

Outcomes of patients with thyroid nodules clinically tested using a combination of mutation and microRNA classification: Interim results of a clinical experience study



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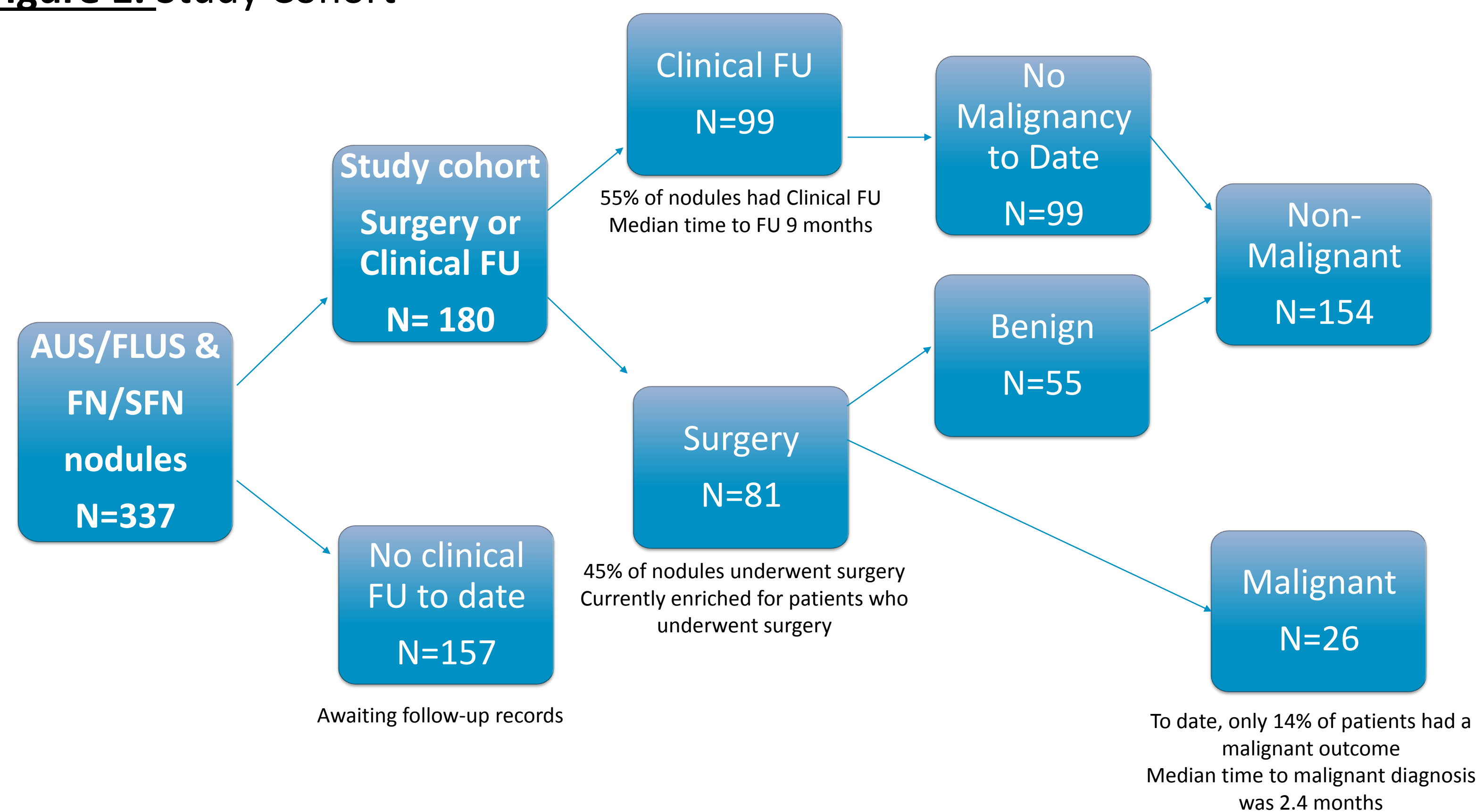
OBJECTIVE:

- We report interim results of a multicenter registry study of patients with thyroid nodules indeterminate by cytology that underwent combined mutation (ThyGenX) and microRNA (ThyraMIR) testing in clinical practice.
- We examined the likelihood at which patients avoided surgery and survived without developing malignancy given combined test results.

METHODS:

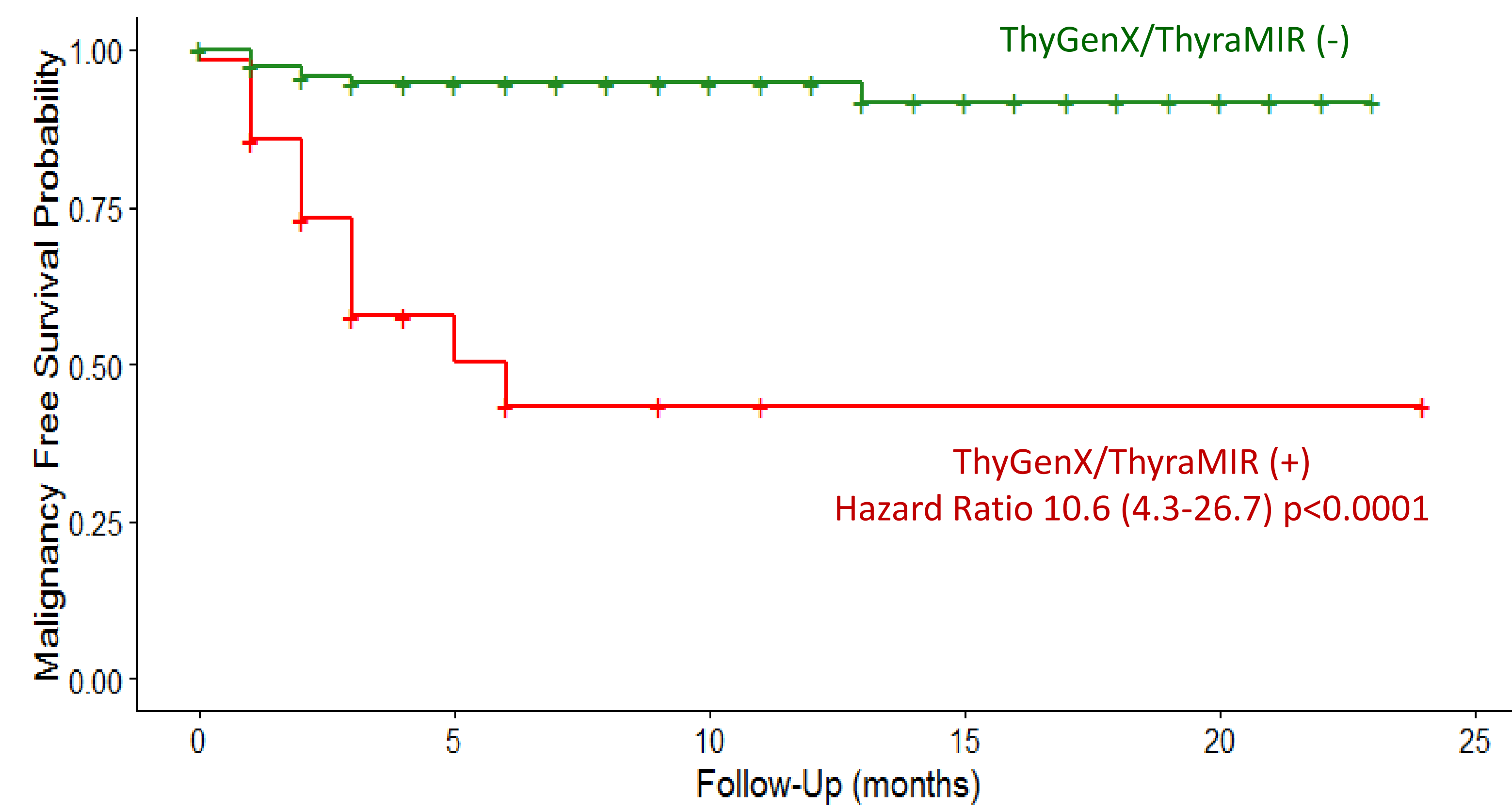
- Study included consecutive patients with B-III (AUS/FLUS) or B-IV (FN/SFN) nodules from 9 institutions that underwent past clinical testing with ThyGenX and ThyraMIR.
- Nodules had either positive or negative combined test results as previously described in the clinical validation study [1]. ThyGenX testing included common oncogenic mutations and fusion transcripts. ThyraMIR testing included expression classification of 10 microRNAs.
- Baseline clinical information at the time of ThyGenX/ThyraMIR testing and follow-up records were reviewed.
- Malignant events were defined as nodules diagnosed as carcinoma by surgical pathology and/or cytology.
- Kaplan-Meier analysis was used to determine the cumulative probability of survival without having a surgical procedure or malignant diagnosis over the course of patient follow-up.

Figure 1. Study Cohort



References: 1. Labourier, et al. doi: 10.1210/jc.2015-1158.

Figure 1. Probability that nodules remain free of malignancy based on ThyGenX and ThyraMIR combination testing

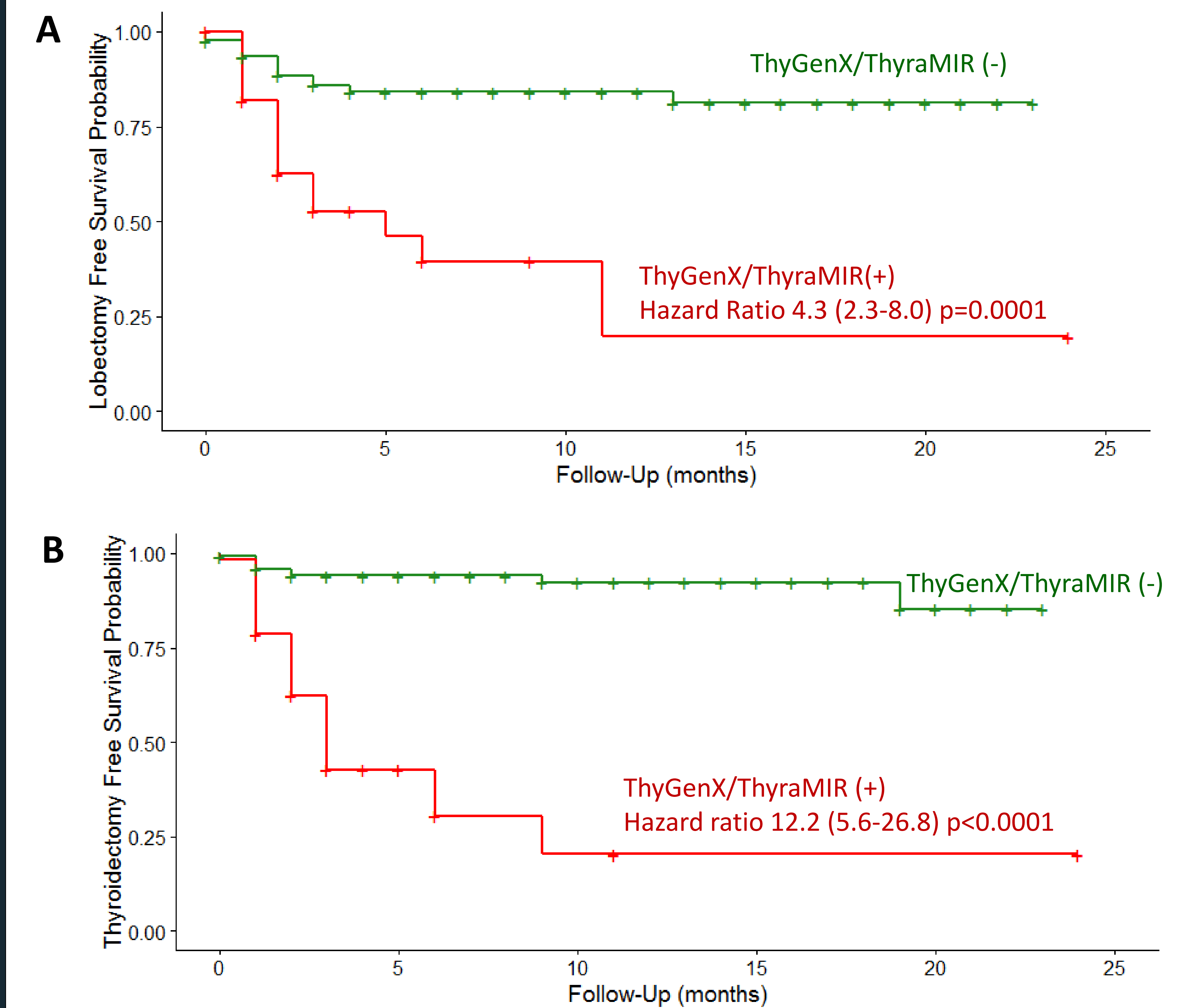


- 69% had negative ThyGenX/ThyraMIR results.
- Nodules with **negative ThyGenX/ThyraMIR** results had a low probability of developing malignancy up to 2 years follow-up.
- Comparatively, nodules with **positive ThyGenX/ThyraMIR** results were at significantly higher risk of malignancy.

CONCLUSIONS:

- The results of ThyGenX and ThyraMIR combination testing has shown a positive impact on surgical decisions of cytologically indeterminate thyroid nodules, both by helping to avoid unnecessary surgical resection and helping to target nodules in need of surgery.
- Importantly, surgical decisions made using ThyGenX and ThyraMIR combination test results were appropriately aligned with risk of malignancy over clinical follow-up, consistent with a combination test that effectively rules in and rules out higher risk of malignancy.

Figure 2. Probability that nodules did not undergo lobectomy (A) or thyroidectomy (B) based on ThyGenX and ThyraMIR combination testing



- Nodules with **negative ThyGenX/ThyraMIR** results had a low probability of undergoing lobectomy and thyroidectomy at 2 years follow-up, and this is expected to be even lower in a population of patients that is not enriched for nodules that underwent surgery.
- Comparably, nodules with **positive ThyGenX/ThyraMIR** results were at significantly higher risk of undergoing lobectomy and even more so, thyroidectomy.