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Research Article

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Prevention of Lymphatic Complications after Pelvic Laparoscopic Lymphadenectomy by Microporous Polysaccharide Absorbable Hemostat

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Abstract

Introduction: *One of the mandatory components of radical treatment of patients with endometrial cancer is the impact on regional lymph nodes. Nowadays, pelvic lymphadenectomy remains not only therapeutic, but also a diagnostic method in case of predicting the effectiveness of treatment. However, it is important to point out that there are a lot of complications which can occur after dissection of lymph nodes. Lymphorrhea and lymphocele are among the most common postoperative complications of pelvic lymphadenectomy, with a reported incidence of 1% to 50%. Except for the occurrence of undesirable symptoms it can increase the time of drainage standing, which contributes to the delay of further stages of combined treatment.*

The aim of the study: *The aim of the study was to evaluate the effectiveness of the intraoperative application of micro porous polysaccharide absorbable hemostat taking into account the functional outcomes to improve the long-term results of surgical treatment.*

Materials and methods: *In order to solve the tasks, we analyzed the treatment of 12 patients with verified diagnosis of endometrial cancer. We divided the patients in 2 different groups. The first group included patients with polysaccharide absorbable hemostat application (6 patients). The second one (control group) included patients who were provided, according to traditional methods, without using polysaccharide application (6 patients). All patients underwent ultrasound examination on postoperative days 7, 14, 28. Groups were comparable in age, risk profile, and lymph node numbers. Postoperative drain loss and development of early and late lymphocyte were analyzed.*

Results: *Group 1 showed a lower drainage volume and in this group there wasn't any lymphocyte development. But the control group (group 2) showed 4 occasions of lymphocyte formation. Also two of them were symptomatic and were treated with percutaneous drainage (duration: 25 days in untreated patients versus 7 days in patients with absorbable hemostat using).*

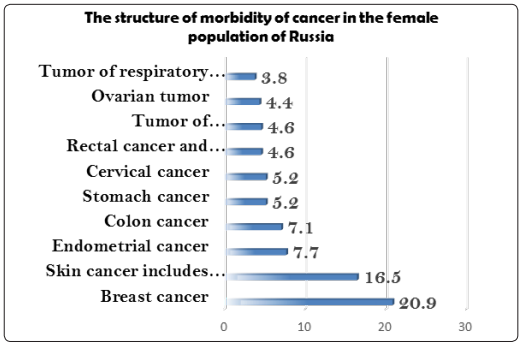
Conclusion: *In this preliminary investigation, the intraoperative application of micro porous polysaccharide absorbable hemostat on lymph node dissection areas significantly decreases total drain loss. In addition, it reduces frequency of lymphocyte formation, which contributes to the timely implementation of further stages of multidisciplinary approach in endometrial cancer's treatment. A multicenter randomized clinical trial with a larger number of patients and longer follow-up is necessary toevaluate the overall outcomes of the combination of laparoscopic lymphadenectomy plus polysaccharide hemostat application.*

Keywords: Lymphocele, Endometrial Cancer, Pelvic Lymphadenectomy, Polysaccharide Hemostat

Introduction

Uterine cancer is the sixth most common cancer worldwide for females, and the 14th most common cancer overall, with more than 319,000 new cases diagnosed in 2012 [1].

Endometrial cancer incidence has increased by around 50% in the United Kingdom since the 1990s, to 8,475 women in 2011 and causing 2,025 deaths in 2012.



To choose the best treatment, to improve postoperative outcomes and prognosis for life we should pay an attention to classification of International Federation of gynecology and obstetrics in order to do the most appropriate treatment.

Early disease (FIGO Stage I and II)

Surgery may be limited to hysterectomy and bilateral salpingo-oophorectomy in those patients with grade 1 or 2 endometrioid adenocarcinoma which appears confined to the uterus.

Late disease (FIGO Stage III and IV)

Complete surgical resection of all visible disease in advanced endometrial cancer may be considered in selected patients who are fit to undergo surgery as limited evidence shows this may prolong survival.

ii - FIGO staging of endometrial cancer and uterine sarcomas

Carcinoma of the Endometrium

Ia	Tumour confined to the uterus, no or < ½ myometrial invasion
Ib	Tumour confined to the uterus, ≥ ½ myometrial invasion
II	Cervical stromal invasion, but not beyond uterus
IIIa	Tumour invades serosa or adnexa
IIIb	Vaginal and/or parametrial involvement
IIIc1	Pelvic node involvement
IIIc2	Para-aortic involvement
IVa	Tumour invasion bladder and/or bowel mucosa
IVb	Distant metastases including abdominal metastases and/or inguinal lymph nodes

Uterine Sarcomas (Leiomyosarcoma, Endometrial Stromal Sarcoma, and Adenosarcoma)

Ia	Tumour limited to uterus ≤5 cm
Ib	Tumour limited to uterus >5 cm
IIa	Tumour extends to the pelvis, adnexal involvement
IIb	Tumour extends to other uterine pelvic tissue
IIIa	Tumour invades abdominal tissues, one site
IIIb	More than one site
IIIc	Metastasis to pelvic and/or para-aortic lymph nodes
IVa	Tumour invades bladder and/or rectum
IVb	Distant metastasis

Adenosarcoma Stage I Differs from Other Uterine Sarcomas

Ia	Tumour limited to endometrium/endocervix
Ib	Invasion to ≤½ myometrium
Ic	Invasion to >½ myometrium

Refs:

Pecorelli S. FIGO committee on gynecologic oncology: revised FIGO staging for carcinoma of the vulva, cervix and endometrium. Int J Gynecol Oncol 2009;105(2):103-4.

Corrigendum to "FIGO staging for uterine sarcomas" [International Journal of Gynecology and Obstetrics (2009) 104:179]. Int J Gynecol Obstet 2009;106:277.

iii - Stratification of endometrial cancer risk of recurrence

Low risk	FIGO grade 1, Stage Ia, Ib FIGO grade 2, Stage Ia
Intermediate risk	FIGO grade 2, Stage Ib FIGO grade 3, Stage Ia
High risk	FIGO grade 3, Stage Ib Non endometrioid cancer

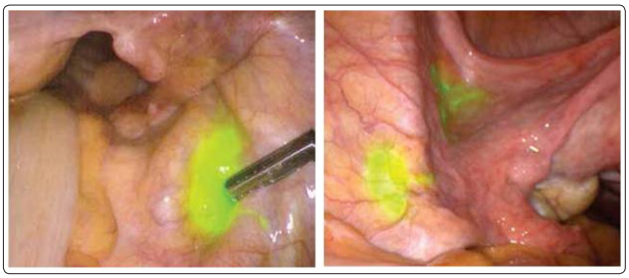
In oncology, a surgical assessment of the lymph nodes is necessary to determine stage and to achieve local control when these are involved by metastatic disease.

Pelvic lymphadenectomy is a routine step during surgical staging and treatment of endometrial cancer, which is a common cancer occurring predominately in postmenopausal women and having as main risk factor unopposed estrogen [3].

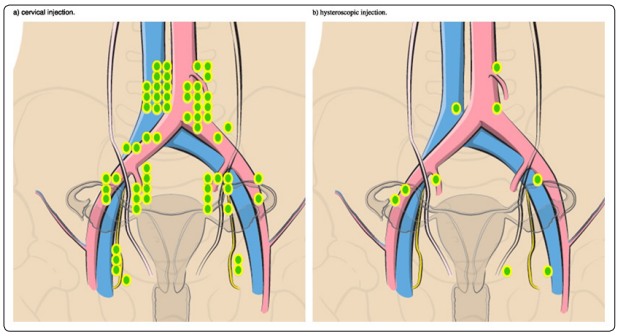
Lymphatic drainage system of the uterus has two segments: the lower drains via the broad ligaments, parametria and paracervical pathway. The upper drains via the infundibulopelvic ligaments.

As for assessment of lymph nodes to achieve adequate staging of cancer we can use method of detection sentinel lymph nodes? These nodes are considered as a kind of filter for tumor cells and are first affected by metastases. Sentinel lymph node biopsy appears to have good diagnostic performance, is likely to provide a useful balance between achieving adequate staging whilst minimizing morbidity and may be a useful service development for centres to undertake.

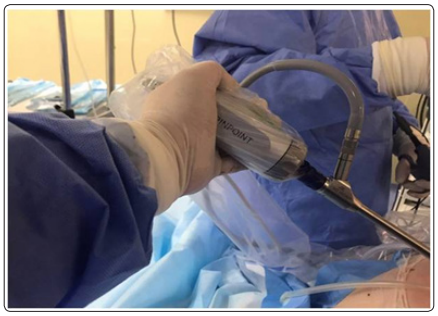
There are a huge amount of researches which provide sentinel lymph node mapping with different coloring substances, for example indocyanin green.

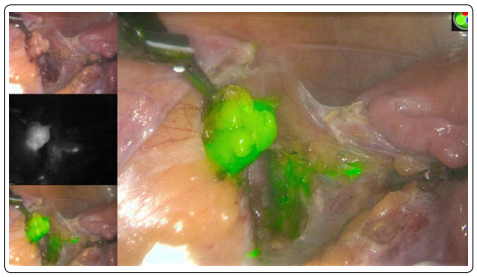


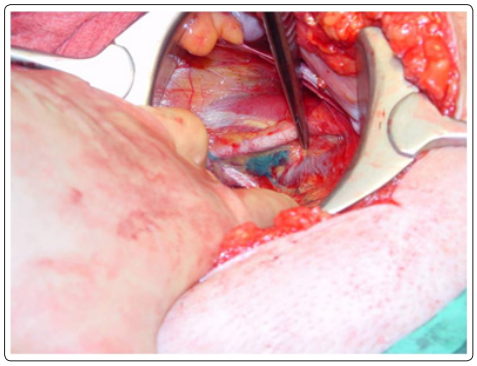
Most of the detected sentinel lymph nodes (90%) were located in the pelvis (external iliac, hypogastric, and obdurate lymph nodes). However, 4% were located in the para-aortic region and 6% were located in the common iliac region [4].



One of the ways to search for SLN is the introduction of a fluorescent diagnostic indocyanin green before surgery to the site of tumor lesion, followed by the identification of the accumulation of the indocyanin in the areas of lymph flow using a video endoscopic Pinpoint with a camera installed in infrared mode.

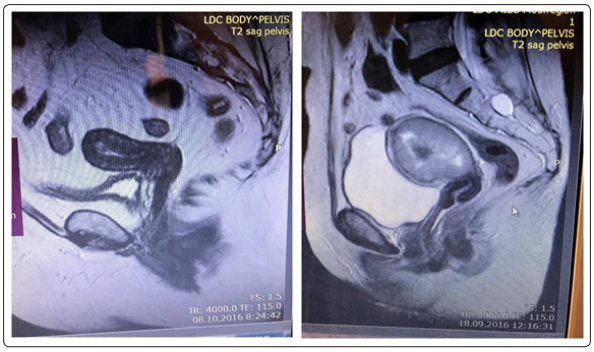






Our recent research included 8 patients with adenocarcinoma of the endometrium G1 (degree differentiation). And we used injection into the cervix of indocyanin green to search for SLN. Then the women underwent pelvic lymphadenectomy.

- Morphological examination of lymph nodes revealed metastases in LN in 6 patients (75%).
- In 6 patients metastases were detected in one SLN (75%).
- No false positive or false negative results were detected that were not displayed when using Indo Cyanine Green & near Infra-Red Fluorescence Imaging.
- In 1 case there was a complication of pelvic lymphadenectomy - lymphocele formation (12.5%).



Although pivotal in oncological management, a radical lymphadenectomy (RLND) is typically characterized by significant short- and long- term morbidity that includes:

- lymphocele, lymphocysts formation
- ascending infection
- uretero-vaginal fistulas
- hypotension of the bladder
- and upper and/or lower extremity lymphedema

Lymphocytes are among the most common postoperative complications of pelvic lymphadenectomy (PL), with a reported incidence of 1% to 50% [5].

Lymphocytes (LC) are collections of lymphatic fluid resulting from leakage of afferent lymphatic vessels as it occurs due to tissue trauma or surgery.

Except for the occurrence of undesirable symptoms it can increase the time of drainage standing, which contributes to the delay of further stages of combined treatment of endometrial cancer.

There are some techniques which may prevent development of lymphatic complications.

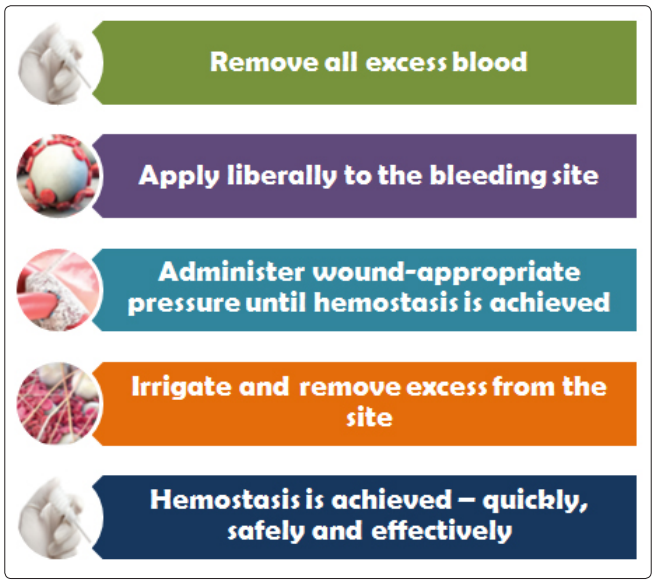
- meticulous surgical technique and careful sealing of lymph vessels
- drainage of retroperitoneal space (blood clots may form in the drains)
- peritonisation (false cysts)
- sealants

But there are some disadvantages of using these methods. For example, if we do peritonisation by omentum it will may form false cysts, because of high resorbable function of peritoneum. So there are a lot of kinds of hemostats and sealents which can allow us to prevent the development of complications.

We use microporous polysaccharide absorbable hemostat, which is different from other sealents because of its structure. Consisting of microporous particles with a controlled pore size, the spheres are designed to act as a molecular sieve. The powerful osmotic action dehydrates and gels the blood on contact to accelerate the natural clotting process.

EFFECTIVE	SIMPLE	SAFE
•Clotting process begins on contact, regardless of patient's coagulation status •Complete hemostasis is achieved in minutes •Provides broad area coverage on rough surfaces and in hard-to-reach areas	•No mixing and no refrigeration •Ready on demand and 5 year shelf life •Pop the cap and apply powder directly to the bleeding site	•Thrombin free, biocompatible and non-pyrogenic •Typically absorbed in 24-48 hours by amylases

Application of this hemostat adheres to the following principles RAPID.



Materials and Methods

We analyzed the treatment of 12 patients with verified diagnosis of endometrial cancer. We divided the patients in 2 different groups. The first group included patients with polysaccharide absorbable hemostat application (6 patients). The second one (control group) included patients who were provided, according to traditional methods, without using polysaccharide application (6 patients).

The only exclusion criterion was any evidence of coagulation disorders, and such cases were excluded from the study.

The method of randomization was in parallel assignment, at a randomization ratio of 1:1. The authors used the most common tests to assess coagulation functions including activated partial thromboplastic time, prothrombin time, fibrinogen, and D-dimer.

- 9 patients withT1aNxMx, 3 patients with T1bNxMx
- Histological examination - adenocarcinoma of the endometrium G1

Characteristic	Group 1 (n=6)	Group 2 (n=6)
Age	50,1 +/- 3,4	52,3+/- 2,5
BMI	24,6+/- 3,8	26,5+/- 4,6
Parity	1,2+/- 1,4	1,6+/- 0,5

We carried out surgery operations according to the last recommendations of European society of gynecologists, which considered performing a type radical hysterectomy and bilateral salpingoophorectomy in patients with endometrial cancer T1 without metastases and first grade differentiation.

Table 3. Querleu-Morrow classification[5]

Type of radical hysterectomy	Paracervix or lateral parametrium	Ventral parametrium	Dorsal parametrium
Type A	Halfway between the cervix and ureter (medial to the ureter-ureter identified but not mobilised)	Minimal excision	Minimal excision
Type B1	At the ureter (at the level of the ureteral bed–ureter mobilised from the cervix and lateral parametrium)	Partial excision of the vesicouterine ligament	Partial resection of the rectouterine-rectovaginal ligament and uterosacral peritoneal fold
Type B2	Identical to B1 plus paracervical lymphadenectomy without resection of vascular/nerve structures	Partial excision of the vesicouterine ligament	Partial resection of the rectouterine-rectovaginal ligament and uterosacral fold
Type C1	At the iliac vessels transversally, caudal part is preserved	Excision of the vesicouterine ligament (cranial to the ureter) at the bladder. Proximal part of the vesicovaginal ligament (bladder nerves are dissected and spared)	At the rectum (hypogastric nerve is dissected and spared)
Type C2	At the level of the medial aspect of iliac vessels completely (including the caudal part)	At the bladder (bladder nerves are sacrificed)	At the sacrum (hypogastric nerve is sacrificed)
Type D	At the pelvic wall, including resection of the internal iliac vessels and/or components of the pelvic sidewall	At the bladder. Not applicable if part of exenteration	At the sacrum. Not applicable if part of exenteration

Results

After that we got some results. Patients in first group showed a lower drainage volume than patients in second group. Also in 1 group there weren't any lymphocele formations. But in 2 groups there were 4 cases of lymphocele. And 2 of them were symptomatic. So patients complained of pain and heaviness in gastrointestinal region.

Variable	Group 1 (n=6)	Group 2 (n=6)
Drainage volume, ml	58 ± 12	117 ± 35
Drainage removal, days	2 ± 0,5	3 ± 0,5
Lymphoceles development, n(%)	-	4 (66,7)
Symptomatic lymphocele	-	2 (33,3)
Percutaneous drainage, n(%)	-	2 (33,3)

The length of hospital stay in group 1 was 4 days (n=6, 100%), but in group 2 was 6 days in patients with asymptomatic lymphocele (n=4, 66, 7%) and 8 days in patients with percutaneous drainage (n=2, 33, 3%). The cost of microporous polysaccharide absorbable hemostat application is 57 pounds. The cost of 1-day hospital stay is 50 pounds. So the use of absorbable hemostat is more profitable in terms of economic efficiency.

Conclusion

Microporous polysaccharide absorbable hemostat used after pelvic lymphadenectomy in preventing lymphocele development demonstrated its efficacy.

Even if Microporous polysaccharide absorbable hemostat seems to provide a useful additional treatment option in preventing symptomatic and asymptomatic lymphocytes and in reducing pelvic lymph drainage volume, our investigation is a preliminary evaluation on a small number of women treated by pelvic lymphadenectomy.

A multicenter randomized clinical trial, possibly including also lumboaortic lymphadenectomy, with a larger number of patients and longer follow-up is necessary to evaluate the overall outcomes of the combination of laparoscopic lymphadenectomy plus Microporous polysaccharide absorbable hemostat application.

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