Flexible Bronchoscopy in Israel 2010: Evidence-Based Clinical Practice Guidelines for the Adult Patient

A concise summary of the recommendations of the Israel Lung Association Task Force

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Flexible bronchoscopy is an integral part of interventional pulmonology and one of the most frequently performed diagnostic and therapeutic procedures in chest medicine. In Israel, most of the bronchoscopies are performed in hospitals, and the bronchoscopic procedure and auxiliaries (diagnostic and therapeutic) are part of the specialty training in pulmonology [1].

In view of the tremendous progress in technology and diagnostic procedures in chest medicine in the last 20 years, the need for comprehensive evidence-based clinical practice guidelines was imperative. Guidelines for FB practice were published in Europe – the United Kingdom [2] and France [3] – and the techniques preferred by physicians were surveyed in the United States [4], Australia and New Zealand [5], Japan [6] and China.

It was patently obvious that the Israel Lung Association also had to establish national guidelines for the practice of FB, based on medical evidence available to date. Thus, in 2008 the Israel Lung Association established a task force to provide national guidelines for performing FB in adult patients. Members of this task force were elected from the country's major medical centers that perform bronchoscopic procedures; and experts from anesthesiology, chest surgery, ear, nose and throat surgery, as well as nursing, were asked to provide accurate and real-life guidelines. (A list of the task force members appears at the end of this report).

These guidelines for performing flexible bronchoscopy in the adult patient in Israel are published here for the first time

The task force's recommendations were not intended to describe indications for FB, but rather, are guidelines for preventing complications while respecting the patient's dignity and the absolute professional independence of the performing physician and his or her dedicated team.

A complete text of the task force's recommendations is available in Hebrew from the Israel Lung Association as a monograph and will be accessible in the near future from the Association's website [7]. The task force targeted six areas for guiding FB practice in the adult patient:

1. Safety of the patient
2. Safety of the performing team
3. Contraindications for FB and complications before, during and after the procedure
4. Infection control in the bronchoscopy suite and sterilization of instruments
5. Where to perform FB in a hospital facility and by whom (the FB staff comprises a physician/s, nurse/s, and technician/s)
6. Sedation/anesthesia for FB

Our recommendations were based on a simplified grading of the British Thoracic Society [2]:

Grade A: requires at least one randomized control trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation

Grade B: requires availability of well-conducted clinical studies but no randomized clinical trials on the topic of the recommendation

Grade C: requires evidence from expert committee reports or opinions and clinical experience of respected authorities.

It is the task force's belief that these guidelines will serve Israeli pulmonologists in their daily activities and will contribute to a high standard of care for our adult patients.

1. SAFETY OF THE PATIENT

The adult patient's satisfaction/acceptance of FB depends on many factors: his previous experience, his personality, his

FB = flexible bronchoscopy

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expectations from FB and its results, the pre-procedure preparations and the explanations provided by the performing team, possible follow-up and therapeutic approach, a comfortable atmosphere and professionalism during the procedure [8-11]. Communication between the patient and the FB team is the decisive factor throughout the whole procedure; this communication should be verbal and should also include the use of printed explanations. Detailed explanations on FB and possible complications, patterns of sedation, procedures performed (biopsies, washings, laser, stents, etc.) should be included in the formal signed consent for the bronchoscopy. The use of radiation (fluoroscopy) should also be mentioned. We strongly recommend the use of a standard form approved by the legal authorities as informed consent for FB. This has to be signed at least 24 hours before an elective procedure. Emergency FB may be decided on in accordance with the patient's medical condition and his or her ability to decide [2-6]. The recommendations are given below:

BEFORE FB PROCEDURES

- Detailed explanation (written and oral) of the procedure and its aims; this significantly improves the patient's tolerance (Grade B)
- A dedicated form for informed consent, detailing all the phases of the procedure and possible complications (Grade C)
- Fast: abstaining from liquids for 2 hours and solid food for 4 hours before FB (Grade B)
- Arterial blood gases for PCO_2 and PO_2 should be checked in patients with severe chronic obstructive pulmonary disease (forced expiratory volume in the first second/forced vital capacity less than 50% or FEV1 less than 1 L) and hypoxemia at rest (O_2 saturation < 93%) (Grade C) [12]
- Blood tests for coagulation and complete blood count are recommended only for patients with known risk factors: severe liver or kidney disease, thrombocytic disorders, and severe immune deficiency as a result of disease or drug therapy (Grade B) [13,14]
- Anticoagulation therapy (anti-vitamin K) should be discontinued at least 3 days before FB (INR not exceeding 1.5), and bridging with low molecular weight heparin (Clexan®) should be considered, while analyzing bleeding vs. thrombosis risk (Grade C) [15]
- Low molecular weight heparin Clexan should be discontinued 24 hours before FB; the performance of biopsies/brushes is based on the risk assessment of thrombosis vs. serious bleeding (Grade C) [16]
- Routine electrocardiography before FB is not necessary (Grade C) [17,18]
- Routine echocardiography before FB is not necessary (Grade C) [19]
- Acute myocardial infarction may postpone FB, if no life-saving procedure is necessary (e.g., life-threatening airway obstruction by secretions, blood clots, etc.) for 6 weeks (Grade C) [20]
- Prophylactic antibiotic therapy is recommended in patients following splenectomy, cardiac valve replacement or history of endocarditis (Grade B) [21,22]
- There is no need to discontinue aspirin, and biopsy procedures can be undertaken with FB (Grade C) [23]
- The use of clopidogrel should be stopped one week before FB (Grade C) [24]
- Inhalation of bronchodilators is recommended as premedication in patients with severe bronchial asthma or COPD (Grade B) [25]
- A peripheral intravenous line is mandatory during FB and following the procedure for drug and fluid administration (Grade C)
- The chronologic age of the patient is not a risk factor for FB (Grade C) [26]
- In pregnant patients, FB may be postponed, if possible, until delivery or at least until completion of the 28th week of pregnancy; the use of minimal dose medication (especially sedation) is recommended (Grade C) [27]
- Recommended sedation for FB outside the operating room is moderate: see paragraph 6 (sedation) (Grade B)

Areas addressed include patient and FB team safety, contraindications and complications of FB, infection control, sites for performing FB, and sedation techniques/medication

DURING FB PROCEDURES

- The patient's monitoring should include pulse, blood pressure, oximetry and 2 lead electrocardiography (Grade B)
- Oxygen supplement up to at least O_2Sat 90% is imperative for preventing serious heart arrhythmias (Grade B)
- The use of lidocaine is recommended with certain precautions (see paragraph 6 on sedation)
- The use of fluoroscopy during FB may improve the yield of certain procedures (like biopsies, brushing, stent placement) and may prevent the danger of iatrogenic pneumothorax (Grade B) [28]
- FB should be performed in designated places by a trained team (Grade C)
- Up-to-date resuscitation facilities (including medication) should be available at the FB procedure site and ready for use (Grade C)

FEV1 = forced expiratory volume in the first second

COPD = chronic obstructive lung disease
O_2Sat = oxygen saturation

FOLLOWING THE FB

- Optimal follow-up after FB should be conducted in a recovery room next to the FB suite or in the hospitalization ward (when the patient is hemodynamically and respiratorily stable) (Grade C)
- The patient's monitoring should continue (the same parameters) as during the FB (Grade C)
- The patient's surveillance is conducted by a bronchoscopy nurse or a nurse familiar with resuscitation and is the physician's responsibility (Grade C)
- The patient's transport to the hospitalization ward is the responsibility of the FB team (Grade C).
- The administration of oxygen may be required in the post-FB period, especially in patients with chronic heart or lung diseases, or following sedation (Grade B)
- Chest X-ray may be necessary in symptomatic patients following transbronchial biopsies up to 2 hours following the procedure (Grade B)
- The recommended follow-up is 2 hours post-FB (Grade C)
- Ambulatory patients should be accompanied home following FB, and explanations on possible complications in the 24 hours post-FB should be provided orally and in written form (Grade C)
- Driving and signing important documents are not recommended (Grade C)

2. SAFETY OF THE FB TEAM

Infectious diseases may be acquired during the FB at all phases as well as during the cleaning and sterilization process. Airborne or needle stick infections may occur with several viruses (hepatitis B and C, human immunodeficiency), bacteria or mycobacteria.

- The safety of the FB team is based on preventing infection or exposure to cleaning and sterilization products (Grade C)
- The FB team should use gowns, non-sterile gloves, glasses and micronic-type masks for protection (grade C)
- Protection against radiation (coats and glasses) is recommended (grade C)
- The FB suite should be ventilated with negative pressure directed outside or through a high efficiency particulate air filter (HEPA) (Grade C)
- Cleaning of the instruments should be performed in a dedicated room with optimal protection (Grade C)
- The FB team should be vaccinated against hepatitis B (Grade C)
- Screening programs (including for radiation) are recommended for the FB team (Grade C)

3. COMPLICATIONS AND CONTRAINDICATIONS FOR FB

FB is a safe procedure. In various reports from the early 1970s until the present, the rate of complications ranged between 0.08% and 1.08%, while mortality ranged from 0.01% to 0.04% [29-31]. The complications from FB may be categorized as major or minor:

MAJOR

- ▷ acute respiratory failure and life-threatening hypoxemia
- ▷ cardiac arrhythmias and cardiac arrest
- ▷ uncontrolled airway/lung parenchyma bleeding

MINOR

- ▷ fever
- ▷ vasovagal reactions
- ▷ controlled bleeding during and after the FB procedures
- ▷ raised intracranial pressure in head trauma patients

The contraindications for FB procedures are:

ABSOLUTE CONTRAINDICATIONS

- uncorrected hypoxemia ($O_2Sat < 90\%$)
- life-threatening cardiac arrhythmias
- unstable anginal syndrome*
- post-acute myocardial infarction*
- uncooperative patient*

*except for life-threatening airway obstruction (secretions, blood clots, etc.)

RELATIVE CONTRAINDICATIONS

- uncorrected coagulation defects
- severe thrombocytopenia ($< 50{,}000/mm^3$)
- serum creatinine > 3 mg/dl
- superior vena cava syndrome

4. INFECTION CONTROL IN THE FB SUITE, AND INSTRUMENT STERILIZATION

Since 2003 several reports have been published on FB-related infections. They included "distal" spread of infection, and transmission to other patients by the instrument or to the FB team. Three main sources of contamination were described [32]:

- Inadequate cleaning of the instrument: defects of the internal channel, uncleaned valves, uncleaned suction channel, repeated use of cleaning fluid or brushes
- Washing machine contamination (including from hospital-supplied water)
- Insufficient sterilization (quantity or concentration of liquids used)

Bronchoscopes, which are "semicritical" instruments (used in non-sterile areas), should be maintained according to the special cleaning and sterilization protocols recommended by the Israel Health Ministry.

CONCLUSIONS OF THE TASK FORCE

- Infection spread by FB is rare (Grade C)
- Most infections are bacterial or fungal, not viral (Grade C)

- There are special difficulties in sterilizing against mycobacteria (mainly non-tuberculous) (Grade C)
- Automatic cleaning/sterilization devices should be used for sterilization (Grade C)
- Forceps/brushes sterilization should be performed in an autoclav (Grade C)
- The protocol for cleaning/sterilization is recommended by the Health Ministry
- Protocols for the quality of cleaning/sterilization procedures have to be adopted by every medical facility performing FB (grade C)

5. SITES FOR FB PROCEDURES IN A HOSPITAL FACILITY AND THE FB STAFF

In Israel, FB is performed mainly in hospital facilities at various sites. The FB suite is usually inside a Pulmonary Unit, but FB may also be performed in radiology rooms, intensive care units or high dependence units, recovery rooms, operating room, and, rarely, bedside in hospitalization wards.

- The FB staff should include a trained physician and at least one dedicated nurse for diagnostic procedures and additional personnel for therapeutic procedures. The task force recommendations are:
- FB should be performed in dedicated suites for both diagnostic and therapeutic targets in every possible medical condition (Grade C)
- FB should be evaluated for risk/benefit ratio in patients hospitalized in intensive care or high dependence units (Grade B)
- FB in intubated patients should be performed with consideration of optimal ventilation and oxygenation; the endotracheal/tracheostomy tube diameter should be 2 mm larger than the outer diameter of the instrument (Grade C)
- A complete record of the procedure and medication used is mandatory (Grade C)
- The FB team should include a trained physician and at least one dedicated nurse for diagnostic procedures; therapeutic procedures may require additional staff for monitoring the patient or for instrumental use (laser, stents, etc) (Grade C)

6. SEDATION/ANESTHESIA FOR FB

Sedation for FB is performed frequently and depends largely on the clinical experience and preference of the FB team. Serious differences of opinion exist between anesthesiologists and bronchoscopists as to the optimal sedation, medication to be used, and monitoring through sedation [33-40]. We tried to reach a consensus with our fellow anesthesiologists based on the updated medical literature and experience. The task force emphasizes again that these guidelines are intended to recommend but not to interfere with a competent decision of every team performing FB in a hospital-based facility. A detailed description of the medication used for sedation and debate regarding their application are available in the monograph [7]. For the purpose of this article we summarize the following recommendations:

- The recommended sedation for FB is moderate sedation if no contraindication exists (Grade B).
- The most used medication is a combination of a benzodiazepine (midazolam) and an opioid (fentanyl, alfentanil); however, the advantage of using this combination over a single drug (midazolam) has not yet been established (Grade B)
- Topical anesthesia with lidocaine is recommended at a maximal dosage of 0.5 mg/kg or maximum 400 mg per adult patient weighing 70 kg (Grade C)
- Sedation medication should be administered at progressively higher dosage until the desired effect is obtained (Grade C)
- The recommended medication for FB sedation is one with an antidote (Grade C)
- Patients undergoing FB should fit the ASA I, II, III categories according to the American Society of Anesthesiologists classification (Grade C)
- If moderate sedation is insufficient for a safe FB, then deep sedation may be necessary with the anesthesiologist's assistance (Grade C)
- For diagnosing FB, moderate sedation is sufficient (Grade C)
- For complex therapeutic procedures (laser, bronchial dilatation, stent placement, etc.), deep sedation may be necessary with the anesthesiologist's assistance (Grade C)
- A least one member of the FB team should be familiar with ACLS (Advance Cardiac Life Support) guidelines (Grade C)

These guidelines were balanced between best standard of care recommendations and the personal experience of the performing FB teams

In conclusion, evidence-based clinical practice guidelines are intended to be a first step towards establishing standards of care. FB is the most used procedure in interventional pulmonology, and the need for accepted standards of care is obvious. The Israel Lung Association Task Force recommendations serve this purpose and will help Israeli pulmonologists in their daily activities. These recommendations should be updated in the next few years.

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