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Artificial Intelligence and Interventional Pulmonology

Are we "stepping in GOD's shoes"?

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Artificial Intelligence (AI) is not a novel concept. The word "Artificial Intelligence" was coined by John McCarthy in 1956, and the first general-purpose mobile robot was developed in 1969. The rapid growth in technology soon created "Super Blue," the "supercomputer," which defeated the world chess champions.

AI is a type of computer science used to create intelligent machines that recognize human speech and objects and learn, plan and solve problems like humans.

AI can be understood in many ways depending on one's perspective, as described below by some world experts and leaders in the field.

- **AI is just math"** - multiple computations that are the basis of AI are also where the technology faces limitations. Jana Eggers, the CEO of Nara Logics
- **AI is just software**. "There's no bright line separating AI software from any other kind of computer software," Michael Littman, a computer science professor at Brown University.
- **The potential of AI lies in its ability to learn, and its learning from humans.** Mikhail Naumov, co-founder, president, and CSO of Digital Genius.
- **Simply put, humans should be focused on teaching machines, so that machines can focus on executing against jobs that are too big for humans to process**." J.J. Kardwell, CEO/co-founder of Ever String

In the eyes of some world experts of technology, such as Elon Musk, CEO of Tesla, AI is a double-edged sword. The potential of AI is fundamentally changing just about any aspect of our lives is so profound and self-perpetuating that the threat of AI getting out of human control makes him say that "AI is a fundamental risk to the existence of human civilization."

AI in medicine has been growing by leaps and bounds in all facets, including diagnostics, therapeutics, research, device development, and drug development. Watson, the infamous supercomputer, can diagnose thousands of diseases with extreme expediency and accuracy. Numerous medical organizations now use it. Google's "AI Retina Doctor" can examine retina scans and diagnose diabetic retinopathy.

AI has also played a crucial role in the growth of Interventional Pulmonology (IP) over the years. The below examples will highlight some revolutionary AI-based developments in IP.

- LungVision system (Body Vision Medical LTD, Israel) is a novel technology that integrates pre-procedural CT imaging into augmented fluoroscopic images, presenting real-time visualization of the airways and location of the pulmonary lesion during transbronchial navigation and biopsy. It enables lesion tracking during breathing movement and improves lesion localization and diagnostic yield. LungVision may provide equivalent diagnostic outcomes to traditional ENB platforms at a fraction of the cost.
- Optical-based navigation systems (such as SIRIO, MASMEC S.p.A., Modugno, BA, Italy) perform Lung Thermal Ablation (LTA). Procedural planning, monitoring, and lesion targeting are generally performed with the help of CT. More recently, the implementation of C-arm cone-beam CT (CBCT) technology has introduced a new image guidance strategy. Navigation systems emerge as a valid tool to reduce procedural times and administration of radiation doses, allowing electromagnetic, optical, or hybrid tracking of the devices used during interventions and their real-time visualization in a model obtained from a previously acquired CT scan. In a recent study published in (1) optical-based navigation system, SIRIO was shown to be an efficient tool to perform CT-guided LTA, displaying a significant reduction ($p < 0.001$) in the number of required CT scans, procedure time, and patients' radiation exposure.
- A computer-aided diagnosis (CAD) system is a machine learning texture model for classifying lung cancer subtypes using preliminary bronchoscopic findings is a CAD system. This CAD system can distinguish cancer types to achieve an

objective diagnosis. A study (2) collected bronchoscopic images of 12 adenocarcinomas and ten squamous cell carcinoma patients. The images were transformed from a red-blue-green (RGB) to a hue-saturation-value (HSV) color space to obtain more meaningful color textures. A prediction model of malignant types was established by combining significant textural features ($P < 0.05$) in a machine learning classifier. The performance of the CAD system achieved an accuracy of 86% (19/22), sensitivity 90% (9/10), specificity 83% (10/12), positive predictive value 82% (9/11), and negative predictive value 91% (10/11) in distinguishing lung cancer types.

- Another CAD system of a pulmonary nodule on CT scans led to improved classification performance with nodule surface features. A fully automated system was designed to segment the nodule from its surrounding structured background in a local volume of interest (VOI) and extract image features for classification. A study (3) demonstrated that the CAD-based segmentation and feature extraction techniques are promising for classifying lung nodules on CT images.
- AI is showing rapid advantages and exciting achievements in diagnostic imaging and evaluation. Many novel deep neural network-based systems have demonstrated the potential for use in the proposed technique for helping radiologists improve nodule detection accuracy with efficiency and cost-effectiveness. In a study (4), 39,014 chest low dose CT screening (LDCT) cases were retrospectively collected. The diagnostic performance of the deep learning (DL) algorithm was evaluated in the multi-center validation set and the external test set (LUNA). In total, 11,840,536 and 134,985 LDCT images obtained from 39,014 imaging studies were assigned to the training set and validation set, respectively. The DL model showed a high degree of agreement with the reference standard.
- In a study (5) of Automatic Image Selection Model Based on Machine Learning for Endobronchial Ultrasound Strain Elastography Videos, the AI-based technology showed 78.02% to 83.52% accuracy in diagnosing malignant from benign mediastinal and hilar lymph nodes based on the relative stiffness of the tissue. This accuracy was much higher than the trainee group and equal to or better than the expert group.

In conclusion, AI has been advancing exponentially in every walk of life, from essential day-to-day functions of turning on a cell phone to flying fighter jets thousands of miles away without a pilot. From human surveillance, financial modeling, fake news, invasive social media, education to religious preaching. AI in medicine has enormous potential to diagnose, track, treat, and cure diseases. Like any other technology in the past, it depends on how we use it.

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Technology Corner

Augmented Imaging for Peripheral Bronchoscopy

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Introduction:

Traditional guided bronchoscopy modalities include standard fluoroscopy, radial ultrasound, and electromagnetic guidance. Despite evolving technology and tools, biopsy yields have remained around 70% in most studies. Robotic bronchoscopy platforms have emerged as options for peripheral bronchoscopy with the promise of better yields due to their ability to better reach peripheral regions of the lung, along with the ability to maintain vision during sampling, all while having better tip stability especially in the case of eccentric lesions sampling. Despite this promise, the first published studies showed only modest improvement in yield (1,2). There are multiple reasons cited for suboptimal yield; these include poor performance of biopsy tools, local atelectasis that develops during the procedure, and CT-body divergence. Using cone beam CT (CBCT), investigators found that there can be significant divergence in nodule location between the pre-procedure CT imaging and lung during procedure (3). This divergence is largest in the lower lobes, and can be greater than 15mm in distance, easily enough to rend a biopsy attempt spuriously away from the intended target, potentially resulting in a falsely negative result. Accepting tool performance as a constant, it appears that accurate targeting of the nodule is therefore a major determinant of yield. Up until recently, the only surrogates of accurate targeting were fluoroscopy and radial ultrasound (rEBUS). Standard fluoroscopy can only be employed when the nodule is visible, and rEBUS is mainly helpful when the lesion is concentrically positioned around the airway. Further, neither rEBUS or fluoroscopy can provide accurate assessments of distance and angular relationships of the tool with the lesion. The emergence of CBCT has overcome these impediments with detailed imaging and 3D reconstruction, offering real insight into tool-nodule relationship. Unfortunately, CBCT is not readily available at all institutions and is expensive. As a result, other imaging modalities have been developed to achieve the same goals. These modalities use enhanced fluoroscopy images, and thus are less costly and use a much smaller space footprint within the bronchoscopy suite, and therefore allow for broader adaptation by proceduralists.

Background:

Augmented imaging refers to any real time imaging (ie fluoroscopy) being augmented by other imaging sources (ie CT, ultrasound, etc). Multiple imaging modalities can then be fused ("image fusion") simultaneously. Though imaging sources can be real-time or historic, the augmentation is real time. Currently there are several technologies on the market that achieve augmented imaging, however only one, LungVision™ (Body Vision Medical INC, NY) uses intraoperative tomography to augment real-time fluoroscopy. The resultant augmented fluoroscopic imaging contains an overlay of both the airway pathway

to the lesion, and the lesion itself (see Fig 1).

Clinical Application:

How we do it

After the patient is anesthetized, a series of fluoroscopy images are performed to achieve CT-body registration. Then, a fluoroscopy spin (typically -50° to +50°) is performed with the nodule at isocenter. After images are reconstructed tomographically, nodule location is updated and the overlay appears for navigation to begin. Once navigation to the nodule is completed, another fluoroscopy spin is performed which gives 3D representation of the nodule with the catheter and/or biopsy tool, and nodule location corrections are performed if needed (see figs 2,3). Catheter and/or biopsy tool location corrections can be made at this time, if necessary, and another spin can be performed to re-image tool-nodule articulation. Once the tool location and projected trajectory is deemed to be adequate, biopsies are done, again using augmented imaging. Though fluoroscopy use is increased during these procedures, cases have shown average doses around 250 mGy, about one tenth that of a cardiac catheterization.

Accuracy

The application of real-time imaging and localization during navigational bronchoscopy has promise, and has been suggested by results from multiple studies. For example, studies that have used advanced navigational technologies in conjunction with real-time CBCT imaging have suggested the additive nature of these technologies compared to their respective individual yields (4). Indeed, published studies using LungVision have shown high localization rates (90-95% using rEBUS and CBCT), albeit with earlier versions of the technology, with yield ranging between 77 and 84% (5,6). This compares well to published rates of robotic bronchoscopy localization (85-90% range) and yield (1,2). It will be interesting to see if merging of augmenting imaging (either CBCT or LungVision) with robotic bronchoscopy will result in higher yield procedures; studies are commencing to evaluate this further.

Conclusion

It is apparent that augmented imaging can play an important role in peripheral bronchoscopy. Though this can be achieved with CBCT, these systems are expensive, have large space footprints, and may be difficult to have access to. Using alternative technologies, such as LungVision, can provide similar imaging with standard fluoroscopy equipment, and can be easily incorporated into the bronchoscopy suite. Further research into the platform itself, as well as combining this platform with robotic technologies is underway.

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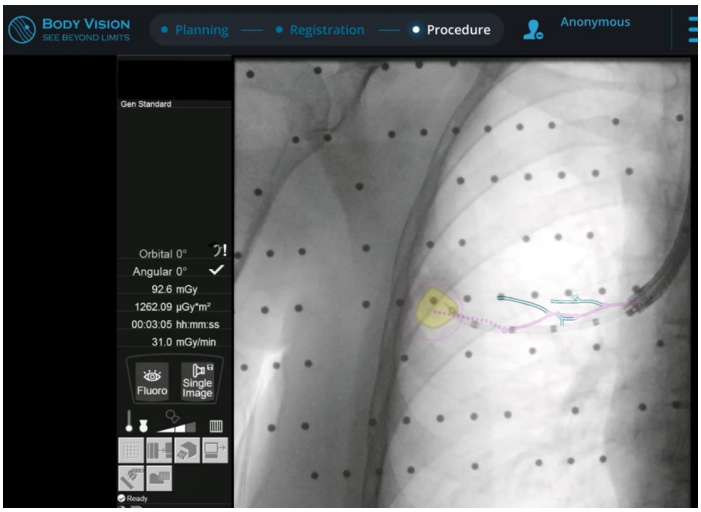


Figure 1: Augmented imaging overlay with pathway and nodule.

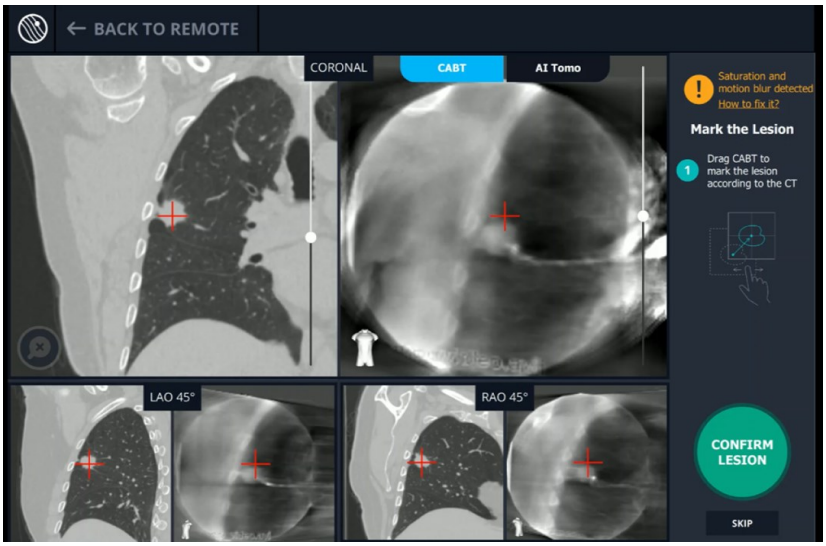


Figure 2: Tomographic reconstruction of nodule with catheter leading into it.

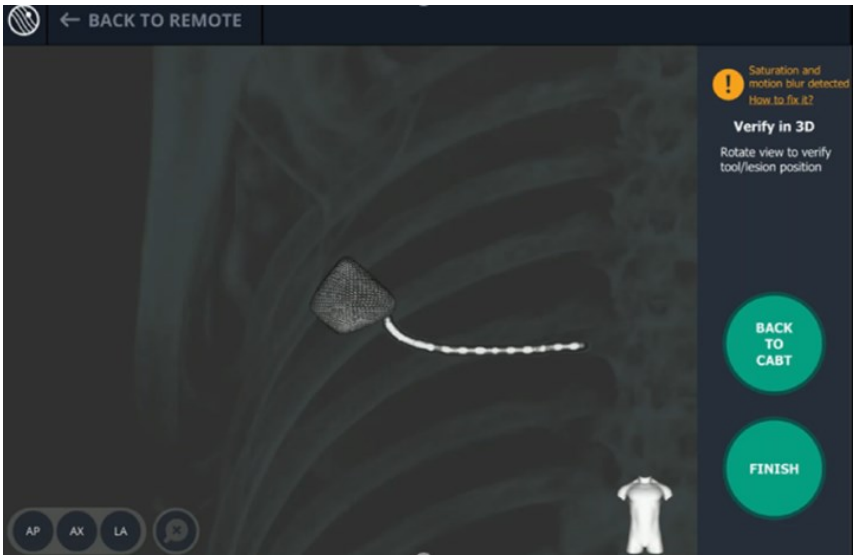
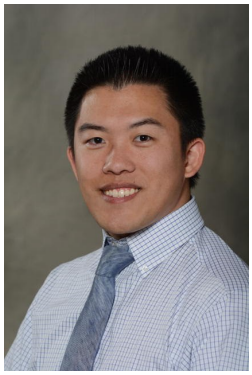


Figure 3: 3D reconstruction of the nodule-catheter relationship.

Using the "Vessel Sign" for Pre-procedural Planning in Navigational and Robotic Bronchoscopy



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Introduction

Diagnostic procedures for sampling peripheral pulmonary lesions (PPL) have developed remarkably over the last two decades as more lung nodules are being identified due to liberalized lung cancer screening guidelines, increasing prevalence of chronic lung disease, and improvements in advanced chest imaging. Two such platforms include electromagnetic navigation bronchoscopy (ENB) and robotic assisted bronchoscopy (RAB), which overall have improved diagnostic yield for PPL sampling [1-6].

Indications

When using ENB or RAB, proprietary planning software uses computed tomography (CT) of the chest with thin-slice protocol (1 mm cuts) obtained during full inspiration to build a virtual bronchoscopic image of the tracheobronchial tree. A computer-generated pathway from the target lesion to a more centrally located airway is constructed, and the bronchoscopist can manually adjust and extend the mapped pathway as needed. This pathway serves as a guide to the target lesion during bronchoscopy. During the procedure, the main platform generates an electromagnetic field around the patient's chest. This enables synchronization of a probe or sensor with the CT scan, and the bronchoscopist can track the synchronized probe or sensor while navigating through the airways.

During the pre-procedural planning phase, the bronchoscopist may adjust or extend the computer-generated pathway by selecting and adding points along visible airways on the CT chest from the target lesion to the central airway. This is often known as the "bronchus sign", which is defined as the presence of an airway leading directly to a pulmonary lesion. The presence of a "bronchus sign" has been associated with an improvement in diagnostic yield. In a meta-analysis of 2,199 lesions, the diagnostic yield was reported as 74.1% when a "bronchus sign" was present vs 49.6% in its absence [7]. Seijo and colleagues also reported an increased diagnostic yield of PPL sampling with ENB with the presence of a "bronchus sign" (79% vs 31%) [8]. Likewise, the diagnostic yield of PPL sampling by RAB was reportedly increased with the presence of a "bronchus sign" in a multi-center study by Chaddha and colleagues (78.3% vs 54.1%) and in the BENEFIT trial (75.0% vs 72.7%) [2,4]. The large multi-center NAVIGATE trial evaluating the ENB system by Medtronic also demonstrated that the presence of a "bronchus sign" was associated with higher diagnostic yield (78.3% vs 67.1%) [9].

However, prior studies have reported that up to 40% of patients lack a "bronchus sign" when undergoing navigational bronchoscopy especially in patients with emphysema, in which the resolution of the CT chest is suboptimal for identifying peripheral airway walls [8,10-12]. Therefore, alternative strategies in these sub-group of patients are necessary to provide navigation precision. Recognizing that vessels, lymphatics and airways are often adjacent in the bronchovascular bundle, in patients where a vessel is seen leading to the target nodule there should also be a contiguous airway which may not be seen on the CT due to the lack of contrast between the peripheral bronchi and surrounding lung parenchyma (Figure 1). The evidence supporting vessels as a surrogate for a "bronchus sign" on CT is well corroborated by developmental biology as blood vessels develop at the same time as airways; and specifically, the pulmonary arteries run alongside the airways and the pulmonary veins show a similar branching pattern to the arteries [13,14]. Therefore, a "vessel sign", defined as a vessel leading directly to a target lesion, can be used as a surrogate for mapping during pre-procedural planning when a "bronchus sign" is absent (Figure 1).

Planning

During the pre-procedural planning phase, the CT chest is first imported into the planning platform. Once segmentation is complete, the bronchoscopist identifies and marks the target lesion. The proprietary software then constructs a computer-generated pathway towards the target lesion, which may be incomplete and require manual adjustment. By appreciating the airways and vessels leading to the target lesion on pre-procedural CT, the bronchoscopist can manually adjust and extend the computer-generated pathway by tracing over and adding points along such airways and vessels from the target lesion towards the central airway. In our experience with ENB and RAB, we have had success using the "vessel sign" as a backup pathway when the registration CT scan lacked a clear "bronchus sign" (Figure 2).

It should be noted, however, that the advancement of navigational technology for PPL sampling is not a replacement for experience and thoughtful review of imaging and airway anatomy. Successful planning of a pathway for PPL sampling using navigation platforms requires appropriate understanding of the tracheobronchial anatomy.

Sampling

Airway inspection using a conventional white light bronchoscope is typically performed prior to conventional ENB and RAB to rule out central endobronchial lesions and aspirate secretions if present. Navigating to the target lesion via guided bronchoscopy using the virtual pathway created on the pre-procedural planning software is then used (Figure 2). Before sampling the target lesion, successful localization to the target lesion is demonstrated based on feedback from the navigation system and typically confirmed with a second method of visualization (e.g. r-EBUS, fluoroscopy, cone beam CT, augmented fluoroscopy) (Figure 2). Once localization is confirmed, endoscopic tools are passed via the working channel of the bronchoscope to sample the target lesion. The presence of rapid onsite cytology evaluation (ROSE) allows for real-time confirmation of whether lesion material is obtained. While ROSE provides value regarding tissue adequacy for molecular profiling, it is unclear whether the use of ROSE affects the diagnostic accuracy for sampling parenchymal lesions [9].

Quality Control

Any software that uses a CT performed at total lung capacity will lead to CT-body divergence, in which the true location of a PPL is not always consistent with the navigated virtual target, under the conditions of general anesthesia. This is due to the differences in lung volume at the time of the planning CT scan and when the actual procedure is performed. This is especially true when the target lesion is in the lower lobes, in which atelectasis is more prevalent during general anesthesia and there is more diaphragmatic excursion. Real-time imaging has been the emphasis of more recent technology to improve PPL localization.

Radial EBUS has been shown to confirm proper placement of the sampling tools and verify its proximity to the target lesion, increasing diagnostic yield [1,10,15]. Prior to the introduction of RAB, the pattern of r-EBUS image usually affected diagnostic yield, in which a higher yield was noted when concentric r-EBUS views are obtained (84%) as compared with eccentric r-EBUS views (48%) [16]. The alignment of the bronchoscope working channel in relation to the target lesion can be adjusted based on the radial EBUS view. Eberhardt and colleagues reported that the combined use of r-EBUS along with ENB improved diagnostic yield of up to 88% as compared with either technology alone [17]. With RAB, some studies show that the yield is not affected by the r-EBUS pattern [2,4].

Digital tomosynthesis via augmented fluoroscopy (AF) with conventional C-arm and cone-beam computed tomography (CBCT) attempt to correct for CT-body divergence and provide real time feedback of the bronchoscope or tool location. This is in effort to allow for fine adjustments of ENB or RAB to better align the working channel with the target lesion and assist with redirecting sampling tools as needed, increasing localization success and potentially diagnostic yield [3,18-20]. To date, there is no evidence, however, that these technologies significantly improve diagnostic yield when compared with RAB technology alone.

Conclusion

Advancements in navigational bronchoscopy and advanced imaging techniques have empowered bronchoscopists to access the periphery of the lung with more confidence and increasing accuracy. As newer advancements in navigational bronchoscopy and software continues to develop, the ability of the bronchoscopist to recognize and plan pathways to the target lesions is even more important.

The "vessel sign" can be used as a potential surrogate for the "bronchus sign" when mapping a pathway for navigational bronchoscopy and an airway leading to the lesion cannot be visualized. Potentially, the use of the "vessel sign" during pre-procedural planning may be able to improve the rate of navigation success for ENB and RAB procedures that lack a "bronchus sign". Studies are needed to confirm the validity of using the "vessel sign" for pre-procedural planning during navigational bronchoscopy and clarify its effect on outcomes including rate of localization success, diagnostic yield, and complication rates.

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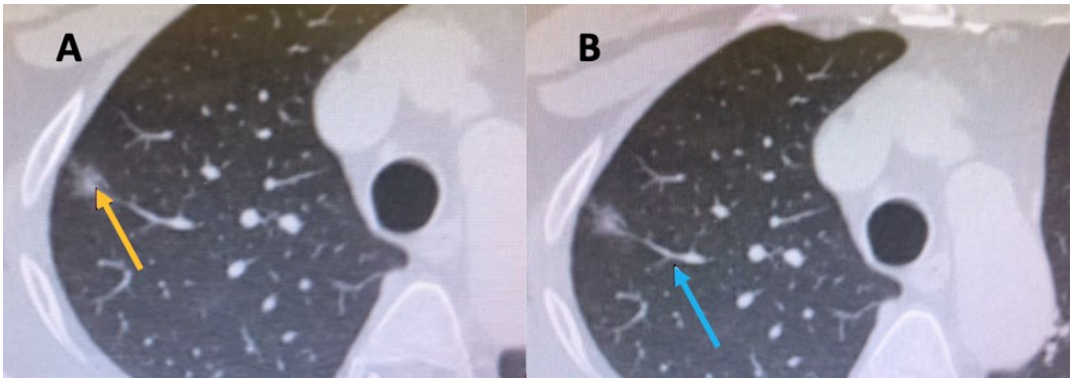


Figure 1. The "Vessel Sign". CT image in the axial plane showing a subsolid peripheral nodule (yellow arrow) without a bronchus sign (A). However, a pulmonary artery branch was identified (blue arrow) leading to the nodule (B).

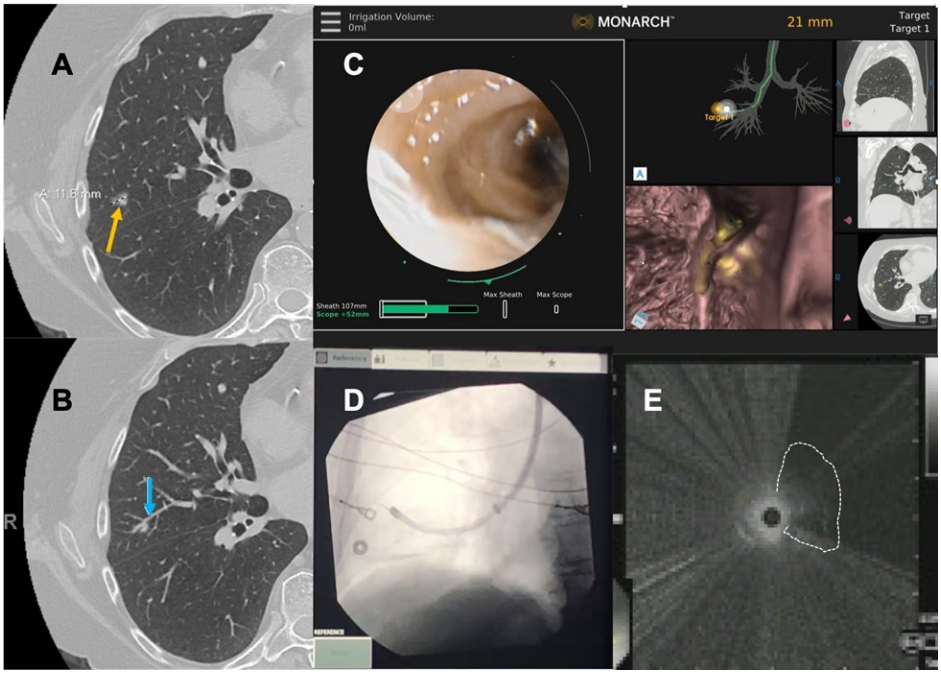


Figure 2. Using the "Vessel Sign" for Lung Nodule Sampling with Robotic Bronchoscopy. The nodule (yellow arrow) is seen in the lateral segment of the right middle lobe (A). A vessel (blue arrow) is seen leading to the nodule and was used for manual planning (B). The robotic bronchoscope is advanced to the target lesion and parked proximal to the lesion while vision is still maintained by air insufflation (C). Fluoroscopy shows the sheath, scope and radial EBUS probe (D). Radial EBUS image shows a small eccentric nodule (highlighted by the dotted line) confirming successful navigation (E).

Ethical Issues about Waiving Intellectual Property Protections for COVID-19 Vaccines

In 1796 Edward Jenner developed the first vaccine by taking material from cowpox lesions on a cow maid and injecting it into an eight-year-old boy. Several weeks later, he injected the boy with live smallpox, with no ensuing infection. The World Health Organisation (WHO) has only ever declared two diseases extinct: the cattle disease rinderpest, and one human disease, smallpox. Both were the result of massive vaccination drives and global campaigning.

However, the road to eradication was not an easy one. The technical and sanitary challenges (particularly in tropical countries) seemed impossible to be overcome. In the 1950s, Leslie Collier developed a freeze-dried vaccine. In the following decade, Benjamin Rubin of Wyeth Laboratories designed the bifurcated needle, which made easier a reliable vaccination. These technical developments but mainly the decision to waive patents and royalties on the needle and vaccine, enabled the WHO to launch its 1966-1977 campaign to eradicate smallpox globally and after 14 years of careful searching and contact tracing and millions of vaccines one of the biggest killers in history was eradicated.

In the last century, few diseases have reached a global devastating effect on mortality in the form of outbreaks of major epidemics. Probably because of that, even when vaccination (together with hygiene and sanitation measures) have dramatically improved life expectancy, the concept of vaccines as a public good was slowly fading.

But now that vaccine inequity leaves lower income countries – many of them in Africa – at the mercy of COVID-19, the ethical discussion about the moral duty of developed nations for waiving patents to vaccinate more quickly the global south has become not only necessary but also urgent.

WHO has set a global target of 70 per cent of the population of all countries to be vaccinated by mid-2022, but to reach this goal a more equitable access to vaccines will be needed. And this is not a necessity only for the underserved communities with insufficient access to vaccination, this is an urgent need for the whole world. As Dr Tedros Adhanom Ghebreyesus, the Director-General of the World Health Organization (WHO) said vaccine equity was “not rocket science, nor charity. It is smart public health and in everyone’s best interest.”

The ethical principles guiding the distribution of vaccines should be considered, especially for those at high risk. It is well known that from late December, 2020, countries started vaccinating their populations, however, those millions of available doses were concentrated in high-income countries, which have purchased 54% of secured doses but which account for only 19% of the global population.

The right balance between private profits and public health is not a new issue but a long-running debate. Many experts and humanitarian NGOs contend that World Trade Organization (WTO) rules on intellectual property (IP) limit poor countries’ access to critical medicines. On the other hand, defenders of conceiving essential medicines as any other commodities, point that the IP rules are needed to incentivize drug makers.

Unfortunately, ethical principles in health policy have often been neglected when they have concerned vulnerable groups, with the distribution of life-saving drugs judged too expensive and unsustainable and the recipients considered unworthy. Lack of foresight, incentives, and political will has caused a serious violation of the principle of justice and the consideration of access to health care as a universal human right.

But beyond the general principle that ethical allocation of every kind of health care resources is crucial for the principle of

justice, the massive and rapid spread of COVID-19 epidemic and the associated high rates of mortality have turned necessary an urgent debate about an essential moral question: is it ethically acceptable to uphold vaccine patents during a global shortage?

The naturalization that low-income countries should and can spend substantially less on saving the lives of their vulnerable groups, sadly indicates that the value of one's life is linked to their country's income. And during a dramatic emergency as a lethal but potentially preventable disease, it has shone a harsh spotlight on the fact that the global community accepts that the lives of those in low-income countries are worth less than the lives of those in high-income countries. The valuation of life solely based on where an individual lives generates unethical guidelines about health policies that negate an individual's human right to health.

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) commits members to guaranteeing twenty-year patents and safeguards for copyrights, trade secrets, and industrial designs, preventing companies other than the inventors from manufacturing those medical products. Based on warranting the access to critical medicines globally, in late 2020, a group of low-income countries led by India and South Africa proposed that the WTO temporarily waive IP protections for vaccines until most of the world's population gets immunization. This would allow other companies, including those in developing countries, to make generic brands of existing vaccines. The U.S. and E.U., as well as countries including the UK, Japan, and Australia among others, opposed the proposal while over 100 other countries have supported the waiver. In May 2021, the Joe Biden administration reversed course and announced its support for a vaccine IP waiver. Not much later, a coalition of developing countries pressing for the waiver, submitted a new proposal quite similar to the first that specified that the waiver would apply to pandemic-related "health products and technologies," and advising the waiver should last for at least three years.

As a result of those events, a heated debate has been settled worldwide. But two different aspects need to be differentiated about this issue. On the one hand, controversy may exist about the efficacy of the waiver in its goal of raising access to Covid -19 vaccines in poor countries, based on the difficulties of companies in developing countries to learn from the original producers how to produce effectively in the short run and the lack of vaccine production facilities and technology. It is argued that the absence of patents will do little to remedy the structural deficiencies that impede a quickly expanding production capacity in developing countries on the scale and speed needed to a large scale production that solve the access problem.

But, although the argument that the patent waiver will, by itself, do little to address the short-run access problems is probably right, a very different issue is the ethical legitimacy of upholding the patents and deliberately denying access to some populations in the pursuit of profits or in order to give priority to certain groups.

Analyzing the subject strictly from a moral point of view one could apply the argument that vaccine patent waivers could allow other countries to produce generic copies and increase the global supply of vaccines and that the increase of vaccines availability could save lives and decrease the prevalence of future COVID variants, which is threatening to prolong the pandemic.

From a Kantian perspective, the answer seems crystal clear. Maintaining patents violates the principle of beneficence, doing good for others, by deliberately refusing to help countries in dire need. It also violates the principle of non-maleficence, avoiding harm to others, as patents can discourage innovators from other countries from developing a novel vaccine for fear of copyright suits.

All the social actors are also moral agents including policy makers, CEOs of multinational companies and scholars or inventors. Being as they are human beings, they must face every day the same question we all human face: is my behavior morally correct, am I honouring my own humanity? We know that all persons, regardless of rank or social class, have an equal intrin-

sic worth or dignity. Human dignity is an innate worth or status that we did not earn and cannot forfeit. Rather, we must strive to make our individual choices worthy of this moral standing, which elevates us above animals and mere things. Kant expresses the principle of humanity (PH) as follows: *"Act in such a way that you treat humanity, whether in your own person or in the person of any other, never merely as a means, but always at the same time as an end"*. It is a principle, Kant holds, that would describe the conduct of fully rational beings toward themselves and each other, so it is a principle that should describe the conduct of human beings toward themselves and each other.

That respect for human dignity requires that everyone fulfils his or her duty. In *The teleological argument*, Kant distinguishes among: a) the case in which a person clearly acts contrary to duty; b) the case in which a person's actions coincide with duty, but are not motivated by duty; and c) the case in which a person's actions coincide with duty because he or she is motivated by duty. And Kant (and much of the post-Kantian philosophy) explicitly expresses that our actions only have moral worth and deserve esteem when they are motivated by duty. Those considerations led to the construction of the Categorical Imperative. Kant characterized the CI as an objective, rationally necessary and unconditional principle that we must always follow despite any natural desires or inclinations we may have to the contrary. Thus, the supreme formal principle of Kant's ethics is: "*Act only on that maxim through which you can at the same time will that it should become a universal law*."

And so the question is: can any human being wish that the rule that financial profit must be always preserved (even at the cost of hundreds of thousands of preventable deaths) become a universal law? And if not: is any reward treasured enough to choose actions against our rational duty and consequently with no moral worth and that does not deserve any esteem and deny our own humanity?

Critics of the proposal argue that a waiver would discourage future innovation. The technology utilized by the Pfizer-BioNTech and Moderna vaccines were only possible through years of research and development from the public and private sector. If companies have no profit incentive to create these new health care products, investments in the industry drop and this could lead to a decline in new technologies. It has also been mentioned that it would create a potential disadvantage for US companies if allowing China and other rival countries to obtain essential IP. The primary basis for this arguments is that the profits IP generates are essential to spur innovation and discovery which in turn, advance society's interests. The question is, even if it were true: how much financial incentives are needed, how much money does it take? In 2021, Pfizer/BioNTech will make 15–30 billion US dollars from COVID-19 vaccine sales, Moderna 18–20 billion US dollars, and Johnson & Johnson 10 billion US dollars. Could these companies earn less and the incentive to innovate remain intact?

Helping others may always have a cost. Even Kant mentions that helping others is "an imperfect duty", and in his conception, an imperfect duty allows flexibility—beneficence is an imperfect duty because we are not obliged to be completely beneficent at all times, but may choose the times and places in which we are. Big companies may argue (and do argue) that they are not charitable organizations, that looking for the highest possible profits is a legitimate aim and that they can choose how and when help others. However, as the notorious contemporaneous philosopher Peter Singer has shown in his famous book "*The life you can save*", that "flexibility" is far from being unlimited.

Singer exemplifies that situation in the simple but categorical philosophical experiment of the drowning child. On your way to work, you pass a small pond. You see a child splashing about in the pond and by getting closer, you see that he is flailing about, unable to stay upright or walk out of the pond. There is no one else around. If you don't wade in and pull him out, he seems likely to drown. Wading in is easy and safe, but you will ruin the new shoes you bought only a few days ago, get your suit wet and muddy and you will be late for work. What should you do? Predictably, most of people respond that you should save the child. The premise behind that well known story is: if it is within our power to prevent something bad from happening, without thereby sacrificing anything of comparable moral importance, we ought, morally, to do it. In a similar way, we may ask ourselves (beyond the practicalities of the real impact of the waiver of patents) if thousands and thousands of

deaths and the consequences of collapsed economies are not worthy of sacrificing some minor financial profits.

The essential feature of capitalism is the motive to make a profit and one of its founding pillars is self-interest, through which people act in pursuit of their own good, without regard for sociopolitical pressure. Nobody expects that neither entrepreneurial businesses nor big firms resign their purpose of making profit or work for losing money. But the question is: are the big pharma companies that develop and manufacture vaccines at the risk of losing money?

Between 2000 and 2018, 35 big drug companies received a combined revenue of $11.5 trillion, with a gross profit of $8.6 trillion. The median net income margin reported by 35 pharma companies between 2000 and 2018 was almost twice as high as it was for the 357 non-pharma companies included in the comparison. Funding for pharmaceutical research and development (R&D) is the result of a complex mix of private and public sources. Governments mainly support basic and early-stage research. Such funding is made through direct budget allocations, research grants, publicly-owned research institutions and funding of higher education institutions. The pharmaceutical industry translates and applies knowledge generated by basic research to develop products, and invests in large clinical trials required to gain market approval. The industry also receives direct R&D subsidies or tax credits in many countries. But despite the pharmaceutical firms are substantially supported by government subsidies, yet the price for most medical products is multiple times the production cost. In products whose availability put lives of people at stake, “the invisible hand” of the market if far from being balanced, as the access to drugs and medical technologies is not a matter of choice but of essential need. Additionally, the huge effort made by the researchers is not a solitary endeavor. The thousands of volunteers that made the testing needed for the approval of the new vaccines possible, the previous basic research on what the new developments are based, the pilots of planes and drivers of trucks who transported the vaccines, the thousands of health care workers involved in the organization and implementation of the vaccination campaigns that did not take any additional profit, all of them were indispensable components of the network required for the vaccines reach every single target subject.

The margins of profits of the big pharma companies has become a heated debate in many countries in the last years. Many have questioned that subsidies given by the governments come from the taxes paid by citizens including vulnerable groups, and the deliberate decision to sell drugs at extremely high prices let those same vulnerable groups that support them by taxes deprived of their right to health because they cannot afford them. In fact, although this year the rapid and effective development of COVID-19 vaccines improved substantially their popularity, for decades, few industries in the US have been as unpopular as Big Pharma.

Many scholars and social and political activists trusted that new winds were arriving in the world economy as a reaction to the many failures that a previously successful system as the capitalism is showing currently all over the world. Many of the world’s eco-systems are on the edge of collapse, inequality increases persistently, and systemic racial and ethnic exclusion disgrace every society on the planet. Even business leaders are voicing these opinions with critics to conventional capitalism and accepting that it is in urgent need of redemption. Ajit Ranade, president of Aditya Birla Group even said capitalism is losing support because of its failure to address widening inequalities. In that sense, one of the challenges seemed to be a renewal of the purpose of the firms—away from only maximizing shareholder value towards including ‘solving public problems profitably and avoiding creating new problems’. It would allow the private sector to become an active partner in creating a just and sustainable society. Many enthusiastic analysts saw an example of that in the initial commitment of Pfizer to provide tiered pricing for middle-income countries while providing the vaccine for free in Africa. However, many of Pfizer's contracts requesting guaranteeing the company indemnity and forcing the governments to compensate for any adverse effects of the vaccine, faded any hope to ensure ethical costing.

Many conservative economists all over the world still support the Milton Friedman’s theory that the social responsibility of business is to increase its profits and that a corporation is a morally neutral legal construct with maximising returns for

shareholders as its single purpose. But even with that self-centered understanding of business, nobody should deny the unmatched value of a human life. The pandemic has transformed the discussions about the impact of inequalities, unfairness and unethicalness from abstract speculations to concrete daily pictures of human deaths. Figures, pictures and personal histories hit us right in the face every day from the news and the social media. Additionally, the political manipulation of the pandemic has created many obstacles for a rational management of the epidemic. The vaccine development process has been linked to election cycles in many countries, with political leaders making not always accurate promises about the vaccine which reduced the trust that individuals have in the results of what appear to be rushed clinical trials. Anti-vaccine groups have gained popularity increasing enormously their followership base since 2019. An irresponsible behavior of many news media and the undeniable history of unethical exploitation of vulnerable groups caused vaccine hesitancy in many populations in different countries, increasing the risk of death and suffering from the disease.

The principle behind the campaign to temporarily waive IP protection for COVID vaccines is that every country should have the right to make its own vaccines during a pandemic. Waiver is surely not the only or even the best solution to increase access and the implementation of the waiver engenders several intrinsic challenges. The tools and technologies required for this purpose are currently owned by only a few pharmaceutical companies and probably not all countries would have on-site pharmaceutical industries that can guarantee adequate protective measures both for the technicians in the laboratories or for the surrounding populations. High safety levels for the associated biological risk are required and difficult to achieve. National health surveillance procedures may not be as strict as desirable to monitor potential risks and side effects. Production in conditions of imperfect biological quality control could result in more adverse reactions. Obviously, loosening the grip of IP protections is not a miracle fix, and there are many other barriers to a safer world. All of these are important arguments, and need to be addressed. But they are not, in themselves, reasons for denying IP relief.

A study by the WHO Regional Office for Europe and the European Centre for Disease Prevention and Control (ECDC) estimates that 470 000 lives have been saved among those aged 60 years and over since the start of COVID-19 vaccination rollout in 33 countries across the WHO European Region, not including lives saved by vaccinating people under 60 nor those saved from the indirect effect of vaccination because of a reduction in transmission. Denying or delaying access to vaccination costs lives, concrete singular lives with names and beloved ones. And no one more death is morally affordable having the resources to prevent it.

Countries backing the IP waiver are not asking for charity, but for the right to develop and make their own vaccines, free from the worry that they will be sued by patent holders.

The rapid development of several vaccines against COVID-19 is an unequalled scientific accomplishment, but the absence of a system that secures equitable access to vaccines has uncovered deep inadequacies in the global governance systems for health. We must critically examine our moral principles when it comes to vulnerable groups, pressing pharmaceutical companies, normative agencies, and political leaders to commit to an ethical behavior and pushing for initiatives that first and foremost promote ethical and equitable solutions.

Affording priority on the basis of economic or political power is a clear deviation from the public-health principles of maximizing lives or life-years saved, and the commitment of assuring that lifesaving resources should not depend on nationality. The United Nations (UN) Sustainable Development Goals (SDGs) instruct that universal preparedness for health requires a radical systems approach: health must be seen in the broadest of contexts, with due attention to social structures and infrastructure, working and living conditions and with strategies to counteract climate change, loss of biodiversity and human destruction of wild habitat.

A pandemic teaches that no one should be left behind and that no one is safe until everyone is safe, and COVID-19 made evident the consequences of not having health insurance or access to healthcare, not having water or a food supply during

lockdown situations, or not having civil rights. However, the COVID-19 pandemic has shown the weak adherence of wealthy nations to the commitments of that UN Agenda 2030, mainly the 'leaving no one behind'. It has revealed democratic deficits, institutional rigidity, weak accountability systems, and inadequate policy space that protects health-governance systems from economic goals. We have seen how deficient global accountability mechanisms are, and the consequences of leaving health care at the mercy of its commercial determinants were clearly exhibited. The absence of legally binding mechanisms that hold market actors accountable for failing to act for the public good and the consequences of this lack of proper regulations were crudely exposed.

COVID epidemics has also shown that an efficient and independent supranational governance system is needed to take the role of an effective global coordination for medicines and vaccines be rapidly ready to be equitably delivered when an epidemic erupts.

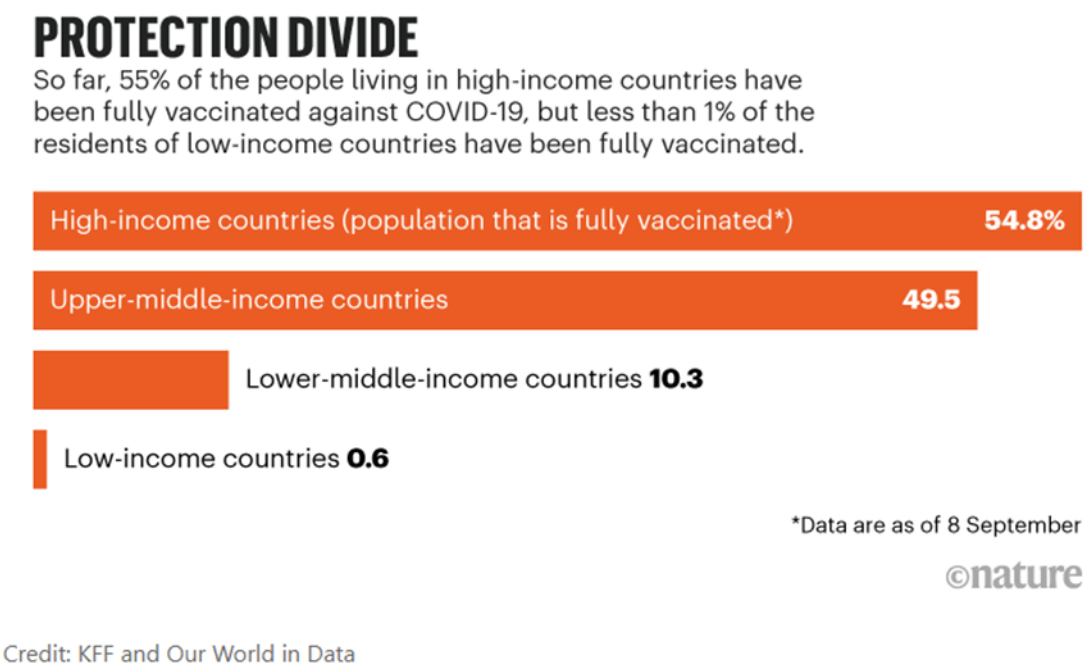
The WHO is facing a crisis which is increasingly challenging the authority and prestige of the United Nations' specialized agencies in general and WHO in particular. "Global health," should really imply the consideration of the health needs of the people of the whole planet above the concerns of particular nations. There are many concerns that the agency's legitimacy and authority in global health matters have been undermined, showing that WHO priorities are disproportionately influenced by a few powerful donors. But the present times require that supranational organizations must be strengthened, not undermined. A not minor issue is that realigning WHO's financial structure would likely safeguard both the agency's autonomy and member states' trust, while alleviating concerns about undue influence from powerful donors.

This crisis has taught that updated global governance mechanisms are needed that better reflect the contemporary geopolitical order and truly encourage international collaboration across sectors, through political and legal solutions rooted in commitments to justice and shared global responsibility. The debate about the waiver of patents has brought wider debates about pharmaceutical company power, predominance of geopolitical strategy and lack of commitment to decrease the impact of health inequalities. It is not simply the matter to become lost in the lights and shadows of a patent waiver. What must remain clear is that the issues of justice (equitable distribution), beneficence (helping other countries), and non-maleficence (avoiding harm to other countries) must be the priority of individuals and political leaders.

This pandemic has been and it is still being a dramatic experience for any human being wherever and however they live. But we cannot be fooled about it: we are not all in it together. COVID-19 is experienced unequally, with much more tragic consequences for the most disadvantaged communities: it is not a socially neutral disease. We have seen as never before how the impact of a disease is magnified by the pre-existing social determinants of health, such as housing and work conditions and access to quality healthcare. We cannot afford adding to those long-term conditions the deliberate restrictions of the access to the only current resource to decrease the disaster of COVID-19: the vaccination.

We are only risking our new shoes; we have only one morally acceptable choice: we must rescue the drowning child if we want to rescue our own human dignity.

**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.*



Credit: KFF and Our World in Data

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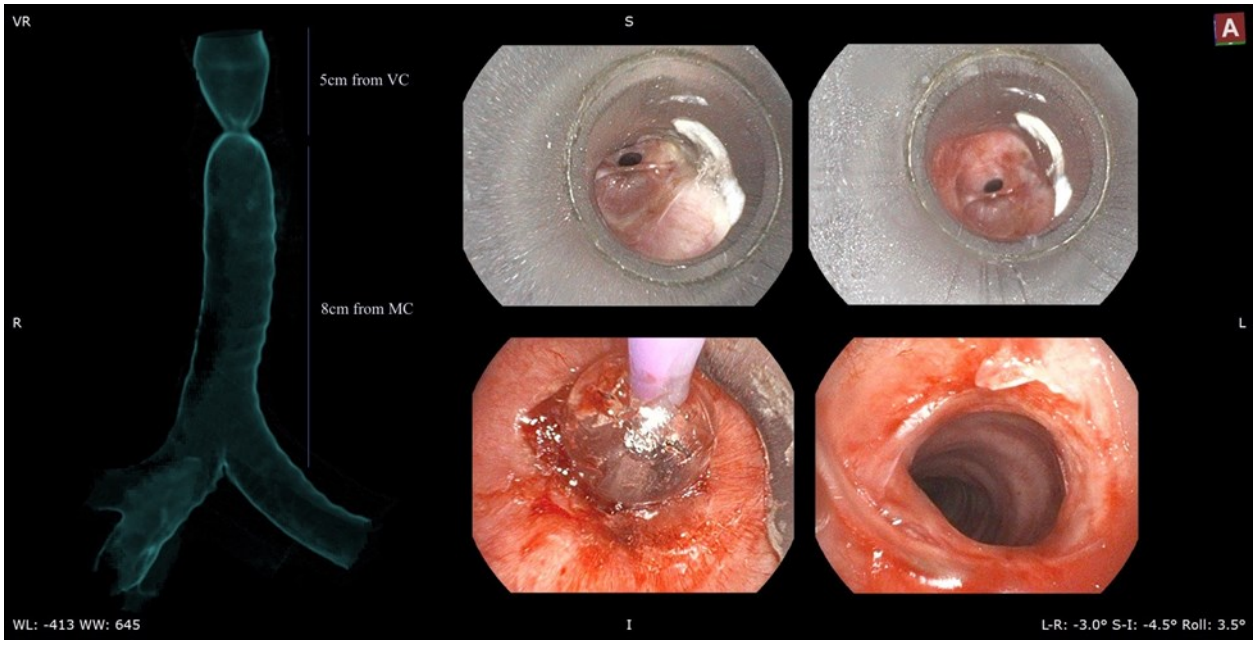
Best Image Contest

Best Image Contest 2022 (1 of 3)



Description:

60 years old gentleman presented with insidious onset of stridor and exertional dyspnea after endotracheal intubation for a Killip-4 anterior myocardial infarction a year ago. CT scan confirmed a tight stenosis at the subglottic region which was successfully treated with balloon dilatation and mitomycin C application via rigid bronchoscope. Patient subsequently underwent definitive surgical correction successfully.

Submitters:

Dr. Kho Sze Shyang & Dr. Jamalul Azizi bin Abdul Rahaman

This image is the 1 of 3 selected among 100+ submissions to our Best Image Contest held in late 2021. 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

This meeting shall be held on Saturday, March 12, 2022, and the Regents who represent their member society will participate and vote on items mandated in our bylaws. The meeting is an integral part of completing our annual registration to retain our status as a non-profit organization in Tokyo Japan.

WCBIP 2022 Marseille France

Marseille 2022 World Congress is coming this October in hybrid format, and we could not be more excited to kick start our offerings to WABIP members. We invite you to start the submission process for:

- Abstracts (Deadline May 2, 2022) Guidelines & submission link at https://www.wcbip.org/abstracts
- Video Festival (Deadline July 1, 2022) Guidelines & submission form at https://www.wcbip.org/videofestival
- WABIP Awards (Deadline July 1, 2022) Guidelines & submission forms at https://www.wabip.com/awards

Registration for on-site and online participation will be open in February 2022.

Endoscopic Ultrasound Section – New members welcome

We are proud to announce that 190 members have joined this new WABIP section, and we are embarking on many related projects and activities. We can still accommodate a few new members, and we welcome you to apply for Endoscopic Ultrasound section membership via https://www.wabip.com/forms/committees

9th Asian Pacific Congress on Bronchology & Interventional Pulmonology

APCB ANNOUNCEMENT

APCB 2021

RESCHEDULED TO 7 – 9 APRIL 2023

The Organizing Committee has arrived at a difficult decision to reschedule the 9th APCB to 2023 due to the uncertainties with regards to COVID-19 in Malaysia.

The 9th APCB will now be held on **7 to 9 April 2023** as an in-person congress **in Kuala Lumpur, Malaysia**.

Please mark these new dates in your calendar. We apologize for any inconvenience caused and look forward to seeing you in Kuala Lumpur, Malaysia come April 2023.

Yours sincerely,
Jamalul Azizi Abdul Rahaman, MD
Congress President of 9th APCB

We would like to announce that the Asia-Pacific congress will now take place in April 2023, moved from original October 2021 date. Dr. Jamalul Azizi and his organizing committee will will ensure an exciting program with didactic lectures, case-based discussions, virtual hands-on workshops, and more. Stay tuned to all related updates at http://www.apcb2021.com

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Research

What Are the Necessary Technologies and Techniques for Transbronchial Ablation of Pulmonary Nodules?

Tsukasa Ishiwata, MD, PhD
University Health Network

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University Health Network

Alexander Gregor, MD
University Health Network

Ablation techniques, including radiofrequency ablation, microwave ablation (MWA), and cryoablation, are promising treatments for malignant pulmonary nodules. Compared to percutaneous approaches, transbronchial ablation therapy for pulmonary nodules has a more favourable safety profile by virtue of avoiding pleural puncture (1-3), although the cumulative clinical experience remains limited. Challenges with transbronchial approaches include increased difficulty accessing peripheral nodules and managing the ablation margin, whereby potential injury to the pleura and other major structures must be avoided.

A recent retrospective study from Chan and colleagues (4) is informative and thought-provoking on successful transbronchial treatment of pulmonary nodules. They summarized results from transbronchial MWA of 30 pulmonary nodules with electromagnetic navigation bronchoscopy (ENB) guidance in a single institution. Their procedure in a hybrid operating room included the following technologies: 1) cone-beam computed tomography (CBCT) at baseline, after positioning the catheter pre-MWA, and post-MWA, 2) ENB to navigate the MWA catheter to the target (± fluoroscopy), and 3) the Transbronchial Access Tool (TBAT) for accessing targets without a bronchus sign. Twenty-two nodules (73%) were in the peripheral-third lung field. Pneumothorax requiring chest tube insertion and hemoptysis occurred in 2 and 1 cases, respectively. Transbronchial MWA achieved local control over the follow-up period of median 12 months.

For pulmonary nodule ablation, precise tool placement is essential. 'Navigation' and 'confirmation' are separate components of precise placement. Commercially-available navigation modalities include virtual bronchoscopic navigation, ENB, and augmented fluoroscopy. They help guide insertion of the bronchoscope and tools into the appropriate bronchus faster. However, selecting the correct bronchus does not mean the tool tip is optimally positioned. This distinction is important when deriving guidance from preprocedural CT images, as CT-to-body divergence needs consideration (5). Ventilation and instrumentation can distort the regional parenchyma, resulting in a discrepancy between the expected target location (i.e., based on preprocedural CT) and the actual target location just prior to ablation. Consequently, the position of navigated

tools relative to the nodule must be confirmed by other modalities. Those often used clinically include radial probe endobronchial ultrasound (RP-EBUS) and CBCT.

In the context of ablation, CBCT has an advantage over RP-EBUS in that it can confirm catheter position relative to the target and to surrounding tissues, permitting more precise calculation of both the potential efficacy and safety of the ablation zone.

A major challenge with transbronchial ablation, regardless the navigation and confirmation technologies used, is that target access has conventionally depended on the presence of a feeding bronchus. Chan and colleagues overcame this issue by using TBAT. The TBAT (6), and other platforms like it (7), create alternative transbronchial routes to the target by tunnelling through the lung parenchyma from a preselected bronchial puncture point. These techniques will be vital for successful ablation of nodules without a bronchus sign, avoiding the need for excessively large ablation fields to fully encompass distant peribronchial targets.

To successfully and safely perform transbronchial ablation of pulmonary nodules, several advanced technologies and techniques are required. More studies are needed to confidently conclude on the performance and safety of transbronchial ablative therapies. Moreover, the learning curve and cost-effectiveness of combining such technologies have not been fully evaluated. Chan and colleagues have, however, established an important benchmark to guide future work.

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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

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