



## **CHEMO-RADIOTHERAPY PLUS HYPERTHERMIA IN LOCALLY ADVANCED CERVICAL CANCER: PRELIMINARY RESULTS OF AN INSTITUTIONAL PHASE II STUDY**

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### **Background:**

Radiotherapy given concurrently with a cisplatin-based regimen has shown a benefit in patients with locally advanced cervical cancer so becoming the new standard treatment according to EBM criteria. Addition of hyperthermia to radiotherapy has also been proved to yield an advantage in survival and local control in pts affected by recurrent and local advanced cervical cancer in the Dutch Phase III trial so that the Consensus Forum of Kadota (Osaka June 2004) included cervical cancer among tumours treatable with hyperthermia. In our institutional multidisciplinary team a pilot study has been designed in order to evaluate feasibility, outcome and toxicity of tri-modality treatment in pts with locally advanced cervical cancer in our daily practice.

### **Patients and Methods:**

Since January 2003 to now eight patients affected by cervical cancer with stage IB2 through IVA N0-N+ pelvic or paraaortic were entered the study. Six patients were treated at initial diagnosis and two patients after chemotherapy which had achieved stable disease. Treatment regimen consisted in 5 courses of weekly chemotherapy (cisplatin 40 mg/mq) with concurrent external radiotherapy to a total dose of 64-66 Gy on CTV1 and 45 Gy on para-aortic nodes plus boost in pts with enlarged nodes identified by imaging. Five weekly sessions of hyperthermia were performed by using BSD 2000 system and sigma 60 applicator.

### **Results:**

No significant toxicity occurred and all of the patients completed tri-modality treatment in accordance with the study protocol. Seven pts experienced a complete clinical remission and one patients a partial remission as defined by clinical and imaging examinations. After four months from the end of the treatment a patients with Stage IIB bulky tumour plus one pelvic positive node who was in complete remission (Clinical examination, MRI and TAC-PET three months from the end of the treatment were negative for evidence of disease) developed a bleeding recto-vaginal fistula plus central pelvic necrosis for which an anterior and posterior exenteration became necessary. The pathological findings documented disease. Patient recovered well and is now alive and free from disease.

### **Conclusions:**

Chemo-radiation plus hyperthermia in cervical cancer is feasible and well tolerated. The rate of complete clinical response observed in our study is consistent with that of other recently reported trials. Follow-up is still too short to prove the impact on disease-free and overall survival. Longer follow up and further investigation are warranted to define late toxicity incidence.