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SENTICOL III: a validation study

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Cervix Cancer Education Symposium, January 2019, South Africa

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Nodal involvement is the most important prognostic factor in ECC

- FIGO 2018 stage IIIc; different treatment

Imaging is not sensitive enough

Lymphadenectomy is the standard today

- small number of positive patients
- 1 or 2 positive nodes in positive patients
- > 10 nodes to be informative
- toxicity of lymphadenectomy if > 10 nodes
- 5% of positive nodes are outside the classical basins
- nodal recurrences in “pN0” patients

De-escalation in ECC

- laparotomy, laparoscopy, fertility sparing surgery
- pelvic +/- paraortic dissection, targeted biopsy

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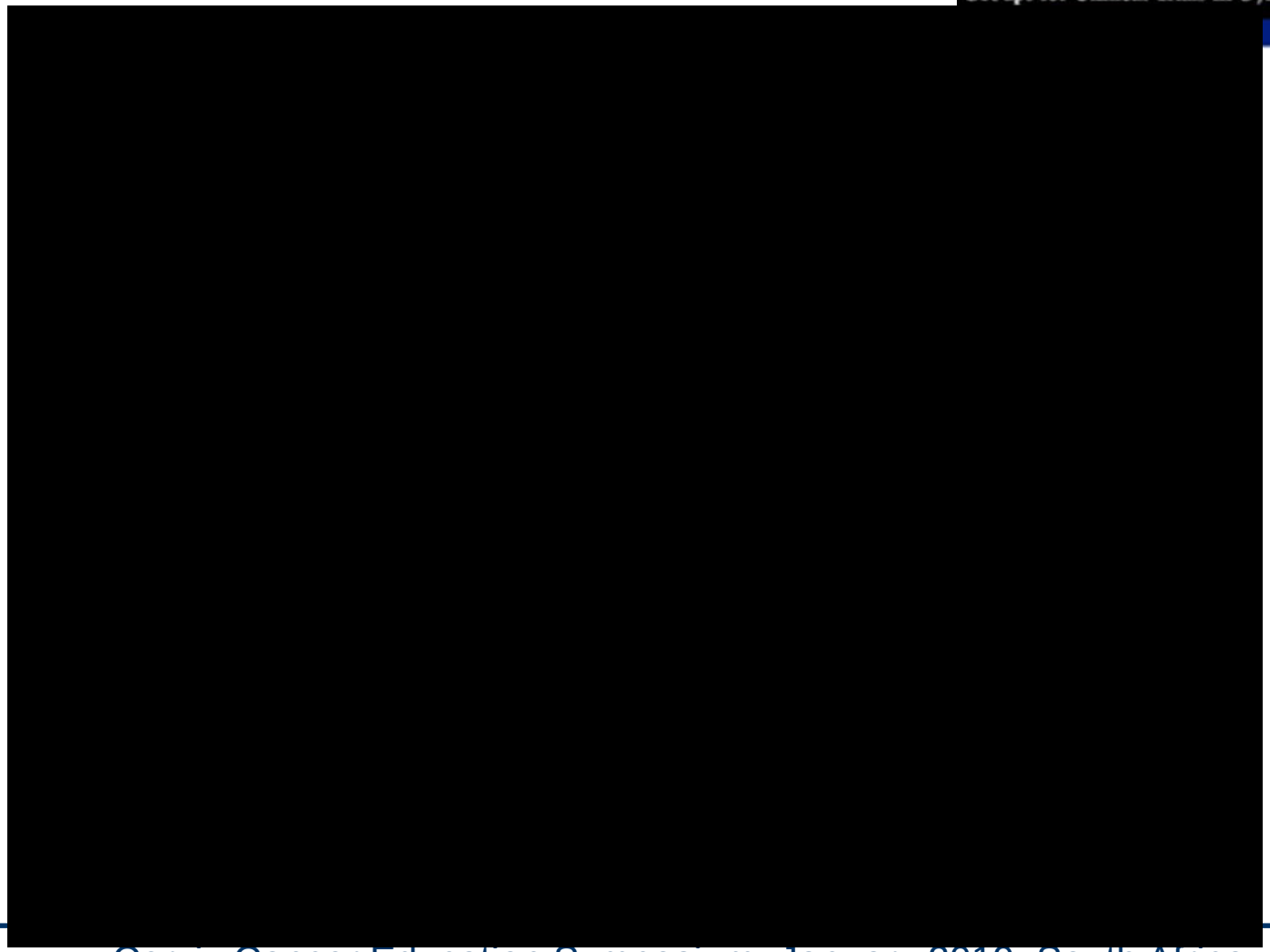

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False negative risk

trained surgeon & team

no nodal involvement (MRI, intraop exploration)

combined technique or ICG

tumor diameter ≤2cm (*)

BILATERAL DETECTION & MSKCC algorithm

ultrastaging

→ FN rate: 1/1257 (0.08%) *Tax C & al 2015*

P Mathevet: Ultrastaging of Non SLN

SENTICOL I: 1 ITC SENTICOL II: no FN

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Enhanced pathological information

- serial sectioning and IHC
- ITC <0.2mm, micromets 0.2-2mm in 15% of N0 patients
- PCR

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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Validation of a diagnostic technique

feasibility
reproducibility
invasiveness
DIAGNOSTIC accuracy
cost
secondary benefits
adverse effects

experimental method vs gold standard

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Specifity of a surgical trial

Surgery is handcraft medicine. **Details !**

We have to be sure that

- the patients are selected correctly
- the technique is performed in the proper manner, by the majority of investigators
- investigators are equally trained for the two techniques
- “blind” assessment of end-points

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Quality assurance in surgical trials

	Total (*n* = 120)	2003 (*n* = 60)	2013 (*n* = 60)	*P*§
Additional items				
30 Preoperative nursing care	46 (38·3)	29 (48)	17 (28)	0·024
31 Postoperative nursing care	45 (37·5)	23 (38)	22 (37)	0·850
32 Anaesthetic management	33 (27·5)	18 (30)	15 (25)	0·540
33 Surgeons' experience	46 (38·3)	14 (23)	32 (53)	0·001
34 Under supervision of an experienced surgeon	8 (6·7)	3 (5)	5 (8)	0·717¶
35 Learning curve	43 (35·8)	21 (35)	22 (37)	0·849

Ju X & al 2017

Specificity of SLN

The objective is to reliably identify women without nodal metastasis, who mostly have a good prognosis, and in whom we want to limit adverse effects of the treatment

SURVIVAL

QUALITY OF LIFE

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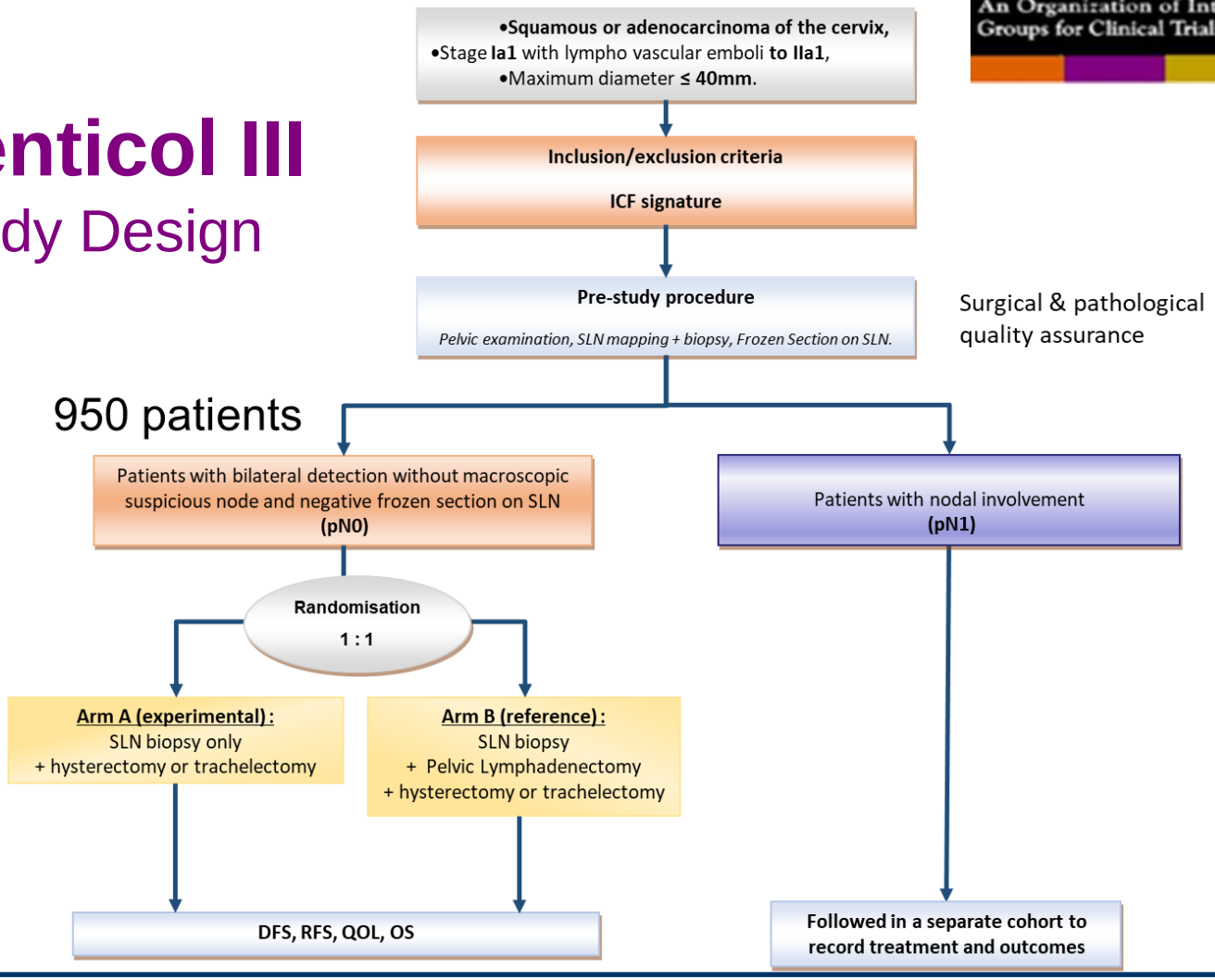
Senticol III
Study Design



Surgical & pathological quality assurance

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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
- GINECO = operational Group
- Application to French authorities (May 2017)
- 50 sites in France
- ***12 patients included***

SENTICOL III: an international task force

- An international study
- Several GCIG groups and centers participation
  - AGO, ANZOG, CCRN, CTI, DGOG, MANGO, NSGO etc.
  - MSKCC, Brazil, etc.
- Unique opportunity to register prospective data on 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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