GOOD SCIENCE
BETTER MEDICINE
BEST PRACTICE

European Society for Medical Oncology

ESMO Preceptorship on
Non-Small Cell Lung Cancer
Copenhagen July 7-8th 2015

Standards of care, evolving paradigm and future perspective

surgical approach for resectable NSCLC

Dominique H. Grunenwald, MD, PhD
University of Paris VI. France

1933 – Graham EA, Singer JJ. Successful removal of an entire lung for carcinoma of the bronchus. JAMA 1933;101:1371-4

cases.

DR. ALFRED A. STRAUSS, Chicago: I agree with everything that Drs. Mason and Walters have said except with that difference that it still has to be decided whether this is a triangular infection.

SUCCESSFUL REMOVAL OF AN ENTIRE LUNG FOR CARCINOMA OF THE BRONCHUS

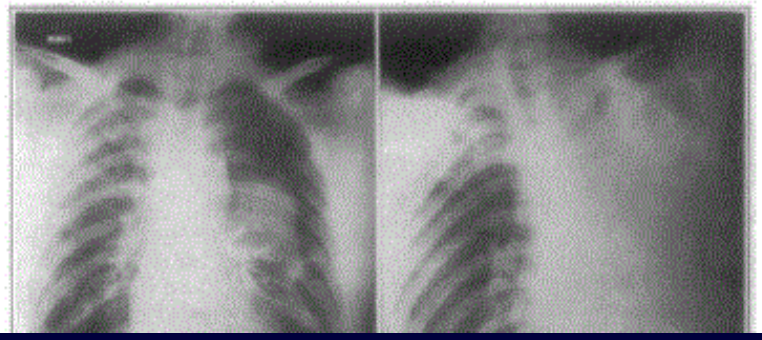
EVARTS A. GRAHAM, M.D.
AND
J. J. SINGER, M.D.
ST. LOUIS

Carcinoma of the bronchus in recent years has become a problem of major importance. It is now known that primary carcinoma of the lung, which almost always arises in a bronchus, constitutes between 5 and 10 per cent of all carcinomas.[1] In frequency, therefore, it is comparable with carcinoma of the large intestine, and it is much more frequent than the malignant tumors of some other organs that have received much more comment. The problem of primary carcinoma of the lung is of special importance, since up to the present time at least the prognosis has been almost uniformly bad because of the complete futility of any methods of treatment other than surgical excision. There is no record in the literature of the successful treatment by radiotherapy of a single case in which the pathologic evidence has been incontrovertible and in which a five year interval without recurrence has

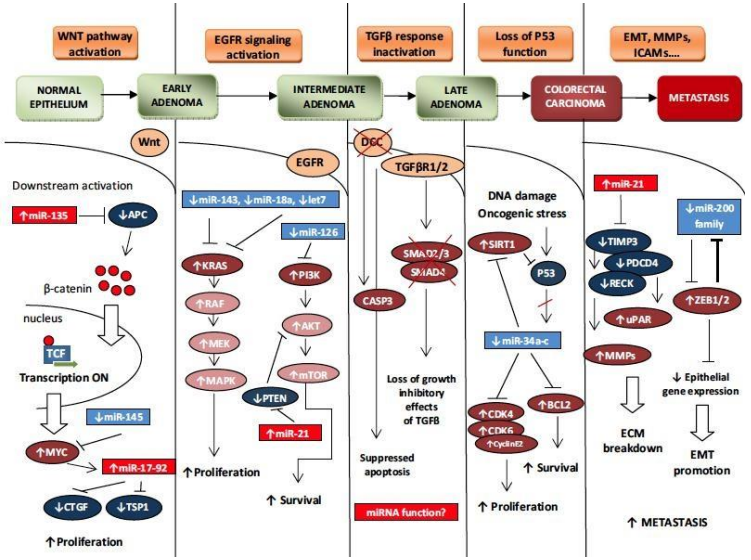
cinoma. In fact, it is apparently the first time in which the whole lung has been deliberately removed at one stage. It is possible that Kümmell [7] removed the whole lung for a carcinoma, but the description of the case is so meager that it is difficult to be sure. At any rate, the patient died. There are two instances in which an entire lung has been removed for bronchiectasis, one by Nissen [8] of Berlin and the other by Haight [9] of Ann Arbor, Mich. In both the latter cases, however, the lung was allowed to slough out after ligation of the hilus. It seems particularly important to call attention to the fact that an entire lung has been successfully removed for carcinoma of the bronchus because if this should prove to be a feasible operation in properly selected cases it is probable that many patients would be saved who otherwise would die of carcinoma.

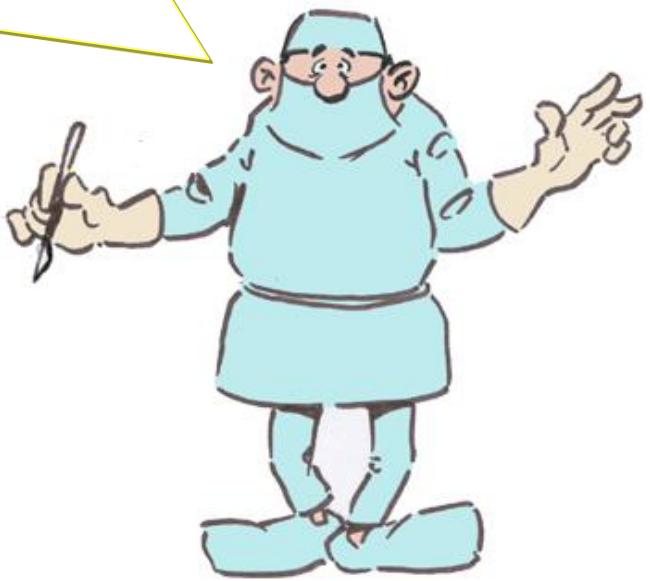
REPORT OF CASE

J. L. G., a man, aged 48, a physician, admitted to the Barnes Hospital, Feb. 27, 1933, had had repeated attacks of cough and fever with pain in the left side of the chest for a period of



is it reasonable to sacrifice a vital organ for treating a molecular disorder ???





what is the impact of surgery on lung cancer survival ?

- is the tumour resectable ?
- is the patient operable ?
- for this surgical patient, will surgery achieve better survival and quality of life
  - than no treatment?
  - than other treatments?
  - in the context of multimodal therapy compared to surgery alone, or no surgery?

"early stage"

definitions

- **a "resectable" tumour can be completely excised by surgery with clear pathological margins**

- an "operable" patient has an acceptable risk of death or morbidity

what is early stage lung cancer?

when lung cancer is defined in this way, it is often referring to cancers that are caught early enough that they have the potential to be cured with surgery

if you are wondering whether or not something you hear about “early stage lung cancer” applies to your particular situation, share your questions with your oncologist

http://lungcancer.about.com/od/glossary/g/Early-Stage-Lung-Cancer.htm

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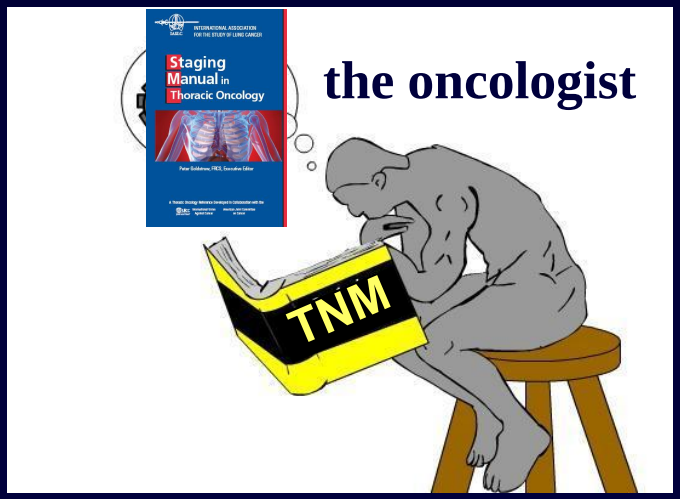
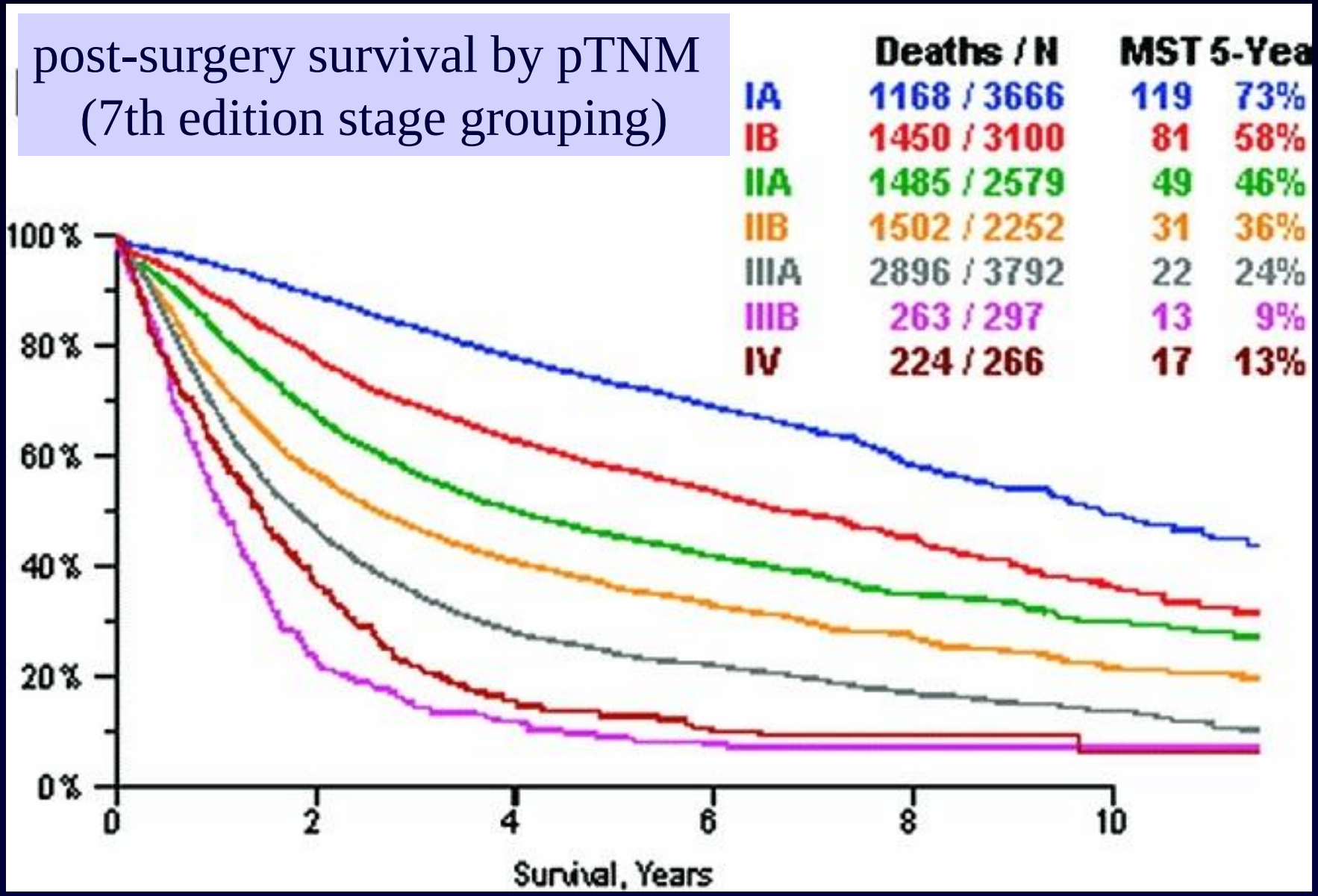


http://lungcancer.about.com/od/glossary/g/Early-Stage-Lung-Cancer.htm

the TNM stage influences survival after surgery

post-surgery survival by pTNM (7th edition stage grouping)



Goldstraw P, et al. J Thorac oncol 2007;2:706-14

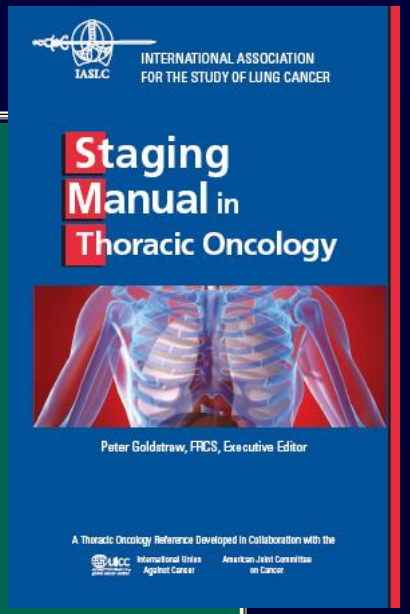
is the tumour resectable ?

stage I	**:**	**IA**	**T1a-b N0 M0** (<2cm;<3cm)
early		**IB**	**T2a N0 M0** (<5cm)
stage II	**:**	**IIA**	**T1a-b N1 M0**
early			**T2a N1 M0**
			T2b N0 M0 (<7cm)
		IIB	**T2b N1 M0**
			T3 N0 M0
stage III	**:**	**IIIA**	**T1-2 N2 M0**
locally advanced			**T3 N1-2 M0**
			T4 N0-1 M0
locally advanced		**IIIB**	**T4 N2 M0**
			T1-4 N3 M0
stage IV	**:**	**Any T, any N, M1a-b**	

surgery

selected patients

no surgery



is the patient operable ?

does the patient have the functional pulmonary reserve to tolerate the proposed resection to maintain a reasonable quality of life?

surgical resection offers little benefit if the patient suffers postoperative pulmonary insufficiency

risks from surgery increase with age and comorbidities

does the patient have the functional pulmonary reserve to tolerate the proposed resection to maintain a reasonable quality of life?

surgical resection offers little benefit if the patient suffers postoperative pulmonary insufficiency … or death

assessment by a multidisciplinary team (MDT)

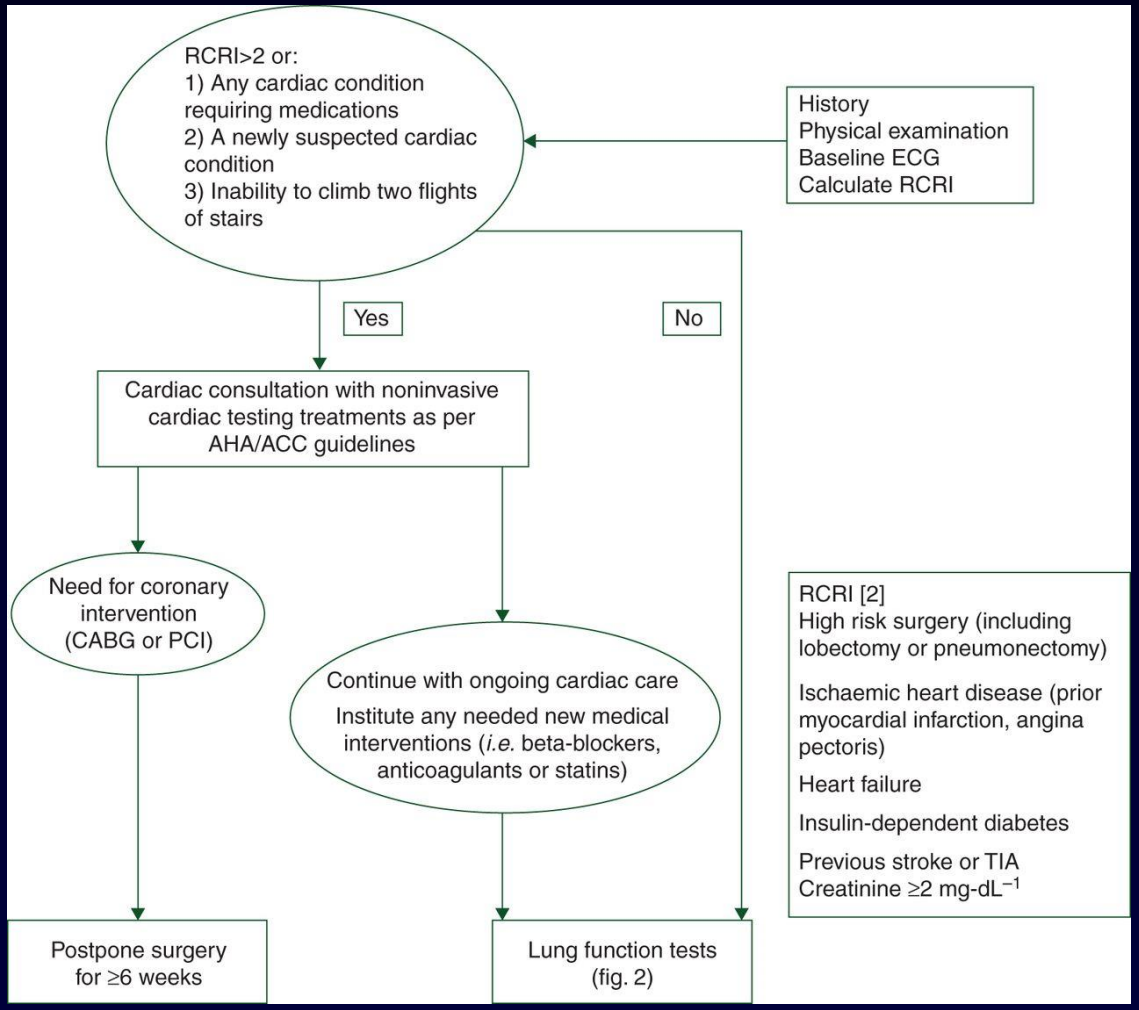
- thoracic surgery
- pulmonology
- oncology
- imaging
- nuclear medicine
- pathology

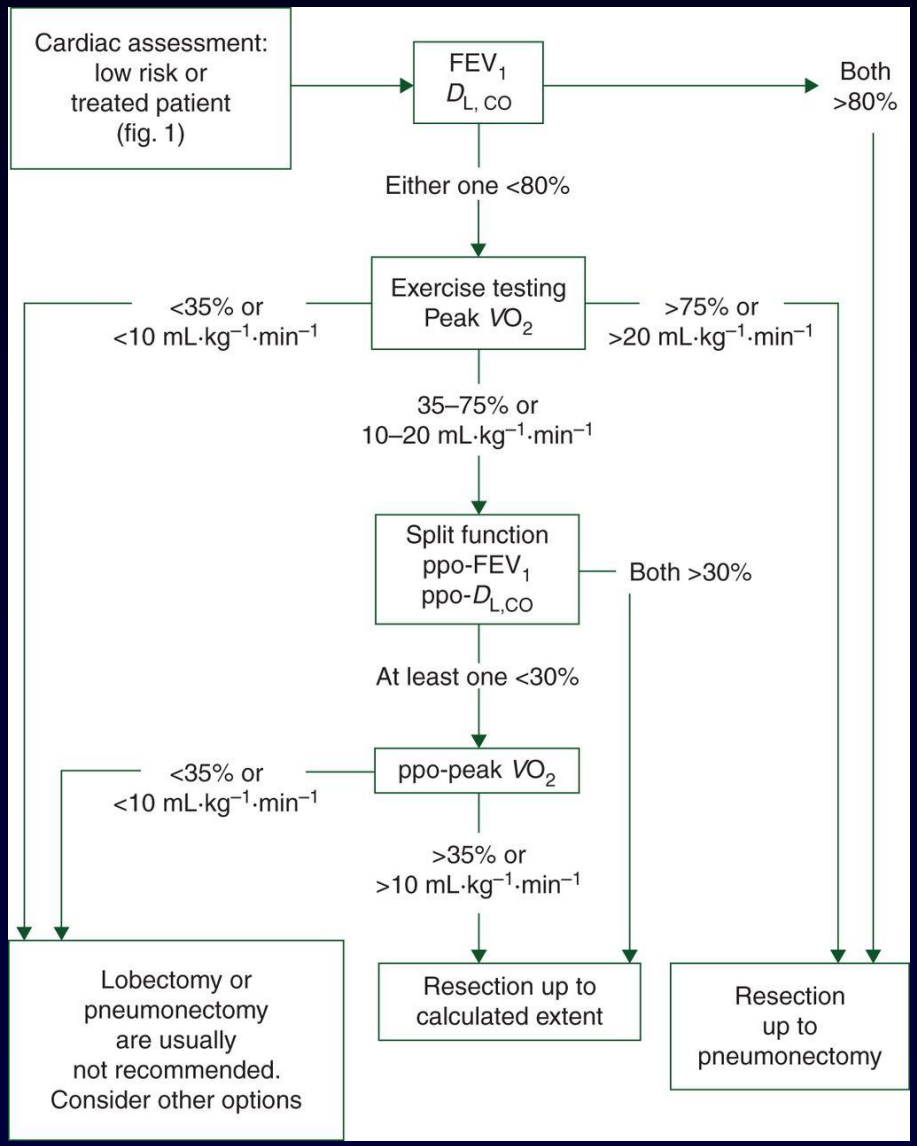
consideration of the patient's general condition

- comorbidity
- lung condition
- cardiac condition

diagnostic and therapeutic indications

Preoperative cardiac and respiratory evaluation (ERS)

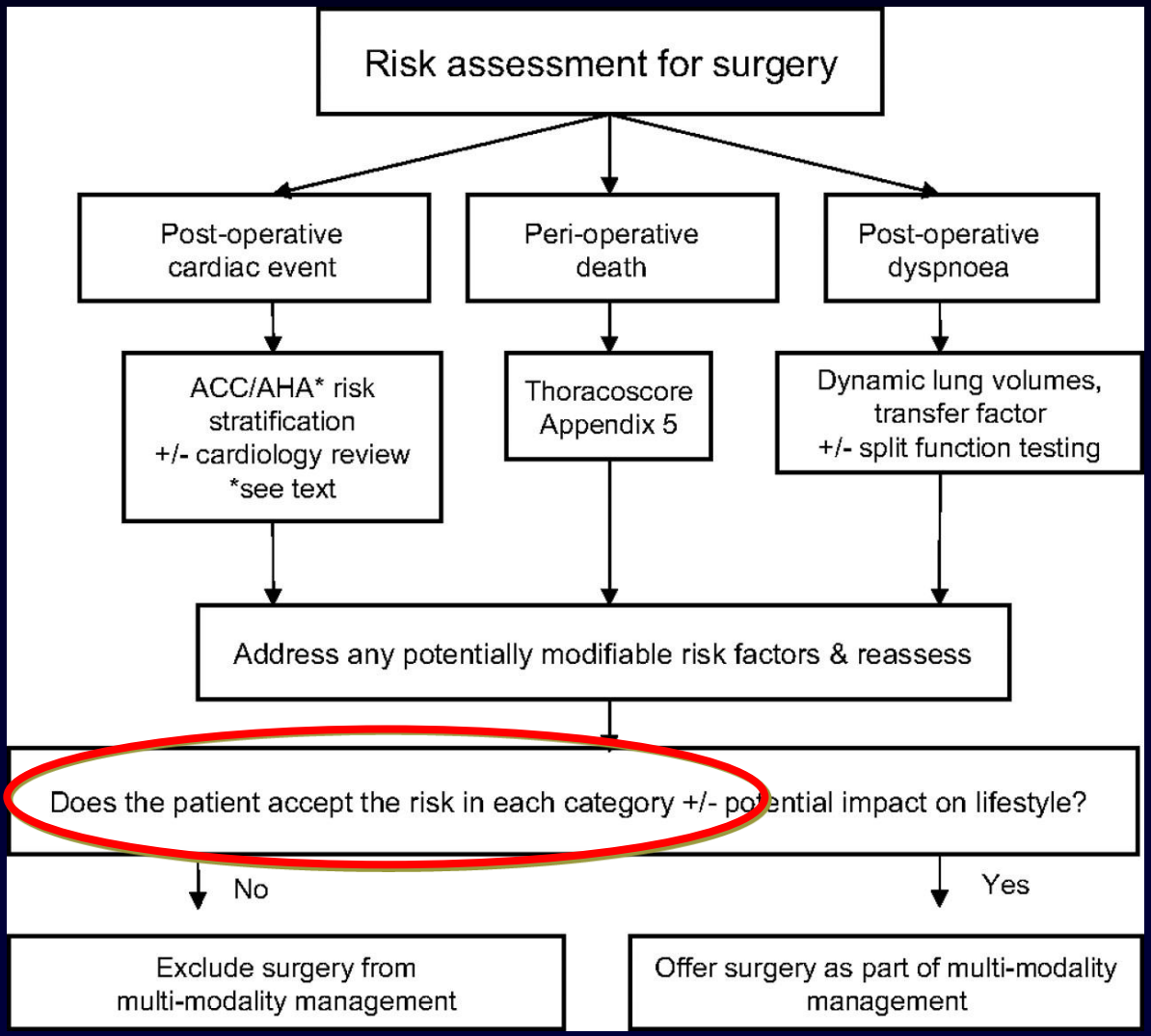


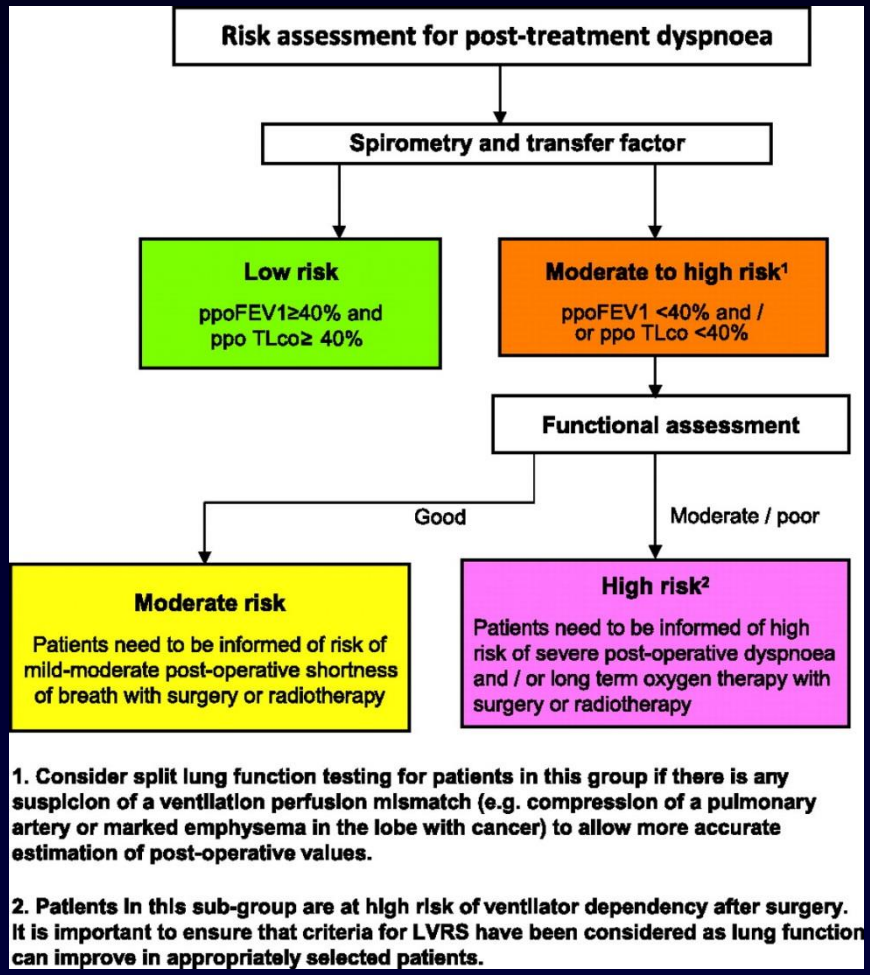


J. Vansteenkiste et al. Ann Oncol 2014;25:1462-1474

Annals of Oncology

Tripartite risk assessment





Eric Lim et al. Thorax 2010;65:iii1-iii27

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and acceptance

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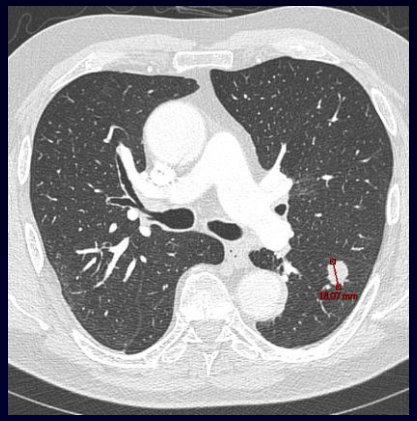
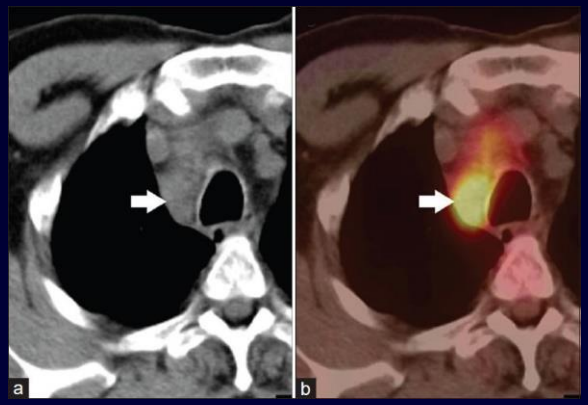
surgical resection of lung cancer controversial situations



stage I tumours

- surgery, SABR, or nothing?
- open or vats?
- lobar or sublobar?



stage III-N2

- surgery or not?
- upfront surgery or induction?
- risks?

locally advanced –T3/4

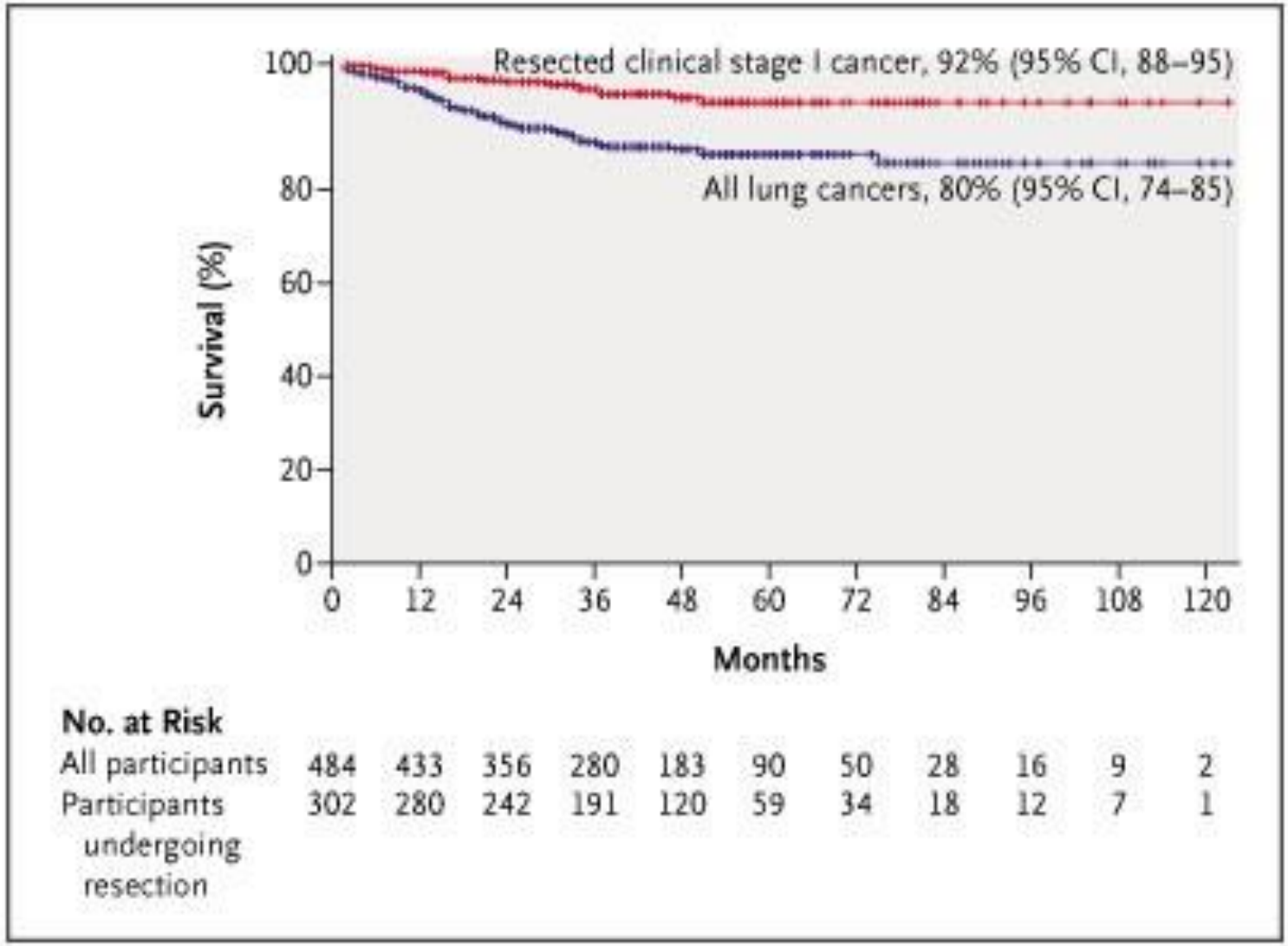
potential to be cured with surgery… alone

Stage I		Stage II		Stage III		Stage IV
IA	IB	IIA	IIB	IIIA	IIIB	
T1a N0 T1b N0	T2a N0	T1a N1 T1b N1 T2a N1 T2b N0	T2b N1 T3 N0	T1 N2 T2 N2 T3 N1 T3 N2 T4 N0 T4 N1	T4 N2 any T N3	any T any N M1a any T any N M1b

the reality

- no randomised trial comparing resection vs. no treatment in early stage nsclc
- risks from surgery increase with age and comorbidities
- in 20% of patients with stage IA, the cancer will recur within 5 years of surgery

better survival and quality of life than no treatment?



Early Lung Cancer Action Program N Engl J Med 2006;355:1763-71

better survival and quality of life than other treatments?

sbrt = on-site destruction

direct comparison of sbrt and sublobar resection is difficult

stereotactic body radiotherapy has become established as an effective modality for treating peripheral cancer in medically inoperable patients

low toxicity and excellent local control rates

different definitions of recurrence

different populations of patients

different methods of classifying morbidity

imaging follow-up not standardized

ACOSOG Z4099/RTOG 1021
a randomized study of sublobar resection compared with stereotactic body radiotherapy for high-risk stage I non-small cell lung cancer

Fernando HC, Timmerman R. J Thorac Cardiovasc Surg 2012;144:S35-8

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ACOSOG

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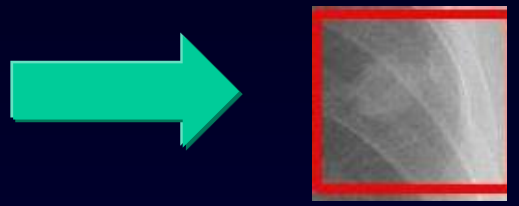
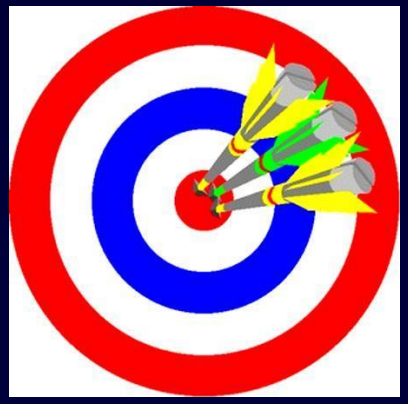
closed
slow accrual

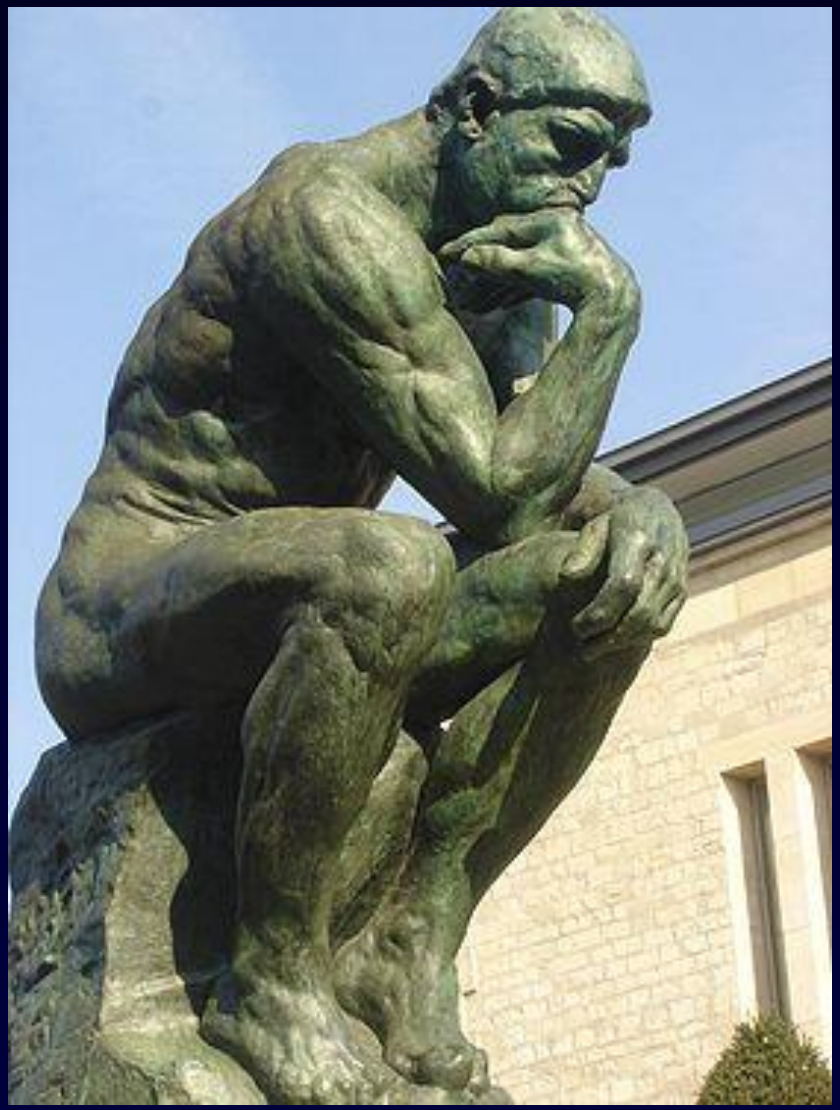
Fernando HC, Timmerman R. J Thorac Cardiovasc Surg 2012;144:S35-8

surgery = extirpation





open or vats* ?



*** video-assisted thoracoscopic surgery**

vats procedures

- comparison of the surgical outcomes of thoracoscopic lobectomy, segmentectomy, and **wedge resection** for clinical stage I nsclc. Nakamura H, et al. Thorac Cardiovasc Surg 2011;59:137-41

- complete video-assisted thoracoscopic surgery **anatomic segmentectomy** for clinical stage I lung carcinoma - technique and feasibility. Witte B, et al. Interact Cardiovasc Thorac Surg. 2011;13:148-52

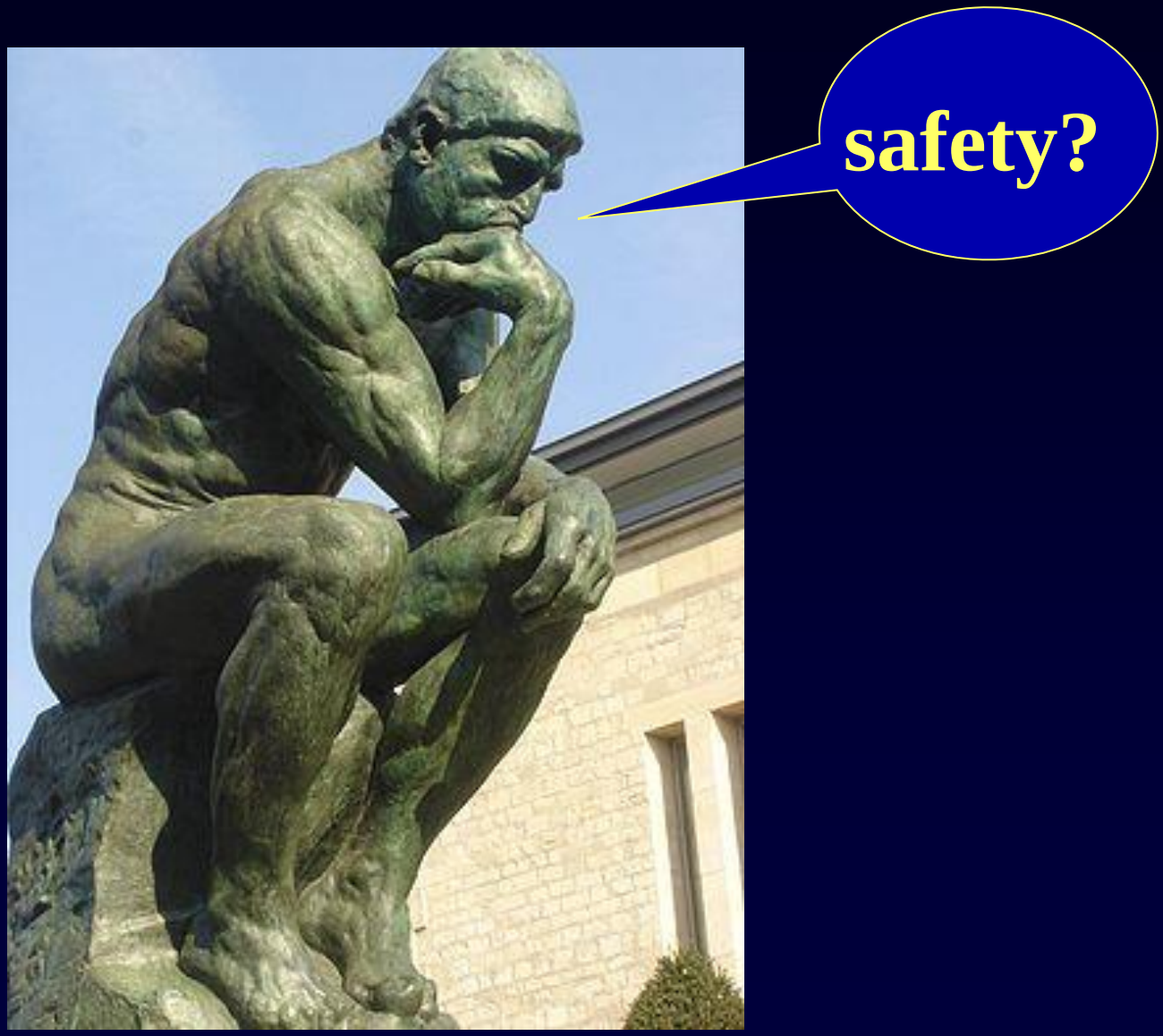
- VATS **lobectomy** for early-stage primary lung cancer. Krueger T, et al. Rev Med Suisse 2012;8:1337-41

- single-incision video-assisted thoracoscopic right **pneumonectomy**. Gonzalez-Rivas D, et al. J Surg Endosc 2012;26:2078-9

- feasibility of hybrid thoracoscopic **lobectomy and en-bloc chest wall resection**. Berry MF, et al. Eur J Cardiothorac Surg 2012;41:888-92

- the role of video-assisted thoracic surgery in the surgical treatment of **superior sulcus tumors**. Truin W, et al. Interact Cardiovasc Thorac Surg. 2010;11:512-4

open or vats* ?



*** video-assisted thoracoscopic surgery**

video-assisted thoracoscopic versus open thoracotomy lobectomy in a cohort of 13,619 patients

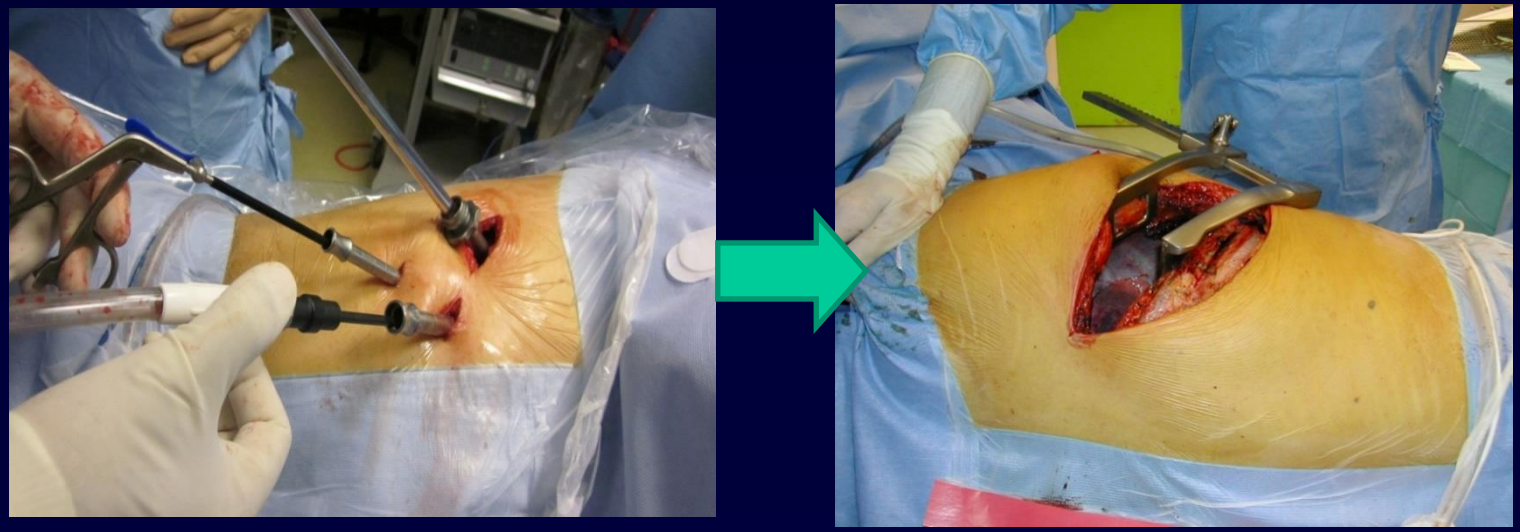
Nationwide Inpatient Sample database

lobectomy thoracotomy (n = 12,860)

vats (n = 759)

vats = higher incidence of intraoperative complications (p = 0.04)

Gopaldas RR, et al. Ann Thorac Surg 2010;89:1563-70



minimal incision = delay in control of bleeding

a national study of **nodal upstaging** after thoracoscopic versus open lobectomy for clinical stage I lung cancer

(nodal upstaging occurs when unsuspected lymph node metastases are found during the final evaluation of surgical specimens)

Danish Lung Cancer Registry

1,513 pts	VATS	717 (47%)
	thoracotomy	796 (53%)

nodal upstaging 281 pts (18.6%)

thoracotomy higher **N1 upstaging** (13.1% vs 8.1%; **p<0.001**)

N2 upstaging (11.5% vs 3.8%; **p<0.001**)

no difference in OS between VATS and thoracotomy

(hazard ratio, 0.98; 95% confidence interval, 0.80 to 1.22, p=0.88).

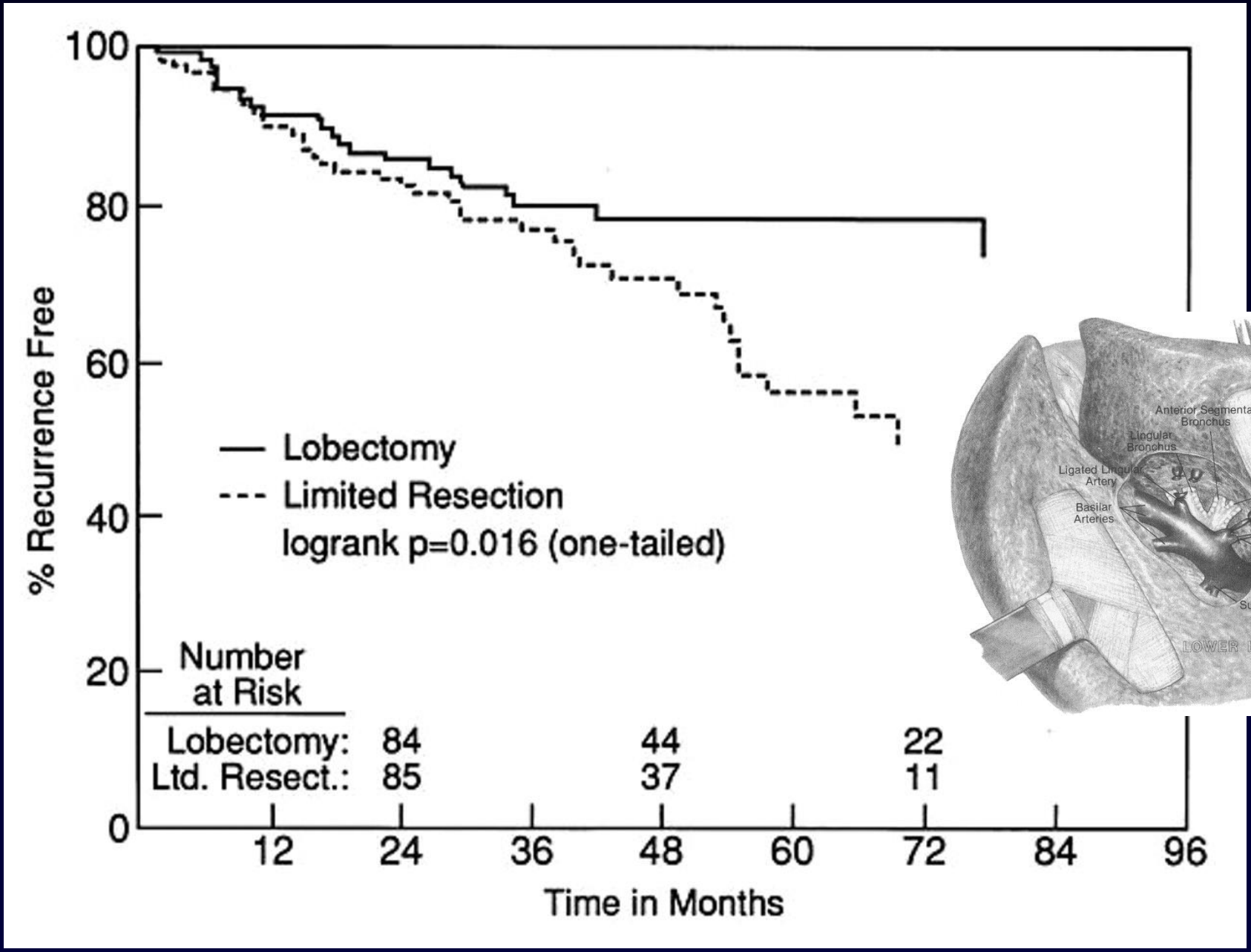
Licht PB, et al. Ann Thorac Surg 2013;96:943-9

video-assisted thoracic surgery for lung cancer: republication of a systematic review and a proposal by the guidelines committee of the Japanese Association for Chest Surgery 2014

VATS lobectomy by an **experienced surgeon** may be considered and applied to patients with clinical stage I NSCLC,
however, **well-established evidence is lacking**
VATS showed better or **at least equivalent outcomes** regarding intra- or postoperative complications compared with thoracotomy, with less invasiveness
long-term survival by VATS lobectomy was suggested to be **at least equivalent**, although there is a **lack of evidence**
(Recommendation grade: Level C1).

Yamashita S, et al. Gen Thorac Cardiovasc Surg 2014:62:701-5

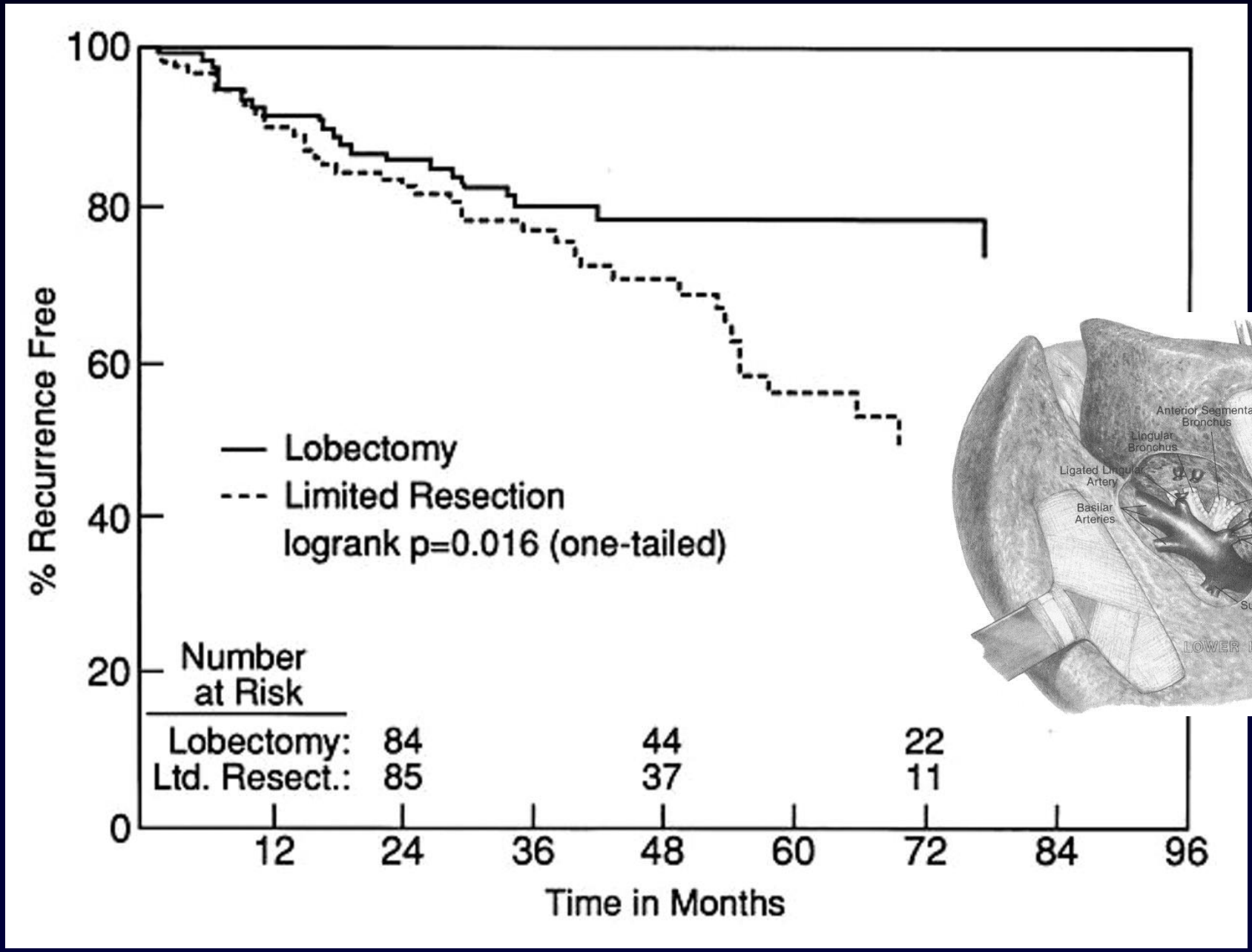
a sublobar resection ?



Time to recurrence (excluding second primaries) by treatment for 247 eligible patients

Ginsberg RJ and Rubinstein LV 1995

the gold standard in stage I is an anatomic lobar resection



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Ginsberg RJ and Rubinstein LV 1995

an evolving paradigm?

sublobar resection: a movement from the Lung Cancer Study Group

1995 LCSG consensus : lobectomy = gold-standard (stage I nsclc)

enhancements in imaging technology
screening programs → **larger cohorts of localized early-stage disease**

minimally invasive surgical resection
reduced perioperative morbidity and mortality
equivalent oncologic effectiveness to open surgery

↓

challenging lobectomy as a standard for small tumors

Blasberg JD, et al. J Thorac Oncol 2010;5:1583-93

survival following lobectomy and limited resection for the treatment of stage I nsclc <= 1cm in size: a review of SEER data

(Surveillance, Epidemiology, and End Results registry)

stage I nsclc </=1 cm in size 2,090

limited resect. (segment. or wr) 688 (33%)

no difference in outcomes among patients treated with lobectomy vs limited resection

overall survival

HR : 1.12 (95% CI: 0.93-1.35)

lung cancer-specific survival

HR: 1.24 (95% CI: 0.95-1.61)

Kates M, et al. Chest 2010

recurrence and survival outcomes after anatomic segmentectomy versus lobectomy for clinical stage I nsclc: a propensity-matched analysis

matched cohorts (n = 312 pts per group)

	segmentectomy (%)	lobectomy (%)	*p*
periop. mortality	1.2	2.5	0.38
locoreg. recurr.	5.5	5.1	1.00
distant recurr.	14.8	11.6	0.29
overall recurr.	20.2	16.7	0 .30
5-yr DFS	70	71	0 .467
5-yr survival	54	60	0 .258

Landreneau RJ, et al. J Clin Oncol 2014;32(23):2449-55

sublobar resection is equivalent to lobectomy for clinical stage 1A lung cancer in solid nodules (International Early Lung Cancer Action Program)

nsclc with a diameter of 30 mm or less (stage 1) n=347

10-yr survival	sublobar res. (n=53)	85%	
	lobectomy (n=294)	86%	***P = .86***

cancers 20 mm or less in diameter ***P = .45***

sublobar resection and lobectomy have equivalent survival for patients with clinical stage IA nsclc in the context of computed tomography screening for lung cancer

Altorki NK, et al. J Thorac Cardiovasc Surg 2014;147:754-62 (I-ELCAP)

the surgical management of stage I and stage II lung cancer

"anatomic lobectomy combined with hilar and mediastinal lymphadenectomy constitutes the oncologic basis of surgical resection"

"however, the role of sublobar pulmonary resection, either anatomic segmentectomy or nonanatomic wedge resection, in patients with subcentimeter nodules may become important"

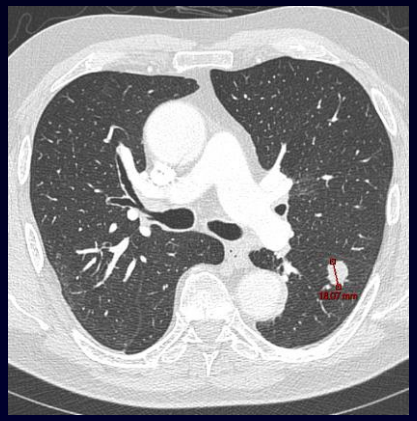
Gorenstein LA, Sonett JR. Surg Oncol Clin N Am 2011;20:701-20

expected results of clinical trials

to determine whether patients with small peripheral NSCLC tumors can safely undergo sublobar resection while maintaining rates of survival and recurrence that are comparable to lobectomy

CALGB 140503
JCOG0802/WJOG4607L

surgical resection of lung cancer standard of care



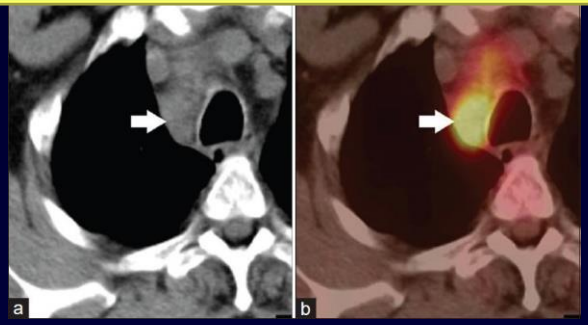
<u>stage I & II tumours</u>

- surgery
- open or vats
- lobar or sublobar?

surgical resection of lung cancer controversial situations

<u>stage III-N2</u>

- surgery or not?
- upfront surgery or induction?
- risks?



<u>locally advanced –T3/4</u>

- surgery ?

what we know from evidence based medicine in N2 disease

- dramatic benefit with induction chemotherapy compared to surgery alone in two small-scale studies [*Roth, Rosell, 1994*]
- no benefit in large european randomized study in stage IIIA category [*Depierre, 2002*]
- stage IIIA benefits from adjuvant chemotherapy following "complete resection" [*Arriagada, 2004; Douillard, 2006*]
- nothing on radiotherapy (Lung-ART still ongoing)
- nothing on surgery

N2 disease – paradigms and opinions

- mediastinal downstaging from induction is the most powerful positive prognostic factor for survival after surgery [*Betticher, 2003; Albain, 2009]*
- rt should be considered the preferred locoregional treatment for pts with stage IIIA-N2 nsclc responders to induction ct [*Van Meerbeck, 2007]*
- good candidates for surgery may still be appropriately managed by using resection rather than radiation [*Vansteenkiste, 2007*]
- the role of surgery is not clearly defined [*Roy and Donington, 2007*]

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no standard of care

outcome of surgery versus radiotherapy after induction treatment in patients with N2 disease: systematic review and meta-analysis of randomised trials

main outcome = survival

805 publications ⟶ final 6 randomised trials (868 patients)

- 4 trials, patients randomised to surgery after chemotherapy

  HR = 1.01 (95% CI 0.82 1.23; P = 0.954)

- two trials, patients randomised to surgery after chemo-radiotherapy

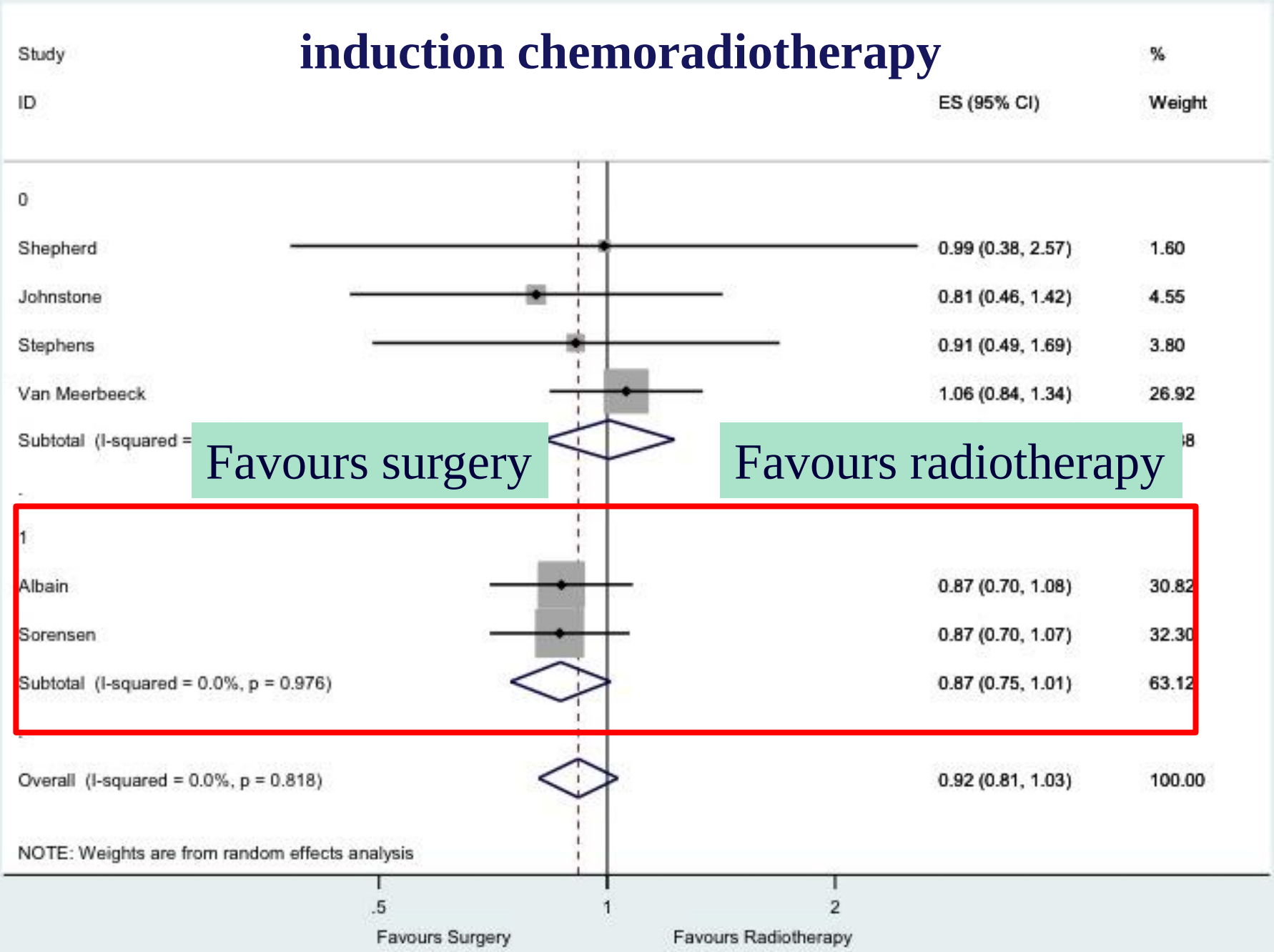
  HR = 0.87 (0.75 1.01; P = 0.068)

overall hazard ratio of all pooled trials = 0.92 (0.81 1.03; P = 0.157).

in trials where patients received surgery as part of trimodality treatment, the overall survival was better than chemo-radiotherapy alone

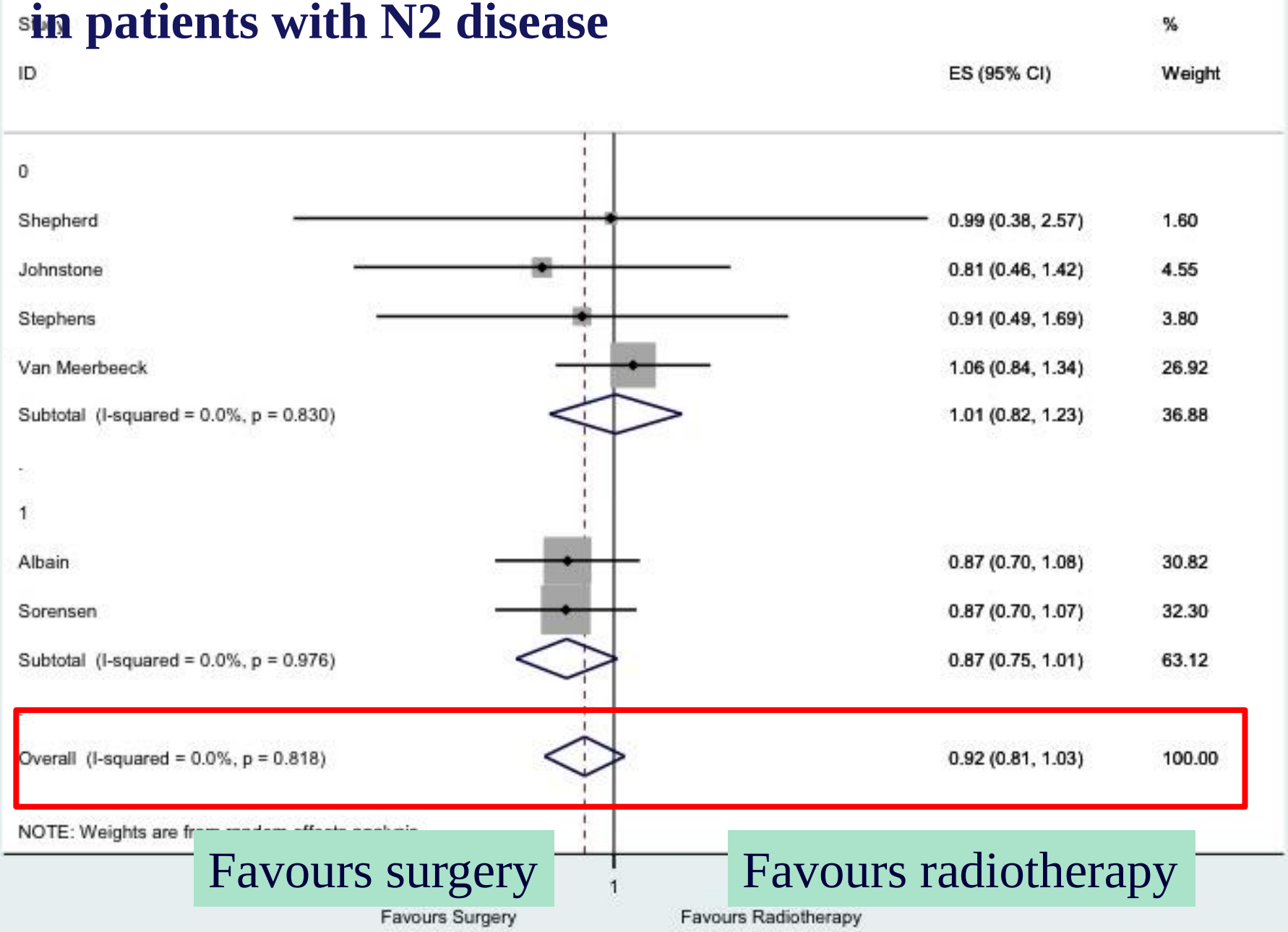
McElnay PJ, et al. Thorax 2015;May 12 [Epub ahead of print]

induction chemoradiotherapy



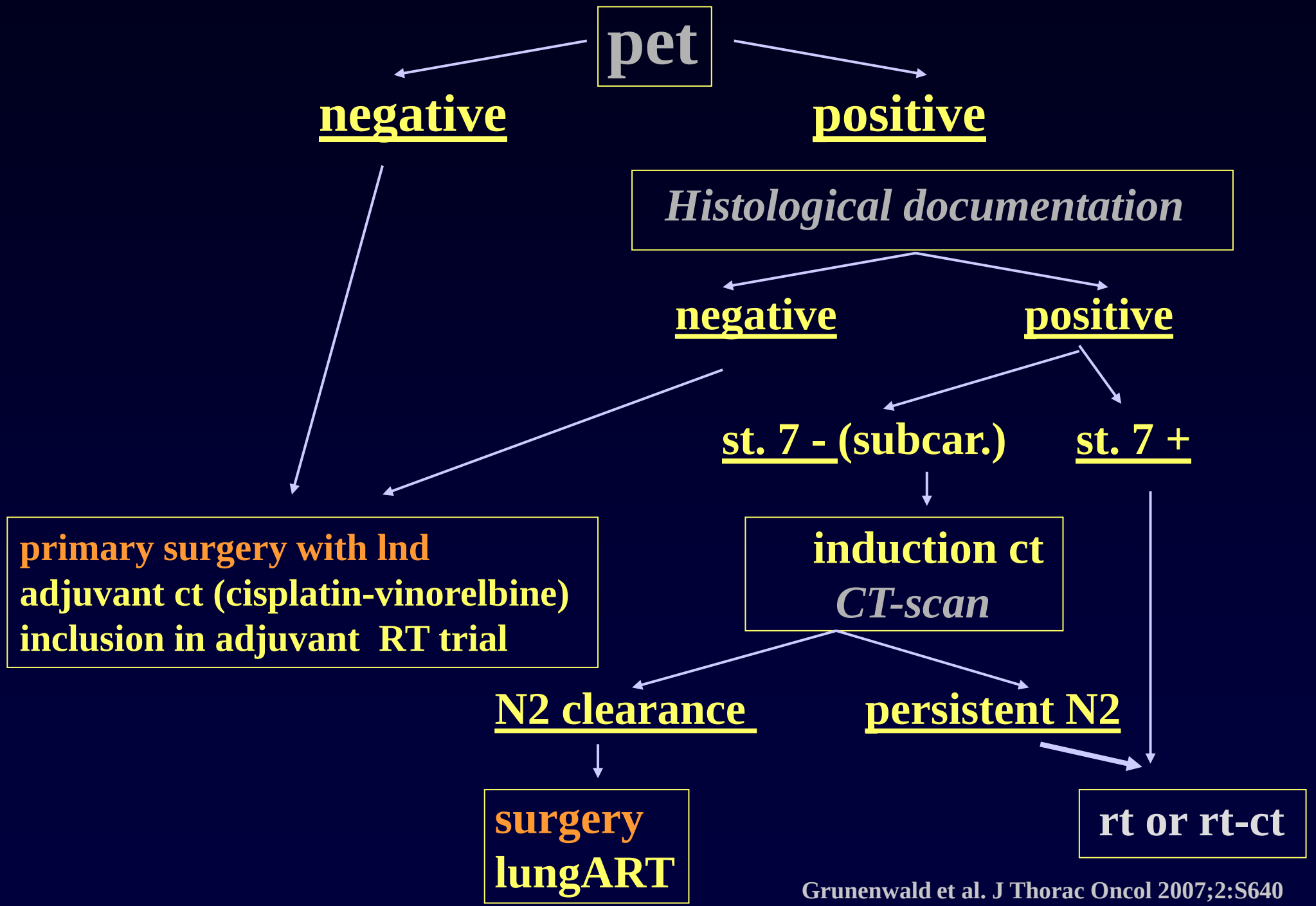
By courtesy of PJ McElnay and E. Lim

surgery versus radiotherapy after induction treatment in patients with N2 disease



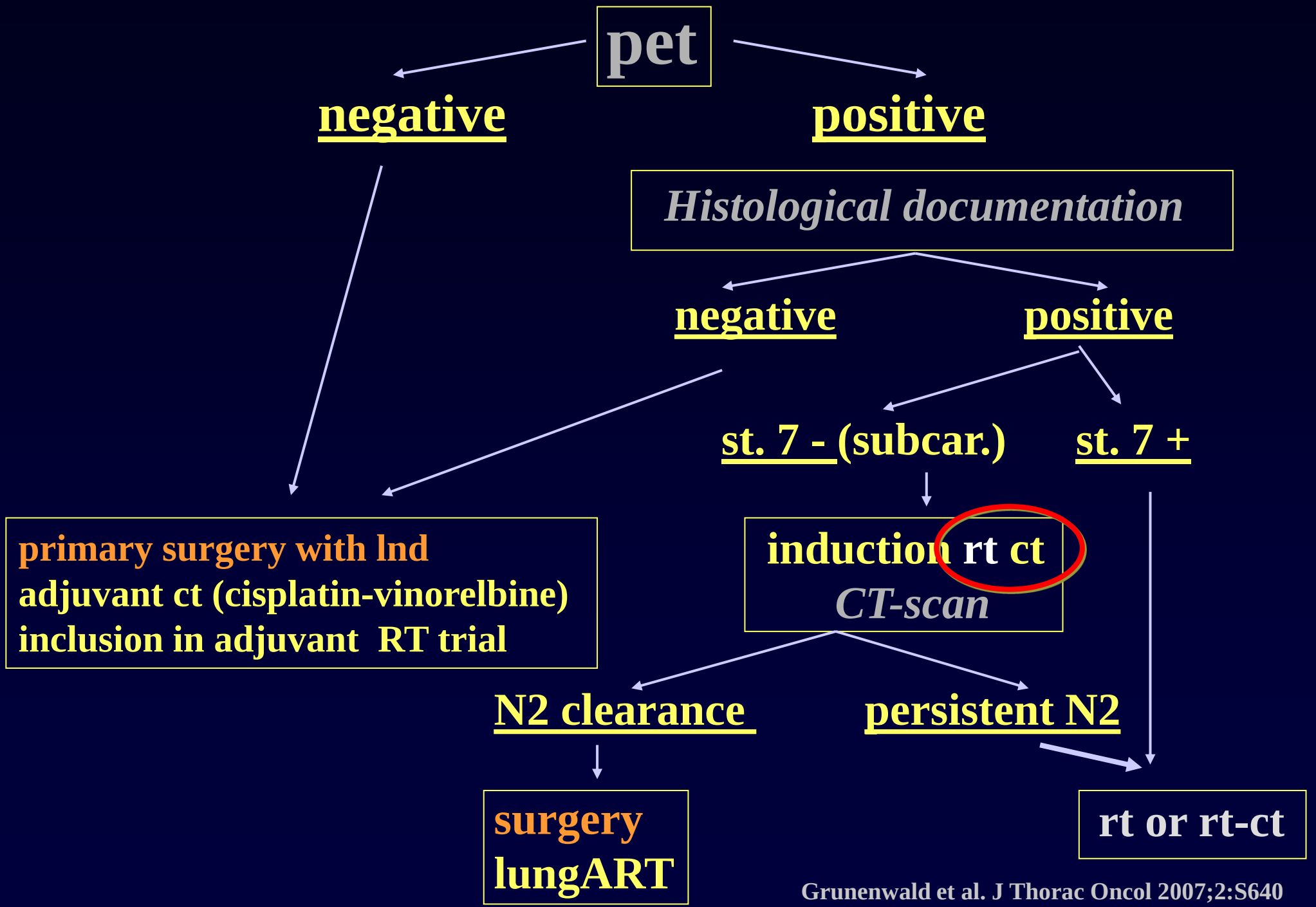
By courtesy of PJ McElnay and E. Lim

algorithm for surgery in c-stage IIIa N2



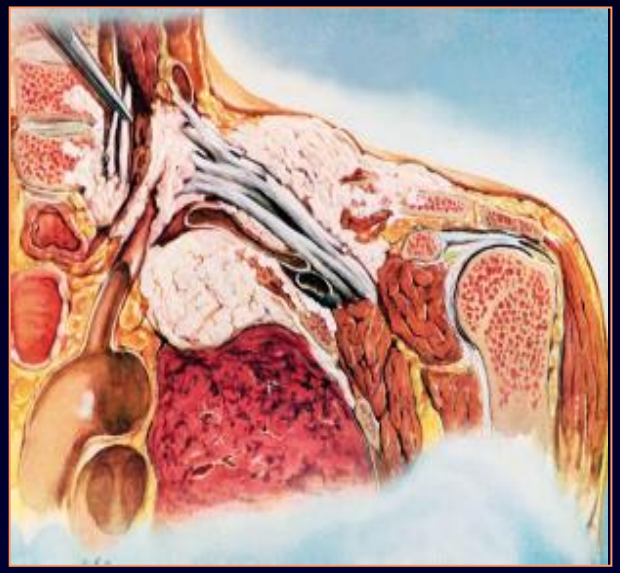
Grunenwald et al. J Thorac Oncol 2007;2:S640

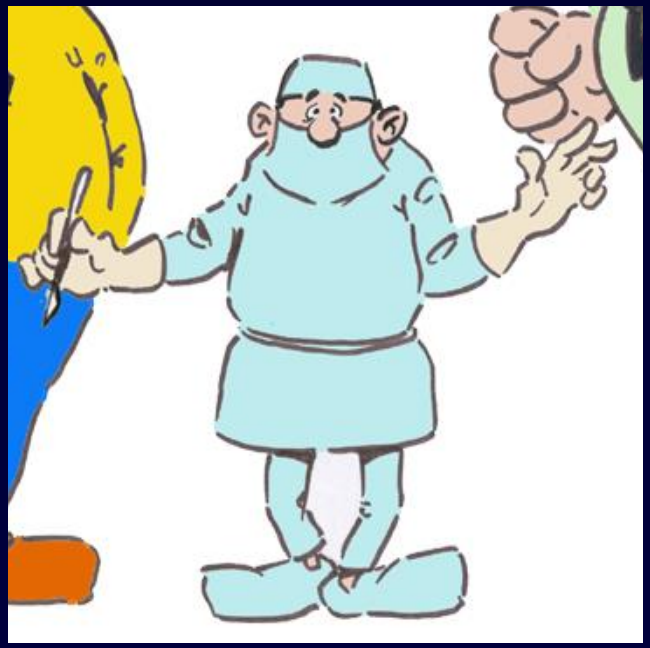
algorithm for surgery in c-stage IIIa N2



Grunenwald et al. J Thorac Oncol 2007;2:S640

locally advanced nsclc are not "surgical", an evolving paradigm?





locally advanced T3-4 superior sulcus tumor

superior sulcus tumors
surgery versus no surgery

surgery with ind. or adj. treatment 139 (S)

rt +/- ct without surgery 96 (NS)

	S	NS	
5-Year OS	35%	8%	p < 0.0001
5-Year DFS	38%	15%	p < 0.0001
5-Year LRC	62%	38%	p < 0.0001

Komaki R, et al Lung Cancer 2005;49S2:S79

induction ct-rt and surgical resection for superior sulcus nsclc

author	year	no.	R0 (%)	pCR (%)	5-yr os (%)
Rusch	2007	80	76	56	44
Marra	2007	29	94	*nr*	46
Kunitoh	2008	57	51	16	56
Kappers	2009	22	22	62	37

en bloc vertebrectomy / intralesional approach upfront surgery / induction rt-ct

	pers.	MDA	Toronto
yr	2006*	2009	2013
induction	none, ct	none	**ct-rt**
surg. technique	en bloc	intralesional	en bloc
pts	34	31	48
partial vert.	28	16	38
total vertebr.	6	15	10
R0 res. (%)	**88**	**56**	**88**
mortality (%)	3	5	6
5-yr surv. (%)	24	27	**61**

** unpublished*

morbi-mortality from combined modality affects survival, a myth ?

an old myth, or a paradigm ?

1993 neoadjuvant therapy for lung cancer: a note of caution **Rusch VW, Benfield JR**

1994 induction chemotherapy becomes popular **Rosell R, et al. ; Roth JA, et al.**

2001 right pneumonectomy is at risk **Martin J, et al.**

2003 surgery is toxic in INT0139 trial **Albain KS, et al.**

2007 radiotherapy preferred (lower morbidity) **Van Meerbeeck J, et al.**

an old myth, or a paradigm ?

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1994 induction chemotherapy becomes popular Rosell R, et al. ; Roth JA, et al.

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2003 surgery is toxic in INT0139 trial Albain KS, et al.

2007 radiotherapy preferred (lower morbidity) Van Meerbeeck J, et al.

2009 post rt-ct pneumonectomy low mortality Weder W, et al.

is "adjuvant" surgery risky ?

is surgical toxicity a restricting factor ?

should surgical toxicity influence therapeutic strategy ?

induction chemotherapy increases perioperative complications in patients undergoing resection for non-small-cell lung cancer. Roberts JR, et al. 2001

preoperative chemotherapy for lung cancer does not increase surgical morbidity. Siegenthaler MP, et al. 2001

retrospective analysis of patients who underwent pneumonectomy after neoadjuvant therapy in 2 centers

pneumonectomies	176	
induction ct	35	20%
induction ct-rt	141	80%
extended resections	138	78%
perioperative mortality	6	3%
90-day major complications	22	13%
5-year survival		38%

by courtesy of Dr. W. Weder, MD

where is the truth ?

- **surgery adds mortality when compared with no surgery**
- **mortality rates are lower in retrospective analyses of academic centers compared with multicenter randomised studies**
- **evidence from INT0139 cannot be applied to academic centers**
- **whether addition of rt to induction ct increases surgical complications is not demonstrated yet**
- **pneumonectomy *per se* is a risk factor for mortality**
- **whether the side (right/left) does matter is not proven**

duties of the surgeon

the patient has to stay on

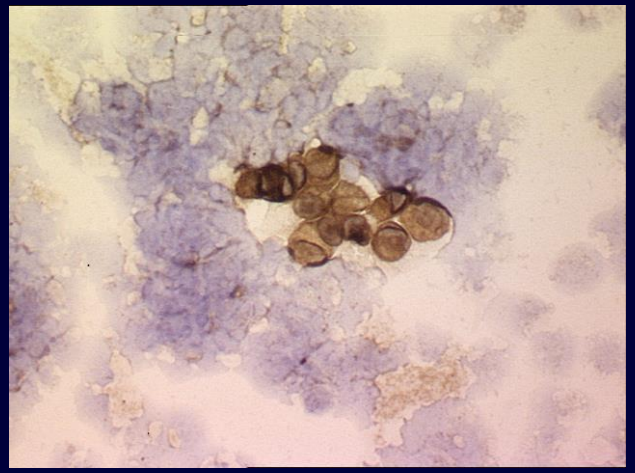
- **alive at 30 days after operation**
- **in good condition at 3 months**
- **without local recurrence at 1 year**

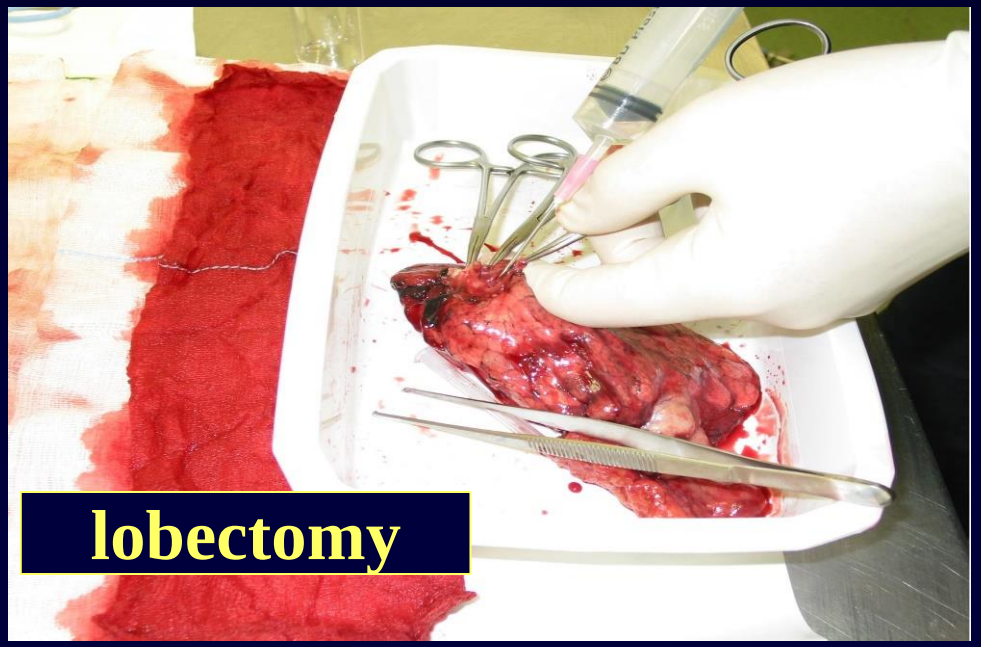
the dearest wish :

- **alive and dis.-free at 5 yrs**

blood-borne cancer cells in pulmonary veins in surgical non-small cell lung cancer

- venous blood is collected from the pulmonary vein in the operating room
- **circulating tumor cells are detected in 81% of the patients**





Grunenwald DH, et al. presented at the 14th WCLC 2011

the future challenges

- to pursue efforts in aggressive surgery
- to improve all modalities (morbidity, mortality)
- to optimize multimodality combinations
- to improve knowledge on predictive factors, biomarkers, circulating tumor cells, new targets
- to apply customized therapy in perioperative setting

guidelines on the radical management of patients with lung cancer. British Thoracic Society and the Society for Cardiothoracic Surgery in Great Britain and Ireland.

offer radical treatment without further mediastinal lymph node sampling if there is no significant uptake in normal sized mediastinal lymph nodes on **PET-CT** scanning. **[C]**

evaluate PET positive mediastinal nodes by further mediastinal sampling. **[C]**

when obtaining diagnostic and staging samples, consider the adequacy of these in the context of selection of patients for targeted therapy. **[D]**

consider **EBUS/EUS-guided TBNA** to stage the mediastinum. **[C]**

confirm negative results obtained by TBNA and EBUS/EUS-guided TBNA by mediastinoscopy and lymph node biopsy where clinically appropriate. **[C]**

adequate TNM staging = the right treatment to the right patient

Lim E, et al. Thorax 2010;65:iii1-27

british guidelines (continued)

offer patients with T3N0–1M0 disease radical treatment. **[D]**

consider selected patients with T4N0–1M0 disease for radical multimodality treatment.**[D]**

consider surgery as part of multimodality management in patients with T1–3N2 (non-fixed, non-bulky, single zone) M0 disease. **[B]**

avoid pneumonectomy where possible by performing bronchoangioplastic resection or non-anatomical resection. **[C]**

consider patients with moderate to high risk of postoperative dyspnoea for lung parenchymal sparing surgery. **[D]**

consider bronchoangioplastic procedures in suitable patients to preserve pulmonary function. **[D]**

consider patients with limited pulmonary reserve for sublobar resection as an acceptable alternative to lobectomy. **[B]**

perform systematic nodal dissection in all patients undergoing resection for lung cancer.**[A]**

remove or sample a minimum of six lymph nodes or stations. **[D]**

Lim E, et al. Thorax 2010;65:iii1-27

treatment of stage I and II nsclc: diagnosis and management of lung cancer, 3rd ed: ACCP evidence-based clinical practice guidelines

surgical resection remains the primary and preferred approach to the treatment of stage I and II nsclc

lobectomy or greater resection remains the preferred approach to T1b and larger tumors

every patient should have systematic mediastinal lymph node sampling at the time of curative intent surgical resection, and mediastinal lymphadenectomy can be performed without increased morbidity

perioperative morbidity and mortality are reduced and long-term survival is improved when surgical resection is performed by a **board-certified thoracic surgeon**

Howington JA, et al. *Chest* 2013;143(5_suppl):e278S-e313S

2nd ESMO Consensus Conference on Lung Cancer: early-stage nsclc consensus on diagnosis, treatment and follow-up

recommendations

- a pre-surgical pathological diagnosis
- surgical resection for patients with a non-centrally located resectable tumour and absence of nodal metastasis on both CT and PET images [I,A]
- pathological confirmation for patients with suspect mediastinal lymph node metastasis on CT or PET images (unless bulky) [I, A]
- needle aspiration under endobronchial or endoscopic ultrasound guidance is the preferred first technique for pathological confirmation [I, A]
- before considering surgical resection, precise assessment of cardiac and pulmonary function is necessary to **estimate risk of operative morbidity** [III, A]

Vansteenkiste J, et al. Ann Oncol 2014;25:1462-74

2nd ESMO Consensus Conference on Lung Cancer (continued)

- comorbidities should be evaluated and optimised before surgery [III, A]
- surgery should be offered to patients with stage I and II NSCLC who are **willing to accept procedure-related risks** [III, A]
- **anatomical resection** (lobectomy) is preferred over lesser resections such as wedge or segment resection [I, A]
- sub-lobar resection is generally considered acceptable for pure GGO lesions or adenocarcinomas *in situ* or with minimal invasion [III, B] Lobectomy is still considered the standard surgical treatment of tumours ≤2 cm in size that have a solid appearance on CT [II, B]
- lymph node dissection should conform to IASLC specifications for staging [III, A]
- either open thoracotomy or VATS access can be utilised as appropriate to the **expertise of the surgeon** [III, A]

Vansteenkiste J, et al. Ann Oncol 2014;25:1462-74

recommendations

- ESMO

  Vansteenkiste J, et al. Ann Oncol 2014;25:1462-74

- BTS-SCTS

  Lim E, et al. Thorax 2010;65:iii1-iii27

- ACCP

  Howington JA, et al. Chest 2013;143(5_suppl):e278S-e313S