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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