ISPOR EU 2024



Shape-Sensing Robotic-Assisted Bronchoscopy: A Meta-Analysis of Diagnostic Performance and Safety

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INTRODUCTION

Lung cancer is the leading cause of cancerrelated deaths worldwide for men and women.^[1] The number of incidentally found pulmonary nodules is increasing due to updated screening recommendations and increased utilization of chest imaging.^[2] There is an urgent need for minimally invasive biopsy techniques that can achieve high diagnostic results while maintaining a low safety risk.

OBJECTIVE

Shape-sensing robotic-assisted bronchoscopy (ssRAB) has potential to improve diagnostic accuracy and maximize yield, while ultimately shortening time to treatment and delivering better outcomes for patients. This single-arm meta-analysis investigated the diagnostic performance and safety of ssRAB.

METHODS

>A targeted search was conducted for papers published between January 2019 and December 2023.

Studies were included if they reported outcomes of interest in adults undergoing lung biopsy with ssRAB.

Studies were excluded if they reported data from cadaver or animal studies, were case reports, review articles, scientific letters, or abstracts.

>Articles were not restricted based on definition of diagnostic yield or use of adjunctive technologies.

≻A meta-analysis was conducted using R software. Pooled diagnostic outcomes and complications were estimated using the Freeman-Tukey transformation. A random effects model was used in the presence of significant heterogeneity ($I^2 > 50\%$ or p<0.05). Systematic literature reviews of alternative biopsy modalities were reviewed for an indirect comparison of results.

Table 1. Lung Nodule Characteristics

Author Year		Median Nodule Size	Upper Lobe Location	Bronchus Sign Present	
	Nodules Biopsied	(mm)	(%)	(%)	

Abia-Trujillo 2023	192	12	50%	50%
Benn 2021	59	14	66%	46%
Brownlee 2023	503	21	50%	24%
Chambers 2022	79	20	57%	56%
Fielding 2018	29	14.8	69%	59%
Hammad Altaq 2023	42	12	69%	59%
Kalchiem-Dekel 2021	159	18	59%	63%
Low 2022	143	17	43%	40%
Meng 2023	52	21	65%	42%
Oberg 2022	120	22	53%	48%
Reisenauer 2022	30	17.5	60%	40%
Stryvoky 2023 [A]	269	18.4	58%	59%
Styrvoky 2022 [B]	209	19	60%	60%
Vu 2022	105	20	54%	25%
Xie 2022	30	16.9	67%	77%
Yu Lee-Mateus 2022	113	18	63%	NR

RESULTS

Search identified 16 publications reporting diagnostic and safety outcomes for ssRAB ►Data was available from 1931 patients and 2134 nodules

➢Median nodule size ranged from 12 mm - 22 mm with most nodules located in the upper lobes.

RESULTS CONT.

Single-arm Meta-Analysis of ssRAB

Pooled diagnostic yield across all studies was 86% (95%) CI; 84-88), $(I^2 = 44\%)$.

Figure 1: Detailed Forest-plot for Diagnostic Yield

Study	Events To	otal	Proportion	95%-CI	Weight
Abia-Trujillo		92		[0.80; 0.90]	8.7%
Benn	51	59		[0.75; 0.94]	4.4%
Brownlee	442 5	503	 0.88	[0.85; 0.91]	11.7%

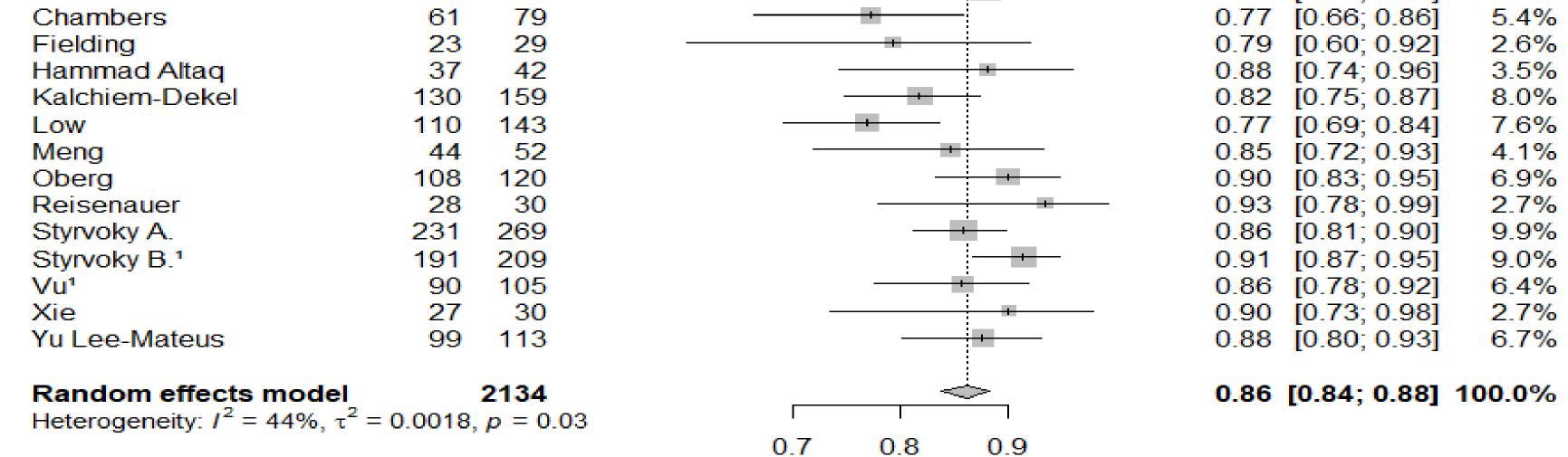
- Pooled sensitivity was 86% (95% CI; 82-89), (I²=61%).
- The overall rate of pneumothorax across studies was 2.2% (95% CI; 1.5-2.9), (I²=0%).
- The rate of pneumothorax requiring intervention was 1% $(95\% \text{ CI}; 0.5-1.6), (I^2=0\%).$
- Bleeding events occurred in less than 0.01% of patients, $(|^2=0\%).$

Indirect Comparison with CT-Guided Transthoracic **Needle Biopsy (TTNA)**

- A recent meta-analysis found TTNA had a pooled diagnostic accuracy between 85% and 90%, with average nodule sizes >30mm.^[3]
- The same meta-analysis found a 23% to 28.9% rate of pneumothorax and a 17.3% to 20.1% rate of bleeding events.^[3]

Indirect Comparison with Electromagnetic Navigation **Bronchoscopy (ENB)**

A recent meta-analysis of ENB reported a pooled diagnostic yield of 70.3%, with average nodule sizes >20mm.^[4]



Styrvoky B. and Vu reported values as diagnostic accuracy

Figure 2: Detailed Forest-plot for Pneumothorax Requiring Intervention

Study	Events	Total	Propor	tion	95%-CI	Weight
Abia-Trujillo	2	173	0	.012	[0.001; 0.041]	8.9%
Benn	1	52		.019	- · ·	2.7%
Brownlee	7	415	0	.017	[0.007; 0.034]	21.4%
Chambers	1	75		.013		3.9%
Fielding	0	29	• 0	.000	[0.000; 0.119]	1.5%
Hammad Altaq	0	42	• 0	.000	0.000; 0.084]	2.2%
Kalchiem-Dekel	2	131	0	.015	[0.002; 0.054]	6.8%
Low	2	133	0	.015	[0.002; 0.053]	6.9%
Meng	0	50	• 0	.000	[0.000; 0.071]	2.6%
Oberg	3	112	0	.027	[0.006; 0.076]	5.8%
Reisenauer	0	30	• 0	.000	[0.000; 0.116]	1.6%
Styrvoky A.	5	241	0	.021	[0.007; 0.048]	12.5%
Styrvoky B.	1	200	0	.005	[0.000; 0.028]	10.3%
Vu	0	105	• • • • • • • • • • • • • • • • • • • •	.000	[0.000; 0.035]	5.4%
Xie	0	30	• 0	.000	[0.000; 0.116]	1.6%
Yu Lee-Mateus	4	113	• 0	.035	[0.010; 0.088]	5.9%
Fixed effects model Heterogeneity: / ² = 0%		1931 = 0.81	0 0.02 0.04 0.06 0.08 0.1	.010	[0.005; 0.016]	100.0%

The same meta-analysis found complication rates of 3.4% for pneumothorax and 1.9% bleeding rate.^[4]

CONCLUSION

- \succ ssRAB presents a safe and effective advancement in navigation bronchoscopy.
- >The pooled results for ssRAB show a higher diagnostic yield than reported values for traditional bronchoscopic techniques and may be comparable to TTNA.
- >These results also demonstrate significant benefit in terms of safety when compared to TTNA, and a comparable safety profile to ENB.



