



Chronic Obstructive Pulmonary Disease Pathway

Background

- COPD is the [number 2](#) cause of mortality in India
- Obstructive lung diseases are [the 2nd most common reason](#) for presentation to primary care practitioners in India
- Up to [70% of COPD worldwide](#) may be un-diagnosed
- Smoking and environmental exposures (e.g. indoor fuel burning) are major risk factors for COPD

India specific challenges to overcome

- Diagnostic challenges
 - o Spirometry access + training of providers
 - Adequate technique required to generate meaningful flow curves for diagnosis
 - o Diagnostic entities unique to India
 - Non-smoker COPD (e.g. biomass fuels)
 - [TB-associated COPD/ Post TB](#)
 - [Occupation associated](#)
 - o In the absence of spirometry, how do we diagnose?
 - Current standard practice in India □ dx based on symptom complex
- Cost barriers
 - o Inhalers are costly
- Cultural barriers
 - o Stigma associated with inhaler use
 - o Compliance issues with increasing number of inhalers (not necessarily India-specific)
- Existing practice
 - o Broad use of theophylline

Diagnosis

- Consider COPD if history of shortness of breath/dyspnoea or chronic cough, and risk factors for COPD – consider duration of symptoms
- Consider and rule out differentials, including:
 - o Respiratory: Asthma, bronchiectasis, TB, obliterative bronchiolitis, diffuse bronchiolitis (sputum and CXR)
 - o Cardiac: heart failure (see CSA HF pathway)
- **Spirometry** is required for diagnosis: post-bronchodilation FEV1/FVC < 0.70
 - o See spirometry instructions in Appendix
 - o Training staff in adequate spirometry technique will be a challenge
- CXR: not diagnostic but can rule out other causes. COPD may present with lung hyperinflation
- IF spirometry unavailable (all CSA sites to be given spiro)



- In the absence of spirometry, diagnosis of COPD in India is often made based on symptom complex
- Symptoms suggestive of COPD include:
- There is significant overlap between COPD symptoms and other lung pathologies, including asthma, bronchiectasis, interstitial lung disease, etc.
- If COPD is diagnosed based on symptoms alone, trial therapy with careful follow up. If no clinical improvement, diagnosis **must** be revisited

Severity Assessment

- COPD severity can be categorised based on symptoms (mMRC scale; see appendix)
- Frequency of exacerbations/hospitalisations for COPD

Management of comorbidities

- COPD specific: sarcopenia/fragility, weight loss – Promote nutrition
- Others: cardiovascular diseases, metabolic syndrome, osteoporosis, lung cancer, mental health
- See CSA pathways for appropriate management

Non-pharmacological management

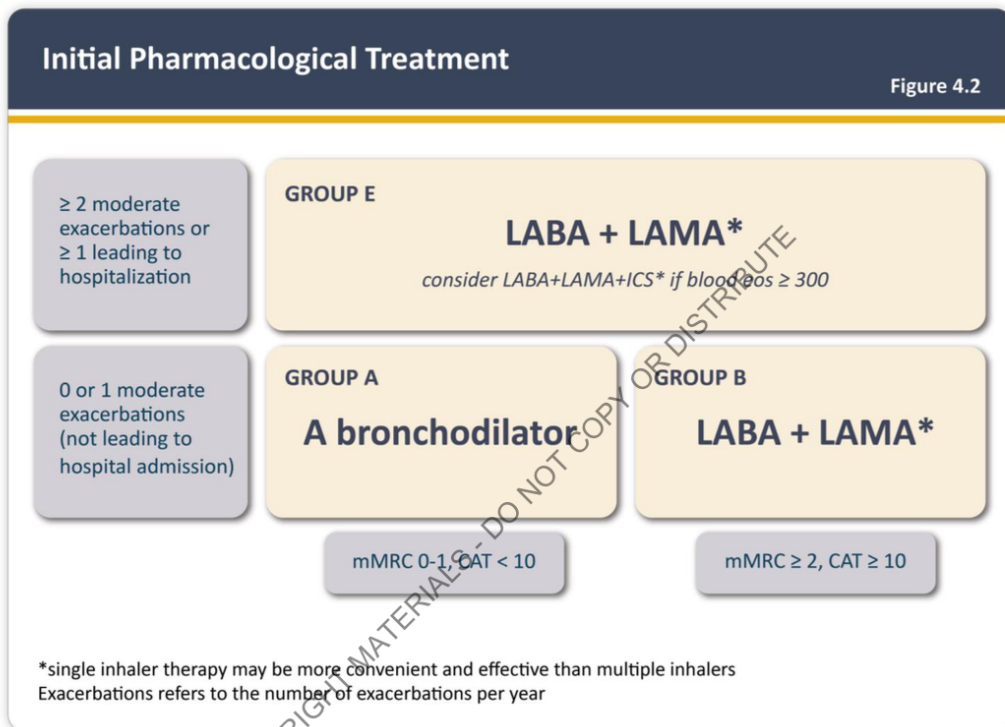
- **Smoking cessation**
 - Do we need a CSA pathway for this?
- Reduce exposure to indoor smoke/[biomass fuels](#)
 - Use of biomass fuels may be more prevalent in rural settings (i.e. places where CSA partner sites are)
 - How do we make this practical for people? This is a big structural issue
- Pulmonary rehab
 - Rehab/physiotherapy pathway TBD
 - Offer alternate occupation
 - Treat comorbidity

Maintenance medical therapy

- [WHO basic minimum package](#):
 - Maintenance: Salbutamol PRN +/- PO theophylline, +/- theophylline if available
 - Exacerbation: abx, pred, salbutamol, O₂
- Need costings for all the below:
- SABA
 - Salbutamol
- LABA
 - Salmeterol or Formeterol
- SAMA
 - Ipratropium
- LAMA
 - Tiotropium
- ICS

Assess disease severity and initiate maintenance therapy

- mMRC system (appendix)
- A – less symptomatic and low risk of exacerbation
 - o PRN bronchodilator – SABA or SAMA (see formulary for options) **OR**
 - o Combination SABA/SAMA
- B – more symptomatic and low risk of exacerbation
 - o Regular long-acting bronchodilator (LABA or LAMA) **AND**
 - o PRN SABA
- E – high risk of exacerbation (>2 moderate exacerbations or >= 1 leading to hospitalization)
- ICS: Can consider if 2 or more exacerbations annually and if blood eosinophils greater than 300



Definition of abbreviations: eos: blood eosinophil count in cells per microliter; mMRC: modified Medical Research Council dyspnea questionnaire; CAT™: COPD Assessment Test™.



- If on LABA + LAMA and if eosinophils > 300 □ LABA + LAMA + ICS
- If on LABA + LAMA and if eosinophils > 100 and if 2+ exacerbations a year □ LABA + LAMA + ICS
- If on ICS and inadequate response to treatment, consider de-escalation of ICS
- How do we want to address roflumilast? Any role for azithro?

Preventative care

- Preventative vaccination
 - COVID (all), flu (all), pneumococcal (65+ and high risk), pertussis

Interventions to avoid

- Do not use methylxanthines (theophylline) routinely for the management of COPD
 - Inhalers are first line therapy – they are safer and more effective
- Do not use inhaled steroids as monotherapy in COPD
- Mucolytic agents are not effective for the treatment of COPD
- Do not use long term oral steroids for the treatment of COPD

Management of advanced COPD (referral to specialist)

- Supplemental O₂
- Procedural interventions
- Palliative care

Indications for home oxygen therapy (given now possible after COVID)

- From [UpToDate](#)
- PaO₂ ≤ 55 mmHg (7.32 kPa) or SaO₂ ≤ 88 percent
- If cor pulmonale AND
 - PaO₂ ≤ 59 mmHg (7.85 kPa) or SaO₂ ≤ 89 percent
 - EKG evidence of P pulmonale
 - Hematocrit > 55 percent
 - Clinical evidence of right heart failure

Management of exacerbations

- Assess stability
 - Transfer patient if unstable, or if signs of airway compromise
- Cardinal symptoms of COPD exacerbation
 - Increased frequency/severity of cough
 - Increase/change in sputum
 - Increased dyspnoea
- Consider differentials (see relevant CSA pathways for management)
 - Respiratory: CAP, COVID, pulmonary embolism, pneumothorax, ptld
 - Cardiac: HF, ACS
 - Other: sepsis
- Airway management
 - All patients: Supplemental O₂ if hypoxic, titrate to SpO₂ 88-92%
 - NIV or intubation according to patient status and operator availability



- Relevant investigations (not required if outpatient management)
 - o ABG – not often available or understood for management
 - o CXR
 - o ECG
 - o Electrolytes
 - o Covid swab (CXR and CBC – infection)
- Determining outpatient vs inpatient management
 - o Potential indications for inpatient management
 -
- Initial therapy
 - o Regular SABA +/- SAMA via spacer
 - o Prednisone 40mg for 5 days
- Threshold for antibiotic administration
 - o 2 or more of:
 - Increased dyspnoea
 - Increased sputum volume
 - Increase sputum purulence
 - o Abx option
 - Azithromycin
 - 2nd or 3rd generation cephalosporin
 - Amox/Clav
 - Potentially cipro for pseudomonal cover (though use in India given TB) – Duration (avoid Levi in view of its anti-tubercular action)
 - only Amox (BHS)

(Elderly + diabetics)

Appendices

mMRC system

mMRC Grade	Description
Grade 0	I only get breathless with strenuous exercise
Grade 1	I get short of breath when hurrying on the level or walking up a slight hill
Grade 2	I walk slower than people of the same age on the level because of breathlessness, or I have to stop for breath when walking on my own pace on the level
Grade 3	I stop for breath after walking about 100 metres or a few minutes on the level
Grade 4	I am too breathless to leave the house or I am too breathless when dressing or undressing

APPENDIX A

List of available drugs along with cost information



Drug Class	Drug name	Type	Brand	Pricing
SABA	Salbutamol	Rotacaps	Cipla - Asthalin	200 mcg - 60 capsules in 1 bottle- Rs 98/pack
		Metered dose inhaler	Cipla - Asthalin	Rs 110/ box
		Respules	Cipla - Asthalin	2.5mg/2.5 ml pack of 5 - Rs 28
	Levisalbutamol	Rotacaps	Cipla- Levolin	100 mcg- 30 capsules in 1 bottle - Rs 30/pack
		Metered dose inhaler	Cipla- Levolin	50 mcg inhaler / Rs 200 per pack
		Respules	Cipla - Levolin , Lupin- Salbair	0.63 Mg/ 1 respule- Rs 5 per respule, 0.63mg/2.5 mL respule - Rs 7 per respule
Combination - SABA and SAMA	Ipravent and Levosalbutamol	Rotacaps	Cipla - Duolin	60 capsules - 100 + 40 mcg/ Rs 144 per bottle
		Metered dose inhaler	Cipla - Duolin Forte	200 mdi inhaler - Rs 393
		Respules	Cipla - Duolin	3 ml respules - pack of 5- Rs 104
ICS	Fluticasone	Rotacaps		
		Metered dose inhaler	Cipla - Flohale	125 mcg/dose, Rs 267/ inhaler



		Respules	Cipla-Flohale	0.5 mg respules - Rs 240
	Budesonide	Rotacaps	Cipla - Budecort	200 mcg , 30 capsules in 1 bottle - Rs 92
		Metered dose inhaler	Cipla-Budesonide inhaler	100, 200 mg- Rs 400
		Respules	Cipla - Budecort respules	0.5 mg respules, Rs 115 - pack of 5
	Ciclesonide	Rotacaps	Cipla - Ciclohale	400 mcg -30 capsules , Rs 195
		Metered dose inhaler	Cipla-Ciclohale, Ranbaxy - Osonide	Ciclohale- 160 mcg- Rs 350, Osonide- 160 mcg- Rs 300
		Respules	NA	
Triple therapy, combination drug ICS+LABA+LAMA	beclometasone dipropionate/formoterol fumarate/glycopyrronium bromide (BDP/FF/G)	pressurized metered-dose inhaler	TRIMBO W®, Chiesi Farmaceutici SpA	Single dosage- 87/5/9 µg (two inhalations twice daily)
	Fluticasone Furoate/Umeclidinium/Vilantero FF/UMEC/VI	Multidose dry-powder inhaler (MDDPI) formulation to be delivered through the ELLIPTA inhaler device (Single-Inhaler Triple Therapy (SITT))	TRELEGY ELLIPTA®, GlaxoSmithKline	Single dosage- 92/22/55 µg (one inhalation per day) - Maintenance treatment of both asthma and COPD

	GlaxoSmithKline FF/UMEC/VI	Dry powder inhaler	Trelegy Ellipta	Once daily - Maintenance treatment of COPD; ₹2822/box
	AstraZeneca BDP/FOR/GP Beclomethasone/Formoterol/Gly copyrronium	pressurized metered- dose inhaler	BREZTRI	Twice daily (CJ: can't find this drug online; probably not sold in India yet)
	Novartis IND/GLY/MF Indacaterol/Glycopyrronium/Mo metasone furoate	Dry powder inhaler	Energair Breezhaler	Once daily (CJ: can't find this drug online; probably not sold in India yet)
	Glenmark GLY/FOR/FP Glycopyrronium/Formoterol/Flu ticasone propionate	Dry powder inhaler	Airz-FF	Twice daily ; ₹535/box of 30 capsules
	Cipla GLY/FOR/BUD Glycopyrronium/Formoterol/Bu desonide	Dry powder inhaler	Glycohale- FB	Twice daily; ₹184.7/box of 10 rotacaps
	Tiotropium/Formoterol/Cicleson ide (TFC)	Dry powder inhaler (DPI)/ Pressured metered dose inhaler (pMDI)	Triohale®, Cipla	18 mcg/12 mcg/400 mcg - once-daily; ₹1132/ inhaler with 200 metered doses



ICS and LABA-combination	Fluticasone and Salmeterol	Rotacaps	Macleods Pharma-Flutrol, Zydus Cadila-Forair R cap, Seroflo-500 rotacaps	Flutrol rota capsule- 50/100 mcg- Rs 155, Forair R cap- 100/50 mcg- Rs 361- for 30 capsules, Seroflo500 rotacaps -500/50 mcg- Rs 472
		Respules	Lupin Labs- Esiflo,	Esiflo- 100/50 mcg- 30 capsules Rs 108
		Metered dose inhaler	Glenmark - Airtec SF, Sun pharma- Combicide	Airtec SF- 50 mcg/100 mcg- Rs 330, Combicide - 25/125 mcg - Rs 292
(rapid onset)	Budesonide and Formoterol	Rotacaps	Zydus cadila - Formonide Resicaps ,	Formonide resicaps- 200/6 mcg- Rs 147- for a bottle of 30
		Respules		
		Metered dose inhaler	Kopran Pharma- VentFB inhaler	Vent FB inhaler - 100/6 mcg- Rs 134
	Fluticasone and Vilanterol	Rotacaps		
ICS and SABA combo	Budesonide (0.5 Mg) + Salbutamol / Albuterol(1.25 Mg)			Budesal 0.5mg 2ml Packet Of 5 Respules for ~ Rs 240
				Derisal 0.5mg 2ml Packet Of 7 Respules for ~ RS 340



	Levosalbutamol (50mcg) + Beclometasone (50mcg)		Cipla	Aerocort Inhaler for ~Rs 270 / 1 Packet 200 MDI Inhaler
		Respules		
		Metered dose inhaler		
LABA+LAMA	Formoterol Fum.	single inhaler device disposable	Tioform	Dosage- 6 or 12 µg (18/12 mcg; 9/6 mcg); ₹677
Prednisolone		(40-50mg)	various brands	40mg oral - avg Rs 25/ strip of 10 tablets
			Depomax S 40mg Injection, Mpss 40mg Injection	Rs 100-150