Ultra-radical surgery in Ovarian Cancer – Where’s the evidence?

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RCTs of surgery in Ovarian Cancer

- Interval debulking
- Neoadjuvant chemotherapy
- Neither studies included the role of optimal debulking as a primary or secondary endpoint hence both trials are under powered for this analysis
Evidence of effect of ultra-radical surgery

- Selected patients reported in case series
- Unclear as to what subsequent treatment these women underwent
- Cochrane review 2011
  - ‘We found only low quality evidence comparing ultra-radical and standard surgery in women with advanced ovarian cancer and carcinomatosis’…. ‘unable to reach definite conclusions about the relative benefits and adverse effects of the two types of surgery. In order to determine the role of ultra-radical surgery in the management of advanced stage ovarian cancer, a sufficiently powered randomised controlled trial comparing ultra-radical and standard surgery or well-designed non-randomised studies would be required’

- How would this surgical approach apply to an all comers situation that we have in the UK
Evidence of effect of ultra-radical surgery

• Many centres that perform this surgery report extensive pre-surgery work up
  – PET/CT
  – VATS to evaluate pleural effusions
  – Laparoscopy to assess suitability and exclude extensive disease affecting small bowel and mesentery
  – Need to undergo training of at least 10 cases with upper GI surgeons to learn how to mobilise liver etc
Evidence of effect of ultra-radical surgery

- Many centres that perform this surgery report extensive pre-surgery work up
  - Intra-hepatic lesions excised in joint procedures with hepato-biliary surgeons
  - In optimal debulked cases intra-peritoneal chemotherapy is given in US
- In UK we are performing yet another RCT in intra-peritoneal chemo to see if it works
If we are only doing more surgery why should we need to do a trial?

• ICON 8
  – Evaluation of a dose/schedule intense regimen of paclitaxol
  – JGOG trial positive so why should we bother to repeat?

• Surgery
  – Causes harm
    • Mortality
    • Morbidity
    • No different from chemo so why should we not properly evaluate it?
Areas where there is no data relating to ultra-radical surgery

- Cost effectiveness
- All NHS trusts lose money on cancer
- All NHS trusts loose even more money on exenterative type surgical procedures
- Training with upper GI surgeons
- QALYs
  - Who knows?
Areas where there is no data relating to ultra-radical surgery

- QOL
- Patient reported outcomes

- US study
  - Asked ovarian cancer patients what they would trade between side effects and improved survival
    - Permanent neuro-toxicity post chemo
    - At least 6 months increase in survival

- Patients may prioritise quality of life over survival
We are falling behind because ultra-radical surgery is now the standard of care

• US study
  – Presented at SGO

• Review of all cancer cases in California against NCCN treatment guidelines
  – 2013 guidelines do not mandate ultra-radical surgery – they may be considered
  – Under 50% of women were managed according to NCCN guidelines
Ultra-radical surgery – where do we go next?

- Case series have posed an interesting finding
- Does ultra-radical surgery
  - Improve survival in UK setting
  - Does it apply to ‘all comers’ or only selected and fully evaluated cases - is so are these biologically different?
  - Is it cost effective
  - What effect does it have on QOL
  - Do patient’s share the same enthusiasm as surgeons given above unknowns
We need a proper clinical trial, as per the Cochrane review, not introduction by default