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Segmentectomy versus lobectomy in small-sized peripheral non-small cell lung cancer (JCOG0802/WJOG4607L): A multicenter, open-label, phase 3, randomized controlled, non-inferiority trial

Hisashi Saji, M.D.[1], Morihito Okada, M.D.[2], Masahiro Tsuboi, M.D.[3], Ryu Nakajima, M.D.[4], Kenji Suzuki, M.D.[5], Keiju Aokage, M.D.[3], Tadashi Aoki, M.D.[6], Jiro Okami, M.D.[7], Ichiro Yoshino, M.D.[8], Hiroyuki Ito, M.D.[9], Norihito Okumura, M.D.[10], Masafumi Yamaguchi, M.D.[11], Norihiko Ikeda, M.D.[12], Masashi Wakabayashi, M.Sc.[13], Kenichi Nakamura, M.D.[13], Haruhiko Fukuda, M.D.[13], Shinichiro Nakamura, M.D.[14], Tetsuya Mitsudomi, M.D.[15], Shun-ichi Watanabe, M.D.[16], Hisao Asamura, M.D.[17] on behalf of the West Japan Oncology Group and Japan Clinical Oncology Group

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COI Disclosure in 2022

HISASHI SAJI, MD, PhD

In connection with the presentation, I disclose COI with the following companies/organizations:

Category	No	Yes	If yes, give names of authors and entities.
1. Employment/Leadership position/Advisory role	✔		
2. Stock ownership	✔		
3. Patent royalties/licensing fees	✔		
4. Honoraria (e.g., lecture fees)		✔	MSD, Boehringer Ingelheim, ETHICON, Covidien, Chugai-pharm, Astellas Pharma, FUJIFILM Medical, Bristol-Myers Squibb, Takeda Pharmaceutical Company Limited, Japan Blood Products Organization
5. Fees for promotional materials (e.g., manuscript fee)	✔		
6. Research funding		✔	Teijin, Chugai-pharm, TAIHO, Boehringer Ingelheim, Lilly, ETHICON, Covidien
7. Others	✔		

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Road to THE LANCET

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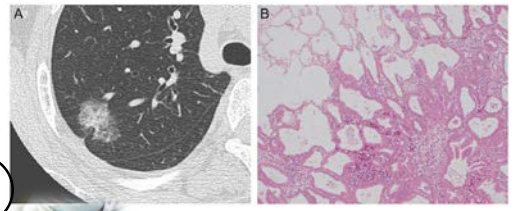
Road to *THE LANCET; JCOG0802/WJOG4607L*

Lung Cancer Study Group (LCSG821). *The Annals of Thoracic Surgery* 1995

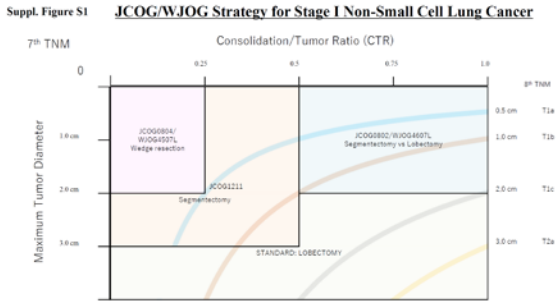
1990s



Noguchi M, et al. Small adenocarcinoma of the lung. Histologic characteristics and prognosis. **Cancer. 1995**

①

2002.Dec.1～2005.May.21: JCOG0201



2009.Aug.10～2014.Oct.21: JCOG0802/WJOG4607L

2009.May.6～2011.Apr.26: JCOG0804

2013.Sep.20～2015.Nov.13: JCOG1211

	イベント数	検出力
2018年10月	105例	71.8%
2019年10月	1254例（＋20例）	78.2%
2020年4月	134例（＋30例）	<80%
2020年9月	144例（＋40例）	83～5%

②

2019.Oct. Final analysis postponed 1 year due to small event.

2020.Oct.1 Final report opened： **Superiority on OS!!!**

③

2021.May.2 **AATS2021 Plenary**

2021.May.21 **1st Try to *NEJM***

2021.Jun.15 **Reject…**

2021.Sep.6 **2nd Try to *THE LANCET***

Sep.24 **Revise, Oct.1 R1, Oct.11 R2, Oct.14 R3. Oct.15 Accept!**

Lancet. 2022 Apr 23;399(10335):1607-1617.

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Key results

Briefly・・・

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Study scheme of JCOG0802/WJOG4607L

Key patient inclusion criteria

- Clinical stage IA peripheral NSCLC or suspected nodule
- Maximum tumor diameter ≤2 cm
- C/T ratio (CTR) >0.5

First registration

Intraoperative confirmation of eligibility

Second (final) registration/ Intraoperative randomization

Adjusted for
- Histology
- Gender
- Age
- CTR=1.0 or not
- Institution

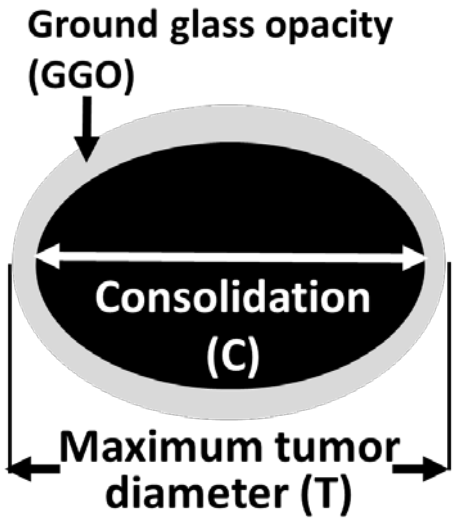
Arm A: Lobectomy N=554

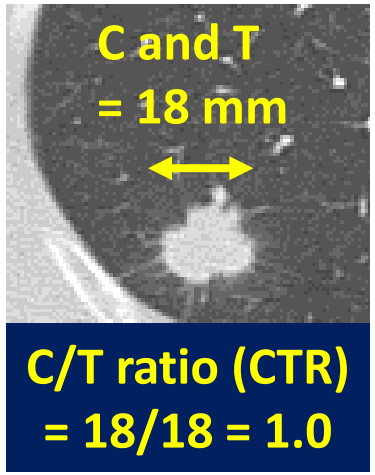
Arm B: Segmentectomy N=552

Primary endpoint
- Overall survival (OS)

Secondary endpoints
- Postoperative respiratory function (6M, 1Y)
- Relapse-free survival (RFS)
- Proportion of local recurrence
- *Adverse events, etc.

Sample size: N=1100
- 5-yr OS of Lob & Seg: 90%
- Non-inferiority margin of HR: 1.54 (5-yr OS of 5%)
- Power: 80%
- One-sided type I error: 0.05
- Accrual period: 3 years
- Follow-up period: 5 years



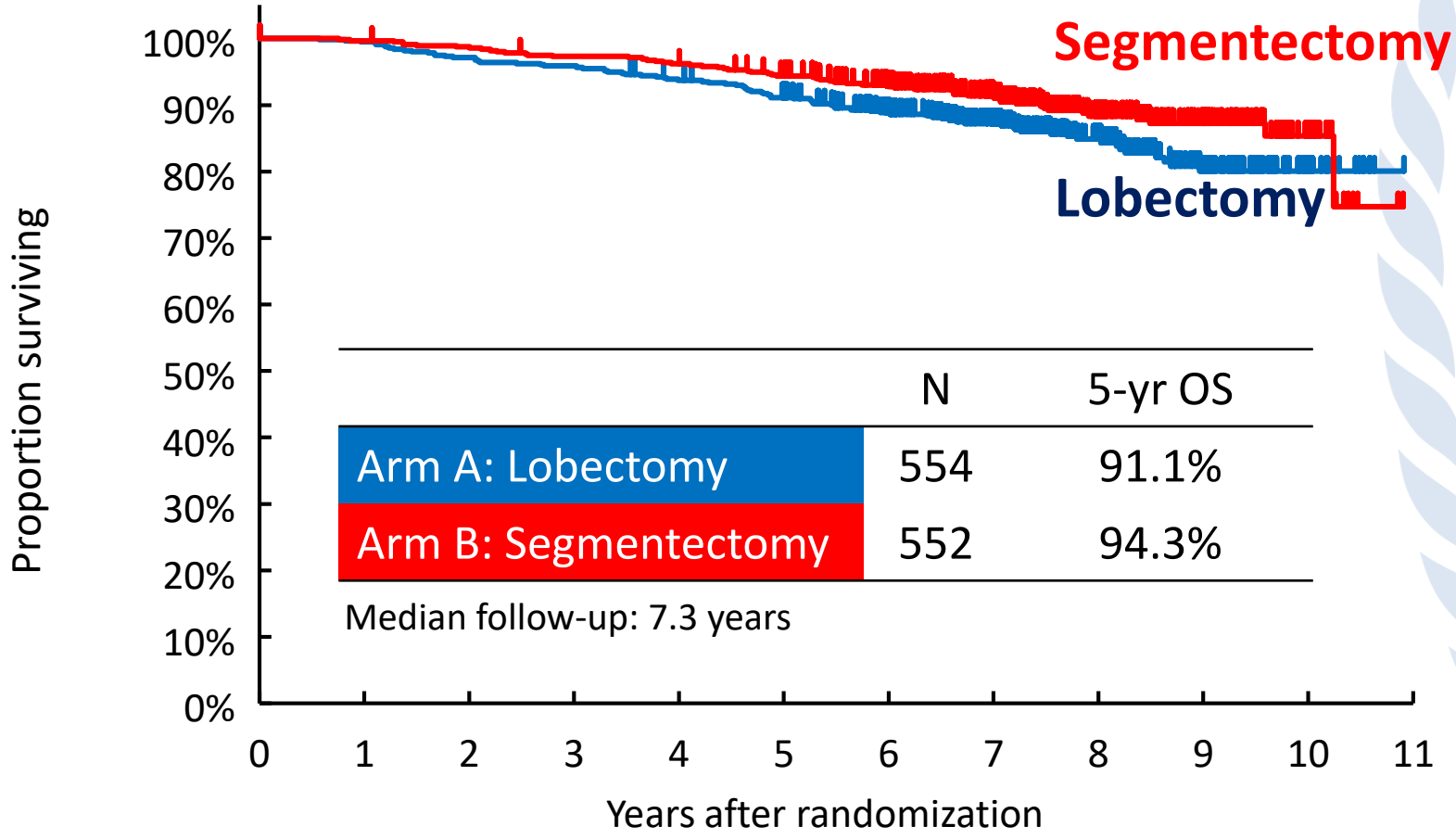


Baseline evaluation after thoracotomy and before second registration (intraoperative)

1) Pleural dissemination
2) Malignant pleural effusion
3) Possibility of lobectomy and segmentectomy
4) Pleural adhesion level
5) Macroscopically nodal involvement (intraoperative frozen section analysis needed when macroscopically nodal involvement suspected) 58% cases checked in both arm

*Details of adverse events previously reported in J Thorac Cardiovasc Surg 2020

Result 1. Overall survival (primary endpoint)



No. at Risk

Lobectomy	554	550	537	530	515	495	426	322	190	90	23	0
Segmentectomy	552	549	543	534	528	512	457	332	202	104	25	0

HR: 0.663

95% CI: 0.474–0.927

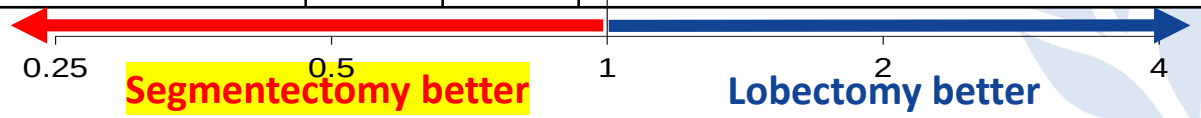
one-sided

P <0.0001 for non-inferiority

P = 0.0082 for superiority

Result 2. Predefined subgroup analyses of OS

Subgroup	N (Seg / Lob)	Hazard Ratio for Overall Survival (95% CI) by stratified Cox regression model
Overall		
All randomized patients	1106 (552/554)	0.663 (0.474-0.927)
Sex		
Male	583 (290/293)	0.622 (0.415-0.930)
Female	523 (262/261)	0.816 (0.444-1.498)
Age		
≥70	422 (341/343)	0.642 (0.413-0.998)
<70	684 (211/211)	0.723 (0.431-1.212)
Smoking status		
Smoker	616 (308/308)	0.699 (0.472-1.036)
Never smoker	490 (244/246)	0.617 (0.324-1.177)
Tumor location		
Right upper lobe	327 (167/160)	0.645 (0.310-1.339)
Right lower lobe	260 (117/143)	0.642 (0.307-1.340)
Left upper lobe	350 (187/163)	0.604 (0.361-1.013)
Left lower lobe	169 (81/88)	0.955 (0.405-2.251)
CTR		
Solid	553 (279/274)	0.641 (0.424-0.969)
Non-solid	553 (273/280)	0.733 (0.413-1.301)
Histological type		
Adenocarcinoma	968 (485/483)	0.746 (0.504-1.104)
Non-adenocarcinoma	138 (69/69)	0.505 (0.263-0.973)



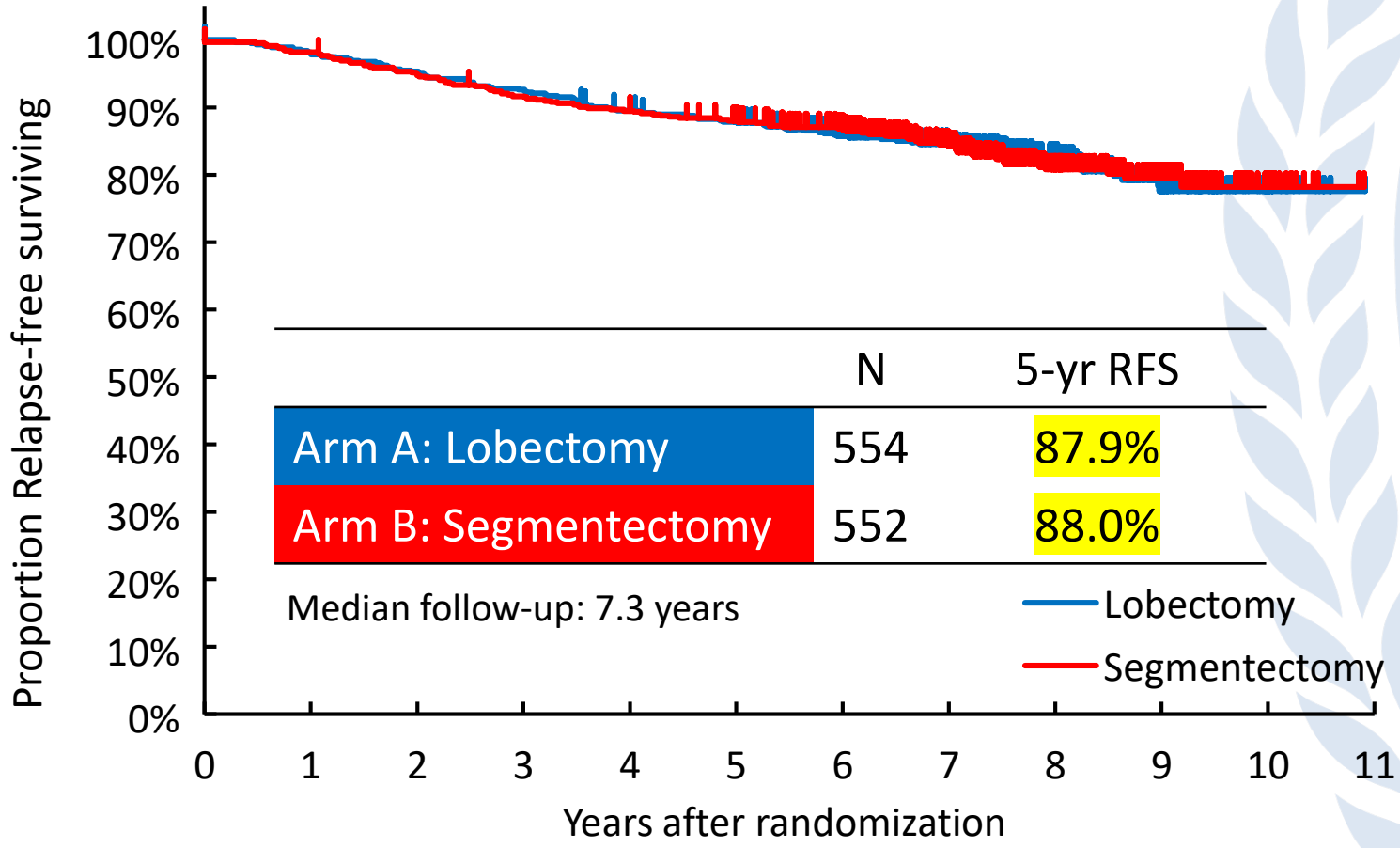
Result 3.
Postoperative respiratory function (key secondary endpoint)

FEV1.0 (mL)	Arm A: Lobectomy (N=554)	Arm B: Segmentectomy (N=552)	Difference	P value*
Post-op 6M	N=454	N=492		
Median	−13.1%	−10.4%	2.7%	<0.0001
Range	−63.8% to 53.5%	−48.6% to 27.9%		
Post-op 1Y	N=526	N=528		
Median	−12.0%	−8.5%	**3.5%**	<0.0001
Range	−57.1% to 49.6%	−37.0% to 30.0%		

Difference at post-op 1Y was smaller than expected criteria (10%).

FEV1.0, forced expiratory volume in 1.0 s.
*Wilcoxon's rank sum test p-value

Result 4. Relapse-free survival (RFS)



HR: 0.998
95% CI: 0.753–1.323
P = 0.9889

No. at Risk

Lobectomy	554	542	527	512	492	477	409	310	184	85	22	0
Segmentectomy	552	541	521	503	491	477	426	304	181	89	21	0

Result 5. Recurrence pattern

- **Proportion of local recurrence = loco-regional +/- distant recurrence among all enrolled patients.**

Recurrence location	Arm A: Lobectomy (N=554)	Arm B: Segmentectomy (N=552)	P value*
Total	44 (7.9%)	67 (12.1%)	0.0214
Loco-regional	17 (3.1%)	38 (6.9%)	
Distant	14 (2.5%)	7 (1.3%)	
Loco-regional + distant	13 (2.3%)	20 (3.6%)	
Unclassified	0	2	
Proportion of local recurrence	30 (5.4%)	58 (10.5%)	0.0018

*Fisher's exact test

Discussion. Causes of death

Causes of death	Arm A: Lobectomy (N=554)		Arm B: Segmentectomy (N=552)
Overall death	83 (14.9%)	>	58 (10.5%)
Lung cancer death	28 (5.1%)	=	26 (4.7%)
Other death	52 (9.4%)	>	27 (4.9%)
Other cancer including second lung cancer	31 (5.6%)	>	12 (2.2%)
Non-malignant disease	21 (3.8%)	>	15 (2.7%)
Respiratory disease	8		4
Cerebrovascular disease	7		2
Cardiovascular disease	4		4
Others	2		5
Unknown	3		5

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Discussion 1:

By chance?

Background・・・

Incidence of second cancers・・・

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Patient characteristics 1 at final registration

Characteristics	Arm A: Lobectomy (N=554)	Arm B: Segmentectomy (N=552)
Median age, years (range)	67 (35-85)	67 (32-83)
Male / Female (%)	293 (52.9%) / 261 (47.1%)	290 (52.5%) / 262 (47.5%)
ECOG performance status: 0 / 1 (%)	541 (97.7%) / 13 (2.3%)	542 (98.2%) / 10 (1.8%)
Smoking history: Yes / No (%)	246 (44.4%) / 308 (55.6%)	244 (44.2%) / 308 (55.8%)
Median max. tumor diameter, cm (range)	1.60 (0.6-2.0)	1.59 (0.6-2.0)
Consolidation / tumor ratio (CTR) (%)		
0≤ CTR ≤0.25	1 (0·2%)	0 (0%)
0.25< CTR ≤0.5	62 (11·2%)	73 (13.2%)
0.5< CTR <1.0	208 (37·6%)	194 (35.1%)
CTR = 1.0	283 (51.1%)	285 (51.6%)
Median FEV1.0, mL (range)	2260 (1110-4760)	2280 (1010-4900)
Median FVC, mL (range)	3050 (1370-5990)	3095 (1590-5940)
Histological type		
Adenocarcinoma	501 (90.4%)	502 (90.9%)
Squamous cell carcinoma	38 (6.9%)	37 (6.7%)
Others	15 (2.7%)	13 (2.4%)
Pathological stage (7^{th} TNM)		
pIA/pIB/pIIA/pIIIA/pIIB/pIV/unknown	455 (82.1%)/64/15/3/16/0/1	468 (84.8%)/46/18/1/17/1/2

Patient characteristics 2 at final registration

Characteristics	Arm A: Lobectomy (N=554)	Arm B: Segmentectomy (N=552)
Comorbidities, %		
Presence/Absence	49·6/50·4	48·9/51·1
1/2/3 and more	31·2/13·9/4·5	29·7/13·9/5·3
Respiratory disease	4·5	5·6
Cerebrovascular disease	1·1	1·6
Cardiovascular disease	4·2	5·4
Liver dysfunction	2·2	2·0
Renal dysfunction	0·2	0·4
Hypertension	30·5	28·3
Diabetes	8·8	10·1
Other disease	20·8	22·6
Video-assisted thoracic surgery		
Yes/No	88·7/21·3	89·7/20·3
Complete resection, %		
R0/R1/R2	100/0/0	99·6/0/0·4
Operation time, min		
Median (range)	174 (68–567)	201 (90–462)
Blood loss, mL		
Median (range)	44·5 (0–900)	50 (0–800)

Lancet. 2022 Apr 23;399(10335):1607-1617.

Lancet. 2022 Apr 23;399(10335):1607-1617.

Frequency of second cancers and second primary lung cancer

Cancer sites	Lobectomy arm (n=554)	Segmentectomy arm (n=552)
Total	**88 (15.4%)**	**84 (15.2%)**
Second primary lung cancer	**36**	**43**
Other cancers	**70**	**69**
Colorectum	11	11
Stomach	12	8
Prostate	4	9
Female breast	4	2
Pancreas	6	2
Esophagus	5	4
Oral cavity and pharynx	5	2
Thyroid	4	5
Bladder	2	3
Liver	2	2

Cancer sites	Lobectomy arm (n=554)	Segmentectomy arm (n=552)
Kidney and other urinary organs	2	2
Malignant lymphoma	2	3
Leukemia	4	4
Multiple myeloma	1	2
Larynx	1	0
Uterus	1	1
Ovary	1	2
Gallbladder and bile ducts	1	3
Skin	1	3
Brain, nervous system	0	1
Unknown origin	1	0
Kidney and other urinary organs	2	2
Malignant lymphoma	2	3
Carcinoma in situ	**11**	**13**
2 sites and more	**1**	**7**

Suppl. Table S4. *Some patients had 2 or more second cancers.

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Discussion 2:

Less invasive?

Respiratory function・・・

Details of post-surgical treatment・・・

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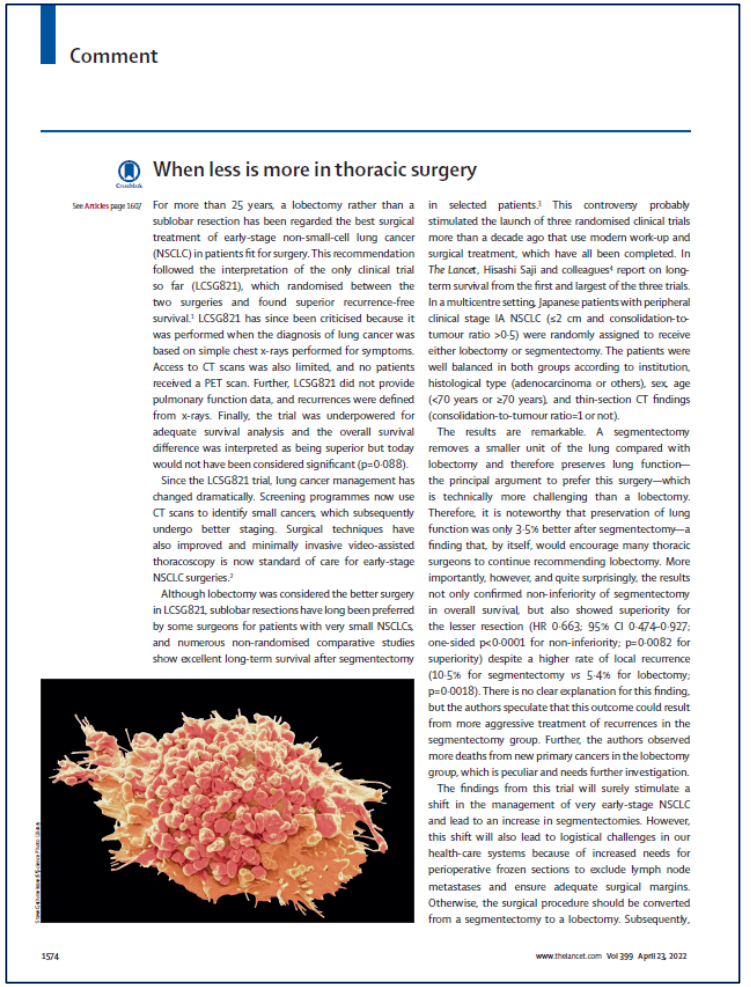
CQ3.

What is less?

Licht PB. When less is more in thoracic surgery. Lancet. 2022 Apr 23;399(10335):1574-1575.



Comment

When less is more in thoracic surgery

See Articles page 1607

For more than 25 years, a lobectomy rather than a sublobar resection has been regarded the best surgical treatment of early-stage non-small-cell lung cancer (NSCLC) in patients fit for surgery. This recommendation followed the interpretation of the only clinical trial so far (LCSG821), which randomised between the two surgeries and found superior recurrence-free survival.[1] LCSG821 has since been criticised because it was performed when the diagnosis of lung cancer was based on simple chest x-rays performed for symptoms. Access to CT scans was also limited, and no patients received a PET scan. Further, LCSG821 did not provide pulmonary function data, and recurrences were defined from x-rays. Finally, the trial was underpowered for adequate survival analysis and the overall survival difference was interpreted as being superior but today would not have been considered significant (p=0·088).

Since the LCSG821 trial, lung cancer management has changed dramatically. Screening programmes now use CT scans to identify small cancers, which subsequently undergo better staging. Surgical techniques have also improved and minimally invasive video-assisted thoracoscopy is now standard of care for early-stage NSCLC surgeries.[2]

Although lobectomy was considered the better surgery in LCSG821, sublobar resections have long been preferred by some surgeons for patients with very small NSCLCs, and numerous non-randomised comparative studies show excellent long-term survival after segmentectomy in selected patients.[3] This controversy probably stimulated the launch of three randomised clinical trials more than a decade ago that use modern work-up and surgical treatment, which have all been completed. In *The Lancet*, Hisashi Saji and colleagues[4] report on long-term survival from the first and largest of the three trials. In a multicentre setting, Japanese patients with peripheral clinical stage IA NSCLC (≤2 cm and consolidation-to-tumour ratio >0·5) were randomly assigned to receive either lobectomy or segmentectomy. The patients were well balanced in both groups according to institution, histological type (adenocarcinoma or others), sex, age (<70 years or ≥70 years), and thin-section CT findings (consolidation-to-tumour ratio=1 or not).

The results are remarkable. A segmentectomy removes a smaller unit of the lung compared with lobectomy and therefore preserves lung function—the principal argument to prefer this surgery—which is technically more challenging than a lobectomy. Therefore, it is noteworthy that preservation of lung function was only 3·5% better after segmentectomy—a finding that, by itself, would encourage many thoracic surgeons to continue recommending lobectomy. More importantly, however, and quite surprisingly, the results not only confirmed non-inferiority of segmentectomy in overall survival, but also showed superiority for the lesser resection (HR 0·663; 95% CI 0·474–0·927; one-sided p<0·0001 for non-inferiority; p=0·0082 for superiority) despite a higher rate of local recurrence (10·5% for segmentectomy *vs* 5·4% for lobectomy; p=0·0018). There is no clear explanation for this finding, but the authors speculate that this outcome could result from more aggressive treatment of recurrences in the segmentectomy group. Further, the authors observed more deaths from new primary cancers in the lobectomy group, which is peculiar and needs further investigation.

The findings from this trial will surely stimulate a shift in the management of very early-stage NSCLC and lead to an increase in segmentectomies. However, this shift will also lead to logistical challenges in our health-care systems because of increased needs for perioperative frozen sections to exclude lymph node metastases and ensure adequate surgical margins. Otherwise, the surgical procedure should be converted from a segmentectomy to a lobectomy. Subsequently,

Pulmonary Functions

CALGB/Alliance 140503

	Lobectomy N=357	Sublobar N=340	P-Value[1]
FEV1 (%predicted)			
Baseline Median (IQR)	N=356 83.0 (72.0-97.0)	N=340 83.5 (73.0,96.0)	
6-months Median (IQR)	N=268 76.5 (64.0,87.0)	N=252 81.0 (69.5,93.0)	
Change from baseline Median (IQR)	N=268 -6.0 (-14.0,-1.0)	N=252 -4.0 (-10.0,2.5.0)	0.0006

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FEV1.0 (mL)	Arm A: Lobectomy (N=554)	Arm B: Segmentectomy (N=552)	Difference	P value*
Post-op 6M	N=454	N=492		
Post-op 1Y	N=526	N=528		
Median	−12.0%	−8.5%	**3.5%**	<0.0001
Range	−57.1% to 49.6%	−37.0% to 30.0%		

- From the available series, it emerges that the mean decrease in FEV1 is −3 to −13% 12 months after segmentectomy.
- This reduction in lung function is significantly lower than that induced by lobectomy, but it saves only a few per cent of pre-operative FEV1.
- Moreover, the results do not firmly establish the pulmonary functional benefit of segmentectomy over lobectomy in patients with poor lung function.

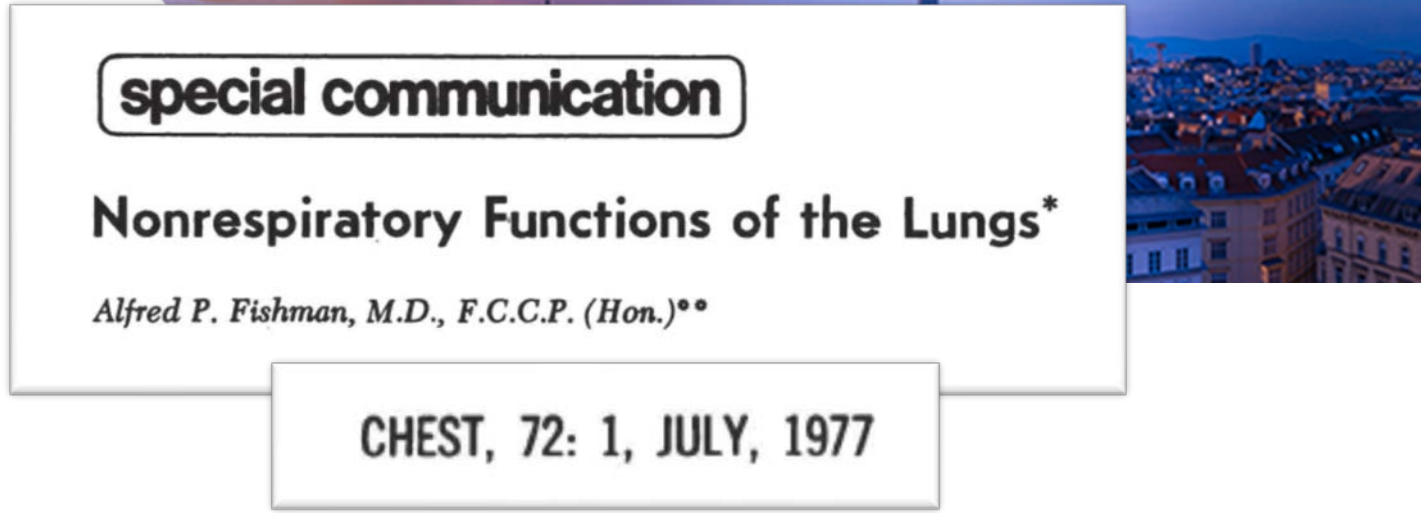
Charloux A, et al. Eur Respir Rev 2017; 26: 170079

TABLE 2 Studies comparing lobectomy and segmentectomy functional consequences

First author [ref.]	Year	Procedure	Patients n	Mean pre-operative FEV1 % pred	PFT delay months	Mean FEV1 change %
Ginsberg [4]	1995	Lobectomy	71	93% patients >50%	6 12–18	−9.1 −11.09
		Segmentectomy	67	93% patients >50%	6 12–18	−1.76# −5.18#
Takizawa [16]	1999	Lobectomy	40	105	0.5 12	−26.7 −13.7
		Segmentectomy	40	109	0.5 12	−24.5# −6.7#
Keenan [8]	2004	Lobectomy	147	75	12	−10¶
		Segmentectomy	54	55	12	−5¶
Martin-Ucar [11]	2005	Lobectomy	12	44	3–6	−12
		Segmentectomy	11	45	3–6	+12#
Harada [5]	2005	Lobectomy	45	74	2 6	−24¶ −18¶
		Segmentectomy	38	75	2 6	−15#,¶ −12#,¶
Okada [13]	2006	Lobectomy	168	2.32 L+	2	−16.8
		Segmentectomy	168	1.93 L+	2	−9.4
Kashiwabara [7]	2009	Lobectomy	47	107	6	Normal FEV1: −18.9 FEV1 <70%: −12.8
		Segmentectomy	71	109	6	Normal FEV1: −12.9# FEV1 <70%: −13.8
Saito [14]	2014	Lobectomy	126	77	1 6	−28 −19
		Segmentectomy	52	78	1 6	−22 −10#
Hwang [6]	2015	Lobectomy	94	101	NA	−11.0
		Segmentectomy	94	102	NA	−8.9
Kim [9]	2015	Lobectomy	227	109	3 12	−13.6 −8.49
		Segmentectomy	73	100	3 12	−4.84# −1.74#
Macke [10]	2015	Lobectomy	70	85	6–36	−8.2
		Segmentectomy	89	79	6–36	−4.3#
Suzuki [15]	2016	Lobectomy	33	75	2 7–12	−29 −11
		Segmentectomy	37	73	2 7–12	−19 −12
Nomori [12]§	2016	Segmentectomy	117	<2 seg: 105 ≥2 seg: 114 LUD: 117 LUL: 114	7 (6–13)	<2 seg: −3# ≥2 seg: −10# LUD: −16 LUL: −17
		Lobectomy	13			

FEV1: forced expiratory volume in 1 s; PFT: pulmonary function test; NA: not available. #: significant difference between lobectomy and segmentectomy; ¶: calculated from data or extracted from figures; +: absolute values in L given where no % pred values available; §: compared resections <2 segments (<2 seg), ≥2 segments (≥2 seg), of the left upper division (LUD) and left upper lobectomy (LUL).

Courtesy of Prof. Tsuboi M


special communication

Nonrespiratory Functions of the Lungs*

*Alfred P. Fishman, M.D., F.C.C.P. (Hon.)***

CHEST, 72: 1, JULY, 1977

CQ3. Spiculation:

Pulmonary function is not less but it is limited in showing what is less.

Segmentectomy, which preserves more lung parenchymal than does lobectomy, might have contributed to the more extensive treatment, resulting in overall survival being significantly exceeded.

From Discussion in Lancet 2022.

Since 1823
by Thomas Wakley, an English surgeon

Impact Factor of 202·731 and **ranks first** among 169 general and internal medicine journals globally (2021 Journal Citation Reports®, (Clarivate 2021).

Discussion 2:

Less invasive?

Respiratory function・・・

Details of post-surgical treatment・・・

JCOG
Japan Clinical Oncology Group

Lancet. 2022 Apr 23;399(10335):1607-1617.

WJOG

Suppl. Table S5. Summary of lung cancer treatment after surgery.

Adjuvant therapy

	Lobectomy (n = 554)	Segmentectomy (n = 552)
Post-operative adjuvant chemotherapy*	67 (12·1%)	46 (8·3%)
Tegafur-uraci		
Cisplatin plus		
Others		

Treatment for relapse

	Lobectomy (n = 554)	Segmentectomy (n = 552)
Relapse	n = 44	n = 67
Treatment for relapse*	35 (80·0%)	
	1	3
Wedge resection	0	2
Others	1	1
Radiotherapy	13	17

Treatment for second primary lung cancer

	Lobectomy (n = 554)	Segmentectomy (n = 552)
Second primary lung cancer	n = 36	n = 43
		36 (83·7%)
		1
		32(89%)
		0
Completion lobectomy	0	2
Lobectomy	2	7
Segmentectomy	7	6
Wedge resection	10	17
Others	0	0
Radiotherapy	9	3

These results suggested that patients who underwent segmentectomy could receive more intensive cancer treatment than those who underwent lobectomy.

Among the patients with relapse, 18 (49%) of 37 patients in the lobectomy arm were alive up to 5-year follow up, whereas 35 (68%) of 51 patients in the segmentectomy arm were still alive (at median time to relapse, 2·5 and 2·7 years, respectively).

JCOG Japan Clinical Oncology Group

*Some patients received more than one treatment.

Lancet. 2022 Apr 23;399(10335):1607-1617.

WJOG

Since 1823
by Thomas Wakley, an English surgeon

Impact Factor of 202·731 and **ranks first** among 169 general and internal medicine journals globally (2021 Journal Citation Reports®, (Clarivate 2021).

Discussion 3:

Less is more in thoracic surgery?

JCOG
Japan Clinical Oncology Group

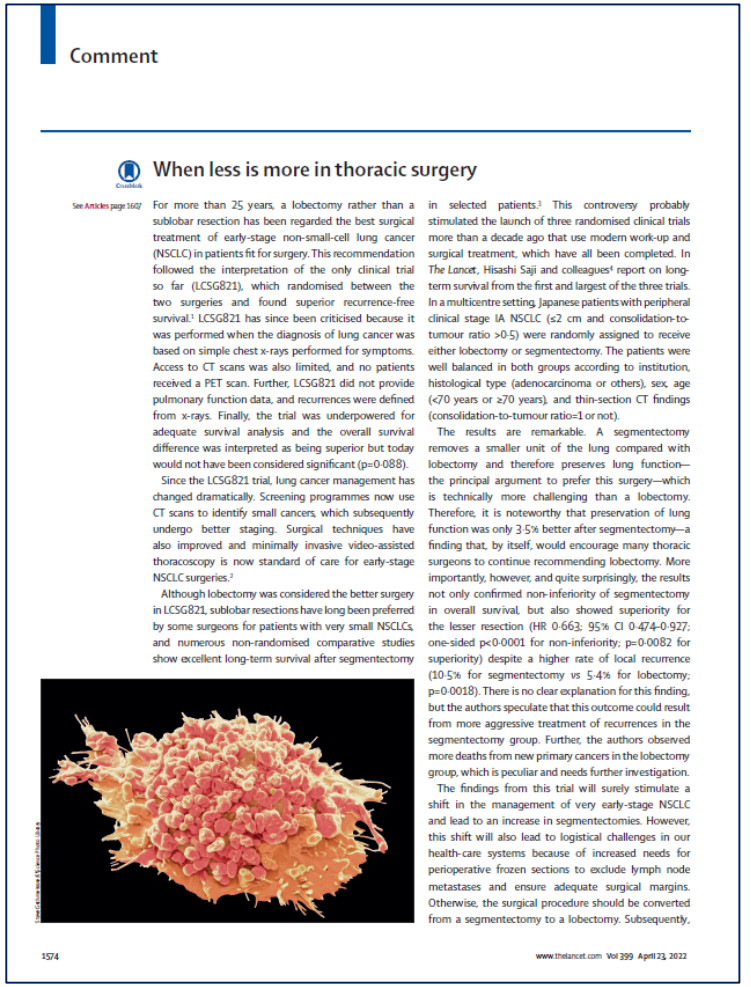
Lancet. 2022 Apr 23;399(10335):1607-1617.

WJOG

CQ2.

When less is more in thoracic surgery?

Licht PB. When less is more in thoracic surgery. Lancet. 2022 Apr 23;399(10335):1574-1575.



Comment

When less is more in thoracic surgery

See Articles page 1607

For more than 25 years, a lobectomy rather than a sublobar resection has been regarded the best surgical treatment of early-stage non-small-cell lung cancer (NSCLC) in patients fit for surgery. This recommendation followed the interpretation of the only clinical trial so far (LCSG821), which randomised between the two surgeries and found superior recurrence-free survival.[1] LCSG821 has since been criticised because it was performed when the diagnosis of lung cancer was based on simple chest x-rays performed for symptoms. Access to CT scans was also limited, and no patients received a PET scan. Further, LCSG821 did not provide pulmonary function data, and recurrences were defined from x-rays. Finally, the trial was underpowered for adequate survival analysis and the overall survival difference was interpreted as being superior but today would not have been considered significant (p=0·088).

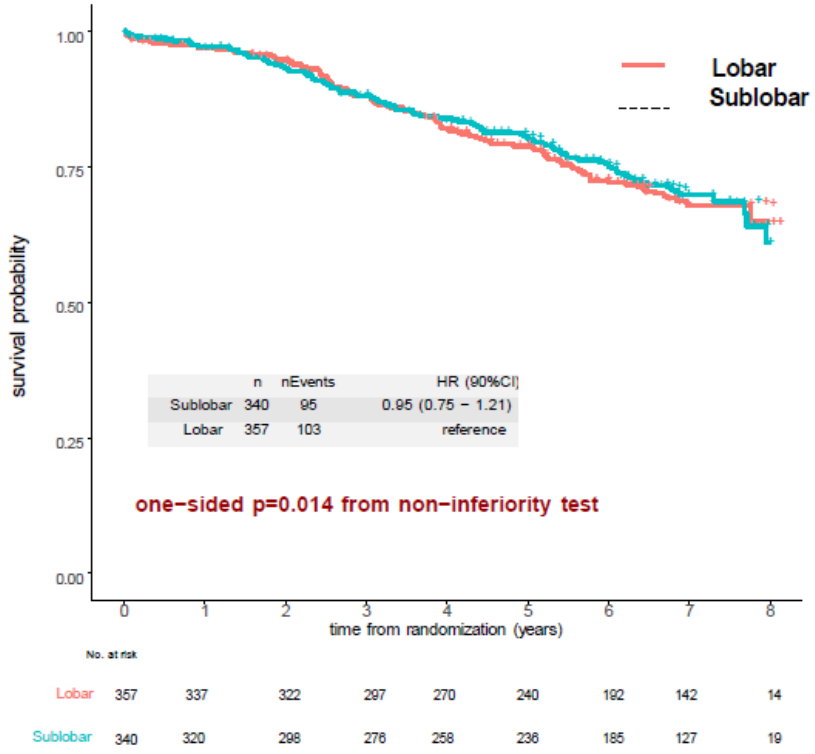
Since the LCSG821 trial, lung cancer management has changed dramatically. Screening programmes now use CT scans to identify small cancers, which subsequently undergo better staging. Surgical techniques have also improved and minimally invasive video-assisted thoracoscopy is now standard of care for early-stage NSCLC surgeries.[2]

Although lobectomy was considered the better surgery in LCSG821, sublobar resections have long been preferred by some surgeons for patients with very small NSCLCs, and numerous non-randomised comparative studies show excellent long-term survival after segmentectomy in selected patients.[3] This controversy probably stimulated the launch of three randomised clinical trials more than a decade ago that use modern work-up and surgical treatment, which have all been completed. In *The Lancet*, Hisashi Saji and colleagues[4] report on long-term survival from the first and largest of the three trials. In a multicentre setting, Japanese patients with peripheral clinical stage IA NSCLC (≤2 cm and consolidation-to-tumour ratio >0·5) were randomly assigned to receive either lobectomy or segmentectomy. The patients were well balanced in both groups according to institution, histological type (adenocarcinoma or others), sex, age (<70 years or ≥70 years), and thin-section CT findings (consolidation-to-tumour ratio=1 or not).

The results are remarkable. A segmentectomy removes a smaller unit of the lung compared with lobectomy and therefore preserves lung function—the principal argument to prefer this surgery—which is technically more challenging than a lobectomy. Therefore, it is noteworthy that preservation of lung function was only 3·5% better after segmentectomy—a finding that, by itself, would encourage many thoracic surgeons to continue recommending lobectomy. More importantly, however, and quite surprisingly, the results not only confirmed non-inferiority of segmentectomy in overall survival, but also showed superiority for the lesser resection (HR 0·663; 95% CI 0·474–0·927; one-sided p<0·0001 for non-inferiority; p=0·0082 for superiority) despite a higher rate of local recurrence (10·5% for segmentectomy *vs* 5·4% for lobectomy; p=0·0018). There is no clear explanation for this finding, but the authors speculate that this outcome could result from more aggressive treatment of recurrences in the segmentectomy group. Further, the authors observed more deaths from new primary cancers in the lobectomy group, which is peculiar and needs further investigation.

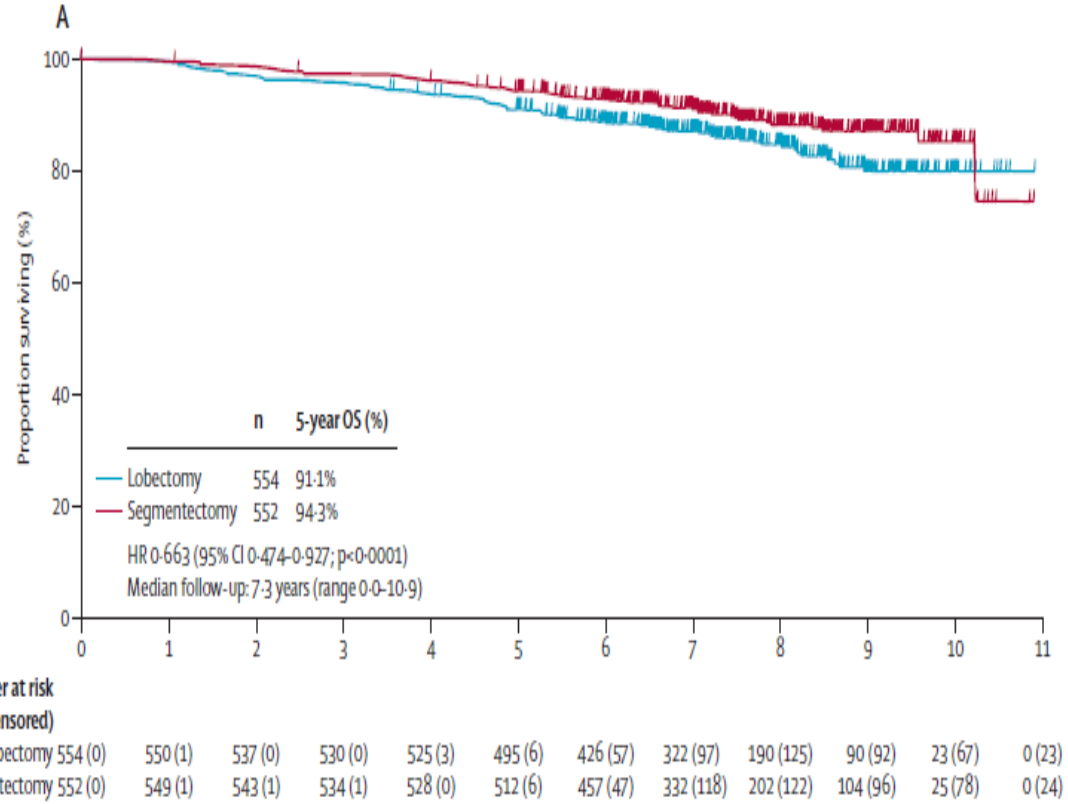
The findings from this trial will surely stimulate a shift in the management of very early-stage NSCLC and lead to an increase in segmentectomies. However, this shift will also lead to logistical challenges in our health-care systems because of increased needs for perioperative frozen sections to exclude lymph node metastases and ensure adequate surgical margins. Otherwise, the surgical procedure should be converted from a segmentectomy to a lobectomy. Subsequently,

3. Overall Survival



Median follow-up: 7 years

Five –year survival
SLR: 80.3%
Lobar: 78.9%



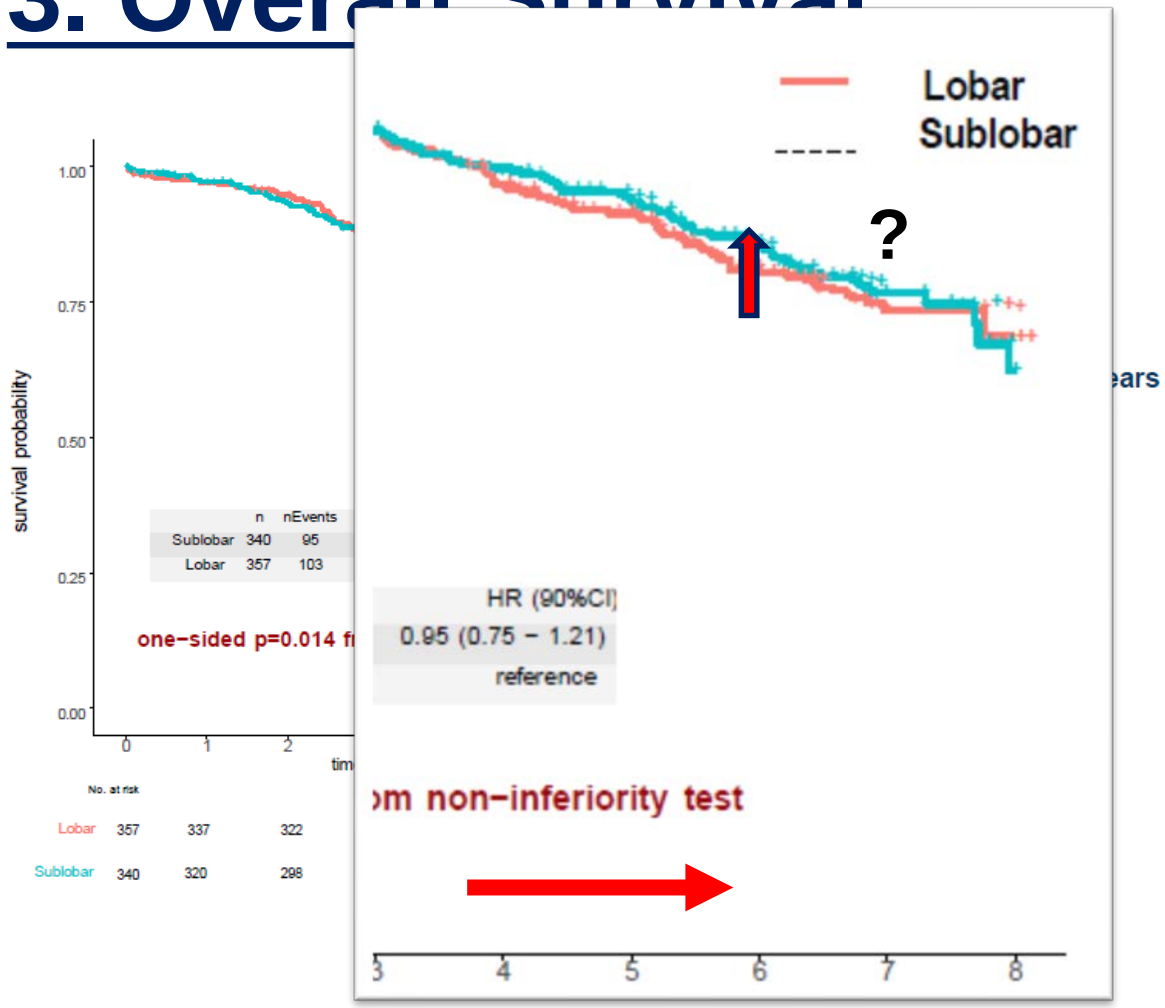
Altorki N et al. PL03.06. WCLC2022

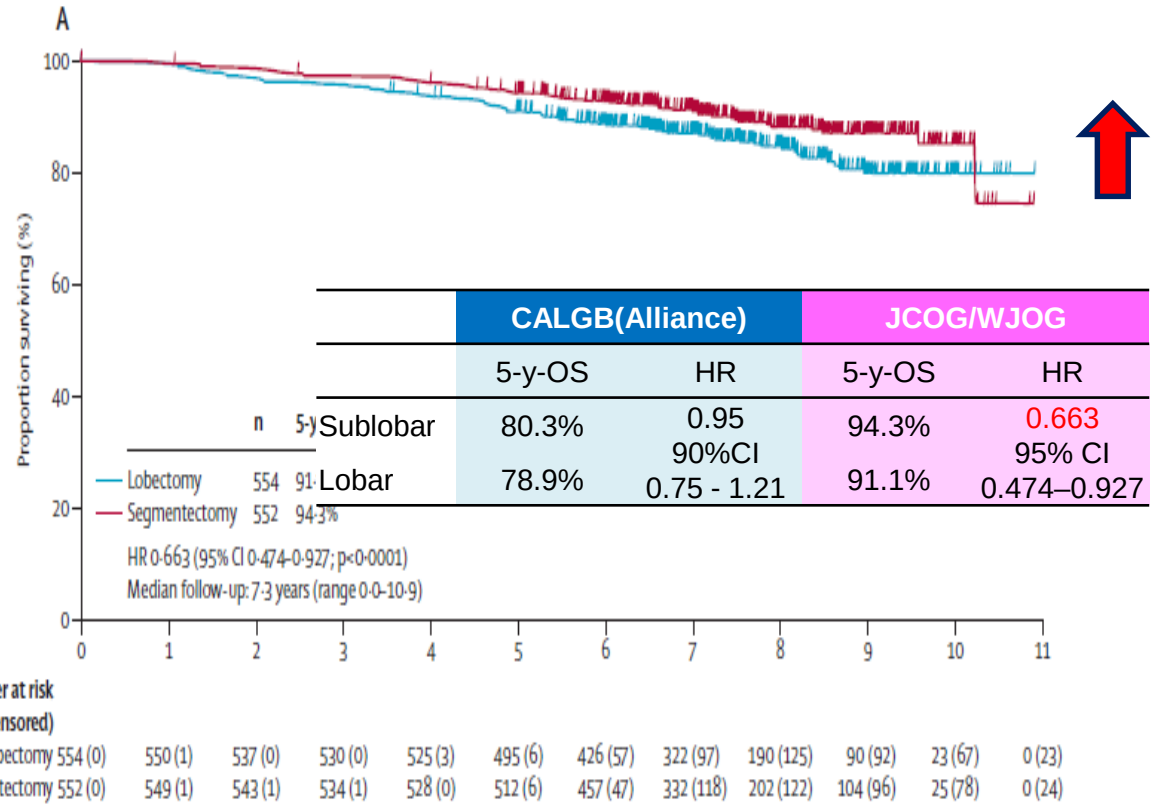
Saji H et al. Lancet. 2022 Apr 23;399(10335):1607-1617

IASLC 2022 World Conference on Lung Cancer

AUGUST 6-9, 2022 | VIENNA, AUSTRIA

3. Overall Survival





	CALGB(Alliance)		JCOG/WJOG	
	5-y-OS	HR	5-y-OS	HR
Sublobar	80.3%	0.95 90%CI 0.75 - 1.21	94.3%	0.663 95% CI 0.474–0.927
Lobar	78.9%		91.1%	

Number at risk (number censored)

Lobectomy	554 (0)	550 (1)	537 (0)	530 (0)	525 (3)	495 (6)	426 (57)	322 (97)	190 (125)	90 (92)	23 (67)	0 (23)
Segmentectomy	552 (0)	549 (1)	543 (1)	534 (1)	528 (0)	512 (6)	457 (47)	332 (118)	202 (122)	104 (96)	25 (78)	0 (24)

Altorki N et al. PL03.06. WCLC2022

Saji H et al. Lancet. 2022 Apr 23;399(10335):1607-1617

VOLUME 26 · NUMBER 21 · JULY 20 2008

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

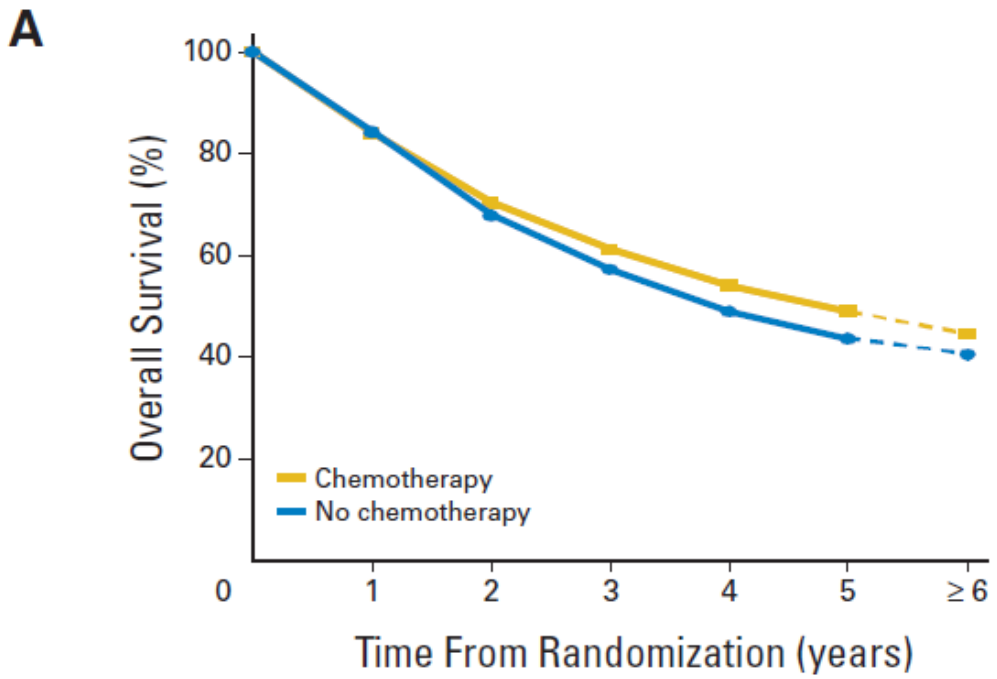
Lung Adjuvant Cisplatin Evaluation: A Pooled Analysis by the LACE Collaborative Group

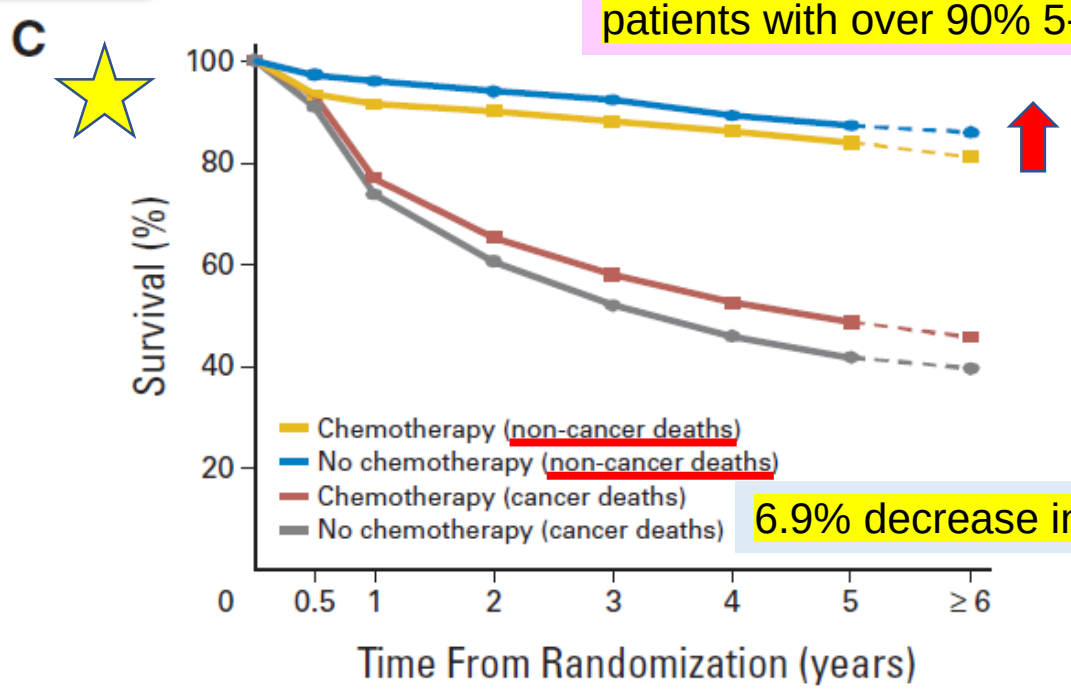
Jean-Pierre Pignon, Hélène Tribodet, Giorgio V. Scagliotti, Jean-Yves Douillard, Frances A. Shepherd, Richard J. Stephens, Ariane Dunant, Valter Torri, Rafael Rosell, Lesley Seymour, Stephen G. Spiro, Estelle Rolland, Roldano Fossati, Delphine Aubert, Kevue Dine, David. Waller, and Thierry Le Chevalier

Patients and Methods

Individual patient data were collected and pooled from the five largest trials (4,584 patients) of cisplatin-based chemotherapy in completely resected patients that were conducted after the 1995 NSCLC meta-analysis.

1.4% increase in non–lung cancer death in patients with over 90% 5-y OS





6.9% decrease in lung cancer death

Deaths / person years by period	Years 0-3	Years 4-5	Years ≥ 6
Control	966 / 5,155	239 / 1,668	49 / 720
Chemotherapy	857 / 5,181	203 / 1,817	76 / 790

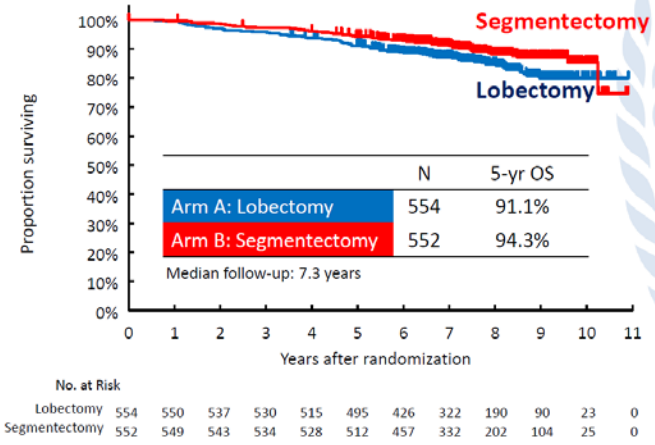
Non-cancer deaths / person years by period	Years 0-3	Years 4-5	Years ≥ 6
Control	88 / 4,353	42 / 1,399	9 / 611
Chemotherapy	141 / 4,635	38 / 1,611	24 / 708
Cancer deaths by period			
Control	878	197	40
Chemotherapy	716	165	52

JCOG
Japan Clinical Oncology Group

WJOG

JCOG0802/WJOG4607L *The LANCET* in press

Result 1. Overall survival (primary endpoint)

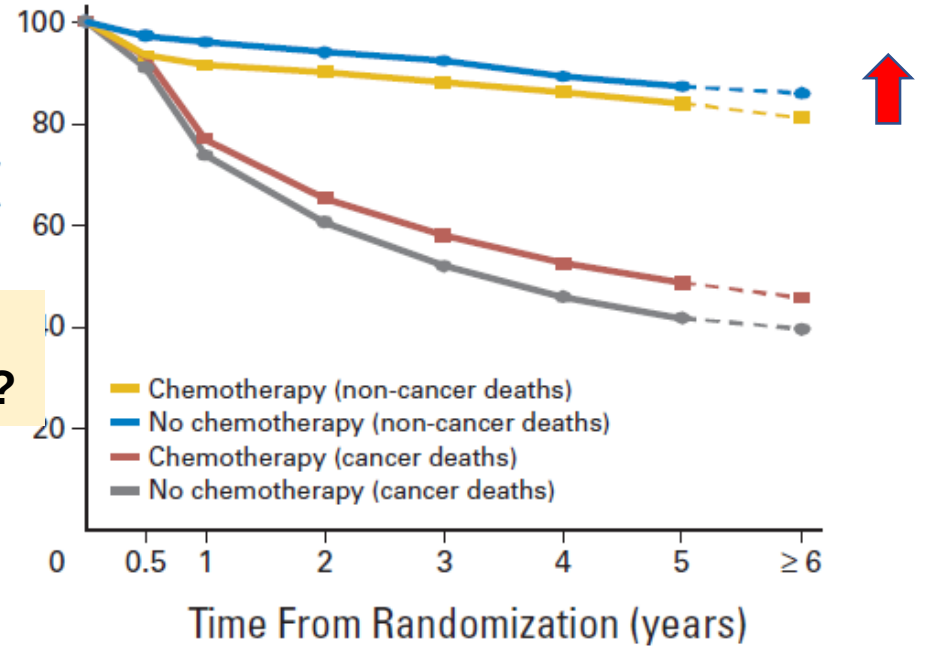


HR: 0.663
95% CI: 0.474–0.927
one-sided

P <0.0001 for non-inferiority
P = 0.0082 for superiority

When less is more in thoracic surgery?

LACE *J Clin Oncol 2008*



RTOG0617 *J Clin Oncol 2020*

Standard Versus High-Dose Radiation for Stage III NSCLC

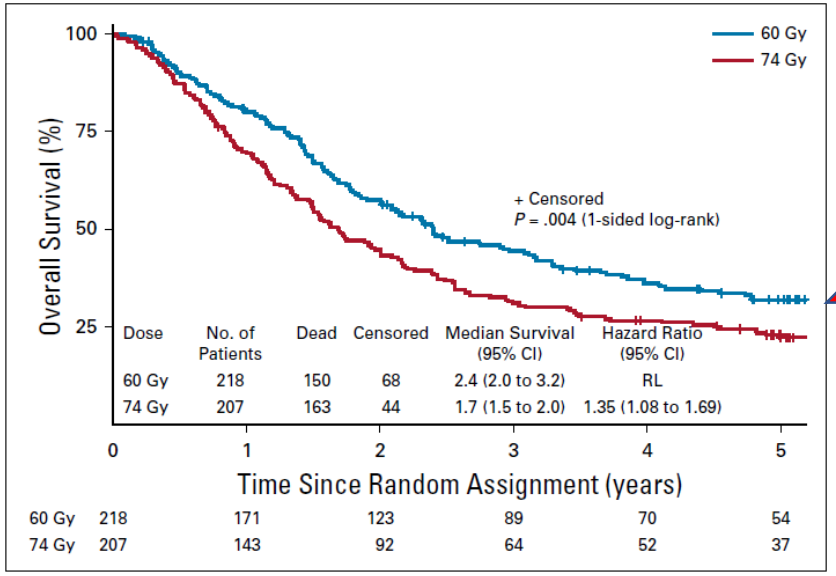


FIG 2. Overall survival by radiation therapy dose. RL, reference level.

Lung ART *ESMO2020*

VIRTUAL 2020 ESMO congress

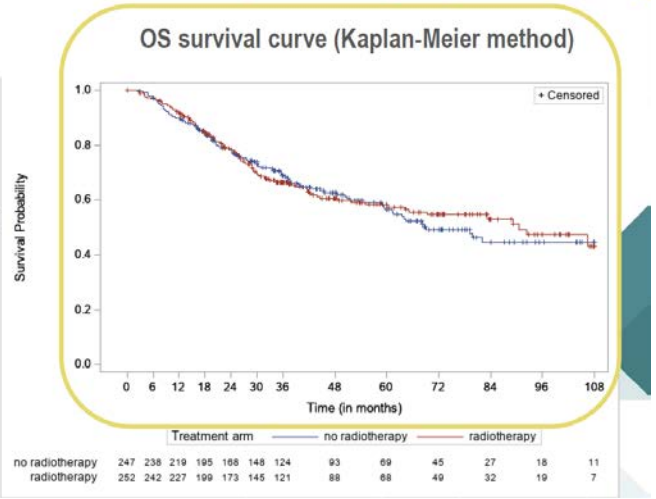
n_{events} = 201 events

Overall Survival rates at 3 years

Control arm: 68.5% (95% CI = [61;75])

PORT arm: 66.5% (95% CI = [59;73])

Overall Survival (Secondary Endpoint; ITT)



CQ2. Spiculation:

Sublobar resection reserves the possibility of more extensive treatment for upcoming life-threatening diseases such as second primary cancer, respiratory disease, or cerebrovascular disease, etc. after curing lung cancer.

From Discussion in Lancet 2022.

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Discussion 3:

Locoregional recurrence?

Comparison between CAGLB140503 and JCOG0802/WJOG4607L trials

JCOG
Japan Clinical Oncology Group

Lancet. 2022 Apr 23;399(10335):1607-1617.

WJOG

5. Disease Recurrence

	CALGB(Alliance) 140503					JCOG0802/WJOG4607L			
	Lobar (n=351)		Sublobar (n=336)			Lobectomy (n=554)		Segmentectomy (n=552)	
	n	%	n	%	vs.	n	%	n	%
Overall	103	29.3	102	30.4		44	7.9	67	12.1
Locoregional only	28	10.0	33	13.4		17	3.1	38	6.9
Regional only	9	2.6	6	1.8					
Any Distant	59	16.8	51	15.2		27	4.9	27	4.9
New primary LC	52	14.8	60	17.9		36	6.5	43	7.9

*The difference of loco-regional only recurrence rate was about 3% between the two arms and in both trials.

Altorki N et al. PL03.06. WCLC2022

Saji H et al. Lancet. 2022 Apr 23;399(10335):1607-1617

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Planed future analysis to resolve these CQs:

1. Detail of respiratory function
   / submitted to Lancet rep. med.
2. Detail of loco-reginal recurrence
   / presented in JLCS, Dec, 2022
3. Detail of solid tumor
   / submitted to AATS, May, 2023

JCOG
Japan Clinical Oncology Group

Lancet. 2022 Apr 23;399(10335):1607-1617.

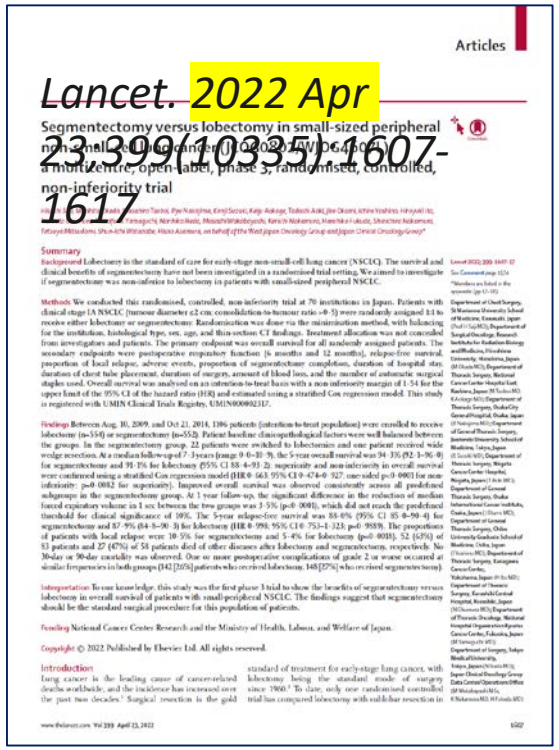
WJOG

おまけ

Plus alfa

Small gift

ST. MARIANNA
UNIVERSITY HOSPITAL


Articles

Lancet. 2022 Apr 23;399(10335):1607-1617

Segmentectomy versus lobectomy in small-sized peripheral non-small-cell lung cancer (JCOG0802/WJOG4607L): a multicentre, open-label, phase 3, randomised, controlled, non-inferiority trial

Summary

Background Lobectomy is the standard of care for early-stage non-small-cell lung cancer (NSCLC). The survival and clinical benefits of segmentectomy have not been investigated in a randomised trial setting. We aimed to investigate if segmentectomy was non-inferior to lobectomy in patients with small-sized peripheral NSCLC.

Methods We conducted this randomised, controlled, non-inferiority trial at 70 institutions in Japan. Patients with clinical stage IA NSCLC (tumour diameter ≤2 cm; consolidation-to-tumour ratio >0·5) were randomly assigned 1:1 to receive either lobectomy or segmentectomy. Randomisation was done via the minimisation method, with balancing for the institution, histological type, sex, age, and thin-section CT findings. Treatment allocation was not concealed from investigators and patients. The primary endpoint was overall survival for all randomly assigned patients. The secondary endpoints were postoperative respiratory function (6 months and 12 months), relapse-free survival, proportion of local relapse, adverse events, proportion of segmentectomy completion, duration of hospital stay, duration of chest tube placement, duration of surgery, amount of blood loss, and the number of intraoperative surgical staples used. Overall survival was analysed on an intention-to-treat basis with a non-inferiority margin of 1·54 for the upper limit of the 95% CI of the hazard ratio (HR) and estimated using a stratified Cox regression model. This study is registered with UMIN Clinical Trials Registry, UMIN000002317.

Findings Between Aug. 10, 2009, and Oct 21, 2014, 1106 patients (intention-to-treat population) were enrolled to receive lobectomy (n=554) or segmentectomy (n=552). Patient baseline clinicopathological factors were well balanced between the groups. In the segmentectomy group, 22 patients were switched to lobectomies and one patient received wide wedge resection. At a median follow-up of 7·7 years (range 0·0–10·9), the 5-year overall survival was 94·336 (92·1–96·0) for segmentectomy and 91·1% for lobectomy (95% CI 88·4–93·2); superiority and non-inferiority in overall survival were confirmed using a stratified Cox regression model (HR 0·663, 95% CI 0·474–0·927; one-sided p<0·0001 for non-inferiority; p=0·0082 for superiority). Improved overall survival was observed consistently across all predefined subgroups in the segmentectomy group. At 1 year follow-up, the significant difference in the reduction of median forced expiratory volume in 1 sec between the two groups was 3·5% (p<0·0001), which did not reach the predefined threshold for clinical significance of 10%. The 5-year relapse-free survival was 88·6% (95% CI 85·0–90·4) for segmentectomy and 87·9% (84·3–90·3) for lobectomy (HR 0·998, 95% CI 0·753–1·323; p=0·9989). The proportion of patients with local relapse were 10·5% for segmentectomy and 5·4% for lobectomy (p=0·0018). 52 (63%) of 83 patients and 27 (47%) of 58 patients died of other diseases after lobectomy and segmentectomy, respectively. No 30-day or 90-day mortality was observed. One or more postoperative complications of grade 2 or worse occurred at similar frequencies in both groups (142 [26%] patients who received lobectomy, 148 [27%] who received segmentectomy).

Interpretation To our knowledge, this study was the first phase 3 trial to show the benefits of segmentectomy versus lobectomy in overall survival of patients with small-peripheral NSCLC. The findings suggest that segmentectomy should be the standard surgical procedure for this population of patients.

Funding National Cancer Center Research and the Ministry of Health, Labour, and Welfare of Japan.

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Introduction

Lung cancer is the leading cause of cancer-related deaths worldwide, and the incidence has increased over the past two decades.[1] Surgical resection is the gold standard of treatment for early-stage lung cancer, with lobectomy being the standard mode of surgery since 1960.[2] To date, only one randomised controlled trial has compared lobectomy with sublobar resection in

番外編

予告を少しだけ。

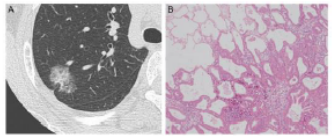
Proof？

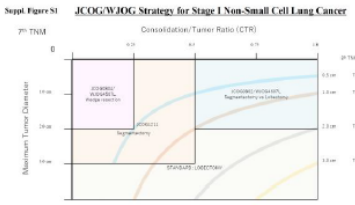
ゲラ修正作業。。。

Road to *THE LANCET*; JCOG0802/WJOG4607L

Lung Cancer Study Group (LCSG821). *The Annals of Thoracic Surgery* 1995

1990s





① 2002.Dec.1～2005.May.21: JCOG0201

2009.Aug.10～2014.Oct.21: JCOG0802/WJOG4607L

2009.May.6～2011.Apr.26: JCOG0804

2013.Sep.20～2015.Nov.13: JCOG1211

② 2019.Oct. イベント不足で1年延期

2020.Oct.1 主たる解析レポート： **Superiority on OS!!!**

	イベント数	検出力
2018年10月	105例	71.8%
2019年10月	1254例（＋20例）	78.2%
2020年4月	134例（＋30例）	<80%
2020年9月	144例（＋40例）	83～5%

③ 2021.May.2 **AATS2021 Plenary**

2021.May.21 **1st Try to *NEJM***

2021.Jun.15 **Reject…**

2021.Sep.6 **2nd Try to *THE LANCET***

Sep.24 **Revise, Oct.1 R1, Oct.11 R2, Oct.14 R3. Oct.15 Accept!**

JCOG Japan Clinical Oncology Group

WJOG

21tl6762
Articles
Rachel B

Manuscript: THELANCET-D-21-06762, Segmentectomy versus lobectomy in small-sized peripheral non-small cell lung cancer (JCOG0802/WJOG4607L): a multicentre, randomised, controlled, phase 3 trial

Dear Prof. Saji,

Thank you for submitting your manuscript to ***The Lancet***. We have read it with interest and we have sent it out for external peer-review.

Your submission has now been assessed by external advisers and discussed by the Editorial team. We would like to invite you to **REVISE** your paper in light of the editorial and reviewers' comments below.

Please be aware that an invitation to revise does not imply acceptance. Our target revision time is 2 working days for fast track, 10 working days for normal track.

RB

フラグを設定し
2022/03/04

CC: rachel.b

Dear Prof. S

I have now e

Production

Alternatively at the end of this email, I have put details of how to access and return your proof.

Please return your corrections to me as soon as possible an by latest March 7, 10 am (UK time via the above link.

We edit all papers to ensure that data are presented clearly and concisely, use of English language and grammar is correct, the report is readable to our international readership, and that ***Lancet*** style is applied to achieve consistency and meet reporting guidelines.

I have explained some changes in the text (marked [A:]), and included some requests for information. Where wording has been changed, please do not revert to your original wording. Instead, please try to clarify the meaning if the sense of your text has been altered.

Please note that your figures have been redrawn by our illustrators. You should check the content of figures, tables and their legends, and any equations. Please also check that all drug names and doses are correct (please note that we use rINNs [recommended international non-proprietary names]).

168 件の注釈

2022/03/4

saji- 3月6日

please add "(p=0·9889)" ?

3月6日

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S. Could you please delete
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3月6日

3月6日

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eceived other adjuvant therapy
ectomy group."

3月6日

saji- 3月6日

Japan Clinical Oncology Group

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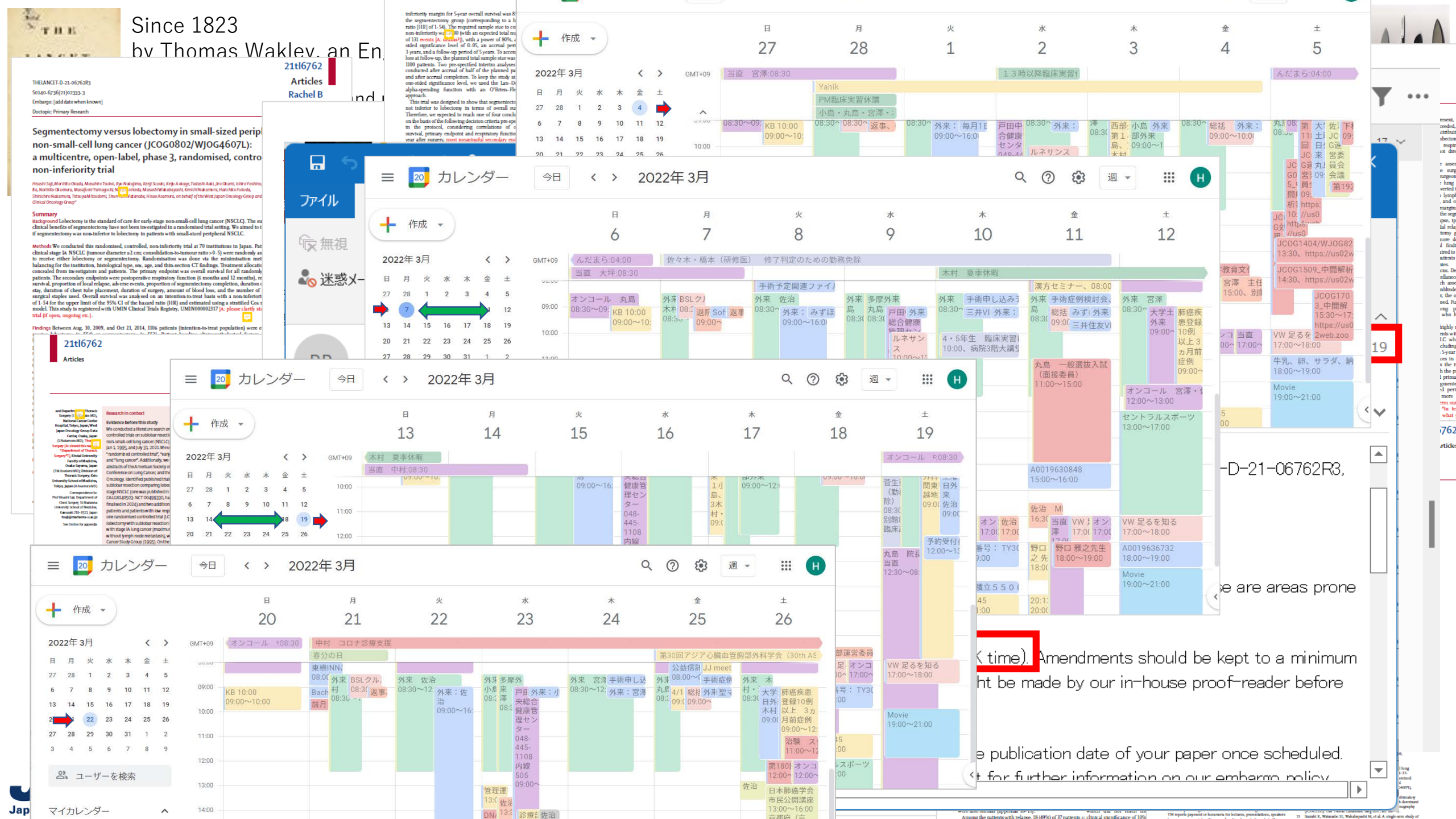
Since 1823
by Thomas Wakley, an En
21tl6762
Articles
Rachel B
Segmentectomy versus lobectomy in small-sized perip
non-small-cell lung cancer (JCOG0802/WJOG4607L):
a multicentre, open-label, phase 3, randomised, contro
non-inferiority trial
Summary
21tl6762
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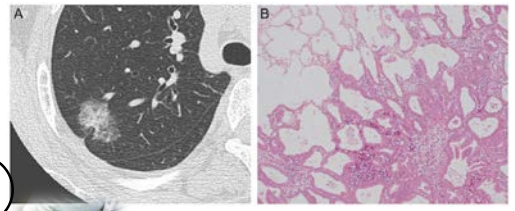
time). Amendments should be kept to a minimum
ht be made by our in-house proof-reader before
e publication date of your paper once scheduled.
t for further information on our embargo policy
ユーザーを検索
マイカレンダー

Road to *THE LANCET; JCOG0802/WJOG4607L*

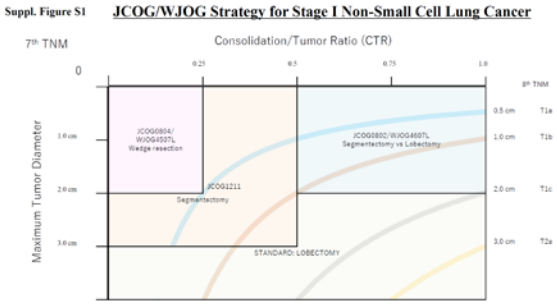
Lung Cancer Study Group (LCSG821). *The Annals of Thoracic Surgery* 1995

1990s



Noguchi M, et al. Small adenocarcinoma of the lung. Histologic characteristics and prognosis. **Cancer. 1995**

① 2002.Dec.1～2005.May.21: JCOG0201



2009.Aug.10～2014.Oct.21: JCOG0802/WJOG4607L

2009.May.6～2011.Apr.26: JCOG0804

2013.Sep.20～2015.Nov.13: JCOG1211

	イベント数	検出力
2018年10月	105例	71.8%
2019年10月	1254例（＋20例）	78.2%
2020年4月	134例（＋30例）	<80%
2020年9月	144例（＋40例）	83～5%

② 2019.Oct. Final analysis postponed 1 year due to small event.

2020.Oct.1 Final report opened： **Superiority on OS!!!**

③ 2021.May.2 **AATS2021 Plenary**

2021.May.21 **1st Try to *NEJM***

2021.Jun.15 **Reject…**

2021.Sep.6 **2nd Try to *THE LANCET***

Sep.24 **Revise, Oct.1 R1, Oct.11 R2, Oct.14 R3. Oct.15 Accept!**

Lancet. 2022 Apr 23;399(10335):1607-1617.

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WJOG

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Road to THE LANCET

THE END

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Lancet. 2022 Apr 23;399(10335):1607-1617.

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Acknowledgement

Japan Clinical Oncology Group (54 participating institutions)

Hokkaido University Hospital, National Hospital Organization Sendai Medical Center, Tohoku University Hospital, Yamagata Prefectural Central Hospital, Iwaki Kyoritsu Hospital, Ibaraki Prefectural Central Hospital and Ibaraki Prefectural Regional Cancer Center, Tochigi Cancer Center, Gunma Cancer Center, Saitama Cancer Center, National Cancer Center Hospital East, Chiba Cancer Center, Chiba University School of Medicine, National Cancer Center Hospital, Kyorin University School of Medicine, Tokyo Medical University Hospital, Metropolitan Komagome Hospital Center for Cancer and Infectious Diseases, Keio University Hospital, Cancer Institute Hospital, The University of Tokyo, Juntendo University School of Medicine, Nippon Medical School Hospital, St. Marianna University School of Medicine, Kanagawa Cancer Center, Yokohama Municipal Citizen's Hospital, Kitasato University School of Medicine, Yokohama City University Medical Hospital, Niigata Cancer Center Niigata Hospital, National Hospital Organization West Niigata Central Hospital, Niigata University Medical & Dental Hospital, Kanazawa University School of Medicine, Saku General Hospital, Shizuoka Cancer Center, Aichi Cancer Center, Nagoya University School of Medicine, Kyoto University Hospital, Osaka University School of Medicine, Osaka City University Hospital, Kindai University Hospital, Osaka International Cancer Center, Osaka Habikino Medical Center, National Hospital Organization Kinki Central Respiratory Center, Osaka City General Medical Center, Kobe University School of Medicine, Hyogo Cancer Center, Kurashiki Central Hospital, Okayama University Hospital, National Hospital Organization Kure Medical Center and Chugoku Cancer Center, Hiroshima University Hospital, National Hospital Organization Shikoku Cancer Center, National Hospital Organization Kyushu Cancer Center, Fukuoka University School of Medicine, Nagasaki University Hospital, Kumam University Hospital, Kumamoto Central Hospital, Oita University Hospital, National Hospital Organization Okinawa Hospital

West Japan Oncology Group (34 participating institutions)

Asahikawa Medical College Hospital, Gifu Municipal Hospital, Gifu University Hospital, Kumamoto Regional Medical Center, Hiroshima City Citizens Hospital, Hiroshima City Hiroshima Citizens Hospital, Kochi Medical Center, Yamaguchi Ube Medical Center, West Niigata Central Hospital, Osaka Toneyama Medical Center, Saiseikai Hiroshima Hospital, Mie University Hospital, Yamagata University Hospital, Yamaguchi University Hospital, Suita Municipal Hospital, Showa Inan General Hospital, Iron Memorial Yahata Hospital, Shinbeppu Hospital, Kobe City Medical Center General Hospital, Kanagawa Cardiovascular and Respiratory Center, Ishikawa Prefectural Central Hospital, Kawasaki Medical School Hospital, Sagamihara Cooperative Hospital, Osaka City University Hospital, Oita Prefectural Hospital, Nagasaki Atomic Bomb Hospital, Tottori University Hospital, Fukushima Medical University Hospital, Hyogo Prefectural Awaji Medical Center, Kitasato University Hospital, Shinshu University Hospital, Kindai University Nara hospital, Hamamatsu Medical University Hospital, Kyushu University Hospital

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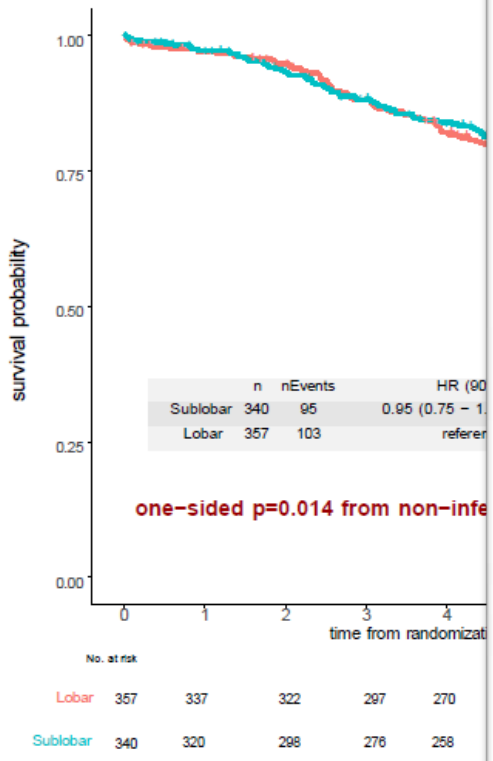
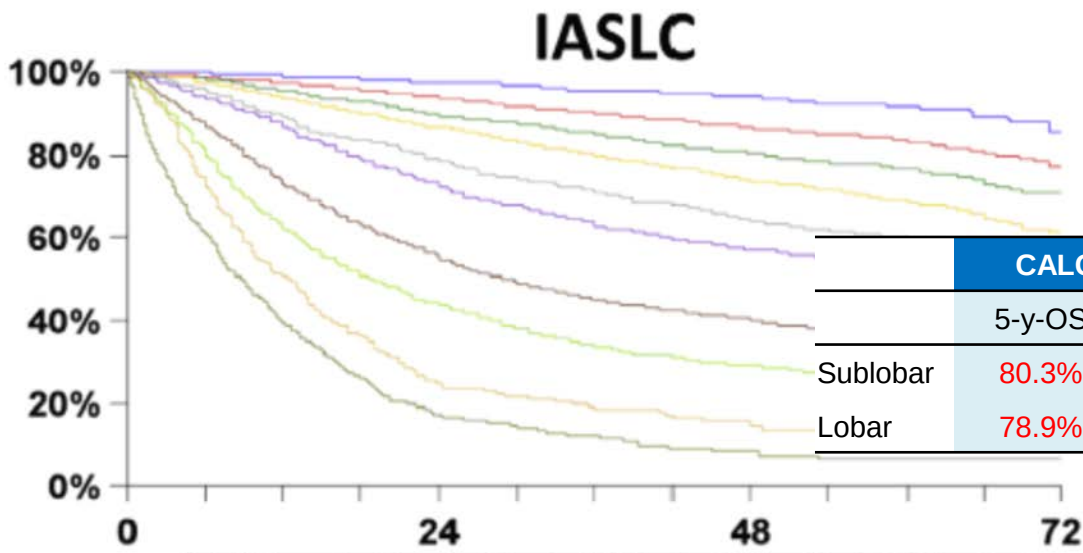
3. Overall Survival



IASLC Lung Cancer Staging Project: 8th TNM

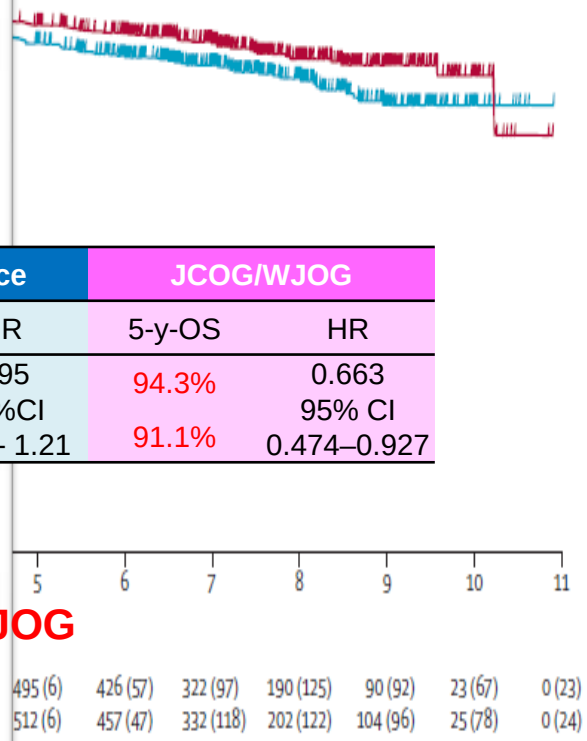


cTNM	Events / N	MST	24 Month	60 Month
IA1	68 / 781	NR	97%	92%
IA2	505 / 3105	NR	94%	83%
IA3	546 / 2417	NR	90%	77%
IR	560 / 1928	NR	87%	68%

	CALGB/Alliance		JCOG/WJOG	
	5-y-OS	HR	5-y-OS	HR
Sublobar	80.3%	0.95 90%CI 0.75 - 1.21	94.3%	0.663 95% CI 0.474–0.927
Lobar	78.9%		91.1%	

JCOG/WJOG
CALGB

J Thorac Oncol. 2017



Life status and value at the time of 5 years follow-up in all the enrolled patients of JCOG0802/WJOG4607L

Major life events		価値 Value	Life status	Arm A: Lobectomy (N=554)		Arm B: Segmentectomy (N=552)
Death	Relapse					
No	No	最善 Best	Survived without relapse	477	=	477
∨	Yes	可 Better	Survived with relapse*	18	<	35
∨	No	不可 Worse	Dead from other disease	34	>	18
Yes	∨ Yes	最悪 Worst	Dead from lung cancer	19	≧	16
			Censored	6		6

＊Pt. with relapse on the time of 5-y-f/u：37 pts. in lob. vs 51 pts. in seg.

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