c], Maya Sophie de Wilde[b], Luz Angela Torres-de la Roche[b], Rudy Leon de Wilde[b]

[a] Obstetrician and Gynecologist, Advanced Gynaecological Minimal - Access Surgery, Dubai London Clinic and Speciality Hospital, Dubai, United Arab Emirates
[b] Clinic for Gynecology, Obstetrics and Gynecological Oncology at the Pius Hospital, University Hospital for Gynecology, Carl von Ossietzky University, Oldenburg, Germany
[c] Dubai London Clinic and Speciality Hospital, Dubai, United Arab Emirates

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ABSTRACT

Purpose: To evaluate the feasibility of using contained endobags (Morsafe®) in the retrieval of the specimen during laparoscopic surgeries in presumably benign myomatous pathology.

Material and methods: We conducted a retrospective single center case – control study on 239 patients, between 01.05.2014 and 31.12.2017 for uterine myomata, presumed to be benign. The analyzed parameters were the method for contained specimen retrieval, the time of bag manipulation, practicability of action and the perioperative complications rate. The present work has been reported in accordance with the STROCSS criteria and guidelines [1].

Results: the main laparoscopic interventions were myomectomy (n = 148 cases) and LASH (laparoscopic supracervical hysterectomy) (n = 68 cases), LASH with bilateral salpingectomy (n = 7), LASH and bilateral adnexectomy (n = 3), LTH (laparoscopic total hysterectomy) (n = 3), LTH and bilateral adnexectomy (n = 1), radical LTH with lymphonodectomy (n = 2), LTH with bilateral salpingectomy (n = 1) and adenomyomectomy (n = 6).

In 3 cases using contained closed bags, there was an evidence of malignancy in the pathological sections: leiomyosarcoma (n = 1) and endometrial carcinoma (n = 2).

There were no adverse events and no intra – or postoperative bag – induced complications. Regarding the intraoperative duration, the time of bag introduction was about 7 min, and morcellation approximately 12 min.

Conclusion: in – bag morcellation through endobag (Morsafe®) proved to be a safe laparoscopic method in retrieval of myomatous tissue, potentially reducing the risk of dissemination and thereby improving the patients' safety avoiding spreading of benign disease and malignancy, but preserving the benefits of *minimally invasive* surgery. The advantages concerned not only the operating time and costs, but also the safety aspects in case of malignancy. As the system can help to reduce risk of cell dissemination it could also reduce the risk in case of occult malignancy.

1. Introduction

The well - known advantages of *minimally invasive* surgery like reduced morbidity, less postoperative pain, better cosmetic results and patients' faster recovery [2,3] have made the laparoscopic entry an ideal approach for hysterectomy and myomectomy as the treatment of choice in benign diseases [2,4,5]. Tissue morcellation proposed by Kurt Semm in 1973 [6,7] to remove the operative specimen has led to the development of electromechanical power morcellators, approved by FDA in 1995 [8]. The risk of tissue dissemination during morcellation has challenged the routine use of this method, due to concerns in benign diseases creating parasitic myoma [9], inoculated endometriosis [10–12], and in possible unknown malignancy [13,14].

The first safety warning announced by the US Food and Drug Administration (FDA) in April 2014 [15] was regarding the risk of intraperitoneal dissemination in case of sarcoma. This issue was revisited

* Corresponding author.
E-mail addresses: rajeshdevassy@gmail.com (R. Devassy), christina.cezar@uni-oldenburg.de (C. Cezar), gynaekologie@annahospital.de (H. Krentel), H.C.Verhoeven@t-online.de (H.C. Verhoeven), rajeshrohan00@gmail.com (R. Devassy), luzangela.torres-delaroche@pius-hospital.de (L.A. Torres-de la Roche), rudy-leon.dewilde@pius-hospital.de (R.L. de Wilde).

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in November 2014 [16], discouraging the routine use of electric morcellation. The FDA estimated a risk of sarcoma being 1:350 women undergoing fibroids' surgery and 1:458 specifically for leiomyosarcoma [16]. In a prognosis study of morcellated sarcoma it was shown that the disease – free survival could be reduced in the case of power morcellation and in vaginal morcellation, compared to *nonmorcellated* cases [17]. Considering these aspects and the FDA's warning, the surgeons were faced with a clinical dilemma, as the advantages of *minimally invasive* interventions could definitely not be ignored [18]. Recently, in – bag morcellation has been proposed as a strategy to overcome this clinical challenge [19–21] by reducing the risk of dissemination, thus potentially improving patients' safety [22] but simultaneously maintaining the important advantages of *minimally invasive* surgery [23,24].

Responding to the challenge of maintaining the principles of *minimally invasive* surgery through small abdominal incisions avoiding laparotomy and at the same time taking into account patient's safety, the goal of the present paper is to describe the feasibility of the contained morcellation system Morsafe®, focusing on the practice of in – bag morcellation to retrieve the specimen from the abdominal cavity.

2. Material and methods

We conducted a retrospective analyze of 239 cases of laparoscopic in-bag morcellation procedures in hysterectomy specimens and fibroids of different sizes and numbers performed over a period of 3 years between 01.05.2014 and 31.12.2017.The analyze of the cases was performed in accordance with the STROCSS criteria and guidelines [1].

The parameters investigated were the time of bag manipulation and the incidence of complications such as bag rupture or herniation at the port sites. Perioperative data were collected, such as the general health of the patients, symptoms and subjective complaints, demographic data like age and weight and the preoperative Papanicolau cervical smear. The Pap smear has been routinely performed in all the cases, except the virgin unmarried women due to religious concerns in the United Arab Emirates. All the cases were screened and were presumed benign with ultrasonography and colour doppler without any significant resistance index, and MRI findings were documented. Most of the myomas were intramural, subserous and few submucous.

Perioperative information referred to the type of procedures performed (LM: laparoscopic myomectomy, LASH: laparoscopic – assisted supracervical hysterectomy, LTH: total laparoscopic hysterectomy, LA: laparoscopic adenomyomectomy), the type of myoma (single, multiple, calcified), specimen weights, the time required for the in – bag morcellation as well as the time needed for the bag introduction.

The IRB (Institutional Review Board) approval of the hospital was obtained for the retrospective study.

In order to reduce infectious complications, a single shot broad spectrum perioperative antibiotic was used in all cases.

In this series, in – bag morcellation with Morsafe® was performed [23] (Fig. 1, Fig. 2). All subjects signed an informed consent regarding the in – bag morcellation to be done, detailing the benefits and possible intra – or post – operative risks.

In – bag morcellation requires relatively large bags (Fig. 3, Fig. 4), with the edges exteriorized to the abdominal wall and *CO2 pneumoperitoneum* maintained in the bag [22,25].

Our protocol performing laparoscopic surgery of fibroids above 5 cms involve placement of at least four trocars. In this method, there are 2–11 mm ports (supraumbilical and umbilical) and 2 or 3–5 mm ports (left and right inguinal or flanks and suprapubic). In case of fibroids smaller than 5 cms, the port configuration would be 3–4, out of which a 11 mm umbilical and 2 or 3 – 5 mm in the left and right inguinal or flanks and suprapubic. The bag in the rolled-up form inside the inserter is pushed through the umbilical port after the trocar is removed or with a grasper passed through the trocar. The telescopic port remains at the supraumbilical port in case of larger fibroids and the bag is pulled through completely, using the ancillary 5 mm ports with

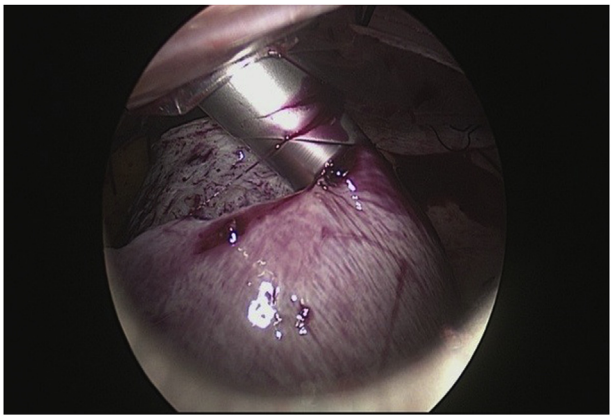

Fig. 1. In – bag morcellation of uterus myoma (Morsafe®).

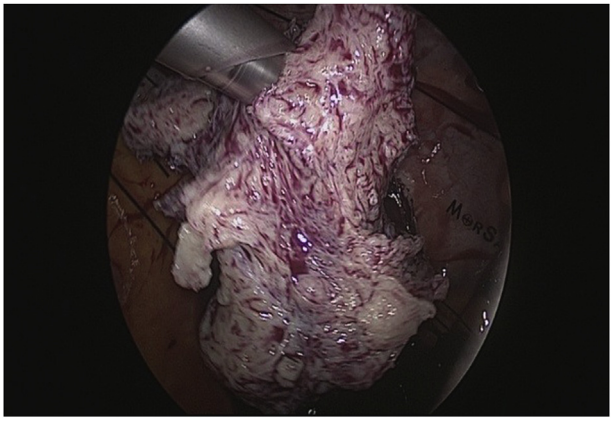

Fig. 2. In – bag morcellation of uterus myoma (Morsafe®).

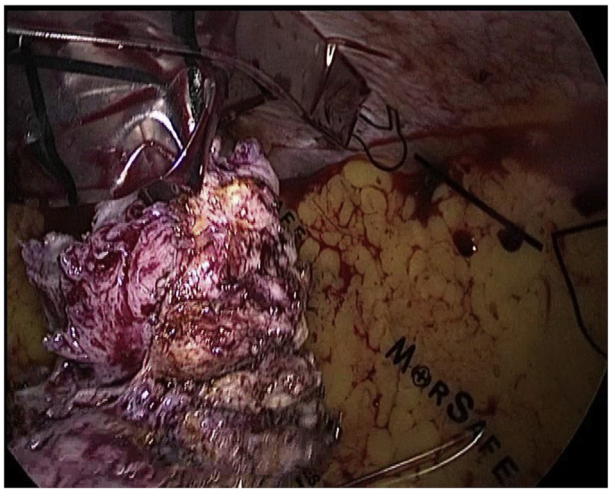

Fig. 3. In – bag morcellation (Morsafe®).

blunt graspers in order to prevent any damage to the bag integrity during traction. An external abdominal hand is compressed firmly on the remaining bag to prevent pneumoinsufflation of the bag which can often block the bag from entering into the cavity like a ballooning effect. Once the telescopic port of the bag is inserted into the abdomen, the trocar is replaced, facilitating a third or fourth grasper insertion into the abdomen. Thereby the bag is unrolled and opened in the abdomen. Two or three graspers hold on the bag opening edges, thus completely facilitating passage of the specimen from the umbilical port. In case where a 3 port maneuver is done in case of a single small myoma, then

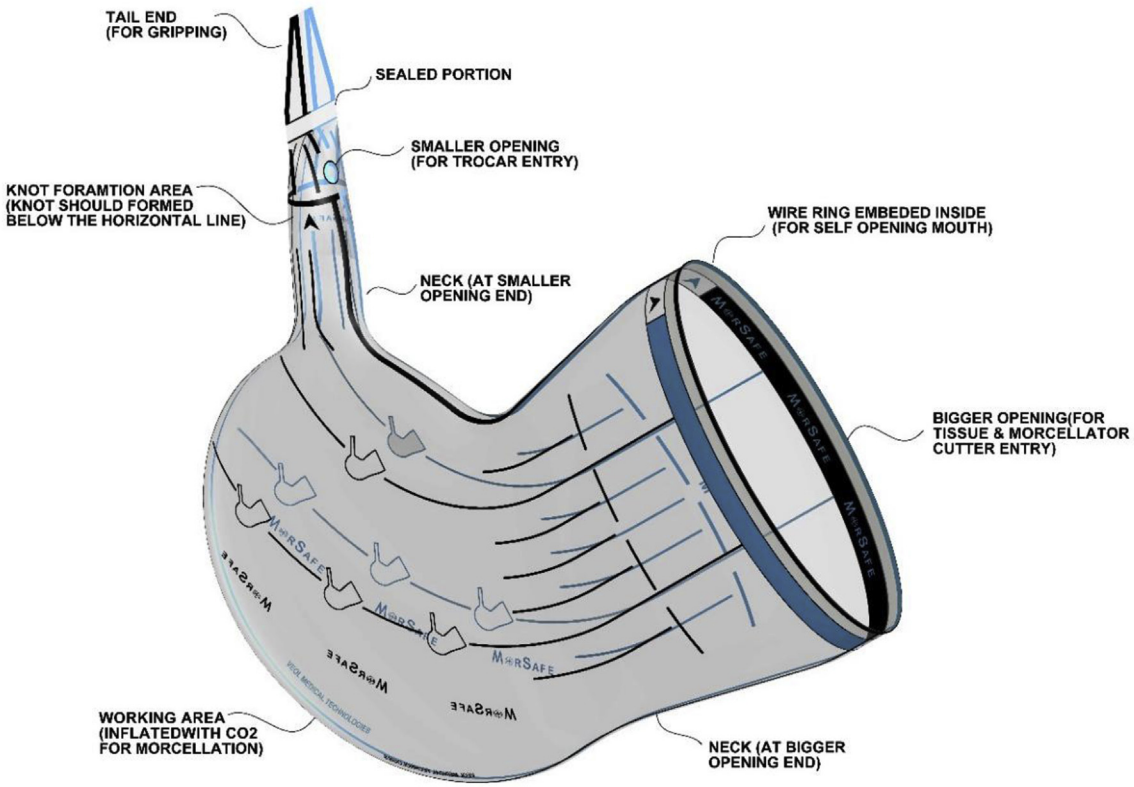

Fig. 4. Morsafe® - Tissue morcellation bag.

the bag edges are held with one grasper ventrally and the other grasper used to maneuver the myoma into the bag and simultaneously lifting the bag edges to prevent slippage. The patient table position is made into Trendelenburg to facilitate gravitational shift and help myoma placement and reduce slippage out of the bag in case of larger myoma. Thereafter the specimen inlet edges are grasped together and pulled out through the trocar out of the abdomen. And either a morcellator trocar with blunt obturator is placed or a finger placed to prevent gas leakage when insufflation is begun into the bag. The telescopic port sleeve of the bag can either be pulled out through the supraumbilical port or through one of the lateral 5 mm ports. Thereafter the respective trocar is removed, the other trocars in place are opened to desufflate the pneumoperitoneum. Thereafter the telescopic sleeve is fitted with a trocar of the respective port size and the telescope inserted. Insufflation is begun into the bag and the telescope is started to slide into the bag under vision; care is taken not to bluntly penetrate. Once inside the pneumocontained bag, the trocar is slid through the telescope and brought inside the bag. The morcellator trocar with blade is introduced. Gas test is done with saline to check any leakage preliminarily. Trocar points and morcellator devices checked simultaneously for leakage. The morcellator trocar shield is placed towards bag and blade placed towards the cavity. This is to prevent inadvertent slicing of the bag, when the morcellation process begins. In case of a large specimen, blood is evacuated at the end to facilitate picking of pieces larger than the port diameter before bag extirpation. Thereafter the telescope is withdrawn, the sleeve is knotted and the bag is pulled through the larger opening.

Regarding the practicability of in – bag morcellation, there was no prospective questionnaire evaluated, however the videos were retrospectively reviewed at the conducting time of this study and the overall satisfaction was appreciated by following 14 parameters:

1. Endobag insertion into the abdominal cavity
2. Achieving a pneumo free bag during introduction
3. Swift reintroduction of umbilical port into the bag
4. Time necessary to transfer the specimen into the bag
5. Positioning of the bag through umbilical port (routine extraction through umbilical port) and reintroducing the 12–20 mm morcellator trocar
6. Ease to divide the abdominal fascia without injuring the bag in order to facilitate larger diameter morcellators
7. Settle the telescopic port of the bag through a trocar and reintroduction of the trocar into the telescopic port with telescopic guidance into the inflated bag
8. Manipulation of myoma within the bag and finding a comfortable position of the surgeon and the monitor screen
9. Occurrence of any bag abruption because of injury while grasping myomatosus tissue
10. Occurrence of any bag abruption due to the blade during morcellation.
11. Aspiration of the blood fluids out of the bag during in bag pneumo compression and subsequent inspection of the bag extra-abdominally
12. Injury of containment bag
13. Total time of morcellation, from deployment to extraction of the bag and submersible check
14. Overall satisfaction of surgeon

Bags were inspected visually for any disruption and thereafter inflated with CO2 and a submersible test under water. Filling the bag with saline was performed to prove any micro leakage of the bag either if by tenaculum graspers or morcellator blade.

3. Results

The average age of the patients was 41.4 years, ranging between 23 and 68 years. Patient weight ranged from 44.0 Kg to 127.6 Kg with a median at 70.8 Kg (Table 1). The most frequent laparoscopic interventions performed were myomectomy, LSH and LTH (Table 2). The

Table 1
Patient and specimen characteristics.

	Median	Range
Patient age (years)	41.4	23–68
Patient weight (Kg)	70.8	44–127.6
Specimen weight (g)	435.5	30–2805

Table 2
Type of laparoscopic intervention.

Surgical intervention	Number of cases
Myomectomy	148
LASH	68
LASH with salpingectomy	7
LASH with bilateral adnexectomy	3
Adenomyomectomy	6
TLH	5
TLH with salpingectomy	1
TLH with bilateral adnexectomy	1

Table 3
Weight of the laparoscopic specimen at histopathology.

Weight of specimen	Number of cases
≤250 g	49
250–500 g	72
500–1000 g	77
≥1000 g	41
Total	239

median weight of the morcellated specimen was 435.5 g, ranging from 30 to 2805 g (Tables 1 and 3).

In most of the cases, histological examination showed the presence of fibroids, but also adenomyosis, endometriosis or endometrial hyperplasia and severe dysplasia of cervix uteri were detected. Malignancy was diagnosed in 3 cases, 2 endometrial carcinoma and one case of sarcoma (Table 4). In these cases, due to the suspicious nature of the intraoperative findings, a frozen section was intraoperatively done, and malignancy was found; therefore laparoscopic radical hysterectomy was performed during the same session. Disease free survival was documented in all cases over 3 years.

The intraoperative time necessary for morcellation and introduction of the endobags is presented in Table 5 – the bag manipulation time was about 7 min and the mean morcellation time 12 min.

In this series, no adverse events like rupture or failure of the bag were reported, and no intra – or postoperative bag – induced complications such as bleeding, infections or herniations at the port sites were described.

The bags consist of a medical – grade flexible plastic and can be classified into three sizes for use, depending on the specimen to be morcellated (Table 6) – small: 23 × 36.5 × 12.5 cm; medium: 25 × 37 × 13.5 cm; large: 26 × 39 × 14.5 cm. In the present series, even the large bags enabled trouble – free morcellation of big species up to 2805 g.

Table 4
Histological examination of the specimens.

Histological examination	Number of cases
Single myoma	114
Multiple myoma	68
Calcified myoma	37
Adenomyosis	12
Uterine leiosarcoma	1
Endometrial carcinoma	2
Severe dysplasia of cervix uteri	2
Endometrial hyperplasia with atypia	1
Endometriosis	2
Total	239

Table 5
Morcellation time for different interventions.

Containing system		Average time	
Type	Total	Mean bag manipulation time (h:min:sec)	Mean morcellation time (h:min:sec)
Morsafe®	239	0:07:03	0:12:42

Table 6
The description of Morsafe® bags.

Containing system	Size in cms	Material	Cost (USD)
Morsafe®	- Small: 23 × 36.5 × 12.5 - Medium: 25 × 37 × 13.5 - Large: 26 × 39 × 14.5	Flexible plastic [38]	~16

Regarding manageability and practicability by surgeon, the overall satisfaction was very good in most of the cases (234/239, 97,9%). Only in 5 cases (2,09%) laborious manipulation was reported, due to the multiple number of fibroids or the large size/diameter to introduce into the bag.

4. Discussion

Laparoscopic morcellation remains a crucial procedure to remove the intraperitoneal specimen in large uteri or myomas [26]. However, the risk of peritoneal dissemination [27] in the case of malignancy should be taken into account [15], even if the risk of malignancy is very low [24,28–31], but in such cases morcellation could potentially lead to a poorer prognosis [24,32–34]. The in – bag morcellation was developed as an alternative to counter this challenge, maintaining the important advantages of *minimally invasive* [5] surgery while preserving patient's safety [26].

The feasibility of in – bag morcellation has recently been shown by pilot studies [8,35,36], demonstrating a technical success of 93,9% [37] and an absence of peritoneal residue [38]. Conforming the literature data, the present series showed effective implementation of contained in – bag retrieval of the intraoperative specimens, even in very large myomatosus tissue. This study strengths are the highest number of in – bag morcellation and the largest weight of extirpated tissue.

However, several studies demonstrated a prolongation of surgery with 20–30 min when the in – bag morcellation was used compared to the classic morcellation without bag [21,39–41]. In the present study, time of bag introduction was about 7 min and for the morcellation itself an average of 12 min was recorded. An important advantage of the bags as contained system is that no after – morcellation intra – abdominal peritoneal cleaning is necessary, thus improving the patient's safety and saving surgery time. Cell dissemination could be possibly higher in myomectomy due to the incision of the myoma and manipulation of the myoma prior to morcellation. The actual dispersal in a containment system if intact is null because any mild abruption would cause gas leakage and collapse of the bag. But the cell dispersal could happen during the myomectomy or hysterectomy itself, in dissecting and grasping. However, this risk is also existing in laparotomy as well.

The size of the sample to be removed did not limit the applicability of the bags, as the largest specimen in this series weighed 2805 g which was extracted without problems, despite of the size, concordant with other smaller series published [23].

Other important advantages are the practicability and the absence of complications such as bag rupture, infections or hernia at the port

sites, consistent with other literature reports [39]. The total number of leiomyosarcoma in this study reflects the statistics, taking into account the high volume of the extirpated tissue [16].

5. Conclusions

Contained in – bag morcellation as innovative technique of tissue extraction proved to be a safe and feasible laparoscopic method potentially reducing the risk of dissemination in benign disease and in case of unsuspected malignancy, maximizing the patients' safety and meanwhile preserving the advantages of *minimally invasive* surgery.

According to the present results, specimen extraction using contained bags proved to be a method with benefits regarding not only the intraoperating time and complications, but also the safety aspects concerning neoplasia and parasitic dissemination, preventing spilling of tissue or cells.

However, prospective and comparative studies with larger cohorts of patients are necessary to confirm the efficiency of contained bags in the routine use of laparoscopic morcellation.

Ethical approval

No Ethical Approval was required.

Sources of funding

Veol Medical Technologies P LTD.

Author contribution

Rajesh Devassy: conception and design of the study, acquisition of data, drafting the article and revising it critically for important intellectual content.

Cristina Cezar: conception and design of the study, analysis and interpretation of data, drafting the article and revising it critically for important intellectual content.

Harald Krentel: acquisition of data and interpretation of data, drafting the article.

Hugo Christian Verhoeven: acquisition of data and interpretation of data, drafting the article.

Rohan Devassy: conception and design of the study, acquisition and interpretation of data, drafting the article.

Maya Sophie de Wilde: acquisition and interpretation of data, drafting the article.

Luz Angela Torres-de la Roche: conception and design of the study, acquisition of data, drafting the article.

Rudy Leon de Wilde: analysis and interpretation of data, drafting the article and revising it critically for important intellectual content, final approval of the version to be submitted.

Conflicts of interest

Dr. Rajesh Devassy received a grant to perform the retrospective data acquisition.

Research registration number

None.

Guarantor

Dr. Devassy, Dr. Cezar, Prof. Dr. Dr. De Wilde.

Consent

None.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijsu.2018.12.013.

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