

# SENTICOL III: a validation study

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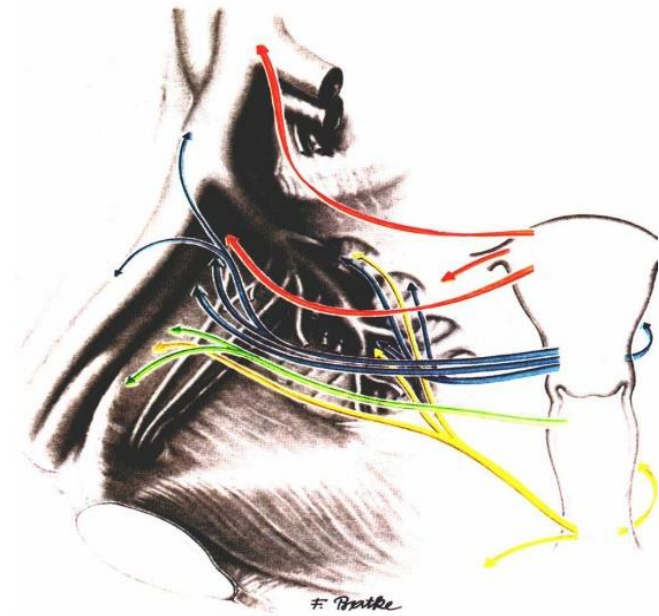
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# Cervical cancer: good candidate

- Low tumor load
  - $\leq 20\%$  N+
  - 1 node in 50%
  - Small size
- Toxicity
  - Intraoperative complications
  - Lymphoceles 30%
  - Lymphedema 15%
- Failure
  - Nodal recurrence in N0 patients



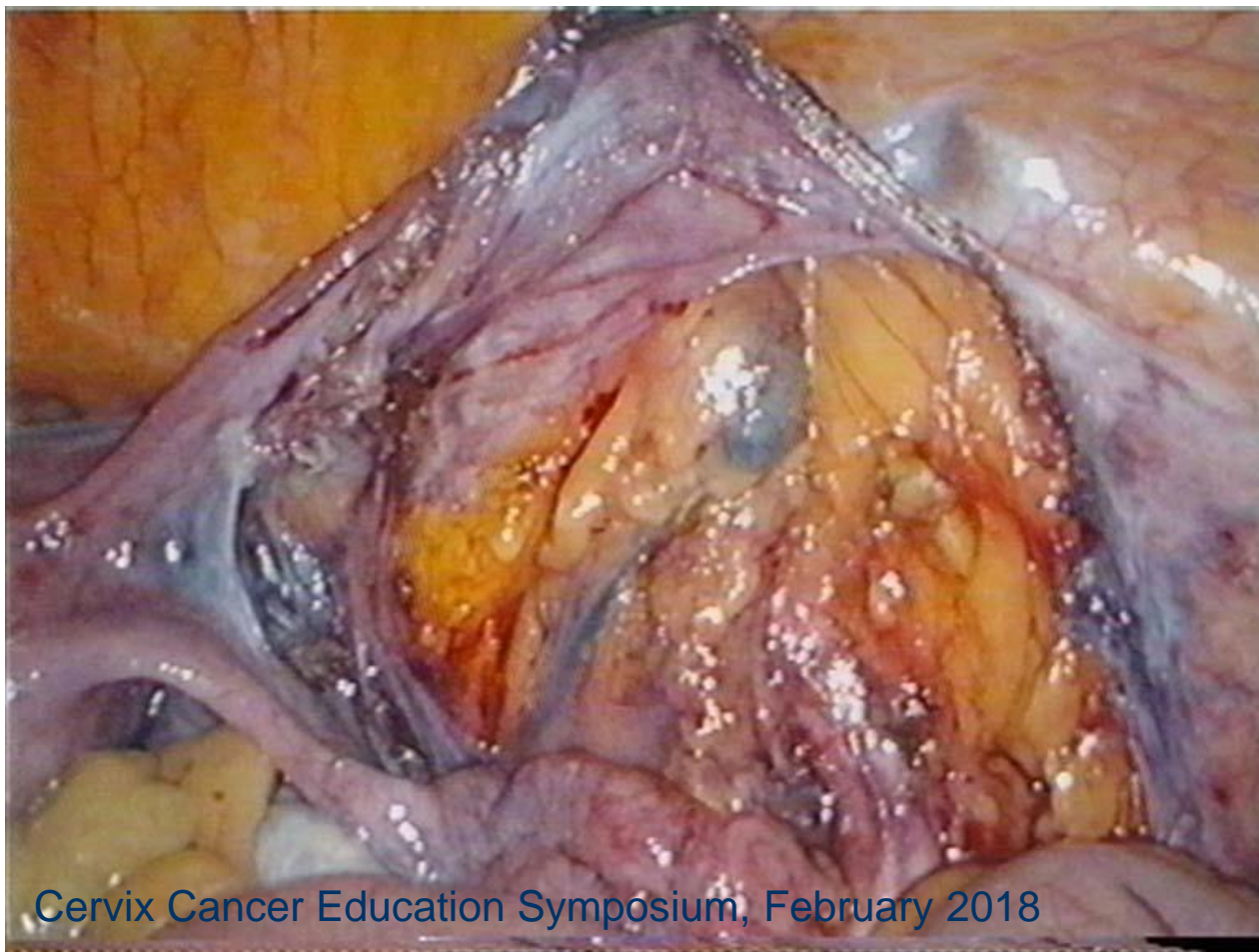
Reiffenstuhl G & al

# Gynecologic Cancer InterGroup Cervix Cancer Research Network

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**GYNECOLOGIC  
CANCER INTERGROUP**

An Organization of International Cooperative  
Groups for Clinical Trials in Gynecologic Cancers



Cervix Cancer Education Symposium, February 2018

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≈150 valuable papers

Review and metaanalyses

## Prospective trials

Altgassen C & al 2008 (AGO)

Darlin L & al 2010

Lécuru F & al 2011

Cormier B & al 2011

Mathevet P & al 2015

van de Lande J & al 2007

Selman T & al 2008

Eiriksson L & al 2010

Palla V & al 2014

Wang X & al 2015

Tax C & al 2016

Diab Y 2017

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## False negative risk

trained surgeon & team

no nodal involvement (MRI, intraop exploration)

combined technique

tumor diameter  $\leq 2\text{cm}$  (\*)

**BILATERAL DETECTION**

ultrastaging



FN rate: 1/1257 (0.08%)

P Mathevet: Ultrastaging of NSLN

SENTICOL I: 1 ITC

SENTICOL II: no FN

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## Enhanced pathological information

serial sectioning and IHC

PCR

ITC <0.2mm, micromets 0.2-2mm in 20% of N0 patients

## Anatomy

SLN in unexpected locations in 38% of patients

+SLN only in unexpected locations in 17% of **pos** patients

## Reduced morbidity

overall lymphatic morbidity, early postop events, neurological symptoms, lymphedema, QoL

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What next ?

- trial for patients with micrometastases
- survival
- qol
- trial for + SLN

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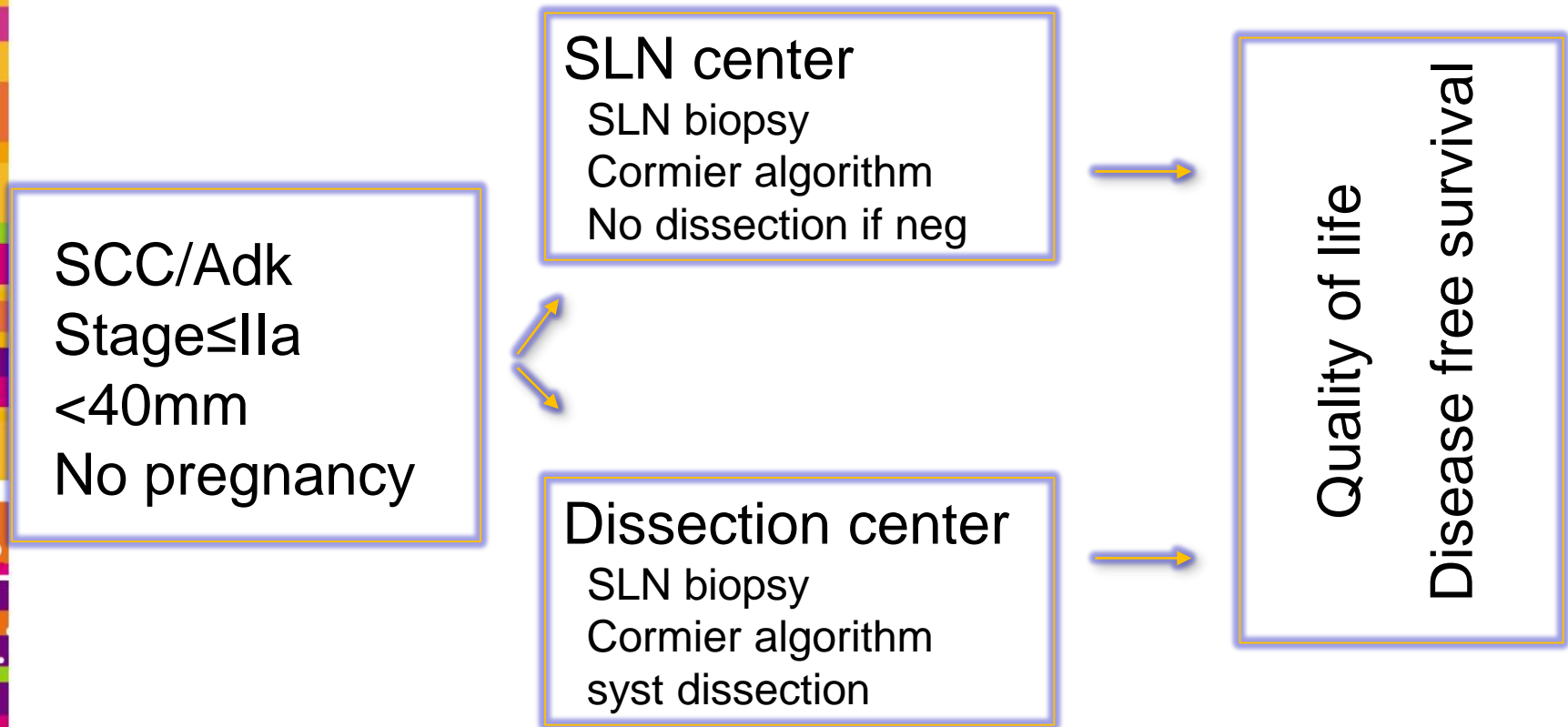
## GCIG MELBOURNE BRAINSTORMING SYMPSIUM ON CC (2014)

- 1) expand fertility-preserving options with neoadjuvant chemotherapy
- 2) *validation of the assessment of sentinel lymph nodes using minimally invasive surgery with an emphasis on identification and management of low-volume metastasis, such as isolated tumor cells and micrometastasis*
- 3) evaluation of hypofractionation for palliative and curative radiation under the umbrella of the GCIG Cervix Cancer Research Network
- 4) Adding to the advances in antiangiogenesis therapy in the setting of metastatic disease
- 5) developing a maintenance study among women at high risk of relapse



# 2015 proposal

## Schema



# Senticol III

## Study Design



- Squamous or adenocarcinoma of the cervix,
- Stage Ia1 with lympho vascular emboli to IIa1,
- Maximum diameter  $\leq 40\text{mm}$ .

Inclusion/exclusion criteria  
ICF signature

Pre-study procedure  
*Pelvic examination, SLN mapping + biopsy, Frozen Section on SLN.*

Surgical & pathological quality assurance

950 patients

Patients with bilateral detection without macroscopic suspicious node and negative frozen section on SLN (pN0)

Patients with nodal involvement (pN1)

Randomisation  
1 : 1

**Arm A (experimental) :**  
SLN biopsy only  
+ hysterectomy or trachelectomy

**Arm B (reference) :**  
SLN biopsy  
+ Pelvic Lymphadenectomy  
+ hysterectomy or trachelectomy

DFS, RFS, QOL, OS

Followed in a separate cohort to record treatment and outcomes



## Quality assurance

- Centre selection
  - Having participated to SENTICOL, SENTICOL II or other prospective study on SLN in cervical or endometrial cancer
  - OR Treating at least 15 cases of early cervical cancer / year
  - OR Trained for SLN + PLN of at least 15 cases of cervical or endometrial cancer
  - AND Trained for the safety algorithm
  
  - Use of isotope +/- blue dye (or ICG)
  - Availability of pelvic/abdominal MRI, planar lymphoscintigraphy or SPECT, frozen section
  
  - Pathologist trained for frozen section of SLN and ultrastaging of SLN
  - Multidisciplinary board, radiation therapy, chemotherapy, clinical research facilities
- Centre assessment
  - Random selection of reports

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## Present status

- Grant for the French part & international coordination
- Sponsor = CHU de Besançon
- Application to French authorities (May 2017)
- 50 sites in France
- ***1st inclusion in February***



## SENTICOL III: an international task force

- An international study
- Several GCIIG groups participation
- Unique opportunity to register data about ECC

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SENTIX trial

Observational study

The null hypothesis is that the recurrence rate after SLN biopsy is non-inferior to the reference recurrence rate of 7 % (at the 24th month of follow-up) in patients after systematic pelvic lymphadenectomy, but that the less radical surgery is associated with significantly lower postoperative morbidity.

300 patients

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# Thank you !

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