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TREATMENT OF ("BULKY") STAGE IB CERVICAL CANCER WITH OR WITHOUT NEOADJUVANT VINCRISTINE AND CISPLATIN PRIOR TO RADICAL HYSTERECTOMY AND PELVIC/PARA-AORTIC LYMPHADENECTOMY: A PHASE III TRIAL OF THE GYNAECOLOGIC ONCOLOGY GROUP

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Objective: A Randomized phase III trial was conducted to determine if neoadjuvant chemotherapy (NACT) prior to radical hysterectomy and pelvic/para-aortic lymphadenectomy (RHPPL) could improve progression-free survival (PFS) and overall survival (OS), as well as operability, with acceptable levels of toxicity. Adjuvant radiation therapy was prescribed for specific surgical/pathological risk factors for both regimens.

Methods: Eligible patients were required to have bulky FIGO stage IB cervical cancer, tumor diameter ≥4 cm, adequate bone marrow, renal and hepatic function, and performance status ≤2. Prospective random allocation was to either NACT (vincristine-cisplatin chemotherapy every 10 days for 3 cycles) before exploratory laparotomy and planned RHPPL (NACT+RHPPL), or RHPPL only.

Results: The study was closed prematurely, because of slow accrual, after 291 patients were enrolled, three were ineligible; thus 288 were eligible and randomly allocated to RHPPL (N=143) or NACT+RHPPL (N=145). There were no notable differences between regimens regarding patients' age, race, performance status, or tumour size. The median follow-up time is 62 months among living patients. The NACT+RHPPL group had very similar recurrence rates (relative risk: 0.998) and death rates (relative risk: 1.008) when compared to the RHPPL group. There were 79% that had surgery in the RHPPL group compared to 78% in the NACT RHPPL group. There were 52% who received post-operative RT in the RHPPL group compared to 45% in the NACT+RHPPL group (not statistically significant).

Conclusion: There is no evidence from this trial that NACT offered any additional objective benefit to patients undergoing RHPPL for suboptimal stage IB cervical cancer.

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