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A Danish nationwide study

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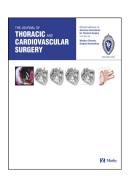
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Assessment of competence in Video Assisted Thoracoscopic Surgery (VATS) Lobectomy: A Danish nationwide study

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Assessment of competence in Video Assisted Thoracoscopic

- 2 Surgery (VATS) Lobectomy: A Danish nationwide study
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5

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21 Central message

- Validity evidence using Messick's framework was provided for a newly developed specific
- assessment tool (VATSAT) allowing for structured and objective assessment of VATS lobectomy

24 competence.

- 27 In the surgical societies around the world there is an increasing focus on ensuring continuous
- 28 education and credentialing of surgical skills according to stringent quality criteria.
- 29 This study provides validity evidence for a newly developed specific assessment tool for VATS
- 30 lobectomy (VATSAT), which may be an important aid the future training and certification of
- 31 thoracic surgeons.

33	Central picture
34	Revised figure 1
35	Central picture legend
36	Box-and-whiskers plot showing relation between the experience level of the thoracic surgeons and
37	the VATSAT score. Beginners n=10 procedures, n=6 surgeons (red dots), intermediates n=28
38	procedures, n= 9 surgeons (green dots), experts n=20 procedures, n=3 surgeons (blue dots). Colored
39	bar: median VATSAT score.

41	Glossary of abbreviations:		
42			
43	ANOVA	Analysis of Variance	
44	GOALS	Global Operative Assessment of Laparoscopic Skills	
45	SD	Standard deviation	
46	VATS	Video-Assisted Thoracoscopic Surgery	
47	VATSAT	Video-Assisted Thoracoscopic Surgery Lobectomy Assessment Tool	

48	Abstract:
49	Background: Competence in VATS lobectomy has previously been established based on numbers
50	of procedures performed but this approach does not ensure competence. Specific assessment tools
51	like the newly developed VATSAT allow for structured and objective assessment of competence.
52	Our aim was to provide validity evidence for VATSAT.
53	Methods: Video recordings of 60 VATS lobectomies performed by 18 thoracic surgeons were rated
54	using the VATSAT. All four centers of thoracic surgery in Denmark participated in the study. Two
55	VATS experts rated the videos. They were blinded to surgeon and center.
56	Results: The total internal consistency reliability, Cronbach's Alpha was 0.93. Inter-rater reliability
57	between the two raters was Pearson's $r=0.71$ (p< 0.001). The mean VATSAT score for the 10
58	procedures performed by beginners were 22.1 (SD 8.6), for the 28 procedures performed by the
59	intermediate surgeons 31.2 (SD 4.4) and for the 20 procedures performed by experts 35.9 (SD 2.9);
60	p<0.001. Bonferroni post-hoc tests showed that experts were significantly better than intermediates
61	(p < 0.008) and beginners $(p < 0.001)$. Intermediates' mean scores were significantly better than
62	beginners (p< 0.001). The pass/fail standard calculated using the contrasting group's method was
63	31 points. One of the beginners passed and two procedures performed by experts failed the test.
64	Conclusion: Validity evidence was provided for a newly developed assessment tool for VATS
65	lobectomy (VATSAT) in a clinical setting. The discriminatory ability between expert surgeons,
66	intermediate surgeons, and beginners proved highly significant. VATSAT could be an important aid
67	in the future training and certification of thoracic surgeons.
68	

Background

Lung cancer is the most deadly cancer worldwide and it is estimated that 1.7 million people died
from lung cancer in 2015 (1). Surgical resection remains the mainstay in curing localized lung
cancer (2). Traditionally, the approach for surgical resection has been a thoracotomy. Video
Assisted Thoracoscopic Lobectomy was introduced 25 years ago and is now the recommended
approach for early stage lung cancer (3). The potential benefits include less postoperative pain,
shorter length of stay, better quality of life (4), better shoulder function, fewer complications (5),
better tolerance of adjuvant chemotherapy (6), and maybe even improved survival (7). Despite the
obvious advantages of this approach, the adoption of the procedure has been slow. Performing a
VATS lobectomy requires a different set of skills compared to thoracotomy, such as overcoming
the fulcrum effect when operating through ports and transforming the 2-dimensional images on the
monitor into a 3-dimensional understanding. The potential risk of hemorrhage due to injury of the
pulmonary artery requires experience and skills to handle in a VATS scenario without causing a
catastrophic intraoperative complication (8). Several papers have addressed the issue of learning
how to perform a VATS lobectomy (9). Recommendations so far have been to attend courses in
VATS lobectomy, visit centers with a substantial experience in VATS lobectomy and then begin in
a step wise manner preferably supervised by an experienced VATS surgeon (mentor) until
competency was achieved (10). Traditionally, competency has been established based on numbers
of procedures performed and experts in VATS surgery have proposed 50 VATS lobectomies as a
threshold for competency (11, 12). However, procedural experience does not ensure competence
(13). Specific assessment tools have been developed to allow for structured and objective
assessment of competence, but it is essential that these provide valid measures (14). The aim of this
study was to provide validity evidence for a newly developed VATS lobectomy assessment tool
(VATSAT) (15).

Methods

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An independent investigator (KG) recorded the videos from VATS lobectomies performed at all
four thoracic centers in Denmark. Only unedited videos were used for assessment and the surgeons
did not have access to their videos. The investigator was present in the operating theatre throughout
the operations to make detailed notes of who performed the single parts of the procedure. The
surgeons were divided into three groups according to their previous experience in VATS lobectomy
at the beginning of the study. Surgeons having performed between one and 49 VATS lobectomies
were grouped as beginners. Surgeons having performed between 50 and 499 VATS lobectomies
were labeled intermediates, and finally experts were surgeons having performed 500 VATS
lobectomies or more. Two independent thoracic surgeons with a solid experience in VATS
lobectomy rated the videos using a newly developed VATS Lobectomy Assessment Tool
(VATSAT) for technical scoring of VATS lobectomies (15). VATSAT score was developed using
the Delphi method as a structured process for collecting and distilling knowledge from a group of
international experts in VATS lobectomy (15, 16). The eight items in the VATSAT are:
1.Localization of tumor and other pathological tissue, 2. Dissection of the hilum and veins, 3.
Dissection of the arteries, 4. Dissection of the bronchus, 5. Dissection of lymph nodes, 6. Retrieval
of lobe in bag, 7. Respect for tissue and structures, 8. Technical skills in general. Each item was
rated one to five, where five were the best score, giving a minimum score of 8 and a maximum
score of 40. The two raters were blinded to the surgeon and the center where the procedure was
performed.

Validity evidence

117	Validity evidence was established based on Messick's framework (17) as recommended by the
118	Standards of Educational and Psychological Testing (18) with the following five major sources of
119	evidence:
120	Content: Content validity for the VATSAT tool was established in a previous study from our
121	research group (15). The content was thoroughly evaluated in three rounds by a large group of
122	internationally recognized VATS lobectomy experts using the Delphi method (16).
123	Response process: The two raters were carefully instructed on how to rate the videos using the
124	VATSAT tool. Both raters rated all videos independently according to their instructions.
125	Internal structure: The degree to which the items in the VATSAT fit the underlying construct was
126	reported by internal consistency reliability and inter-rater reliability.
127	Relations to other variables: VATSAT's discriminatory ability between beginners, intermediates,
128	and experts was calculated using mean scores and ANOVA (analysis of variance) with Bonferroni
129	post hoc tests. The correlation coefficient between the number of VATS lobectomies performed
130	(expressed in the logarithmic scale) and the VATSAT score was calculated.
131	Consequences: Impact of the VATSAT scores was assessed using the contrasting group's method
132	(a method to identify a cut score based on overlapping frequency distributions of two groups) to
133	calculate the mean pass/fail VATSAT score and explore false positives and false negatives.
134	
135	Ethics

136	An application was send to the local ethics committee (journal no H-16041772), but was waived.
137	According to Danish law, educational studies do not need approval. Written and oral informed
138	consent was obtained from all participating surgeons.
139	Statistics
140	Cronbach's alpha, Pearson's r, and ANOVA with post hoc analysis were calculated using IBM
141	SPSS statistics version 23 (IBM, New York, USA). A value of p<0.05 was considered statistically
142	significant.
143	
144	Results
145	From December 19 th 2016 until July 5 th 2017, 60 VATS lobectomies performed at the four thoracic
146	centers in Denmark were video recorded and enrolled into the study. Eighteen thoracic surgeons
147	performed the 60 procedures. Their personal experience in VATS lobectomy ranged from 9 to 1200
148	procedures completed at the beginning of data collection. Fifteen of the 18 surgeons were
149	specialists in Cardio-thoracic Surgery and the remaining three surgeons were senior residents in
150	Cardio-thoracic Surgery. A specialist supervised all procedures (n=8) performed by residents. If the
151	supervisor had to interfere in the procedure and perform part of it, the investigator noted this and the
152	corresponding item received the minimum score of one point. Two VATS lobectomies were
153	converted to open surgery during the procedure. They were excluded from the study, since the
154	raters were unable to use the assessment tool (VATSAT), which is constructed for VATS specific
155	issues only. The remaining 58 VATS lobectomies were included in the final data analysis. Patient
156	characteristics and surgical outcome are listed in table 1.

157	<i>Internal structure:</i> The total internal consistency reliability, Cronbach's Alpha was 0.93 with a
158	value of 0.89 for rater 1 and 0.91 for rater 2. Inter-rater reliability between the two raters was
159	Pearson's r=0.71 (p< 0.001).
160	Relation to other variables: The mean VATSAT score for the 10 procedures performed by
161	beginners were 22.1 (SD 8.6; range 8.0-34.0), for the 28 procedures performed by the intermediate
162	surgeons 31.2 (SD 4.4; range 24.0-38.0), and for the 20 procedures performed by experts 35.9 (SD
163	2.9; range 29.0-39.5); p<0.001, presented as a Box plot in figure 1.
164	ANOVA with Bonferroni post-hoc tests revealed that mean scores for experts were significantly
165	better than for intermediates and beginners, $p < 0.008$ and $p < 0.001$, respectively. Intermediates'
166	mean scores were significantly better than beginners (p $<$ 0.001). The logarithmic relation between
167	number of VATS lobectomies performed and the mean VATSAT score is shown in figure 2. The
168	Pearson's Correlation is r=0.68 (p< 0.001).
169	Evidence based on consequences of testing: The pass/fail mean standard calculated using the
170	contrasting group's method was 31 points. One procedure performed by a beginner passed the test
171	with a mean score of 34 (false positive) and two procedures performed by experts failed the test
172	with mean scores of 29 and 30.5 points (false negatives). See figure 3.
173	
174	Discussion
175	Validity evidence has previously been demonstrated for the VATSAT used in a simulated
176	environment (15). In this study, validity evidence for the VATSAT used in a clinical situation with
177	live surgical cases from four different centers being video recorded and the raters blinded for the
178	institution and the surgeon is demonstrated.

179	Our group has previously published an assessment tool targeted towards VATS wedge resections,
180	but VATSAT is the first assessment tool developed specifically to assess VATS lobectomy (19). A
181	systematic review published in 2015 identified 29 articles focused on procedural tasks. The majority
182	of studies addressed tasks related to general surgery and the remaining to obstetrics/gynecology,
183	vascular surgery, orthopedics, cardiac surgery, plastic surgery, and minor surgical procedures by
184	family physicians (20). Minimally invasive thoracic surgery and perhaps especially VATS
185	lobectomies are highly specialized procedures and there is a need for dedicated assessment tools
186	(21).
187	The total internal consistency reliability, Cronbach's Alpha of 0.93 shows that the eight items in the
188	VATSAT measure the same trait and thereby provides evidence for the well-aligned content of the
189	tool. A high Cronbach's Alfa indicates a very strong correlation between the eight individual items
190	in the VATSAT. Surgeons who have a high score high in one item also have a high score in the
191	other items (22). This internal consistency reliability is similar to what have been demonstrated for
192	the Global Operative Assessment of Laparoscopic skills (GOALS) that were developed by Vassilou
193	et al in 2005. They found an internal consistency reliability of 0.91-0.93 by assessing 21
194	participants performing laparoscopic cholecystectomies by two trained observers present in the
195	operating theatre and by the attending surgeon assisting the procedures (23).
196	In our study the inter-rater reliability between the two blinded raters at a Pearson's r 0.71 was
197	highly significant (p< 0.001), meaning that there was a significant agreement in the total score
198	between the two raters. An inter-rater reliability in the range of 0.70 to .079 may be applied for
199	formative assessments such as feedback after a completed training course. For moderate stake
200	summative assessments as end of year examination in medical school an inter-rater reliability
201	between 0.80 and 0.89 is expected. High stake tests as a board certification and licensure require

202	inter-rater reliability above 0.90 (22). The inter-rater reliability can be improved by increasing the
203	number of rated procedures per surgeon or by increasing the number of raters (24). Our results
204	clearly show, that certification aided by VATSAT scores should be based on assessment of more
205	than one procedure per trainee.
206	Rating of VATS lobectomy is a time consuming task and the use of a VATS specialist is costly.
207	Therefore it is important that a potential test do not need too many raters. The use of video
208	recordings has several advantages compared to direct observation in the operating theatre that will
209	always be prone to bias. A previous study showed that direct observation favored operators well
210	known by the rater or considered competent due to their position (25). Another advantage of video
211	recordings is that the VATS expert rater can schedule the rating to an appropriate time and place
212	(26). Using non-experts or novice raters may be considered, since the availability is easier and the
213	costs are less. This approach should be used with some caution but recent work has shown good
214	inter-rater reliability between expert and non-expert raters (27, 28).
215	The logarithmic relation between the experience level of the thoracic surgeons and the mean VATS
216	score shows good consistency. However, a Pearson's Correlation of r=0.68 (p< 0.001) is not a
217	perfect correlation. In figure 1 it can be seen that it is not possible to precisely predict competence
218	based on the VATSAT score from a certain experience level – a threshold of e.g. 50 procedures will
219	not ensure that all surgeons are competent. The VATSAT score is increasing with increasing
220	experience level and at the same time the variance in performance is decreasing (figure 3). This is in
221	accordance with the model for skills acquisition by Fitts and Posner: Performance is variable in the
222	beginning of the learning process but as the performance improves the variability also decreases
223	and the performance characteristics become more similar (29). The use of volume cut off to
224	determine the beginner, intermediate and expert surgeons are not ideal, but a necessary step at this
225	point.

The VATSAT test was able to discriminate between expert surgeons and surgeons with an
intermediate experience and between intermediates and beginners using the ANOVA with
Bonferroni post-hoc test, and this were highly significant (p < 0.008 and p < 0.001 , respectively). In
the simulation study we were not able to discriminate between intermediate surgeons and expert
surgeon. This may be due to the challenging and maybe impossible task to make simulators reflect
every aspect of real live surgery (30). The pass/fail standard of 31 points, calculated using the
contrasting groups' method established good validity evidence for consequences (31). One of the
beginners passed the test and two of the experts failed the test. In a simulation study case difficulty
can be standardized (30). Other studies with live surgical procedures have tried to reduce the effect
of disease and patient variability (32). This was not possible due to the nationwide design in this
study. VATS lobectomies were heterogeneous in terms of difficulty level and a considerable bias
may reflect the variation observed. This underlines the point of basing important decisions on more
than one procedure – even a beginner can do okay on a very easy patient and competency cannot be
determined based on a single case.
The strengths of this study are the nationwide participation of thoracic surgeons from all
departments of thoracic surgery in Denmark. This adds to the generalizability of our findings.
Having 18 thoracic surgeons perform 60 VATS lobectomies reduced construct underrepresentation.
The fact that we were able to show a highly significant discrimination of experts, intermediate
surgeons, and beginners with only two raters is an important finding indicating that the VATSAT
may aid in training and credentialing of VATS surgeons.
and the state of t
Limitations of the study and a threat to validity evidence of the assessments may be construct-
irrelevant variance in the form of rater errors. Raters may express restriction of range in their rating
(33). Interestingly none of the participating expert surgeons scored the mean maximum of 40 and
only one of the beginners scored the mean minimum score of 8. Despite the raters were blinded, we

cannot rule out the possibility that special instruments or certain movements were recognizable.
Therefore possible identification of a center or individual surgeons may have biased the raters. It is
important to emphasize that the focus was technical skills. Non-technical skills are import and may
interfere with the overall performance (34, 35), but this was not captured in the current study.
Conclusion
Validity evidence was provided for a newly developed assessment tool for VATS lobectomy
(VATSAT) in a clinical setting with 18 surgeons representing all thoracic units in Denmark based
on video recording of 60 VATS lobectomies and two blinded raters. Internal consistency reliability
was high and inter-rater reliability acceptable. The discriminatory ability between expert surgeons,
intermediate surgeons, and beginners was highly significant with a pass/fail standard of 31 points.
One of the beginners passed the test (false positive) and two experts failed the test (false negatives)
We believe that the VATSAT can be a valid and important tool to aid in deciding when thoracic
surgeons are competent to perform VATS lobectomies.

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365	Figure Legends		
366	Figure 1: Box-and-whiskers plot showing relation between the experience level of the thoracic		
367	surgeons and the VATSAT score. Beginners n=10 procedures, n=6 surgeons (red dots),		
368	intermediates n=28 procedures, n=9 surgeons (green dots), experts n=20 procedures, n=3 surgeons		
369	(blue dots). Colored bar: median VATSAT score.		
370	Figure 2: Logarithmic relation between number of VATS lobectomies performed (n=58) and the		
371	VATSAT score. Red dots represents VATSAT scores for beginners, green dots represents		
372	VATSAT scores for intermediates and blue dots represents VATSAT scores for experts. Black		
373	dotted line is the pass/fail ratio of 31.		
374	Figure 3: Pass/fail VATSAT score assessed using the contrasting group's method for beginners		
375	(red, n=10 procedures) and expert thoracic surgeons (blue, n=20 procedures).		
376			
377	Video legend		
378	Video: Right lower VATS lobectomy rated using the VATSAT tool.		

Table 1. Patient characteristics and surgical outcome.

			381	
Patient characteristics, n=58				
		Mean (SD)		
Age		70 (8.2)	383	
Gender	Male/female	29/29		
FEV ₁ *		89 (22.0)	384	
Tumor size		26 (11.9)		
Type of lobectomy	Lower lobes	21 (36%)	385	
	Middle lobe	5 (9%)		
	Upper lobes	30 (52%)	386	
	Bi-lobectomy	2 (3%)	207	
Surgical outcome, n=58				
		Median (interquartile ra	ange)	
Procedural time (minutes)		101 (88; 123)		
Procedural bleeding (ml)		100 (20; 150)	389	

* FEV₁ (forced expiratory volume in one second)

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