GYNECOLOGIC CANCER INTERGROUP

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

SYMPTOM BENEFIT WORKSHOP

Cervix cancer

GCIG

Chicago, Thursday, May 31, 2012

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Specificities, cervix cancer

- Younger/others gynaecological cancer pts
- Social context
  - Education, Poor income, access to health care
  - Return to work
- Familial situation

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Specificities, localized cancer

- Since 2000, chemo-radiation for stage ≥ IB bulky,
  - Cisplatin CT
  - More toxicity than radiation alone
- Localized cancer : curable disease with long term life expectancy
- But no long term QOL follow-up studies, no QOL data on long term survivors treated with Chemo-RT

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Specificities, advanced disease

- Advanced disease: poor survival
- Toxicity of different CT regimens
- QDV = main issues
  - Low benefit of CT
  - Importance to develop treatment strategies that minimize toxicity and maximize QOL
- QOL and prognostic factor?

QOL and clinical trials for advanced cancer

- Only 3 trials that have included QOL evaluations

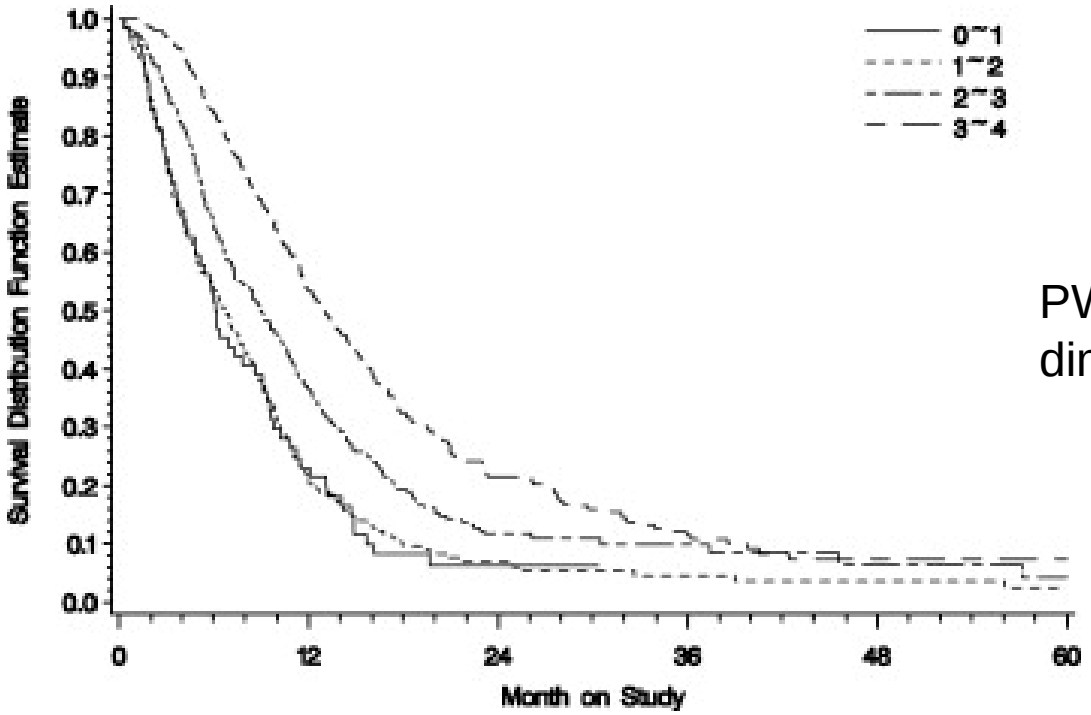
Studies	Regimens	Tools
GOG 169 (Moore, 2004)	C/C-Paclitaxel	Fact-G, Fact-CX Fact-NX, BPI
GOG 179 (Monk 2005)	C/C-Topotecan	Fact-G, Fact-Cx, Fact-NX, BPI, UNI (Before, cycles 2-5 - post 9mths)
GOG 204 (Monk& Cella 2010)	C-Paclitaxel/C Topotecan/C Gemcitabine/C Vino	Fact-G, Fact-CX Fact-NX (Before, cycles 1-2-5- post 9mths)

QOL and clinical trials for advanced cancer

- Results

Studies	Results	Remarks
GOG 169	No difference	More dropped out in C alone arm
GOG 179	No difference between groups. BaselineFact G-Cx: OS prognostic	No impact on QOL of regimen but base Fact-CX= prognostic factor
GOG 204	No difference QOL Trend to worse NX if TC regimen	Low power (55%)

Initial QDV – Survival - 3 Trials



PWB (physical) = prognostic dimension of OS

MIS : mean item score
0 to 4 (Bad to good)

Chase et al, Gyn Oncol 2012

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QDV – Limits– 3 Trials

- A priori clear QoL hypothesis is not well identified (excepted GOG 204)
- Psychosocial impact not evaluated
- No evaluation of fatigue
- Impact of the treatment on the mains symptoms non explored?

QOL– Current GCIG cervix studies (1)

Studies	Regimens	Tools
EORTC 55994	Neo-adj CT-Surgery/ ChemoRT Stage IB2,IIa,IIb	QLQ-C30, base 6-12-18 months, annually (16yrs)
Anzgog0902 /GOG0274	ChemoRT-CT/ChemoRT	QLQ-C30,C24,OV28,SVQ, Base during &end treatment
GOG263/ KGOG-0801	Surgery-RT/surgery-ChemoRT Stage I,II	Fact-G, NTX,BPI, base and periodically (max 3 yrs)
GOG 240	C-Paclitaxel or topotecan/ C-Paclitaxel or topotecan-Beva Stage IV, recurrent	Fact CX TOI, Fact NTX, BPI, base, 2&5 cycles, 6 and 9 mths after CT

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QOL– Current GCIG cervix studies (2)

Studies	Regimens	Tools
RTOG-0724	ChemoRT/ChemoRT-CT High risk early cervical C	Fact-CX,FactNtx, FactD (base,6-12-24 mths after tt)
SHAPE	Simple hysterectomy and Early cervix cancer	QLQ-C30,CX24, FSDS
NCIC-CX5	Radical hyst-node dissection/Simple hyst-node dissection Low risk early cancer	QLQ-C30,CX24, FSFI, FSDS

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QOL– Current GCIG cervix studies (3)

Studies	Regimens	Tools
MIRO CERV2	Paclitaxel-carbo+/- cetuximab Stage IV and recurrence	?
MRC/NCRI Interlace	ChemoRT/weekly CT-ChemoRT Locally advanced cancer	?
KGOG- TGCS TACO	Weekly/3 weekly ChemoRT Locally advanced cancer	?

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Discussion – Propositions from the SB group

- **Localized disease**
  - QOL of long term survivors?
    - Retrospective study from ChemoRT old trials
    - Survivorships? (i.e. other types of cancers)
  - Others considerations than treatments sequelae (psychosocial impact, ……)
  - Long term follow-up are needed (in the current studies)
- **Interventional studies**
  - (ex: educational programs) after treatment of localized cervix cancer?

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Discussion – Propositions from the SB group

- **Advanced disease**
  - PRO : main endpoint : must to be included in all trials
  - With an a-priori QOL Primary endpoint
  - Impact of treatment on symptoms?
    - Identification of symptoms (as it is done in ovarian cancer)

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