

An EORTC vulva cancer module

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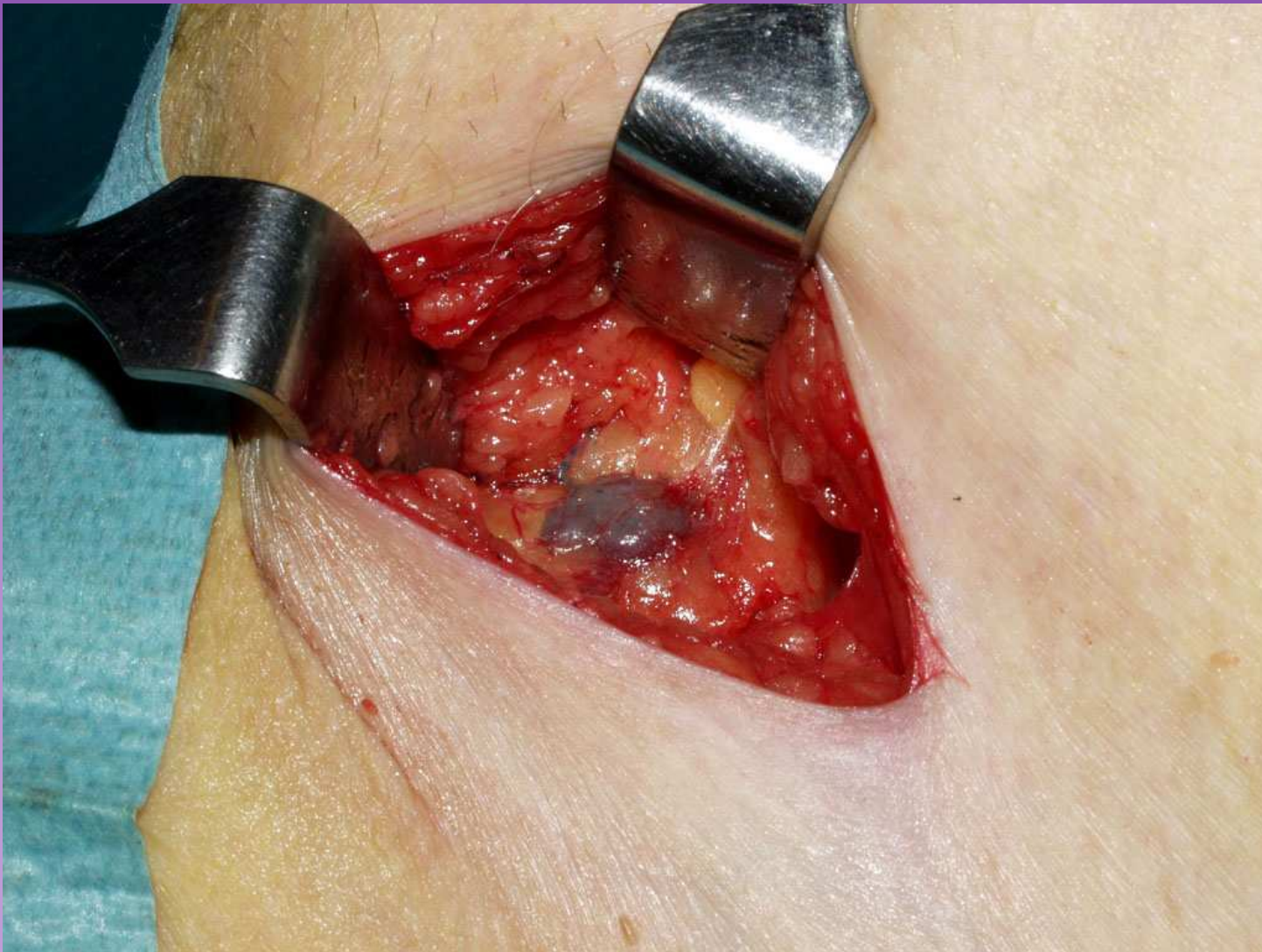
A female cancer with a very low incidence

- 2-3 per 100.000 women
- 100 in DK each year
- Each larger cancer center in Europe will probably operate around 20-30 patients every year

Treatment

- Primary vulva surgery
- Inguinal radical lymphadenectomy or sentinel node procedure
 - Depends on tumor size, location, and results of CT or MR
- In advanced vulva cancer
 - Primary surgery if possible + adjuvant chemo-irradiation
 - Primary chemo-irradiation, vulva + inguina
 - Potential secondary surgery

Inguinal dissection sentinel node technique



Lymphoedema after inguinal radikal lymph- adenectomy +/- RT



Other potential domains

- Body image/Femininity/attractiveness
- Sexuality
- Urological morbidity
- Rectal morbidity
- Vulvo-vaginal changes
- Fear of dying/fear of recurrence
- Skin problems

Recruitment Considerations

- Low / slow recruitment rate due to limited patient availability
- Optimal to include different patients for each validation phase
- A patient group
 - With a high degree of co-morbidity
 - Many pts are old
 - Unwilling to complete questionnaires?

Recruitment Considerations

- High morbidity related to treatment
- High prevalence of symptomatology, psychological and sexual issues
- Very few studies on QOL
- A few studies on sexuality
- Necessary to include patient interviews before final list of issue list
- Necessary to consult professionals outside EORTC QOL group for addition of relevant issues

On going European observational study

- GROINSS-V II
- Dutch multicenter study with participation
 - Danish (three centres)
 - Swedish (Karolinska?)
 - Norwegian (Radiumhemmet?)
 - UK (Addenbrook H Cambridge?)
 - Austria (Graz?)

GROINSS-V II

- GROningen International Study on Sentinel nodes in vulva cancer
- Purpose
 - To evaluate the safety of replacing radical inguino-femoral lymphadenectomy with adj. RT (+ chemo) in pts with early stage vulva cancer with pos. sentinel node
 - To evaluate short- and longterm morbidity with sentinel node procedure and adj. (chemo)-irradiation
 - To evaluate the safety of observation in patients with negative sentinel node

Phase 1

- Literature search
 - Pernille (Copenhagen) do the literature search to identify potentially relevant quality of life issues
 - As part of her expert education in gynecologic oncology
 - Danish external funding
 - Write a review article together with Eva on behalf of the gyn. group.

Tasks

- **Pernille**
 - present the proposal and the MDC meeting spring 2009
 - will start phase 1a, literature search
 - External funding
 - Write a protocol for ethical approval for phase 1 through 4
 - Write a funding application for phase 3 and 4
- **The gyn. Group:**
 - Has agreed to join the study
 - Has decided not to include vulva dysplasia
 - Has decided to invite professionals outside the EORTC QOL group for addition of issues, if necessary