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Statins and immunotherapy: togetherness makes strength. The Potential Effect of Statins on Immunotherapy for NSCLC.

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BACKGROUND

Statins are commonly used agents in primary and secondary prevention of cardiovascular disease , but recent studies suggested that they can display pleiotropic effects on several cancer-related cellular processes, such as proliferation, apoptosis, angiogenesis, and metastasis. Even though the promising molecular features, results of randomized clinical trials investigating the combinations between statins and anticancer treatments have been controversial so far. A recent meta-analysis of observational studies and randomized clinical trials suggested that statins could positively affect the risk of all-cause mortality and improve OS in lung cancer patients; conversely, no influence on PFS and overall response rate was observed. Preclinical studies suggested that these drugs could synergize with immunotherapy in the treatment of lung cancer. However, a large cohort study that could help validate these findings is still lacking in clinical practice. Given the encouraging *in vitro* and *in vivo* results of available evidence, we analyzed the data collected from 162 patients treated with immunotherapy for Non-small Cell Lung Cancer (NSCLC) in I and II line setting.

METHODS

In this observational study, we enrolled 162 Lung cancer patients who were treated at our institution between October 2015 and April 2020. All patients were candidate for immunotherapy, according to the tumor molecular profile. Descriptive statistics were used to analyze patients' baseline features. Tumor response was evaluated using RECIST version 1.1 guidelines. Uni and multivariate analysis were conducted to investigate the relationship between statin use and response to immunotherapy, using the $\chi 2$–test. Kaplan-Meier curves were used to estimate both OS and PFS in statin and non-statin users.

RESULTS

Among all 162 screened patients, 122 met the requested criteria (52 in the non-statin group, 70 in the statin group) and were included in the final analysis. Median PFS was 17,57 months in the statin group and 9,57 months in the non-statin group, with a p=<0.001. Also median OS was superior in the statin-users group, with a statistically significant difference (19,94 vs 10,94 months, p=<0.001).

CONCLUSIONS

In our study, we demonstrated a significant relationship between improved PFS and OS and statin use when compared to those achieved in non-statin users. Although interesting, this result needs to be validated with randomized clinical trials and larger cohorts.

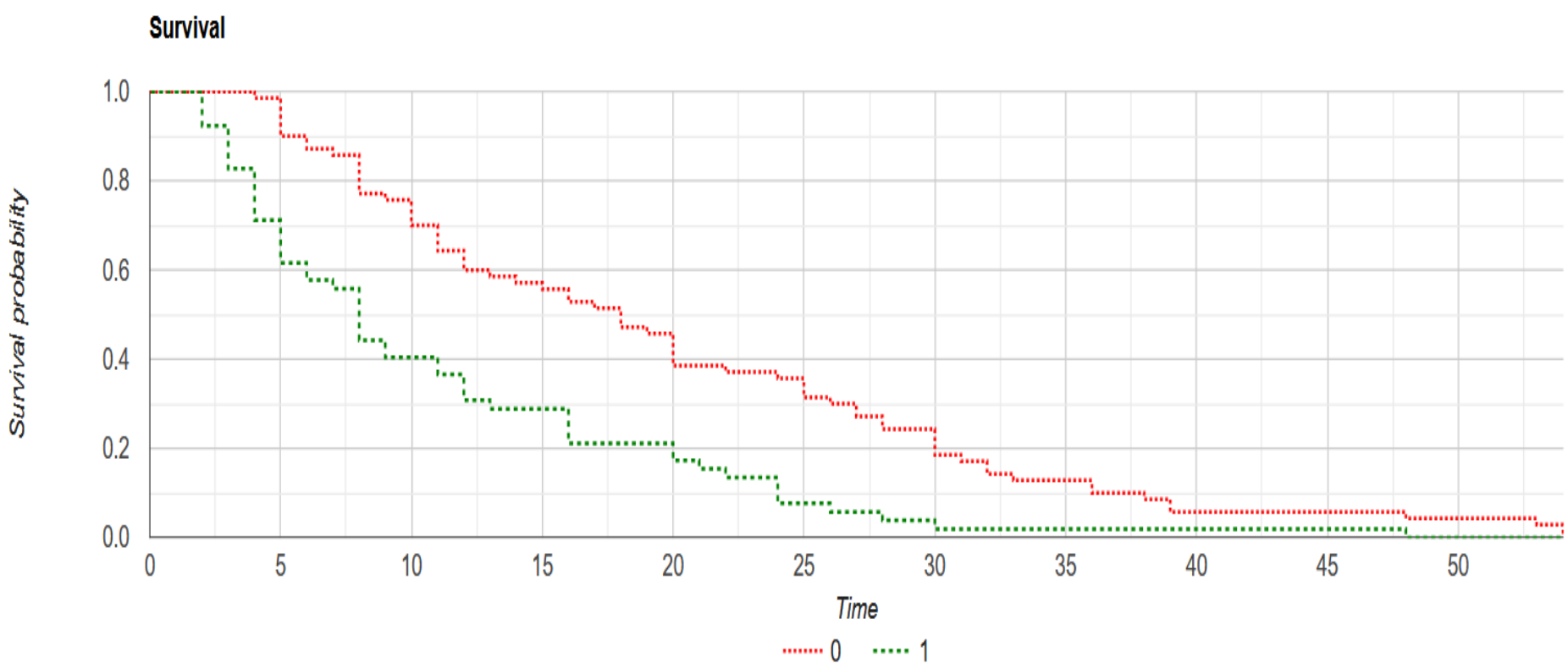

Figure 1. Overall survival, according to Investigator assessment.