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Diagnostic Yield: Apples, Oranges, and Paradigm Incommensurability

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In the past two decades, unprecedented advances in technology have led to the commercialization of new bronchoscopy platforms which have been widely adopted as standard of care procedures by interventional pulmonologists around the globe. In the US and in Europe, these novel medical devices were cleared by regulatory stakeholders in the absence of comparative effectiveness studies, based on the assumption that similarities in form and function to already available devices obviated the need for such data. Thus, most studies published to date reporting on the diagnostic test performance of these novel devices have been single-arm observational studies using the surrogate endpoint of diagnostic yield (DY). (1)However, DY captures more than the technical ability of these devices to navigate to the targeted lesion, and is affected by many other relevant variables, which include targeted nodule characteristics, operator skills and cancer prevalence, among others. Perhaps more importantly, DY has been defined in many different ways in studies published to date which further complicate comparisons across single-arm studies.

Diagnostic yield (DY) is strictly defined as the likelihood that a biopsy will provide a histopathological diagnosis sufficient to guide management with confidence. Typically, this would include malignant diagnoses, usually, although not always, uncontroversial, and benign diagnoses deemed specific enough to convince the pathologist that the lesion in question was indeed adequately sampled. These would include granulomatous inflammation, robust neutrophilic infiltration, or hamartomas among others. Diagnostic yield is often confused with diagnostic accuracy, which represents the degree to which histopathological diagnosis reflects the ground truth.(2) Inflammation, while non-specific and thus excluded from the prior definition, could in fact represent lesional tissue, but often remain inconclusive at the time of diagnosis, leading to subsequent interventions. Thus, diagnostic accuracy requires sufficient clinical follow-up to adjudicate non-specific benign diagnoses. Studies on diagnostic test performance of bronchoscopy have often conflated these two notions and used them interchangeably, leading to incommensurable estimates of diagnostic test performance even when accounting for differences in patient population. We have been comparing apples to oranges.

The impact of these different definitions on DY was recently evaluated in a Monte-Carlo simulation by Vachani and colleagues. In “The Impact of Alternative Approaches to Diagnostic Yield Calculation in Studies of Bronchoscopy”, published in CHEST in 2022, a hypothetical cohort of 1000 patients undergoing diagnostic bronchoscopy was assessed using 3 commonly used but distinct methods for DY calculation: (1) a strict approach, which corresponds to actual DY as defined above, (2) an intermediate approach, in which non-specific benign diagnoses were considered diagnostic if clinical follow-up did not reveal malignancy, and (3) a liberal approach, according to which even non-diagnostic samples (such as normal lung or pleura) were considered diagnostic if follow-up did not reveal malignancy. Expectedly, estimates of “DY” varied considerably, ranging from 67% to 88%, a 21% absolute difference simply due to an arbitrarily chosen method of reporting the data.(3)

The implication of these observations is obvious: studies using different definitions of DY are difficult, if not impossible to compare. Definitions of DY should be explicitly and

transparently reported, with data available to allow reviewers and readers to re-calculate DY based on their preferred approach. While we do not recommend one method over another, we suggest that the liberal method be abandoned, as it is most likely to be influenced by cancer prevalence: for example, with a 10% cancer prevalence in the population studied, the estimate of DY will approach 90% even if most lesions are missed. Unfortunately, this method has been the traditional method used in the bronchoscopy literature until recently.(4) More fundamentally, even if the entire bronchoscopy community was to uniformly agree on a DY definition, variations in cancer prevalence, nodule characteristics, operator skillset and biopsy tools used would still affect estimates of DY independently of the actual technical ability of the bronchoscopy platform. Thus, DY should be regarded as a surrogate for diagnostic test performance, more accurate estimates of which may only emerge through the proper conduct of methodologically sound comparative studies, with randomized controlled trials standing firm as the pinnacle of comparative effectiveness research, uniquely able to account for both known, and unknown confounders.

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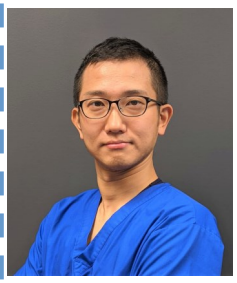
Technology Corner

Endobronchial Ultrasound-Guided Radiofrequency Ablation for Lung Cancer



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INTRODUCTION

Transbronchial ablation therapy has been evaluated to reduce the high rate of complications associated with percutaneous ablation for lung cancer.[1-5] Although there is limited clinical evidence for transbronchial ablation, preliminary data suggests it has a better safety profile than percutaneous ablation.[3,4] One major challenge with transbronchial ablation is the placement of the electrodes, particularly when there is no single bronchus leading to the tumor (negative bronchus sign).[6]

BACKGROUND

Olympus Corporation developed a needle-type (19 gauge) bipolar radiofrequency ablation (RFA) device that is compatible with current convex-probe EBUS bronchoscopes. The needle's distal portion serves as an electrode and is echogenic for easier ultrasound visibility. Once the needle is inside the targeted nodule, a second electrode is deployed from the tip. In animal models, we evaluated the safety of EBUS-guided RFA, as well as the correlation between energy delivery and ablation extent.[7] Room-temperature saline was continuously injected throughout the ablation at a predetermined rate via an integrated infusion channel to enhance electrical conductivity. Promising safety and efficacy data prompted a clinical pilot study of EBUS-guided RFA.[8]

CLINICAL APPLICATION

Study design

A prospective, single-arm, ablate-and arm, ablate-and-resect trial (ClinicalTrials.gov, NCT03400748) was conducted at Toronto General Hospital (Toronto, Canad**a).** The primary outcome of this pilot study was short-term safety. Immediately following RFA, resection was performed to assess the ablated area histologically, including adjacent healthy peritumoral tissue. Adult patients aged 18 and older who had either (1) pathologically proven stage I or stage II lung cancer with a primary tumor larger than 1 cm, or (2) a metastatic lung nodule larger than 1 cm, and for whom this tumor/nodule was accessible by convex-probe EBUS bronchoscope were included in this study.

Procedures

The RFA probe was inserted into the target lung nodule under EBUS guidance followed by ablation with a total supplied energy of 4 to 8 kJ. The total energy was purposefully determined to avoid complete tumor ablation, as the objective of this study was to evaluate the short-term safety of EBUS-guided RFA. During RFA, the position of the electrodes was monitored using cone-beam CT fluoroscopy. After EBUS-guided RFA, bronchoscopy and a contrast CT were performed to document off-target injuries. Following the acquisition of all images, the patient had surgical resection in the same operating room under the same anesthetic.

Study results

In five different individuals, five primary lung malignancies were ablated (adenocarcinoma in four cases, squamous cell carcinoma in one case). For 4 kJ, 6 kJ, and 8 kJ, the mean ablation times were 13.8 min, 8.4 min, and 15.6 min, respectively. Throughout the RFA procedure, the position of the RFA device was continuously monitored and verified within the target using EBUS. The average procedure time was 36.2 min (range, 26-51 min). There were no significant immediate complications related to EBUS-guided RFA. Particularly, neither during insertion, deployment of the second electrode, nor ablation was there any major hemorrhage that required for intervention. On post-RFA bronchoscopic examination, there was no evidence of thermal injury to the bronchial wall. The post-RFA contrast CT revealed no pneumothorax or hemothorax.

Advantages

As the RFA probe does not pass through the pleura, the transbronchial approach naturally has a lower risk of pneumothorax than the transthoracic approach. Doppler mode EBUS can help avoid intervening vessels, which may lower the risk of bleeding or development of bronchovascular fistulas. The study design did not allow evaluation for late sequelae of bronchial thermal injury; however, the absence of acute injury is reassuring. This technique's ultimate goal is to treat lung tumors in the middle- and central-third lung fields. The current 6.9 mm-EBUS bronchoscope has limited access to lung lesions not adjacent to the central airways. It will probably be necessary to combine EBUS-guided RFA with a thin EBUS bronchoscope to improve access to the periphery. Our team has published the performance of a prototype thin bronchoscope (distal end outer diameter: 5.9 mm), showing noticeably enhanced access to the sublobar bronchi.[9] Transbronchial RFA in the middle lung field may have even further advantages over central RFA. This includes potential improvements in safety (greater distance from the heart, large vessels, central airway, and esophagus) and efficacy (reduced heat sink effect due to decreased vessel diameter in the lung periphery).

CONCLUSION

This pilot study showed that EBUS-guided RFA may access lung tumors close to airways, enabling real-time monitoring of the electrode deployment and ablation with no immediate complications. EBUS-guided ablation may avoid some of the morbidity of percutaneous ablation.

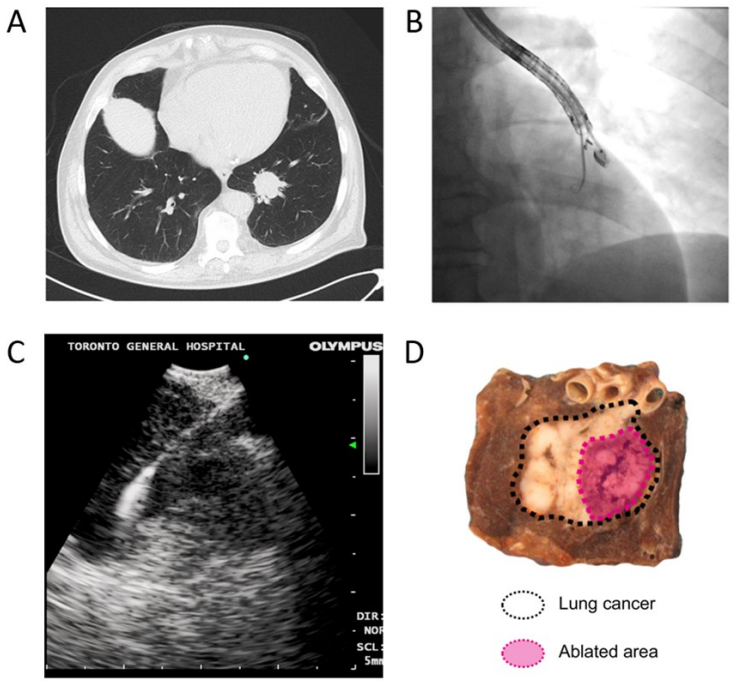

Figure: A representative case of EBUS-guided RFA. (A) A pre-RFA CT axial view (71-year-old male with stage IB squamous cell carcinoma. (B) Fluoroscopic confirmation of the electrode position. (C) An EBUS image before ablation. The RFA electrode was continuously observed throughout the ablation. (D) Gross pathological examination of the resected specimen.

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EBUS-GUIDED TRANSBRONCHIAL MEDIASTINAL CRYOBIOPSY

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Introduction

Endobronchial ultrasound transbronchial needle aspiration (EBUS-TBNA) has an excellent diagnostic yield for primary pulmonary malignancies, but the amount of tissue might be insufficient to allow for a firm diagnosis of lymphoproliferative disorders or even sarcoidosis. These entities, especially lymphomas, require histopathologic rather than cytologic samples for the evaluation of the overall background architecture and correct subtyping (1). Cryobiopsy is an endoscopic technique mostly used in the diagnostic approach to interstitial lung disease, based on rapid cooling, crystallization, and subsequent collection of tissue. Herein we share our approach in performing EBUS-TBNA and transbronchial mediastinal cryobiopsy (TMC) during the same procedure for diagnostic purposes of mediastinal lesions and lymph nodes.

Indications

1. Proven or suspected malignancy, either of solid or hematologic origin and sarcoid suspicion.
2. Mediastinal lymph nodes with diameter ≥ 1 cm in the short axis.
3. Patients with at least one mediastinal/hilar lesion irrespective of the lymph node station.
4. Necessity to undergo endoscopic mediastinal assessment for diagnosis, staging or molecular characterization.
5. Patients with previous non diagnostic EBUS-TBNA.

Planning

The planning for performing a TMC begins with the CT or PET-CT images. If it´s a diagnostic procedure, and feasible, we recommend selecting the hilar stations first; in our experience the 1.1 mm cryo-probe (Erbecryo 20402-401, Tubingen, Germany) enters these areas more smoothly than the mediastinal ones. It is important to identify the lymph node stations that are closest to the bronchial or tracheal wall, since those that are further away will be more difficult to access with the cryoprobe, making the procedure longer and more complex.

Sampling and Procedure

We perform the procedure under conscious (moderate) sedation. Herein we describe the step-by-step approach applying our method (2) through a clinical case description. A 42-year-old female was referred to our Interventional Pulmonology Unit (IPU) due to enlarged mediastinal and hilar lymph nodes. The PET-CT scan showed an increased FDG uptake at stations 7 and 11L (Figure 1A). After identification of an enlarged station 7 lymph node on EBUS (*Pentax* Medical EB19-J10U), we performed three passes of TBNAs with 22-gauge needle (SonoTip® TopGain: Medi-Globe) (Figure 1B). After initial puncture with the TBNA needle, a 1.1 mm cryo-probe was introduced into the working channel of the EBUS bronchoscope. The cryo-probe is advanced towards the puncture site and inserted gently through the previous puncture site created by the TBNA needle. The EBUS image confirmed the cryo-probe position within the lymph node. The cryo-probe was cooled down for 4 s, and then retracted with the bronchoscope and the frozen biopsy tissue attached to the tip of the probe (Figure 1C-G). The cryobiopsy site was immediately examined and no bleeding was observed (Figure 1H). Cryobiopsies were retrieved in saline and fixed in formalin (Figure 1I). Samples confirmed the diagnosis of sarcoidosis (Figure 2).

Quality Control

It is important to mention that our method for performing TMC is mainly based on always introducing the cryoprobe under ultrasound guidance; we do not focus on trying to introduce the cryoprobe through the puncture site only. We are guided by the track left in the lymph node by EBUS-TBNA needle. It is key to introduce the cryoprobe at the same angle in which the previous EBUS-TBNA punctures were performed. Every time we obtain a TMC, we immediately return with the EBUS to the punctured station and spend ~ 2 min visualizing its ultrasonographic characteristic under Doppler mode, looking for signs of bleeding within the lymph node.

Zhang et al. conducted a trial that included a total of 197 patients who underwent EBUS-TBNA and TMC in the same procedure to assess the diagnostic yield and safety of this technique. For TMC they performed a small incision in the tracheobronchial wall adjacent to the mediastinal lesion using a high-frequency needle-knife (3). An important difference in our method is the way we perform the procedure. We have shown that the high-frequency needle knife is not essential, and we eliminated this step of the process by directly introducing the 1.1 mm cryo-probe always under echo guidance through the puncture site created by the EBUS-TBNA needle. This modified technique allows us to perform the procedure in a faster and less invasive way. Prior studies reported an intranodal forceps biopsy (IFB) strategy for mediastinal lesions, which emphasizes the essentiality of sample amount for improving diagnostic sensitivity (4). Agrawal et al. performed a meta-analysis and concluded that the addition of EBUS-IFB to EBUS-TBNA improves the overall diagnostic yield of sampling intrathoracic adenopathy when compared with EBUS-TBNA alone. The complication rates of the combined approach were higher than with EBUS-TBNA (5). In our practice, TMC does not have greater complications than EBUS-TBNA. It would be interesting to compare the diagnostic yield and complications between TMC and IFB in the future.

Conclusion

We believe EBUS-guided TMC, compared to EBUS-TBNA, provides more adequate histological samples, adding value to current diagnostic approaches for mediastinal diseases, especially for lymphoproliferative disorders, or when more tissue is needed for molecular determinations. Further studies are needed to address safety and outcomes of this technique.

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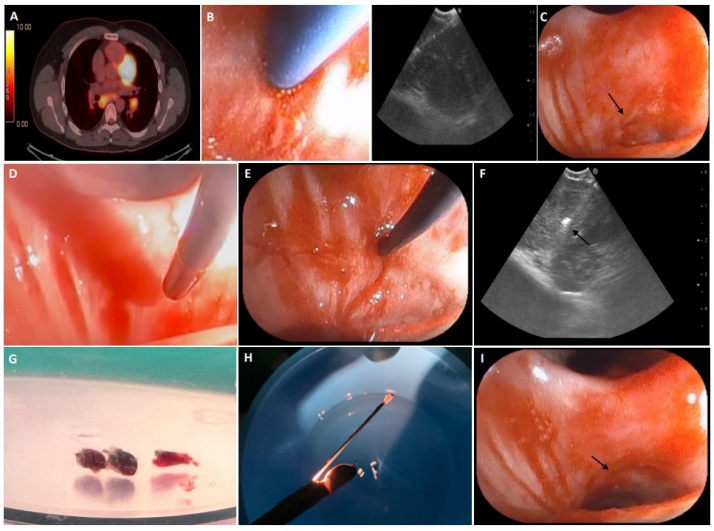


Figure 1. PET-CT scan showed an increased FDG uptake at stations 7 and 11L (A). Performing EBUS-TBNA in station 7; TBNA needle sheath (B). Puncture site made by TBNA needle, black arrow (C). Tip of the cryo-probe approaching the puncture site (D), and a tip of the cryo-probe completely inside the node (E). EBUS image showing the tip cryo-probe within the lymph node, black arrow (F). Tip of the probe has the lymph node tissue obtained by cryo-nodal biopsy (G). Bronchoscopic view of the puncture site after performing cryo-nodal biopsy, black arrow (H). Samples obtained from transbronchial mediastinal cryobiopsy (I).

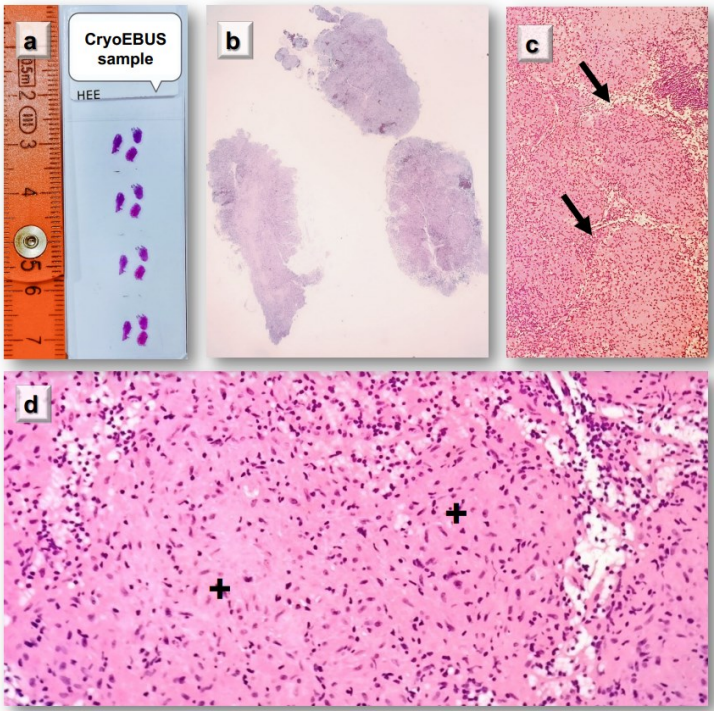


Figure 2. Gross-micro view of the cryobiopsy specimen, with 0.5 cm fragments (A-B). Histological section (H&E). Hypercellular areas organized in nodules are observed (arrows). No necrosis (C). Nodular areas composed of epithelioid cells clusters (+), forming granulomas. Non-necrotizing granulomatous lymphadenitis, compatible with sarcoidosis (D).

Humanitarian News

WABIP's Institute of Interventional Pulmonology

Written by Ali I. Musani

The World Association for Bronchology and interventional Pulmonology (WABIP) has come a long way since its inception, particularly in the last decade. The membership has grown steadily over the years to almost 10 thousand. The educational, philanthropic, and social endeavors have expanded at an impressive pace. WABIP has shown remarkable progress, and its leadership should be proud of these achievements.

Focusing on our organization's fundamental goals and concerted efforts to achieve them is vital. WABIP's goals, as outlined in the mission and goal statement of the WABIP, are "*to strengthen global ties between regional and national societies or groups from around the world to enhance patient care, research, and education in bronchology and related fields.*"

I firmly believe that we are at an inflection point in our society's history to do something far beyond what we have done. With our thousands of experts worldwide, access to rapidly developing and state-of-the-art technologies, close relationship with industry, and our unified mission across continents, we have an enormous potential to do great things for the dissemination of science and the field of Interventional Pulmonology. We can genuinely democratize the field of Bronchology and Interventional Pulmonology and eventually disseminate the knowledge, skills, and technology to improve patient care across the globe. We desperately need to blur the line between resource-poor and resource-rich areas worldwide. Those lines are men made, after all.

I have a dream!

WABIP Interventional Pulmonology Institute (IPI)

For the last ten years, I have been quietly exploring locations, business models, educational structure, organizational feasibility, and other aspects of developing several institutes of Interventional Pulmonology around the globe. I have had significant breakthroughs in the last three years, first in Kuala Lumpur, Malaysia, and then in Istanbul, Turkey.

Both sites have most, if not all, the prerequisites for a fantastic training site for doctors from around the world regardless of their country of origin, financial, and social background. We (local IP leaders in Malaysia, Turkey, and me) have had numerous meetings with the leadership of both institutions. We have developed a memorandum of understanding (MoU) and negotiated the basic tenets of our partnerships. We presented the progress report of our potential collaboration to the board of directors and the board of regents of the WABIP. The project received overwhelming support, official approval, and financial support from the executive board of the WABIP to move forward. I have accepted the honor of chairing the ad hoc committee of the WABIP for the development of IPI and formed multiple committees to achieve these projects' administrative and educational goals. Fundamentally, the IPI will have a multifaceted education, training, technology transfer, and research mission. Please see below for the details.

IPI Concept:

WABIP will collaborate with public and private hospitals and local IP experts affiliated with WABIP around the world. In partnership with the host hospital, WABIP will set up Institutes of Interventional Pulmonology to offer IP education and training for doctors worldwide and IP-related health services to regional patients.

The host hospital will provide:

• The host hospital will provide the infrastructure for education, training, and health care delivery, including a facility equipped with operating rooms, bronchoscopy suite, pre and post-operative areas, a clinic, an office, a conference room, and an in-patient facility.

Humanitarian News

• The host hospital will provide devices necessary for training IP and patient care, such as flexible and rigid bronchoscopes, Endobronchial Ultrasound (EBUS), Radial ultrasound (REBUS), Navigation bronchoscopy system, pleuroscope, airway stents, laser, and electrocautery.

• The host hospital will also provide financial support for the educational program, including airfare, transportation, residence, and food for up to 24 faculty (provided by the WABIP) per year.

• The host hospital will arrange malpractice insurance for the faculty.

• The host hospital will aid in obtaining a short-term medical license without going through extensive testing or documentation from the local government to allow WABIP physicians and trainees to perform procedures on local patients.

• WABIP and the host hospital will seek funding from philanthropic organizations, individuals, and industry to support the mission of IPI. They will also collect device donations (new, used, or refurbished) from industry and hospitals in the resource-rich parts of the world.

WABIP will provide:

- Expert faculty for teaching and training as well as for performing state-of-the-art procedures on the local patients
- Curriculum and training infrastructure for IP fellowship/mini-fellowship/training for the international trainees
- The Fellowship committee will screen, invite, train, and certify international doctors in different disciplines of the IP

WABIP Fellowship:

The fellowship committee comprised of world experts of IP educators will develop fellowships in specific IP-related areas such as advanced diagnostic bronchoscopy (including EBUS, Radial EBUS, peripheral bronchoscopy), therapeutic bronchoscopy (including rigid bronchoscopy, ablation, and airway stenting), and Pleurology (including pleural procedures). They will develop policies and processes for selecting fellowship applicants, curriculum, create or use already established standardized educational tools and training methods, and certification processes. A certified fellow from WABIP IPI will be able to start an IP program in their country and train others after a necessary period of practice.

WABIP will strive to train fellows who would be able to set up IP programs in their countries with their personal/national or WABIP resources and teach more people and open more centers in the region (the trickle-down effect)

Where are we now?

We selected the first partner site with the help of Dr. Jamalul Azizi in-Kuala Lumpur, Malaysia. Dr. Azizi is the Chair of the Malaysian Association of Bronchology and Interventional Pulmonology and a well-known national and international leader in IP. The Cardiac Vascular Sentral of Kuala Lumpur (CVSKL) has a state-of-the-art medical facility where Dr. Azizi practices IP. We had several meetings with the leadership of CVSKL, including Mr. Khairul Amin Mohd Nordin, Director of the Clinical Services Division, Tan Eng Ghee, CEO, and others. Basic MoU has been negotiated. We are finalizing some last details and hope to discuss and complete the legal contract in three to six months.

Humanitarian News

Meetings between the IPI (WABIP) leadership and Cardiac Vascular Sentral Kuala Lumpur (CVSKL) leadership.

Top left, Dr. Jamalul Azizi Abdul Rahaman; Top right, Dr. Ali Musani; Middle left, Lim Wang Ying, Head of Health Screening; Middle right, Tan Eng Ghee, CEO; Bottom, Khairul Amin Mohd Nordin, Director of Clinical Services Division

Our second partner site is Liv Hospital Group, Istanbul, Turkey, led by Dr. Levent Dalar.

Dr. Dalar is a well-respected Interventional Pulmonologist in Europe. He has served Turkish and the World Association of Bronchology and Interventional Pulmonology for several years. I met with the CEO of the Liv Hospitals in Istanbul in February of 2022 and then with the CEO of the entire hospital group multiple times via zoom. Our progress in Istanbul has been swift. We have ironed out most of the significant aspects of our collaboration through a detailed MoU. The two most relevant areas recently sorted out include medical licenses and malpractice coverage for international physicians. The Turkish government will allow WABIP faculty to perform procedures for educational purposes as a guest lecturer, temporarily appointed at the İstinye University, the academic partner of the Liv Hospital Group. The fellows will be covered to do procedures under the supervision of the faculty. The hospital will provide malpractice insurance for all faculty and fellows.

Dr. Mehmet Akif Benk, CEO-General Manager Liv hospital Istanbul and Dr. Levent Dalar, Interventional Pulmonologist at Liv hospital, on the right.

Top right, Dr. Levent Dalar; bottom right, Meri Istiroti, CEO of Liv hospital system Turkey.

We are entering the final stages of the MoU for IPI, after which we will draw a formal, legally binding contract for both parties. We will then put together a list of faculty for each IPI and apply for local approval and malpractice through the respective hospital/university mentioned above. We hope to achieve these by the first quarter of 2023 and start the programs soon after, with an expected ramp-up period of two years. We will be looking for many WABIP faculty to volunteer for teaching and training at these institutes.

Our industry and marketing efforts have already started. Dr. Dalar and I met with several European device industry representatives. The group outlined many areas of collaboration, including fellowship sponsorships, device donations, and finan-

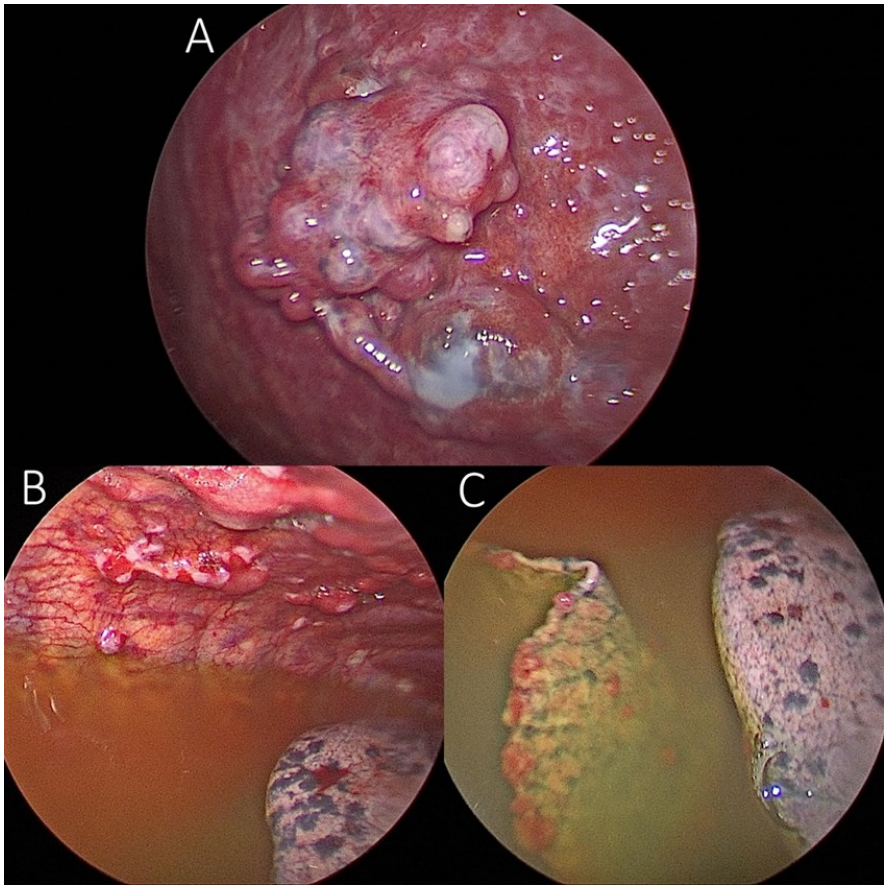
cial donations. We look forward to meeting with a much larger industry liaison group in Marseille during the WCB to launch a large-scale campaign for IPI.

After these two projects are up and running, I want to establish more institutes in North Africa and South America in the next few years.

**The views expressed in this article are those of the author (Ali Musani) 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 2022 (3 of 3)



Description:

Diffuse Malignant Infiltration by Lung Cancer
A: Malignant nodules on the diaphragm, B: Malignant nodules on the parietal pleura, C: Malignant nodules on visceral pleura

Submitters:

Dr. Preeti Vidyasagar, Dr. Hari Kishan Gonuguntla

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

Celebrating the 2022 WABIP Awards

We are happy to announce the results of the 2022 WABIP Awards. The below list of awardees are recognized for their accomplishments and commitments to bronchology and interventional pulmonology, and it is with great honor to celebrate these recipients at our Awards ceremony of our upcoming WCBIP congress in Marseille France.

Gustav Killian Centenary Medal 2022 Recipient

Martin Phillips, MD (Australia)

WABIP-Dumon Award 2022 Recipient

Septimiu Murgu, MD (USA)

WABIP Lifetime Achievement Award 2022 Recipient

Teruomi Miyazawa, MD (Japan)

WABIP News

Celebrating the 2022 WABIP Awards (cont.)

Distiguished WABIP Regent Award 2022 Recipient

Spasoje Popević, MD (Serbia)

Heinrich Becker Young Investigator Awards for Research and Clinical Innovation 2022 Recipients:

1. **Keisuke Kirita, MD (Japan)** for the WCBIP accepted abstract titled:
   Development of artificial intelligence system classifying malignant and benign cells for rapid on-site cytologic evaluation (ROSE) samples of bronchoscopy
2. **Øyvind Ervik, MD (Norway)** for the WCBIP accepted abstract titled:
   Automatic identification and segmentation of mediastinal lymph nodes and blood vessels in endobronchial ultrasound (EBUS) using a deep neural network
3. **Sandip Saha, MD (USA)** for the WCBIP accepted abstract titled:
   A First for Robotic Navigational Bronchoscopy and the Use of "Tele-ROSE" in diagnosing lung pathology

Register for WCBIP Virtual 2022

We are pleased to have already 850 confirmed on-site attendees at our coming WCBIP in Marseille France. This is the perfect opportunity for delegates to network and learn from some of the top experts in the field.

If you can't attend in person, you can still participate via Zoom (virtual), as we will broadcast live selected sessions. Additionally, on-demand playback of all sessions will be available after the congress.

- View the Program Schedule Virtual
- View the Program Schedule ALL
- REGISTER HERE

Research

The Devil Is In The Detail

Ali I. Musani MD, FCCP
University of Colorado School of Medicine, Denver

Lung cancer accounts for almost 1.8 million deaths yearly and is responsible for more than 18% of cancer-related mortality worldwide. Lung cancer is traditionally classified by histology; small-cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC). NSCLC is more common than SCLC and is further subdivided into squamous and non-squamous categories. Adenocarcinomas constitute most non-squamous NSCLC cancers. Tobacco smoking is strongly associated with SCLC and squamous cell carcinoma but remains associated with all histologic subtypes. Recently, a greater understanding of disease biology and the identification of oncogenic driver alterations has revolutionized the therapeutic landscape of NSCLC. Consequently, the new classification algorithms of NSCLC characterize them molecularly into actionable mutations with targeted therapies.

Molecular testing has become a mandatory component of the NSCLC workup. There are almost a dozen NSCLC molecular targets that have approved therapies. The detection of EGFR, BRAF, and MET mutations and ALK, ROS1, RET, and NTRK translocations is now the standard of care. Targeted therapies for EGFR exon 19 deletion and L858R mutations and ALK and ROS1 rearrangements are well established. Several other biomarkers, e.g., KRAS G12C substitutions and HER2 activating alterations, are becoming mainstream in NSCLC workup with anticipated targeted therapies. Most centers now routinely perform analysis of PD-L1 protein expression to utilize immune checkpoint inhibitors. The immune checkpoint inhibitors in the NSCLC management also contributed to the significant improvement of disease outcomes, particularly in patients lacking TKI-sensitizing mutations.

Molecular characterization of NSCLC requires analysis of biological markers such as DNA, RNA, and proteins, which in turn requires multiple platforms such as PCR, FISH, and DNA sequencing. High throughput sequencing technologies such as next-generation sequencing (NGS) have served very well in this regard. However, it's time-consuming (10 or more working days) and expensive. Hopefully, this technology will become

more efficient and cost-effective.

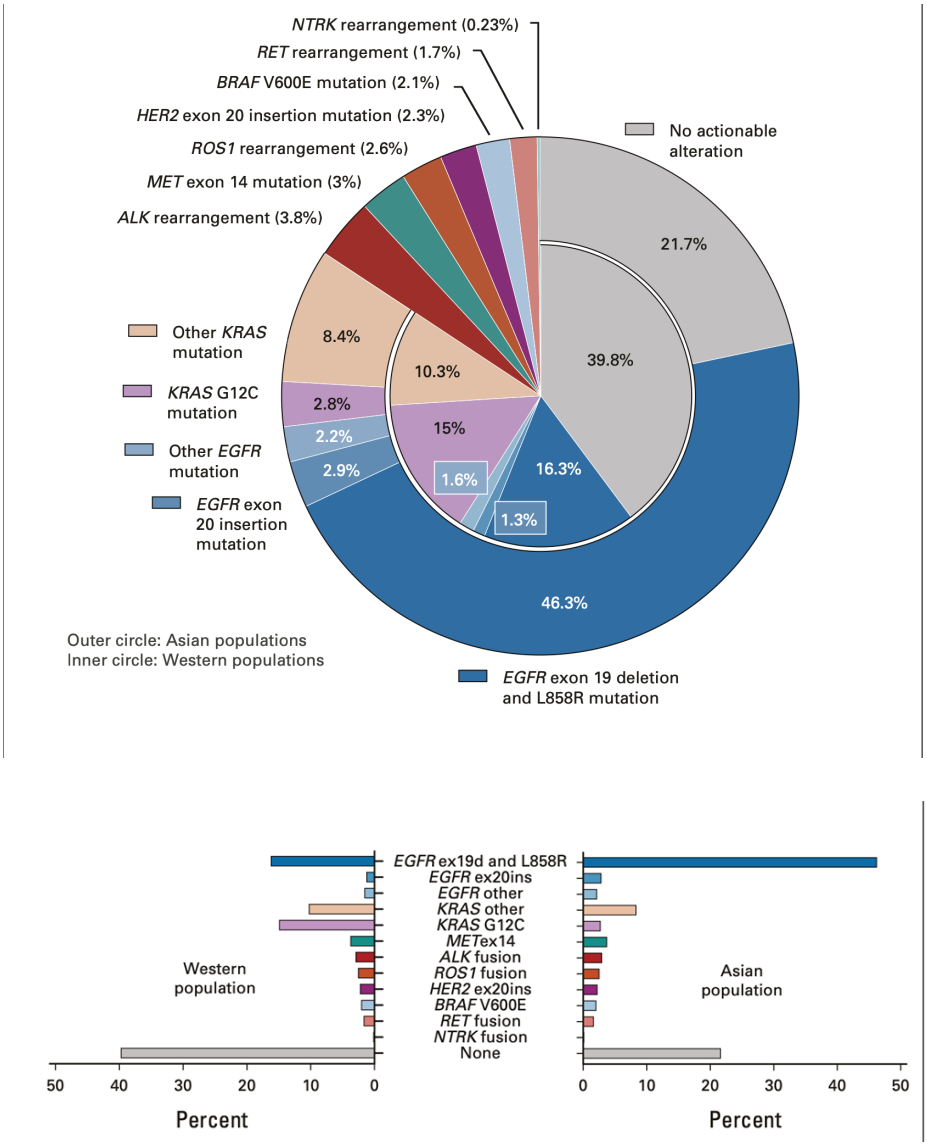


Figure 1. Frequency of targetable oncogenic driver molecular alterations in NSCLC (adenocarcinoma). Incidences of oncogenic driver alterations extracted from the studies by Burnett et al,Dearden et al,Jordan et al, Shi et al,and Solomon et al.d, deletion; ex, exon; ins, insertion; NSCLC, non–small-cell lung cancer. (1)

Approximately 50–70 % of Asian and 30–40 % non-Asian NSCLS (non-squamous) patients carry targetable mutations (fig 1) and, when treated appropriately, show significantly (several folds) improved survival. Unfortunately, most of this progress has not translated into squamous cell carcinoma patients. Regardless, the last decade has shown a tremendous improvement in personalized and precision therapy of NSCLC and is exemplary in medical oncology.

When tissue sampling is not feasible in situations such as recurrent disease, liquid biopsy can provide important information about tumor evolution during the treatment course. It does, though, require a high tumor burden. There are assays utilizing circulating tumor cells. However, it is not clear whether they are representative of the entire tumor or a fraction of heterogeneous cancer. The amount of circulating tumor DNA correlates with tumor response or lack thereof and can be utilized as a marker of the efficacy of therapy.

The tremendous promise lies in more profound discoveries in tumor biology, broad-based clinical trials, and rapid drug development.

References:

1. Tan AC et al. J Clin Oncol. 2022 Feb 20;40(6):611-625. doi: 10.1200/JCO.21.01626. Epub 2022 Jan 5. PMID: 34985916.

2. Imyanitov E et al. Crit Rev Oncol Hematol.2021 Jan;157:103194

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.

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