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Opinion/Editorial

New Guideline for Routine Molecular Testing in Patients with Non-Small Cell Lung Cancer

In the past decade, there has been a paradigm shift in the treatment of non-small cell lung cancer (NSCLC). Homogeneous standard therapy for NSCLC is no longer acceptable. The treatment and management of patients with newly diagnosed adenocarcinoma are based in part on the presence of epidermal growth factor receptor (*EGFR*) mutation and anaplastic lymphoma kinase (*ALK*) translocation status. The need to identify lung cancer patients that will benefit from molecular targeted treatment has raised several issues that need to be addressed by treating oncologists as well as pathologists. In order to establish evidence-based guidelines for addressing which patients and samples should be tested for *EGFR* and *ALK*, when and how testing should be performed, the College of American Pathologists (CAP), the International Association for the Study of Lung Cancer (IASLC), and the Association for Molecular Pathology (AMP) jointly issued a guideline this year for the selection of lung cancer patients for *EGFR* and *ALK* testing [1-3].

The Clinical Practice Guideline addressed 5 principal and 14 corollary questions regarding molecular testing in NSCLC. The principal questions includes 1) When should molecular testing for NSCLC be performed?; 2) How should *EGFR* testing be performed?; 3) How should *ALK* testing be performed?; 4) Should other genes be routinely tested in lung adenocarcinoma?; and 5) How should molecular testing of lung adenocarcinomas be implanted and operationalized? There were 15 evidence grade A/B recommendations in the new guideline, but the major recommendations are to use testing for *EGFR* mutations and *ALK* fusions to guide patient selection for therapy *EGFR* or *ALK* inhibitor in all patient with advanced-stage adenocarcinoma, regardless of sex, race, smoking history, or other clinical risk factors and to prioritize *EGFR* and *ALK* testing over other molecular tests.

Apart from the major recommendation, there are several key learning points for bronchoscopists. To determine *EGFR* and *ALK* status for initial treatment selection, primary tumors or metastatic lesions are considered equally suitable for testing. In patients with metastatic mediastinal lymph nodes, the lymph nodes are easily accessible with EBUS-TBNA and would be an ideal approach for tissue sampling and mutational studies. Processing of specimens for mutational testing is also an important issue that was addressed. Based on expert consensus opinion, pathologists should use formalin-fixed, paraffin-embedded (FFPE) specimens or fresh, frozen, or alcohol-fixed specimens for PCR-based *EGFR* and *ALK* tests. Cytologic samples are also suitable for *EGFR* and *ALK* testing, with cell blocks being the preferred over smear preparations. Other detailed sample testing recommendations are discussed in the guideline which I encourage the bronchoscopists to review together with the pathologists/cytologists at their institution.

Providing sufficient tissue sampling for mutational studies will become mandatory for bronchoscopists involved in the diagnosis and management of patients with lung cancer. Bronchoscopists need to insure that the specimens are acquired and processed in a proper fashion that provides information that is sufficient to guide treatment in the era of targeted therapy [4].

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Editor-in-Chief

Kazuhiro Yasufuku

THE WABIP REMEMBERS

November these past two years has been a month of sadness and mourning. Last year (November 2, 2012) we lost Professor **Chris T. Bolliger**. This year (November 25, 2013) we lost Professor **Yoichi Watanabe**. Both men contributed much to the art and science of Interventional Pulmonology. They will be sorely missed.

Yoichi was a soft-spoken man, a good friend of many and a dedicated teacher and mentor. With his ready smile and warm manners, he is perhaps most well known for the Watanabe Spigot.

Chris, with his occasional and popular flair for the dramatic, used his powers of persuasion to help make interventional pulmonology a part of medical nomenclature.

Both men passed away at the all too young age of 62.

Doctor Watanabe graduated from Tottori University Faculty of Medicine in 1976 and went on to become a Clinical Professor at Okayama University School of Medicine, where he was Head of Interventional Pulmonology and Executive Vice President of the Japanese Red Cross Okayama Hospital in Okayama, Japan.

Doctor Bolliger trained in Basel and Lausanne, obtaining his medical degree, also in 1976. Traveling to South Africa in the 1980s as part of an exchange program, he volunteered to work as a medical delegate with the International Committee of the Red Cross in Iraq, Iran, Turkey, Namibia, and South Africa where he met the then political prisoner, Nelson Mandela.

Doctor Watanabe devoted much of his research to the establishment and development of lung cancer cell lines. His interests in COPD and cystic fibrosis led to his being named President of the 15th annual meeting of the Japan Society of Pneumothorax and Cystic Diseases in 2011. He worked closely with a French company (Novatec) to design and distribute a bronchial silicone plug that became known as the Endobronchial Watanabe Spigot (EWS®), used in the bronchoscopic management of patients with pneumothorax, emphysema, and bronchopleural fistulas. Many of his lectures and workshops included commentary regarding concepts behind bronchial occlusion therapy for these disorders.

Doctor Bolliger was named Professor in Pulmonary Medicine at Stellenbosch University and Tygerberg Academic Hospital, Cape Town, South Africa, in 1999. In addition to his numerous publications pertaining to lung cancer, pulmonary physiology, thoracoscopy, and bronchoscopy, he coauthored guidelines on smoking cessation in Africa and the Middle East and was actively pursuing his research interest in imaging techniques and fiduciary markers. He was the editor-in-chief of the medical journal *Respiration*, and editor of the international book series *Progress in Respiratory Research*. An officer of the European Respiratory Society and member of the Global Healthcare Alliance for Treatment of Tobacco Dependence, he was also the President of the European Association for Bronchology and Interventional Pulmonology (EABIP, 2006-2011).

Professors Watanabe and Bolliger are fine examples of individuals who dedicated their professional lives to their patients as well as to teaching and mentoring fellow colleagues and students. In recognition, Dr. Watanabe was the recipient of the prestigious Ohata and Ikeda awards from the Japanese Society of Respiratory Endoscopy. Dr. Bolliger received a Lifetime Achievement Certificate at the 16th WCBIP (Budapest, Hungary, 2010).

It is with great sorrow that we mourn the passing of these two respected leaders of our global community. Our heartfelt condolences go to their loving families. Yoichi and Chris's creative spirits, meanwhile, live on in the work and dreams of interventional bronchoscopists, easily visible in our daily efforts and in our profession's growing ability to help patients around the world.

Henri Colt MD, Chairman WABIP

Yoichi Watanabe
Japanese Red Cross
Okayama Hospital

Chris T Bolliger
Stellenbosch University and
Tygerberg Academic Hospital

Technology Corner

Technology corner: Lasers in Therapeutic Bronchoscopy

Introduction: Biomedical lasers have been used and continue to be developed for the treatment of airway processes. The laser-induced tissue effects are influenced by lasers' wavelength, power setting, power density, duration of exposure, pulse intensity, tissue pigmentation and water content. The desired effect on tissues depends on the disease process and therefore knowledge of basic laser physics is warranted to assure optimal treatment and patient safety. This section will discuss the physical characteristics of commonly used airway lasers and describes how these modalities differ from each other in terms of coagulation, cutting, vaporization and expected depth of penetration.

Background: A laser beam applied on tissues is reflected, absorbed, propagated (transmitted) or scattered. "Laser" is an acronym for Light Amplification by Stimulated Emission of Radiation. The principle, originally described by Albert Einstein (1917), states that the electrons of some atoms may be stimulated by external energy source to achieve a higher level of energy. When the electrons fall back to the normal level of energy, there is emission of energy in the form of photons. When a population of atoms at higher level of energy is greater than the population at lower energy level (i.e. population inversion), an amplification of radiation stimulated emission takes place. Contrary to the normal light, the light generated by laser systems is monochromatic (wavelength depends on the medium, with the radiant energy concentrated in a narrow spectral band), coherent (the waves are in phase in time and space) and collimated (waves travel along parallel lines, reducing the loss of intensity) (1). Table 1 summarizes the characteristics and expected tissue effects of various lasers used in bronchoscopy depending on their specific wavelengths. The lasers most frequently used for treatment of tracheobronchial airway lesions are the Nd:YAG laser, the YAP laser, and the KTP laser.

Clinical applications: The rationale for using laser energy in bronchoscopy relies on the fact that tissues (benign or malignant) may be damaged by the radiant energy induced by the laser. On living tissues, Nd:YAG, YAP, and KTP laser energies are converted into heat, which vaporizes the water and creates pressure waves that ruptures tissues or creates plasma (hot gas of electrons and positive ions). There is additional generation of kinetic energy, which could cause molecular breakdown and chemical energy, which could result in disruption of cell membrane integrity. Laser energy can be applied via flexible or rigid bronchoscopy, depending on the type, laser fiber diameter, indication and operator's experience or preference. Clinical applications for specific types of lasers depend on the desired coagulation property, depth of penetration, cutting precision and expected collateral damage (Table). As a general principle, lasers with high absorption in water (Nd: YAP, Ho:YAG, CO_2, Thulium) or hemoglobin (KTP) have a shallower depth of penetration than lasers with a high absorption in proteins (Nd:YAG). These properties are relevant when one decides to perform radial incisions in laryngotracheal stenoses with minimal collateral mucosal damage. A laser with precise cutting is preferable for this indication (eg. CO2, but also KTP using high power density)(2). Deep coagulation, on the other hand, is desirable to facilitate laser-assisted mechanical debulking of endobronchial tumors and thus a laser with deep penetration effects is preferable (eg. Nd:YAG, particularly at low power density)(3, 4). Knowledge of the physical aspects of the laser is warranted to properly select the correct laser type, settings and optimally operate the system for specific indications. Laser power, for instance, is the time rate (energy/time) at which energy is generated by the machine, expended, transmitted or converted; it is preset by the operator and is measured in Watts (W or Joules/second). *Power density* is perhaps the most important element determining laser-tissue effects. Power density refers to power per unit of volume or area within which energy is released, transmitted or absorbed and is measured in Watts/$cm^{2.}$ Total laser energy is affected by the time of application and is expressed in Joules (Watts x Seconds). These parameters are documented by the bronchoscopist in the procedure report.

Conclusions: Laser selection for airway use requires a good understanding of the absorptive, scattering, and transmissive properties, which depend on tissue characteristics (color, blood supply, water content) and on laser physics (wavelength, absorption in Hb, H_20 or proteins) (5) (Figure). The goal of therapeutic laser use in the airway is to achieve the desired cutting or coagulation effects while minimizing damage to normal structures.

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Laser medium	Wavelength (nm)	Cutting	Coagulation of proteins/ hemostasis	Vaporization	Penetration (mm)	Clinical Applications in the airways
CO2	10600	Excellent	Poor	Excellent	Shallow (0.1)	Radial incisions
Nd: YAG	1064	Poor	Excellent	Excellent	Deep (3-15)	Coagulation and devitalization of tumors
KTP	532	Average	Poor	Average	Average (1-2)	Radial incisions
Ho: YAG	2100	Excellent	Poor	Average	Shallow (0.5)	Radial incisions
Nd: YAP	1340	Average	Excellent	Poor	Average (3)	Coagulation and devitalization of tumors
Thulium	2000	Poor	Excellent	Poor	Shallow (1)	Coagulation and devitalization of tumors

Figure: Laser induced tissue effects depending on laser physics, power density and tissue color. A hyperpigmented and vascular tumor (top left) becomes black due to surface absorption of the Nd: YAG laser even at low power density (bottom left). A less pigmented lesion (top middle) shows mixed areas of blanching (coagulation) and charring as a result of Thulium laser application at low power density (bottom middle). A non-vascular, hypopigmented lesion shows only blanching after Nd:YAG laser application at low power density.

Length, diameter, and customization of silicone airway stents

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Introduction

Since the late 1980s, the Dumon-style endoluminal silicone stent, with small studs on its external surface to prevent migration (1), has been the gold standard in airway stenting for patients with benign and malignant stenoses (2). Three major indications have been established (counteracting extrinsic compression from tumors or lymph nodes, stabilizing airway patency after endoscopic removal of intraluminally growing cancer, and treating benign strictures). The stent is also used to stabilize collapsing airways, and to help seal airway-mediastinal or airway-esophageal fistulas.

Silicone stents are inserted using rigid bronchoscopy. Considering the large variety of stents currently available, it is usually possible to select a stent that will fit the diseased airway. In the next paragraphs, I will address two questions that arise at the time of stent selection.

1. How do you choose the appropriate length and diameter of the silicone stent?
2. How might a stent be customized so it can be inserted at the secondary carina or in the area of the take off of the right upper lobe bronchus?

1. Stent Length and Size: tips for silicone stent selection and insertion

Insertion of a silicone stent is usually performed using rigid bronchoscopy under general anesthesia. In addition to serving for stent introduction and deployment, the rigid bronchoscope is useful for mechanical tumor debulking and/or airway dilation prior to stent insertion.

The appropriate length of the stent is determined intra-operatively by using the rigid telescope or a flexible bronchoscope to measure the length of the lesion to be treated. Preoperatively, preliminary measurements can be estimated from the CT images and confirmed endoscopically. Ideally, the stent should extend 5 mm beyond and 5mm proximal to the abnormality.

In my opinion stent length and diameter are best determined during rigid bronchoscopy. The choice is based on the largest diameter rigid bronchoscope barrel used to maximally mechanically dilate the airway as well. Tactile feedback (feeling the airway dilate as the rigid bronchoscope is passed through the narrowed airway passage) is also helpful. Some airways feel very stiff, while others may dilate easily. Although stent diameter is decided upon on a case-by-case basis, some guidelines can be followed. In stenotic lesions of the trachea, 14–18-mm stents are often selected (selection depending on results of tactile feedback). The 12- to 14-mm and 10- to 12-mm diameter stents are usually appropriate for stenoses involving the mainstem bronchi and bronchus intermedius, respectively. In patients with fistulas and tracheobronchomalacia, stents might be intentionally oversized because there is no constricting airway to prevent migration

In one technique of stent introduction, the stent is loaded into the dedicated stent deployment device and positioned just distal to the lesion. The stent is subsequently pulled proximally into its ideal position using rigid forceps. It is wiser to pull a stent proximally than to push a stent distally because pushing of the risk of perforation at the level of the pathologic airway. Y-stent placement follows the same rule (pull-back technique) (3). Upon deployment, the stent may not completely open, and a balloon catheter or one of the rigid instruments (rigid scope itself or the forceps) may be used to complete the expansion of the stent (Figure 1).

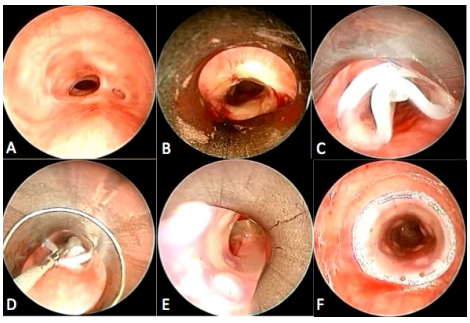

Figure 1: Technique of silicone stent placement:
A) Tracheal stenosis
B) Preliminary dilation using a rigid bronchoscope
C) The stent is inserted at the level of the stenosis
D) Rigid forceps unfold the proximal edge of the stent
E) The rigid tube is used to unfold the body the stent
F) Final result after complete opening

In my experience, the initial incomplete deployment of the stent suggests a lower risk of migration. Indeed, a stent that opens too easily is generally undersized and tends to migrate.

2. Stent Location and Airway Configuration: tips for on-site customization of silicone stent

A major advantage of silicone stents is the possibility to manipulate, remove and customize them during the procedure. Techniques exist to preserve ventilation to lobes that may be covered by an endobronchial stent, most commonly the right upper lobe using straight stents or Y stents (4). These include making fenestrations with a dedicated instrument (Figure 2).

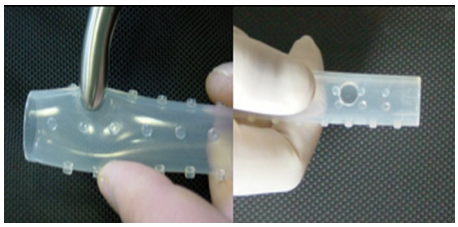

Figure 2: On-site customization of a Dumon Stent (dedicated instrument to create an orifice in order to ventilate a collateral bronchus).

I almost always customize Y-stents given that commercially available lengths are more than 15 cm in length, which in practice, is unnecessary. Both bronchial and tracheal limbs can be trimmed according to the measurements of the required airway being treated. Y stents can also be inserted to treat lesions involving the secondary carina (5) or the junction right main stem bronchus (RMSB)-right upper lobe bronchus (RULB)-bronchus intermedius (BI). For this latter location, an alternative to Y-stent insertion is the Oki stent, specifically designed and dedicated for this area (6), or a customized Montgomery T-Tube (the horizontal branch being inserted into the RULB) (7).

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Education and Training

As condors stretched their wings gliding high in the air in the azure sky outdoors, practitioners and trainees from Peru gathered in Arequipa, a historic city located 2300 meters above sea level, just below the edge of the Altiplano. Here, the Peruvian Pulmonary Society and the Peruvian Association for Bronchology and Interventional Pulmonology held its first regional Introduction to Flexible Bronchoscopy Program. The course was a great success as Peruvian certified instructors introduced participants to the use of checklists, bronchoscopy assessment tools, patient-centered practical approach exercises, structured didactic lectures, interactive sessions, and a technical skills workshop centered on the Fundamentals of Bronchoscopy© curriculum. The WABIP gratefully acknowledges Dr. Pedro Garcia Mantilla, Professor Oscar Gayoso President of the Peruvian Pulmonary Society, and master instructor Patricia Vujacich for their leadership and enthusiasm, as well as the Pentax Corporation and all the Peruvian trainers and participants who helped make this program a widely acclaimed success.

For more information about upcoming programs in other countries, go to the education page on the WABIP website.

Figure 1: Andean condor, one of the largest birds in the world, gliding effortlessly on air currents in the skies above Areguipa, Peru.

Figure 2: Certified Instructor and program director, Dr. Pedro Garcia Mantilla assisting a participant with step by step bronchoscopy instruction.

Figure 3: Professor Oscar Gayoso, President of the Peruvian Pulmonary Society and Coordinator of the Residency program at Cayetano Heredia Private University (center wearing necktie) with program instructors doctors Mario Paredes, Pedro Mantilla, Patricia Vujacich, and Elizabeth Becerra.

Research

Ground Glass Opacities
A completely different ball game!

Ground glass nodules (Ground Glass Opacities – GGO) are areas of increased density in which one can visualize bronchovascular structures and normal lung parenchyma. It's a well-known fact that the natural history of GGO is different from solid pulmonary nodules. The important questions about GGO are 1) which characteristics are associated with malignancy? and 2) what is their natural history? Answers to these questions could help clinicians predict which GGO lesions are likely to be so indolent that they are not clinically relevant.

Recently, the Fleischner Society published an additional set of guidelines that focus on GGO, or as they term them, "subsolid nodules" (1). The guidelines recommend no additional follow up for GGO lesions <5 mm. Lesions with solid components should be considered to have a high probability for malignancy. Lesions in the third category — pure GGO nodules greater than 5mm — have a less clear natural history. The study by Chang et al. (2) provides support for classification of GGO nodules >10 mm with or without solid components as being high risk for malignancy. Age, smoking history, number of lesions, and sex was not found to be predictive of growth. The high variability in individual growth patterns and lag times before growth further highlight the difficulty in developing guidelines for appropriate management of GGO nodules.

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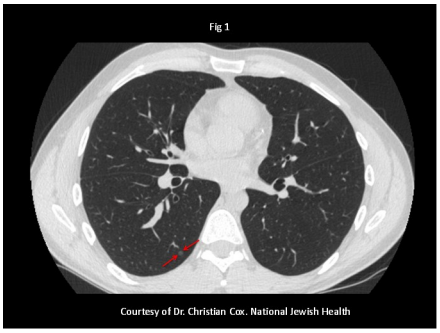

Fig 1: 5 mm pure Ground Glass Opacity

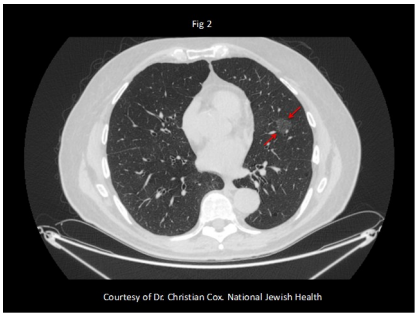

Fig 2: 1.6 cm pure Ground Glass Opacity

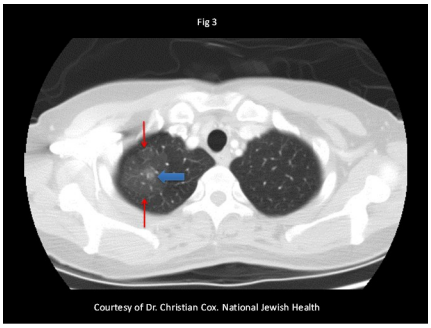

Fig 3: A right upper lobe large Ground Glass Opacity with solid center.

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WABIP News

ITEM 1: The WABIP is proud to welcome three new member societies into our global family; the Russian Association for Bronchology and Interventional Pulmonology, under the leadership of Professor Sokolov Victor Viktorovich, the Hellenic Thoracic Society Bronchology and Interventional Pulmonology Group under the auspices of Dr. Grigoris Stratakos, and the Asian Pacific Association for Bronchology and Interventional Pulmonology (APAB), led by Professor Takehiko Fujisawa (Japan).

ITEM 2: WABIP members are encouraged to nominate individuals for the Killian Centenary Medal or the WABIP-Dumon award. A description of the awards and nomination forms can be downloaded from the awards page at www.wabip.com! All applications will be reviewed by the WABIP Awards committee chaired by Professor Menaldi Rasmin (Indonesia). All committee rosters can be found on the committee page of the WABIP website at www.wabip.com.

ITEM 3: We are proud to announce the creation of a WABIP ad hoc Research Committee chaired by Dr. Lonny Yarmus (Johns Hopkins University, USA). This ad hoc research committee's first and important task is to advise the board of regents on the potential need and desire for an Interventional Pulmonary Clinical Trials Global Initiative (IPCTGI). Should such an initiative be accepted by the Board, it will be necessary to identify individuals interested in forming a WABIP international clinical trials group reflecting research interests of the global IP community.

ITEM 4: Please note the call for abstracts for the 2014 Kyoto WCBIP&WCBE. We encourage young investigators to submit abstracts and to compete for the *Heinrich Becker awards for research and clinical innovation*. A description of the award can be found on the WABIP website awards page at www.WABIP.com. All abstracts eligible for these awards will be reviewed and judged by the WABIP Awards committee.

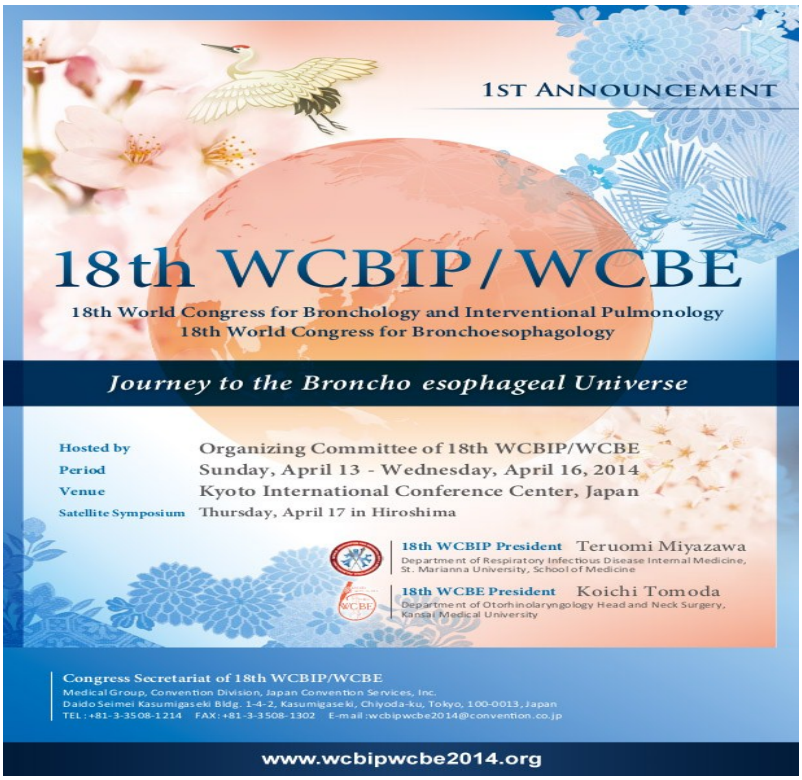
ITEM 5: The WABIP is proud to announce the successful 2013 meetings of the European Association for Bronchology and Interventional Pulmonology (EABIP President Professor Felix Herth, conference organization Dr. Semra Bilaceroglu and Dr. Benan Caglayan) in Izmir, Turkey and of the Asian Pacific Association for Bronchology and Interventional Pulmonology (APAB Chair Professor Takehiko Fujisawa, conference organization Professor Hojoong Kim) in Seoul, Korea). The next biennial meetings of these societies are scheduled for Barcelona (Spain), and Bangkok (Thailand) in 2015.

Figure 1: Drs. Caglayan and Bilaceroglu (2^{nd} and 3^{rd} persons from left in photo)

Figure 2: Drs Fujisawa and Kim (2^{nd} and 3^{rd} persons from left in photo)

Advertising

18th World Congress in Kyoto, Japan, April 2014



Links

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References: 1. Castro M, et al, for the AIR2 Trial Study Group. *Am J Respir Crit Care Med.* 2010;181:116-124. **2.** Wechsler M, et al; for the AIR2 Trial Study Group. *J Allergy Clin Immunol.* 2013; 132:1295-1302.