The role of Sentinel Lymph Node Biopsy in High Risk Endometrial Cancer

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Faculty Disclosure

X	No, nothing to disclose
	Yes, please specify:

	Honoraria/ Expenses	Consulting/ Advisory Board	Funded Research	Royalties/ Patent	Stock Options	Ownership / Equity Position	Employee	Other (please specify)

Off-Label Product Use

Will you be presenting or referencing off-label or investigational use of a therapeutic product?	
X	No
	Yes, please specify:

SLN in Endometrial Cancer

- History
- Current state of play
- Oncological outcomes
- Future study

Burden of Disease

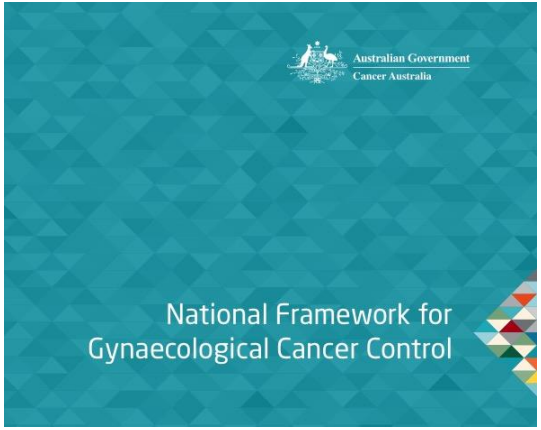
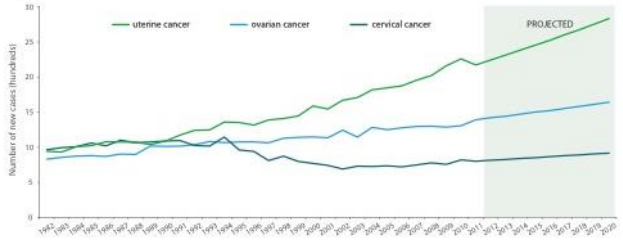


Figure 2-1 – Trends in number of new cases of uterine, ovarian and cervical cancers, Australia, 1982-2020

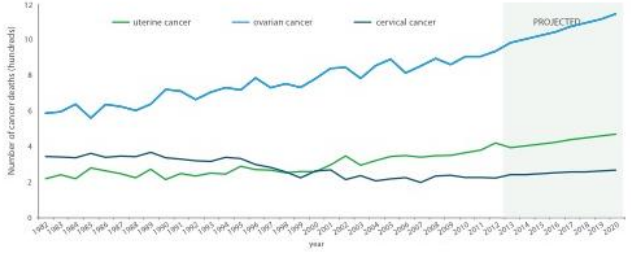


Source: Australian Institute of Health and Welfare. Australian Cancer Incidence and Mortality (ACIM) books. Canberra: AIHW. http://www.aihw.gov.au/acim-books. Accessed: July 2015; and Australian Institute of Health and Welfare & Cancer Australia. 2012. Gynaecological cancers in Australia: an overview. Cancer series no. 70. Cat. no. CAN 66. Canberra: AIHW.

Impact

Gynaecological cancer incidence, in particular uterine cancer, is projected to increase. There will be a resulting increase in demand for services along the gynaecological cancer control continuum, especially treatment and supportive care.

Figure 2-2 – Trends in number of cancer deaths due to uterine, ovarian and cervical cancers, Australia, 1982-2020



Source: Australian Institute of Health and Welfare. Australian Cancer Incidence and Mortality (ACIM) books. Canberra: AIHW. http://www.aihw.gov.au/acim-books. Accessed: July 2015; Australian Institute of Health and Welfare. 2014. Cancer in Australia: an overview 2014. Cancer series No 90. Cat. no. CAN 88. Canberra: AIHW; and Australian Institute of Health and Welfare. National Mortality Database. Cancer mortality projections: 2013 to 2025. http://www.aihw.gov.au/cancer/mortality-trends-projections. Accessed: August 2015.

Endometrial cancer staging

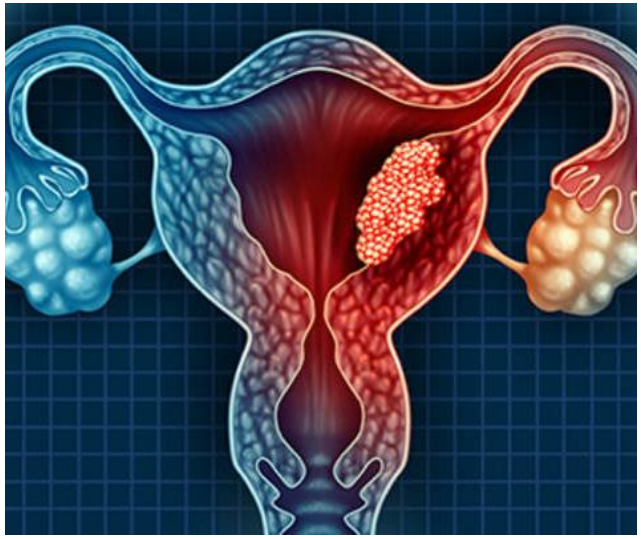


Table 1: 2009 FIGO staging system for carcinoma of the endometrium

Stage I[a]	Tumor contained to the corpus uteri		
	IA	No or less than half myometrial invasion	
	IB	Invasion equal to or more than half of the myometrium	
Stage II		Tumor invades the cervical stroma but does not extend beyond the uterus[b]	
Stage III[a]		Local and/or regional spread of tumor[c]	
	IIIA	Tumor invades the serosa of the corpus uteri and/or adnexas	
	IIIB	Vaginal and/or parametrial involvement	
	IIIC	Metastases to pelvis and/or para-aortic lymph nodes	
		IIIC1	Positive pelvic nodes
		IIIC2	Positive para-aortic lymph nodes with or without positive pelvic lymph nodes
Stage IV[a]		Tumor invades bladder and/or bowel mucosa and/or distant metastases	
	IVA	Tumor invasion of bladder and/or bowel mucosa	
	IVB	Disant metastases, including intra-abdominal metastases and or inguinal lymph nodes	

FIGO = International Federation of Gynecology and Obstetrics
[a] Includes grades 1, 2, or 3
[b] Endocervical glandular involvement only should be considered as stage I and no longer as stage II.
[c] Positive cytology has to be reported separately without changing the stage.

Endometrial Cancer Treatment

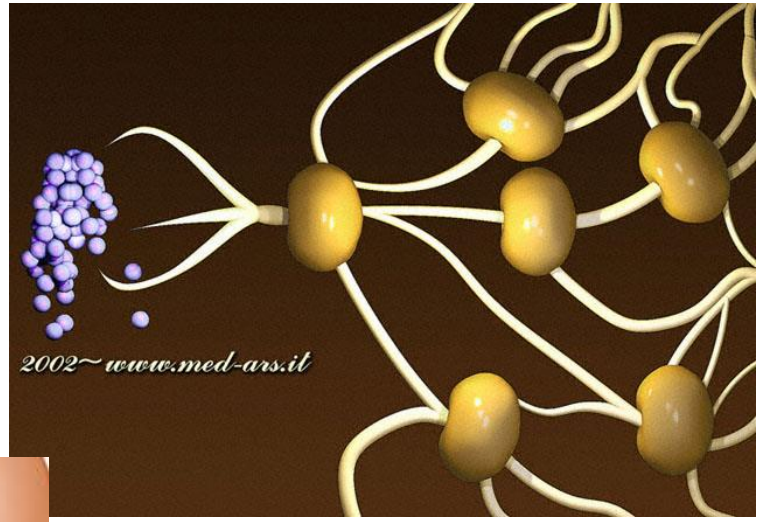
- Cochrane review & 2 Randomised Studies: ASTEC & Panici

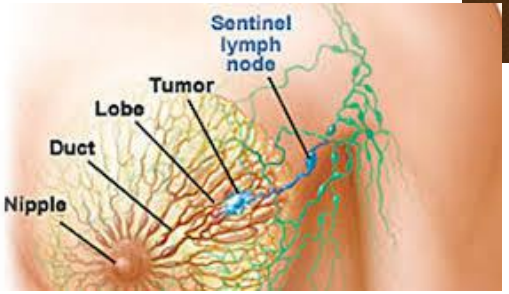
  - The high prevalence of low risk disease means low prevalence of lymph node disease
  - Pelvic LAN alone will miss isolated Para-aortic disease quoted as 3 to 5%
  - There was no difference in the use of radiotherapy in both arms
  - The average number of nodes removed was low – therefore was LAN inadequate in patients who had it?

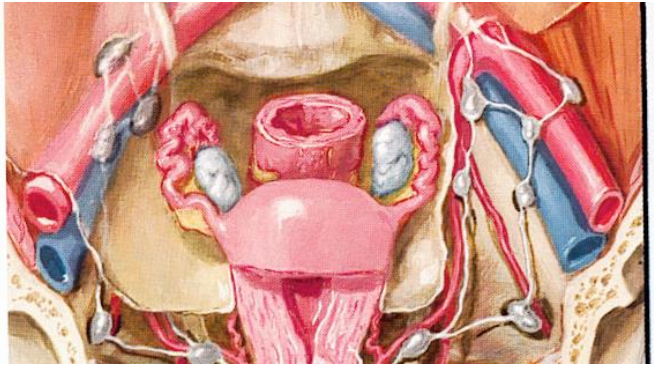
An alternative to lymphadenectomy Rationale for Sentinel Lymph Node

- Nodal status is highly prognostic
- Nodal status allows tailoring or avoidance of adjuvant therapy

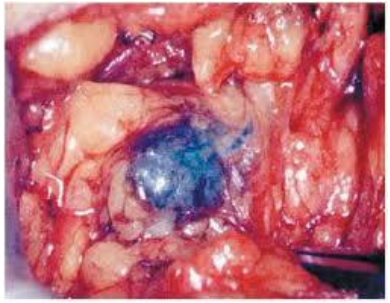
Principle of SLN Mapping







Burke 1996 MSK ➔



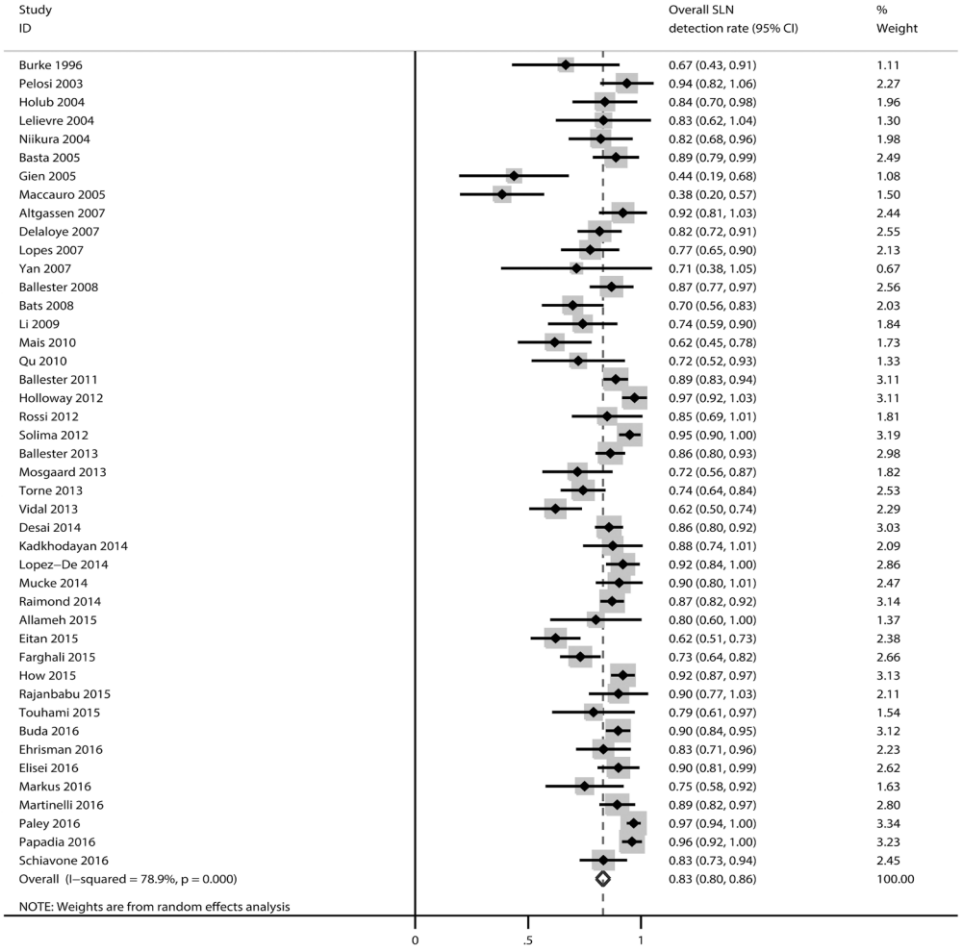
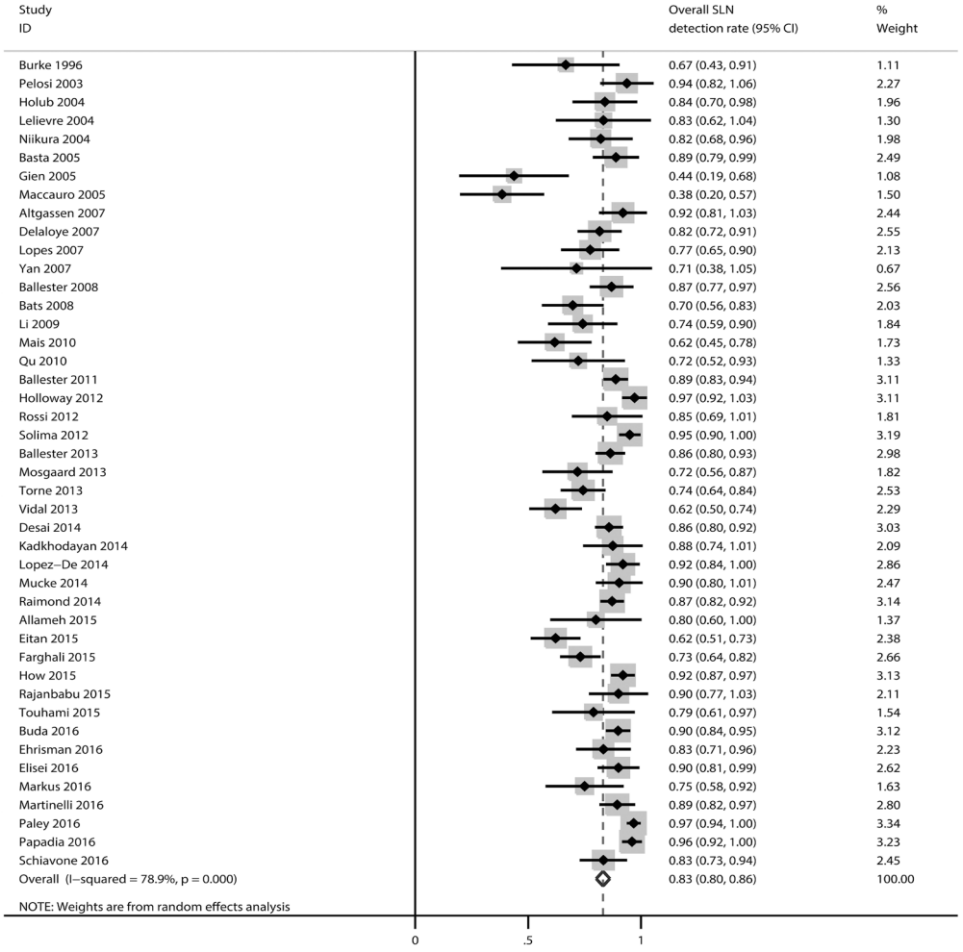


Figure 4: Forest plot of pooled overall detection rate and 95% CI in SLN mapping in endometrial cancer.

Burke 1996 MSK ➔

Prague 2010 ➔

IGCS



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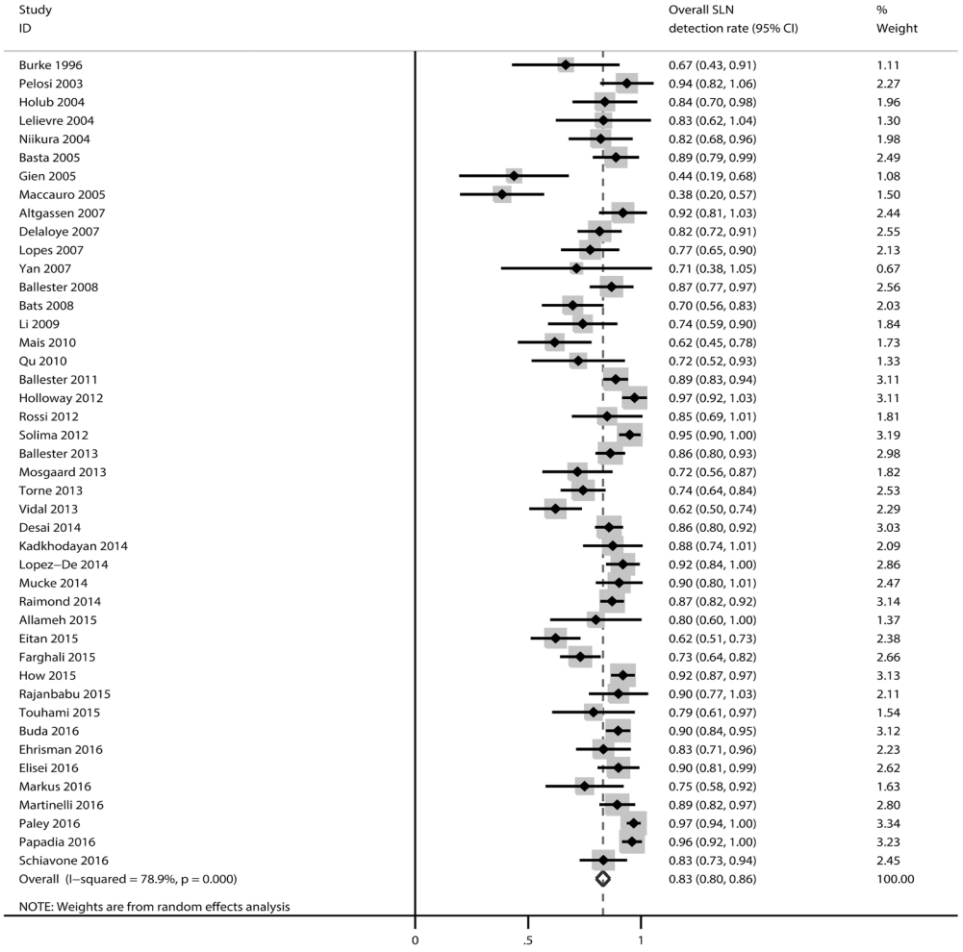
Burke 1996 MSK ➔

RWH Melbourne 2015 ➔



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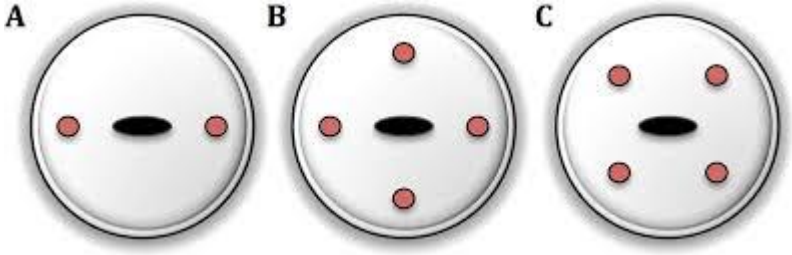
NCCN Endometrial Cancer Guidelines: Version 3-2019

Principles of Sentinel Lymph Node(s) Mapping for Endometrial Cancer Staging10-26

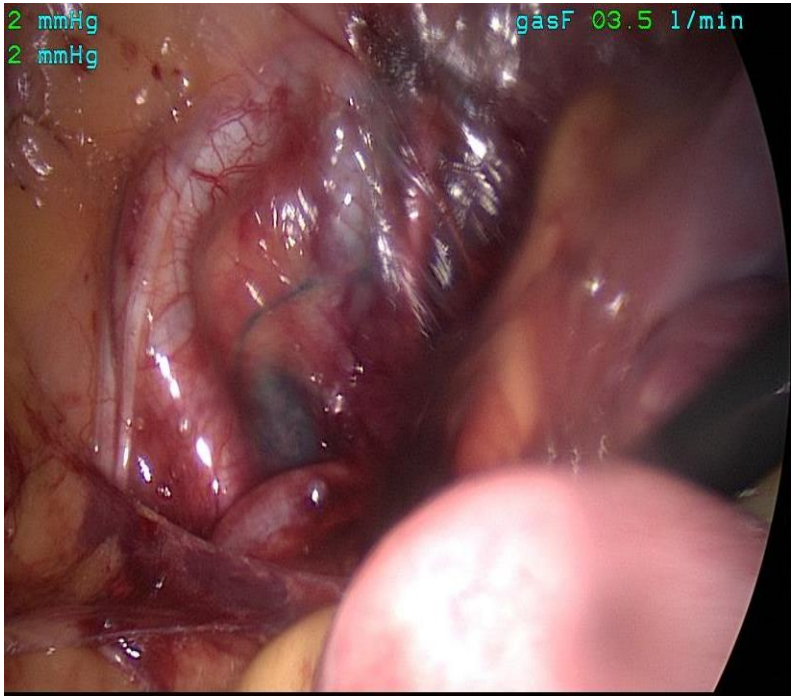
- **Prospective and retrospective studies demonstrate that compared to systemic lymphadenectomy, SLN mapping with ultrastaging may increase the detection of lymph node metastasis with low false-negative rates in women with apparent uterine-confined disease.**
- **If SLN mapping is considered, the expertise of the surgeon and attention to technical detail is critical.**
- **Recent evidence indicates that sentinel node mapping may also be used in high-risk histologies (serous carcinoma, clear cell carcinoma, carcinosarcoma).24,25**
- **SLN mapping can be considered for the surgical staging of apparent uterine-confined malignancy when there is no metastasis demonstrated by imaging studies or no obvious extrauterine disease at exploration.**

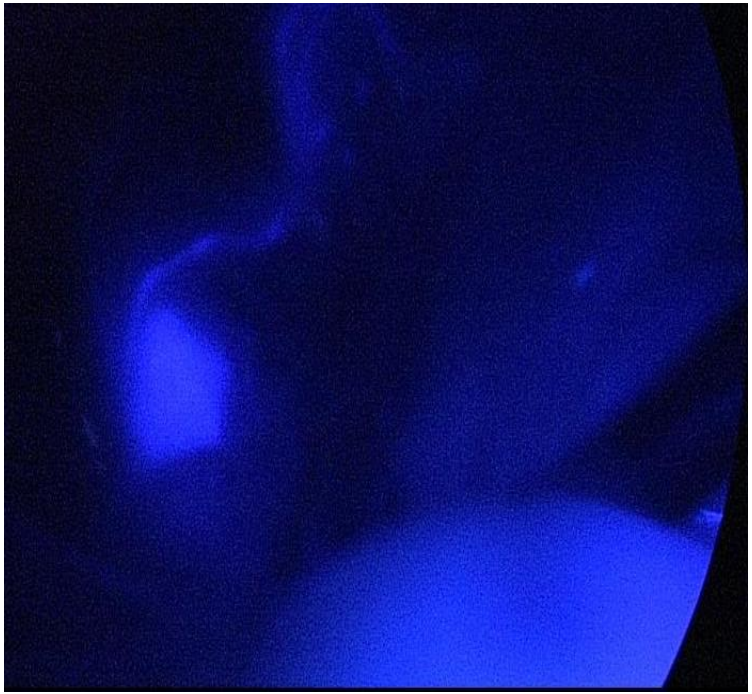
NCCN Endometrial Cancer Guidelines:

- **A cervical injection with dye has emerged as a useful and validated technique for identification of lymph nodes that are at high risk for metastases (ie, SLN in patients with early-stage endometrial cancer**
- **Superficial (1–3 mm) and optional deep (1–2 cm) cervical injection leads to dye delivery to the main layers of lymphatic channel origins in the cervix and corpus, namely the superficial subserosal, intermediate stromal, and deep submucosal lymphatic sites of origin**
- **Injection into the uterine cervix provides excellent dye penetration to the region of the uterine vessels and main uterine lymphatic trunks that condense in the parametria and appear in the broad ligament leading to pelvic and occasionally paraaortic sentinel nodes.**



Cervical vs Fundal injection

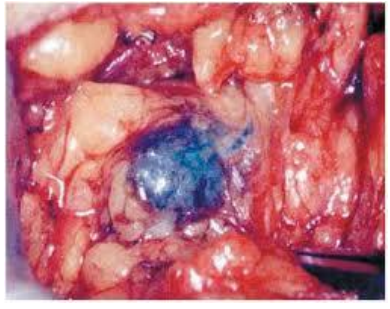


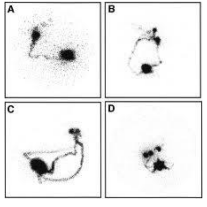


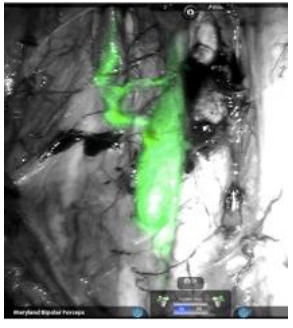
NCCN Endometrial Cancer Guidelines:

- **The radiolabeled colloid most commonly injected into the cervix is technetium-99m (99mTc); colored dyes are available in a variety of forms (Isosulfan Blue 1% and Methylene Blue 1%, Patent Blue 2.5% sodium).**

- **Indocyanine green (ICG) recently emerged as a useful imaging dye that requires near-infrared camera for localization, provides a very high SLN detection rate, and is**



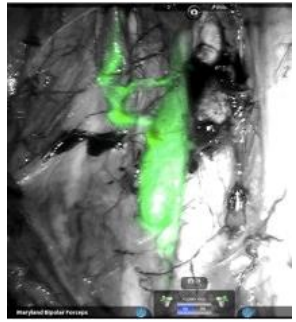


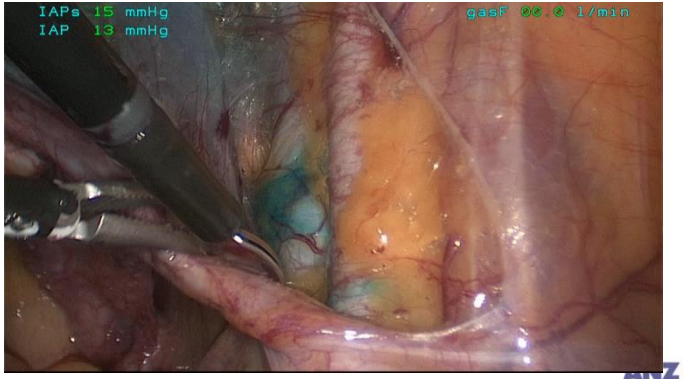


NCCN Endometrial Cancer Guidelines:

- **The uterine body lymphatic trunks commonly cross over the obliterated umbilical artery with the most common location of pelvic SLN being medial to the external iliac, ventral to the hypogastric, or in the superior part of the obturator region**

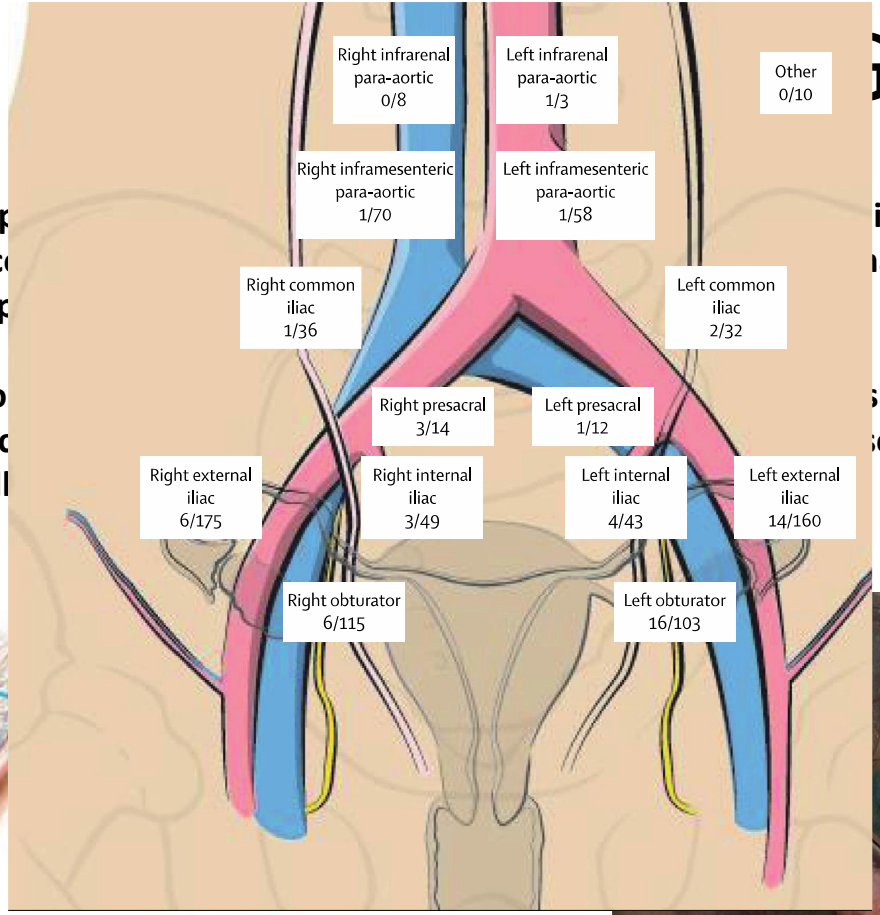
- **A less common location is usually seen when the lymphatic trunks do not cross over the obliterated umbilical and move cephalad following the mesoureter; in these cases, the SLN is usually seen in the common iliac presacral region**

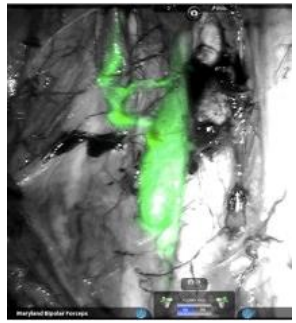


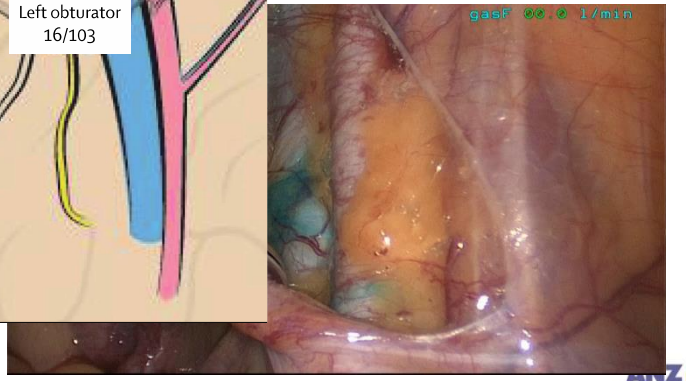


NCCN E Guidelines:

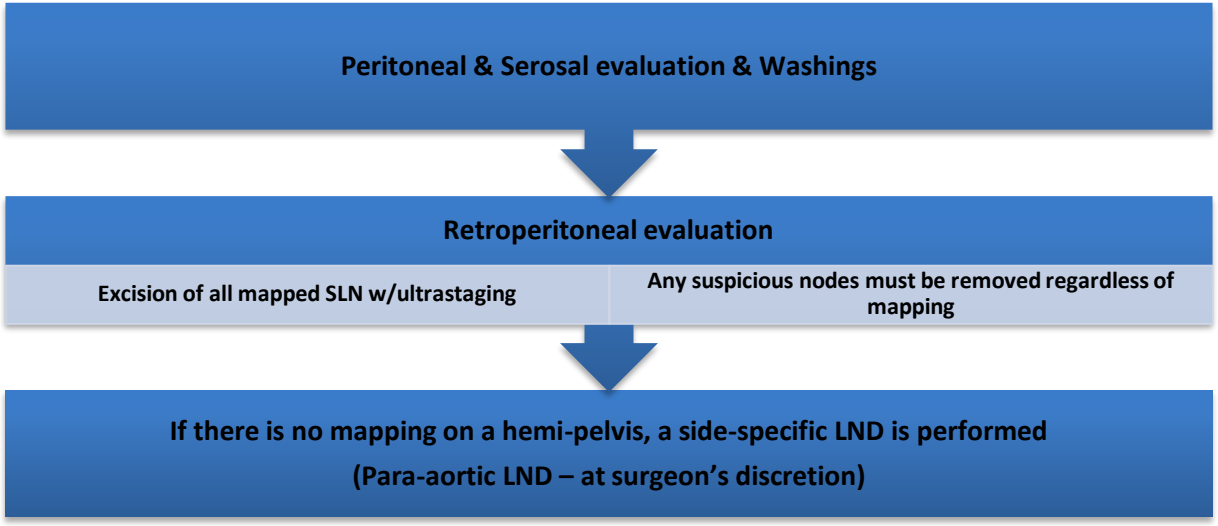
- The uterine body lymp ical artery with the most c al iliac, ventral to the hyp
- A less common locatio s over the obliterated umbilic e cases, the SLN is usuall



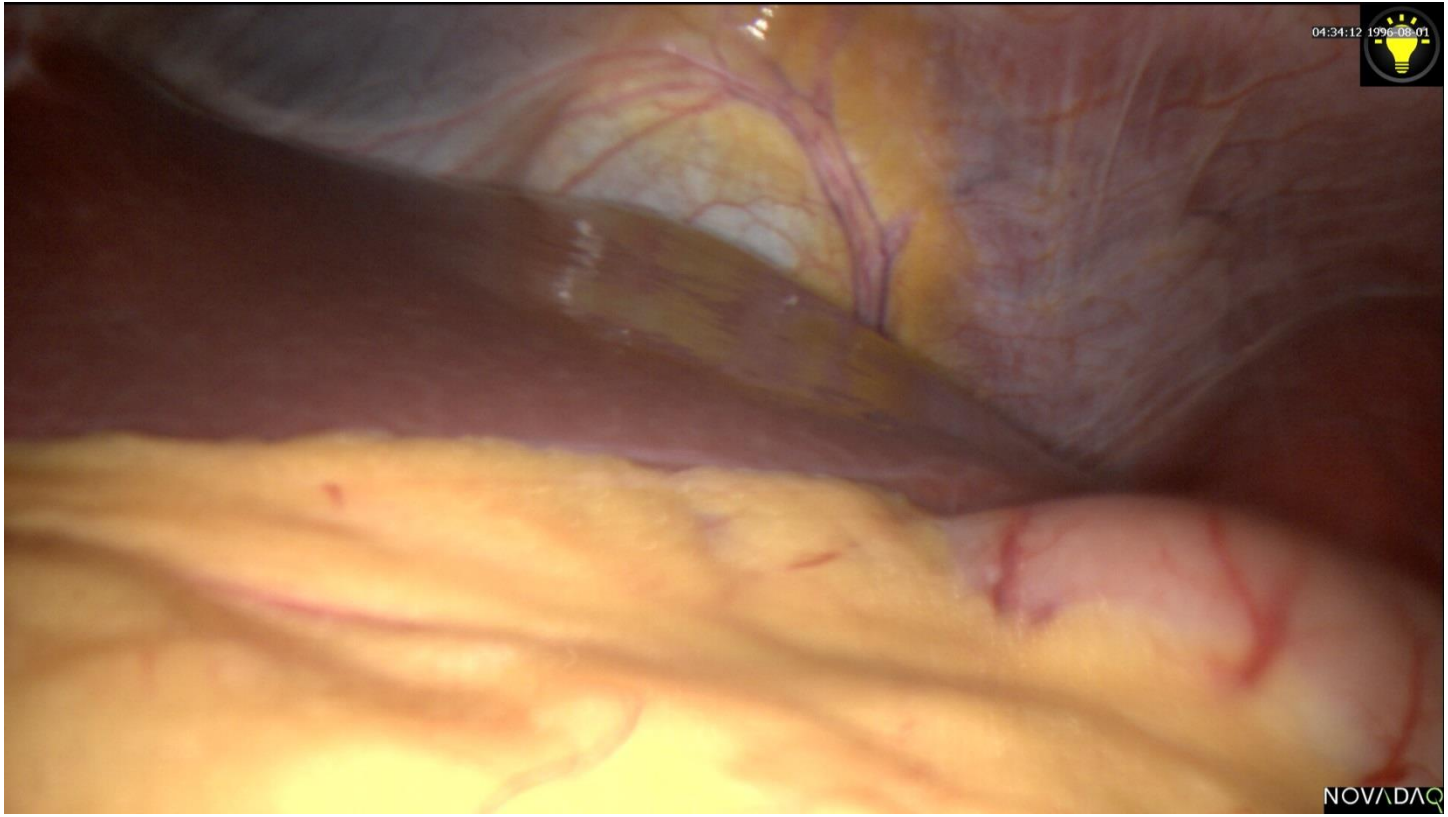




MSK Sentinel Lymph Node Surgical algorithm



Barlin J et al, GynOnc 2012; 125:531-35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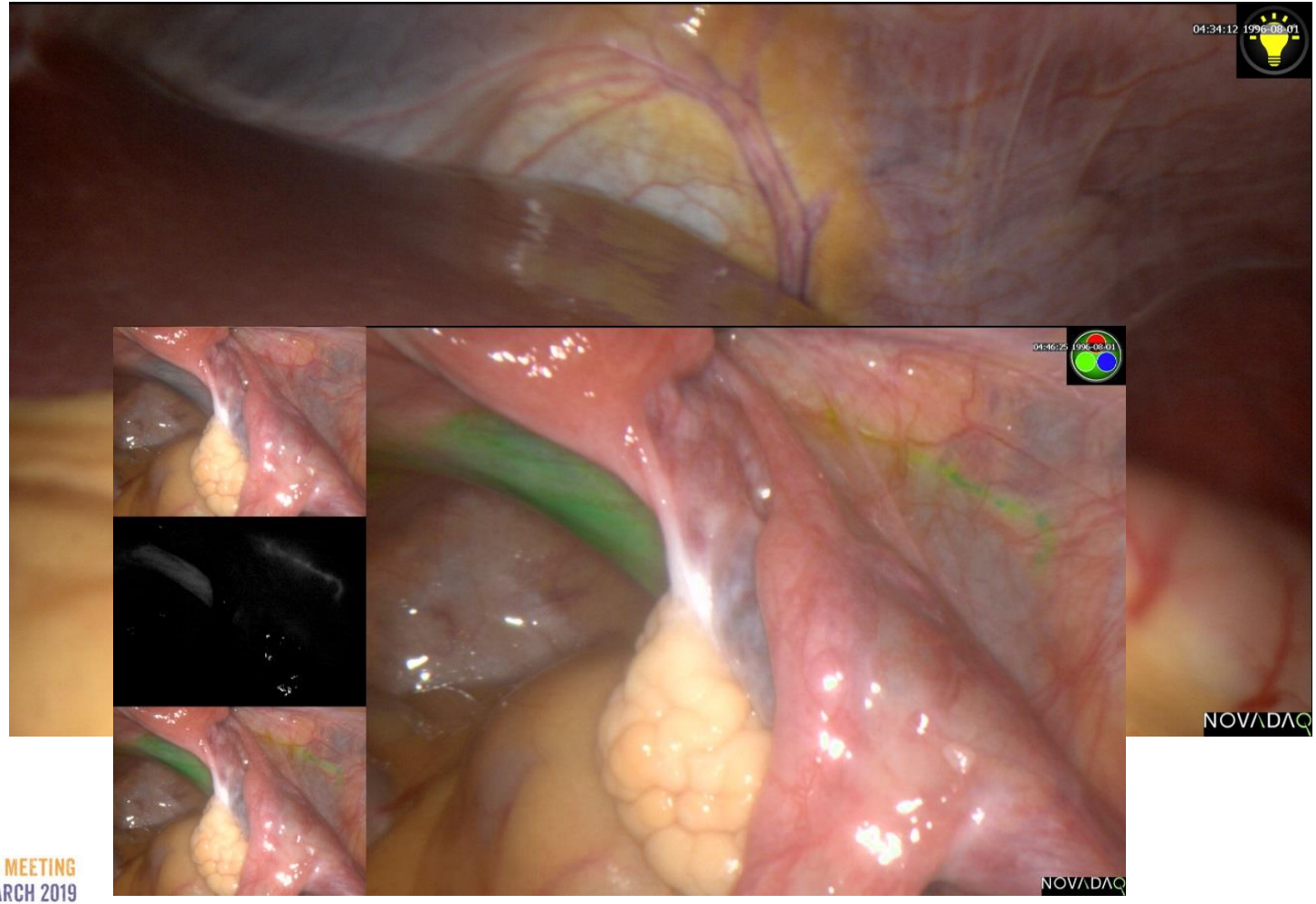
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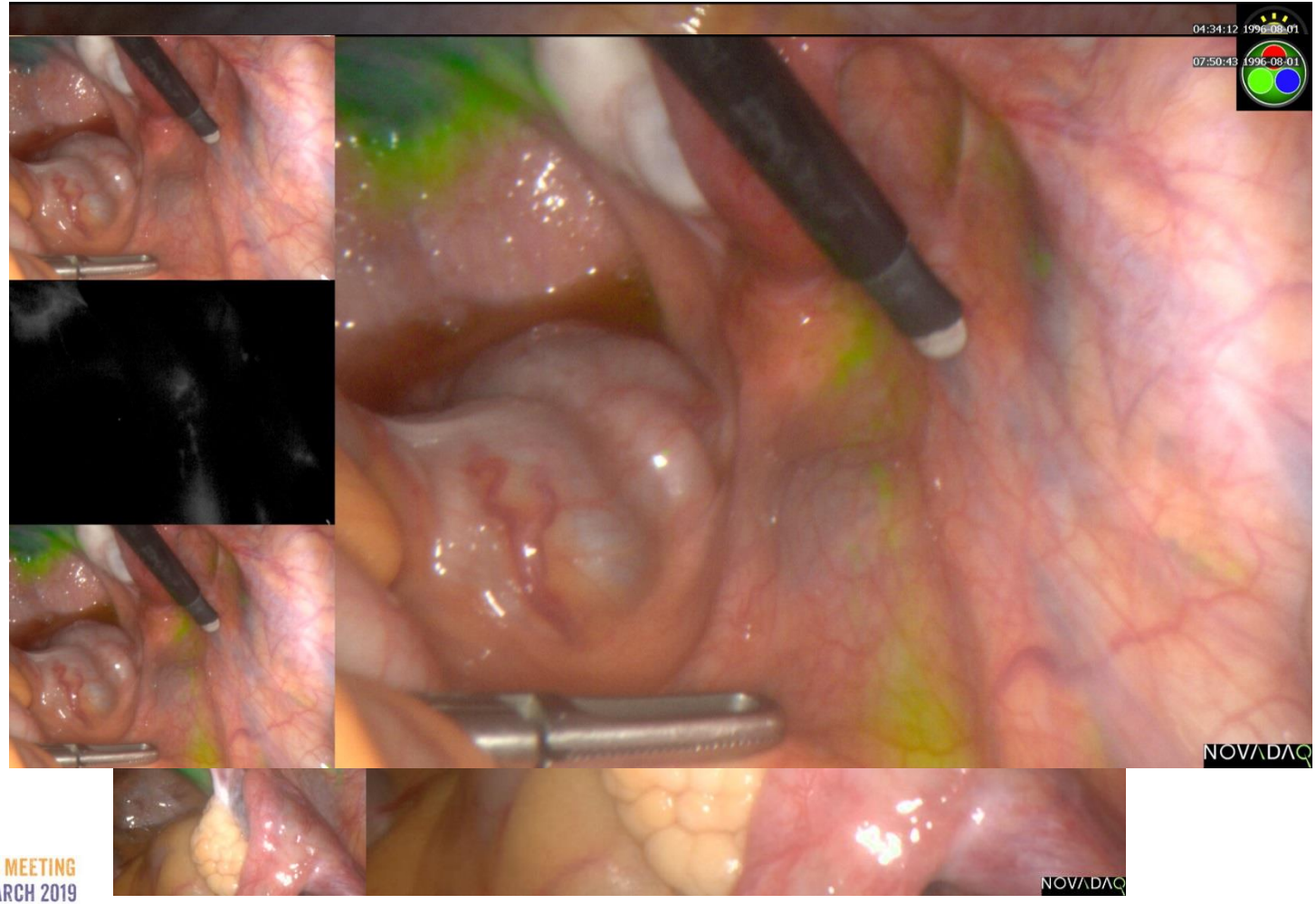
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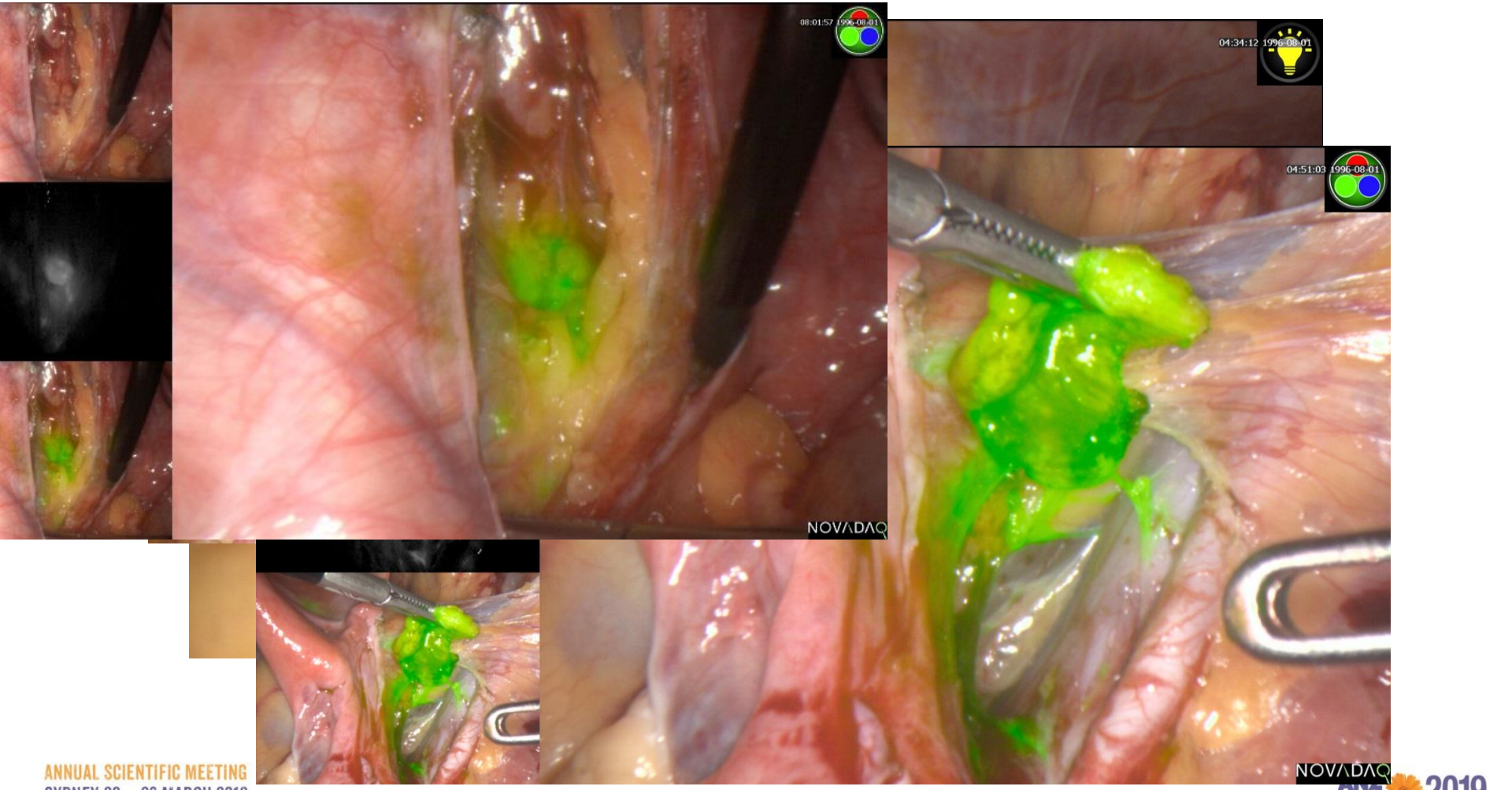
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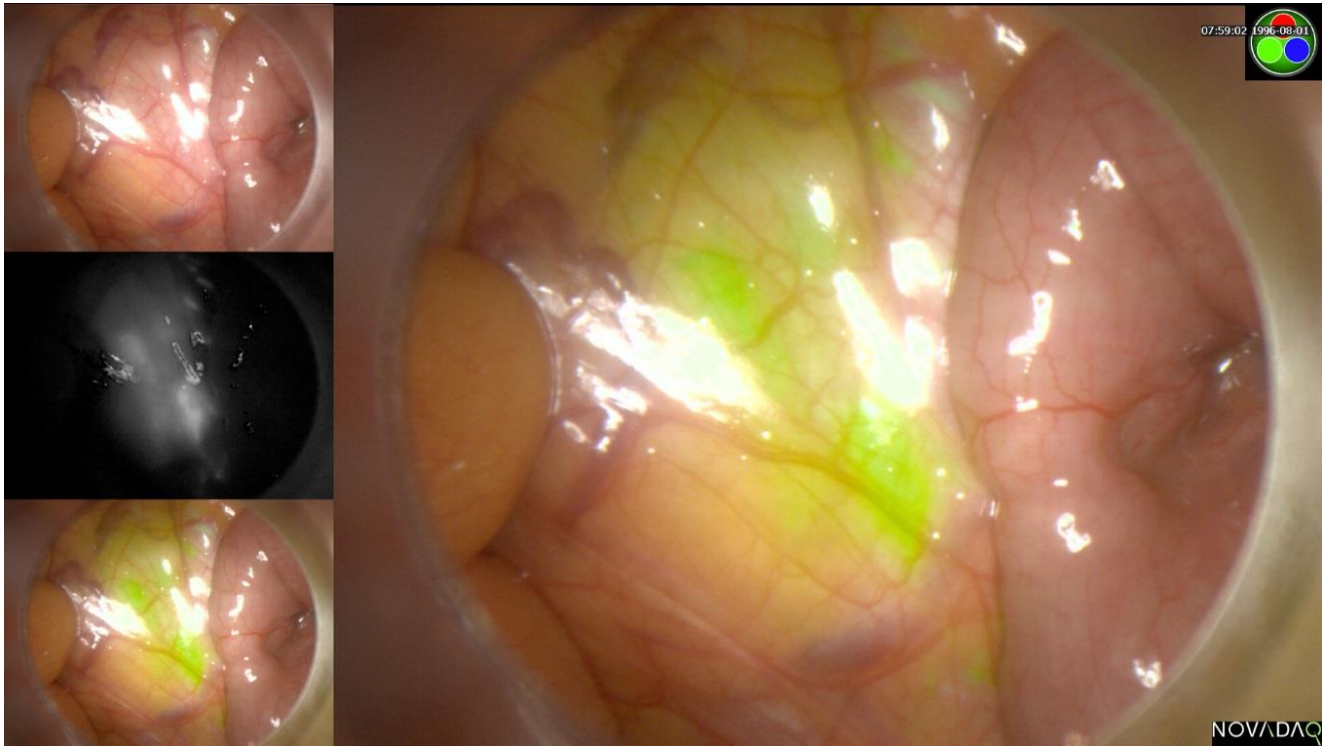
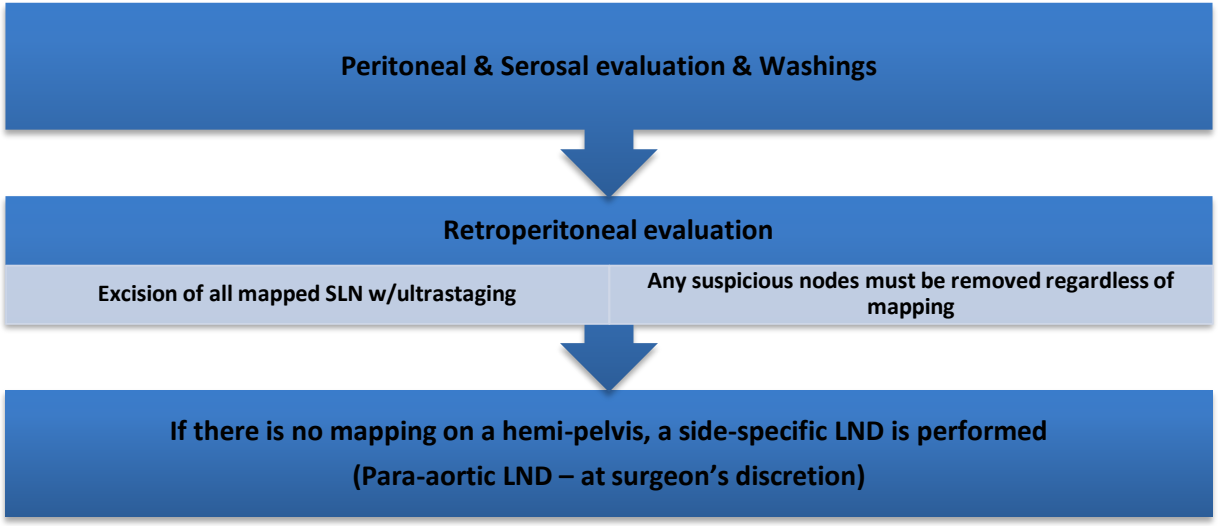
Para-aortic area….



MSK Sentinel Lymph Node Surgical algorithm



Barlin J et al, GynOnc 2012; 125:531-35

MSK Sentinel Lymph Node Surgical algorithm

	MSK 2012 N= 498
Detection rate: >/= 1 SN • Unilateral pelvic • Bilateral pelvic • Para-aortic only	81% 30% 51% 0.5%
Sensitivity	85.1%
False negative rate	14.9%
Negative predictive value	98.1%

Barlin et al, Gyn Onc 2012; 125;531-535

MSK Sentinel Lymph Node Surgical algorithm.

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False negative rate	1.9%	14.9%
Negative predictive value	99.8%	98.1%

Barlin et al, Gyn Onc 2012; 125;531-535

Oncological Outcomes…

A comparison of sentinel lymph node biopsy to lymphadenectomy for endometrial cancer staging (FIRES trial): a multicentre, prospective, cohort study

Emma C Rossi, Lynn D Kowalski, Jennifer Scalici, Leigh Cantrell, Kevin Schuler, Rabbie K Hanna, Michael Method, Melissa Ade, Anastasia Ivanova, John F Boggess

	Patients
Final pathology (postoperative grade) (n=356)*	
Endometrioid grade	292 (82%)
Grade 1	152 (43%)
Grade 2	102 (29%)
Grade 3	38 (11%)
Serous	41 (12%)
Carcinosarcoma	13 (4%)
Clear cell	6 (2%)
Other	4 (1%)
Postoperative stage (n=344)†	
IA	228 (66%)
IB	47 (14%)
II	15 (4%)
IIIA	10 (3%)
IIIB	0
IIIC	41 (12%)
IV	3 (1%)

Data are n (%). *Patients who received complete study intervention (injection of dye, attempted sentinel-lymph-node mapping, and complete surgical staging) †Patients who received complete study intervention (injection of dye, attempted sentinel lymph node mapping, and lymphadenectomy).

Table 1: **Clinical-pathological features**

	Patients (n=340)
Pelvic lymphadenectomy	340 (100%)
Pelvic and para-aortic lymphadenectomy	196 (58%)
Successful mapping of sentinel lymph nodes	293 (86%)
Bilateral mapping	177 (52%)
Para-aortic sentinel lymph node detected	81 (23%)
Isolated para-aortic sentinel lymph node detected	3 (<1%)
Median number of sentinel lymph nodes removed	2 (0–20)
Mean number of total nodes removed	19 (10·3; 1–61)

Data are n (%), median (range), or mean (SD; range).

Table 2: **Surgical results in patients who had pelvic lymphadenectomy**

	Node negative (n=269)	Node positive (n=40)
Tumour size		
<2 cm	86 (32%)	3 (8%)
≥2 cm	183 (68%)	37 (92%)
Grade		
1 or 2	199 (74%)	20 (50%)
3	30 (11%)	6 (15%)
Non-endometrioid	40 (15%)	14 (35%)
Lymphovascular space invasion		
Absent	225 (84%)	15 (38%)
Present	44 (16%)	35 (62%)
Myometrial invasion		
None	96 (36%)	1 (3%)
<50%	120 (44%)	16 (40%)
≥50%	53 (20%)	23 (57%)
Lower uterine segment involvement		
Absent	181 (67%)	19 (48%)
Present	88 (33%)	21 (52%)
Age (years)		
<50	25 (9%)	3 (8%)
50–69	183 (68%)	25 (63%)
≥70	61 (23%)	12 (29%)

Data are n (%). Includes 309 patients who had lymphadenectomies and in whom complete pathological risk-factor data were available.

Table 4: **Risk factors for lymphatic metastasis**

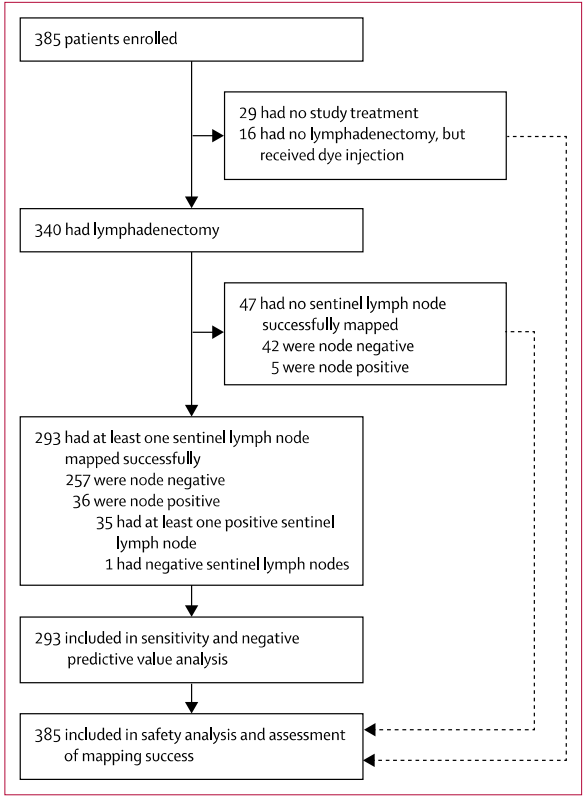

Figure 1: **Trial profile**
Assessment of mapping=a surgeon assessing the proportion of patients who mapped at least one sentinal lymph node, and whether the sentinal lymph nodes were found bilaterally.

FIRES Trial

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Endometrioid grade	292 (82%)
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- Median age 63 yrs (29-83)
- Median BMI 33.4 kg/m2 (18-60)

- 9% adverse events
- One ureteral injury

Rossi *et al*, Lancet Oncol, 2017, 18:384

Oncological Outcomes: FIRES

- N= 344 *(High grade disease=100)*
- SLN followed by LAN
- 19 surgeons, 10 institutions
- Sensitivity – 97.2%, NPV = 99.7%
  - 41 had nodal mets: 36 mapped nodes with the metastasis in the SLN in 35
- Isolated PA nodes with negative SLN in 3 (<1%)

Rossi EC , Kowalski LD , Scalici J , Cantrell L , Schuler K , Hanna RK , et al. A comparison of sentinel lymph node biopsy to lymphadenectomy for endometrial cancer staging (FIRES trial): A multicentre, prospective, cohort study. Lancet Oncol. 2017;18:384–392.28159465

SENTI-ENDO

- France *Ballester M, Lancet Oncol 2011*
- Multicentre - 9
- Prospective
- Overall Detection rate 89% (Para-aortic 5%
- Sensitivity 84%/NPV 97%
- 3 false positives – 2 in contralateral pelvis can 1 in PA node
- 50 month RFS 84% - SLN=LAN *Darai E et al, Gyn On 2015*

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Oncological Outcomes: N= 1,100

- LAN = 493
- 43%
- Pelvic nodes removed 58%
- PA nodes removed

	Mayo	MSK	P value
Any node			
Pelvic nodes	58%	93%	<0.001
Para-aortic nodes	50%	14.5%	<0.001
Metastases (including Micro & ITCs	5.1% 1.0%	2.6% 0.8%	P=0.03 P=0.75
DFS 3 years	94.9%	96.8%	95% CI

Zahl Eriksson AG, Ducie J, Ali N, McGree ME, Weaver AL, Bogani G, et al. Comparison of a sentinel lymph node and a selective lymphadenectomy algorithm in patients with endometrioid endometrial carcinoma and limited myometrial invasion. Gynecol Oncol 2016;140:394-9

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Metastases (including Micro & ITCs	5.1% 1.0%	2.6% 0.8%	P=0.03 P=0.75
DFS 3 years	94.9%	96.8%	95% CI

Zahl Eriksson AG, Ducie J, Ali N, McGree ME, Weaver AL, Bogani G, et al. Comparison of a sentinel lymph node and a selective lymphadenectomy algorithm in patients with endometrioid endometrial carcinoma and limited myometrial invasion. Gynecol Oncol 2016;140:394-9

GOG-33: Risk of LN involvement

PELVIC NODES	Grade 1	Grade 2	Grade 3
Endometrium only	0%	3%	0%
Inner 1/3	3%	5%	9%
Middle 1/3	0%	9%	4%
Outer 1/3	11%	19%	34%
PARA-AORTIC NODES	**Grade 1**	**Grade 2**	**Grade 3**
Endometrium only	0%	3%	0%
Inner 1/3	1%	4%	4%
Middle 1/3	5%	0%	0%
Outer 1/3	6%	14%	23%

Creasman et al Cancer 60, 2035, 1987.

NCCN Endometrial Cancer Guidelines: Version 3-2019

Principles of Sentinel Lymph Node(s) Mapping for Endometrial Cancer Staging10-26

- **Prospective and retrospective studies demonstrate that compared to systemic lymphadenectomy, SLN mapping with ultrastaging may increase the detection of lymph node metastasis with low false-negative rates in women with apparent uterine-con ned disease.**
- **If SLN mapping is considered, the expertise of the surgeon and attention to technical detail is critical.**
- **Recent evidence indicates that sentinel node mapping may also be used in high-risk histologies (serous carcinoma, clear cell carcinoma, carcinosarcoma).24,25**
- **SLN mapping can be considered for the surgical staging of apparent uterine-confined malignancy when there is no metastasis demonstrated by imaging studies or no obvious extrauterine disease at exploration.**

	Soliman 2017 MDA	Schiavone 2017 MSK	Schiavone 2017 MSK	LePlante 2017 Canada	Rossi 2017 FIRES	Buda 2018 Italy
N	123, SLN & LAN	248 • 153 SLN • 95 LAN	136 • 48 SLN • 88 LAN	128 • SLN & LAN	100/344 • SLN & LAN	266 • 61 SLN • 139 LAN
Histology	G3, Serous, Clear, CCO Cx involve. G1&2	Serous	CCO	G3, Serous, Clear, CCO, Undifferentiated	G3, Serous, Clear, CCO, Undifferentiated	HI and HR
Design	Prospective	Retrospective	"Prospective"	Retrospective	Prospective cohort Multi-instutional	Retrospective 2 institutions
Detection rate: >/= 1 SN Unilateral pelvic Bilateral pelvic Para-aortic only	 55% 40% 2%	124 of 153 Overall = 81% 66% 34%	40 of 48 Overall 83% 15% 85%	115 of 128 Overall = 90% 90% 63% (5% ?not isolated)	Overall = 86% 52% <1%	 77%
Node number SLN LAN	2 (1-9)	12 (0-15) 21 (1-75)	8 (1-55) 19.5 (1-50)	2.2 (0-7) 17.3 (3-76)	2 (0-20) 19 (1-61)	2(0-4) 20(2-74)
Sensitivity	95%	-	-	95.8%	97.2%	SLN>LAN
Negative predictive value	98.6%	-	-	98.2%	99.6%	SLN>LAN
PFS ***median 40 months**	**N/A**	**SLN = 77%*** **LAN = 71%***	**SLN = 38.7%** **LAN = 47.6%**	**N/A**	**N/A**	**SLN = LAN**

	Soliman 2017 MDA	Schiavone 2017 MSK	Schiavone 2017 MSK	LePlante 2017 Canada	Rossi 2017 FIRES	Buda 2018 Italy
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Sensitivity	95%	-	-	95.8%	97.2%	SLN>LAN
False negative rate	5%	-	-			
PFS *median 40 months	N/A	SLN = 77%* LAN = 71%*	SLN = 38.7% LAN = 47.6%	N/A	N/A	SLN = LAN

SLN vs LAN in the detection of Stage111C Endometrial Cancer

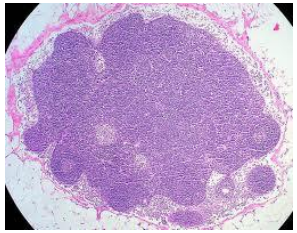
- MSK & Mayo
- SLN algorithm: LAN
- N – 412
- Endometrioid >50% invasion, USPC, Clear cell,

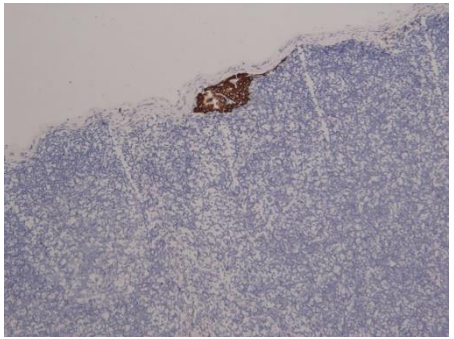
	SLN	LAN	P value
Lymphatic disease			
Intermediate risk Overall Para-aortic	 35.4% 10.7%	 28.0% 20.8%	 N/S N/S
High risk Overall Para-aortic	 21.7% 17.9%	 19.4% 15.9%	 N/S N/S

Defining lymphatic disease

- NCCN Endometrial Cancer Guidelines: Pathology

• Low-volume nodal metastasis to SLN detected only by enhanced pathologic ultrastaging is another potential value to staging with SLN.





NCCN Endometrial Cancer Guidelines: Pathology

• Low-volume nodal metastasis to SLN detected only by enhanced pathologic ultrastaging is another potential value to staging with SLN.

- (Macrometasis – tumour cells in clusters of >2mm)
- Micrometasis – microscopic clusters and single cells measuring > 0.2mm to </= 2mm
- Isolated tumour cells – microscopic clusters and single cells measuring </= 0.2mm***. (NCCN guidelines advise that these should be noted but designated pN0(i+)***

NCCN Endometrial Cancer Guidelines: Pathology

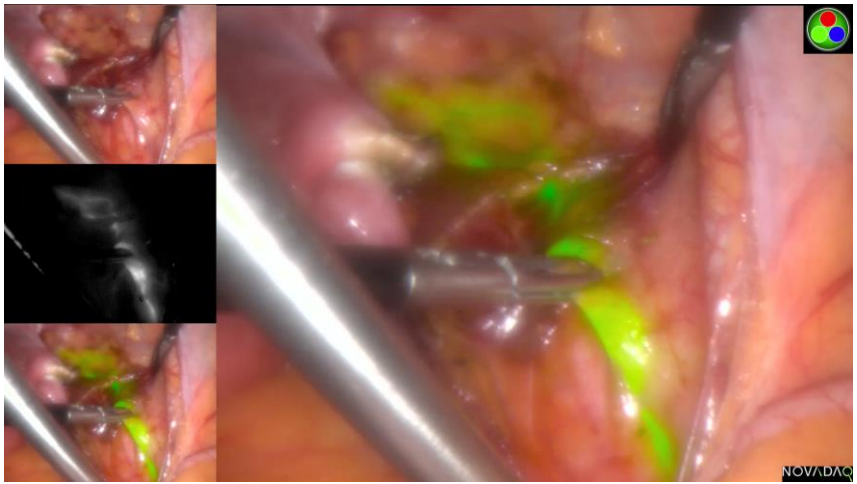
- **Low-volume nodal metastasis to SLN detected only by enhanced pathologic ultrastaging is another potential value to staging with SLN.**

N	Macro	Micro	ITC	Neg
519	43	11	31	434
Nodal mets	51%	13%	36%	0
PFS	58.5%	85.5%	95.5%	87.6%

Plante M et al Gynecol Oncol 2017;146:240-6.

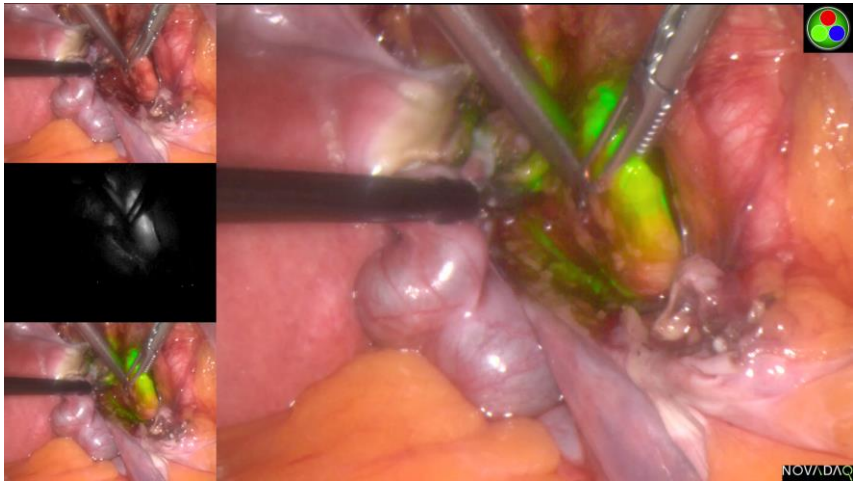
Conclusion….

- There is role for SLN mapping in Endometrial Cancer
- Learning curve, time….
- Strict adherence to the Surgical Algorithm
- NCCN guidelines



Ongoing concerns…..

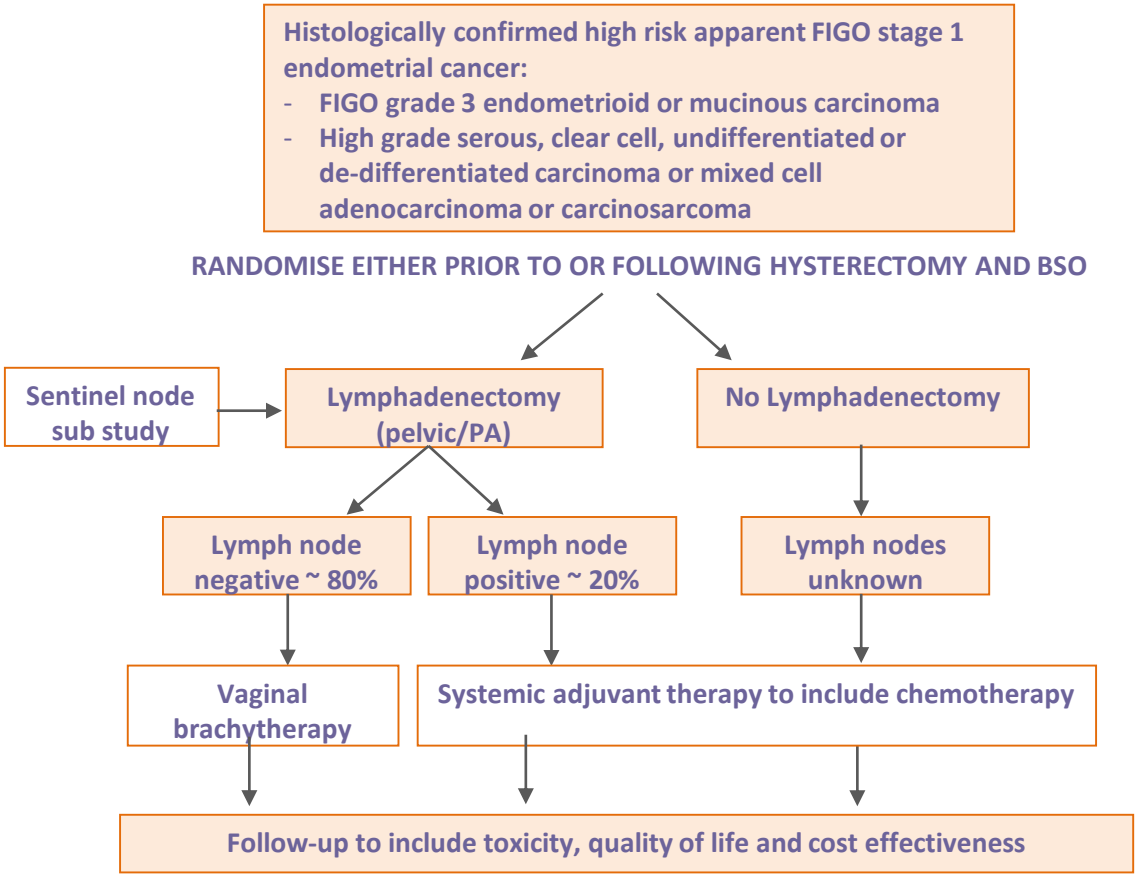
- “Real world” – large variation in practice
- Para-aortic nodal disease
- Audit practice:
  - Has patient been adequate staged?
  - SLN pathological protocol
    - “contains fat!”
    - Fragmented nodes
    - Isolated tumour cells
  - MSK algorithm applied
  - Has adjuvant treatment rate changed?
  - Morbidity



On the horizon…..

- **STATEC Study:** A randomised trial of non-**S**elective versus selective adjuvant **T**herapy in high risk **A**pparent s**T**age 1 **E**ndometrial **C**ancer
- **SeLECT:** Sentinel lymph node in endometrial cancer trial.
- ANZGOG: SLN Registry study
- Molecular classification: ProMise

STATEC


Histologically confirmed high risk apparent FIGO stage 1 endometrial cancer:
- FIGO grade 3 endometrioid or mucinous carcinoma
- High grade serous, clear cell, undifferentiated or de-differentiated carcinoma or mixed cell adenocarcinoma or carcinosarcoma
RANDOMISE EITHER PRIOR TO OR FOLLOWING HYSTERECTOMY AND BSO
Sentinel node sub study
Lymphadenectomy (pelvic/PA)
No Lymphadenectomy
Lymph node negative ~ 80%
Lymph node positive ~ 20%
Lymph nodes unknown
Vaginal brachytherapy
Systemic adjuvant therapy to include chemotherapy
Follow-up to include toxicity, quality of life and cost effectiveness

On the horizon…..

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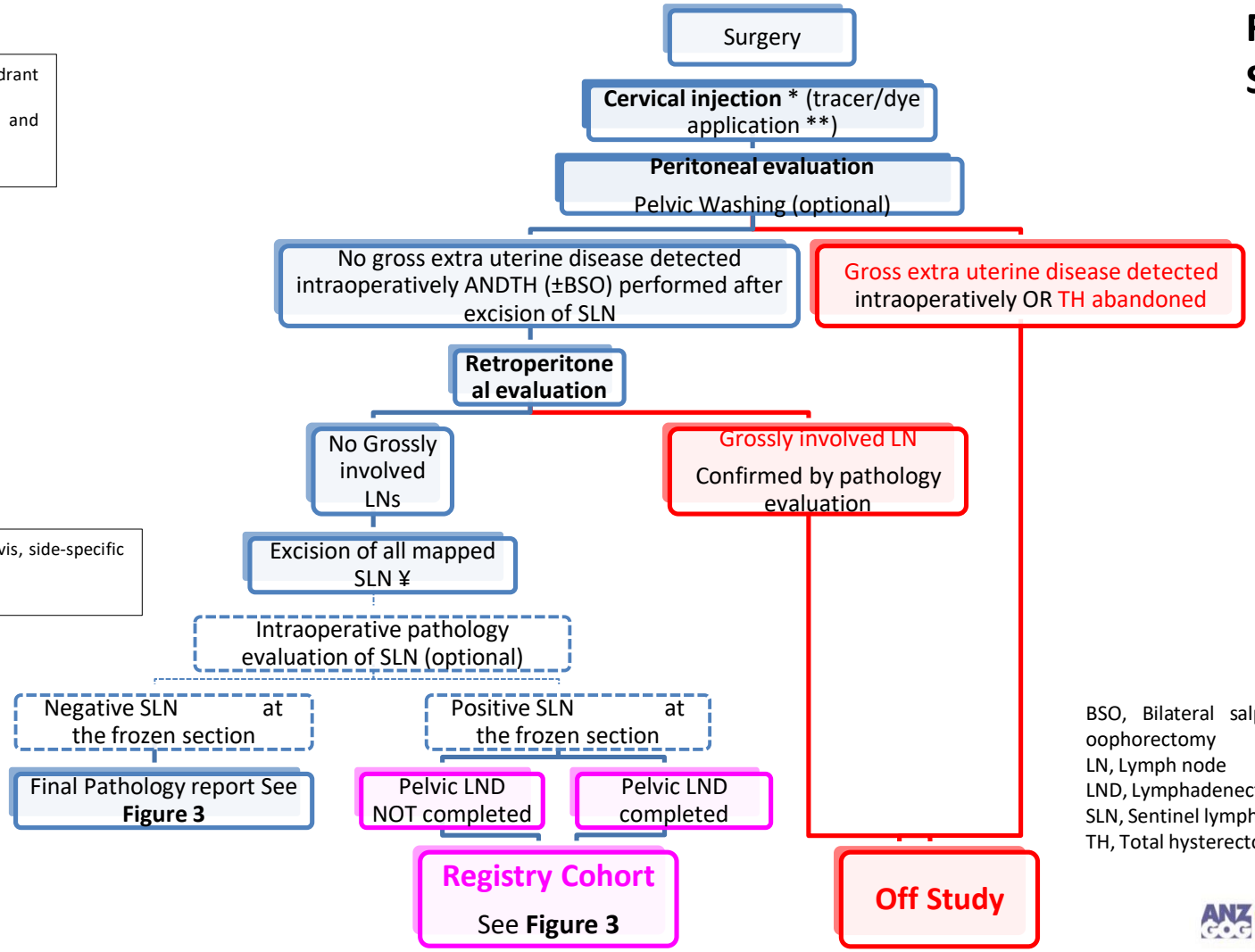
Fig. 2 Surgery



* 3-9 o'clock (at least) or 4 quadrant injection (optional)
Superficial injection (mandatory) and deep injection (optional)
** ICG or Blue dye ± Technetium

¥ If no SLN detection on a hemi-pelvis, side-specific LND recommended
Para-aortic LND optional

BSO, Bilateral salpingo-oophorectomy
LN, Lymph node
LND, Lymphadenectomy
SLN, Sentinel lymph node
TH, Total hysterectomy

On the horizon…..

- **STATEC Study:** A randomised trial of non-**S**elective versus selective adjuvant **T**herapy in high risk **A**pparent s**T**age 1 **E**ndometrial **C**ancer
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