



LATEST ONCOLOGY UPDATES

Title: Randomized Phase III Trial Comparing Retroperitoneal Lymph Node Dissection With One Course of Bleomycin and Etoposide Plus Cisplatin Chemotherapy in the Adjuvant Treatment of Clinical Stage I Nonseminomatous Testicular Germ Cell Tumors: AUO Trial AH 01/94 by the German Testicular Cancer Study Group.

Background:

- Options for stage I NSGCT include: active surveillance, retroperitoneal lymph node dissection (RPLND), or adjuvant chemotherapy (usually two cycles of BEP). The North American approach has traditionally been active surveillance with an expected relapse rate of 20-30 %. Patients who relapse and are treated appropriately should have a similar outcome to those treated upfront.

Study design:

- Randomized phase III trial
- 2 arms:
 - RPLND (n = 191)
 - BEP x 1 (n = 191)
- Primary Endpoint
 - recurrence rate
- Statistics
 - powered to detect a 7 % reduction (from 10 → 3 %) of recurrence with chemo compared to surgery.
- Median follow-up
 - 4.7 years

Study results:

	RPLND	BEP x 1	p value
N	191	191	125
Recurrences	15	2	0.0011
2 yr Relapse-Free Survival	91.87% (86.87-95.02)	99.46% (96.20-99.92)	0.0033
Grade 4 Toxicity	2.3%	2.3%	43.3%

- HR to experience a recurrence with surgery vs. chemo = 7.937 (95% CI = 1.808 – 34.48).
- Chemo recurrences: at 15 & 60 months, both salvaged.
- RPLND recurrences: all recurred within 17 months; 5 in RPLN, 2 in RPLN & mediastinal LN, 2 scrotal relapses, 4 pulmonary metastases; all salvaged.



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Conclusions:

- BEP x 1 is superior to RPLND in preventing recurrences in clinical stage I NSGCT patients in this study.
- Very high relapse rate in retroperitoneum in RPLND arm (7/13), 2 scrotal relapses. This study included community based urologists.
- This study emphasizes the importance of experienced surgeons and centres.

Study commentary:

- Large randomized trial in clinical stage I NSGCT (and there have not been many).
- BEP x 1 has a lower relapse rate than RPLND.
- Most other data with adjuvant BEP would be with 2 cycles.
- Surgical technique was obviously suboptimal. Previous results from Germany showed a 1.2 % retroperitoneal recurrence rate post RPLND.

Bottom line for Canadian medical oncologists:

- Surveillance would still be the option of choice in most stage I NSGCT patients because:
 - limits treatment & toxicity to those who need it
 - avoids over treating 70-80 % of patients
 - reduces the amount of total chemo & surgery given
 - survival will still be close to 100 %

Website link to source: www.jco.org (J Clin Oncol 2008; 26:2966-2972)