WABIP Newsletter

Volume 09

Issue 01

January 2021

Inside This Issue

WABIP Newsletter

VOLUME 9, ISSUE 1 JANUARY 2021

Editorial: 21st WCBIP 2020 at a Glance

Guangfa Wang MD
Beijing, China
President WCBIP 2020

We are pleased to report that the 21st congress and the first virtual congress of the WABIP was an astounding success. This 2 ½ day event was comprised of world class presentations by IP experts from North America, South America, Europe, Africa, Oceania and Asia.

In the evening of Nov 19, 2020 (Beijing time), the opening ceremony began with a brief introduction video on history of interventional pulmonology, to its phenomenal growth, and to the current state of the WABIP with nearly 10,000 members worldwide. The ceremony also highlighted the rapid development of IP in China. Myself, the president of WCBIP 2020, underscored the complexities organizing this event, especially during the age of COVID-19. Also in the ceremony were leaders from Chinese Thoracic Society, Chinese Endoscopist Association, Chinese Medical Association and China National Health Commission. They expressed their sincerest gratitude and warm congratulation on the congress, and especially to our colleagues fighting against COVID-19. Last but not least, WABIP Chair Prof. Silvia Quadrelli gave a wonderful presentation on the WABIP, and announced the WABIP Awards recognizing those with significant contributions to bronchology and interventional pulmonology.

The total number of registrants is 13,240 from 72 countries and regions, and the total visits to the congress is 162,177. The most viewed session was "Interventional pulmonology in the pandemic of COVID-19", which had 32,613 total viewers. And tied for 2nd most popular sessions were "the Challenges of COVID-19 pandemic to Interventional Pulmonologists" by myself and "Clinical Utility of Ultrathin Bronchoscopes" by Dr. Masahide Oki from Japan.

While COVID-19 was indeed a hot topic of the congress, lung cancer remained one of the main focuses of the event. Many topics and discussions were related to early diagnosis, precision staging, genetic or pathologic technologies and interventional therapies. Early lung cancer therapies with PDT, microwave, radiofrequency or cryotherapy aroused great interest from the audiences. These novel technologies might be the standard therapies to lung cancer tomorrow. Additionally, the interventional therapies attracted great attention to the attendees either on different modalities, complications, long term outcomes and peri-procedure care. Stem cell and gene therapy on COPD were also discussed on the congress. The congress also covered other technologies or fields in bronchology and interventional pulmonology such as benign or malignant airway stenosis, cryobiopsy, thoracoscopy, trans-vascular or trans thoracic modalities and IP education. Suffice to say, WCBIP 2020 offered a full spectrum of topics on bronchology and interventional pulmonology.

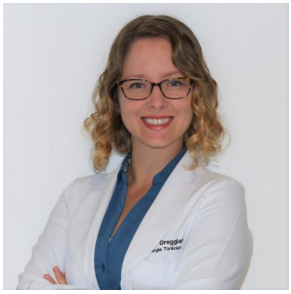
Lastly, we are pleased to have had a closing ceremony attracting thousands of audiences globally. The ceremony began with "Forbearance with Bronchoscopy A Review of Gratuitous Indications", a presentation by Dr. Atul Mehta, which highlighted the boundary of bronchoscopy procedures and reminded us these technologies should be not be used for gratuitous indications. Additionally, organizing committee member Dr. Jie Zhang announced 5 best oral winners and 10 best poster winners for their excellent presentations based on the scoring of session chairs. I gave a summary of the congress, emphasizing participation of 256 confirmed speakers who conducted 398 speeches in 125 academic sessions. Only 3 speakers were absent from the congress. Among 50 oral presentations, only four were absent.

Also in the closing ceremony, the new chair of WABIP, Dr. Hideo Saka, had affirmed the success of the congress and expressed his gratitude to all involved. He also noted some improvement in the future WCBIPs. Last but not least, as per tradition in all WCBIP closing ceremonies, the WABIP flag was transferred (but virtually this time) to Dr. Philippe Astoul who will be organizing the next WCBIP in 2022 in Marseille, France.

In conclusion, the congress created a milestone for WABIP with the above mentioned number of participants, sessions, and over 25 company sponsors, and 17 industry symposia and workshops. But there is no mistaking that we owe the success of this congress to you and WABIP members who submitted over 600 abstracts and participated in our many offerings. It has been my honor and pleasure to be the 21st President of the WCBIP. Let us take satisfaction in the success of WCBIP 2020, while we look forward to WCBIP Marseille and having another wonderful scientific event .

Technology Corner

Currently Available EBUS-TBNA Needles



Camila Greggianin MD
Division of Thoracic Surgery,
Toronto General Hospital,
University Health Network

Kazuhiro Yasufuku MD, PhD, FRCSC
Division of Thoracic Surgery,
Toronto General Hospital,
University Health Network

INTRODUCTION

The oncological approach to lung cancer was revolutionized forever after the introduction of linear EBUS in the early 21st century [1,2] as a tool for invasive mediastinal staging. The development and improvement of the materials and equipment used are ongoing and are unlikely to end soon - something that should always be in the mind of those who deal with cases as complex and challenging as lung cancer can be. Therefore, since Olympus launched their first EBUS-TBNA needle, the dedicated 22-gauge TBNA needle (NA-201SX-4022, Olympus, Tokyo, Japan)[3]; several other needles have emerged on the market. The purpose is to achieve the most reliable sample, less trauma to the biopsied tissue, increased safety for the patient and the life of the bronchoscope and improved ergonomics for the bronchoscopist. In addition, other diagnoses are also possible using EBUS, such as sarcoidosis, lymphoma and granulomatous infectious diseases - situations in which the maintenance of adequate tissue architecture is even more important.

In this article, we will review the current needles available on the market and their particularities.

BACKGROUND

Important qualities for EBUS-TBNA needle:

- Ergonomics: ergonomic handle for comfortable use by bronchoscopy.
- Safety: easy and safe locking mechanism, avoiding accidental protrusion of the needle during puncture and needle passage.
- Elegance and softness: needle penetration as smoothly as possible, so the force necessary to cross the airway and the lymph node capsule is minimized, avoiding damage to the cartilage and contamination of the sample with airway material and blood.
- Flexibility: adequate flexibility to reduce the distance from the tip of the bronchoscope with the airway wall that occurs when it is inserted into the distal portion of the working channel.
- Visibility: Echogenic tip for adequate real-time visibility of the needle under ultrasound during the procedure.

In order to encompass all these characteristics in the best possible way, several needles have emerged on the market over the years as new technologies have been developed and new needs have been perceived.

CLINICAL APPLICATION - CURRENT NEEDLES AVAILABLE ON THE MARKET [4–9]

There is no published clinical trial comparing the accuracy of all available needles, so the current ones will be listed, highlighting their particularities and potential advantages. In this article, we will not cover mini-forceps.

Olympus

- ViziShot:

The classic needle developed since its prototype together with the EBUS linear bronchoscope. The available sizes are 21g and 22g.

- ViziShot 2:

The design and the material of the outer sheath have been revised which now provides better flexibility of the needle with 10 degrees more angulation when set on the bronchoscope. The tip of the sheath is also green in color, which allows for easier endoscopic viewing. There is also less movement of the outer sheath when advancing the needle out. The tip of the needle is redesigned to be sharper, for a less traumatic tissue insertion. The available sizes are 25g, 22g, 21g.

Within the Vizishot 2 family, there is also the 19g FLEX needle, which, due to its internal diameter of 1 mm, is able to sample tissue for histopathological analysis, not only cytological. Despite the larger diameter, due to the spiral laser cuts along the sides of the needle surface, the flexibility is improved compared to the classical ViziShot lineup. The result is a greater angle which facilitates the visualization of the most challenging lymph node stations.

Recently, the newest 25g size Vizishot 2 needle was launched. This needle can cover all the quality expected for the product, with extreme smoothness during penetration. In general, smaller needles generate less trauma in the sample, and therefore less blood contamination - which is a crucial factor during rapid on-site cytological evaluation.

Cook Medical

- EchoTip^{R} Ultra

In its design, this needle features a highly flexible spiral sheath, with the aim to facilitate access to regions where greater bronchoscope angulations are required. In addition, the tip is a ball tip type configuration. Available in sizes 22g and 25g.

- EchoTip ProCore^{R}

This Cook needle is designed for the acquisition of histological material, regardless of caliber, due to the design of its tip. The 22g needle is designed with a built-in ball tip, while the 25g needle has a beveled tip. Both, although different, aim to incise lymph node tissue during the passage of the needle and collect the material inside the needle.

Boston Scientific

- Expect^{TM} Pulmonary

Available in sizes 22g and 25g, the material of this needle is cobalt-chromium which is 24% harder than stainless steel (data provided by the company), thus being more resistant to deformation after several passages and excellent traction properties. However, due to the rigidity of the needle the insertion angle of the needle is not as steep as the Olympus needle. It also has great clarity in the echographic image. A non-inferiority was shown in a study comparing 22g with 25g needles[10].

- Acquire^{TM} Pulmonary

The main feature of this needle is its Franseen style tip. This design was already used for other radiological approaches to fine-needle puncture and aims to collect histological material even for smaller diameter needles. Like the Expect, it is also made of chromium-cobalt, maintaining its same qualities: good needle penetration, better ability to push, resistance to torsion and deformation after several passes. However, similar to the Expect needle, the insertion angle of the needle is not as steep as the Olympus needle.

Medi-Globe

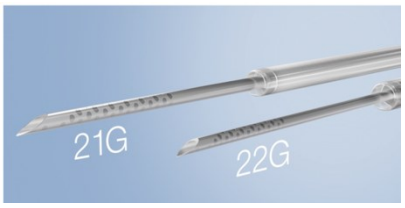
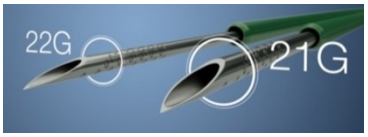
- SonoTip® EBUS Pro Flex:

Derived from the EUS needles already made by the company. It is the first needle completely made from Nitinol. Made of nitinol or stainless steel, compatible with Olympus, Pentax and Fujifilm EBUS-scopes. Sharpe tip as most of the other needles. Available only in size 22g.

- SonoTip TopGain® EBUS-TBNB:

It has a tip like Boston Acquire, which is called a "crown cut" by the manufacturer, with the aim of reducing the fragmentation of the material when the needle is introduced. Available only in size 22g, but in stainless steel and nitinol.

Table 1: Comparison between needles.

Brand and type of the needle	Picture	EBUS scope compatibility	Needle size (g)				
			25	22	21	20	19
Olympus ViziShot		Olympus		x	x		
Olympus ViziShot 2		Olympus	x	x	x		x
Cook Medical EchoTip® Ultra		Olympus, Pentax	x	x			
Cook Medical EchoTip Pro-Core®		Olympus, Pentax	x	x			
Boston Scientific Expect™ Pulmonary		Olympus	x	x			

Boston Scientific Acquire™ Pulmonary		Olympus	x	x			
Medi-Globe SonoTip® EBUS Pro Flex		Olympus, Fujifilm, Pentax		x			
Medi-Globe SonoTip TopGain® EBUS-TBNB		Olympus, Fujifilm, Pentax		x			

CONCLUSION

Minimally invasive strategies with the greatest possible accuracy should be the focus of today's bronchoscopist. Performing a trans-bronchial puncture is not limited to the bronchoscopic technique alone. The acquisition of an adequate sample for diagnosis starts with the indication of the procedure, adequate training, knowledge and choice of the needle according to the diagnostic hypothesis and purpose of EBUS, in addition to a multidisciplinary relationship between the bronchoscopist and the cytologist.

References:

1. **Yasufuku K et al. Chest 2004;126:122–8. https://doi.org/10.1378/chest.126.1.122.**
2. **Krasnik M et al. Thorax 2003;58:1083–6. https://doi.org/10.1136/thorax.58.12.1083.**
3. **Yasufuku K et al. Lung Cancer 2005;50:347–54. https://doi.org/10.1016/j.lungcan.2005.07.013.**
4. **Dincer HE et al. Med Devices Evid Res 2016;9:467–73. https://doi.org/10.2147/MDER.S62724.**
5. **Olympus America | Medical | n.d. https://medical.olympusamerica.com/ (accessed December 20, 2020).**
6. **Medical Devices for Minimally Invasive Procedures | Cook Medical n.d. https://www.cookmedical.com/ (accessed December 20, 2020).**
7. **Boston Scientific- US - Boston Scientific n.d. https://www.bostonscientific.com/en-US/Home.html (accessed December 20, 2020).**
8. **SonoTip Pro Control - Medi-Globe GmbH EN n.d. https://www.medi-globe.de/en/sonotip-pro-control.html (accessed December 20, 2020).**
9. **Medical Technology, Services & Solutions Global Leader | Medtronic n.d. https://www.medtronic.com/ca-en/index.html (accessed December 20, 2020).**
10. **Di Felice C et al. J Thorac Dis 2019;11:3643–9. https://doi.org/10.21037/jtd.2019.04.20**

Technique and Timing of Tracheostomy for Patients with COVID-19

Ajay Wagh, MD
The University of Chicago

Christine Argento, MD
Northwestern Memorial Hospital

Introduction

Percutaneous tracheostomy placement for patients with respiratory failure requiring long-term weaning from mechanical ventilation is a standard practice in the intensive care unit. The COVID-19 pandemic has brought new concerns regarding the safety, timing, and technique for tracheostomy placement due to the potential for transmission to healthcare workers (HCWs). As a result, expert consensus statements have been formulated and updated as we continue to gain experience with thoughtful adaptations for tracheostomy placement in patients affected by COVID-19.

Indications:

At our institutions, patients who require long-term ventilator management and weaning including patients with COVID-19, are considered for tracheostomy placement. In order to safely perform tracheostomy placement, the patient must be hemodynamically stable and be able to withstand periods of apnea during the procedure. Ideally, tracheostomy placement will assist hospitals to decompress the intensive care units and allow for the safe transfer of patients to long term acute care facilities for weaning from mechanical ventilation.

Procedural Considerations

Planning

When considering tracheostomy placement at our institutions for COVID-19 patients, the following questions are being addressed.

1.What is the overall prognosis of the patient? Have goals of care been discussed with the patient or family members?

2. How stable is the patient? Is medical optimization required prior to tracheostomy for coagulopathy, shock or hypotension requiring high doses of pressors, or high ventilator requirements (>40-60% FiO2 or PEEP 10-14cmH20).

3. Will the team be able to successfully perform the tracheostomy at the bedside? Or should a surgical approach be considered in the operating room?

4. Is enhanced personal protective equipment (PPE) available?

5. Which team members are necessary in the room? In our experience with the percutaneous approach, an operator and bronchoscopist are required along with a respiratory therapist and nurse. Alternatively, an anesthesia team member may replace both the respiratory therapist and nurse during the procedure in order to minimize exposures and conserve PPE.

Technical Guidelines

Recommendations from consensus statement have been described and summarized below (1,2).

1. Tracheostomy should be considered when prolonged mechanical ventilation is anticipated.
2. Both open surgical and percutaneous approaches for tracheostomy are acceptable.
3. Use of enhanced PPE to mitigate risk to HCWs is encouraged.

4. Tracheostomy should be performed in a negative-pressure room.
5. Utilize the least number of providers with the highest level of experience.
6. Maintain closed circuit ventilation while patient is on mechanical ventilation with in-line suction.
7. Use techniques and equipment with which operators are familiar, confident, and experienced.
8. Encourage the maintenance of a bloodless field, minimal use of diathermy, and use of smoke evacuator when using an open surgical approach.
9. Consider a trial of apnea after preoxygenation with FiO2 of 100% and PEEP of 5cmH2O to evaluate physiological readiness.

Suggested Timing

The timing of percutaneous tracheostomy placement for patients with COVID-19 has been unclear with insufficient evidence for any firm recommendations (1). Our institutions follow the suggestions from the published expert panel reports (1, 2).

1. Delay the procedure until at least day 10 of mechanical ventilation.
2. Consider only when patients are showing signs of clinical improvement.

Due to prior studies demonstrating absence of viral shedding after 21 days from symptom onset, some groups have suggested waiting this period of time prior to performing tracheostomy. In a single system, multi-center study, Chao and colleagues reported that it is reasonable to consider tracheostomy before 14 days since they found a (weak) positive correlation (R^2 0.1382, p=0.04) where patients who underwent earlier tracheostomies tended to achieve earlier ventilator liberation (3). Another study from Avilés-Jurado and colleagues found that the successful weaning rate was higher in the early bedside surgical tracheostomy group (<10 days intubation) compared with the late tracheostomy group (>10 days intubation) with no infections among surgeons identified at the end of the study (4). An analysis of 148 patients who underwent tracheostomies in the first 2 months of the pandemic in New York City, showed that early tracheostomy was noninferior to late tracheostomy and it did not contribute to increased infections of clinicians (5).

That being said, there is now data showing that the peak of infectivity of COVID-19 is between day 1- 5 of symptom onset with a significant decline after days 10- 15. Machine learning models suggest that tracheostomy in COVID-19 patients should be considered between days 13 and 17. This is a patient-centered approach as in the first 12-14 days of mechanical ventilation patients may either be successfully weaned off the ventilator or do not survive their critical illness (6).

Other Suggestions

Best practices are discussed in detail in the aforementioned CHEST guidelines (1). Angel and colleagues suggested the use of bronchoscopic visualization alongside the endotracheal tube as a novel method to reduce exposure to aerosol while visualizing proper tracheostomy tube placement (7). Additional modifications to the standard percutaneous tracheostomy procedure utilized at our institutions to minimize aerosol exposure include:

1. Clamping of the endotracheal tube prior to insertion of the bronchoscope (with the bronchoscope adapter) into the endotracheal tube as well as minimizing re-entry of the bronchoscope.
2. Draping or covering the face and endotracheal tube and packing the nose and mouth during bronchoscopy.
3. Utilizing manual ventilation with periods of apnea during high aerosol generating moments of the procedure (i.e., when dilating the stoma and during placement of the tracheostomy tube).
4. Occasional assistance from anesthesia colleagues to ensure adequate sedation and offer hemodynamic support during the procedure to help minimize additional personnel in the room while maintaining expertise with airway, sedation and mechanical ventilation.
5. We have successfully utilized disposable bronchoscopes for use during tracheostomy (Figure 1), although the suboptimal suctioning, visibility, and stiffness of these scopes may be limiting factors for an optimal procedure. Studies are needed to confirm the long-term outcomes of patients who undergo any interventional procedure using these disposable devices.

Quality Control

After tracheostomy, patients may be transferred to the medical floor once they demonstrate a stable ventilator/oxygen requirement or a long-term acute care facility where ongoing weaning can take place as appropriate. Once the patient is liberated from the ventilator, tracheostomy decannulation protocols are followed with modifications such as maintaining a closed circuit using a heat and moisture exchanger

(HME) along with a viral filter, minimizing inner cannula or tracheostomy tube changes, and maintaining cuff inflation even while off mechanical ventilation until the patient has either tested negative for COVID-19 or is ready for decannulation. Any patient noted to have difficulty phonating or breathing following tracheostomy requires a bronchoscopy to evaluate for laryngotracheal stenosis, or obstructing granulation tissue.

Conclusions

The COVID-19 pandemic has complicated routine tracheostomy placement for patients with COVID-19 related respiratory failure due to concerns for increased risk of aerosolized exposure of virus to HCWs. Several adjustments to percutaneous tracheostomy procedural technique have been proposed to improve safety and have demonstrated success. Professional societies continue to collaborate to ensure safety for healthcare workers involved in placement and care of patients requiring tracheostomy.

Figure 1: Percutaneous tracheostomy procedure performed at Northwestern Memorial Hospital utilizing enhanced PPE and use of a disposable bronchoscope (Ambu ®).

References:
1. Lamb C et al. Chest. 2020 Oct; 158(4): 1499-1514. PMID: 32512006
2. McGrath B et al. Lancet Respir Med 2020; 8: 717-25. PMID: 32422180
3. Chao T et al. Annals of Surgery. Sept 2020. 272(3): e181-186. PMID: 32541213
4. Avilés-Jurado et al. JAMA Otolaryngol Head Neck Surg. Oct 2020. PMID: 33034625
5. Kwak PE et al. JAMA Otolaryngol Head Neck Surg. Published online December 17, 2020. doi:10.1001/jamaoto.2020.4837
6. Takhar A, et al. Crit Care Explor. 2020; 2 (11) e0279
7. Angel L et al. Ann Thorac Surg. 2020 Sep;110(3):1006-1011. PMID: 32339508

Ethical Issues of Vaccination

Scientists have estimated that 60 to 90 percent of a country's population needs to be vaccinated against COVID-19 for countries to achieve herd immunity and prevent mass future breakouts.

Although traditionally the vast majority of individuals get vaccinations as recommended, more recently vaccine hesitancy has increased, mainly fueled by misinformation through social media but also political oppositions around the world.

Rational academic analysis clearly show that with any new anti-COVID vaccine, serious side effects are extremely rare and can be detected only after millions of people are vaccinated. Like in any other vaccine, if those extremely rare events are detected, society should balance that very low probability of serious reactions with the very real possibility of millions of deaths related to COVID-19 and/or to the collapse of the health care systems if a large amount of the population does not acquire immunity soon.

But in spite of those obvious benefits, many nations could struggle to achieve the required percentage of immunization. In Italy, a study has found that nearly 40 percent of Italians will opt not to take the vaccine. In the UK, a study carried out by King's College and Ipsos Mori in August 2020 found that just 50 percent of the UK population would be willing to be vaccinated and a similar reluctance has been found in France with 54 percent of people surveyed by Ipos showing that would decline a vaccination. Results of surveys in the US are variable but even the more optimistic do not show more than 60% of the population would definitely or probably get inoculated.

The potential harm of these beliefs is that reluctance to get a COVID-19 vaccine could hamper its effectiveness.

In 2015, the World Health Organization (WHO) declared that the United Kingdom had eradicated rubella and in 2016 it was designated as measles-free country. Immunization rates in UK children were high at that time. By 2016, more than 95% of the country's 5-year-olds had received one dose of MMR, and roughly 85% had received the pre-school booster that maximizes immunity. But during the first half of 2019, Europe had 90,000 cases of measles — more than 17 times the number reported in the whole of 2016 and several European countries (including the United Kingdom) lost its measles-free status. Similarly, the United States, is experiencing a remarkable increase of cases of measles cases since 1992.

Those figures made WHO consider hesitancy to vaccinate as one the ten gravest threats to global health and governments around the world started to discuss the possibility of adopting policies that would make vaccinations mandatory. That is because evidence of vaccination's effectiveness is unequivocal and, for instance, Government agency Public Health England estimates that the measles vaccine combined with mumps and rubella vaccines have prevented 20 million cases of measles and saved 4,500 lives. In terms of improving public health, vaccination is second only to providing clean drinking water.

One of the main factors that explains that relaxed attitude towards vaccines is that many people thought that many infectious diseases were relatively harmless. The introduction of some vaccines, has dramatically reduced the number of infections in the developed world; such reduction, in turn, made invisible to many people the possible severe consequences of certain infectious diseases and, accordingly, the benefits of vaccines. For example, as reported by the Oxford Vaccine Group, the year before the measles vaccine was introduced in the UK (1967), there had been 460,407 suspected cases of measles in the country, with 99 measles-related deaths. After the introduction of the vaccine, the number of measles cases per year dropped to around 10,000, with one or two deaths, by the end of the 1980s. Vaccines made and are still making a difference. But in a sense, this success backfired: people started to forget, because they could no longer see, that certain infectious diseases can have very severe consequences and even be lethal for certain vulnerable people.

Humanitarian News

Legal compulsion is a strategy that governments have used previously to overcome such reluctance. In England, the vaccination of all infants was made mandatory in 1853, and parents who failed to vaccinate their children faced fines or prison. Obviously it was a controversial decision as many British people consider that it was a rational way to guard against the danger of resurgent smallpox, but many others saw a violation of their bodies and rights. Legal compulsion resulted in a strong anti-vaccination movement that resisted the law through protests and demonstrations and that got in 1898 the addition of a "conscience clause" that excused parents who believed that vaccination would harm their children's health. Unfortunately it meant that by 1911 only about 56 percent of newborns were being vaccinated. Vaccination was also made mandatory in other European nations as Germany in 1873 after its experience in the Franco-Prussian War.

In the United States, the first school vaccination requirements were enacted in the 1850s to prevent smallpox. There were many court challenges from people who considered those policies a violation of constitutional liberties. Conflicting decisions in these cases culminated in the landmark Supreme Court case Jacobson v. Massachusetts in 1905, which held that compulsory vaccination was a legitimate exercise of state governments' "police powers" to guard the health, welfare, safety, and morals of citizens. Several federal and state efforts to eradicate measles in the 1960s resulted in many mandates policies. By the 1990s, all 50 states required students to receive certain immunizations, and most states required coverage for those in daycare centers .

Ethical debates and objections about mandates arise because some individuals and communities disagree with the mandates, and/or have religious or philosophical beliefs that conflict with vaccination. Tension results when individuals want to exercise their right to protect themselves and/or their children by refusing vaccination, if they do not accept existing medical or safety evidence, or if their ideological beliefs do not support vaccination.

In that context: is there any ethical justification for the governments to prioritize the common good over individual autonomy and create policies for mandatory vaccination?

There is a large body of literature on the justification for the use of coercion in public health, mainly in infectious diseases. Mandatory vaccination is usually justified on Millian principles: harm to others. According to John Stuart Mill, the most prominent arguments from bioethicists appeal to preventing harm to others.

In fact, at least two plausible principled justifications may be offered for mandatory vaccination: the harm principle and the prevention of free riders.

The harm principle, described by John Stuart Mill in On Liberty, considers that the only justification for coercive action against an individual is the presence of imminent harm to other members of society. A person's own good is insufficient reason. Those who sustain the legitimacy of mandates, point that people who refuse to be vaccinated or to have their children vaccinated harm others. On the other hand, the counter-argument is that while being vaccinated clearly benefits others, it is less obvious that the failure to be vaccinated harms others as some other factors influence the likelihood of disease transmission.

The argument that each individual has within his or her power the ability of self-protection and so can choose to receive a vaccine, and has no moral claim to force another person to receive it, is extremely weak. Some people cannot undergo vaccination because of medical contraindications or have a diminished biological capacity to develop immunity in response to a vaccine, not taking into account that no vaccine is 100 percent effective and some people can receive the vaccine and fail to develop the intended immunity. All these people may be placed in danger by infectious diseases that unvaccinated members of the community may spread.

Other potent argument for the use of compulsion is to prevent the problem of free riders, those people who use a public good without assuming their fair share of the cost. The herd immunity created by high levels of immunization can be considered a public good, by being nonexcludable (if it is available to some people, it must be available to everyone), and nonrivalrous (the protection that one individual gets does not diminish the protection of others). An individual's self-interested strategy would be to allow everyone else to assume the small risk of vaccination but avoid vaccination himself and in that way

taking selfish profit of the risks other people have faced.

Regarding to herd immunity Hardin has described the phenomena of the "tragedy of the commons". In this situation, the availability of a shared resource is undermined by self-interested actions. If only one individual refuses vaccination, he will not affect the protection of the whole community, but if many people make that choice, herd immunity will eventually not be achieved and the community will stay vulnerable to disease outbreaks.

We many see free riding and the tragedy of the commons as problems of distributive justice, in which the benefits and burdens of immunization are not fairly distributed among all members of society.

Additionally "the clean hand principle" has been described as the situation in which moral imperative prohibits people from becoming accomplices in the collective harm that would result from the failure to achieve herd immunity.

In most of these views, compulsory vaccination is justified by the fact that the state has an obligation to preserve the common good of herd immunity in order to protect vulnerable people .

In the specific case of COVID-19 the impact of the failure of vaccination is not only in terms of deaths from the disease but also in the enormous economic, health and social consequences of alternative control measures, as lockdown or travel restrictions and the unavailability of health care resources for other acute or chronic disease management, consequences which may be long-term even after a relative control of the epidemic.

As Julian Savulescu recently described in the Journal of Medical Ethics there is a strong case for making any vaccination mandatory (or compulsory) if four conditions are met: a) there is a grave threat to public health, b) the vaccine is safe and effective, c) mandatory vaccination has a superior cost/benefit profile compared with other alternatives and d) the level of coercion is proportionate.

As in any ethical analysis, all those variables have to be pondered as it happens with the conflict amongst different ethical principal and, consequently, there is always some subjectivity in the given value to each one of them.

Taking that into account, even facing the variation in testing rates, and ways of assigning deaths from country to country, after months of persistence of the epidemic, there is no doubt that COVID-19 health implications may present a grave public health problem not only as an acute disease but also amongst survivors because of the potential long-term consequences. Of course, some will argue that this disease is not "grave" enough to warrant mandatory vaccination, compared for instance with the Spanish influenza that killed around 50–100 million people and afflicted younger rather than older people. The judgement if COVID-19 is sufficiently grave requires more data than the available ones, but most of people in the academic and political environments would agree that COVID-19 is a grave public health emergency.

The item about the safety of the vaccine is especially sensitive as there are concerns that testing has been rushed and the vaccine may not be safe or effective. However, the statistical probability anticipates that no vaccine could be said to be 100% safe. There will be risks as in any other vaccines and it is not impossible that they will be greater than with well-established vaccines. But again, the judgement of how much effective and how much safe it must be to warrant mandatory vaccination will be a matter of discussion. Of course, safety would need to be very high, but a 0% risk option is realistically unlikely.

Mandatory vaccination must be considered justifiable when there are benefits to the individual and to the whole community by preventing transmission. But an important additional justification would be to prevent exhaustion of healthcare resources and to protect other adults who cannot be vaccinated for medical reasons.

Thirdly: has mandatory vaccination a superior cost/benefit profile compared with other alternatives? In an ideal world, everyone would want to be vaccinated against Covid and there would be enough vaccine to do that job. We don't live in that world. Unfortunately the surveys mentioned above open doubts about the willingness of the population about receiving COVID-19 vaccine. But additionally, not only reaching herd immunity is important but how fast we reach it in equally im-

portant. A delay in reaching herd immunity may mean tens of thousands of lost lives all over the world. People particularly vulnerable (those that cannot be vaccinated for medical reasons or the elderly or chronically sick people) critically depend on stopping the spread of the disease as soon as possible.

There are other policies that are alternatives to the vaccination. They include mainly prolonged or intermittent lockdown and vigorous track and trace programs or enforced quarantines with tracking devices. But on one hand most of those policies are actively resisted by the population (because of the economic, social and emotional consequences) and additionally the long-term costs and benefits of such policies are not completely known. It means it cannot be accurately pondered if a mandatory policy of COVID-19 vaccination is ethically justified until the exact costs of the vaccine, the impact of the problem and the effectiveness of the alternative measures is more scientifically grounded. However, in spite of the lack of definitive figures, it is certainly feasible that it could be justified.

If it is considered that coercive vaccination can be justified, those who defend freedoms at all costs must admit that, in any country, there are many other situations in which mandatory actions exist. In the gravest emergencies, where there is danger for the whole population, people are mandated to take arms to serve their country, in spite of the high risk of death or permanent injury. Taxes are not optional to be paid, the use of seat belt or abstention of alcohol when driving is mandatory. Even in those countries whose policies favour interventions of the government as limited as possible, there are public policies that are mandatory in order to protect and promote the common good.

Mandatory public health policies include any policy that contains a non-voluntary element to vaccine consent. It may be through the imposition of a penalty or cost for refusal. There are a range of possible penalties or costs which can coerce people. Australia has the “No Jab, No Pay” scheme which withholds child benefits if the child is not vaccinated, and a “No Jab, No Play” scheme which withholds kindergarten childcare benefits. Italy introduced fines for unvaccinated children who attend school. In the USA, state regulations mandate that children cannot attend school if they are not vaccinated, and healthcare workers are required to vaccinate.

Finally, proportionality between the level of coercion and the gravity of the problem should exist. Coercion is justified when the restriction of liberty is both minimized and proportionate to the expected advantages offered by the more coercive policy.

The Nuffield Council of Bioethics produced an influential report on public health which considers when coercion and mandatory vaccination might be justified: “When assessing whether more directive policies are acceptable, the following factors should be taken into account: the risks associated with the vaccination and with the disease itself, and the seriousness of the threat of the disease to the population. In the case of incentivized policies, the size of the incentive involved should be appropriate so that it would not unduly compromise the voluntariness of consent.”

The result of this approach is an “Intervention ladder”, which includes measures as education and incentives, as well as coercive measures. In some way it reflects the principle of the “duty of easy rescue” : if the cost to an individual is small of some act, but the benefit or harm to another is large, there is a strong moral obligation to perform that act (the classical example is “if you notice a child has fallen in and appears to be drowning and to wade in and pull the child out would be easy but it will mean that you get your clothes wet and muddy, you have the moral obligation to rescue the child? As the importance of saving a child so far outweighs the cost of getting one’s clothes muddy and missing a class”). That principle appropriately balances respect for autonomy with justice.

Most of experts agree on considering two circumstances in which quasi-mandatory vaccination measures are more likely to be justified. First, for highly contagious and serious diseases and second for disease eradication if the disease is serious and if eradication is potentially possible.

Even this summary analysis show that mandatory vaccination can be ethically justified but, although it has existed in various forms for more than 200 years, there is a paucity of good epidemiological studies of the effects of different mandates. The introduction of laws for mandatory vaccination is usually accompanied by other measures of education and publicity, which

makes it harder to identify the specific effects of legislation. It makes answering the relevant question whether mandatory vaccination is effective, a complicated task.

But even taking those confounding variables into account, there is some evidence that mandatory vaccination may help. In the United States, nationwide surveys in the 1970s showed that the incidence of measles was higher in states without mandates, and lowest in states where mandates were strictly enforced. Also in Italy and France immunization coverage has risen with the introduction of mandates. And the No Jab, No Pay legislation withholding state benefits in Australia coincided with full immunization rates rising by around 3% allowing to achieve a nationwide coverage nearly 95%.

However the World Health Organization considers that persuading people on the merits of a COVID-19 vaccine would be far more effective than trying to make the jabs mandatory. Most of data show that the problem is not vaccine refusal, but vaccine hesitancy. In most countries, the proportion of the population that staunchly opposes vaccines is less than 2% and the bigger problem is the large group of people with some concerns about vaccination that might make them hesitant. It is reasonable to think that the minority of people who refuse vaccines will rarely change their minds but the hesitant population, may respond to information campaigns. It would favour a greater investment in education and more efforts to facilitate meaningful conversations between concerned people and health-care professionals. But every context is different and it must be taken in consideration that in the last decade the power of mass media and mainly of tools as social media and non-expert influencers is increasingly strong and that power is not easily balanced by the traditional communication tools of the governments.

Another problem of the restrictive policies is that even being initially very successful, its effectiveness vanishes over time. A study on the effectiveness of state-level varicella vaccination mandates indicates that “the impact of the mandate is a short-run phenomenon. The importance of the mandate effect relative to the aggregate time trend (…) is cut by more than a half by the fourth year after the mandate and disappears completely approximately six to seven years after the mandate” .
Coercion may be applied through penalties or costs but also through incentives. The different types of vaccination policies could be successful in achieving herd immunity, depending on factors such as particular socio-economic circumstances or cultural contexts. But deciding which policy to implement should always consider the principles of least infringement and of least restrictive alternative.

The principle of least infringement states that public health authorities, when choosing between available policies for achieving a certain public health goal, should select the health policy that infringes the least upon certain individual rights. Such rights include the right not to be harmed, the right to receive beneficial medical treatments, the right to free movement and association, and the right to bodily integrity and to personal autonomy.

Not only penalties may be restrictive, the restrictiveness of any type of intervention depends on variables of the context of individuals targeted. Giving financial incentives might exert a different influence on the decision-making of those who are in great need of money (for whom is almost impossible to reasonably refuse those incentives) while others might remain indifferent to that same incentive.

The principle of least restrictive alternative (PLRA) advises to implement the least restrictive policy that is effective, and it means that governments should test the efficacy of possible policies, starting from the least to the most restrictive: persuasion, nudging, provision of incentives, withholding of financial benefits, imposition of financial penalties, withholding of social services and goods and, as a last resort, compulsory vaccination. Compulsory vaccination should be seen as a measure of last resort and some of the less restrictive options discussed should be sufficient for the realization of herd immunity.

Convincing people to vaccinate without coercing them is always preferable, and where some coercion is necessary to achieve herd immunity, a lower degree of coercion is always preferable. Besides, coercive policies would be necessary only where outright vaccine refusal is a significant factor in low vaccination rates; where this is not the case, alternative and less restrictive policies such as nudging, improving accessibility and minimizing logistic barriers to vaccination are not only ethically preferable on the basis of the PLRA but probably also very effective .

As one of the main goals is to limit as much as possible the amount of people who are burdened with restrictions on liberty or autonomy, the governments should grant non-medical exemptions to a certain number of people who have deeply held beliefs against vaccination, provided they are not too large a group.

In summary, it can definitely be said that there is a collective responsibility, or collective moral obligation, to achieve herd immunity and that there is an individual moral obligation to contribute to the realization of herd immunity by being vaccinated. At the same time, the state has an institutional responsibility to implement vaccination policies that can guarantee at least the realization of herd immunity and the policies should follow the principle of least restrictive alternative that would be effective in achieving this goal.

On the other hand, a principle of fairness requires that everybody—not just the smallest number of people that can realize herd immunity—makes their fair contribution to herd immunity by getting vaccinated. The state is morally justified in requiring each individual to be vaccinated in the absence of legitimate medical reasons for exemptions; and compulsory vaccination without non-medical exemptions is ethically justified.

Even when mandatory vaccination can be ethically justified it is quite possible that some mixture of altruism and financial and non-financial benefits will obviate the need to introduce mandatory vaccination. It is much better that people voluntarily choose on the basis of reasons to act well, rather than being forced to do so, and in any case, coercion by incentives is better than imposing penalties. Education, communication and structuring the rewards and punishments in a just and fair way is one way of giving people reasons for action.

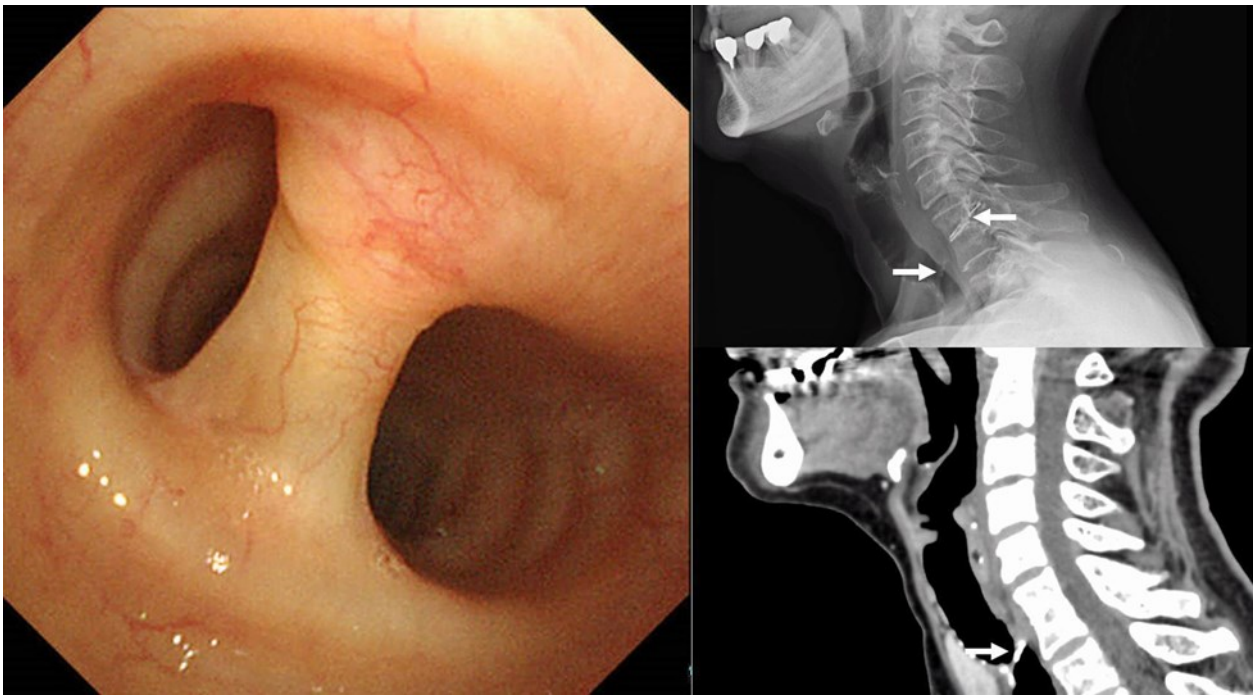
References:

1. Savulescu J. J. Med. Ethics Published Online First: 05 November 2020. doi: 10.1136/medethics-2020-106821
2. Flanigan J. HEC Forum 2014;26(1):5–25. doi:10.1007/s10730-013-9221-5
3. Nuffield Council on Bioethics. Public health: ethical issues. London: Nuffield Council on Bioethics, 2007: 60.
4. Giubilini A. J Appl Philos 2020;37(3):446–66. doi:10.1111/japp.12400
5. Giubilini A. The ethics of vaccination. Palgrave Macmillan, 2019.
6. Nuffield Council on Bioethics. Public Health: Ethical Issues. London, 2007
7. Drew L. Nature 575, S58-S60 (2019) doi: https://doi.org/10.1038/d41586-019-03642-w8. Salmon, D.A et al... Emerging Themes in Epidemiology. 2006;3:13.
9. Colgrove J. Immunization and Ethics: Beneficence, Coercion, Public Health, and the State.The Oxford Handbook of Public Health Ethics. DOI: 10.1093/oxfordhb/9780190245191.013.38

**The views expressed in this article are those of the author (Silvia Quadrelli) and do not necessarily reflect the official positions of the Executive Board or International Board of Regents of the WABIP.*

Best Image Contest

Best Image Contest 2021 (1 of 3)



Description:

A 74-year-old woman was found to have a foreign body in her trachea during follow-up for a parotid tumor. Neck X-ray and computed tomography revealed a metallic material penetrating the vertebral body and trachea (arrow). Bronchoscopy showed that the organized material was penetrating the trachea. She had received acupuncture for neck stiffness more than 20 years ago, so the foreign body was suspected of being a broken acupuncture needle. The patient had no complaints related to the foreign body; therefore, we decided to follow the patient.

Submitter:

Takahiro Nakajima, MD

(Department of General Thoracic Surgery, Chiba University Graduate School of Medicine)

This image is 1 of 3 selected among 100+ submissions to our **Best Image Contest** held in late 2020. Please stay tuned to the next Image Contest opening later this year! Find the above image and more at the WABIP Academy Image Library at https://www.WABIPacademy.com/imagelibrary

WABIP News

Annual Board of Regents Meeting 2021

With the new business year, the WABIP Regents (member society representatives) shall meet and vote on WABIP activity and financial reports for our annual filings as a non-profit organization in Japan. The meeting will be held via teleconferencing on MARCH 20, 2021. Regents may also submit their votes to approve our annual reports and government documents via proxy.

WCBIP 2020 & Beyond

We are very pleased to have successfully concluded WCBIP 2020, amid especially challenging circumstances before and during the event. This WCBIP proves that running huge virtual events with 35,000+ total participants is completely possible for the WABIP. We will be using some components of this virtual model as a basis for our WCBIP events going forward, especially as we strive to include participation from our 10,000 WABIP members from around the world, whether on-site or virtually. See you at WCBIP 2022 in Marseille France, and WCBIP 2024 in Bali Indonesia!

New Open Committee Positions

As we begin a new term, a number of new committee positions are now open. We cordially invite you to apply for open positions in our: Awards Committee, Bylaws Revision Committee, Conflict of Interest Oversight Committee, or Continued Medical Education Committee. Send your application via https://www.wabip.com/forms/committees

Announcing the 2021 APCB & 2021 ECBIP

Our dear friends and partners at the Asia Pacific Association and the European Association will be hosting their biennial events this year, which will both be in October of this year.

Research

Even Perfection Has Room for Improvement

Appropriate staging of lung cancer is the most crucial aspect of the workup of lung cancer. The proper management and the prognosis hinges upon the correct stage of lung cancer. Under-staging lung cancer has been a chronic problem leading to sub-optimal therapy, a high "relapse" rate, and poor outcomes.

We have come a long way in surgical and minimally invasive lung cancer staging with modalities such as Endobronchial Ultrasound (EBUS) guided Transbronchial Needle Aspiration (TBNA) of the mediastinal and hilar lymph node. EBUS-TBNA has made lung cancer staging more accessible and cheaper.

Despite surgical and medical procedural advancements and meticulous staging guidelines, the discrepancy between the clinical and pathological staging of lung cancer persists at an alarming rate.

A recent study (1) evaluated the accuracy of the complete clinical lymph node staging by assessing the agreement between imaging, clinical, and pathological nodal stage in patients with Non-Small Cell Lung Cancer (NSCLC) eligible for surgery and evaluate the incidence and localization of occult lymph node metastasis (OLM). Three hundred and ninety patients with NSCLC from a single center were studied. The clinical staging based on CT/PET and lymph node biopsies with EBUS-TBNA or mediastinoscopy were confirmed by final pathological staging after anatomical resection. Any patient who did not go thru surgical resection was excluded from the study since their pathological stage could not be verified. Similarly, patients with enlarged lymph nodes in station 5 and 6 were excluded since EBUS-TBNA could not evaluate them.

Overall, final clinical staging corresponded to surgical staging outcomes in 65.5 % of patients.

In the subgroup of patients staged as clinical stage, cN0 (clinically no nodal involvement), 23.1 % had OLM. Patients who underwent staging by EBUS/EUS were inaccurately staged in as much as 50 % of cases, involving both over staging (39.6 %) and under staging (11.3 %). Remarkably, of all patients with OLM, 50.0 % had primary tumors ≤30 mm.

The study shows that in the absence of an anatomical parenchymal resection with systematic mediastinal lymph node dissection, 23% of patients with clinical stage N0 would have been undertreated due to the presence of OLM. These patients would have risked being under staged and undertreated with sub-lobar resection (segmentectomy or wedge resection) or non-surgical treatment modalities such as Stereotactic Ablative Radiotherapy (SABR). Unidentified OLM would not only result in missed removal of these involved nodes but could also result in missed opportunities to offer patients adjuvant chemotherapy resulting in poor outcomes and survival.

Based on this study and many others in the past, OLM is frequently identified in clinically N0 and N1 NSCLC, tumors <3 cm, and often in regions beyond the reach of current staging techniques. These findings raise a valid concern in patients managed non-surgically (SABR) or with sub-lobar resections since they are never subjected to the final scrutiny of pathological staging. It is conceivable that novel therapeutic approaches such as bronchoscopic ablation of parenchymal tumors will face similar challenges once they are FDA approved and adapted as mainstream modalities for a select group of patients.

Our struggles to improve must go on!

Ali I. Musani MD

Reference:
1. Beyaz F et al. Lung Cancer. 2020 Dec;150:186-194. doi: 10.1016/j.lungcan.2020.10.022. Epub 2020 Nov 7. PMID: 33189983.

WABIP ACADEMY- WEBCASTS

The WABIP has started a new education project recently: *THE WABIP ACADEMY.* The WABIP Academy will provide free online webcasts with new and hot topics that will interest pulmonologists and interventionalists.

Current webcast topic: **Tissue acquisition for biomarker directed therapy of NSCLC**

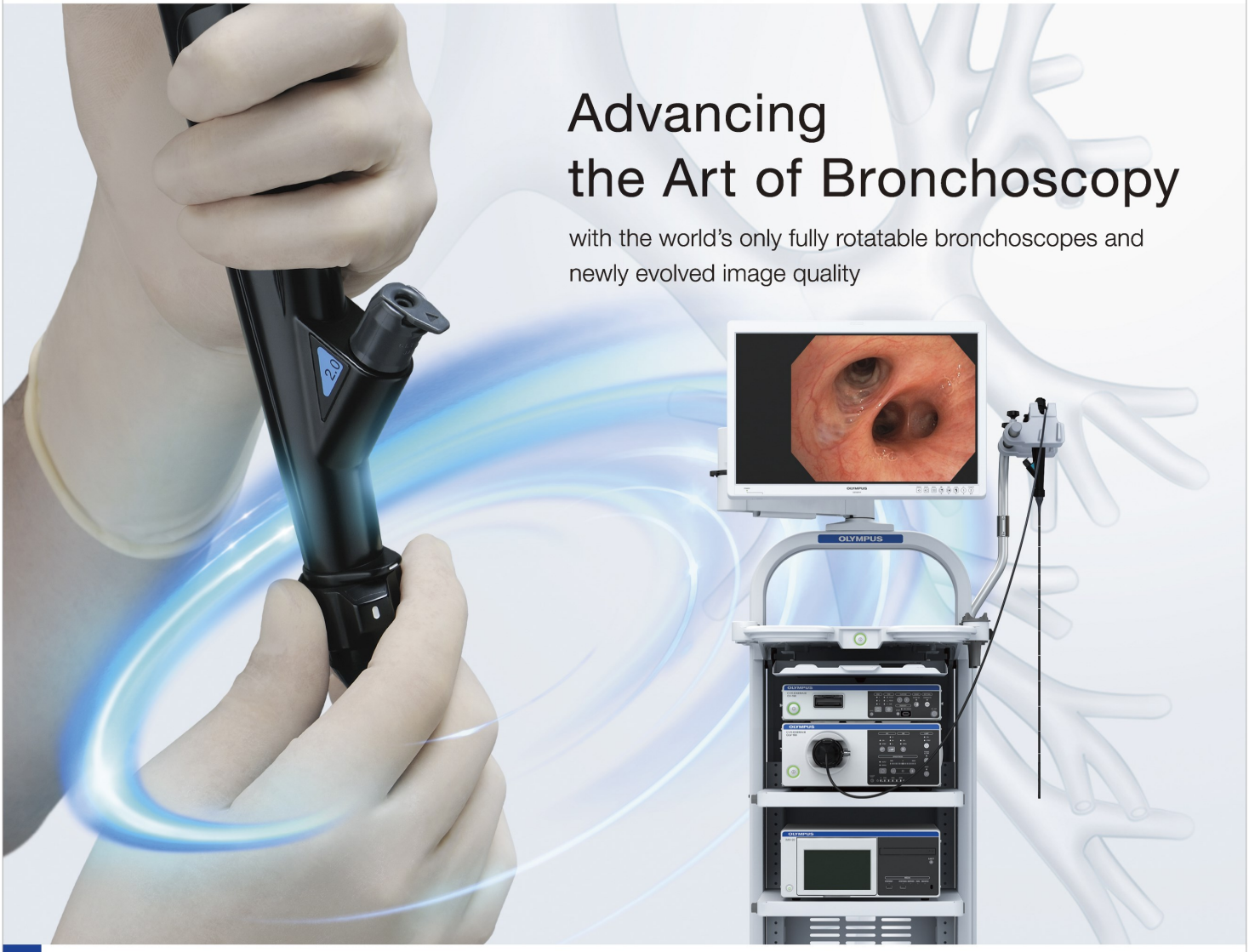
You can reach these webcasts by using this link: http://www.wabipacademy.com/webcast/

Links

www.bronchology.com	Home of the Journal of Bronchology
www.bronchoscopy.org	International educational website for bronchoscopy training with u-tube and facebook interfaces, numerous teachiing videos, and step by step testing and assess ment tools
www.aabronchology.org	American Association for Bronchology and I nterventional Pulmonology (AABIP)
www.eabip.org	European Association for Bronchology and Interventional Pulmonology
www.chestnet.org	Interventional Chest/Diagnostic Procedures (IC/DP) NetWork
www.thoracic.org	American Thoracic Society
www.ctsnet.org	The leading online resource of educational and scientific research information for cardiothoracic surgeons.
www.jrs.or.jp	The Japanese Respirology Society
sites.google.com/site/asendoscopiarespiratoria/	Asociación Sudamericana de Endoscopía Respiratoria

OLYMPUS®

Your Vision, Our Future



Advancing the Art of Bronchoscopy

with the world's only fully rotatable bronchoscopes and newly evolved image quality

OLYMPUS pursues perfection in the art of bronchoscopy with major advances in maneuverability and visualization.

Advancing Maneuverability

New features including Insertion tube rotation function, improve handling and in-procedure maneuverability of bronchoscopes.

Advancing Visualization

The new HDTV bronchoscopes achieve an outstanding level of clarity and detail enabling the bronchoscopist to perform more precise observation and diagnosis.

EVIS EXERA III

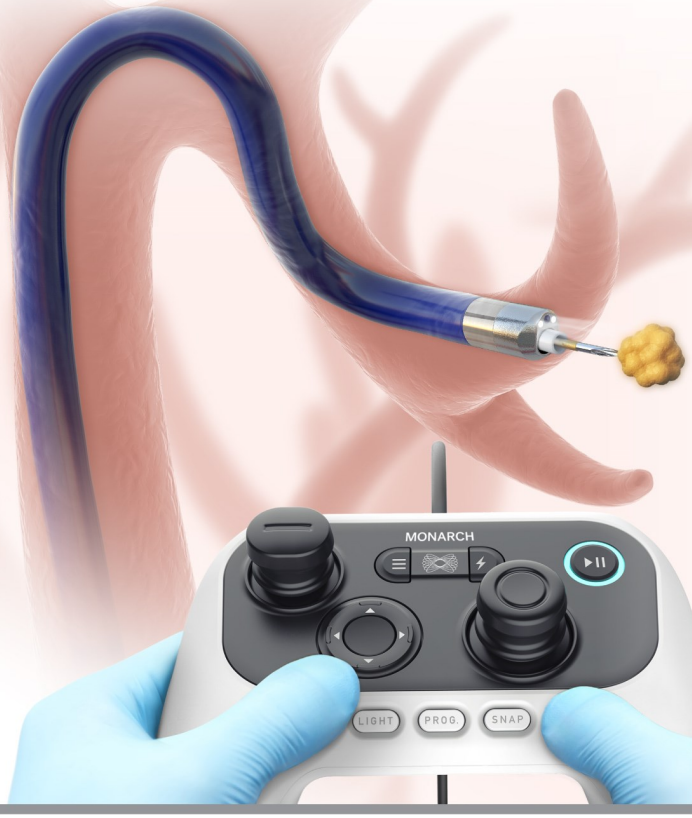
EVIS LUCERA ELITE

OLYMPUS MEDICAL SYSTEMS CORP.
Shinjuku Monolith, 2-3-1 Nishi-Shinjuku, Shinjuku-ku, Tokyo 163-0914, Japan

* EVIS EXERA III and/or EVIS LUCERA ELITE are not available in some areas

BENEFIT STUDY

THE FIRST MULTICENTER PROSPECTIVE ROBOTIC BRONCHOSCOPY TRIAL



96.2%

MONARCH® + r-EBUS localization

70%

diagnostic yield on eccentric nodules

Robotic Bronchoscopy for Peripheral Pulmonary Lesions: A Multicenter Pilot and Feasibility Study

The diagnostic yield of 70% for eccentric lesions is encouraging as this compares favorably to the yields of 30–40% reported in the literature in this patient population.[1]

The 55-patient BENEFIT study led by Alexander C. Chen, M.D., of St. Louis, MO and Gerard A. Silvestri, M.D., of Charleston, SC assessed the safety and feasibility of utilizing a robotic system to aid in the diagnosis of peripheral pulmonary lesions.

To read the full study visit https://journal.chestnet.org/action/showPdf?pii=S0012-3692%2820%2934233-1

NEVER LOSE SIGHT

at the most critical moments

MONARCH®

AURISHEALTH.COM | | MBRPRO-000219-00 Rev B

DISCLAIMERS: The MONARCH® Platform is only available commercially in the US. The needle shown is for illustration purposes and is representative of commercially available needles.

1. Chen AC, Pastis NJ, Silvestri GA, et al. Robotic Bronchoscopy for Peripheral Pulmonary Lesions: A Multicenter Pilot and Feasibility Study (BENEFIT) Chest 3525, 19 August 2020,

CLINICIANS TRUST MERIT ENDOTEK

Merit Endotek's family of fully-covered, laser-cut AERO tracheobronchial stents and advanced over-the-wire and direct visualization delivery systems deliver consistent, reliable results.

AERO®

FULLY COVERED TRACHEOBRONCHIAL STENT

- Fully covered
- Enhanced proprietary anti-migration struts
- Virtually no foreshortening or elongation
- Hydrophilic coating

AEROmini®

FULLY COVERED TRACHEOBRONCHIAL STENT SYSTEM

- Ergonomic handle and trigger provide accurate single handed deployment of the preloaded stent
- Low profile 12F & 16F delivery system for crossing tight strictures
- Increased working length for ease of deployment into distal anatomy
- Distal Catheter Flex Zone designed to increase trackability of the stent deployment system into tortuous anatomy

AERO DV®

DIRECT VISUALIZATION TRACHEOBRONCHIAL STENT SYSTEM

- Visualize proximal and distal ends of stenosis during deployment
- Eliminates the need for fluoroscopy and guide wire
- Procedure can be performed bedside

AEROSIZER®

TRACHEOBRONCHIAL STENT SIZING DEVICE

- Diameter sizing arms
- Length sizing marks
- Compatible with diagnostic bronchoscopes
- Color-coded with stent packaging

EXPANDING THE POSSIBILITIES™

WWW.MERIT.COM/ENDOTEK

MERIT MEDICAL ENDOTEK®