Preliminary Results of a Phase II Clinical Trial: Total Neoadjuvant Therapy Facilitates Organ Preservation for Patients Diagnosed with Locally Advanced Rectal Cancer

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ABSTRACT BODY:
Purpose/Background: We aim to conduct phase II clinical trial to evaluate the feasibility of achieving organ preservation in patients diagnosed with locally advanced rectal cancer (LARC) (T3, N0-1). All patients received total neoadjuvant therapy (TNT) with the goal of improving the tumor pathological response and to increase the rate of organ preservation.

Methods/Interventions: The study population consisted of eleven patients enrolled in our ongoing phase II clinical trial aiming to evaluate the utility of full-thickness local excision for patients diagnosed with LARC, whose tumors exhibited complete clinical response following TNT. Nine patients completed the planned treatment goals and their data are available for this analysis. All patients received 6 cycles of FOLFOX chemotherapy and after three weeks rest, a conventional course of chemoradiotherapy was added. The radiation therapy dose ranged between 45 and 54 Gy depending on the tumor response to the induction chemotherapy. Evaluation of the tumor clinical response was determined by the digital rectal exam, flexible sigmoidoscopy and endoscopic ultrasound examination as well as MRI. Patients with tumors deemed to be in complete clinical response underwent full-thickness local excision. Other patients underwent total mesorectal excision surgery (TME).

Results/Outcome(s): The duration between completion of radiation therapy and surgery ranged between 7-13 weeks with a median value of 8 weeks. The complete pathological response rate was achieved in 4/9 (44%). Three of nine (33%) patients had full-thickness local excision. The fourth patient had a low anterior resection surgery (LAR) as his tumor was falsely thought to have residual disease at the time of pre-surgery clinical evaluation. Two patients had undergone full-thickness local excision and were advised to undergo completion TME surgery because of the presence of microscopic residual disease. One of those patients underwent abdominoperineal resection (APR) and the other patient refused any further surgery. Three patients had undergone TME after completion of TNT (2 patients had LAR and the third patient had APR). Currently, there are two patients in the trial who achieved complete clinical response after induction chemotherapy and waiting for full-thickness local excision.

Conclusions/Discussion: This study suggests that adding only six cycles of neoadjuvant FOLFOX before CRT improved pathological downstaging of LARC and facilitated organ preservation surgery. This strategy needs to be investigated in a larger phase III trial to validate these findings.