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肺癌多基因變異檢查方法學比較

AmoyDx Pan Lung cancer Panel (PLC) vs 次世代定序 (NGS)

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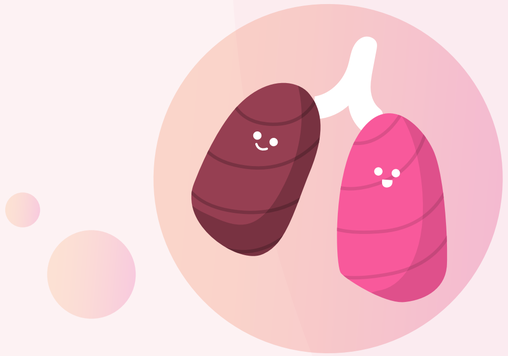
LC-Scrum-Asia爲一日本發起的亞洲大規模肺癌基因研究，LC-Scrum大規模採用AmoyDx Pan Lung cancer試劑做爲肺癌基因檢測一線篩檢，至今已有數萬名受試者採用，高成功率以及與NGS高度一致之結果相當值得信賴。



晚期非小細胞肺癌 (NSCLC) 進行標靶藥物的治療需要確認基因突變的位點，使用次世代定序 (NGS) 確認突變位點對於患者精準用藥有幫助，然而NGS檢測對於樣本需求要求高，肺癌期刊 Lung cancer 近期發表使用AmoyDx Pan Lung cancer試劑對肺癌患者進行基因變異和突變的檢測，比較了AmoyDx和NGS檢測的成功率、檢測率、結果一致性和報告完成時間等數據。

結果顯示

AmoyDx Pan Lung cancer試劑具有高成功率、高檢測率、報告完成時間短和較高的突變檢測能力。該研究還發現，在NGS檢測失敗的樣本中，AmoyDx Pan Lung cancer試劑仍然可以成功獲得檢測結果。

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Clinical application of the AMOY 9-in-1 panel to lung cancer patients

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發表文章使用PCR-base試劑AmoyDx Pan Lung cancer Panel，涵蓋11個用藥相關基因，共167個DNA mutation和RNA fusion基因變異位點。NGS-base 試劑以Oncomine Comprehensive Assay v3 (OCA) 和Oncomine Precision Assay (OPA) 進行試驗。

本試驗共收錄406個樣本進行檢測，樣本類型來自支氣管鏡組織(39.7%)、支氣管鏡淋巴結穿刺(23.4%)、手術切片樣本 (22.7%)、的胸腔積液樣本(8.6%)和CT或超音波引導下穿刺的樣本(5.7%)。

其中11個樣本只進行AmoyDx檢測，6個樣本在AmoyDx和NGS檢測中皆失敗，42個樣本在AmoyDx檢測成功但在NGS檢測失敗。347樣本在AmoyDx和NGS檢測皆分析成功。AmoyDx檢測成功率爲98.5%，NGS檢測的成功率爲87.8%。

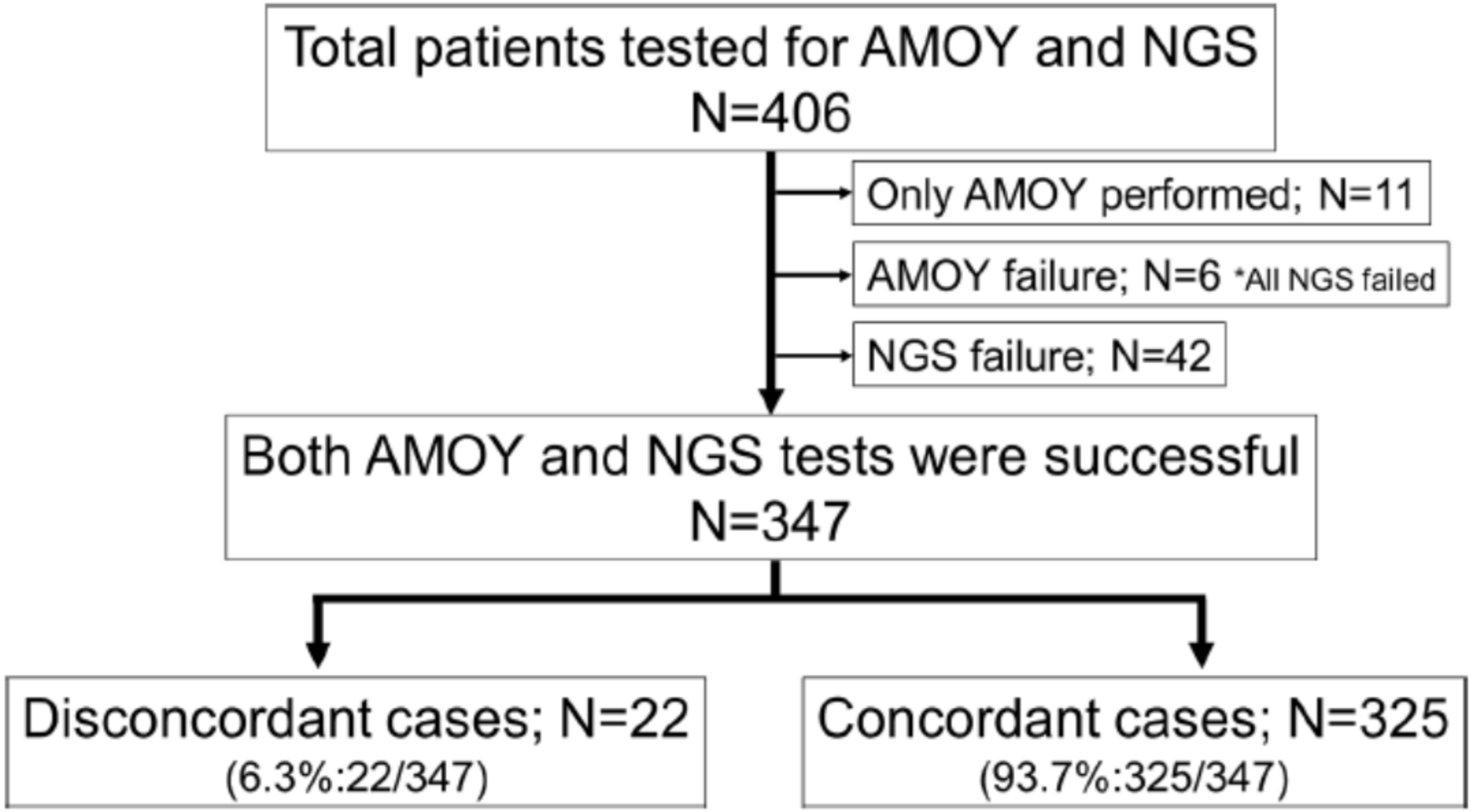

Fig. 1. Patient flow chart Flow chart of the 406 patients who were analyzed by the AMOY panel.

此試驗樣本中AmoyDx和NGS可偵測基因變異比例檢測率分別爲54.9%和50.5%。詳細的基因變異分布如下圖。

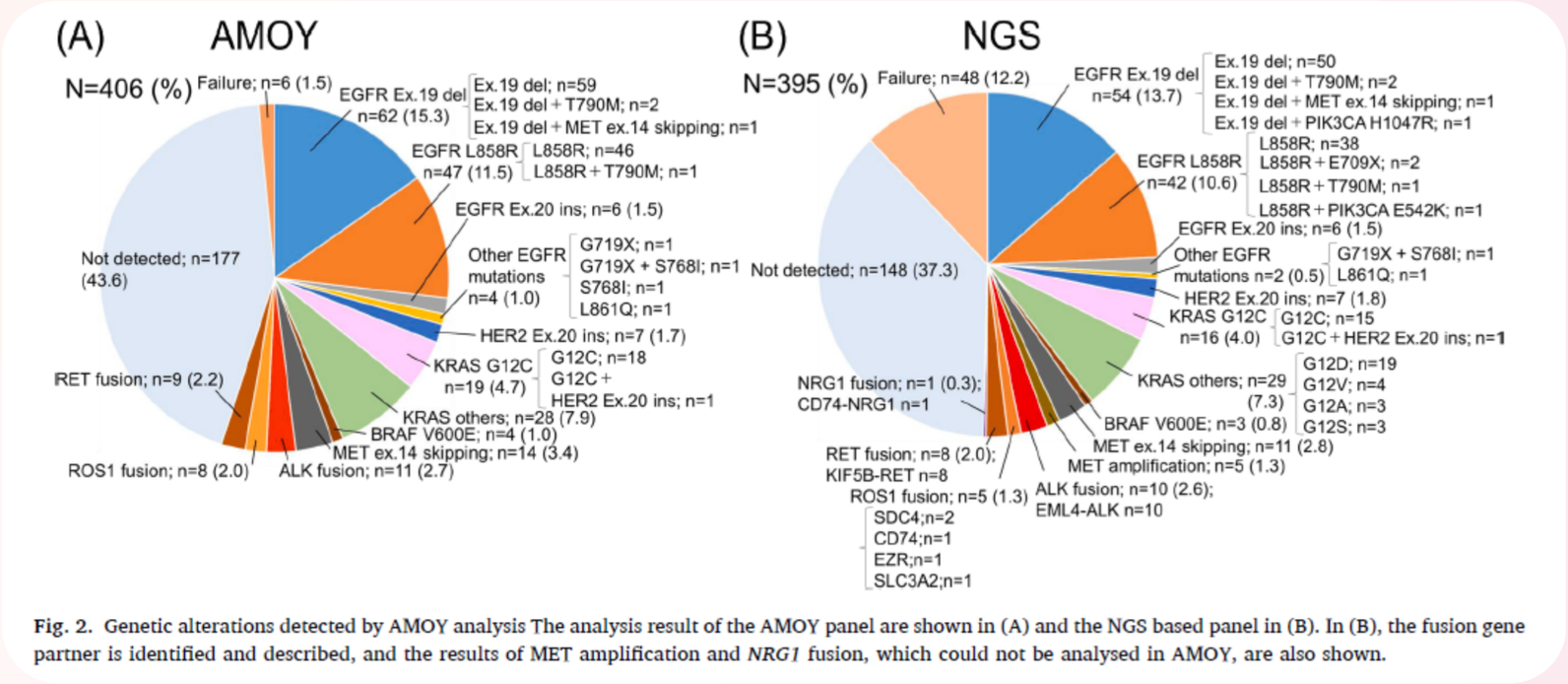

Fig. 2. Genetic alterations detected by AMOY analysis The analysis result of the AMOY panel are shown in (A) and the NGS based panel in (B). In (B), the fusion gene partner is identified and described, and the results of MET amplification and *NRG1* fusion, which could not be analysed in AMOY, are also shown.

兩種檢測平台皆分析成功的347個樣本中，結果一致性比例爲93.7%，22個樣本結果存在差異，其中4個樣本於NGS檢測到的變異位點在AmoyDx試劑沒有引子設計可偵測，另外6個肋膜積液樣本中，有5個樣本是AmoyDx 檢測成功但在NGS檢測失敗。

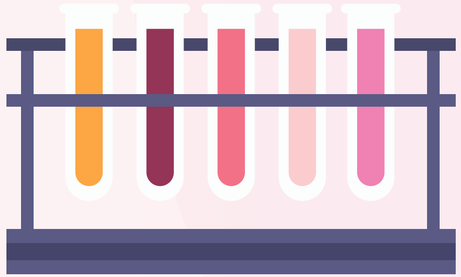

Table 2
Caseswith disconcordant results between AMOY and NGS.

Case	Age	Sex	Histology	Sampling	NGS	AMOY	Other method	Targeted treatment	Progression Free Survival
NGS detected variants not covered by AMOY									
1	77	F	Ad	Surgical	EGFR E709_T710delinsD	(-)		Afatinib	12 months(N.R.)
2	72	F	Ad	TBB	EGFR L858R + E709G	EGFR L858R		Osimertinib	12 months(N.R.)
3	69	M	Ad	Surgical	EGFR L858R + E709K	EGFR L858R		Osimertinib	11 months(N.R.)
4	79	F	Ad	TBB	EGFR A763 _ Y764insFQEA	(-)		NA	NA
Other disconcordant cases									
5	56	M	Ad	CTGB	(-)	ROS1 fusion		NA	NA
6	38	F	Ad	TBB	(-)	EGFR Ex19del	CobasRT-PCR	Osimertinib	2 months
7	78	F	Ad	TBB	KRAS G12D	(-)		NA	NA
8	70	F	Ad	Surgical	EZR-ROS1	(-)	OncomineDx	NA	NA
9	47	M	Ad	TBB	EML4-ALK	(-)	IHC (+)	NA	NA
10	69	F	Ad	Surgical	KRAS G12D	(-)		NA	NA
11	70	F	Ad	TBB	KRAS G12D	(-)		NA	NA
12	74	F	Ad	Surgical	(-)	KRAS Others		NA	NA
13	81	M	Ad	Pleural effusion	(-)	KRAS G12C		NA	NA
14	64	M	Ad	TBB	(-)	BRAF V600E	OncomineDx	Dabrafenib+ Trametinib	13 months(N.R.)
15	73	M	Ad	TBB	BRAF D594N	EGFR S768I		NA	NA
16	74	F	Ad	Pleural effusion	(-)	EGFR Ex.19 del	CobasRT-PCR	Osimertinib	12 months(N.R.)
17	73	M	Ad	TBB	ERBB2 Ex.20 ins (Y772_A775dup)	ERBB2 ex.20 ins + KRAS G12C		NA	NA
18	70	F	Ad	Pleural effusion	EML4-ALK + MET ex.14 skipping	ALK fusion	IHC (+)	Lorlatinib	6 months(N.R.)
19	85	F	Ad	TBB	(-)	KRAS Others		NA	NA
20	73	M	Ad	Pleural effusion	(-)	KRAS G12C		Sotorasib	4 months(N.R.)
21	72	M	Ad	Pleural effusion	(-)	EGFR L858R		EGFR-TKI	5 months(N.R.)
22	80	F	Ad	Pleural effusion	(-)	EGFR L858R		EGFR-TKI	4 months(N.R.)

在此篇研究中 AmoyDx Pan Lung cancer 試劑報告完成時間平均爲5天，NGS試劑報告完成時間平均爲14天(OPA)和22天(OCA)，AmoyDx 顯著性縮短報告完成時間。