

Neoadjuvant Chemotherapy or Primary Surgery in Ovarian Cancer

The Value of QoL Outcomes

Intergroup Study EORTC 55971/NCIC OV13
PI: Ignace Vergote

EORTC GCG - EORTC 55971 Quality of Life REPORT

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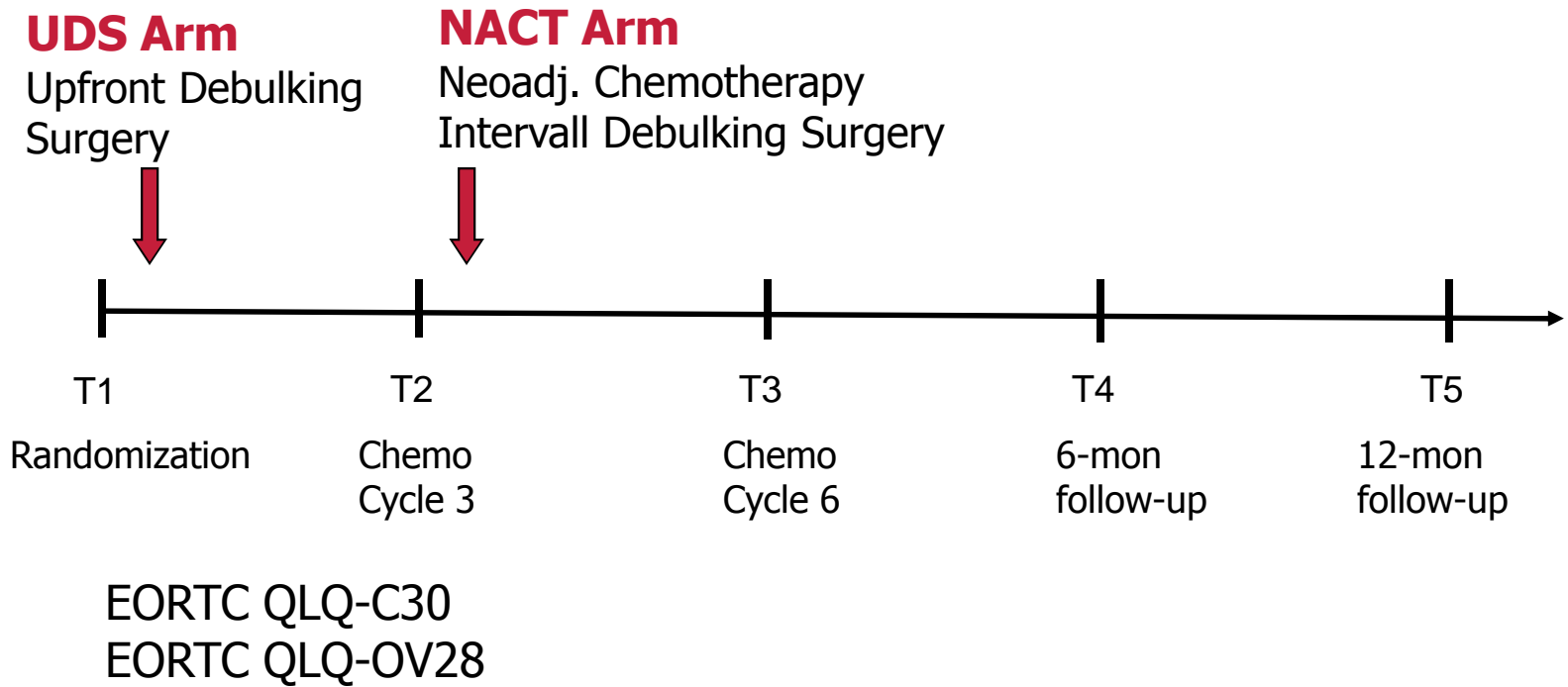
Project Manager: An Demeester

Coordinating physician: Bjorn Penninckx

Secondary Study Objective

Does neo-adjuvant chemotherapy followed by interval debulking surgery (NACT Arm) lead to improved QoL compared with upfront debulking surgery followed by postoperative chemotherapy (UDS Arm)?

QoL Assessment



QoL Measures

EORTC QLQ-C30	EORTC QLQ-OV28
<p data-bbox="394 574 764 623">Functional Scales</p> <ul data-bbox="436 633 852 880" style="list-style-type: none">Physical FunctioningRole FunctioningCognitive FunctioningEmotional FunctioningSocial Functioning <p data-bbox="394 922 747 971">Symptom Scales</p> <ul data-bbox="436 980 1020 1029" style="list-style-type: none">Fatigue, Nausea/Vomiting, Pain <p data-bbox="394 1055 789 1104">Single Item Scales</p> <ul data-bbox="436 1114 1108 1263" style="list-style-type: none">Dyspnoea, Insomnia, Appetite Loss, Constipation, Diarrhoea, Financial difficulties <p data-bbox="394 1289 919 1338">Global health status/QoL</p>	<p data-bbox="1155 574 1297 623">Scales</p> <ul data-bbox="1197 678 1915 1182" style="list-style-type: none">Abdominal/Gastrointestinal SymptomsPeripheral NeuropathyOther Chemotherapy Side-effectsHormonal/Menopausal SymptomsBody ImageAttitude to Disease and TreatmentSexual Functioning

Overall Compliance

Assessment time	N forms Received	N forms Expected	% compliance
Baseline	485	670	72.4
Cycle 3	271	589	46.0
Cycle 6	297	536	55.4
6 months FU	260	559	46.5
12 months FU	176	483	36.4

Compliance by Treatment Arm

QoL Compliance	Timing of Assessments					
	Baseline	Cycle 3	Cycle 6	6 months FU	12 months FU	Total
	NACT					
Received Compliance %	251 75.15	145 46.62	161 57.71	137 47.90	97 39.75	791
	UDS					
Received Compliance %	234 69.64	126 45.32	136 52.92	123 45.05	79 33.05	698

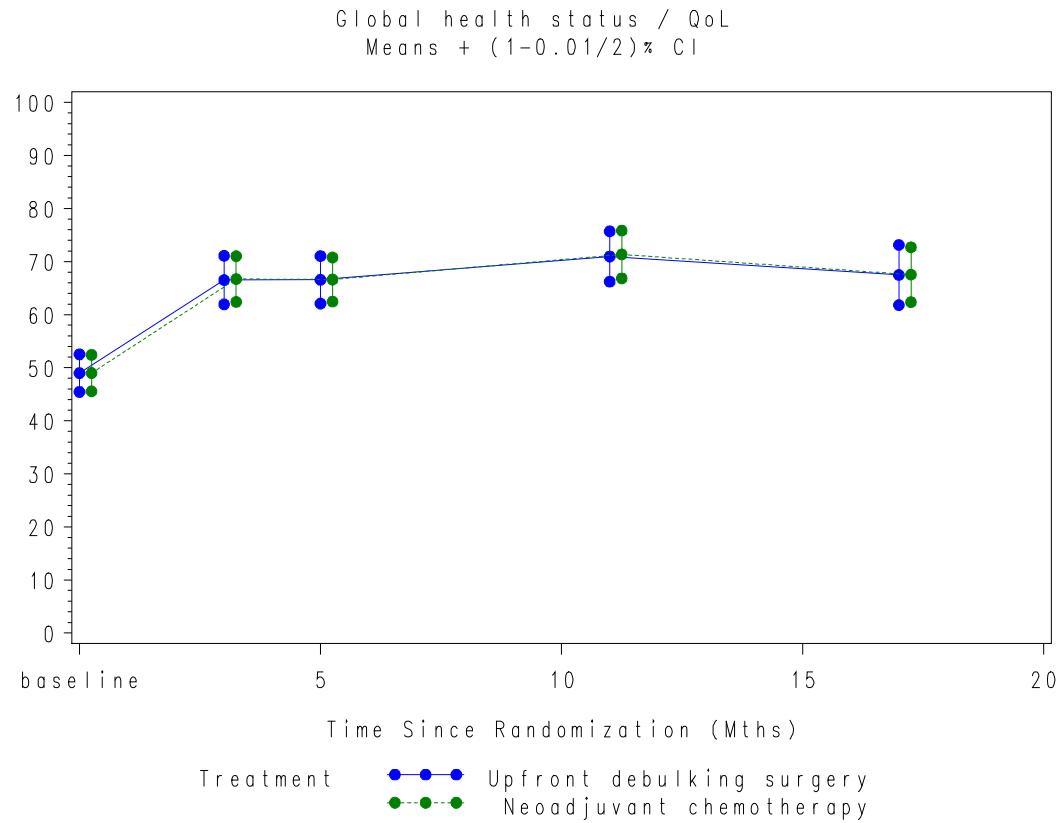
No statistical differences between the treatment arms

Reasons for Non-completion

Treatment forms	Treatment		
	UDS (N=259)	NACT (N=249)	Total (N=508)
	N (%)	N (%)	N (%)
Main reason			
Patient felt too ill	4 (1.5)	3 (1.2)	7 (1.4)
Clinical deemed patient too ill	3 (1.2)	8 (3.2)	11 (2.2)
Inconvenient	43 (16.6)	43 (17.3)	86 (16.9)
Privacy	24 (9.3)	23 (9.2)	47 (9.3)
Language problem	2 (0.8)	8 (3.2)	10 (2.0)
Administrative failure	183 (70.7)	164 (65.9)	347 (68.3)

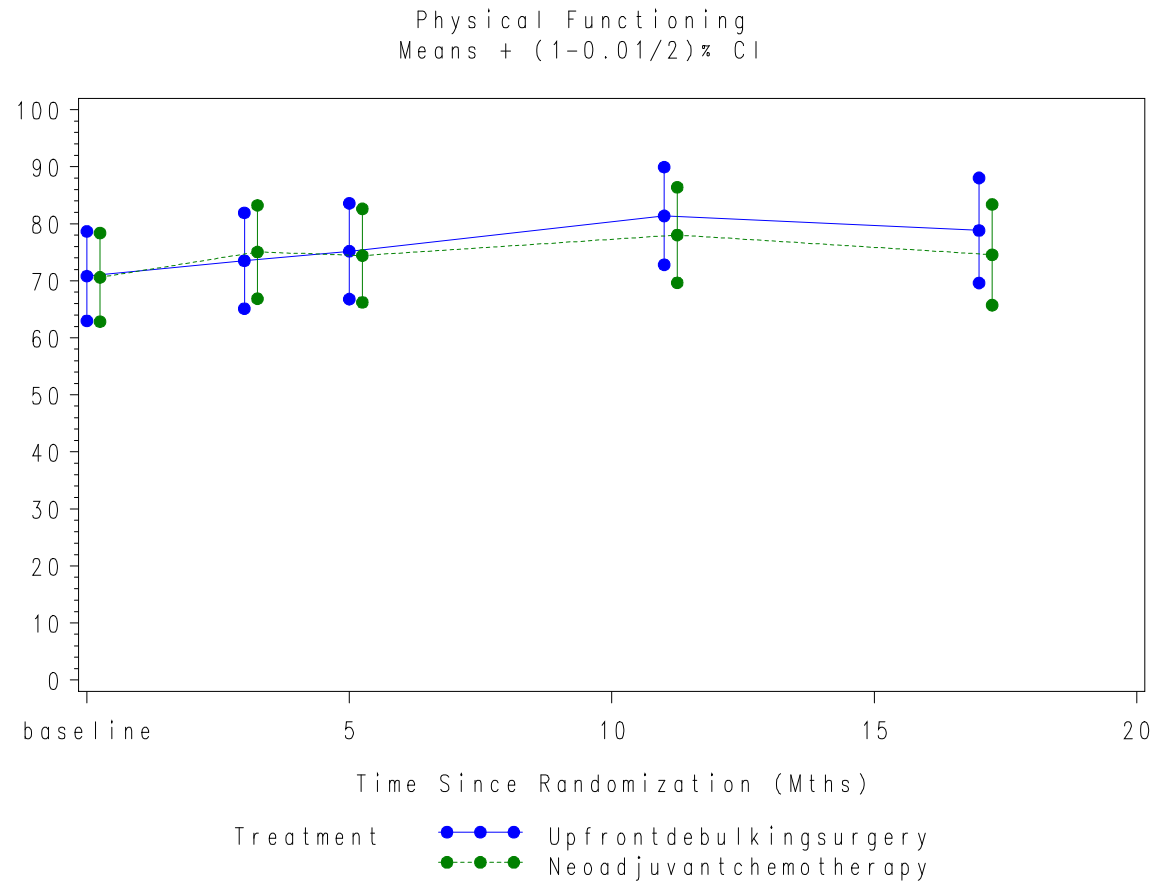
Quality of Life Results

QLQ-C30 Global Score



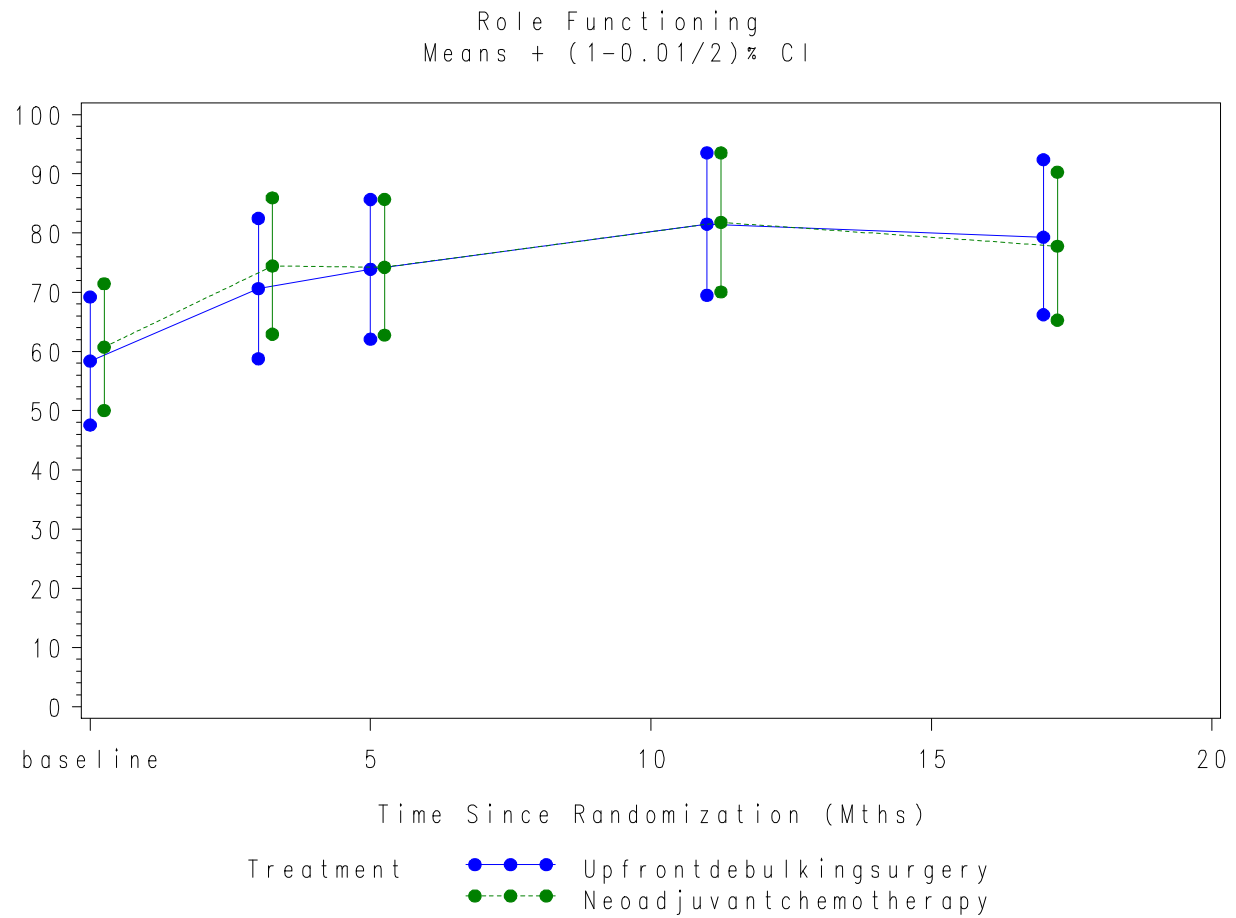
Treatment comparison	Num DF	Den DF	F Value	P-value
Global health status / QoL	1	1471	0.06	0.8057

QLQ-C30 Functioning Scales



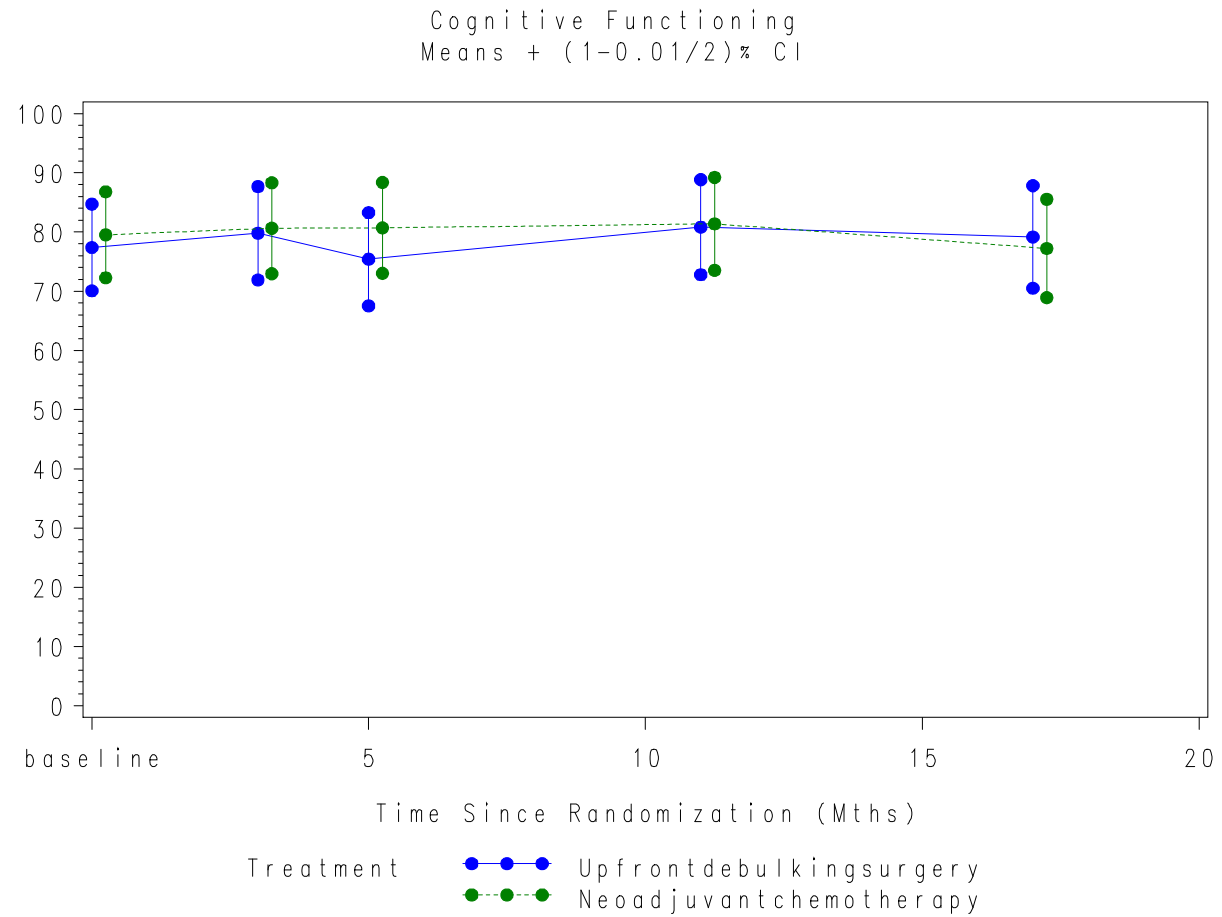
Treatment comparison	Num DF	Den DF	F Value	P-value
Physical Functioning	1	877	0.52	0.4709

QLQ-C30 Functioning Scales



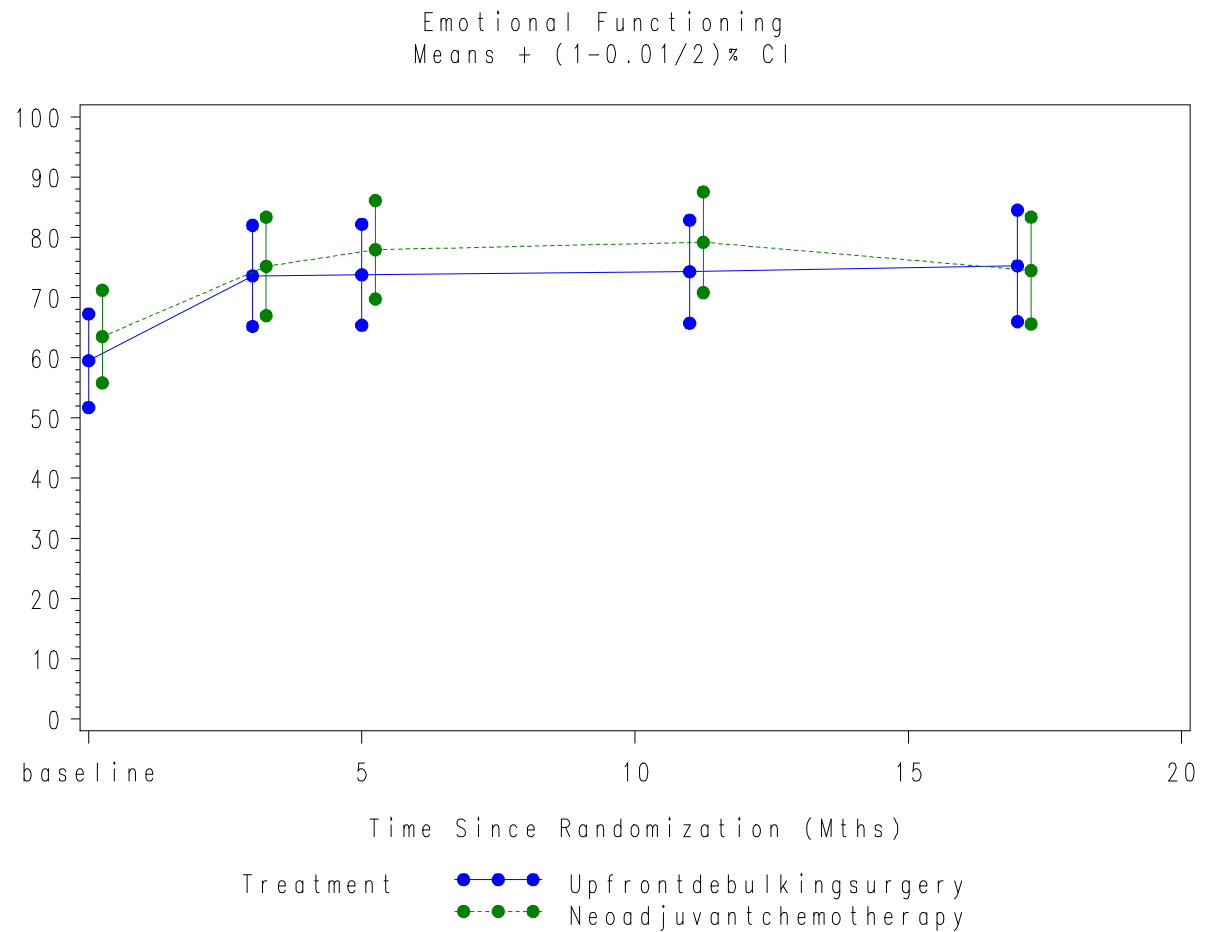
Treatment comparison	Num DF	Den DF	F Value	P-value
Role Functioning	1	875	0.26	0.6115

QLQ-C30 Functioning Scales



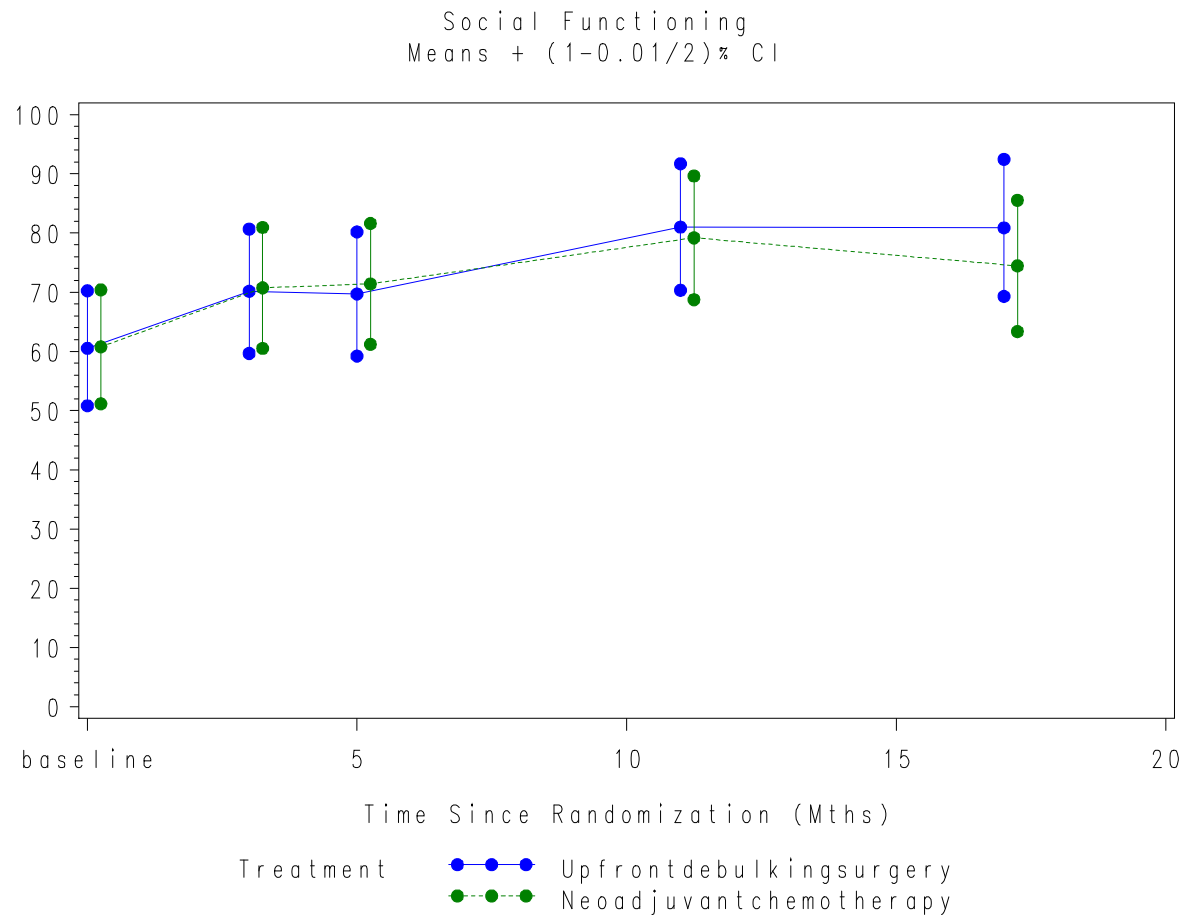
Treatment comparison	Num DF	Den DF	F Value	P-value
Cognitive Functioning	1	875	0.23	0.6345

QLQ-C30 Functioning Scales



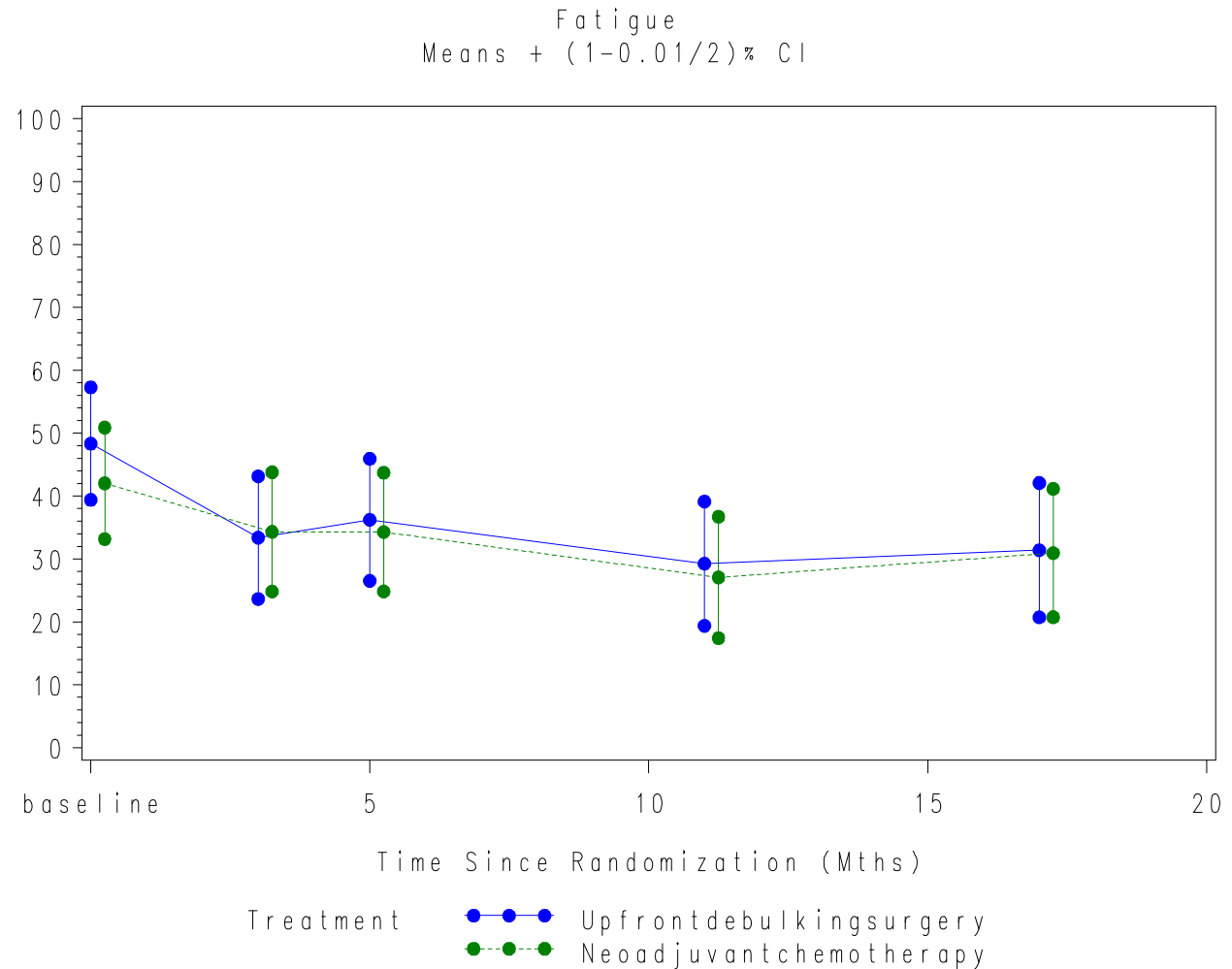
Treatment comparison	Num DF	Den DF	F Value	P-value
Emotional Functioning	1	874	0.51	0.4771

QLQ-C30 Functioning Scales

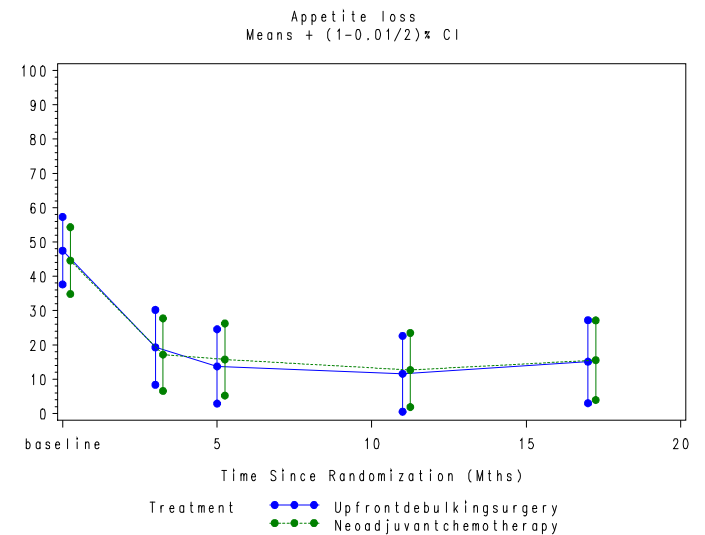
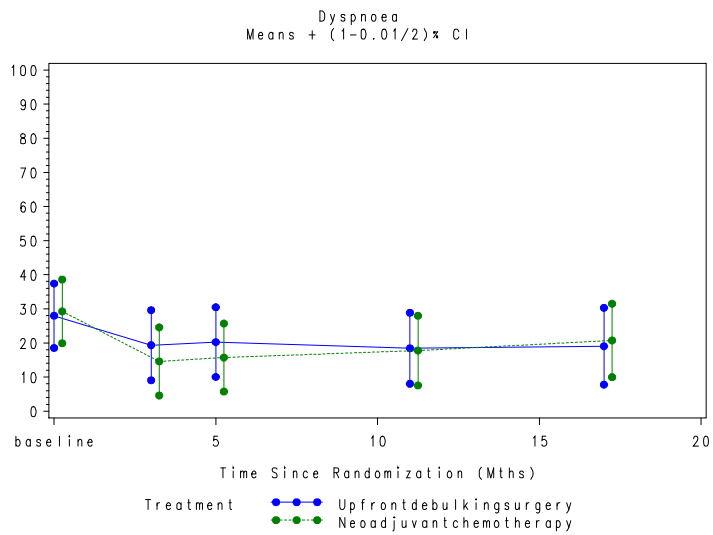
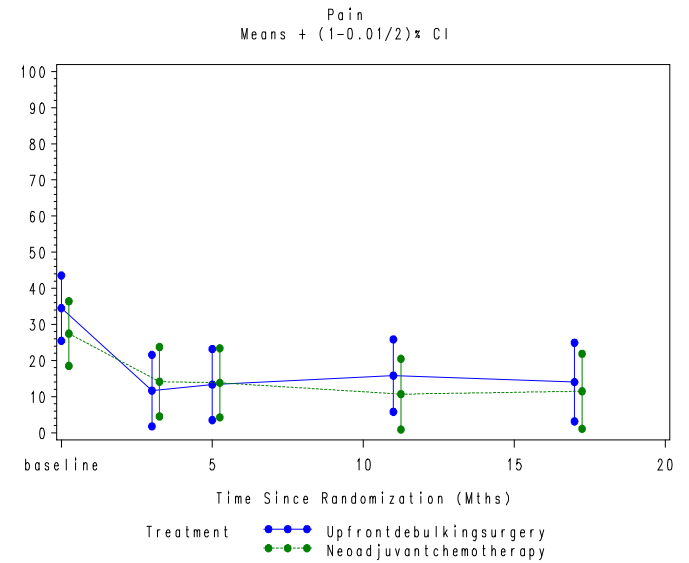
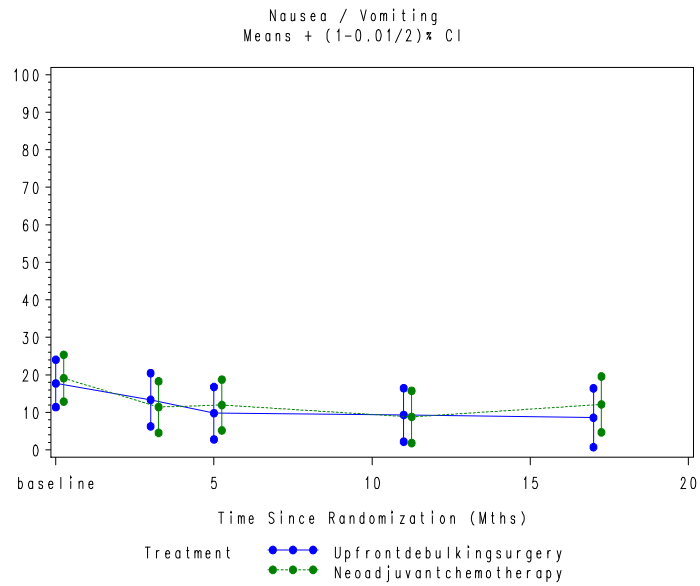


Treatment comparison	Num DF	Den DF	F Value	P-value
Social Functioning	1	871	0.40	0.5249

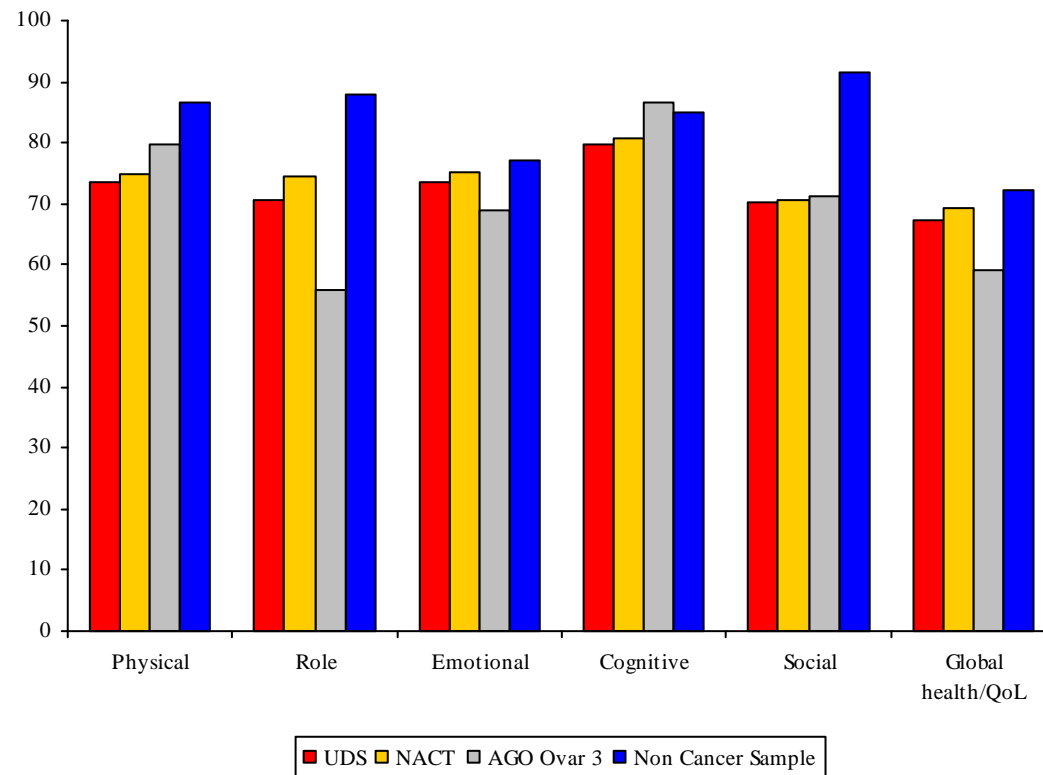
QLQ-C30 Symptom Scales



QLQ-C30 Symptom Scales



Comparison with other Samples During Treatment

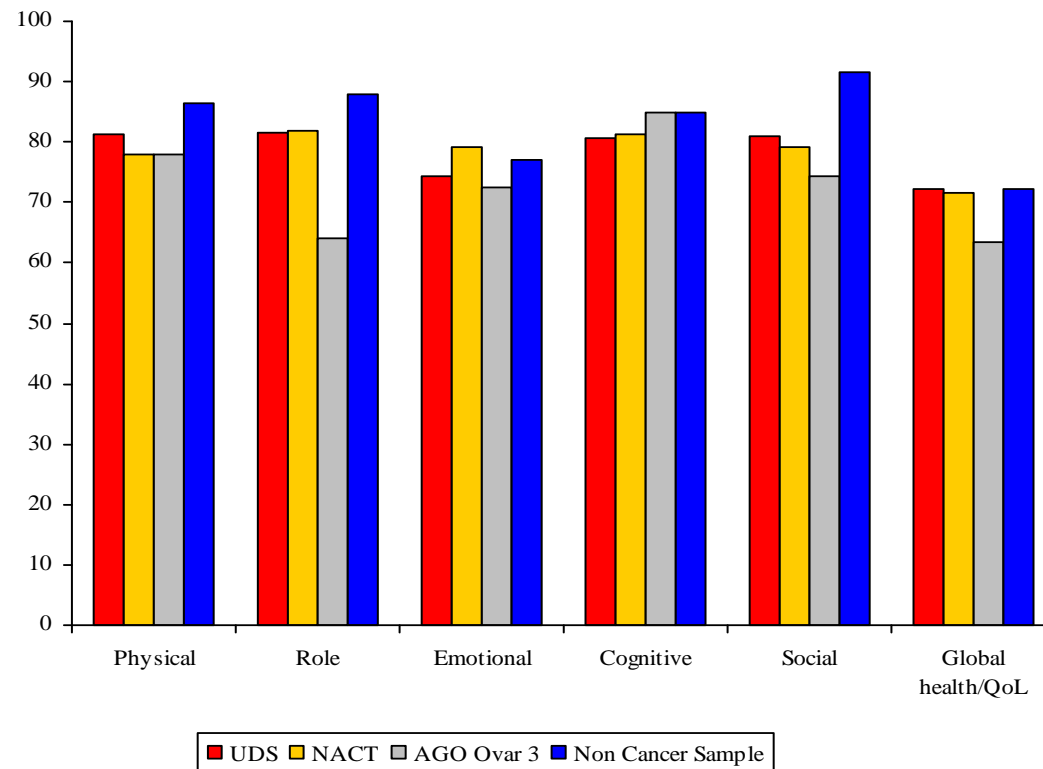


Reference data:

Greimel et al. J Clin Oncol 24:579-586, 2006
 N=366 Ovarian Ca Patients Stage IIB-IV (Carbo/Paclitaxel Arm)

Schwarz et al. Eur J Cancer 37:1345-1351, 2001
 General female population (N=1139)

Comparison with other Samples Follow-up



Reference data:

Greimel et al. J Clin Oncol 24:579-586, 2006
N=366 Ovarian Ca Patients Stage IIB-IV (Carbo/Paclitaxel Arm)

Schwarz et al. Eur J Cancer 37:1345-1351, 2001
General female population (N=1139)

Summary I

- Survival and QoL was similar in the UDS and NACT arm
- No differences in the QLQ-C30 functioning and symptom scales
- No significant treatment effect on global health/QoL

Summary II

- Poor prognosis (stage IIIc or IV disease)
Median survival: UDS 29 mon; NACT 30 mon
- QoL improved from baseline to follow-up
- Relatively good QoL during and after treatment in both arms

What is the Value of QoL Data?

- QoL is an important treatment goal in patients with advanced ovarian
- QoL data are useful for the decision making process for clinicians and patients
- Patients can be informed about the impact of treatment on survival and QoL

My Special Thank to

EORTC Gynecological Cancer Group

Ignace Vergote (Principal Investigator)

Corneel Coens (Statistician)

Maarten Derouck (Data Manager)

An Demeester (Project Manager)

Bjorn Penninckx (Coordinating physician)