Is the Pressure from Blue Dye Cervical Injection Associated with Sentinel Lymph Node Detection in Laparoscopic Surgery for Endometrial Cancer?

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Abstract

Introduction Sentinel lymph node biopsy (SLNB) has been proven to be a safe procedure in the treatment of endometrial cancer, and the instillment of a dye/marker in the cervix is the most used technique. Various studies have correlated the body mass index (BMI) impact as well as menopausal status and staging with the rate of lymph node detection, but few studies have evaluated if the high density of the cervix decreases detection.

Objective To quantify the injection pressure of the marker in the uterine cervix and to correlate it with the sentinel lymph node detection rate in endometrial neoplasia.

Materials and Methods Patients with endometrial cancer with programmed laparoscopic SLNB were selected to have the cervical injection pressure assessed. Immediately following the extraction of the uterus, saline solution was reapplied to measure injection pressure with a device attached to the syringe. We investigated the possible correlation of injection pressure with lymph node detection rate and the clinical data of the patients.

Results A total of 18 women participated in the study; a correlation between injection pressure and lymph node detection rate was not identified, neither was greater injection pressure detected in smaller uteruses or cervices. The pressure of the deep injection is greater than that of the superficial one, but the more medial application, or more lateral in relation to the midpoint, does not alter the injection pressure.

Conclusion The presence of greater resistance in the instillment of stain into the cervix was not associated with a lower lymph node detection rate.

Keywords
- sentinel lymph node dissection
- endometrial cancer
- detection rate

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Introduction

Endometrial cancer is the most common cancer among women in the United States,[1] and it is the fourth most common gynecological neoplasia in Brazil,[2] with more than 7,500 cases of uterine cancer in 2023.[2] This scenario is a result of the population aging, associated with obesity. More than 40 million Brazilians are obese, according to the Health Ministry.[3]

Sentinel lymph node biopsy (SLNB) has increasingly substituted systematic lymphadenectomy, as it reduces surgical morbidity[4] without failing to provide important staging information on the lymph node status.[5–7] The injection in the uterine cervix is the most used technique, as it is simple, reproducible, and has acceptable rates of pelvic SLNB.[6,8–11] Although indocyanine green (ICG) is the most recommended marker for the best detection rates,[12,13] the high cost of the technology involved engenders the use of patent blue dye in many hospitals. The bilateral detection rate with patent blue is approximately 45 to 55%,[12] and it would be most opportune to perform an investigation into how to optimize these numbers.

The surgeon's experience is capable of greatly optimizing the rate of bilateral sentinel lymph node detection.[6,10] Clinical factors, such as body mass index (BMI),[14] advanced stage disease, and increased cervical dimensions[10] may limit detection. Non-detection of the sentinel lymph node can lead to complete lymphadenectomy, at least in the hemipelvis without detection,[1] and, for this reason, it is important to improve the injection techniques for bilateral detection.

Difficulty in injecting the stain into stiff cervices is frequently reported by surgeons.[10] It is possible that this anatomy makes detection more difficult,[15] but, as far as we know, the high resistance during the injection, associated with the stromal density, has never been quantified, nor correlated to the detection rate. We believe it is opportune to quantify this greater resistance and correlate it with the lymph node detection rate and with constitutional and clinical factors.

Materials and Methods

The patients were selected for this study in preoperative consultations at the Gynecologic Oncology outpatient unit of Hospital do Servidor Público Estadual – Francisco Morato de Oliveira (HSPE – FMO). The surgeries were performed, and outpatient follow-up was employed in this same hospital. All patients involved in the study signed a free and informed consent form, and the study was approved by the hospital's ethics committee.

This is a pilot study without sample calculation to verify a gross tendency towards impaired dye migration in dense cervical tissue. An exploratory analysis could help to verify tendencies in sentinel lymph node detection between stiff vs fibroelastic cervical tissue as this parameter has not been quantified yet. We also evaluate if specific clinical features had any relation with consistency of cervical tissue: age, uterine volume, cervical dimensions, parity, and menopausal interval.

Eighteen endometrial cancer patients with recommendations for laparoscopic hysterectomy, salpingo-oophorectomy, and SLNB were selected sequentially. We usually employ patent blue stain in our routine, as the ICG and technetium detection technologies are not available at the hospital. The application is performed with a 20-to-22 G spinal anesthesia needle in the stroma of the uterine cervix, 2 ml at 3 o'clock and 2 ml at 9 o'clock, with 1 ml applied superficially and 1 ml deeply (approximately at 2 cm). The application was performed simultaneously with the installation of a trocar and the inventory of the cavity, and the lymph node biopsy was performed 15 to 20 minutes after the injection.

The stain application pressure was quantified after the removal of the uterus. The site was identified by means of the stain mark itself in the cervix, and physiological saline solution was applied to the same site of the surgical injection, to a more medial site (without reaching the endocervix), and to a more lateral site (without reaching the pericervical ring). The same surgeon who performed the intraoperative application also performed the pressure assessment after the surgery to improve the pressure quantification precision.

The data were uploaded into an SPSS (version 25) spreadsheet for analysis and descriptive statistics. Considering the small sample size without normal distribution, we opted for the Spearman bivariate correlation for quantitative variables or the Mann-Whitney test in the comparison of qualitative and quantitative variables.

Instructions on the Use of the Device

The Blue Diamond device (Merit Medical Systems, Inc., South Jordan, UT, USA) is commonly used to measure the cerebrospinal fluid (CSF) pressure, aiming to quantify and control cases of increased intracranial pressure. It possesses a 20 ml syringe composed of an integral pressure transducer connected to an LCD visor with retro illumination. The Blue Diamond was conceived to generate and monitor pressures in an interval of −0.4 to +30.0 ATM/BAR (−6–441 PSI) and it seemed appropriate to quantify the cervical dye injection pressure in the present study. Two devices were donated by Merit Medical to enable this study.

Following the manufacturer's recommendations, the device was inspected before use to verify that the ampoule line was open to atmospheric pressure with the safety valve open. Upon turning on the device, the LCD registers "0" for 2 seconds, after which the device is ready for use. At this point, the syringe begins to register the passage of time, and the pressure is configured in the mode ATM/BAR.

To verify the pressure at the site in which the marker was injected and at other positions previously defined in the cervical stroma, the trigger is pulled at the same time the plunger is pushed forward. The injection pressure is exhibited on the LCD visor in ATM/BAR.

Results

The cohort of this study was 63 years old on average, and 77% were in the initial stage (tumor restricted to the uterus). Their mean BMI was 32.3 g/m^2 (►**Table 1**). In all these women, the stain was applied in the medium third of the uterine cervix at 3 and 9 o'clock. The pressures at each cervical point are displayed in ►**Supplementary Table S1**.

Table 1 Epidemiological profile of the cohort

Parameter	Mean (minimum–maximum)
Age (years)	63.4 (40–82)
BMI (kg/m^2)	32.3 (22–49)
Time after menopause (years)	12.9 (1–31)
Largest cervical diameter (cm)	3.4 (2.5–4)
Uterine volume (cm^3)	151.4 (27–776)

Abbreviation: BMI, body mass index.

On average, the deep injection presented at least 10% more resistance than the superficial one on both sides (►**Table 2**). The lateral and medium injections presented a correlation with the medium point (►**Supplementary Table S2**). Difficulty in the injection was not associated with uterine volume, nor with uterine cervical dimensions (►**Supplementary Table S3**).

Difficulty in superficial and deep injection at the medium point was not related to the parity, nor to the time in menopause. Older patients did not present greater resistance to the deep injection, nor to the superficial one (►**Supplementary Table S3**).

The lymph node detection rate was unilateral in 83.3% and bilateral in 55.6% of the patients. The detection rate was not associated with the decrease in resistance during dye injection (►**Figure 1**). The more advanced age of the patients or the longer menopausal interval did not significantly interfere in the detection rate (►**Supplementary Table S4**).

Discussion

The prediction of success in lymph node detection has previously been studied, including the creation of a nomogram to presume the lack of success in lymph node detection preceding surgery.[16] In the Memorial Sloan Kettering Cancer Center (MSKCC) protocol, the non-detection of the sentinel lymph node implies in pelvic complete lymph node dissection at least on the side in which there was no detection,[1,17] which entails an increase in perioperative and late morbidity.[18,19]

In presumably initial cases with an elevated risk for postoperative lymphedema, it is adequate to investigate the risk factors which may decrease lymph node detection rate other than the obstruction of lymphatic ducts by neoplastic cells. Some patients eventually could be spared from having to undergo lymphadenectomy, and the present study could contribute to this end.

The profile of the included patients is equivalent to the epidemiological profile of other studies with larger numbers of cases: mean age, BMI, and menopausal status are compatible with the Bokhman type-I classification or with cancers without the p53 mutation by molecular classification.[20]

The cervical injection technique consists in the slow infiltration of the marker using a fine needle into the stroma of the uterine cervix at 3 o'clock and at 9 o'clock, as has been previously described.[8,21,22] In addition to the cervical

Table 2 Injection pressures

Injection pressure	Mean (SD)	Median (minimum–maximum)
Left superficial medium point pressure	17.2 (±5.7)	17.5 (9–26)
Left deep medium point pressure	19.1 (±6.6)	19 (10–30)
Left superficial lateral	15.6 (±5.2)	15 (7–28)
Left deep lateral	18.7 (±4.0)	19 (9–25)
Left superficial medial	17.5 (±5.4)	17 (7–25)
Left deep medial	18.6 (±5.8)	19 (9–28)
Right superficial medium point	17.2 (±4.8)	16 (9–30)
Right deep medium point	19.8 (±6.0)	20 (10–30)
Right superficial lateral	17.5 (±5.5)	16 (12–28)
Right deep lateral	20.6 (±5.3)	20 (12–32)
Right superficial medial	17.2 (±4.0)	17 (10–25)
Right deep medial	19.5 (±3.7)	20 (13–25)
Superficial medium pressure (right + left)	17.3 (±4.2)	17 (9.5–25)
Superficial medial point pressure (right + left)	17.4 (±4.6)	18 (9–28)
Superficial lateral pressure (right + left)	16.9 (±4.3)	16 (12–27)
Deep medium pressure (right + left)	19.1 (±4.2)	20 (11–24.5)
Deep medial point pressure (right + left)	19.7 (±5.8)	20 (10–30)
Deep lateral pressure (right + left)	19.7 (±3.7)	20.5 (11.5–27)

Abbreviation: SD, standard deviation.

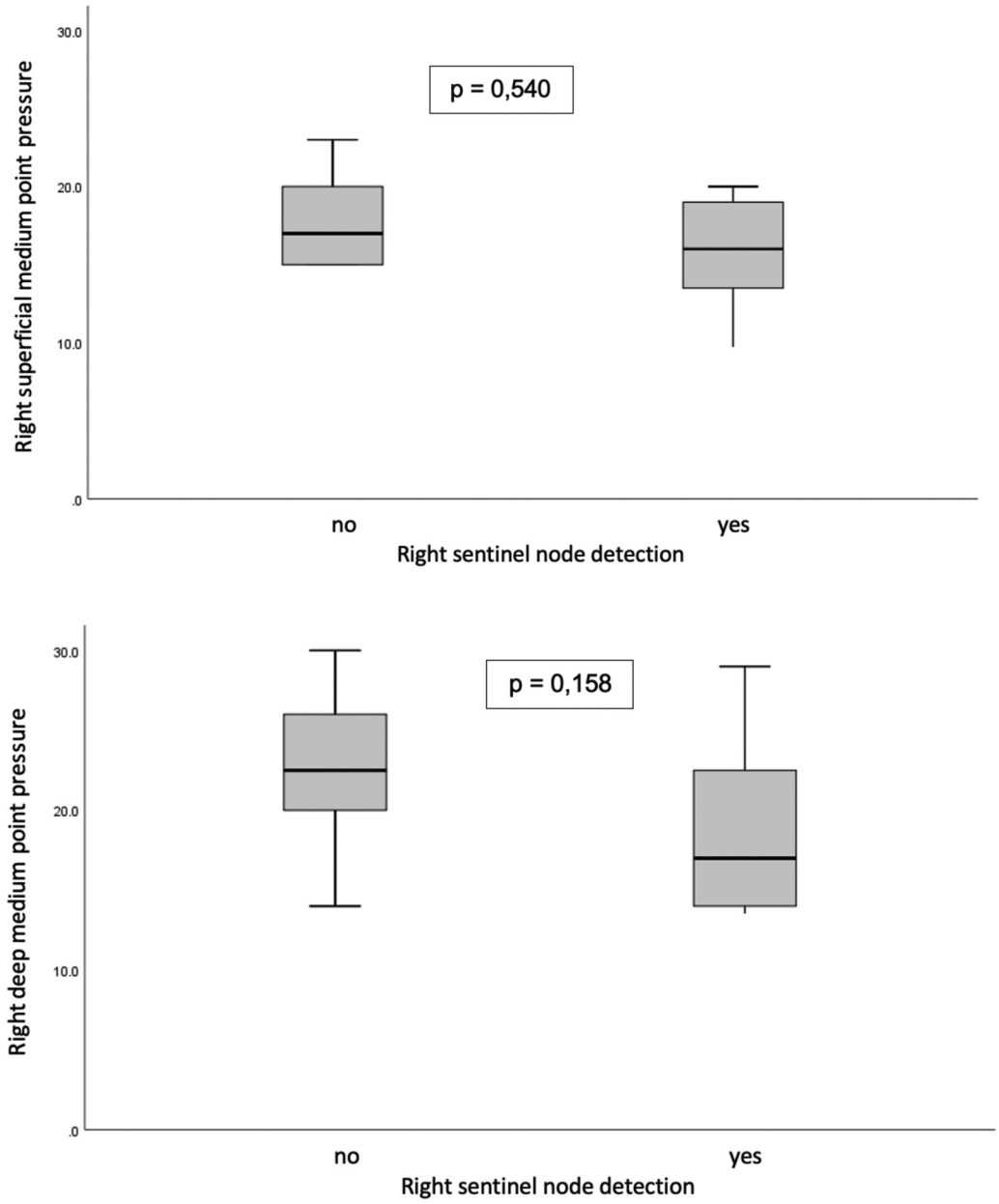

Fig. 1 Injection pressure and lymph node detection in each cervical point.

injection, the hysteroscopically-guided infiltration into the subserous uterine fundus, myometrium, and tumor subendometrium have been previously investigated.[2,4] These techniques offer higher detection rates for para-aortic nodes, but present logistic implications and greater technical difficulties,[8,11] with the risk of uterine perforation and eventual tumor dissemination.

The choice of the marker is very important to the success in sentinel lymph node detection.[12] Patent blue stain (isosulfan blue 1%) is widely used worldwide, as it presents low cost, rapid absorption, and adequate accumulation in the sentinel lymph node for approximately 10 to 20 minutes after its infusion.[5] The risk of allergic reaction is approximately 1%.[1,5] Patent blue stain may interfere in the peripheral blood oxygen saturation measurement, leading to false readings of low saturation.[19] None of our patients presented with anaphylaxis or drop in saturation.

Indocyanine green is a water-soluble stain that emits a greenish coloration when stimulated with an infrared beam. It proved to be superior and present lower risk of adverse events when compared to patent blue,[11,13,23] particularly in obese patients;[24] however, access to it is lower due to the need of specialized technology of detection.[1] Unfortunately, few Brazilian public hospitals have this technology available, including out institution, where neither ICG nor a laparoscopic probe for laparoscopic radiotracer detection is available. Simultaneous blue dye and technetium have similar sentinel detection rates to ICG.[25]

The infiltration must be performed slowly to maximize the absorption into the lymphatic vessels and minimize the

coloration of the deep pelvic tissues.[1] On average, the application on each side took from 30 seconds to 1 minute.

Technical and clinical factors, which can potentially cause detriment to the migration of the stain are presented in ►**Table 3**. In general, the clinical factors are more controversial.[26] The injection pressure, patient age, BMI, and menopausal status did not have a negative impact on the detection rate. The surgeon's experience has the potential to greatly improve the detection rate[8,11,18,27]; the three surgeons involved in the study have similar experience, each one with over 50 cases of SLNB.

The individual characteristics of each patient regarding the volume and density of the cervix have been previously described and are potentially helpful in individualizing the marker injection site and speed of injection.[26] The description of a stiff cervix is frequent in the postmenopause phase and occurs in over 10% of the population.[15] We were unable to identify studies attempting to quantify objectively the difficulty in the instillment of the stain and associating it with the sentinel lymph node detection rate.

Greater injection pressure apparently does not negatively impact the sentinel lymph node detection. Patients with greater uterine densities did not present lower volume uterus in the definitive pathologic report; in the same manner, larger uteruses were not associated with worse sentinel lymph node detection rates, as was previously reported.[18] It could be supposed that a smaller and more atrophic uterus would have a denser conjunctive tissue with a more difficult stain migration. On the other hand, there is proportionately more stain available for the cervical tissue in smaller volume uteruses/cervixes, which might compensate for any difficulty in lymphatic migration.

Possibly, there is a process of lymphatic vessel sclerosis associated with more advanced age, which might compromise the SLNB.[30] This would explain the worse detection with advanced age or with a long menopausal period interval.[15] It is possible that a small variation in age and the small number of cases in the present study did not permit an association of the patient age/menopausal period with the lymph node detection rate or with the increase in the stain infiltration resistance.

Due to the risk of extravasation of the stain into the cervical orifice or the instillment into the parametrial tissue,[23,24] we always strive to inject the stain into the medium third of the cervix, as previously described.[10] The similarity in the more medium or more lateral pressures in relation to the medium point of the injection suggests that there is a safe cervical stroma region to receive the stain and distribute it in the lymphatic system.

The needle should not be introduced very deeply (at most 2 cm.), as it is believed that the deeper instillment can reach the parametrial tissue with rapid venous clearance and/or the risk of neural lesion.[10] The superficial injection presents lower pressure than the deep one, possibly by the lesser density of the stromal conjunctive tissue. We did not evaluate the individual impact of the superficial injection or the deep one on the detection rate, but both complement one another in the lymphatic drainage of the uterus.[10,21] Studies on IG suggest that only the superficial injection can be sufficient due to the greater stain migration.[18]

Finer needles and larger syringes can entail an increase in the cervical pressure during the injection.[10] The use of 18 to 26 G needles is recommended[21]; larger needles can make the injection more comfortable.

The syringe of the device for pressure measurement has a volume of 20 mL, and we used a 5 mL syringe in the patent blue instillment, which had approximately 1/3 of the injection pressure for the same solution volume (according to bulb diameter), but as the criterium used was the similarity in the difficulty in the instillment (and not the injected volume or injection length), we believe that the measured pressure corresponded to that which was perceived intraoperatively. It was not possible to directly use the blue diamond device during the surgery (in vivo) due to its large dimensions.

The present study was planned with a small number of cases to evaluate gross tendencies in the injection resistance associated with the clinical characteristics of the population and the detection rate. We believe that a larger number of cases could detect significant differences, but possibly with a more questionable practical relevance.

The small number of cases did not permit an association between the lymph node positivity and the difficulty in the detection of the sentinel lymph node. The lymphatic vessel obstruction by neoplastic cells is one of the factors which makes the migration of the stain more difficult[22,23,27] and supports the lymph node dissection in the hemipelvis without detection.[13,24] Unfortunately, we did not identify characteristics within the technical details of the SLNB, which would support omitting the lymphadenectomy in the case of the non-detection of the sentinel lymph node.

The presumption of difficulty in detecting the sentinel lymph node is important in the planning of the surgical time, minimizing the risk of perioperative morbidity and developing strategies which could optimize the migration of the stain into the lymphatic vessels. A greater resistance to the injection of patent blue did not prove to be a significant risk factor for a lack of success in the detection of sentinel lymph nodes.

Table 3 Clinical and technical conditions which make detection of pelvic sentinel lymph nodes more difficult

Clinical	Technical
Age[15,18]	Stain used[12]
Elevated BMI[16,23,27]	Surgical pathway[28]
Menopausal status[15]	Surgeon's experience[10,18,22,23,27]
Staging[18,24]	Injection site[23,29]
Size of cervix[10]	
Density of cervix[15]	

Abbreviation: BMI, body mass index.

Authors' Contributions

MS: collection and assembly of data, conception and design, data analysis and interpretation, final approval of the manuscript, writing of the manuscript, and provision of study materials or patient; MBMA: collection and assembly of data, conception and design, and writing of the manuscript; NT: conception and design and final approval of the manuscript; EVLLM: data analysis and interpretation, and provision of study materials or patient; IMA: collection and assembly of data and data analysis and interpretation; LM: collection and assembly of data, conception and design, and final approval of the manuscript; MA: final approval of the manuscript; AMST: conception and design, final approval of the manuscript, and provision of study materials or patient.

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Clinical Trials

None.

Conflict of Interests

The authors have no conflict of interests to declare.

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