

Watch and Wait Protocol - Rectal cancer - Our results

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To improve local control and resectability of locally advanced rectal cancer, patients are treated with neoadjuvant therapy: radiotherapy/chemoradiotherapy or total neoadjuvant treatment followed by total mesorectal excision. About 20 to 30% of patients developed a complete pathological response after neoadjuvant treatment with the disappearance of the tumor (1, 2). The excellent oncologic outcome in patients who achieved pathologic complete response after neoadjuvant treatment questioned the need for radical surgery. Major resection surgery for rectal cancer is associated with significant morbidity, mortality, and functional impairment and can lead to temporary or permanent colostomy, compromising quality of life. Because of the negative impact of rectal cancer surgery, organ preservation strategies after the achievement of complete clinical response (cCR) to neoadjuvant therapy have developed. One of these strategies with no immediate surgery and close surveillance of patients with complete clinical response is the Watch and Wait (W&W) strategy, first described in 1998 (3).

The goal of the W&W strategy is to avoid surgical treatment of patients with cCR after neoadjuvant therapy. Tumor response to neoadjuvant therapy is time-dependent, but even if a longer time is allowed for tumors to respond, not every patient will achieve a cCR. Most tumor response after neoadjuvant therapy occurs within the first 6 weeks after RT completion. The initial evaluation of tumor response to treatment should be about 6–8 weeks after the end of neoadjuvant therapy. Careful local surveillance includes digitorectal examination, proctoscopy, and MRI. Patients with cCR after neoadjuvant therapy rarely achieves

all clinical, endoscopic, and radiological criteria for cCR at first assessment. Most patients with cCR presented all 3 strict criteria for a cCR after 16 weeks from RT completion, and very few patients required more than 6 months to achieve a cCR.

To identify a complete clinical response, a digitorectal examination confirmed a normal bowel wall without ulcer, irregularity, stenosis, or palpable tumor. On endoscopic examination, a white scar with telangiectasias and hyperemia often confirmed cCR with no ulceration or tumor. MRI is the most essential radiological examination to assess tumor response to neoadjuvant treatment. PET/CT is also important in identifying patients with complete responses. A biopsy of the tumor or scar to confirm the local regrowth is not recommended. Patients with near-complete responses frequently have negative endoscopic biopsies (4). Surveillance after achieving a cCR is for detecting local regrowth and the distant progression of the disease. Despite cCR, patients are at risk for developing distant metastases. About 30% of patients who achieve cCR will develop tumor regrowth. If a local regrowth develops, it should be detected as soon as possible when surgical salvage is still possible with radical resection. The risk for local regrowth decreased after 3 years to less than 5%. Because of this, they recommended intensive follow-up during the first 3 years every 3 months. The intensity of active surveillance in patients managed by a W&W strategy could be reduced if they achieve and maintain a cCR within the first 3 years of starting this approach (5). Proctoscopy is very important because more than 95% of local regrowth is located in the bowel wall, and only 3% of patients are dia-

gnosed with regrowth only in the regional lymph nodes (6). In patients with cCR, local regrowth at any time is a risk factor for distant metastases. Patients with local regrowth showed a 5-fold higher risk of developing distant metastases than those without local regrowth (7).

In the last 5 years, in our hospital, more than 40 patients with complete clinical response after neoadjuvant treatment had been managed by watch & wait strategy. Out of 42 patients, 10 developed local regrowth, all in the first year after the end of neoadjuvant therapy. Seven patients were successfully (R0 resection) treated with salvage surgery based on the principles of TME, one patient with local excision, and one with R1 resection elsewhere. In a group of 7 patients with cCR, distant metastases were confirmed; 5 patients developed local regrowth with distant metastases and only two distant progressions without local regrowth. Two patients, one with local regrowth and one without, died because of the distant progression of the disease.

Conclusions: Watch & Wait strategy seems safe with reasonable local control after achieving a cCR. W&W can be an excellent alternative to surgery. Selection of patients is critical, and surveillance should be done very carefully. Local regrowth is a risk factor for developing distant metastases. Our results with patients with cCR managed by W&W strategy are in accordance with other studies.

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