子宮内膜がんに対する膣内小線源放射線療法（Abstract #: LBA5503）

高リスクの子宮内膜がん再発予防目的の膣内小線源放射線療法は外照射療法と比較し有効性は同等で毒性は少ない

Vaginal brachytherapy is equally effective and less toxic than external beam radiation in preventing recurrence of higher-risk endometrial cancer

高リスクの子宮内膜がん再発予防目的の膣内小線源放射線療法は外照射療法と比較し有効性は同等で毒性は少ない、とAmerican Society of Clinical Oncology学会で発表された。PORTEC-2 phase IIIトライアルでは、中等度～高リスクの子宮内膜がん患者427人のうち214人を骨盤外照射療法に、213人を膣内シリンダーを用いた小線源放射線療法に無作為に割り付けた。全ての患者は両側卵管卵巣摘出術を含む子宮摘出術を施行された。3年間の追跡調査後、膣、骨盤内、および遠隔転移は小線源療法でそれぞれ0%、1.3%、および6.4%であり、外照射療法ではそれぞれ1.6%、0.7%、および6.0%であった。全生存期間（90.4%対90.8%）または無増悪生存期間（89.5%対89.1%）には有意差はなかったが、小線源療法を受けた患者の方が外照射を受けた患者よりも訴える副作用のレベルが低かった。

Full Text

The first phase III study of its kind has found that vaginal brachytherapy is as effective at preventing recurrence of higher-risk endometrial cancer as external beam radiation therapy with fewer side effects and a better quality of life, according to a presentation at the annual meeting of the American Society of Clinical Oncology.

"Based on this study, we expect that vaginal brachytherapy will be adopted as the new standard of care for patients with this type of endometrial cancer," said Remi A. Nout, MD, a resident in radiation oncology in the department of clinical oncology at Leiden University Medical Center and the study's lead author.

"This treatment is simpler and just as effective as external beam radiation, and it allows patients to have a better quality of life both during and after treatment. This new strategy will make treatment and recovery for many patients much more manageable moving forward."

For intermediate-to-high risk disease, determined by tumor grade, disease stage, and patient age, the standard treatment has been surgery followed by external beam radiation therapy. Brachytherapy is currently used in combination with external beam radiation for more advanced disease. Patients with low-risk disease are treated with surgery alone.

The PORTEC-2 study, a multicenter Dutch trial, randomized 427 patients with intermediate-to-high risk endometrial cancer into one of two arms: 214 patients received external beam pelvic radiotherapy and 213 received vaginal brachytherapy with a cylinder placed into the vagina.

All patients had previously undergone hysterectomy with bilateral oophorectomy. At three years of follow-up, rates of vaginal, pelvic, and distant relapse were 0 percent, 1.3 percent, and 6.4 percent for brachytherapy and 1.6 percent, 0.7 percent, and 6.0 percent for external beam radiotherapy.

There were no significant differences in overall survival (90.4 percent vs. 90.8 percent) or progression-free survival (89.5 percent vs. 89.1 percent).

Patients who received brachytherapy, however, reported a lower level of side effects than patients who received external beam radiotherapy. The most common side effect was diarrhea. After completion of radiotherapy, 22 percent of external beam radiotherapy patients reported moderate to severe diarrhea compared with 6 percent in the vaginal brachytherapy group. As a result, 13 percent of external beam radiotherapy patients reported moderate to severe limitation in their daily activities due to intestinal problems compared with 5 percent in the vaginal brachytherapy group.

Although these side effects gradually decreased over time, two years after treatment 6 percent of external beam radiotherapy patients still reported moderate to severe diarrhea compared with 1 percent in the vaginal brachytherapy group, which resulted in 5 percent and 2 percent moderate to severe limitation in daily activities due to intestinal problems, respectively.

Physicians reported significantly higher rates of gastrointestinal toxicity during external beam radiotherapy: 35 percent of patients had mild diarrhea or cramping and 19 percent had moderate diarrhea greater than five times a day during external beam radiation therapy, compared with 12 percent and 1 percent for brachytherapy.