Review

Endoscopic Ultrasound

OPEN

Controversies in endobronchial ultrasound

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ABSTRACT

Endobronchial ultrasound (EBUS) is a minimally invasive highly accurate and safe endoscopic technique for the evaluation of mediastinal lymphadenopathy and mediastinal masses including centrally located lung tumors. The combination of transbronchial and transoesophageal tissue sampling has improved lung cancer staging, reducing the need for more invasive and surgical diagnostic procedures.

Despite the high level of evidence regarding EBUS use in the aforementioned situations, there are still challenges and controversial issues such as follows: Should informed consent for EBUS and flexible bronchoscopy be different? Is EBUS able to replace standard bronchoscopy in patients with suspected lung cancer? Which is the best position, screen orientation, route of intubation, and sedation/anesthesia to perform EBUS? Is it advisable to use a balloon in all procedures? How should the operator acquire skills and how should competence be ensured? This Pro-Con article aims to address these open questions.

Key words: EBUS; Mediastinal masses; Lung cancer staging

INTRODUCTION

A group of interdisciplinary authors (pneumologists, gastroenterologists, surgeons, and radiologists) recently initiated and published a series of articles on "how to perform" EUS and "controversies" in EUS and its subspecialties' in a narrative search and review form.[1–6] The current article discusses key issues starting with indications and consenting, then preparation and setup, and intubation and techniques, and ending with training and assessment.

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SHOULD CONSENTING FOR ENDOBRONCHIAL ULTRASOUND DIFFER FROM BRONCHOSCOPY CONSENTING?

Introduction

Endobronchial ultrasound (EBUS)–related complications are generally rare and consist mainly of mediastinitis, bleeding, and pneumothorax and depend on the type of diagnostic or therapeutic intervention. Apart from the type of procedure, the incidence of complications is associated with the experience of the endoscopist, the nature of the disease, the general health condition of the patient, and the type of echoendoscope used. It is important that the endosonographer knows the potential risks involved for any endoscopic procedure he/she suggests for the patient and can explain the technique, intended benefit, and possible risks in simple terms. For example, necrotic lesions are a risk factor of post-EBUS infection, and their puncture should be avoided.[7] The staff should be sure on how to treat bleeding in the airways and that a pleural drainage system is in place and ready for use.

Pro

The distal ultrasound tip and limited view of the instrument could lead to a higher risk of complications than conventional bronchoscopy. The rigid tip and the diameter of the instrument (tip diameters of currently available EBUS scopes range from 6.6 to 7.3 mm) can damage the airway, and the patient should be informed of the possible risks to make an informed decision. Also, the manipulation of the EBUS scope in the esophagus and stomach may lead to different complications from standard bronchoscopy.[8] Especially if an intervention is planned, the patient must be informed of the risks and benefits of the method used, and alternatives must be explained. Usually, a bronchoscopy does not include the specific risks of fine needle aspiration puncture such as very rare mediastinal infections or bleeding, pericarditis, and pneumomediastinum.[9–13]

Con

There are no studies pointing out a difference in complications from bronchoscopy and EBUS. Even if fine needle aspiration is used, there

is no disparity in complication rates compared with "blind" transbronchial needle aspiration (TBNA) performed during bronchoscopy. The rate of severe adverse events with EBUS-TBNA is low as 0.05% according to a meta-analysis from 2014[10] and 0.11% according to survey data from the Netherlands.[9] Therefore, very rare complications are mainly reported in case studies.[13] The risk of infectious complications seems to be higher with a transesophageal access route (EUS–guided fine needle aspiration [EUS-FNA], EUS with bronchoscope-guided fine needle aspiration [EUS-B-FNA]) compared with a transbronchial access route (EBUS-TBNA).[9,10,12] Special risk factors are related to mediastinal lymph nodes with imaging features of necrosis and in patients with sarcoidosis.[12] If there is only a theoretical higher risk in connection with EBUS, the patient does not need to know about the difference to make an informed decision if he or she agrees to the investigation.

Authors' conclusion

In summary, the consent process should enable the patient to make an informed decision balancing the individual risks of the procedure with its potential diagnostic benefit. Therefore, we need to explain the goals and techniques. The information provided to the patient before US-guided interventions should relate as specific as possible to the intervention and should be based on a thorough consideration of risk factors and alternative procedures. All EBUS performing units should have specific patient information for EBUS procedures. Bronchoscopic blind TBNA should not be performed if EBUS-TBNA is available.

CAN EBUS REPLACE BRONCHOSCOPY IN PATIENTS SUSPECTED OF LUNG CANCER?

Introduction

The operator normally performs inspection of the bronchial tree with the standard bronchoscope initially.[14] In patients with proven or suspected lung cancer, accurate staging is crucial for planning optimal treatment, and it is mandatory to supplement bronchoscopy with EBUS with real-time guided TBNA (EBUS-TBNA). The newest guidelines recommend combining EBUS-TBNA with EUS-FNA.[15] EBUS-TBNA provides access to structures close to the large airways, whereas EUS-B-FNA gives access to paraesophageal structures plus structures under the diaphragm. The combination of EBUS and EUS-B provides access to central lung and mediastinal masses, all mediastinal and subdiaphragmatic lymph node stations, and the left adrenal. If a standard EUS scope is also used, the right adrenal gland, almost all abdominal-retroperitoneal lymph node stations up to about the aortic bifurcation, and the left liver lobe and larger parts of the right liver lobe are also accessible as potential metastatic localizations of lung cancer.[16–20]

Does "one scope fit all"?

Traditionally, EUS-FNA was done using a dedicated EUS scope, but studies show that the EBUS endoscope is excellent for performing the latter (EUS-B-FNA). Hence, it is possible to perform the entire diagnostic workup using two scopes—a bronchoscope and an EBUS scope—but this could be further reduced to a single scope if we could also perform the bronchoscopy with the EBUS scope. The purpose of the traditional bronchoscopy in patients with suspected or confirmed lung cancer is to provide a total overview of the bronchial tree to the level of the bronchial segments. The procedure must allow the operator to note any important anatomical abnormalities and describe or rule out any visible malignancies in the central airways. This is best done with a slim and agile scope. The new generation of bronchoscopes incorporates an upward tip flexibility of up to 210 degrees upward and 130 degrees downward, and the tip is slim (usually 4.8–5.8 mm) and gives the operator a straight-ahead view, that is, 0-degree optic viewing angle. Moreover, state-of-the-art video bronchoscopes provide HDTV imaging with a wide range of innovative imaging modes for mucosa characterization.

Pro

A so-called hybrid EBUS endoscope (H-EBUS) with a 10-degree forward oblique view exists (EB19-J10U; Fujifilm). It aims to combine the functionality of an EBUS scope with the maneuverability and high-definition optics of a conventional bronchoscope.[21] In a randomized study, Yarmus et al.[22] assessed airway inspection effectiveness using this endoscope in one arm ($N = 30$) and the first generation of the Olympus EBUS endoscope in the other arm ($N = 32$). If the operator did not feel there was adequate visualization of the bronchial tree, the examination was considered inadequate, and a standard bronchoscope was introduced for full airway examination. This assessment was based on an independent agreement consensus between at least two operators. No patients had tumors in the airways. The authors found that there was a better segmental visualization when using the H-EBUS endoscope. They concluded that the use of H-EBUS might improve the ability to perform an adequate airway inspection potentially obviating the need for a conventional bronchoscope. However, this conclusion is not necessarily true. The authors did not use an objective validated assessment score, and the operator knew the type of endoscope used. Thus, the conclusion is fraught with great uncertainty and bias. Based on this study and the lack of other studies having explored the issue, the research question is still open.

However, the technological evolution might supersede further scientific studies in this area. An EBUS scope could totally replace the traditional bronchoscope for ALL procedures if (when!) it is possible to construct it with a 0-degree viewing angle, a 180-degree angulation (with a tool in the working channel), a slim scope tip allowing access into all segments, and at a reasonable price. It is impossible to say when this is going to happen, but the industry is working toward this goal. The newest generation of the Olympus EBUS scope (BF-UC190F) has a slimmer tip (6.6 mm), a shorter rigid part of the tip, a tip angulation up to 160 degrees up (*vs.* 120) and 70 degrees down, a field of view of 80 degrees, and a viewing direction of 20 degrees oblique forward (*vs.* 35 degrees; Figure 1). A new prototype EBUS scope with a tip diameter of only 5.9 mm (BF-Y0086; Olympus Medical Systems Corp), a 14-degree oblique forward view, and a bending angle increased to 170 degrees upward and 70 degrees downward has been proven to allow deeper peripheral airway access compared with the 6.6-mm EBUS scope (BF-UC190F) available currently on the market and a 5.5-mm video bronchoscope (BF-H190; Olympus Inc.). Despite its thicker tip diameter, the access reach of the thin EBUS scope was nearly equal to that of a 4.8-mm video bronchoscope (BF-Q190). However, the increased peripheral access reach of the device is at the expense of the diameter of the instrumentation channel (1.7 mm), which is only sufficient for 25G needles.[23,24] When EBUS-TBNA and EUS-FNA are indicated, there are obvious practical and logistic advantages in using the EBUS endoscope to perform the initial bronchoscopy as well.

Con

The traditional EBUS endoscopes have "bulky" ultrasound transducers on the tip of the endoscope that prevent the operator from

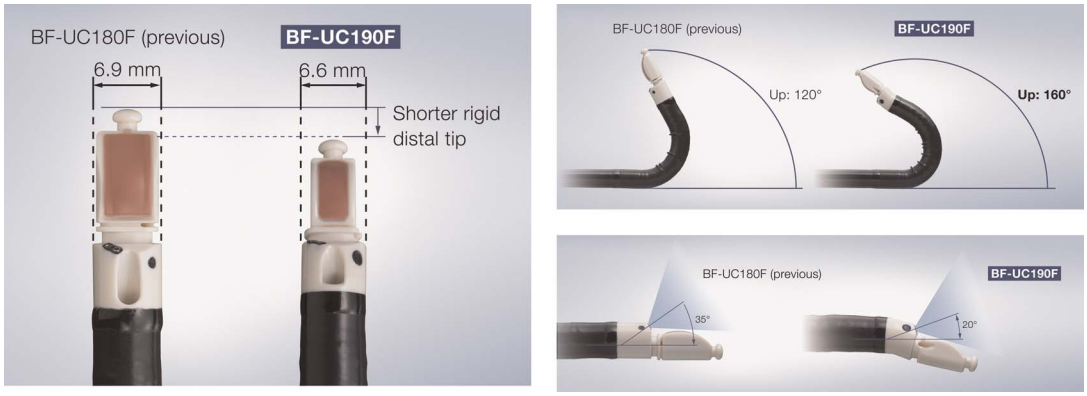

Figure 1. Olympus EBUS scope (BF-UC190F) with specific parameters for handling. EBUS: endobronchial ultrasound.

looking straight ahead, for example, the EB19-J10U from Pentax has a 45-degree oblique viewing direction and the BF-UC180F from Olympus has a 35-degree oblique viewing angle. Furthermore, their tip angulation is reduced to 120 degrees, which reduces maneuverability and can make it difficult to enter the upper lobes, especially with tools in the working channel. The oblique viewing angle, the reduced tip angulation, and the bulky tip may cause a decreased ability to perform a complete inspection of the bronchial tree with the EBUS endoscope. Moreover, optical imaging resolution of EBUS scopes is lower compared with HDTV chip technology in new-generation bronchoscopes [Figure 2]. Consequently, there is a theoretical risk of overlooking tumors and other abnormalities in the airways. The costs of the EBUS scopes are prohibitive for use in every bronchoscopy procedure. There are no existing studies showing that EBUS can replace bronchoscopy.

Authors' conclusion

There is no evidence that EBUS can replace conventional bronchoscopy because the complete bronchial tree cannot be reliably evaluated using an echoendoscope. If the technical advantages of the bronchoscope and the EBUS endoscope can be combined in one single endoscope ("uniscope"), it is probable that the EBUS scope can replace the bronchoscope in patients with proven or suspected lung cancer. However, there is no indication for when this will happen in the future.

IS THERE AN OPTIMAL POSITION OF THE OPERATOR AND PATIENT?

Introduction

Different positions have been proposed. The most common position for the endoscopist seems to be behind the head of the patient, with the patient in a supine but slightly toward an upright position. The supine or semirecumbent positions are "more intuitive" for the pneumologist who, in many countries, is used to perform bronchoscopy in that way. From this side, it is also easy to complete the staging with a transesophageal ultrasound using the same probe. From an anesthesiologist point of view, this could be a better location for airway control. The left lateral position is mostly used by gastroenterologists for the conventional transesophageal endosonography because of the assumption of a lower risk of aspiration and easier placement of the necessary ultrasound equipment. Some examiners have adopted the "gastroenterology position" for bronchoscopy and EBUS as well.

Pro supine

The supine position helps with the orientation within the patient's airway. Most operators performing bronchoscopy are maneuvering the scope in this position and familiar with this anatomy viewpoint, and probably some never used another. Because of the location of the investigator, turning the scope to the left advances it to the left side of the patient and the other way around. In case of bleeding from TBNA performed at the right or left bronchial tree, the blood will not go directly to the contralateral side and cause oxygenation or ventilatory problems.

Con supine

The placement of the patient in supine position sometimes causes problems with the location of the ultrasound device. Especially if the procedure is done under general anesthesia (GA) and with a possibility of using simultaneous fluoroscopy, there is not much space left for the necessary equipment and staff. There is also a higher risk of aspiration, if the patient suffers from delayed emptying of the stomach, in case it is not intubated. The left lateral position keeps the fundus region of the stomach as the lowest point preventing regurgitation in these patients. If regurgitation happens, the food does not congeal in the laryngeal area, which lowers the risk of aspiration. Airway complications due to loss of tone of the tongue base and hypopharyngeal muscles potentially occur less frequently in the left lateral position. If the endoscopist is used to this position and experienced in orientating himself in the airway, it can be advantageous.

Authors' conclusion

Most EBUS procedures will be performed in the supine position because of the preference of the operators. Some authors found equipment arrangement easier in left lateral positions, whereas others do not. Special attention was given considering the risk of aspiration in supine position without intubation. There are no hard data supporting one position as superior over the other. Supine position may be the more frequently used one, whereas, if accordingly trained, the endoscopist can also use the left lateral position.

IS THERE AN OPTIMAL SCREEN ORIENTATION?

Introduction

Orientation of the sonographic image obtained during longitudinal EUS is variable, with the "near point" or cranial end of the

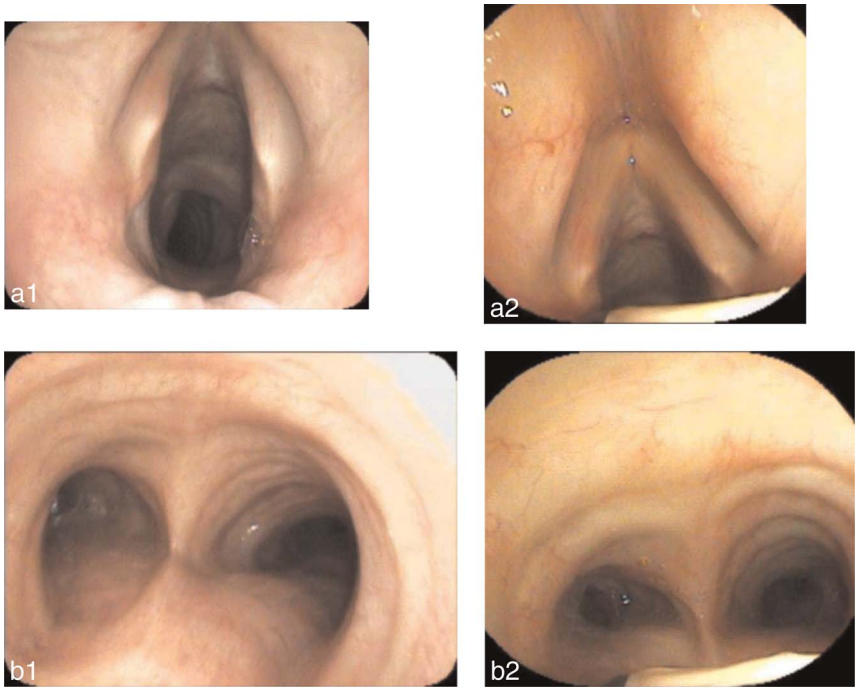

Figure 2. Comparison of field of view and image quality between the EBUS Videoscope EB 19-J10U and the Videobronchoscope EB 19-10 (PENTAX Medical, Hamburg, Germany) at the level of larynx (a1, a2). Comparison of field of view and image quality between the EBUS Videoscope EB 19-J10U and the Videobronchoscope EB 19-10 (PENTAX Medical). Visualization of the tracheal bifurcation (b1, b2). EBUS: endobronchial ultrasound.

transducer in relation to the endoscope able to be located either on the left or right side of the ultrasound screen. Differences in utilization of screen orientation continue to exist among different endosonographers, with preference typically determined by an individual's training.

Pro cranial to the right side

The "cranial to the right side" approach is based on the examiner's position to the right of the patient's bed from the examiner's perspective, as he/she approaches from the foot of the bed. The patient is in the left lateral position, and the tip of the echoendoscope is introduced into the mouth and upper esophagus from the right side. By pushing the scope gently forward, more distally located anatomical structures move into the screen from the left side. Needles and other instruments are introduced into the instrument channel from the right side, and the needle tip will consequently appear at the right side of the screen. Therefore, the orientation "cranial to the right side" reflects the natural course of movements by the endoscopist and the echoendoscope.

Con cranial to the right side

Training and experience in percutaneous ultrasound are a major advantage for operators performing EUS and are considered by many to be mandatory. Because of the overlap in standard probe positions required to illustrate specific anatomical structures/relationships (e.g., aorta with celiac trunk and mesenteric artery) and to allow meaningful comparisons between percutaneously and endoscopically obtained images, the orientation of the longitudinal picture should be cranial to the left. This has the added benefit of facilitating initial training in EUS and avoids the challenges of interpreting mirrored images.

Authors' conclusion

We would prefer to use one approach in all pulmonology procedures (EBUS, EUS-B, EUS, thoracic ultrasound) to shorten learning curves and prevent operator confusion.

TRANSNASAL OR ORAL ENDOSCOPE INSERTION?

Introduction

A randomized study was conducted comparing the oral and nasal insertion routes for linear EBUS on 220 patients. Procedural characteristics were similar (EBUS duration, doses of sedatives and lidocaine, number of stations sampled, complications). There was no difference between the nasal and oral groups in subjects' comfort, overall patient satisfaction, subjects' willingness to return, physician-reported subject comfort, adequate specimens, and diagnostic yields. This study demonstrated that the two approaches are similar and patient and physician preferences should dictate the route of insertion.[25]

Pro transnasal route

Using the transnasal approach avoids the gag reflex of the patient and does therefore need less sedation than the oral approach. The second advantage is the stable position of the instrument once it is introduced through the nose. The patient can still swallow regularly, which diminishes aspiration of the saliva. The transnasal route also has the advantage that most operators are trained in bronchoscopy beforehand and probably more used to the transnasal than the transoral route. According to studies, transnasal insertion of the EBUS scope was possible in 73.5%,[26] 75.5%,[25] and 87.4%[27] of cases. Moreover, the transnasal insertion of the EBUS scope may prevent bite damage of the scope if no teething ring is used

and should be considered as a feasible alternative in patients with conditions preventing oral introduction of the EBUS scope, for example, in patients with restricted oral opening due to temporomandibular joint disease or oral malignancies.[28,29]

Con transnasal route

The approach through the nose has multiple disadvantages. The relatively stiffness of the instrument and the sideward positioned optic increases the risk of damaging the mucosa of the nose and leading to epistaxis, what can be the reason to abandon the procedure. The only randomized study was performed with an EBUS scope with a tip diameter of only 6.2 mm (BF-US160F; Olympus Inc.). All EBUS scopes currently available on the market have a diameter of the rigid tip of 6.6 to 7.3 mm, which prevents or at least complicates transnasal insertion in a relevant number of patients. Mostly EBUS will be used for fine needle aspiration cytology. If several insertions are necessary (in case of bad vision due to blood or mucus), the transoral route is advantageous. In two recent Indian surveys, the oral route was preferred in 93.3% of all EBUS-TBNA examinations,[30] whereas 94% of flexible bronchoscopy examinations were performed using the nasal route.[31]

Authors' conclusion

When performing EBUS, the transoral insertion seems to be a better approach than the transnasal route. However, anatomical considerations, the patients' wish, or the operators' preference can influence the decision.

ORAL INTUBATION VIA ENDOTRACHEAL TUBUS ("WHICH SIZE") OR WITHOUT TUBUS ("FREE HAND")?

Introduction

Some investigators prefer a tube for introduction of the EBUS scope (e.g., endotracheal tube, rigid scope, laryngeal mask). It has the advantage of an easy way to introduce the scope into the patient. This can be of importance if multiple insertions are required. In this case, the minimum tubus internal diameter is at least 8 to 9 mm depending on the size of the scope. There is the possibility of attaching the tube to a breathing machine or use a mild sedation and let the patient breathe through the tubus on his own (Figure 3).

Pro endotracheal tube

One of the major advantages of the use of a tubus is the easy way to introduce the scope into the patient. This is especially of importance in planned multiple passages or in case of complications where switch to conventional bronchoscope is necessary. The second advantage is the option of immediate mechanical ventilation of the patient in case of a complication like dangerous low oxygen level due to the sedation. The third advantage is the relative prevention of aspiration. In some cases, it is as well possible to use a laryngeal mask instead of an endotracheal tube. This gives easy access to the airway of the patient and has the advantage of not damaging the vocal cords.

Con endotracheal tube

The insertion of an endotracheal tube can have complications, for example, lesions to the larynx or trachea. In untrained endoscopists, it makes an additional medical doctor/anesthetist necessary. In some cases, it is not possible to intubate the patient with an endotracheal tube of sufficient diameter. The only way around would be the use of a laryngeal mask. If the target structure is close to the upper part of the trachea, endotracheal intubation is a hindrance when the tube is between scope and target.

Authors' conclusion

The necessity of using a tube as a helping device is depending on the procedure planned. If it is a high-risk procedure in an unstable patient or multiple introductions of the scope are required, using a tube seems to be the better option. In the majority of diagnostic cases or if simple FNAs are planned, freehand route seems to be advantageous.

IS THE USE OF A BALLOON ADVISABLE?

Introduction

EBUS can be used either with direct contact to the mucosa or with a balloon attached at the tip of the echoendoscope. The advantages of a balloon depend on the location of the target lesion as well as the experience of the examiner. For hygienic reasons, the use of the balloon is recommended. Although a balloon for the endosonography probe is commercially available and recommended by the manufacturers, investigators may be disturbed by handling and possible air interference and therefore by impaired view.

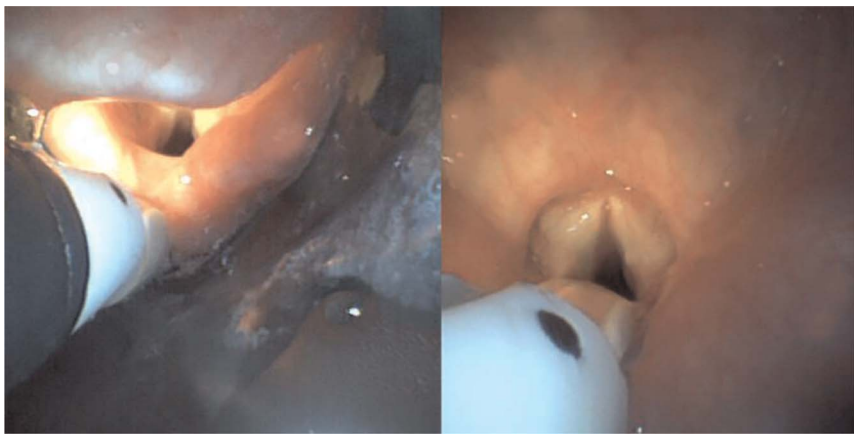

Figure 3. EBUS scope through a laryngeal mask. Entrance through the esophagus (left image) and through the vocal cords into the tracheobronchial tree (right image). EBUS: endobronchial ultrasound.

Pro

Using the scope's dedicated balloon can be of advantage because it improves the contact of the ultrasound tip of the scope with the airway mucosa and may promote stabilization of the insertion tube in the larger airways. Regarding its difference from gastrointestinal endosonography, the tip of the scope cannot be imbedded into soft tissue by simply performing suction because the trachea and the bronchi are hard and not as mobile. Using the balloon can even this out, especially if used in the bronchi.

Con

If the balloon of the scope is not correctly filled and contains air bubbles, the balloon can turn into an obstacle instead of help. Trapped air bubbles cannot easily be removed from the balloon once the procedure has started. Using the balloon excessively in the trachea may block ventilation and lead to desaturation. The use of a balloon is costly and may be time-consuming for unexperienced teams. If EBUS and EUB-B are going to be performed in the same procedure for staging, the balloon is usually removed before entering the esophagus because it is needless.

Authors' conclusion

Balloons are commercially available and recommended by the manufacturers for hygienic reasons. The balloon may be of help in selected cases with decreased contact of the scope to the rigid airway.

GENERAL ANESTHESIA OR MILD SEDATION?

Introduction

Current guidelines do not address the question about what type of anesthesia to prefer[15] or suggest that moderate (MS) and deep sedations (DS) are both reasonable approaches,[32] without providing any clear criteria for the degree of sedation or drugs to use. This contrasts with bronchoscopy guidelines, which recommend MS with a combination of an opioid and midazolam.[14,33]

There are striking differences among countries and institutions regarding sedation protocols that arise from distinct center expertise, team preferences, facilities settings, available medications, and different practitioners' clinical privileges for administration of sedation. These may affect patients' tolerance and comfort, procedure duration, diagnostic yield, recovery time, complication rates, and costs.

Because EBUS is a complex and time-consuming procedure, the question is if GA with DS should be preferred over MS.

Pro

A study by Yarmus and coworkers[34] favors GA with DS, who evaluated the influence of the type of sedation on the diagnostic yield of EBUS-TBNA and reported a greater diagnostic yield with DS. However, these results must be interpreted with caution because the procedures took place in two different institutions—thus the different types of sedation did not necessarily cause the divergence. An argument in favor of GA is that some bronchoscopists, anesthesiologists, and even patients may prefer this.

Con

A recent retrospective analysis of EBUS-TBNA performed under GA or DS revealed similar diagnostic yield and complication rate, meaning that, in an appropriate setting, EBUS-TBNA can be performed safely under DS.[35] In a randomized controlled study of EBUS-TBNA under GA versus MS, Casal et al.[36] found no significant difference in diagnostic yield between the two groups and no difference in the number of lymph nodes sampled. Furthermore, the average number of lymph nodes sampled per patient in the MS group was higher than the average number sampled in the DS group, when comparing with the study by Yarmus and colleagues.[34] Total duration of EBUS was shorter for the MS group (27.2 ± 15.3 minutes in the GA group *vs.* 20.6 ± 9.7 minutes in the MS group, $P = 0.02$)).[36] These findings are in contrast to those reported by Yarmus et al.,[34] who found longer procedural time associated with MS (46.9 *vs.* 36.4 minutes)—but again this was noticed by comparing two different centers, meaning that many other factors could have influenced this finding. In a systematic review, time consumption was the same for the two types of anesthesia.[37] Avoidance of GA shortens the postprocedure recovery time and reduces cost.[38] There was no significant difference in patient satisfaction and complication rate between the GA and MS groups.[36] These results are in accordance with the findings of a prospective, multicenter study that showed no difference in diagnostic yield, complication rate, and patients' comfort and satisfaction when comparing MS and GA for EBUS-TBNA[39] and in agreement with the systematic review.[37] Patient satisfaction with EBUS-TBNA under MS is high,[39–41] with 98% reporting they would "definitely return" for EBUS-TBNA in the future if required.

Authors' conclusion

GA instead of deep or moderate sedation for EBUS-TBNA does not improve diagnostic yield or patient satisfaction and may be time- and cost-consuming. However, the choice of sedation depends on operator experience, local conditions, patient characteristics, and preferences. In addition, the intervention planned can require GA. The number and the evidence of published studies are low, and there is the need for prospective multicentric studies.

SHOULD THE OPERATOR APPLY NEEDLE SUCTION TO IMPROVE SAMPLE COLLECTION?

Introduction

Numerous technical aspects of EBUS-TBNA and EUS-B-FNA have been evaluated regarding their effect on diagnostic yield, such as number of needle passes, needle size (21G *vs.* 22G *vs.* 19G *vs.* 25G), use of rapid on-site evaluation (ROSE), presence or absence of inner stylet during puncture, and use or lack of needle suction once within the targeted anatomic structure.[11,17] Concerning this last issue, there are conflicting data about the value of applying needle suction during EBUS-TBNA or EUS-B-FNA. Nevertheless, most needle sets include a 10- to 20-mL vacuum syringe, and sampling is usually taught with its attachment to the proximal part of the system, creating a negative pressure that is turned off before retraction of the needle, pausing suction. In real life, interventional units differ in their routines, based on operator's expertise and clinical perception (Figure 4).

Pro suction

Attaching the vacuum syringe to the needle does not require a significant amount of time and may increase the quantity of material avoiding further needle passes that prolong the examination. A study by Shiroyama et al.[43] showed that the use of suction allows the collection of greater cytological samples. A randomized controlled crossover trial showed the benefit of applying suction during EBUS-TBNA, enhancing

Figure 4. High-pressure suction applied directly to the needle (as described by Tsaknis et al.[42]

diagnostic yield on cellblocks.[44] This is in accordance with the result of another randomized controlled study showing that using suction increases the histology yield of EBUS-TBNA.[45] Also, in a retrospective study, the application of extra pressure suction (40 kPa), using a standard suction tubing connected to the needle driver, promoted a higher sample volume avoiding further procedures for molecular profiling in patients with lung cancer,[42] It is worth mention that the overall yield and blood content were similar between the high-pressure and standard suction technique.

In some cases, additional material can be found in the suction syringe during TBNA, and this can be collected and analyzed, increasing diagnostic yield and providing further cells for immunohistochemistry or genetic studies.[46]

Con to suction

In most articles, there is no difference in yield, sensitivity, specificity, or negative predictive value by applying suction or not during TBNA with 21G or 22G needles.[45] A randomized controlled trial by Lin et al.,[45] with 97 patients, evaluated the influence of suction plus a stylet versus suction only versus stylet only, and there were no significant differences in diagnostic yield.

Another important point is that histological cores can be obtained with or without aspiration and may be useful for additional studies. The slow-pull capillary technique has been described to improve the acquisition of tissue cores from mediastinal lymph nodes when compared with standard needle suction.[48]

In addition, the quality of samples may be significantly better without suction because of a lower rate of aspiration/contamination by blood.[49] Bloody samples create clots that are likely to occlude the needle lumen and increase time between punctures.

Authors' conclusion

Use of suction remains controversial. There are several techniques that can be used during TBNA sampling, and the operator should know them and have the possibility to adapt throughout procedure. In cases where the initial punctures acquire low material, switching to alternative techniques may be of benefit. If the first needle passes retrieve bloody samples or the aimed lesion is highly vascular, assessed by color Doppler, one can decide to omit suction. One should always discuss sample quality and quantity with the pathology department to improve the technique and assure optimal collection.

TO ROSE OR NOT TO ROSE?

Introduction

Whether the ROSE of the required specimen is sufficient is always a tricky question. In several articles, ROSE with EBUS-TBNA has been described, but there is a limited access to ROSE for several centers. In addition, ROSE requires personal and economical resources. Thus, we must decide whether to advise ROSE or not.

Pro ROSE

If the investigator doubts the result of an FNA, he or she can decide to raise the number of needle insertions, which results in prolongation of the investigation and perhaps the chance for adverse events. If few days after the procedure the result is inconclusive, the investigator may decide to repeat the procedure, in which case the chance for adverse events is elevated.

Con ROSE

In a systematic review and meta-analysis performed by Sehgal et al.,[50] ROSE for TBNA for mediastinal lymph node sampling was assessed. They investigated conventional and EUS-FNA studies. In 5 studies including more than 600 subjects, the authors found that ROSE did not raise diagnostic yield but resulted in fewer needle passes. The procedure time was not different. The complication rate was lower only for conventional TBNA.

In a study by Madan et al.,[51] 80 patients with suspected sarcoidosis were prospectively randomized into 4 groups for each combination of conventional TBNA, EBUS-TBNA, with and without ROSE. They described that conventional TBNA without ROSE was inferior to the other combinations. The biopsy success for EBUS-TBNA with and without ROSE was not significantly different.

Authors' conclusion

The evidence suggests that ROSE is beneficial only in conventional TBNA. Nevertheless, the question is not simple, and additional studies could delineate further aspects. When centers have easy access for ROSE, it seems obvious to continue. The current data are not enough to suggest ROSE in all centers. Perhaps, ROSE could be beneficial in a second procedure after a failed first attempt. A proper specimen handling, smear preparation, and processing are a crucial part in the success of EBUS-TBNA. Pulmonologists should

be trained to do a careful macroscopic on-site evaluation of the specimens, and in some cases, ROSE could also be performed by a trained pulmonologist. This would eliminate the need for the increased resource consumption of a cytopathologist in the operating room.

HOW SHOULD WE ACQUIRE AND ENSURE COMPETENCES?

Introduction

The success of every EBUS-TBNA procedure is dependent of the competence of the operator, making it essential that new trainees acquire the necessary knowledge and skills before performing unsupervised procedures. Traditionally, physicians in training acquire new technical skills by shadowing a more experienced colleague and gradually taking over the performance of the procedure in a supervised manner. This so-called apprenticeship training (AT) has also been dominant for EBUS training, but the invention of realistic phantoms, animal models, and virtual reality (VR) simulators has made it possible to acquire EBUS competencies using simulation-based training (SBT).[52,53] Similarly, EBUS certification can now be done by ensuring competence using assessment tools with solid evidence of validity in both simulated and clinical environments[54,55] instead of demanding that trainees perform a certain number of procedures. A systematic review reported a number of about 37 to 44 EBUS-TBNA procedures to attain an accuracy of at least 80% in lung cancer staging. However, the number of supervised EBUS procedures required to achieve sufficient methodological competence varies greatly depending not only on the training methodology but also on individual trainee skills.[53] SBT and objective assessment of competence are now recommended in guidelines,[15] and standardized, evidence-based training and certification programs have been developed, for example, by the European Respiratory Society.[56] However, a majority of EBUS operators do not practice systematically on simulators and do not pass an evidence-based test before performing procedures on patients.

Pro SBT

SBT provides a standardized learning environment without any risk for the patient. Trainees can practice repeatedly without having to wait for suitable patients or risking "supervisor takeover" because of concerns for patient safety, diagnostic yield, or procedure duration. VR simulators offer automatic feedback that allows trainees to learn from their mistakes. An international, randomized study showed that VR simulator training was significantly more effective than AT in the early part of the EBUS learning curve.[55] Assessment of competence in endoscopy has been shown to motivate trainees and increase the efficacy of training,[57] but perhaps most importantly, it is the only way to ensure their competences.

AT increases procedure time, amount of sedation, the number of complications,[58] and the cost for scope repairs.[59] The endoscopy suite is an expensive training environment where AT can jeopardize the teams' efficacy and might result in (costly) complications and repairs. The learning curves of individual trainees are different, which makes it impossible to define a certain number of necessary procedures that ensures competence for all.[54,60]

Con SBT

AT with a dedicated and careful supervisor can maximize the trainee's yield and reduce the risk of procedural complications. However the most obvious advantage of AT is that it is easy to arrange; the patients are already scheduled for the procedure so why not let a trainee practice his/her skills at the same time? Convenience (and perhaps force of habit) is also the main reason for certification based on numbers of procedures. Trainees simply note their experience in a logbook, and when they have performed a certain number (e.g., 25, 40, or 50), they are free to perform procedures on patients without supervision. Furthermore, the trainee can also learn EUS-B-FNA, which is recommended as a complementary procedure to EBUS-TBNA.[15] Moreover, simulation does not allow to create all possible real-life examination situations.

SBT takes resources to arrange, and furthermore, the current pandemic has made it more difficult to travel to courses including hands-on training. A VR endoscopy simulator including EBUS modules is relatively expensive and can easily cost more than 50,000 US dollars, making it necessary for departments and even hospitals to share the price to provide cost-effective training. Furthermore, the trainee cannot learn EUS-B-FNA, which is recommended as a complementary procedure to EBUS-TBNA, because no simulator for this exists. Apart from a little extra supervisor time, it is difficult to describe any cons against the use of assessment for both formative (i.e., feedback) and summative (i.e., certification) purposes.

Authors' conclusion

It is not possible to choose between SBT and AT because simulation cannot replace supervised training on patients for acquiring EBUS competence. However, training EBUS in a patient-safe environment should be mandatory before proceeding to performing clinical procedures to avoid those patients have to bear the burden of each operator's initial learning curve. It is easier to answer the question about certification based on assessment or on numbers of procedures performed: No "correct" number of supervised procedures exists; competence can only be ensured by objective assessment of operators' performance. The optimal training and certification program should consist of theory followed by hands-on training on simulators before supervised practice on patients, and each of these three steps should end with a test that must be passed before progression.

CONCLUDING REMARKS

We described controversies in EBUS by following a pro-con didactic approach. This article does not claim to be a guideline or an expert consensus, and in many cases, we could not answer our questions simply with "yes" or "no." Nevertheless, we found it appropriate to sum up points, giving the evidence of literature when available, and to evaluate possible ways in between.

Conflicts of Interest

Christoph F. Dietrich is the coeditor-in-chief of the journal; Michael Hocke, Lars Konge, and Christian Jenssen are editorial board members. This article was subject to the journal's standard procedures, with peer review handled independently of the editors and their research group.

Author Contributions

Christoph F. Dietrich contributed to the study conception and all authors contributed to the study design. Material preparation, data collection, and analysis were performed by all authors. The first draft of the manuscript was written by Christoph F. Dietrich and all authors commented on the previous versions of the manuscript. All authors read and approved the final manuscript.

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