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Inhibitor drug improves overall survival in older radioiodine resistant thyroid cancer

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The drug lenvatinib can significantly improve overall survival rates in a group of thyroid cancer patients whose disease is resistant to standard radioiodine treatment, according to new research from the Perelman School of Medicine at the University of Pennsylvania. The study, published today in the *Journal of Clinical Oncology*, is the first to show lenvatinib has a definitive impact on overall survival (OS). Researchers found OS improves in patients older than 65 years of age and that the drug is well-tolerated.

"Due to limitations of study design, it has been hard to prove that multikinase inhibitors improve overall survival, although we have suspected it," said the study's lead author Marcia Brose, MD, PhD, an associate professor of Otorhinolaryngology and a member of Penn's Abramson Cancer Center. "These findings put that doubt to rest for the group of patients over 65 treated with lenvatinib."

Most cases of differentiated thyroid cancer (DTC) are treated with radioiodine therapy. Since the thyroid absorbs nearly all of the iodine in the human body, radioactive iodine given to a patient will concentrate in thyroid cancer cells, killing them with little effect on the rest of the body. The treatment can be curative, but about 15 percent of DTC patients have cancers that are resistant to the therapy.

Levatinib is one of two first-line therapies approved by the U.S. Food and Drug Administration for patients who are resistant to radioiodine treatment. The drug is a multi- kinase inhibitor (MKI)—meaning it

targets the specific enzymes that are required for growth in DTC.

"It was approved based on previous trials that showed it had a benefit for progression-free survival, but until now, nobody has shown it also has a benefit for overall survival," Brose said.

Brose and her team participated in the SELECT trial to study the effects of levatinib on DTC, and Brose directed the further analysis published in this report which specifically looked at OS and safety of lenvatinib in younger and older patients. Patients were divided into two groups: Those 65 or younger, and those older than 65. The median age of the younger group was 56. For the older group, it was 71. Each group contained patients on the drug and patients receiving a placebo.

Researchers found significant differences in overall survival between those on the drug and those on the placebo in the older age group. Among the older cohort, those on the placebo had an OS of 18.4 months. For patients receiving the drug, OS was not reached, but confidence intervals show the expected survival would exceed 22 months. In the younger cohort, overall survival was not reached for either group.

"There's a belief that these drugs should be withheld from older patients due to concerns about toxicity and other medical concerns, but our results show just the opposite," Brose said. "Not only do older patients benefit from these drugs, but they generally tolerate them well."

Brose says the results of this study can have an immediate impact in clinical care, and several other studies are ongoing to find new uses for lenvatinib in other types of thyroid cancer.

More information: Marcia S. Brose et al, Effect of Age on the Efficacy and Safety of Lenvatinib in Radioiodine-Refractory Differentiated Thyroid Cancer in the Phase III SELECT Trial, *Journal*

of Clinical Oncology (2017). DOI: 10.1200/JCO.2016.71.6472