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Is Watch and wait approach feasible for patients with complete response post neoadjuvant therapy in Low Middle Income Countries?

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Background - Neoadjuvant chemoradiation (NACTRT) followed by surgery and adjuvant systemic therapy remains the management option for locally advanced (T3-T4N+) rectal tumours.
APR remains the surgery of choice for distal rectal tumours which leads to permanent colostomy , loss of urinary and sexual functions and altered quality of life. This colostomy also leads to stigmatization of patients who are relatively young (median age 47 years) especially in the Low Middle Income Countries leading to a dropout rate or refusal for APR in more than 20% of the patients [1-2].
For patients achieving good and complete clinicoradiological response the Watch and Wait strategy was proposed by Habr-Gama and hence been implemented and reported in many studies [3-4]. However, this strategy involves strict follow up schedule and doing surgery at the time of regrowth. Can this strategy be implemented in LMIC's where the understanding of this approach and adherence to follow up schedule may be difficult. Also is it more economical compared to the patients undergoing surgery. In this study we retrospectively analyzed the outcomes of patients managed by wait and watch approach in terms of organ preservation rate, recurrence rate and survival. We also looked at the compliance and cost benefit compared to the patients undergoing surgery at our institution.
Methods and materials- Patients with rectal tumours, clinically T2-T4 N+ tumours, were included in the study. All the patients were staged with MRI pre and post 6 -8 weeks of NACRT.
All patients received NACTRT –EBRT to a dose of 45-50Gy in 1.8-2Gy/# with concurrent capecitabine.
All patients were assessed at end of radiation for response.
Twenty-two (40%) patients with near complete or complete clinical response (cCR) on DRE, escalated dose of radiation were given in form of endorectal brachytherapy mostly 8Gy/2# or EBRT 5.4Gy/3# (if DRE was painful).
Further response evaluation was done at 6th week and 12th week post treatment completion.
Patients with near complete or cCR response at 12th week were given option of immediate surgery vs wait and watch, and patients refusing surgery, after obtaining consent, were observed with 3 monthly with DRE, MRI pelvis and sigmoidoscopy.
Here we present the results of the patients attaining near complete or cCR at 12th week and kept on wait and watch.
Results- 55 patients were followed up from December 2013 to December 2019, among which 39 had cCR (71%) while 16 had nCR(29%) post NACTRT.
Majority (80%) were distal rectal tumours (0-5 cm from anal verge) and 74.5% were T3 tumours. Tweny-two (40%) of the patients received brachytherapy boost.
61.5% of patients had achieved cCR at 12th week post NACTRT and rest continued to have nCR.
At a median follow-up of 33 months, overall 11(20%) patients have local regrowth; six patients with nCR and 5 with cCR.
Out of the 11 patients who had local regrowth, seven underwent surgery (4 APR, 2 ISR and 1 LAR), 4 refused surgery and is still alive with disease. Overall compliance rate to the protocol was 92.7%.
The overall organ preservation rate was 87%.
Six (11%) patients developed distant metastasis (3 along with local regrowth and 3 without). Three patients had metastasis in liver , 2 lung and 1 leptomeningeal.
Five of 6 patients with DM underwent metastatectomy and are disease free till follow up, whereas only one patient in the entire cohort died of leptomeningeal metastasis.
The 3 year colostomy free survival, non regrowth recurrence free survival, and OAS was 92.7%,94.5% and 98%.
On performing cost benefit analysis patients on W&W approach mean cost per patient in the W&W group was 1.4 Lacs INR (1854 USD) where as it was 4.5 Lacs (5960 USD) in patients undergoing routine NACRT followed by surgery.
Conclusions- This study has shown wait and watch approach is a possible alternative management option for patients attaining cCR after NACTRT with local regrowth risk being 20% but majority of which is surgically salvageable. This leads to excellent survival with added benefit of organ preservation in majority.

It is acceptable and feasible with a good compliance and economically 3 times cost effective compared to patients undergoing surgery. This is very relevant for patients in Low Middle Income Countries where expertise is available.

References

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Country or Int. Organization

India

Affiliation

Tata Memorial Centre, Mumbai

Primary author: ENGINEER, Reena (Tata Memorial Centre, Mumbai, India)

Co-authors: Dr DESOUZA, Ashwin (Tata Memorial Centre); Prof. SAKLANI, Avanish (Tata Memorial Centre); Dr DUTTA, Debanjali (Tata Memorial Centre); Dr PATIL, Prachi (Tata Memorial Hospital); Dr ARYA, Supreeta (Tata Memorial Hospital); Dr CHOPRA, Supriya (Tata Memorial Centre)

Presenter: ENGINEER, Reena (Tata Memorial Centre, Mumbai, India)

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