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Gynaecology

Radiotherapy Versus Inguinofemoral Lymphadenectomy as Treatment for Vulvar Cancer Patients With Micrometastases in the Sentinel Node: Results of GROINSS-V II.

Oonk MHM, Slomovitz B, Baldwin PJW, van Doorn HC, van der Velden J, de Hullu JA, Gaarenstroom KN, Slangen BFM, Vergote I, Brännström M, van Dorst EBL, van Driel WJ, Hermans RH, Nunns D, Widschwendter M, Nugent D, Holland CM, Sharma A, DiSilvestro PA, Mannel R, Boll D, Cibula D, Covens A, Provencher D, Runnebaum IB, Luesley D, Ellis P, Duncan TJ, Tjong MY, Cruickshank DJ, Kjølhede P, Levenback CF, Bouda J, Kieser KE, Palle C, Spirtos NM, O'Malley DM, Leitao MM, Geller MA, Dhar K, Asher V, Tamussino K, Tobias DH, Borgfeldt C, Lea JS, Bailey J, Lood M, Eyjolfsdottir B, Attard-Montalto S, Tewari KS, Manchanda R, Jensen PT, Persson P, Van Le L, Putter H, de Bock GH, Monk BJ, Creutzberg CL, van der Zee AGJ.

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PURPOSE

The Groningen International Study on Sentinel nodes in Vulvar cancer (GROINSS-V)-II investigated whether inguinofemoral radiotherapy is a safe alternative to inguinofemoral lymphadenectomy (IFL) in vulvar cancer patients with a metastatic sentinel node (SN).

METHODS

GROINSS-V-II was a prospective multicenter phase-II single-arm treatment trial, including patients with early-stage vulvar cancer (diameter < 4.0 cm) without signs of lymph node involvement at imaging, who had primary surgical treatment (local excision with SN biopsy). Where the SN was involved (metastasis of any size), inguinofemoral radiotherapy was given (50 Gy). The primary end point was isolated groin recurrence rate at 24 months. Stopping rules were defined for the occurrence of groin recurrences.

RESULTS

From December 2005 until October 2016, 1,535 eligible patients were registered. The SN showed metastasis in 322 (21.0%) patients. In June 2010, with 91 SN-positive patients included, the stopping rule was activated because the isolated groin recurrence rate in this group went above our predefined threshold. Among 10 patients with an isolated groin recurrence, nine had SN metastases > 2.0 mm and/or extracapsular spread. The protocol was amended so that those with SN macrometastases (> 2.0 mm) underwent standard of care (IFL), whereas patients with SN micrometastases (\leq 2.0 mm) continued to receive inguinofemoral radiotherapy. Among 160 patients with SN micrometastases, 126 received inguinofemoral radiotherapy, with an ipsilateral isolated groin recurrence rate at two years of 1.6%. Among 162 patients with SN macrometastases, the isolated groin recurrence rate at two years was 22% in those who underwent radiotherapy, and 6.9% in those who underwent IFL ($P = .011$). Treatment-related morbidity after radiotherapy was less frequent compared with IFL.

CONCLUSION

Inguinofemoral radiotherapy is a safe alternative for IFL in patients with SN micrometastases, with minimal morbidity. For patients with SN macrometastasis, radiotherapy with a total dose of 50 Gy resulted in more isolated groin recurrences compared with IFL.