Evaluation of perioperative chemotherapy for operable gastroesophageal and gastric cancer In western Denmark June 2008- August 2010

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Background

- **The MAGIC trial** *Cunningham et al NEJM 2006*
  - *Resectable gastric or lower esophageal adenocarcinomas benefits from perioperative regimes of chemotherapy ECF:*
  - *Epirubicin iv (50mg/m2),*
  - *Cisplatin iv (60mg/m2)*
  - *5-fluorouracil (200mg/m2 per day) iv continuously*
- **ACCORD07-FFCD 9703 trial.** *Boige et al ASCOO 2007*
  - *Perioperative regimes of chemotherapy CF:*
  - *Cisplatin iv (100mg/m2)*
  - *5-fluorouracil (800mg/m2 every 28 days) iv continuously*

Aims

- To evaluate results of perioperative chemotherapy ad modum MAGIC in Denmark
- To study patient population characteristics
- To investigate toxicity by retrospective
- To study compliance and reasons for early drop out
- To study results of surgery after preoperative chemotherapy
- To compare results with similar reports

Study population

All patients referred to the departments of oncology in Odense, Aarhus and Aalborg for intended perioperative chemotherapy (intention to treat) for operable adenocarcinoma in GEJ and stomach

> stage Ia from the treatment introduction in June 2008 through August 2010

Regiments in DK

- EXE-regime (cycle 21 days):
  - Oxaliplatin 130mg/m2 iv day 1
  - Epirubicin 50 mg/m2 iv day 1
  - Capecitabine 1000mg/m2 bid continuously
- ECX-regime (cycle 21 days):
  - Cisplatin 60mg/m2 iv day 1
  - Epirubicin 50 mg/m2 iv day 1
  - Capecitabine 1000mg/m2 bid continuously
- FLOX-regime (cycle 21 days):
  - Oxaliplatin 85mg/m2 iv
  - Epirubicin 50 mg/m2
  - 5FU iv-bolus day 1 and 2

Departments and Regiments

Odense
53 patients
Start November 2008
Regimes: EXE and FLOX

Aarhus
29 patients
Start January 2009
Regime: ECX

Aalborg
49 patients
Start June 2008
Regime: EXE

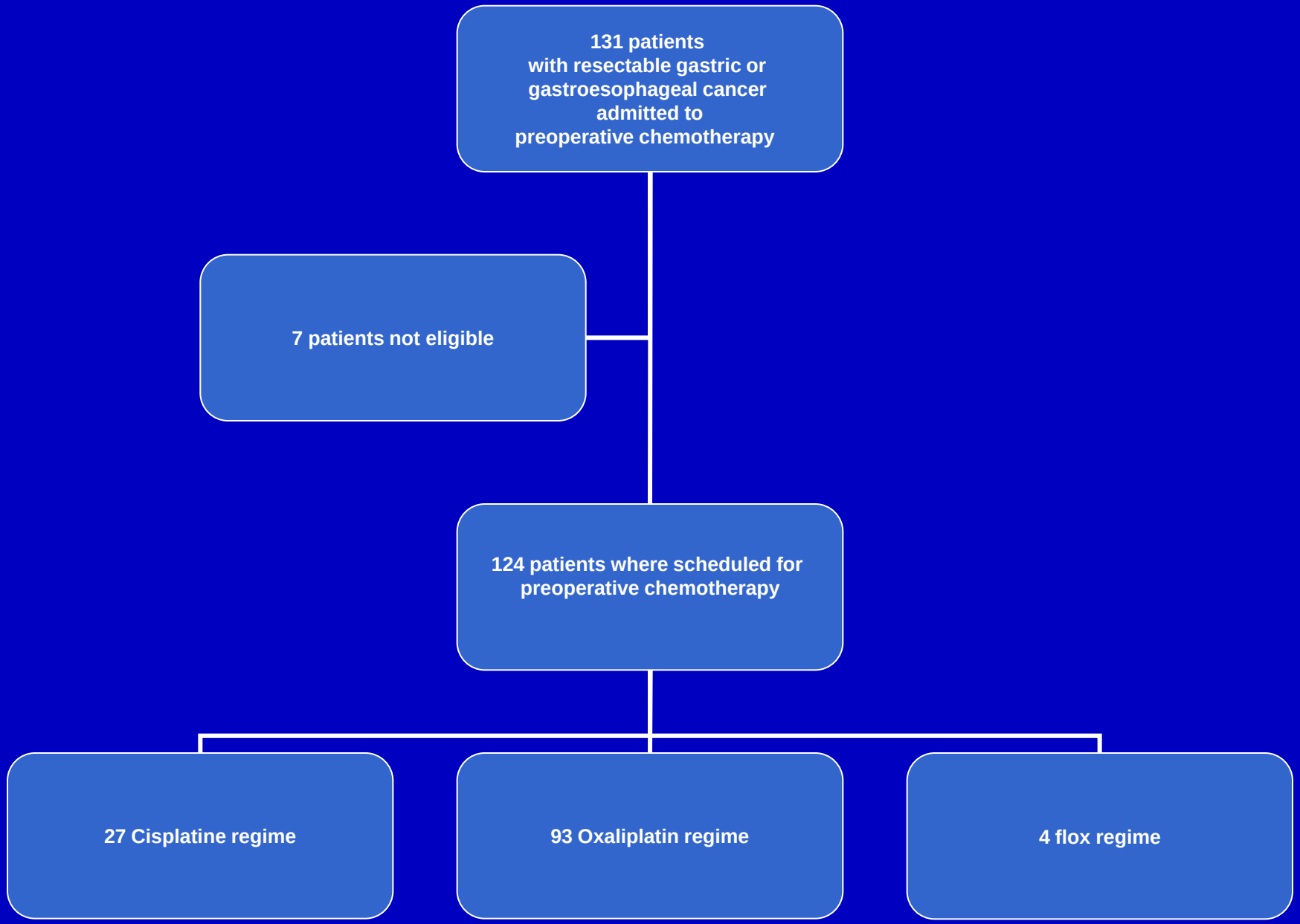
Demography

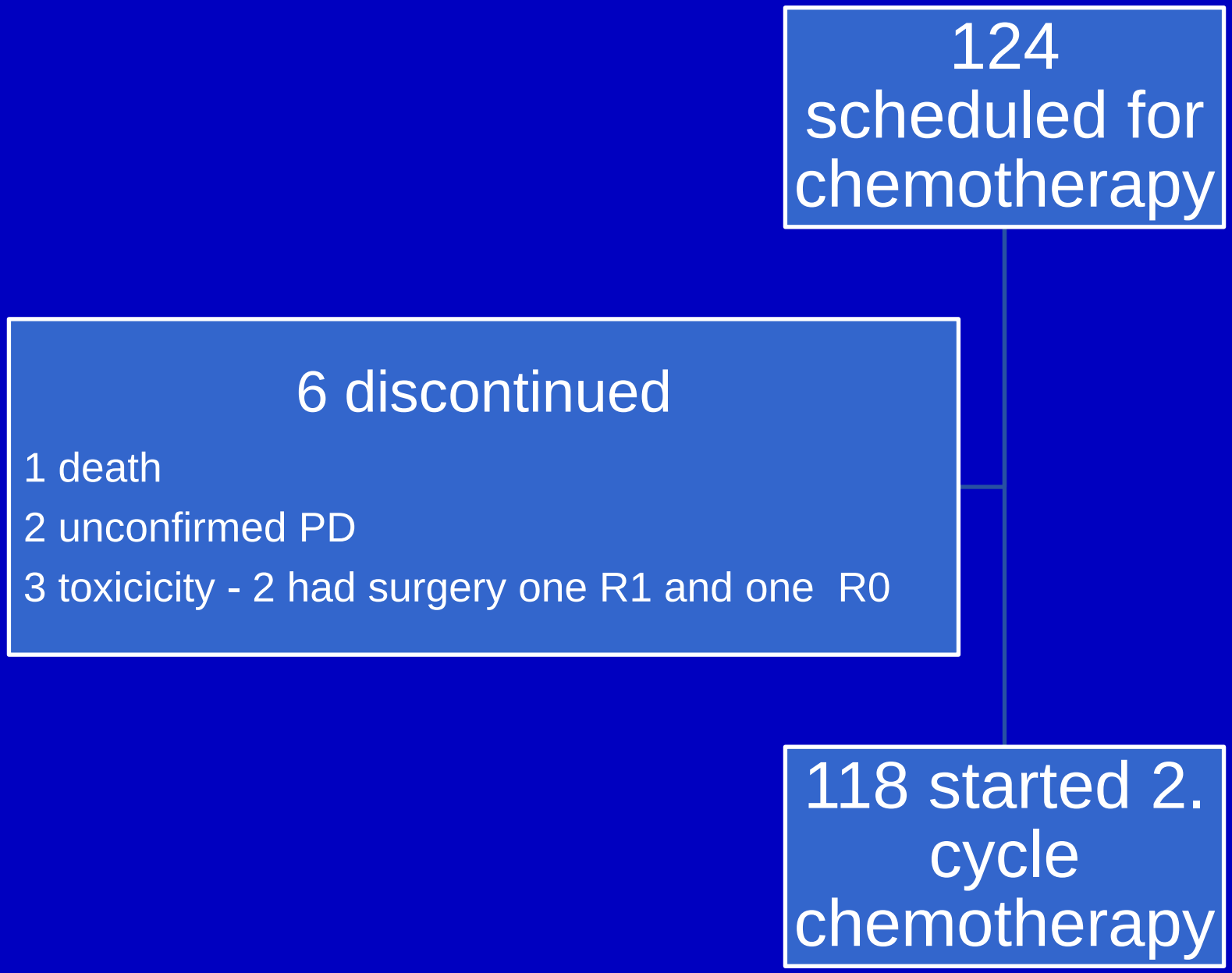
- N=131
- Age mean 64 years (range 32-80)
- Gender
  - Male 105
  - Female 26

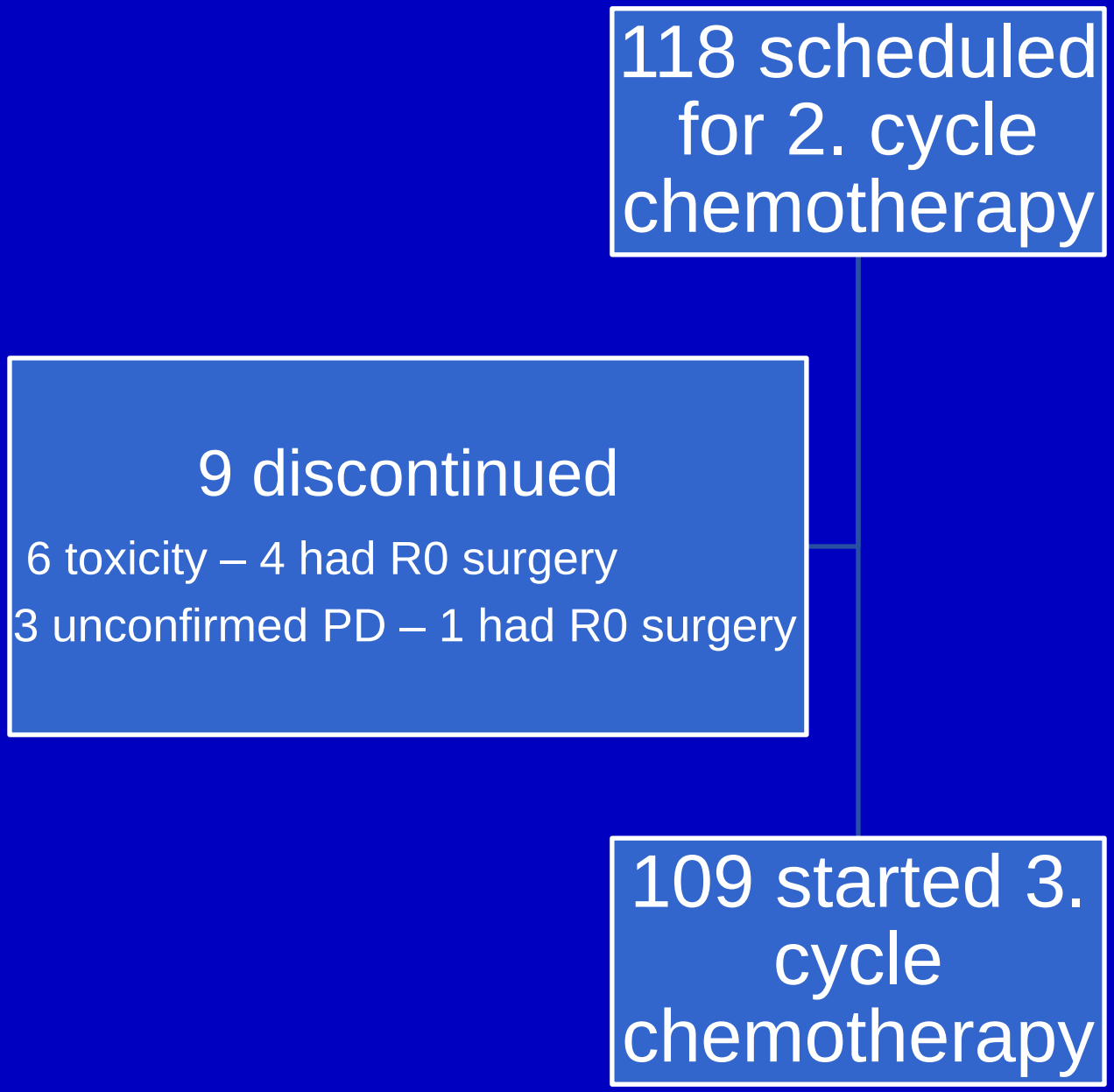
Tumor Characteristics

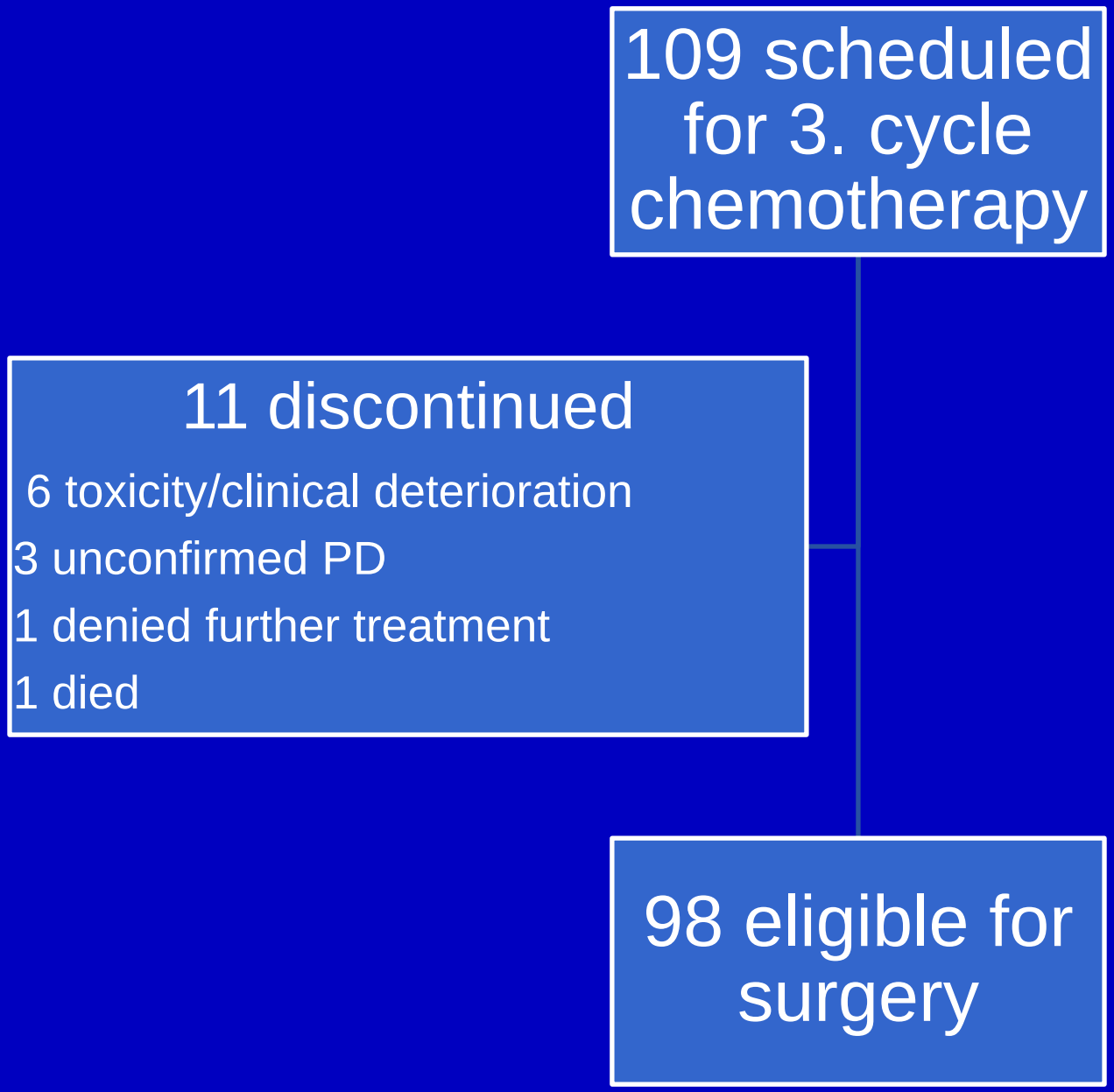
- Esophagus lower 6
- GEJ 191
- Gastric 24
- Undefined 10

All adenocarcinomas


131 patients
with resectable gastric or
gastroesophageal cancer
admitted to
preoperative chemotherapy
7 patients not eligible
124 patients where scheduled for
preoperative chemotherapy
27 Cisplatine regime
93 Oxaliplatin regime
4 flox regime


124 scheduled for chemotherapy
6 discontinued
1 death
2 unconfirmed PD
3 toxicicity - 2 had surgery one R1 and one R0
118 started 2. cycle chemotherapy


118 scheduled for 2. cycle chemotherapy
9 discontinued
6 toxicity – 4 had R0 surgery
3 unconfirmed PD – 1 had R0 surgery
109 started 3. cycle chemotherapy


109 scheduled for 3. cycle chemotherapy
11 discontinued
6 toxicity/clinical deterioration
3 unconfirmed PD
1 denied further treatment
1 died
98 eligible for surgery

98 curative intended resections

33 discontinued

1 dead
1 denied further treatment
12 Postoperative complications including death
5 clinical deterioration
9 non curatively resected
5 no data available

65 Scheduled for postoperative chemotherapy

Toxic effects was registered

- Analysis of toxicity is ongoing
- In general commonly known toxicities were reported such as:
  - nausea, fatigue, vomiting and neuropathies diarrhea, constipation, alopecia was seen as expected.
  - Neutropenia without fever was the most common cause of delaying chemotherapy
  - Very few cases were reported with admission due to neutropenic fever.
  - Phlebitis, DVT and Lung embolia

Pathological Staging

N=operated	Cisplatin (N=23)	Oxaliplatin (N=75)
ypT0	1 (4%)	10 (13%)
ypT1	1 (4%)	5 (7%)
ypT2	13 (54%)	31 (41%)
ypT3	7 (30%)	24 (32%)
ypT4	0 (0%)	5 (7%)
ypTx	1*	0

*data not complete

	Magic Cunninham et al NEJM 2006	Norway Hølmebakk et al EJSO 2010	West – DK ØGC-seminare
Regime	ECF	ECF	ECF+EXE
Period	1994-2002	2006-june 2009	Nov. 2008 – june 2010
N=intention to treat	250	169	131
Completed preoperative Chemotherapy	215/237(90%)	152/169(90%)	109(88%)
Started postoperative chemotherapy	137/250(58%)	92/169(54%)	65(52%)
Completed All cycles	104/250(42%)	68/169(40%)	37(30%)**
R0	169/244(69%)*	123/144(86%)	**
ypT0	None reported	7/144(5%)	11/98(11%)
ypN0	42/135(31%)	67/145(48%)	37/98(38%)

*according to surgeon

**data not complete

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