Saudi Lung Cancer Guidelines

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ON BEHALF OF SAUDI LUNG CANCER ASSOCIATION

LCAAC, Oct 2014
### Lung Cancer Guidelines
**Saudi Lung Cancer Association**

<table>
<thead>
<tr>
<th>Name</th>
<th>Specialty</th>
<th>Institution</th>
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<tbody>
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</table>
The Algorithm Flow

Diagnosis → Preparatory Stage → Decision making point
Decision → Evaluate outcome → Subsequent decision
Evaluate subsequent outcome → Closing decision

Closing decision: Palliative Care referral, consider clinical trial, physician discretion.
Recommendation SHOULD ADDRESS FIVE POINTS:

1. Confirming the diagnosis.
2. Determining the proper stage.
3. Offering a curative treatment; whenever possible.
4. Help prolong survival when cure is not attainable or offer better symptom control & palliation.
5. Encourage participation in clinical trials.
EVIDENCE LEVELS:

The following evidence levels (EL) were adopted for these guidelines:

- (EL-1) High Level: well conducted phase III randomized studies or well done meta-analyses.
- (EL-2) Intermediate Level: good phase II data or phase III trials with limitations.
- (EL-3) Low Level: observational or retrospectives studies expert opinions.
Disclaimers

• We are borrowing the evidence.... Need to determine our own evidence
• Guidelines does NOT replace judgment and experience
• “The guideline world” some times faces the harsh reality of the real world... economy and the rules of big brother (government, hospital leaders, etc)
I. ALL LUNG CANCER PATIENTS

1.1 INITIAL PATIENT ASSESSMENT

1.1.1 Perform history and physical examination, and document smoking history and performance status.

1.1.2 Perform the following laboratory tests: Complete blood count (CBC), differential, liver function test (LFT), renal function, electrolytes, calcium, serum albumin, magnesium and phosphorus.

1.1.3 Two-view chest x-ray.
1.2 DIAGNOSIS

1.2.1 Obtain adequate tissue specimen for diagnostic and predictive markers.

1.2.2 Confirm histopathological diagnosis of lung cancer and determine the histological subtypes of non-small cell lung cancer i.e. adenocarcinoma vs squamous cell vs large cell carcinoma using most recent pathological classification of lung cancer. Utilization of proper immunohistochemistry staining (minimal panel to include TTF1 (most important), CK7, and CK20 for adenocarcinoma and P40 (preferred) or P63 to minimize the diagnosis of “not otherwise specified” (NOS).

1.2.3 Obtain epidermal growth factor receptor (EGFR) mutation testing by PCR in certified laboratory for all histology except pure squamous cell.

1.2.4 In EGFR Wild Type (WT) tumors, obtain EML4-ALK fusion test by FISH in certified laboratory.
1.3 STAGING

1.3.1. Non-Small Cell Lung Cancer

1.3.1.1 Obtain contrast enhanced CT scan of the chest and abdomen.

1.3.1.2 Obtain Magnetic Resonance Imaging (MRI) of brain for stages IB-IV (preferred over contrast enhanced CT scan).

1.3.1.3 Obtain total body positron emission tomography/computed tomography (PET/CT) scan when available if the patient is considered for radical therapy (such as surgery or chemoradiotherapy).

1.3.1.4 Obtain bone scan for stages IB-IV if PET/CT is not done.

1.3.1.5 Perform mediastinoscopy in selected cases; i.e. clinical stages (IB-III). Mediastinoscopy can be omitted if PET/CT Scan is negative.

1.3.1.6 Determine precise TNM staging using 7th edition (2009).
1.3.2. Small Cell Lung Cancer

1.3.2.1 Obtain contrast enhanced CT scan of chest and abdomen.

1.3.2.2 Obtain Magnetic Resonance Imaging (MRI) of brain for stages IB-IV (preferred over contrast enhanced CT scan which can be if MRI is not available).

1.3.2.3 Obtain PET/CT scan if the disease in stages I-III.

1.3.2.4 Obtain bone scan if PET/CT is not done.

1.3.2.5 Determine precise TNM staging using 7th edition (2009).
1.4 PRE-TREATMENT ASSESSMENT

1.4.1 Discuss all new cases in a multidisciplinary conference (Tumor Board).

1.4.2 Obtain pulmonary function tests if surgery or curative radiotherapy is considered.
1.5 GENERAL

1.5.1 Offer available clinical research studies.

1.5.2 Counsel about smoking cessation and pulmonary rehabilitation.
II. NON-SMALL CELL LUNG CANCER

2.1 CLINICAL STAGE IA

2.1.1. Anatomical surgical resection and mediastinal lymph node sampling.

2.1.2. No need for adjuvant chemotherapy (EL-1).

2.1.3. If optimal surgery cannot be performed, consider limited surgery (wedge resection or segmentectomy) (EL-1).

2.1.4. For positive surgical margins perform re-resection (EL-1). If not possible offer curative radiotherapy (EL-2).

2.1.5. If surgical resection is not possible, offer curative radiotherapy (EL-1).

2.1.6. Follow up and surveillance per section 2.8 (follow up of non small cell lung cancer).
2.2 CLINICAL STAGE IB

2.2.1 Anatomical surgical resection mediastinal lymph node sampling (EL- 1) or dissection (EL- 3).

2.3.2 For lesions ≥ 4 cm or high-risk features (poorly differentiated, wedge resection, minimal margins, vascular Invasion), consider adjuvant chemotherapy. (EL- 2).

2.3.3 Chemotherapy of choice: 4-6 cycles of cisplatin (carboplatin only if cisplatin is contraindicated) with docetaxel, gemcitabine or venorelbine (EL- 1) or carboplatin and paclitaxel.

2.3.4 If optimal surgery cannot be performed, consider limited surgery (wedge resection or segmentectomy) (EL- 1).

2.3.5 For positive surgical margins perform re-resection (EL- 1) and if not possible, offer curative radiotherapy (EL- 2).

2.3.6 If surgical resection is not possible, offer curative radiotherapy (EL- 1).

2.3.7 Follow up and surveillance per section 2.8 (follow up of non small cell lung cancer).
2.3 CLINICAL STAGE IIA

2.3.1 Anatomical surgical resection with lobectomy or pneumonectomy and mediastinal lymph node sampling (EL-1) or dissection (EL-3).

2.3.2 Offer adjuvant therapy as per 2.2.3 (EL-1).

2.3.3 If optimal surgery cannot be performed, consider limited surgery (wedge resection or segmentectomy) (EL-1).

2.3.4 For positive surgical margins perform re-resection (EL-1) and if not possible, offer curative radiotherapy (EL-2).

2.3.5 If surgical resection is not possible, offer curative radiotherapy (EL-1).

2.3.6 Follow up and surveillance per section 2.8 (follow up of non small cell lung cancer).
2.4 CLINICAL STAGE IIB

2.4.1 Anatomical surgical resection and mediastinal lymph node sampling (EL- 1) or dissection (EL- 3).

2.4.2 Offer adjuvant therapy similar to 2.2.3 (EL- 1).

2.4.3 Superior sulcus tumors patients should be induced by cisplatin/etoposide with concurrent radiation therapy followed by surgical resection (EL- 2). Assess disease extent by using MRI at baseline and pre-operative.

2.4.4 For T3 N0 M0 perform en-bloc resection (EL- 1).

2.4.5 If optimal surgery cannot be performed, consider limited surgery (wedge resection or segmentectomy) (EL- 1).

2.4.6 For positive surgical margins perform re-resection (EL- 1) and if not possible, offer curative radiotherapy (EL- 2).

2.4.7 If surgical resection is not possible, offer curative radiotherapy (EL- 1).

2.4.8 Follow up and surveillance per section 2.8 (follow up of non small cell lung cancer).
2.5. CLINICAL STAGE IIIA

2.5.1 For T3 N1 M0 perform en-bloc resection (EL-1).

2.5.2 For superior sulcus tumor, offer treatment similar to 2.4.3 (EL-2).

2.5.3 For N2 disease offer neoadjuvant concurrent chemo-radiotherapy (EL-1) assess response. If resectable, offer surgery. For non-resectable tumors, continue with the appropriate treatment based on disease status.

2.5.4 If positive N2 disease discovered during surgery by frozen section abort surgery if pneumonectomy is required (EL-2).

2.5.5 Incidental pathological N2 disease, adjuvant chemotherapy is indicated (EL-1) radiotherapy can be considered (EL-3).

2.5.6 For T4 (2 nodules in ipsilateral separate lobes), offer pneumonectomy followed by adjuvant chemotherapy.

2.5.7 T4 (mediastinal involvement or main airway involvement), offer surgery if potentially curative, if not possible, offer definite concurrent chemoradiotherapy (2.5.1.)

2.5.8 For non N2 stage IIIA, not specified above, offer surgical resection with adjuvant chemotherapy (EL-1). Adjuvant radiotherapy may be considered (EL-3).

2.5.9 Follow up and surveillance per section 2.8 (follow up of non small cell lung cancer).
2.6.1 Offer concurrent chemo-radiotherapy (EL1) followed by chemotherapy (EL2). Surgical resection for selected cases could be offered.

2.6.2 Follow up and surveillance per section 2.8 (follow up of non small cell lung cancer).
# Metastatic NSCLC Management Guidelines

## Diagnosis

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Performance Status</th>
<th>1. Determining Histology Subtype</th>
<th>2. EGFR Mutation Testing</th>
<th>3. EML4-ALK-Fusion Testing</th>
<th>Squamous Cell Carcinoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non Squamous Cell Carcinoma</td>
<td>EGFR+</td>
<td>EML4-ALK+</td>
<td>EGFR WT</td>
<td>EGFR Unknown</td>
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<tr>
<td>First line</td>
<td>0-2</td>
<td>TKI or Platinum doublet (Pemetrexed) +/- Bevacizumab</td>
<td>Crizotinib or Platinum doublet (Pemetrexed) +/- Bevacizumab</td>
<td>Platinum doublet (Pemetrexed) +/- Bevacizumab</td>
<td>Platinum doublet (Pemetrexed) +/- Bevacizumab</td>
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<tr>
<td></td>
<td>3</td>
<td>TKI, single agent chemotherapy</td>
<td>Crizotinib, TKI, single agent chemotherapy or TKI</td>
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<td>4</td>
<td>TKI* Palliative Care</td>
<td>Crizotinib* Palliative Care</td>
<td>Palliative Care</td>
<td>TKI* Palliative Care</td>
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<tr>
<td>Maintenance</td>
<td>0-2</td>
<td>TKI or Pemetrexed Bevacizumab**</td>
<td>Crizotinib, TKI, Pemetrexed Bevacizumab**</td>
<td>Pemetrexed or TKI Bevacizumab**</td>
<td>TKI or Docetaxel</td>
</tr>
<tr>
<td>Second Line</td>
<td>0-2</td>
<td>TKI if not used. Pemetrexed or docetaxel</td>
<td>Crizotinib if not used. Ceritinib if Crizotinib is used. TKI, Pemetrexed or docetaxel</td>
<td>Pemetrexed if not used. TKI or Docetaxel</td>
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<tr>
<td></td>
<td>3</td>
<td>TKI</td>
<td>Crizotinib, ceritinib, TKI</td>
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<tr>
<td></td>
<td>4</td>
<td>TKI if not used</td>
<td>Crizotinib, ceritinib or TKI if not used</td>
<td>Palliative Care</td>
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<tr>
<td>Third Line</td>
<td>0-3</td>
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<td>Palliative Care</td>
<td>Palliative Care</td>
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Modified From: ARJ, Saudi Lung Cancer Guidelines, JIPH, 2012

TKI: Tyrosine Kinase Inhibitor: Erlotinib or Gefitinib
* Selected cases; ** Continue bevacizumab, if given first line.
2.7 STAGE IV

2.7.1 Systemic Therapy (See Tables 1 and 2)

2.7.1.1. Stage M1a (with pleural effusion) assess the need for thoracentesis and pleurodesis. Offer systemic therapy as below.

2.7.1.2. With brain metastases
   • Consider surgery for patient with single brain metastasis.
   • Refer to radiation oncology for local treatment of the CNS disease.
   • After CNS disease control, start systemic therapy as in 2.7.1.4.

2.7.1.3. Isolated adrenal metastasis. Consider surgical resection (confirm histologically before surgery). Discuss with multidisciplinary team.

2.7.1.4. No brain metastases/Treated brain disease, no prior systemic treatment for metastatic disease. (See Table 1)
2.7 STAGE IV

2.7.1.4.1. Adenocarcinoma/non-squamous EGFR Mutation (excluding exon 20 mutations)

A. First line:
1. Performance Status 0-2:
   Use TKIs (Erlotinib, Gefitinib, or Afatinib) EL1. Preferred option.
   Systemic chemotherapy (platinum doublet +/-bevacizumab) (Pemetrexed is preferred over gemcitabine).

2. Performance Status 3:
   Use TKIs (Erlotinib, Gefitinib, or Afatinib). Preferred option.
   Single agent chemotherapy (Pemetrexed is preferred over gemcitabine)

3. Performance Status 4:
   Use TKIs (Erlotinib, Gefitinib, or Afatinib)
   Palliative care
2.7 STAGE IV

2.7.1.4.1. Adenocarcinoma/non-squamous EGFR Mutation (excluding exon 20 mutations)

B. Maintenance:

1. Performance Status 0-2:
   Continuation or switch maintenance with TKIs. If was not started on TKIs, patient should be switched to TKIs ASAP. Continue Bevacizumab, if started in first line.

2. Performance Status 3 and 4:
   Continuation or switch maintenance with TKIs. If was not started on TKIs, patient should be switched to TKI ASAP.
2.7 STAGE IV

2.7.1.4.1. Adenocarcinoma/non-squamous EGFR Mutation (excluding exon 20 mutations)

C. Second line

1. Performance Status 0-2:
   Use **TKIs**, if not used in first line.
   Systemic Chemotherapy (platinum doublet+/-bevacizumab)
   (Pemetrexed is preferred over gemcitabine).

2. Performance Status 3:
   Use TKIs, if not used in first line.
   If TKI used, consider single agent chemotherapy (Pemetrexed preferred over gemcitabine).

3. Performance Status 4:
   Use TKIs, if not used in first line.
   If TKIs were used, refer to palliative care.
2.7 STAGE IV

2.7.1.4.1. Adenocarcinoma/non-squamous EGFR Mutation (excluding exon 20 mutations)

D. Third Line and Beyond

1. Performance Status 0-2:
   Use TKIs, if not used before.
   Systemic chemotherapy (single agent chemotherapy, Pemetrexed if not used, docetaxel, etc)

2. Performance Status 3 and 4:
   Use TKIs, if not used in first line.
   If TKIs were used, refer to palliative care.
2.7 STAGE IV

2.7.1.4.2. Adenocarcinoma/non-squamous ALK fusion positive

A. First Line
1. Performance Status 0-2:
   Use Crizotinib. EL1. Preferred option.
   Systemic Chemotherapy (platinum doublet+/bevacizumab) (Pemetrexed preferred over gemcitabine) EL 2.

2. Performance Status 3:
   Use Crizotinib. EL1. Preferred option.
   Single agent chemotherapy (Pemetrexed preferred over gemcitabine)

3. Performance Status 4:
   Use Crizotinib. EL1. Preferred option.
   Palliative care
2.7 STAGE IV

2.7.1.4.2. Adenocarcinoma/non-squamous ALK fusion positive

B. Maintenance

1. Performance Status 0-2:
   Continuation or switch maintenance with Crizotinib. If was not started on Crizotinib, patient should be switched to Crizotinib ASAP.
   Continue Bevacizumab, if started in first line.

2. Performance Status 3 and 4:
   Continuation or switch maintenance with Crizotinib. If was not started on Crizotinib, patient should be switched to Crizotinib ASAP.
2.7 STAGE IV

2.7.1.4.2. Adenocarcinoma/non-squamous ALK fusion positive

**C. Second Line**

1. **Performance Status 0-2:**
   Use Ceritinib, if Crizotinib used before
   Use Crizotinib, if not used in first line.
   Systemic Chemotherapy (platinum doublet+/-bevacizumab) (Pemetrexed is preferred over gemcitabine).

2. **Performance Status 3:**
   Use Ceritinib, If Crizotinib used before
   Use Crizotinib, if not used before.

3. **Performance Status 4:**
   Use Ceritinib, if Crizotinib used before.
   Use Crizotinib, if not used before.
2.7 STAGE IV

2.7.1.4.2. Adenocarcinoma/non-squamous ALK fusion positive

D. Third Line and Beyond

1. **Performance Status 0-2:**
   Use Crizotinib or Ceritinib, if not used before.
   Systemic Chemotherapy (single agent chemotherapy, Pemetrexed, if not used, docetxel, etc)

2. **Performance Status 3 and 4:**
   Use Crizotinib or Ceritinib, if not used in first line.
   If both agent is used, palliative care.
2.7 STAGE IV

2.7.1.4.3. Adenocarcinoma/non-squamous EGFR/ALK wild type

A. **First Line**

1. Performance Status 0-2:
   Systemic Chemotherapy (platinum doublet+/−bevacizumab) (Pemetrexed preferred over gemcitabine).

2. Performance Status 3:
   Single agent chemotherapy (Pemetrexed is preferred over gemcitabine)
   Palliative care.

3. Performance Status 4:
   Palliative care
2.7 STAGE IV

2.7.1.4.3 Adenocarcinoma/non-squamous EGFR/ALK wild type

B. Maintenance

1. Performance Status 0-2:
   Continue or switch maintenance with Pemetrexed.
   Continue Bevacizumab, if started on first line.

2. Performance Status 3:
   Continue or switch maintenance with Pemetrexed.

3. Performance Status 4:
   Palliative care
2.7 STAGE IV

2.7.1.4.3. Adenocarcinoma/non-squamous EGFR/ALK wild type

C. Second Line

1. Performance Status 0-2:
   Single Agent Systemic Chemotherapy (Pemetrexed if not used, Docetaxel).
   Erlotinib (not gefitinib) can be used. EL3.

2. Performance Status 3:
   Single Agent Systemic Chemotherapy (Pemetrexed if not used, Docetaxel).
   Erlotinib (not Gefitinib) can be used. EL3.

3. Performance Status 4:
   Palliative care.
2.7.1.4.3. Adenocarcinoma/non-squamous EGFR/ALK wild type

D. **Third Line and Beyond**

1. **Performance Status 0-2:**
   Single agent systemic therapy.
   Erlotinib (not Gefitinib) can be used. EL3.

2. **Performance Status 3 and 4:**
   Palliative care.
2.7 STAGE IV

2.7.1.4.4. Adenocarcinoma/non-squamous EGFR status is unknown

A. First Line

1. Performance Status 0-2:
   Systemic Chemotherapy (platinum doublet+/- bevacizumab)
   (Pemetrexed preferred over gemcitabine).

2. Performance Status 3:
   Single agent chemotherapy (Pemetrexed preferred over gemcitabine)
   Use TKIs (Erlotinib, Gefitinib).

3. Performance Status 4:
   Palliative care
2.7 STAGE IV

2.7.1.4.4. Adenocarcinoma/non-squamous EGFR status is unknown

B. Maintenance

1. Performance Status 0-2:
   Continue or switch maintenance with Pemetrexed.
   Continue Bevacizumab, if started on first line.

2. Performance Status 3:
   Continue or switch maintenance with Pemetrexed.

3. Performance Status 4:
   Palliative care
2.7 STAGE IV

2.7.1.4.4. Adenocarcinoma/non-squamous EGFR status is unknown

C. Second Line

1. Performance Status 0-2:
   Single Agent Systemic Chemotherapy (Pemetrexed if not used, Docetaxel).
   Erlotinib (not gefitinib) can be used. EL2.

2. Performance Status 3 and 4:
   Palliative care.
2.7 STAGE IV

2.7.1.4.4. Adenocarcinoma/non-squamous EGFR status is unknown

D. Third Line and Beyond

1. Performance Status 0-2:
   Systemic Chemotherapy (single agent chemotherapy, Pemetrexed if not used, docetaxel)

2. Performance Status 3 and 4:
   Palliative care.
2.7 STAGE IV

2.7.1.4.5 Squamous cell carcinoma:

A. First Line

1. Performance Status 0-2:
   Systemic Chemotherapy (platinum doublet) (No Bevacizumab or Pemetrexed).

2. Performance Status 3:
   Single agent chemotherapy (No Pemetrexed)

3. Performance Status 4:
   Palliative care
2.7 STAGE IV

2.7.1.4.5 Squamous cell carcinoma:

B. Maintenance

1. Performance Status 0-2:
   Continuation or switch maintenance with docetaxel.

2. Performance Status 3 and 4:
   Palliative Care
2.7 STAGE IV

2.7.1.4.5 Squamous cell carcinoma:

C. Second Line

1. Performance Status 0-2:
   Single agent systemic Chemotherapy (No Pemetrexed).

2. Performance Status 3:
   Single agent systemic therapy

3. Performance Status 4
   Palliative Care
2.7 STAGE IV

2.7.1.4.5 Squamous cell carcinoma:

D. Third Line and Beyond

1. Performance Status 0-2:
   Single agent systemic therapy

2. Performance Status 3 and 4:
   Palliative care.
2.8. FOLLOW UP OF NON SMALL CELL LUNG CANCER

Evaluation includes: History and physical examination, laboratory and chest x-ray.

2.8.1 For tumor stage I-III: evaluation every 3 months for 2 years then every 6 months for 3 years then annually. CT scan of the chest every 6 months for 2 years then annually for 3 years.

2.8.2 Stage IV: evaluation every 2-3 months as clinically indicated.
III. SMALL CELL LUNG CANCER

3.1 Stage I-III (Previously called limited stage):

3.1.1 Offer cisplatin/etoposide with radiation therapy then consolidate with two cycles of cisplatin/etoposide (EL-1). May substitute cisplatin with carboplatin in patients with neuropathy, renal dysfunction or hearing problem.

3.1.2 After definitive therapy with Complete Response (CR) or near CR offer prophylactic cranial irradiation (PCI) (EL-1).

3.1.3 For stage (T1-2 N0 confirmed by mediastinoscopy), offer surgical resection followed by chemotherapy, radiotherapy and prophylactic brain radiotherapy (EL-2).

3.1.4 Follow up and surveillance per section 3.3.
3.2 STAGE IV

3.2.1 Offer cisplatin/ etoposide or cisplatin/irinotecan x 6 cycles (EL-1).

3.2.2 After definitive therapy with evidence of response and good performance status offer PCI (EL-1).

3.2.3 For previously treated patients who relapsed in less than 6 months from initial treatment, offer topotecan (EL-1) or cyclophosphamide, adriamycin and vincristin (CAV), or camptozar.

3.2.4 For relapse after six months from initial treatment, may use original regimen.

3.2.5 Follow up and surveillance per section 3.3.
3.3 FOLLOW UP AND SURVEILLANCE

3.3.1 Evaluation includes: history and physical examination, laboratory data and chest x-ray.

3.3.2 Stage I-III: evaluation every 3 months for 2 years then every 6 months for 3 years then annually. CT scan of the chest every 6 months for 2 years then annually for 3 years.

3.3.3 Stage IV: evaluation every 2-3 months as clinical indicated
Future Direction

- Modification → Publication
- Dissemination → Monitoring and Auditing