Evidenced-Based Clinical Problem Solving Article

Are quality of life outcomes comparable following stereotactic radiotherapy and minimally invasive surgery for stage I lung cancer patients?

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Abstract: A best evidence topic in thoracic surgery was produced in accordance with published guidelines. The question addresses the effect of stereotactic ablative radiotherapy (SABR) and minimally-invasive anatomical lung resection on quality of life (QoL) in patients with stage I non-small-cell lung cancer. Altogether more than 428 papers were found using the reported search. Only one small RCT of 22 patients was identified that addressed the effect of SABR and surgery on QoL and found global health status to be statistically significantly worse for surgical patients when compared to SABR. Sixteen further studies provided some supporting evidence, but not directly compared QoL between the two treatment modalities. Consequently, there is no general consensus currently available from the literature. Among the nine SABR-only studies, only five specified the percentage of patients who were medically operable but refused surgery. None of the studies identified significant difference in most of the QoL domains 12 months after treatment. Within the surgical papers, patients recovered well after video-assisted thoracoscopic surgical (VATS) anatomical lung resection for stage-I NSCLC. Confirming previous evidence of open surgery, three studies demonstrated worsening of QoL domains from 8 weeks to 3 months and a return to baseline after 12 months. Emotional functioning (EF) showed an improvement across both treatments, often superseding baseline scores. Given the different population characteristics of all the available evidence, further appropriately powered and randomised studies are necessary to clarify this issue.

Keywords: Patient Reported Outcomes Measures (PROMS); quality of life (QoL); lung cancer; stereotactic ablative radiotherapy (SABR); video-assisted thoracoscopic surgical (VATS); BET

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Introduction

A best evidence topic was conducted according to recognised guidelines in the surgical field (1).

Clinical scenario

An 80-year-old male patient presents to your clinic complaining of shortness of breath and weight loss. Preoperative staging confirms a peripheral stage-I NSCLC in the right upper lobe. The lung function test returns a forced expiratory volume in 1 second (FEV1) of 50% and diffusing capacity of 40%. The cardio-pulmonary exercise test (CPEX) showed a VO2Max of 11.5 mL/kg/min.

Although a lobectomy would represent the standard

oncological treatment, tests indicated high surgical risk. You discuss with the patient possible alternative non-surgical treatment, including stereotactic ablative radiotherapy (SABR). The patient asks how these two treatments will affect his quality of life (QoL). You resolve to check the literature yourself.

Three-part question

In (patients with stage I non-small-cell lung cancer) what effect do (SABR and minimally-invasive surgery) have on (QoL)?

Search strategy and study selection

The English language scientific literature was reviewed primarily by searching MEDLINE and EMBASE from 1996 through December 2017 using the Ovid Interface: [quality of life.mp OR patient reported outcome.mp OR eortc qlq.mp OR short-form 36.mp] AND [surger*.mp OR lobectom*.mp. OR segmentectomy.mp OR sleeve resection.mp] AND [Stereotactic ablative radiotherapy.mp. OR SABR.mp OR sbrt.mp] AND [NSCLC.mp OR lung cancer.mp OR stage I]. Studies with less than 20% video-assisted thoracoscopic surgical (VATS) procedures were excluded.

Four hundred and twenty-eight papers were found using the reported search. From these, only one small randomized controlled trial (RCT) was identified that provided evidence addressing the specific question: in patients with stage I non-small-cell lung cancer what effect do SABR and minimally-invasive surgery have on QoL? Sixteen studies provided supporting evidence, as not directly comparing QoL in these two treatment modalities. All the seventeen studies appraised in this manuscript are summarised in *Table 1*.

Results

Sixteen studies were identified, which separately investigated the effect of SABR or VATS lobectomy for early stage NSCLC on QoL. Only one RCT of 22 patients has been identified which directly compared the QoL outcomes of medically operable stage IA NSCLC patients treated with either SABR or surgery (2). Time to deterioration (TTD) in QoL domains was used to detect changes during the follow-up. It was calculated from the time of randomization to first appearance of a clinical significant difference in QoL scores. Validated instruments at baseline, and up to 24 months post-treatment were used: the European Organization for Research and Treatment of Cancer QoL Core questionnaire (EORTC QLQ-C30) and its lung cancer supplement (LC-13).

Patients without a documented clinically meaningful difference in Patient Reported Outcomes Measures (PROMS) were censored at the time of last PROM assessment.

The authors found similar results in most of the QoL scales. They concluded that SABR may have advantages in the global QoL and indirect cost of productivity loss. However, only TTD of global health status was found to be significantly worse on univariable COX proportional hazard modelling for surgical patients when compared to SABR.

SABR studies

Out of nine evaluating the impact of SABR on QoL, only five studies specified the percentage of patients who refused surgery. In all the other studies patients who had the SABR treatment were patients considered medically inoperable and therefore generally with worse comorbidities and poorer cardio-pulmonary functions than patients undergoing to surgery.

Lagerwaard *et al.* (3) conducted the largest study on 382 patients over a period of 24 months. Physical functioning was the only QoL domain to statistically significantly worsen, though by less than the clinical meaningful significance of 10 points (19). Physical functioning in fact decreased by more than 10 points in 26% of patients, remained stable in 53%, and had improved in 22% after 1 year.

Mathieu (4) reported favourable long-term QoL and pulmonary function in 45 patients treated with SABR with a follow-up longer than 3 years. They also reported a QLQ-LC30 emotional score improvement at 36 months. However, the exclusion of patients with recurrent disease may have affected the QoL results.

Ubels *et al.* (5) prospectively studied QoL in 39 inoperable patients for 5 years. Although the emotional functioning (EF) scores improved significantly, dyspnea slowly worsened 2 years after SABR. The trajectory of the global health showed that it was near the baseline value during the first year, improved at 18 months and then significantly declined to the baseline value during the next years.

One of the first studies to explore the QoL after SABR treatment was from van der Voort van Zyp *et al.* (6). The only significant change observed was an improvement in EF.

Table 1 Studies included in the narrative synthesis

Author, date and country, study type (level of evidence)	Patient group	Outcomes	Key results	Comments
RCT trial				
Louie *et al.*, *Radiother Oncol*, Netherlands [2015] (2), RCT: small sample size (level 2b)	Secondary analysis of a non-blinded, phase 3 RCT of SABR versus surgery for stage IA NSCLC patients. 22 patients. Tools: EORTC QLQ-C30 and LC-13; EQ-5D. FU: baseline, and then 3, 6, 2, 18, and 24 months	Time to deterioration of at least 10 points decrease (global/ functional scales) and of at least 10 point increase (symptom scales/items)	GH: surgery 8, SABR 2 (HR 1 *vs.* 0.19, P=0.038). RF: surgery 7, SABR 4 (HR 1 *vs.* 0.47, P=0.22). EF: surgery 4, SABR 1 (HR 1 *vs.* 0.25, P=0.21)	Small sample size
SABR studies				
Lagerwaard *et al.*, *JTO*, Netherlands [2012] (3), Cohort study (level 3)	382 patients. QoL tool: EORTC QLQ-C30 FU: baseline, 3, 6, 12, 18 and 24 M	Baseline GH	62.9±1.1	15.4% of patients refused surgery. Drops-out: 64% and 61% of patients, were unavailable for at 18 and 24 months
		Baseline PF	61.8±1.1	
		Baseline RF	63.5±1.5	
		Dyspnea	47.1±1.7	
		Fatigue	37.4±1.3	
		Insomnia	21.1±1.6	
		Changes over time	PF decreased in 24M (P<0.01) but not clinically significant than 10 points)	
Mathieu *et al.*, *Pract Radiat Oncol*, France [2015] (4), Cohort study (level 3)	45 patients. QoL tool: QLQ-C30 and QLQ-LC13. FU: baseline, 2, 6, 12, 18, 24, 30, 36 M	Baseline GH	66%±20%	16% of patients refused surgery. Data from patients who had disease recurrence were excluded. Collection of QoL data at the 2 and 3 Y in 63% and 33%
		Baseline PF	73%±22%	
		Baseline EF	77±26	
		Social functioning decline	Transient declines: 12%±29% 12 M; 11%±29% 24 M	
		QLQ-LC13 coughing symptom	Reduction:13%±17% 30 M; 13%±22% 36 M	
Ubels *et al.*, *Radiation Oncology*, Netherlands [2015] (5), observational study (level 3)	39 patients. QoL tool: EORTC QLQ-C30, EORTC QLQ-LC13. FU: baseline, 3 weeks, 2, 4, 6, 9, 12, 15, 18, 21, 24 M, then every 6 M until 5 years	GH	Near the baseline in the first year, then improve to decline again over the 5 years (P<0.0001)	15% refused surgery. At 5 years only 10 patients were still alive without progression and had filled the QoL survey
		PF, RF and cognitive functioning	Significantly improved over time; fatigue deteriorated over time (P=0.05)	
		Dyspnea	Deteriorated over time (P=0.006)	
		EF	Improved significantly at 1 year compared to the baseline	

Table 1 (*continued*)

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Author, date and country, study type (level of evidence)	Patient group	Outcomes	Key results	Comments
van der Voort van Zyp *et al.*, *Int J Radiation Oncology Biol Phys*, Netherlands [2010] (6), observational study (level 3)	39 patients. QoL tool: EORTC QLQ-C30, EORTC QLQ-LC13. FU: baseline, 3 weeks, 2, 4, 6, 9, 12 M	GH, PF, RP, SP	No changes over time	15% patients refused surgery. Small sample size. The lack of >10-point changes suggests that there are no perceived changes in QoL scores
		EF	Improvement over time (P=0.02)	
Widder *et al.*, *Int J Radiation Oncology Biol Phys*, Netherlands [2011] (7), Cohort study (level 3)	Medically inoperable patients: 27 3D-CRT *vs.* 202 SABR. QoL tool: EORTC QLQ-C30 GH and PF + dyspnoea LC13. FU: 3, 6, 12 months	Dyspnea	Increase by 3.2 (95% CI: 1.0–5.3; P<0.01)	Different sample sizes (202 *vs.* 27). Comparison between techniques
		PF	Stable for all patients except for those with a high CCI	
		GH	No significant changes	
Ferrero *et al.*, *Lung Cancer*, Italy [2015] (8), Cohort study (level 3)	30 patients with inoperable Stage I NSCLC. QoL tool: Lung Cancer Symptoms Scale (LCSS). FU: baseline, 1.5, 4.5, 7.5, 10.5 M	Fatigue (baselines *vs.* 135 D)	29 *vs.* 39.8, P=0.05. No other significant changes	Small sample size
Jain *et al.*, *Radiat and Oncol*, UK [2013] (9), RCT (level 2b)	54 patients with NSCLC <5 cm. Comparing two groups: Group 1: 4 days of SABR. Group 2: 11 days of SABRQoL tool: EORTC QLQ-C30 and LC-13. FU: discharge, 1 and 4 M	(Group 1 *vs.* group 2): PF	BS: 79 *vs.* 68.6, 4 M: 71.3 *vs.* 69.9	Small sample size and limited follow-up
		RF	BS: 93.8 *vs.* 71.6, 4 M: 83.3 *vs.* 77.3	
		Dyspnea	BS: 25.9 *vs.* 44.4*, 4 M: 38.5 *vs.* 26.7	
		% of patients with a clinically meaningful worsening (>10 points)	Dyspnea: 1 M, 44.4% *vs.* 15.4%*; 4 M, 38.5% *vs.* 12.0%*. PF: 4 M, 46.2% *vs.* 16%*	
Videtic *et al.*, *Support Care Cancer*, USA [2013] (10), Cohort study (level 3)	22 patients. QoL tool: FACT-L and UCSD SOBQ (University of California at San Diego Medical Centre-Pulmonary Rehabilitation Program Shortness-of-Breath Questionnaire). FU: baseline, 3, 6, 9 and 12 months	Global scores: difference 1–12 M	109 *vs.* 112	4.8% patients refused surgery. Limited sample size. A non-significant 9-point drop in mean UCSD SOBQ dyspnea scores
Sun *et al.*, *J Community Support Oncol*, USA [2014] (11), Cohort study (level 3)	Observational study on 19 patients treated with SABR. QoL tool: FACT-L, Memorial Symptom Assessment Scale (MSAS) and FACIT-Sp-12. FU: baseline, 6 and 12 weeks	QoL	No detrimental changes in QOL scores over time	Small sample size
		Emotional domains	Improvement in nervousness and worry scores over time but no significant change in overall emotional functioning	

Table 1 (*continued*)

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Author, date and country, study type (level of evidence)	Patient group	Outcomes	Key results	Comments
VATS studies				
Bendixen *et al.*, *Lancet Oncol*, Denmark [2017] (12), RCT (level 2a)	RCT VATS *vs.* anterolateral thoracotomy. 201 patients. QoL tools: EORTC QLQ-C30 and EQ-5D. FU: baseline, 2, 4, 8, 12, 26, and 52 weeks	GH	VATS baseline: 73.2, open baseline: 73.3; VATS 4 W: 67.5, open 4 W: 64.8; VATS 52 W: 77.2, open 52 W: 74.1	All the differences were only in few time points. They did not use the Lung Cancer module of the EORTC QLQ-C30
		PF	VATS baseline: 88.6, open baseline: 88.4; VATS 4 W: 83.9, open 4 W: 75.8*; VATS 52 W: 86.1, open 52 W: 82.9	
		EF	VATS baseline: 77.5, open baseline: 77.4; VATS 52 W: 90, open 52 W: 83.03*. EQ5D only significant differences were in self-care and anxiety	
Burfeind *et al.*, *J Thorac Cardiovasc Surg*, USA [2007] (13), Cohort study (level 3)	422 patients submitted to lobectomy. QoL comparison. Group 1: <70 years and group 2: ≥70 years. QoL tool: EORTC QLQ-C30+2 scales of LC13. FU: 3, 6, 12 months	Group 1 *vs.* 2: PF	Baseline: 83.7 *vs.* 81, 3 months: 77.9 *vs.* 73.9, 12 months: 81.9 *vs.* 78	Retrospective analysis. The most commonly missed survey time point was the 3-month survey with 28% of group 1 and 38% of group 2
		EF	Baseline: 74.1 *vs.* 78.9, 3 months: 74.2 *vs.* 77.2, 12 months: 78.5 *vs.* 82.4	
		GH	Baseline: 18.3 *vs.* 16.8, 3 months: 33.4 *vs.* 26.1, 12 months: 22.2 *vs.* 17.6	
Handy *et al.*, *Eur J Cardiothorac Surg*, USA [2010] (14), retrospective study (level 3)	241 patients submitted to lobectomy (open: 192 *vs.* VATS: 49). QoL tool: Short Form 36 Health Survey (SF-36) and Ferrans and Powers quality-of-life index (QLI). FU: baseline and 6 months	Difference from baseline to 6 M (open *vs.* VATS): PF	−11.6 *vs.* −1.4 (P=0.042)	Limited follow-up (6 months)
		GH	−3.3 *vs.* 4.8 (P=0.010)	
		Bodily pain	−4.4 *vs.* 9.6 (P=0.020)	
		Role physical	−18.6 *vs.* 12 (P=0.002)	
		MH	−0.5 *vs.* 4.2 (P=0.38)	
		Energy	−3.6 *vs.* 5.3 (P=0.054)	
Khullar *et al.*, *Ann Thorac Surg*, USA [2017] (15), Cohort study (level 3)	127 patients. QoL tool: 7 fixed-length PROMIS instruments. FU: baseline, 1 and 6 months	PF	Significantly lower (worse) at 1 M visit than at baseline	Short follow-up. Only 70 VATS lobectomies included
		Pain intensity, interference, fatigue, and sleep impairment	All significantly higher (worse) at the 1 M. No difference identified at 6 M	
		Anxiety/fear and depression	Significantly improved after the operation	

Table 1 (*continued*)

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Author, date and country, study type (level of evidence)	Patient group	Outcomes	Key results	Comments
Rizk *et al.*, *Ann Thorac Surg*, USA [2014] (16), Cohort study (level 3)	206 stage I NSCLC patients (74 VATS *vs.* 132 thoracotomy). QoL tool: SF-36, physical component summary and mental component summary (MCS). FU: baseline, 2 weeks, 4.8 and 12 months	MCS	Baseline: 42.4 *vs.* 43.5; 4 M: 43.6 *vs.* 44.9 (P=0.036); 12 M: 47.2 *vs.* 49 (P=0.08)	Only 59% patients completed all the surveys
		PCS	Baseline:48.9 *vs.* 50.3; 4 M: 45.7 *vs.* 45.5 (P=0.86); 12 M: 48.1 *vs.* 48 (P=0.93)	
		Pain	BPI: no statistical difference between two groups	
Fagundes *et al.*, *J Thorac Cardiovasc Surg*, USA [2015] (17), Cohort study (level 3)	60 stage I–II NSCLC patients treated with open and VATS lobectomy. QoL tool: MD Anderson Symptom Inventory (MDASI). FU: baseline, 3 and 5 days after surgery, and weekly for 3 M	Moderate to severe symptoms	Day 3: 51.6% for pain, 59.7% for fatigue, 54.8% for drowsiness, 33.9% for shortness of breath, and 56.5% for disturbed sleep. 3 months: all symptoms had improved to better than preoperative	No objective measures affecting duration of hospital stay
Li *et al.*, *Chest*, China [2002] (18), cross-sectional study (level 3)	51 patients with NSCLC following resection, comparing VATS with thoracotomy. QoL tool: EORTC QLQ-C30, EORTC QLQ-LC13, Self-developed module. FU: 33.5 mo (VATS) and 39.4 M (open)		Fatigue (74–92%), coughing (75–82%), dyspnea (75–85%), pain (67–71%)	Additional non-validated surgery-related questions. One-off survey

*, statistical significant. FACT-L, Functional Assessment of Cancer Therapy-Lung questionnaire; FACIT-Sp-12, Functional Assessment of Chronic Illness Therapy-Spirituality Tool; GH, general health; RF, role functioning; EF, emotional functioning; HR, hazard ratio; PF, physical functioning; CCI, Charlson comorbidity index; MCS, mental composite score; PCS, physical composite score; MH, mental health.

Widder *et al.* (7) looked prospectively at longitudinal changes of QoL parameters after SABR or three-dimensional conformal radiotherapy (3D-CRT). They found that global QoL and physical functioning were stable at any follow-up within the first year. They also reported a statistically significant increase in dyspnea, although the observed changes were not clinically significant.

The Ferrero *et al.* (8) study of 30 patients is the only one to report a clinically and statistically significant increase in fatigue after 135 days.

Jain *et al.* (9) reported that dyspnea, fatigue and coughing to be worse at baseline in patients treated with SABR over 11 days compared to 4 days of treatment. However, more patients treated on 4 consecutive days experienced a clinically meaningful increase in dyspnea at 1 and 4 months after treatment.

Videtic *et al.* (10) conducted a small prospective study which did not find any statistical difference after 12 months in terms of QoL. They reported however, a 9-point drop from baseline to 12-week scores on the patients' UCSD dyspnea questionnaire, approaching clinical significance of 10 points.

Sun *et al.* (11) showed that QoL was not seriously impacted in a small cohort of 19 early-stage lung cancer patients after 12 months of follow-up. The functional domain had the lowest score of all the subscales measured with the Functional Assessment of Cancer Therapy-Lung (FACT-L).

VATS studies

The surgical studies investigating specifically the effect of minimally-invasive anatomical lung resection (studies with more than 20% VATS) on QoL were characterized by small sample sizes and limited longitudinal assessments. Five out of 7 studies' primary aim is in fact the direct comparison between different surgical accesses (open versus thoracoscopic).

Bendixen *et al.* (12) conducted the first RCT describing the trajectory of pain and QoL of open versus VATS lobectomies for cancer. With a follow-up of 52 weeks, they found QoL in the VATS group was significantly better than that of an age-matched cohort from the Danish population. After two weeks the worst levels of QoL were observed and then QoL gradually improved over 52 weeks.

Burfied *et al.* (13) showed that QoL worsened at 3 months. However, at 6 and 12 months, all domains had returned to baseline except physical functioning, which remained below baseline in patients older than 70 years. EF improved postoperatively in older and younger patients.

Handy *et al.* (14) reported that compared with preoperative, 6-month postop VATS patients were not significantly different in physical function, role physical, role-emotional, social function, mental health or energy. Postoperative categories of bodily pain and general health were significantly improved over preoperative values in the VATS group.

Most recently Khullar *et al.* (15), in the first attempt to implement patient-reported-outcomes measures (PROMS) into national databases, evaluated 127 patients with the National Institutes of Health Patient-Reported Outcome Measurement Information System (PROMIS) platform. They confirmed a significant worsening in pain, fatigue, and sleep scores and a decrease in physical function after 1 month from the operation. By 6 months, these had generally improved toward baseline. Anxiety/fear and depression both significantly improved after the operation. In 2014, Rizk *et al.* (16) prospectively compared VATS and open lobectomies. In both groups, QoL scores improved throughout the 12 months, and pain scores approached baseline levels by 4 months.

Fagundes *et al.* (17), conducted an interesting investigation on weekly symptom assessments in surgical stage I patients from the third postoperative day to 3 months. All symptoms (except fatigue) returned to preoperative levels by the end of the first month. Fatigue remained the most persistent symptom during the study.

Li *et al.* (18) included surgery-related questions in their retrospective study and found that lung cancer patients following surgical treatment without recurrence had good QoL and high levels of functioning after a mean of 33.5 months follow-up, with no significant differences between the VATS and open groups.

Clinical bottom line

We acknowledge the paucity of evidence in PROMS evaluation for these treatment modalities. Only one small RCT (N=22 patients) was identified that provided evidence addressing the specific question reporting that global health status deteriorates in more of the surgical patients compare to the SABR ones.

Sixteen studies provided supporting evidence but did not directly compared QoL between the two treatments. The overall impression from these studies which assessed a total 832 SABR patients and 686 receiving anatomical VATS

resections, is that physical components of QoL decrease immediately after treatment up to 3 months, returning to baseline after 1 year. EF often supersedes the pre-operative values across treatments. Trials like the SABRTooth (20), STABLE-MATES (NCT01622621) (21) and VALOR (Veterans Affairs Lung-Cancer-Surgery or Stereotactic-Radiotherapy) (22) will give us information necessary to clarify this issue.

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Footnote

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