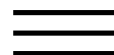


A phase III trial of surgery with or without adjunctive external pelvic radiation therapy in intermediate risk endometrial adenocarcinoma: a Gynecologic Oncology Group.

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## Gynecologic Oncology

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A phase III trial of surgery with or without adjunctive external pelvic radiation therapy in intermediate risk endometrial adenocarcinoma: a Gynecologic Oncology Group study

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### Abstract

*Background.* Despite their low risk for recurrence, many women with endometrial adenocarcinoma receive postoperative radiation therapy (RT). This study was developed to determine if adjunctive external beam irradiation lowers the risk of recurrence and death in women with endometrial cancer International Federation of Gynaecology and Obstetrics (FIGO) stages IB, IC, and II (occult disease).

*Methods.* Four hundred forty-eight consenting patients with "intermediate risk"

endometrial adenocarcinoma were randomized after surgery to either no additional therapy (NAT) or whole pelvic radiation therapy (RT). They were followed to determine toxicity, date and location of recurrence, and overall survival. A high intermediate risk (HIR) subgroup of patients was defined as those with (1) moderate to poorly differentiated tumor, presence of lymphovascular invasion, and outer third myometrial invasion; (2) age 50 or greater with any two risk factors listed above; or (3) age of at least 70 with any risk factor listed above. All other eligible participants were considered to be in a low intermediate risk (LIR) subgroup.

*Results.* Three hundred ninety-two women met all eligibility requirements (202 NAT, 190 RT). Median follow-up was 69 months. In the entire study population, there were 44 recurrences and 66 deaths (32 disease or treatment-related deaths), and the estimated 2-year cumulative incidence of recurrence (CIR) was 12% in the NAT arm and 3% in the RT arm (relative hazard (RH): 0.42;  $P = 0.007$ ). The treatment difference was particularly evident among the HIR subgroup (2-year CIR in NAT versus RT: 26% versus 6%; RH = 0.42). Overall, radiation had a substantial impact on pelvic and vaginal recurrences (18 in NAT and 3 in RT). The estimated 4-year survival was 86% in the NAT arm and 92% for the RT arm, not significantly different (RH: 0.86;  $P = 0.557$ ).

*Conclusions.* Adjunctive RT in early stage intermediate risk endometrial carcinoma decreases the risk of recurrence, but should be limited to patients whose risk factors fit a high intermediate risk definition.



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## Keywords

Uterine cancer; Endometrial adenocarcinoma; Radiation therapy; Radiation therapy for endometrial adenocarcinoma; Intermediate risk endometrial adenocarcinoma; Phase III study of radiation therapy for endometrial adenocarcinoma

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