Gynaecological Oncology News

LACE - Laparoscopic Approach to Cancer of the Endometrium

Dear Colleague,

This is the "Christmas" edition of the Gynaecological Oncology News. Please feel free to download the News from my website http://www.obermair.info/publications.shtml.

With this newsletter I would like to introduce you to a randomised trial called ***LACE***, a clinical trial on **L**aparoscopic **A**pproach to **C**ancer of the **E**ndometrium, which has been opened in Brisbane, Sydney, Melbourne, Perth on 5. November 2005. All gynaecological oncologists at the QLD Centre for Gynaecological Cancer support this trial and take part in it.

What do we want to achieve with this trial? At present, in Australia and worldwide, the standard of care for endometrial cancer is a laparotomy, TAHBSO and depending on depth of invasion and grade a lymph node dissection. Compared to laparotomy, laparoscopic techniques have been shown to be associated with less postoperative pain (morphine consumption 4 mg vs. 80 mg), lower complication rates (17% vs. 47%), shorter hospital stay (2 versus 5 days) and quicker return to family and work[1]. In retrospective studies we have shown that laparoscopy did not adversely influence survival[1]. Therefore it seems appropriate to offer laparoscopic surgery to patients with endometrial cancer. However, to change the standard of care, a randomised clinical trial must show superiority of this new technique over the current standard treatment. ***LACE*** will randomly allocate patients in one of two treatment arms: TAH (Total Abdominal Hysterectomy) or TLH (Total Laparoscopic Hysterectomy). A Lymph node dissection will be done open or laparoscopic. Randomisation is essential to avoid selection bias.

Who is eligible? Patients with endometrioid cancers, clinically confined to the uterus (apparent stage 1) irrespective of histological grade will be included. All patients will need a Chest X-ray, CT scan of the pelvis and the abdomen and a serum CA125 preoperatively.

Who is ineligible? Patients with serous papillary and clear cell cancers and patients with sarcomas will not be eligible as they represent a different tumour biological behaviour. Patients with obvious spread to other organs will not be eligible for ***LACE***.

What are the endpoints? Disease-free survival will be the primary endpoint of the study. Other endpoints include quality of life, treatment-related morbidity, hospital stay, cost-effectiveness, patterns of recurrence and overall survival. We plan to enrol 600 patients over a four-year period. Gynaecological Cancer Centres in the U.K. and Europe will join in 2006 and will also enrol patients. The randomisation process and the data base are U.S. FDA compliant and will run paperless on a self constructed web-based application.

Why is this important? Since more than two thousand women are diagnosed with uterine cancer every year in Australia and the incidence is steadily rising at a rate of 1% per annum, the ***LACE*** trial will hopefully change the way we will treat patients with endometrial cancer in the future.

Participating surgeons must be specifically accredited for this trial. Prospective surgeons need to perform a minimal number of 20 documented total laparoscopic hysterectomies successfully before accreditation. This guarantees that surgeons are proficient with both, laparoscopic and open techniques to operate on patients.

Please do not hesitate to contact me to discuss specific cases on the phone (☎ 3847 3033; Page 3830 5824).

Thank you very much for your support and trust in the last year. I hope that in 2006 I will be able to look after your patients at least as well as last year. Best wishes!

Andreas Obermair

[1] Literature available on request or at http://www.obermair.info/publications.shtml#clinical