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# Systematic Review of Clinical Utility and Longer-Term Follow-up of Afirma GEC Testing

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# Systematic Review of Clinical Utility and Longer-Term Follow-up of Afirma GEC Testing



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## INTRODUCTION

Medical policy coverage for novel diagnostics requires demonstration of clinical utility defined as the use of a diagnostic to change patient management and improve patient health outcome. We aimed to conduct a systematic review of published studies to measure if the Afirma GEC has reduced unnecessary surgeries among patients with indeterminate thyroid nodules.

## METHODS

A systematic literature review was conducted in PubMed through March 21, 2016 using the keyword search phrase—thyroid gene expression classifier. Studies were included that reported results for GEC benign and GEC suspicious patients. We abstracted the rates of GEC benign and GEC suspicious results, operative rates in each group, malignancies found at surgery, and median follow-up. Meta analyses were constructed of the impact of patient management using the GEC compared with historical control groups reported in these studies, and longer-term follow-up when reported.

## RESULTS

The keyword search yielded 57 results of which 40 citations were excluded for not reporting on patients managed with the GEC. Seventeen studies report on use of the GEC to manage patients in clinical practice. Thirteen report rates of GEC benign and suspicious results, three report on only GEC benign and one reports on only GEC suspicious. In the thirteen studies reporting on consecutive patients managed with GEC

testing, the number of patients tested ranged from 13 to 497. In total 1842 patients in the thirteen studies underwent GEC testing that yielded a diagnostic result. Among these patients 833 (45.2%) were GEC benign, of which 87 (10%) underwent surgery and 7 (1%) were malignant. The GEC was suspicious in 1009 (54.7%) patients, of which 756 (74.9%) underwent surgery and 243 (33%) were malignant (Table 1). Three studies compared management with the GEC to historical control groups from their institutions and reported that 900 of 1569 (61.3%) patients with indeterminate nodules proceeded to thyroid surgery. In comparison, across thirteen studies 843 of 1842 (45.8%) patients managed with the GEC proceeded to surgery, a 25.2% lower overall surgical rate than the historical control groups ( $p < 0.01$ ) (Figure 1). Follow-up of Afirma GEC benign nodules was reported in six studies on 457 patients. The median follow-up time ranged from 7-26 months, during which 393 (86%) of Afirma GEC benign patients remained unoperated (Figure 2).

## CONCLUSION

Clinical utility of the GEC to reduce unnecessary surgeries was established in thirteen published studies. Only 1% of GEC benign nodules were reported as histologically malignant, suggesting a very low false negative rate of the assay in real-world practice. Overall we found a 25.2% reduction in surgical rates among patients managed with the GEC compared to historical control groups. Studies reporting longer-term follow-up suggest that 86% of GEC benign patients remain unoperated.

FIGURE 1. Operative Rates Pre and Post Utilization of the Afirma GEC

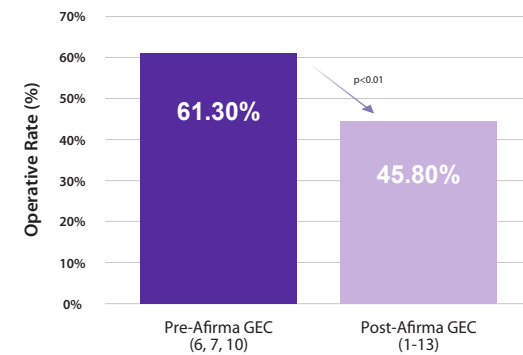


FIGURE 2. Operative Rates for Afirma GEC Benign Patients for Extended Follow-up Studies

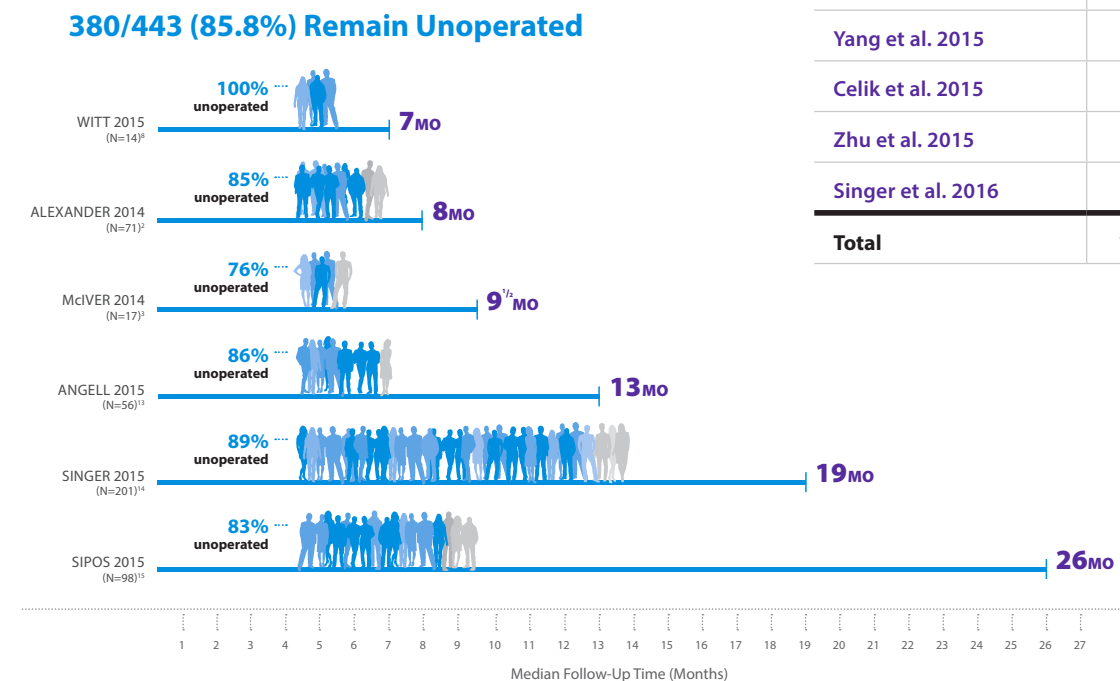


TABLE 1. Afirma GEC Results Across 13 Clinical Utility Studies

Study	Total Patients	Afirma GEC B	Afirma GEC S	% Benign
Harrell et al. 2013	56	20	36	35.7%
Alexander et al. 2014	322	174	148	54.0%
McIver et al. 2014	60	16	44	26.7%
Lastra et al. 2014	132	70	62	53.0%
Sullivan et al. 2014	13	6	7	46.2%
Brauner et al. 2015	71	26	45	36.6%
Marti et al. 2015	165	61	104	37.0%
Witt et al. 2015	29	14	15	48.3%
Wu et al. 2015	197	90	107	45.7%
Yang et al. 2015	200	93	107	46.5%
Celik et al. 2015	56	22	34	39.3%
Zhu et al. 2015	44	23	21	52.3%
Singer et al. 2016	497	218	279	43.9%
<b>Total</b>	<b>1842</b>	<b>833</b>	<b>1009</b>	<b>45.2%</b>

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