PRESS RELEASE

ESMO 2024 – *Presidential Symposium*

Villejuif, 15 September 2024

RADIATION THERAPY FOR WOMEN WITH BREAST CANCER WILL NOW LAST FOR NO MORE THAN THREE WEEKS

The phase III HypoG-01 study, sponsored by Unicancer and led by Dr Sofia Rivera, a radiotherapist oncologist at Gustave Roussy, will change the global management of patients treated for breast cancer. The results, presented during a presidential session at the ESMO conference, demonstrate that a hypofractionated radiation therapy course of 15 sessions over 3 weeks is equivalent to a normofractionated radiation therapy of 25 sessions over 5 weeks for locoregional breast cancer. HypoG-01 is the first global study to demonstrate this prospectively and randomly, making the three-week course a standard of care for all women with node-invasive breast cancer.

Abstract no. 231O presented orally at a presidential session by Dr Sofia Rivera on Sunday 15 September at 4:52 pm.

Watch the video online.

Breast cancer is the most prevalent type of cancer among women, with more than 60,000 new cases diagnosed each year in France. It is the leading cause of premature death among this population. Approximately 30% of breast cancers are diagnosed at a locoregional stage, that is, they are spread to the breast and surrounding lymph nodes, and therefore more advanced. For these patients, after surgery, the standard radiation therapy course, known as normofractionated, was up to now spread over five weeks, with 25 sessions of irradiation of the breast or chest wall and lymph node area.

"Our multi-centre, randomised study was conducted in France in cancer centres, hospitals and private centres. It demonstrates real progress for patients as the treatment is shorter (3 weeks) and less burdensome but offers the same benefits as the five-week course. Our results set a new standard of radiation therapy treatment in this indication," says Dr Sofia Rivera.

A pragmatic trial for direct patient benefits

In the *HypoG-01* prospective, randomised trial, sponsored by Unicancer, 1,265 patients with locoregional breast cancer were randomly assigned to two radiation therapy courses. The trial was conducted at 29 sites in France between September 2016 and March 2020. The mean age of the participants was 58 years. Finally, patients with different breast tumour subtypes were included in the trial, such as HER2+, RH-positive, or triple-negative breast cancers. These relatively flexible inclusion criteria make this study a pragmatic trial, with conclusions that may be applicable in routine clinical practice.

Patients included in the hypofractionated course received 15 radiotherapy sessions over a period of 3 weeks, with 40 Gy delivered in total, i.e. 2.67 Gy per session. Patients included in the normofractionated course received 25 radiotherapy sessions over a period of 5 weeks, with 50 Gy delivered in total, i.e. 2 Gy per session. The primary endpoint of the study was the onset of lymphoedema, a side effect of radiotherapy leading to swelling of the arm. Secondary endpoints were locoregional relapse-free survival, relapse-free survival, and overall survival.

Stronger radiation sessions without increasing side effects

The objective of the HypoG-01 study was to demonstrate that the new course of treatment provides the same benefits as the current longer standard course and does not cause more side effects.

Results show that the frequency of onset of lymphoedema in the hypofractionated course is not higher than in the standard course and locoregional relapse-free survival, relapse-free survival, and overall survival are similar in both courses.

Previous studies had set the standard for short-term radiotherapy treatment in women with early localised breast cancer without lymph node involvement. Today, the results of the HypoG-01 study reach the same conclusion in locoregional breast cancer, which requires irradiation of the breast or chest wall and lymph nodes. *"All in all, all women with breast cancer will now be able to undergo a shorter course of radiotherapy, with numerous advantages, both for the comfort of patients and for healthcare reimbursement bodies,"*concludes Dr Rivera, adding, "*This study, which is entirely academic and funded by the French National Cancer Institute, also demonstrates that France is capable of conducting ambitious clinical trials, with direct benefits for patients".*

This study was supported by the National Cancer Institute (Inca, PHRC-K 15-146).

***Abstract* no. 231O**

Locoregional hypo vs normofractionated RT in early breast cancer: 5-year results of the HypoG-01 phase III UNICANCER trial.

Sunday, 15 September 2024 | 4:52 pm.

Background on Gustave Roussy

Ranked as the leading French and European Cancer Centre and fourth in the world, Gustave Roussy is a centre with comprehensive expertise and is devoted entirely to patients suffering with cancer. The Institute is a founding member of the Paris Saclay Cancer Cluster. It is a source of diagnostic and therapeutic advances. It caters for almost 50,000 patients per year and its approach is one that integrates research, patient care and teaching. It is specialized in the treatment of rare cancers and complex tumors and it treats all cancers in patients of any age. Its care is personalized and combines the most advanced medical methods with an appreciation of the patient's human requirements. In addition to the quality of treatment offered, the physical, psychological and social aspects of the patient's life are respected. 4,100 professionals work on its two campuses: Villejuif and Chevilly-Larue. Gustave Roussy brings together the skills, which are essential for the highest quality research in oncology: 40% of patients treated are included in clinical studies. For further information: www.gustaveroussy.fr/en, X, Facebook, LinkedIn, Instagram.

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