Reviewer's report

Title: Paclitaxel and concomitant radiotherapy in high-risk endometrial cancer patients: preliminary findings.

Version: 2 Date: 6 February 2006

Reviewer: Krystyna Serkies

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General

This manuscript describes an institutional Phase I/II study involving 23 high-risk endometrial cancer patients (HR EC) irradiated postoperatively with concomitant chemotherapy consisted of weekly paclitaxel (50 mg/m2 once weekly, x 5) followed by 3 additional cycles of weekly paclitaxel (80 mg/m2).

The feasibility of this combined approach in the group of the first such 13 patients (including two treated with extended field RT) was described elsewhere (Gynecol Oncol 2001). Eleven of these 13 patients completed chemoradiotherapy.

Considering increasing role of chemoradiotherapy in both improving local control and decreasing distant failure rate in several primaries, this approach seems to be of great interest. However, some improvements of this manuscript are required. A few specific comments regarding this manuscript are listed below:

1. The manuscript focused on efficacy of chemoradiotherapy regimen. The study population is too small and heterogenous to draw the firm conclusion. Indeed, no data about therapy tolerance were included in Abstract. Thus, the alternative conclusion may be that "This small series demonstrates pelvic radiotherapy in combination with weekly paclitaxel followed by three consolidation chemotherapy cycles as an effective combined approach in HREC patients".

2. The authors include into this analysis only patients who received at least full 5 planned cycles of paclitaxel?. I suggest all patients enrolled into this institutional protocol should be analyzed (as intent-to-treat analysis).

3. Does the study group include patients analyzed in the previous manuscript?. How many patients were administered extended field irradiation?. This might influence treatment toxicity.

4. I my opinion actuarial pelvic control and survival should be calculated using the Kaplan-Meier method. These data should include Abstract section.

5. Were the patients with cancer relapse treated?. How?.

6. The combined treatment strategy is accompanied by enhanced toxic effects. In some cases the addition of chemotherapy to RT may results in increased acute toxicity necessitating an unplanned gap of RT. It will be interesting to report in details the treatment compliance. It should be clearly described how many CHT cycles- during and after RT completion, were administered in patients who relapsed. This may be of great importance as only cancer recurrence outside of the irradiated field was observed.

7. Except treatment outcome this manuscript includes information about acute toxicity which should be clearly stated in the text and in the title of Tab. 2. Toxicity scale used should be added.

8. I recommend that the authors include evaluation of late toxicity, as the median follow-up is nearly 3 years. Long-term complications of combined therapy in pelvic malignancies is still not fully determined.

9. High-risk EC patients may be treated using various methods including whole abdomen RT. I recommend that the authors discuss their results in relation to study population and therapy used by other authors in more details.
Some minor remarks:
1. The authors stated that “A total of the 157 cycles of paclitaxel were administered concomitantly with RT”. This is not true – 23 pts x 5 cycles administered during RT = 115 cycles. Similarly in the sentence “Brachytherapy was used in IIIB patients”. According to data from Tab. 1 there was only one patient (no. 18) with stage IIIB EC.
2. The units should be used in unique manner (SI scale) in all the study.
3. The first few sentences of the part Results should be in Material and Methods.
4. In the first sentence in Materials and Methods “or” should be replaced by “and”. Similarly in Introduction “anatomical-surgical” by “clinicopathological” prognostic factors.
5. The reference presented only in abstract – No.24 dose not include any important information and may be excluded.

Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No

Declaration of competing interests:

I declare that I have no competing interests