

Outpatient Surgery Restores Urinary Continence

BY BRUCE K. DIXON
Chicago Bureau

CLEVELAND — Surgeons at the Cleveland Clinic have developed an outpatient procedure for creating a continent catheterizable channel to the bladder or neobladder in patients with lower urinary tract dysfunction, Dr. Raymond R. Rackley said at the annual international meeting of the Endourological Society.

"While we've made great advances in helping people with failure-to-store con-



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DR. RACKLEY

ditions, this is probably one of the first minimally invasive procedures that helps those with failure-to-empty conditions," Dr. Rackley said in an interview.

"That's the real frontier left in lower urinary pelvic reconstruction," he added.

Surgeons formed this "continent neo-urachus" by making a tube of skin from an in situ abdominal skin flap over an 18F catheter that extends from the umbilicus

to the dome of the bladder. The skin tube is placed through an opening between the braiding or crossing of the overlying rectus muscle fibers to form an external compressive continence mechanism, said Dr. Rackley, a professor of surgery at Case Western Reserve University, Cleveland.

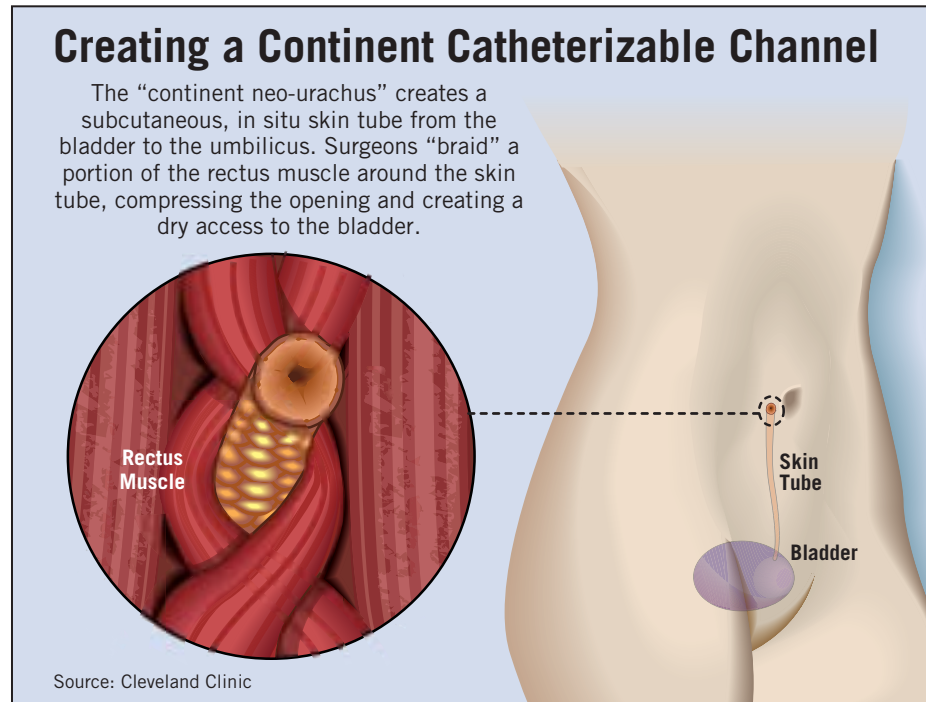
"We form a subcutaneous tunnel to the dome of the bladder and make that bladder access dry by surrounding it and compressing it with the muscles of the patient's abdomen," he said.

The abdominal skin is reapproximated, and the 18F catheter through the neostomal channel is left to heal for about 6 weeks while providing bladder drainage to a leg bag. Once the channel heals, the catheter is removed and the patient begins intermittent catheterization on a regular basis.

The surgery is all subcutaneous, unlike the traditional 8-hour procedure, in which intestines are harvested and reconstruction performed to create a continent mechanism, Dr. Rackley said. The new procedure "takes less than 1 hour under minimal sedation," he noted.

In addition to being less invasive, the procedure eliminates the need for a foreign body or chronic catheter in the bladder, thereby reducing the risk of infection.

The procedure is a good alternative for those who wish to avoid a catheter in their native urethra or who can't catheterize in



the sitting position because of a spinal cord injury or neurologic condition.

"It's also a good choice for patients who have had pelvic reconstruction and are not dry because of leaking channels," Dr. Rackley said.

The continent neo-urachus, now with 18 months of follow-up, has been successful in more than 20 patients at the Cleveland Clinic and has been performed

by urologists worldwide since its recent inception, he said.

The concept of braiding or crossing the rectus muscle for a continence mechanism may be extended to revisions of non-diversion channels that have developed incontinent catheterizable stomas due to outlet resistance pressure that is less than the bladder or neobladder filling pressure, Dr. Rackley said. ■

Postmastectomy Radiotherapy of Benefit in Node-Positive Ca

BY BRUCE WILSON
Contributing Writer

PHILADELPHIA — Radiotherapy after mastectomy decreases breast cancer-specific and overall mortality, but only for patients who are at substantial risk of local-regional failure, such as those with node-positive disease, Paul McGale, Ph.D., reported at the annual meeting of the American Society for Therapeutic Radiology and Oncology.

Moreover, if local-regional failure is not a substantial risk, postmastectomy radiotherapy can increase overall mortality, said Dr. McGale, an investigator with the Early Breast Cancer Trialists' Collaborative Group (EBCTCG) and a statistician with the Clinical Trial Service Unit, Oxford, England.

In an EBCTCG meta-analysis of 26 trials with 11,000 women who had undergone axillary clearance, radiotherapy did not reduce 15-year breast cancer-related mortality in women with no nodal involvement (pN0) and overall mortality was poorer with radiotherapy than without it. But on average, 15-year survival was improved for women with pN1-3 or pN4+ disease.

These results provide updated information to guide clinicians in their decisions about which breast cancer patients should receive radiotherapy. The 2000 National Institutes of Health consensus conference recommendations state that women with a high risk of locoregional tumor recurrence after mastectomy (those with pN4+ disease or an advanced primary tumor) would benefit from postoperative radiotherapy (www.consensus.nih.gov/2000/2000AdjuvantTherapyBreastCancer114.html.htm).

These recommendations are now supported by the EBCTCG meta-analysis.

But at that time, the role of postmastectomy radiotherapy for women with one to three positive lymph nodes was uncertain, and the EBCTCG findings reveal that they too can benefit from radiotherapy.

The EBCTCG was inaugurated in 1984-1985 with the aim of reviewing, every 5 years, the worldwide evidence on the treatment of early breast cancer through direct collaboration among the trialists. According to Dr. McGale, "systematic overviews can help limit selective biases from undue emphasis on particular studies and also help limit random errors in assessing long-term outcome." Two reports from the fourth 5-year cycle were published last year (*Lancet* 2005;365:1687-717; *Lancet* 2005;366:2087-106). The current cycle of data collection involves more than 150 trial centers with more than 300,000 women with breast cancer randomized to approximately 400 trials over the past few decades.

During the first 9 years of the meta-analysis, 5,000 women died, and from year 10 onward, 2,000 women died,

Dr. McGale said. In all trials, radiotherapy was directed at the axilla or supraclavicular fossa, and in most trials, it involved the chest wall and internal mammary chain. A total of 34% of 1,847 node-negative patients and 67% of 9,106 node-positive patients received systemic therapy.

The meta-analysis showed that at 15 years, radiotherapy had no significant effect on breast cancer mortality in women with pN0 disease; however, women with pN1-3 or pN4+ disease who received radiotherapy had lower mortality rates than those who did not. With regard to all-cause mortality, radiotherapy had a clear detrimental effect on patients with pN0 disease but significantly benefited patients with nodal involvement. (See box.)

Dr. McGale noted that overall mortality after radiotherapy is a balance of benefits and hazards. "With better radiotherapy regimens, reductions in breast cancer mortality may be more, and hazards of radiotherapy may be less. If absolute recurrence risks are lower nowadays, absolute gains from radiotherapy may be correspondingly lower," he said.

In a discussion, Dr. Abram Recht of the department of radiation oncology at Harvard Medical School, Boston, noted that although the EBCTCG meta-analysis has the typical advantages of meta-analyses (large patient numbers, reduction of publication bias), it has limited or no data on important prognostic factors, such as histopathology and hormone receptor status. Also, the efficacy and toxicity of treatments used in different trials may vary markedly, but these factors tend to be overlooked. And finally, the results do not give information about the long-term toxicity of more modern postmastectomy radiotherapy regimens, especially in combination with cardiotoxic systemic therapy, he said. ■

15-Year Mortality After Mastectomy and Axillary Clearance

Nodal status	Radiotherapy	No radiotherapy
Breast Cancer Mortality		
pN0	26.6%	26.0%
pN1-3	43.3%	50.9%
pN4+	69.5%	76.4%
All-Cause Mortality		
pN0	41.3%	37.4%
pN1-3	50.9%	56.1%
pN4+	72.8%	79.0%

Notes: All differences were significant except breast cancer mortality in women with pN0 disease. Based on a meta-analysis of 26 trials involving 10,593 patients.

Source: Dr. McGale