**Abstract:**

*LION – LYMPHADENECTOMY IN OVARIAN NEOPLASMS. A PROSPECTIVE RANDOMIZED AGO STUDY GROUP LED GYNECOLOGIC CANCER INTERGROUP TRIAL.*

**Aims**

There is no level-1 evidence on the role of systematic pelvic and para-aortic lymphadenectomy (LNE) in patients with advanced ovarian cancer (AOC) with macroscopic complete resection and clinically negative lymph nodes (LN) and surgical management is very heterogeneous.

**Method**

Patients with newly diagnosed AOC FIGO IIB-IV with macroscopic intraperitoneal complete resection and pre- and intra-operatively clinical negative LN were randomized intra-operatively to LNE vs no-LNE. The primary endpoint was overall survival.

**Results**

647 patients were randomized between 12/08 and 1/12 to LNE (n=323) or no-LNE (n=324). The median number of removed LN was 57 (pelvic 35 and para-aortic22). Microscopic LF metastases were diagnosed in 56% of the pts in the LNE arm. Median OS was 69 and 66 months in the no-LNE and LNE arm respectively (HR 1.06, 95%CI 0.83-1.34, p=0.65) and the median PFS was 26 months in both arms (HR 1.11, 95%CI 0.92-1.34 p=0.30). In the LNE arm a 64 minutes increased surgical duration (352 vs 288 min), higher blood loss (median 650 vs 500 ml), and a higher transfusion rate (67% vs 59%) were reported. Serious post-operative complications occurred more frequently in the LNE arm (e.g. rate of re-laparotomies 12.1% vs 5.9% [p=0.006], hospital re-admittance rate 8.0% vs 3.1% [p=0.006] and deaths within 60 days after surgery 3.1 vs 0.9% [p=0.049]).

**Conclusion**

Systematic pelvic and para-aortic LNE in patients with AOC with both intra-abdominal complete resection and clinically negative LN neither improve overall nor progression-free survival, therefore it should be omitted to reduce post-operative morbidity and mortality.

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