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Prospective Comparative Study of Laparoscopic Narrow Band Imaging (NBI) Versus Standard Imaging in Gynecologic Oncology

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Abstract

Background.—Narrow band imaging (NBI) is an optic filtration enhancement for endoscopy that uses two wavelengths of light (415 and 540 nm) to highlight superficial microvascular patterns. It has been successfully utilized to improve identification of lesions with abnormal vasculature, which is associated with endometriosis and endometrial cancer. Case studies suggest it may also facilitate surgical staging of gynecologic cancer, which is critical in determining appropriate adjuvant therapies. A technology that enhances the ability to identify metastatic disease during minimally invasive surgery (MIS) could make an important difference in patient outcomes.

Methods.—A prospective comparative study was conducted to evaluate patients with clinical indication for diagnostic or operative laparoscopy. All received white light imaging followed by NBI during the same procedure. Suspicious lesions were examined and photographed, using both modalities, before excision. The two techniques were compared. Positive predictive value, negative predictive value, and diagnostic accuracy in identifying histologically confirmed metastatic lesions were assessed, using appropriate statistical methods.

Results.—Of 124 patients enrolled in the study, 94 were evaluable; 30 did not undergo MIS and were therefore excluded. A significantly higher number of peritoneal abnormalities were identified with NBI versus white light imaging ($P = 0.0239$). However, no statistically significant difference ($P = 0.18$, patient level) was observed in identification of histologically confirmed metastatic disease.

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DISCLOSURE

The authors have no conflicts of interest. None of the authors have any relevant disclosures to make.

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Conclusions.—NBI imaging provides a unique contrast between peritoneal surface and microvascular patterns. However, the results of this study suggest that NBI-enhanced laparoscopy does not provide superior detection of peritoneal surface malignancy compared with standard white light high-definition laparoscopy.

Narrow band imaging (NBI) is an optical imaging modality that utilizes the specific light absorption wavelengths of hemoglobin to boost visibility of mucosal vascular abnormalities during minimally invasive surgery (MIS). Developed in Japan, it was first described in 2001. In 2009, the Food and Drug Administration (FDA) approved it for use during laparoscopy.^{1–3} Several studies, particularly in the fields of gastroenterology,^{4–14} urology,^{15–18} and pulmonology,^{19–21} have reported that NBI is useful in detecting premalignant lesions, offering different delineation of mucosal tissue compared with standard white light imaging.

In gynecology, NBI has demonstrated usefulness in laparoscopic/hysteroscopic diagnosis²² and treatment of benign conditions such as endometriosis^{23–26} or abnormal uterine bleeding.^{27–31} When compared with white light imaging alone, NBI technology increases the number of endometriotic lesions identified during laparoscopy. NBI also appears to significantly increase sensitivity in detecting low- and high-risk hyperplasia during hysteroscopy. This has the potential to facilitate diagnosis of pre-neoplastic and neoplastic pathologies.^{29–31}

Based on these results, interest in investigating the role of NBI technology in gynecologic oncology has grown. As surgery is the initial step in treating ovarian, endometrial, and early-stage cervical cancer, the search continues for novel imaging modalities to improve identification of early peritoneal, pleural, and retroperitoneal metastasis. Increased sensitivity and specificity in identification of metastatic disease during MIS would impact counseling and might potentially improve patient outcomes. The key benefits of the NBI system are enhanced visualization of superficial structures and vasculature within the mucosal layer. Thus, it is thought that NBI may improve detection of metastatic lesions, compared with the white light imaging that has traditionally been used in laparoscopy.

Currently, there is only one case report examining use of NBI in laparoscopic diagnosis and management of recurrent, platinum-sensitive ovarian cancer.³² The authors reported that NBI was a good adjunct to laparoscopic evaluation, enhancing clarification of observed anatomic structures and facilitating diagnosis of recurrence.

It is not yet possible to determine the extent to which NBI may be superior to white light imaging, especially in the early stages of pleural and peritoneal processes. We designed a prospective analysis to examine whether this new technology improves accuracy in diagnosing peritoneal metastasis from a primary gynecologic tumor. Such improvement would make staging procedures more reliable, and might affect adjuvant treatment recommendations and patient outcomes. Our primary objective is to determine the feasibility of NBI during laparoscopic or robotic surgery. Our secondary objective is to determine what percentage of patients had surface metastasis that was identified by NBI but not by white light imaging.

MATERIALS AND METHODS

This comparative, prospective study was approved by the Institutional Review Board of Memorial Sloan Kettering Cancer Center (MSKCC). Enrollment took place between January 2011 and October 2014. Adult women (> 18 years old) undergoing planned MIS (laparoscopic or robotic) for a risk-reducing adnexal procedure or adnexal mass removal, or who had a preoperative diagnosis of ovarian, fallopian tube, primary peritoneal carcinoma (all histologies, stages, and grades), or endometrial cancer (all histologies, stages, and grades) were considered eligible to participate. There were no laboratory examinations or imaging studies required, specific to participation. Participation in other research protocols was not a criterion for exclusion. Patients were not eligible to participate if they were pregnant, were not candidates for MIS, or were unable to provide consent. Each patient was enrolled and consented by her primary attending surgeon, during a preoperative visit.

All participants received a standardized laparoscopic assessment (for both robotic and laparoscopic cases), and the same system (Olympus®) was used in all cases. All procedures began with collection of peritoneal washings. Four-quadrant inspection of the peritoneal cavity under white light imaging (standard of care) was followed by repeat four-quadrant examination of the peritoneal cavity using NBI (experimental component). The number and location of suspicious lesions were recorded, as was the modality used to identify them. Each lesion was categorized into one of three categories: (1) seen with white light only, (2) seen with NBI only, or (3) seen with both modalities. All suspicious areas were photographed with white light and with NBI. If multiple lesions were seen in a quadrant, lesions were considered distinct if normal-appearing tissue was visible between them. Suspicious lesions were biopsied only after examination with both modalities. If more than one suspicious lesion per quadrant was present, at least one biopsy per quadrant was taken. If no suspicious lesions were noted, random peritoneal biopsies were taken at the discretion of the attending surgeon. At time of biopsy, the surgeon was asked to specify whether the suspicious area was likely benign or malignant, based on his/her clinical judgment. All biopsies were sent for pathologic review.

The data collected, including patient demographic data, pathology results, and data sheet responses, were recorded in an Excel database. All captured images were numbered according to trial enrollment and stored in deidentified manner on a password-protected hard drive. Each biopsy was reviewed by an MSKCC pathologist. To evaluate the relationship between identified peritoneal abnormalities and mode of detection (white light versus NBI), we performed two types of analysis: (1) analysis for number of observations (nodule level) with logistic regression, applying generalized estimation equation (GEE) to consider the cluster effect of nodules per patient, and (2) analysis for patient level using the McNemar test. Laparoscopic findings with white light and with NBI were compared on histology, which was considered the criterion standard. Positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy of each technique in distinguishing between benign and malignant lesions were calculated, and confidence intervals (CI) estimated.³³

Two sets of univariate logistic regressions were conducted at patient level. These were used to identify the statistical relevance of clinical variables in interfering with the ability of the

experimental modality (NBI) to detect peritoneal abnormalities. Set 1 examined whether a lesion was found on NBI (yes vs. no). A bivariate model was also built. Set 2 examined lesions detected only by NBI versus lesions detected by both modalities or by white light alone. We did not perform multivariate analysis for set 2, due to the small sample size. Statistical significance was set at P value < 0.05 .

RESULTS

From January 2011 to October 2014, 124 patients signed informed consent and were enrolled in the study. Of these, 30 did not undergo MIS and were therefore excluded. The remaining 94 were considered for the final analysis. No deviation from protocol was noted in the final sample group.

Patient characteristics, including demographics and baseline clinical data, are presented in Table 1. Thirty-five (37.2%) opted to undergo prophylactic surgery (risk-reducing bilateral salpingo-oophorectomy) for documented increased gynecologic cancer risk (*BRCA* positivity). An additional 58 (61.7%) had previously been diagnosed with a gynecologic cancer, or were diagnosed at time of surgery. One patient had a gastrointestinal cancer presenting with adnexal masses. The most common tumor was endometrial cancer (29/59 patients, 49.1%), followed by ovarian cancer (24/59 patients, 25.5%). One patient had concurrent ovarian and endometrial cancer. Table S1 presents the distribution of patients with cancer, by type and Fédération Internationale de Gynécologie et d'Obstétrique (FIGO, International Federation of Gynecology and Obstetrics) stage. The majority of endometrial cancer patients in the study presented with early-stage disease: 16/29 (55.2%) FIGO stage I; 2/29 (6.9%) FIGO stage II. Most of the ovarian cancer patients presented with advanced disease: 18/24 (75%) were FIGO stage III or IV.

In two cases, following laparoscopic evaluation of the peritoneal surface, the procedure was converted to laparotomy due to adhesions and extension of disease. These cases were included in our analysis because the study protocol had been completed prior to intraoperative conversion.

In all patients, the abdominal cavity was sufficiently illuminated with NBI; contrast of microvasculature and organ surface pattern was enhanced, compared with white light imaging (Fig. S1). No technical difficulties were encountered in abdominal inspection with either imaging technique. The number of lesions detected and the pathology results are presented in Table 2. NBI was associated with a statistically significant increase in the number of total peritoneal abnormalities detected at nodule level ($P = 0.0239$). At patient level, there was no statistically significant difference ($P = 0.18$) in the number of patients who had surface abnormalities identified with NBI. In other words, in the identification of pathologically confirmed metastatic disease, there was no significant difference between NBI and standard white light imaging.

Overall, 44 suspicious nodules were biopsied. On final histology, 25 were malignant and 19 benign. A total of 36 suspicious nodules were seen on white light, with a median of 1.5 (range 0–7) per patient. Three of these nodules were not seen on NBI, and one was

diagnosed as malignant on final pathology. Of the suspicious-appearing nodules, eight were seen using only NBI. On final pathology, three of these were confirmed as malignant.

Overall, 35 “not suspicious” nodules were confirmed as benign on final pathology. A total of 25 “not suspicious” nodules were seen on white light, with a median of 1 (range 0–4) per patient. One of these nodules was not seen on NBI (Fig. S2). NBI detected an additional 10 nodules, which were benign on final pathology (Fig. S3). The NPV, PPV, and diagnostic accuracy of each technique are also reported in Table 2.

In any surgical intervention, confounders may be present that could potentially interfere with the normal appearance of tissue. In this case, poor imaging of the peritoneal surface or a change in its appearance could affect the ability of NBI to detect peritoneal abnormalities. We took into consideration certain clinical variables that had the potential to confound, including previous abdominal surgeries, previous chemotherapy, or abdominal radiotherapy. We performed two different sets of univariate logistic regressions to identify the statistical relevance of these variables at patient level. No statistically significant differences were identified (Tables 3, 4). Set 1 examined whether a lesion was found on NBI (yes vs. no). Set 2 examined lesions detected only by NBI versus lesions detected by both modalities or by white light alone. The detailed distribution for the clinical factors per specific outcome is listed in Table S2. For the first set of logistic regressions, we also provide the bivariate model in Table 5. We did not perform multivariate analysis for set 2 due to small sample size (only seven patients had lesions detected by NBI only).

No intraoperative complications were associated with either white light or NBI during laparoscopy. Twelve of 94 (12.8%) patients had minor postoperative complications: 4 required postoperative blood transfusion, 2 complained of dyspnea and tachycardia immediately after surgery, 1 had low oxygen saturation level immediately after surgery, requiring oxygen supplementation, 2 developed cellulitis at trocar sites, 2 presented with mild, transient paresthesia of the thighs, and 1 had transient urinary retention. There were no long-term sequelae. No surgery-related deaths were recorded.

DISCUSSION

In gynecologic oncology, accurate surgical staging is critical in determining appropriate adjuvant therapy. Improved sensitivity and specificity in identifying metastatic disease during MIS could impact staging, leading to more effective patient counseling, and might ultimately improve patient outcomes.³⁴ Angiogenesis is a cornerstone of tumor growth.^{1–3} As NBI exaggerates the contrast between background tissue and superficial vasculature, it has the potential to improve visual identification of the abnormal vascular patterns associated with malignant peritoneal disease, during thoracoscopy, laparoscopy, and robotic surgery.^{4–31} Theoretically, NBI could be particularly useful in the setting of early-stage peritoneal processes, for which minimally invasive approaches are commonly employed. Identification of early metastatic disease would impact postoperative counseling and treatment.

The results of the present study suggest that NBI laparoscopy is not superior in detecting peritoneal metastases when compared with standard white light laparoscopy alone. Our results concur with those of Schnelltdorfer et al.,³⁵ who reported on 23 patients with gastrointestinal or gynecologic malignancies randomized to receive either white light followed by NBI laparoscopy or NBI followed by white light. They found that NBI provided adequate illumination of the abdominal cavity, and a unique contrast that enhanced microvasculature and architectural surface pattern; however, they also found that NBI was not superior in detecting peritoneal metastases, compared with standard white light laparoscopy. In our case series, NBI detected a significantly higher number of peritoneal abnormalities. The size of the lesions may have played a role in influencing the performance of NBI versus white light, even if no statistical analysis was performed to confirm this theory. However, of the eight additional suspicious nodules visualized on NBI, only three were confirmed as malignant on final pathology; of the additional ten benign-appearing nodules visualized on NBI, none were malignant on final pathology. All surface malignancies identified on NBI were also seen on white light imaging, even when located in different areas. Sample size could have played a role in the failure to detect a statistically significant difference, even if, as previously stated, histology was benign and no malignancies were missed on white light imaging.

Our results differ from those reported by Kikuchi et al., who used NBI to differentiate benign from malignant peritoneal lesions in gastric cancer staging.³⁶ A similar number of biopsied patients were enrolled in their study and ours (37 and 39, respectively). However, a statistically significant difference was noted by Kikuchi, suggesting that NBI was superior to white light imaging alone in detecting abnormal microvascular findings suggestive of metastases. We did not observe such a difference. In our study, the surgeon's impression regarding the nature of the lesion never changed when switching from one modality to the other; of the eight cases in which NBI detected a suspicious lesion not seen on white light, the histology was malignant in only three. Our results may have been influenced by the fact that, in all cases, white light was used first, followed by NBI (there was no crossover). The surgeons' interpretations of NBI findings were always prefaced by knowledge of how the lesion appeared under white light alone; the use of white light as the first imaging modality in every case may have influenced the surgeon's evaluation and interpretation of a lesion when subsequently using NBI. Therefore, we acknowledge that confirmation bias may have influenced our results. Other studies have addressed this bias with a crossover design, randomizing patients into NBI-first or white-light-first groups.³⁵

The greatest limitation of the current study is sample size. To our knowledge, this case series is the largest to evaluate NBI in the setting of gynecologic malignancy. However, we did not meet our enrollment goals during the study period. In order to detect peritoneal metastases in 10% of the population, we would have needed a sample size of 220 patients. The study was underpowered, limiting our ability to detect a statistically significant difference between the two modalities.

CONCLUSIONS

NBI provides adequate visualization of the abdominal cavity, and enhances visualization of superficial microvascular patterns that may characterize lesions with abnormal angiogenesis. However, our results suggest that NBI laparoscopy does not provide an advantage in detecting early peritoneal disease during MIS. Larger studies with crossover design are needed to determine whether addition of NBI increases the sensitivity of white light laparoscopy in detecting peritoneal metastases.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1Patient characteristics (*N* = 94)

Variable	<i>N</i> (%)
Age (years)	
Median (range)	55.5 (26–79)
Body mass index (kg/m ²)	
Median (range)	26.2 (18.1–46.8)
Race	
White	84 (89.4%)
Black	6 (6.4%)
Hispanic	2 (2.1%)
Asian	0
Unknown	2 (2.1%)
Diagnosis	
Prophylactic surgery	35 (37.2%)
Endometrial cancer	28 (29.8%)
Ovarian cancer	23 (24.5%)
Fallopian tube cancer	3 (3.2%)
Peritoneal cancer	2 (2.1%)
Cervical cancer	1 (1.1%)
Nongynecologic cancer	1 (1.1%)
Synchronous (ovarian and endometrial cancer)	1 (1.1%)
Procedure	
Laparoscopic USO or BSO	30 (31.9%)
Robotic TLH, BSO ± lymph node dissection	26 (27.7%)
Diagnostic laparoscopy ± IP port placement	13 (13.8%)
Laparoscopic enterostomy closure	10 (10.6%)
Robotic USO or BSO	6 (6.4%)
Laparoscopic hysterectomy and BSO ± lymph node dissection	5 (5.3%)
Other	4 (4.2%)
Conversion to laparotomy	2 (2.1%)
Previous abdominal surgery	59 (62.8%)
Previous chemotherapy	43 (45.7%)
Previous abdominal radiotherapy	3 (3.2%)
Complications	
Intraoperative	0
Postoperative	12 (12.8%)
Grade 3 (Dindo classification)	0

USO unilateral salpingo-oophorectomy, *BSO* bilateral salpingo-oophorectomy, *TLH* total laparoscopic hysterectomy, *IP* intraperitoneal

Table 2Results of white light and NBI compared with histological findings ($N = 79$)

Laparoscopic technique	Histology		NPV % (95% CI [*])	PPV % (95% CI [*])	Diagnostic accuracy % (95% CI [*])
	Benign	Malignant			
White light					
Benign	40	3	93% (75.8–99.3%)	61.1% (43.5–76.9%)	78.5% (63.8–89.2%)
Malignant	14	22			
NBI					
Benign	38	0	100%	61% (44.5–75.8%)	79.7% (68.1–88.6%)
Malignant	16	25			

NPV negative predictive value, PPV positive predictive value

* 95% CI estimated using Clopper-Pearson (exact) confidence limits by applying SAS SURVEYFREQ procedure considering the cluster effect

Table 3

Univariate logistic regression for NBI lesion: yes versus no (odds ratio modeled for lesion being identified)

Variable	Odds ratio	95% CI lower limit	95% CI upper limit	P value
Previous ABD surgery: yes versus no	3.262	1.275	8.349	0.0136
Previous chemo: yes versus no	1.213	0.529	2.782	0.649
Previous ABD RT ^{**} : yes versus no	0.764	0.067	8.738	0.8285

ABD abdominal

^{**} Due to the small number of patients (only three) in certain levels for this variable, the estimated CI is very wide and the *P* value is unreliable for pre-ABD RT

Table 4

Univariate logistic regression for lesions identified by NBI but missed by white light versus others (odds ratio modeled for lesions identified by NBI but missed by white light)

Variable	Odds ratio	95% CI lower limit	95% CI upper limit	P value
Previous ABD surgery: yes versus no	1.528	0.28	8.33	0.6243
Previous chemo: yes versus no	0.881	0.186	4.174	0.8734
Previous ABD RT: yes versus no	-	-	-	-

ABD abdominal

Table 5

Bivariate logistic regression model for NBI-identified lesion: yes versus no ($N=94$; patient-level analysis)
(odds ratio modeled for lesion identified)

Variable	Odds ratio	95% CI lower limit	95% CI upper limit	<i>P</i> value
Previous ABD surgery: yes versus no	3.239	1.257	8.344	0.015
Previous chemo: yes versus no	1.057	0.445	2.509	0.901

ABD abdominal