CONTRIBUTION OF INTERSTITIAL NEEDLES
CONTESSA/NEOCON-F TRIAL: ASSESSING
INTERSTITIAL NEEDLES DURING IMAGE GUIDED BRACHYTHERAPY
IGBT AFTER RADIONUCLIDE CHEMOTHERAPY RCT IN THE MANAGEMENT OF LOCALLY
ADVANCED CERVICAL CANCER

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Introduction/Background Evaluate benefit with interstitial (IC/IS) IGBT in terms on dose on target volume while managing LACC, after external RCT, compared to treatment with only intracavitary (IC) IGBT.

Methodology All patients were treated with IC/IS IGBT after RCT. IC/IS IGBT was compared to IC IGBT for target volume cover (GTV, HR-CTV, IR-CTV). We evaluated overall survival, local control and toxicity with IC/IS IGBT. Local control was analysed by years of treatment to assess improvement over time.

Results From 01/2017 to 12/2020, 99 patients (p) were analysed. FIGO 2009 classification: IIA 6p, IIIB 45p, IIIB 22p, IVA 20p, IVB 6p. FIGO 2018: 24p IIIC1 and 28p IIIC2. Mean High Risk Clinical Target Volume (HRCTV) was 40 cm3 (9.6–103) with 66 (66.7%) patients presented a volume >30cc. The median Overall treatment Time (OTT) was 55 days (50 – 62). The mean D90 HR-CTV was 80,3Gy for patients treated by IC/IS, and 75,1Gy for IC (p<0.0001). A decrease of the delivered dose for all Organs at Risk (OAR) was found: D2 Bladder less than 80Gy to IC/IS in 66,7% of patients and 27,3% of patients without IS (p<0.0001); D2 Rectum is less 65Gy in 32,3% of patients with IC/IS and 17,2% of patients without (p<0.001); and D2 Sigmoid is less than 70Gy in 99% of patients with IC/IS and in 94,9% of patients without (p<0.05). The overall survival (OS) was 66,2% at 2 years, and local control (LC) was 56,5% at 2 years. Local survival improved over time, with better control in 2020 (p=0.036).

Conclusion Dose to HRCTV is higher with IC/IS IGBT compared to IC IGBT with lower doses to OAR in patients managed for LACC after RCT.

Conclusion The optimal management of FIGO 2018 stage IB2 cervical cancer patients who desire to preserve fertility is unknown. Therefore, the CONTESSA/NEOCON-F trial (NCT04016389) aims to evaluate a promising, new fertility-sparing treatment: neoadjuvant chemotherapy (NACT) followed by fertility-sparing surgery (FSS).

Methodology This trial is an ongoing, phase II clinical trial, which will accrue 90 pre-menopausal, lymph-node negative, FIGO 2018 stage IB2 cervical cancer patients, aged between 18 and 40 years and who desire to preserve their fertility. All patients will receive three cycles of paclitaxel and platinum containing chemotherapy. Following NACT the response will be evaluated by clinical examination and MRI. Patients must achieve a complete or partial response (residual lesion <2 cm) to be eligible for FSS: a conisation or simple trachelectomy. Patients with suboptimal response (residual lesion ≥2 cm) will go off-study and receive definitive treatment, radical hysterectomy or chemoradiation as per local protocol. Patients will be followed for three years following FSS. The safety of this trial will be continuously monitored using Bayesian posterior probability and the stopping rule will be activated if there is at least 70% probability that two-year recurrence rate is above 10%.

Results The primary outcome is the rate of functional uterus defined as successful FSS and no need for adjuvant therapy post procedure. Secondary outcomes include the safety of the treatment, the response rate to NACT, and the recurrence-free and overall survival after two and three years. Finally, this trial will also explore the effect of NACT on ovarian function. Translational research will explore disease monitoring in blood plasma (HPV ctDNA) and cervical scrapes (DNA hypermethylation), and patients’ quality of life will be assessed by questionnaires.

Conclusion The CONTESSA/NEOCON-F trial is opened for accrual in the Netherlands, Canada, and the United States. Currently, 10% of the target accrual has been reached.

Abstracts