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Issue 10: Pulmonary & Critical Care Insider

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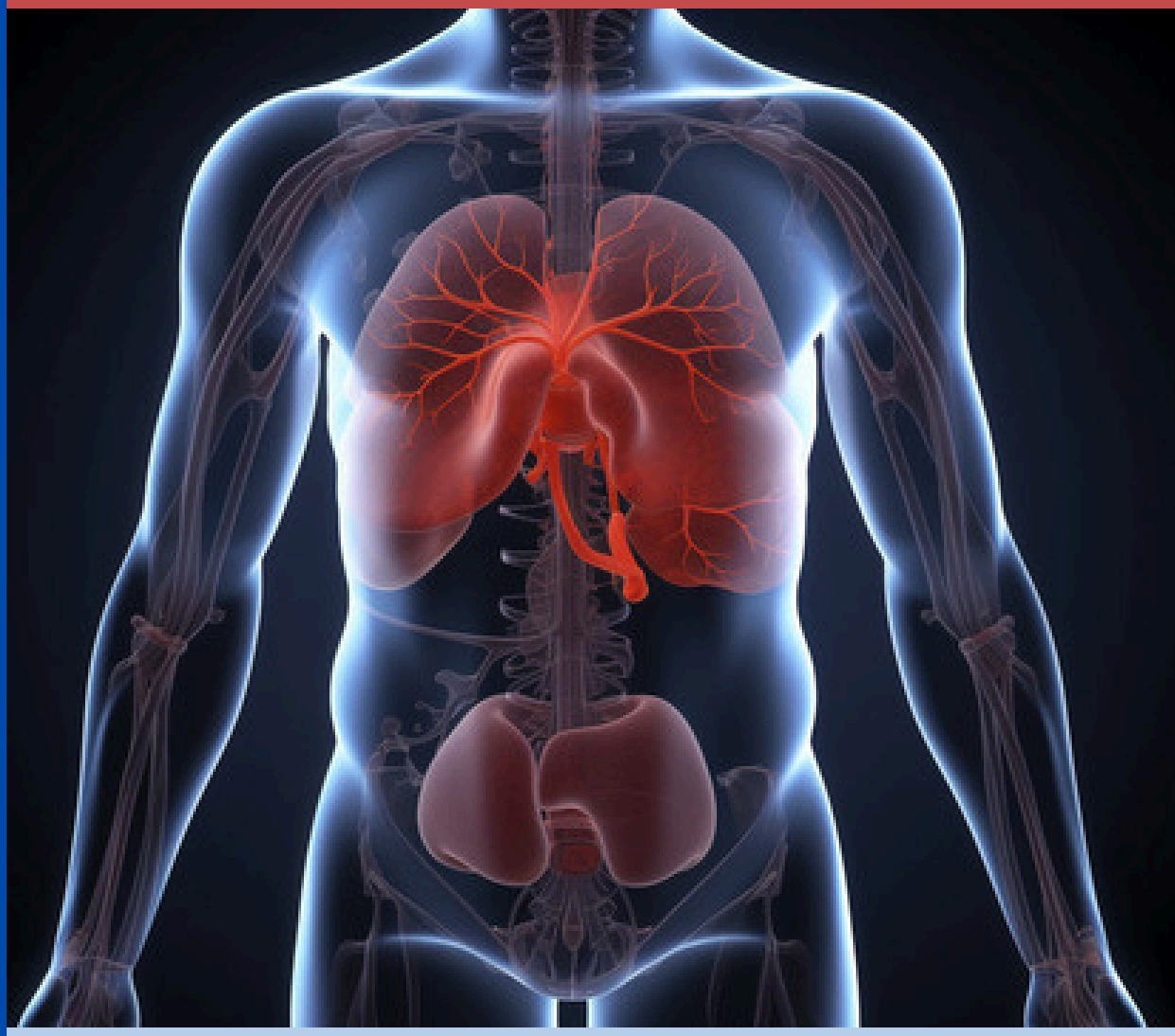
PULMONARY & CRITICAL CARE INSIDER



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VIEWPOINT: BIOLOGICS FOR TREATING UNCONTROLLED SEVERE ASTHMA

VIEWPOINTS COMPILED BY BHARAT BAJANTRI, MD.
ADOPTED FROM PULMCC AND CITED ARTICLES.

So many options! Doc, what is the best biologic therapy?

There is growing evidence supporting the use of biologics for treating uncontrolled severe asthma. This has led to the adoption of various biologics, often guided by patient-specific laboratory characteristics such as serum eosinophil levels, IgE levels, eosinophilic infiltration of the bronchial mucosa, fractional exhaled nitric oxide, or frequent corticosteroid use due to recurrent exacerbations. Additionally, the choice of biologic therapy can be influenced by cost and insurance coverage. However, no head-to-head randomized clinical trials have been conducted to compare the effectiveness of different biologics. It is unlikely that such trials will be performed by different pharmaceutical companies.
The closest evidence available is this meta-analysis, which compares the effectiveness of various biologic therapies for asthma.

The article "A Comparison of the Effectiveness of Biologic Therapies for Asthma" provides a comprehensive review and meta-analysis of various biologic therapies for asthma.

Biologics included in the study are:
Tezepelumab, Dupilumab, Mepolizumab, Reslizumab, Benralizumab, Omalizumab, Astegoliumab, Fevipiprant, Tralokinumab, Itepekimab and Itepelimab

Here are the key points summarized from the document:

Objective: To compare the effectiveness of different biologic therapies for asthma in adult patients with moderate to severe asthma.

Methods: The study involved a systematic review and network meta-analysis of randomized controlled trials. Key outcomes assessed included exacerbations, asthma control, lung function, hospital admissions, reduction in oral corticosteroid use, and adverse events leading to discontinuation.

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Key Findings:

- Exacerbations: The analysis showed that biologic therapies were generally effective in reducing asthma exacerbations compared to placebo, but tezepelumab and dupilumab did it with high certainty.
- Asthma Control: The Asthma Control Questionnaire (ACQ) was used to measure asthma control. Dupilumab showed low-certainty evidence of improving asthma control in patients with high eosinophils, but no other biologic demonstrated moderate or high-certainty evidence for significant improvement in asthma control.
- Lung Function: Lung function improvements were noted with some biologics, particularly in patients with high eosinophil counts. but tezepelumab and dupilumab did it with high certainty.
- Hospital Admissions: The impact on hospital admissions varied, with some biologics showing a reduction in admissions. Tezepelumab and dupilumab did reduce hospital admission compared to placebo with moderate certainty (Which was most compared with other biologics).
- Reduction in Oral Corticosteroid Use: A significant reduction in oral corticosteroid use was observed with some biologic therapies.
- Adverse Events: The safety profile of the biologics was generally acceptable, though some adverse events led to discontinuation in certain cases.

Conclusions

The study concluded that biologic therapies are effective in reducing exacerbations and improving certain clinical outcomes in asthma patients, particularly those with high eosinophil counts. The evidence varies in certainty, with dupilumab and tezepelumab showing the most promise in terms of asthma control, rate of exacerbations and improved lung function for specific patient groups. For patients with low eosinophils, clinicians should be more cautious in using biologics, including tezepelumab, as they are unlikely to provide significant benefits.

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Perspective:
This trial alone isn't sufficient to conclude that Dupilumab and Tezepelumab are the only biologics worth considering, but they certainly appear to have come out ahead in this round of the battle of biologics.

This information is valuable when discussing treatment options with patients. Just as asthma treatment needs to be personalized, it's crucial to carefully evaluate each patient to determine the most suitable biologic for their specific situation. Key factors to consider include the asthma phenotype, comorbidities such as other hypereosinophilic syndromes, nasal polyposis, eosinophilic esophagitis, eosinophilic granulomatosis with polyangiitis (EGPA), and eczema, which might make one biologic more appropriate and easier to obtain insurance approval for, as well as patient preferences, like dosing frequency.

Additionally, recent evidence suggests that bronchial thermoplasty could offer improved patient-centered outcomes and may be a viable option for those who do not respond well to biologics due to lack of significant eosinophilia or other reasons.

VIEWPOINT: DON'T YOU QUIT ON CANNOT QUIT SMOKERS!

VIEWPOINTS COMPILED BY BHARAT BAJANTRI, MD.
ADOPTED FROM PULMCC AND CITED ARTICLES.

Viewpoint from Smoking Cessation After Initial Treatment Failure with Varenicline or Nicotine Replacement: A Randomized Clinical Trial.

Study Design:
Participants: 490 individuals, average age 48, smoking about 20 cigarettes per day, initially treated with either varenicline (2 mg/day) or combined NRT (21-mg patch plus 2-mg lozenge).

Phases: The study was conducted in two phases over six weeks each. Non-abstinent participants after the first phase were rerandomized to either continue their current treatment, switch to the other treatment, or increase their dosage.

Key Findings:

Varenicline Group:

- Increased Dosage to 3 g daily: Participants who increased their varenicline dosage had a 20% end-of-treatment abstinence rate.
- Switch to NRT: Those who switched to NRT had a 0% abstinence rate.
- Continued Same Dosage of 2 g daily: Continued initial dosage resulted in a 3% abstinence rate.
- Conclusion: Increasing the varenicline dosage was significantly more effective than continuing the initial dosage or switching to NRT.

NRT Group:

- Increased Dosage: Participants who increased their NRT dosage had a 14% end-of-treatment abstinence rate.
- Switch to Varenicline: Switching to varenicline also resulted in a 14% abstinence rate.
- Continued Same Dosage: Continued initial dosage led to an 8% abstinence rate.
- Conclusion: Both increasing the NRT dosage and switching to varenicline were more effective than continuing with the initial NRT dosage.

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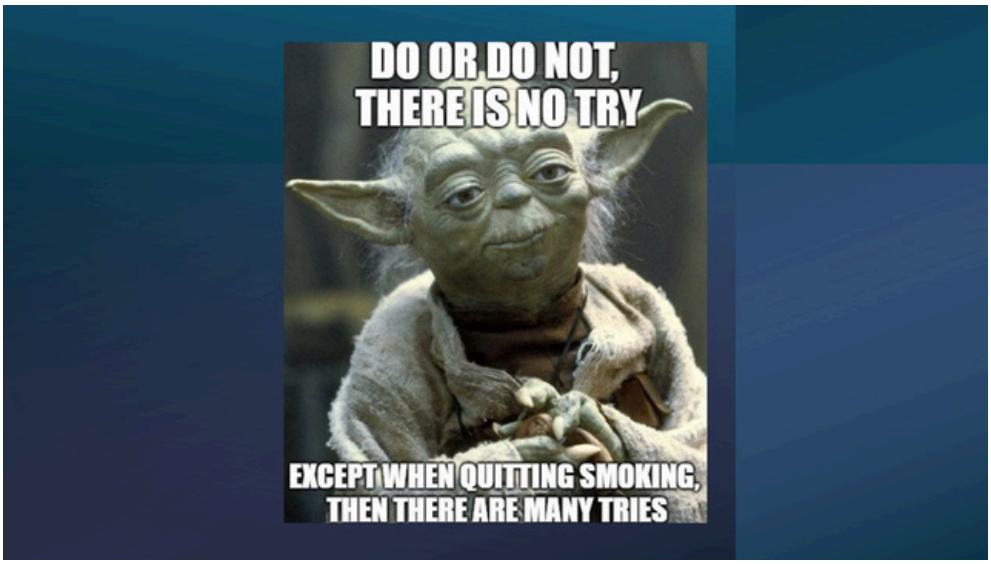

Long-Term Outcomes:
Continuous Abstinence: Only the increased dosages of both varenicline and NRT led to higher continuous abstinence rates at six months compared to continuation of the initial treatment dosages.

Implications:
The study indicates that for smokers who do not quit after an initial treatment with varenicline, increasing the dosage is the most effective strategy. For those initially treated with NRT, either increasing the dosage or switching to varenicline is beneficial. These findings suggest that adjusting treatment strategies rather than persisting with the initial dosage is crucial for achieving smoking cessation.

Perspective:
It's not uncommon to prescribe Chantix and nicotine replacement therapies for extended periods. This study encouraged me to consider higher doses and assist with smoking cessation. It is important to ensure patients are aware of all potential side effects of these medications. It is reassuring that the FDA has withdrawn the black box warning for neuropsychiatric effects and depression, given the lack of such incidents. Additionally, it is reasonable to believe that the carcinogenic risk of smoking far outweighs the potential theoretical risk associated with long-term ingestion of nitrosamines, a component in Chantix.

VIEWPOINT: PAXLOVID MAY NOT BE YOUR MAGIC BULLET FOR COVID-19 INFECTION!

VIEWPOINTS COMPILED BY BHARAT BAJANTRI, MD.
ADOPTED FROM PULMCC AND CITED ARTICLES.

Patients at without elevated risk for progression to severe disease did not benefit from Paxlovid.

The U.S. National Institutes of Health guidelines currently recommend nirmatrelvir/ritonavir (Paxlovid) as first-line therapy for outpatients with COVID-19 who are at high risk for progressing to severe disease. This recommendation stems from the initial randomized trial of Paxlovid, which showed that the drug lowered risk for hospitalization and death among high-risk, unvaccinated adults. In subsequent observational trials, benefits have varied, depending on the patient population included.

Now, in a manufacturer-sponsored trial, researchers examined the effectiveness of Paxlovid among standard-risk patients. About 1300 adults (median age, 42) with symptomatic COVID-19 received 5-day courses of Paxlovid or placebo. Participants were fully vaccinated with at least one risk factor for severe disease (e.g., smoking, hypertension, obesity), or they had no risk factors and were unvaccinated (i.e., never vaccinated or no vaccine within the past year). Fewer than 2% of patients had heart or lung disease, and only 5% were 65 or older.

The primary outcome—time to sustained alleviation of symptoms—did not differ between the Paxlovid and placebo groups. A secondary outcome (COVID-related hospitalization or death from any cause) occurred in 5 Paxlovid recipients and in 10 placebo recipients; this difference was not significant.

As noted in the study's editorial, some observational studies have indicated a link between symptoms and a viremia rebound effect following a course of Paxlovid. However, this rebound is typically short-lived and mild. Consequently, concerns about rebounding should not prevent the use of nirmatrelvir-ritonavir in patients who could benefit from it. Ongoing trials are exploring different treatment durations for acute COVID-19 and the effectiveness of a second course in cases of rebound.

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Antivirals approved or authorized outside the United States, such as ritonavir-boosted simnotrelvir, ensitrelvir, and mindeudesivir, have demonstrated clinical benefits. The varying results between this trial and other studies might be due to differences in factors like treatment timing (e.g., studies showing benefit started treatment within 72 hours of symptom onset), participant characteristics, assessment methods for symptom improvement, SARS-CoV-2 variants (noting that small-molecule drugs like nirmatrelvir-ritonavir target viral enzymes and are expected to be effective against all detected variants), or the antiviral potency of the medications.

Implications to my clinical practice: Unvaccinated healthy adults and fully vaccinated individuals with specific comorbidities seem to gain no significant benefit from Paxlovid. Note that the participants in this study were young and healthy, with no severe comorbidities. I will still recommend Paxlovid for patients who are older, immunosuppressed, or have serious chronic illnesses, especially those who are unvaccinated.

ORIGINAL STUDY SUMMARIES: DANGER TRIAL

BY BHARAT BAJANTRI, MD

Do We Finally Have a Device of Choice for Cardiogenic Shock? Maybe… But Not for Everyone !

Cardiogenic shock affects 5 to 10% of patients who experience acute myocardial infarction, with over half not surviving their initial hospital stay. Even though primary percutaneous coronary intervention is the standard treatment, mortality rates remain high.

A potential treatment option includes temporary mechanical circulatory support devices such as the intraaortic balloon pump (IABP), Impella microaxial flow pump (Abiomed), or venoarterial extracorporeal membrane oxygenation (ECMO). However, randomized trials of the IABP and venoarterial ECMO for patients with acute myocardial infarction complicated by cardiogenic shock have not shown a reduction in short-term mortality compared to standard care.

The Danish-German (DanGer) Shock Trial, led by Møller and colleagues, investigated 360 patients with acute ST-segment elevation myocardial infarction and severe shock. These patients were randomly assigned to receive either the Impella CP microaxial flow pump along with standard care or standard care alone, with all undergoing revascularization. The trial protocol included specific criteria for hemodynamic management and the removal of the microaxial flow pump. The primary endpoint, death from any cause at 180 days, was significantly lower in the microaxial flow pump group compared to the standard care group (45.8% vs. 58.5%; hazard ratio, 0.74; 95% confidence interval, 0.55 to 0.99; P=0.04). Additionally, patients in the microaxial flow pump group had more days alive out of the hospital and fewer cardiac adverse events. These results represent the first successful treatment strategy for improving outcomes in patients with acute myocardial infarction complicated by cardiogenic shock since the landmark SHOCK trial in 1999 established percutaneous coronary intervention.

ORIGINAL STUDY SUMMARIES: DANGER TRIAL

BY BHARAT BAJANTRI, MD

The outcomes of the DanGer Shock trial sharply contrast with those of the IABP-SHOCK II and ECLS-SHOCK trials. Although all three trials had similar inclusion and exclusion criteria, 45.0% and 77.7% of the patients in the IABP-SHOCK II and ECLS-SHOCK trials, respectively, underwent resuscitation before randomization, compared to only 20.3% in the DanGer Shock trial. Additionally, the DanGer Shock trial excluded patients who had a Glasgow Coma Scale score lower than 8 (range: 3 to 15) after resuscitation. This exclusion criterion meant that the DanGer Shock trial included patients who had a higher chance of neurologic recovery and were more likely to benefit from mechanical circulatory support. These differences in patient characteristics, timing of endpoints, and the varying degrees of hemodynamic support provided by different devices may explain the discrepancies in outcomes. Notably, the DanGer Shock trial excluded patients less likely to benefit neurologically from mechanical circulatory support, potentially influencing the positive outcomes observed.

Despite the significant reduction in mortality seen with the microaxial flow pump, there were higher rates of complications such as bacteremia (11.7% vs 4.5%), bleeding (21.8 % vs 11.9%), limb ischemia (5.6% vs 1.1%), and acute kidney injury requiring renal replacement therapy (42% vs 26.7%) associated with hemolysis especially when highest support is run for more than 2 days.

ORIGINAL STUDY SUMMARIES: DANGER TRIAL

BY BHARAT BAJANTRI, MD

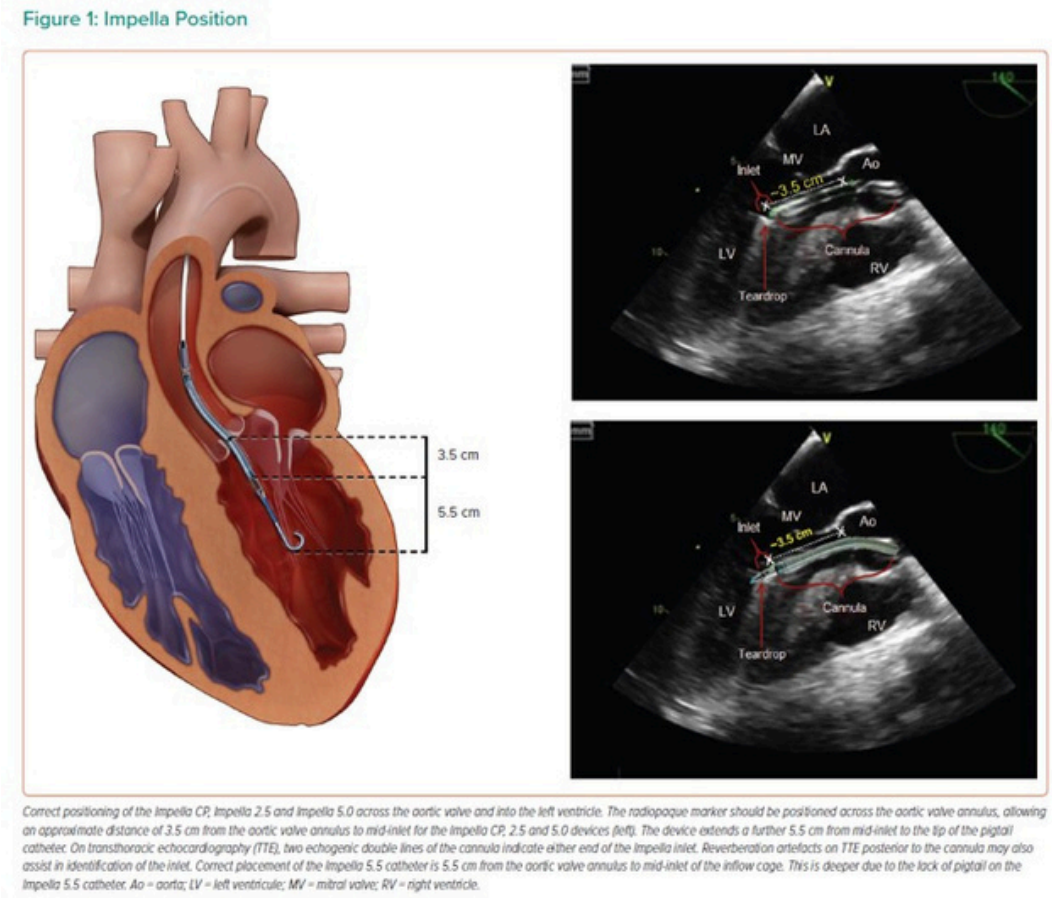


Figure 1 retrieved from A Review of the Impella Devices. Zein, 2022

Clinical Implications: This trial represents the first significant advancement in device-based treatment for cardiogenic shock in the past few decades. While these results show promise, they highlight that not all patients with cardiogenic shock due to acute myocardial infarction will benefit equally. Early initiation of mechanical support seems to be most beneficial, but the increased risk of complications such as limb ischemia and the need for renal replacement therapy associated with hemolysis especially when highest support is run for more than 2 days continues to be a significant concern. Careful patient selection and thorough informed decision-making are essential for moving forward. Strategies such as using antegrade catheters in the ipsilateral limb to maintain distal perfusion, ultrasound-guided vascular access, and careful device placement are essential to mitigate these risks.

ORIGINAL STUDY SUMMARIES: THE ACCESS TRIAL

BY BHARAT BAJANTRI, MD

Community-Acquired Pneumonia? Make that a double please!

Guidelines suggest treating patients hospitalized with community-acquired pneumonia (CAP) using a combination of a β-lactam antimicrobial and a macrolide antibiotic, such as azithromycin or clarithromycin (NEJM JW 2019 and ATS 2019). These recommendations are largely based on observational studies indicating that this dual regimen is linked to higher survival rates compared to monotherapy.

Design: A randomized placebo-controlled trial named ACCESS (A randomized clinical trial of oral Clarithromycin in Community-acquired pneumonia to attenuate inflammatory responses and improve outcomes).

Blinding: The trial employed concealed treatment allocation and blinding of patients, clinicians, data collectors, and outcome assessors.
Setting: The trial was conducted across 18 internal medicine departments in public hospitals in Greece.

Patients: The study included 278 adults aged 18 years or older (mean age 81 years; 61% men; all White) who were hospitalized with radiologically confirmed CAP and exhibited at least two CAP-related symptoms: cough, purulent sputum, dyspnea, or pleuritic chest pain, at least two systemic inflammatory response syndrome criteria, a total Sequential Organ Failure Assessment (SOFA) score of 2 or more, and a procalcitonin concentration of at least 0.25 mg/mL.

Key Exclusions: Patients were excluded if they had been treated with any macrolide for the current CAP or corticosteroids in the past 15 days, had active SARS-CoV-2 or HIV infection, neutropenia, or had been hospitalized for more than 2 consecutive days in the past 90 days.
Interventions: Participants were randomly assigned to receive either oral clarithromycin (500 mg twice daily for 7 days) plus standard care (n = 139) or placebo plus standard care (n = 139). Standard care included intravenous (IV) ceftriaxone (2 g/day) or an IV β-lactam plus β-lactamase inhibitor combination, administered 3 or 4 times per day with dosage adjustments based on renal clearance.

ORIGINAL STUDY SUMMARIES: THE ACCESS TRIAL

BY BHARAT BAJANTRI, MD

Outcomes: The composite primary endpoint of improved respiratory symptoms and an improved SOFA score (or improved procalcitonin level) by day 4 was achieved by significantly more patients in the dual-antibiotic group compared to the monotherapy group (68% vs. 38%; number needed to treat [NNT], approximately 3). Additionally, patients in the dual-antibiotic group were significantly less likely to develop sepsis (13% vs. 24%; NNT, 10), significantly more likely to be discharged and alive at 3 months (79% vs. 62%; NNT, 6), and somewhat less likely to be readmitted within 90 days (8% vs. 15%; NNT, 14; P=0.09).

Clinical Interpretation: In my view, this trial really underscores the benefits of combining a macrolide with β-lactam therapy for patients hospitalized with community-acquired pneumonia (CAP). Even though the study focused on those with moderate CAP and didn’t include ICU patients, many of the participants seemed quite ill, meeting criteria for severe sepsis. Because of this, I think it’s reasonable to extend these findings to more severe cases of CAP. This dual therapy approach is already part of the standard guidelines, and the study backs up its continued use for 5-7 days as opposed to early discontinuation of macrolides often justified by negative serologies for legionella and mycoplasma. What's particularly interesting is the evidence the authors present about the macrolide's role in modulating the immune response. They suggest that it might work by adjusting the balance between anti-inflammatory and proinflammatory cytokines, with a notable impact on TNF alpha and IL-10 levels.

ORIGINAL STUDY SUMMARIES: THE PREOXI TRIAL

BY BHARAT BAJANTRI, MD

PREOXI shows how to preoxygenate!

The Pragmatic Trial Examining Oxygenation Prior to Intubation (PREOXI) trial enrolled 1,301 adults from seven emergency departments (27% of the intubations) and 17 ICUs (73% of the intubations) in the U.S. between 2022 and 2023.

Methodology: Patients were randomly assigned in equal numbers (1:1 ratio) to receive preoxygenation via either noninvasive ventilation (NIV) or an oxygen mask. Due to the intervention's nature, clinicians and research staff were aware of the group assignments.

Noninvasive ventilation group	**Supplemental oxygen group**
Tight-fitting mask connected to either a conventional mechanical ventilator (with invasive mechanical ventilation capabilities) or a dedicated noninvasive ventilator	Either a non-rebreather mask or a bag-mask device without manual bagging (operator choice)
Settings: • FiO2 100% • Back up Respiratory rate 10 per min • EPAP ≥ 5 • IPAP ≥ 10	Settings: • Highest available flow rate of oxygen (at least 15 liters per minute)
Both groups ❖ Start of preoxygenation to initiation of laryngoscopy in both the groups. Duration ≥ 3 min	
❖ Allowed use of a bag-mask device for ventilation after anesthesia induction if needed. ❖ Supplemental oxygen could be provided via standard nasal cannula or high-flow nasal cannula during preoxygenation, between anesthesia induction and the start of laryngoscopy, and during the interval between the start of laryngoscopy and tracheal intubation.	

Disclaimer (conditions apply): Encephalopathy (also known as altered mental status) and acute hypoxemic respiratory failure were the most common reasons for intubation. These intubations were not "emergency" intubations as typically defined in most ICUs. All patients were spontaneously breathing and not in critical distress, which excluded about 20% of patients initially considered for enrollment. The PREOXI trial focused on preoxygenation strategies for patients requiring intubation but who had some time for preparation.

ORIGINAL STUDY SUMMARIES: THE PREOXI TRIAL

BY BHARAT BAJANTRI, MD

Salient features of the Trial:

- About half had acute hypoxemic respiratory failure, and less than 10% had hypercarbic respiratory failure (these groups might overlap);
- Half had oxygen saturations (SpO2) of 95% or higher, and three-quarters were at 92% or higher;
- Only 25% required supplemental oxygen with a fraction of inspired oxygen (FiO2) greater than 0.66, and half were receiving FiO2 of 0.33 or less;
- None had received BiPAP (they were excluded);
- Approximately 27% were receiving vasopressors;
- Encephalopathy was prevalent, with 60% of patients affected: half had a Glasgow Coma Scale (GCS) score of less than 12, and a quarter had a GCS score of less than 8.
- During preoxygenation, the interquartile range for SpO2 was 99 to 100% in the noninvasive ventilation (NIV) group and 97 to 100% in the oxygen mask group.
- Anesthesia, typically with etomidate, and paralysis were then induced in most patients.
- A video laryngoscope was used in about 83% of patients, achieving a first-pass intubation success rate of 82%.
- Both groups had a median time of about two minutes (approximately 115 seconds) from induction to intubation.

Results:

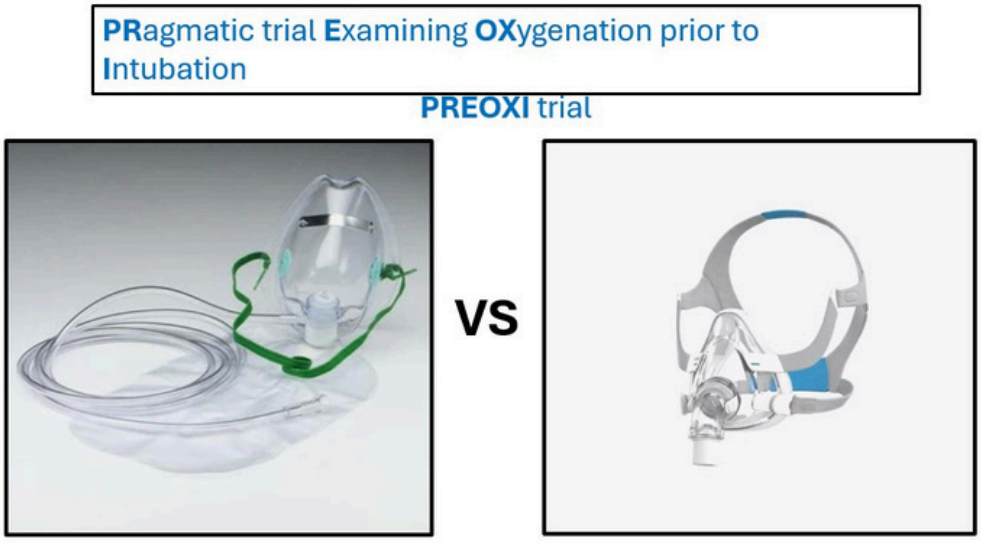
Patients randomized to NIV experienced half as much hypoxemia (SpO2 ≤ 85%) as those in the oxygen mask group (9.1% vs. 18.5%). The NIV group had one cardiac arrest (0.2%) compared to seven in the oxygen mask group (1.1%), a statistically significant difference.

- There was no increase in aspiration events among patients receiving NIV (0.9% vs. 1.4%).
- Obese patients and those with the most severe acute hypoxemic respiratory failure benefited the most, demonstrating a clear dose-response relationship. Even patients breathing room air had less hypoxemia with NIV preoxygenation.

ORIGINAL STUDY SUMMARIES: THE PREOXI TRIAL

BY BHARAT BAJANTRI, MD

Conclusion:
For critically ill adults needing tracheal intubation in an emergency department or ICU, using noninvasive ventilation for preoxygenation led to a lower incidence of hypoxemia compared to using an oxygen mask.



Clinical interpretation:
Trial results validate the widespread use of noninvasive ventilation for preoxygenation in most patients with acute hypoxemic respiratory failure who require intubation. Although true emergencies and emergent intubations were excluded from PREOXI, the findings suggest that NIV with the trial's settings is the best modality for preoxygenation in controlled, semi-elective intubation situations. Aspiration risks, once a significant concern, appeared to be lower than previously thought, though it remains prudent to aspirate stomach contents in any patient with an enteral tube and consider placing an NG tube in those at high risk for aspiration.

Figure 1 from **Monitoring capillary refill time in septic shock**

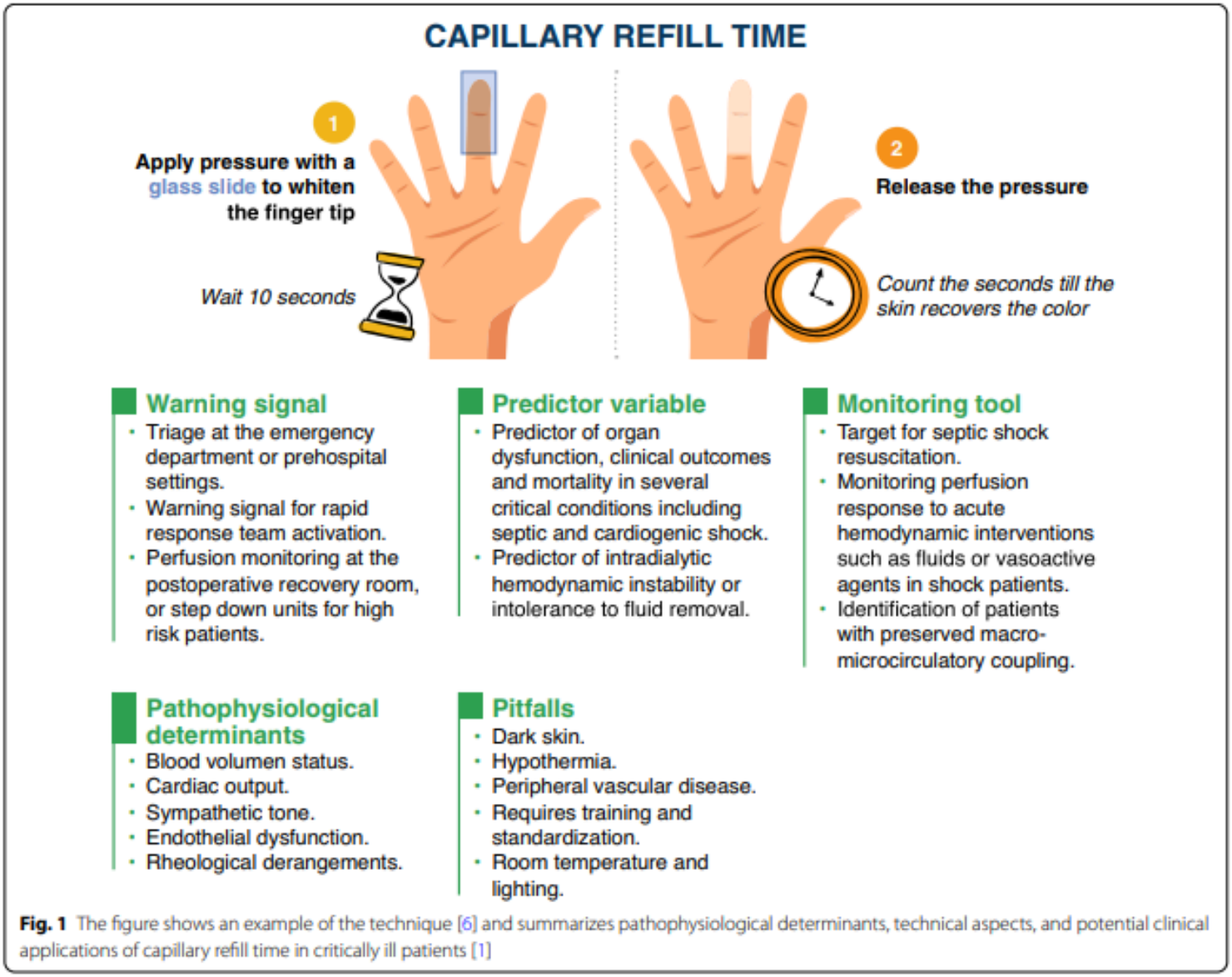
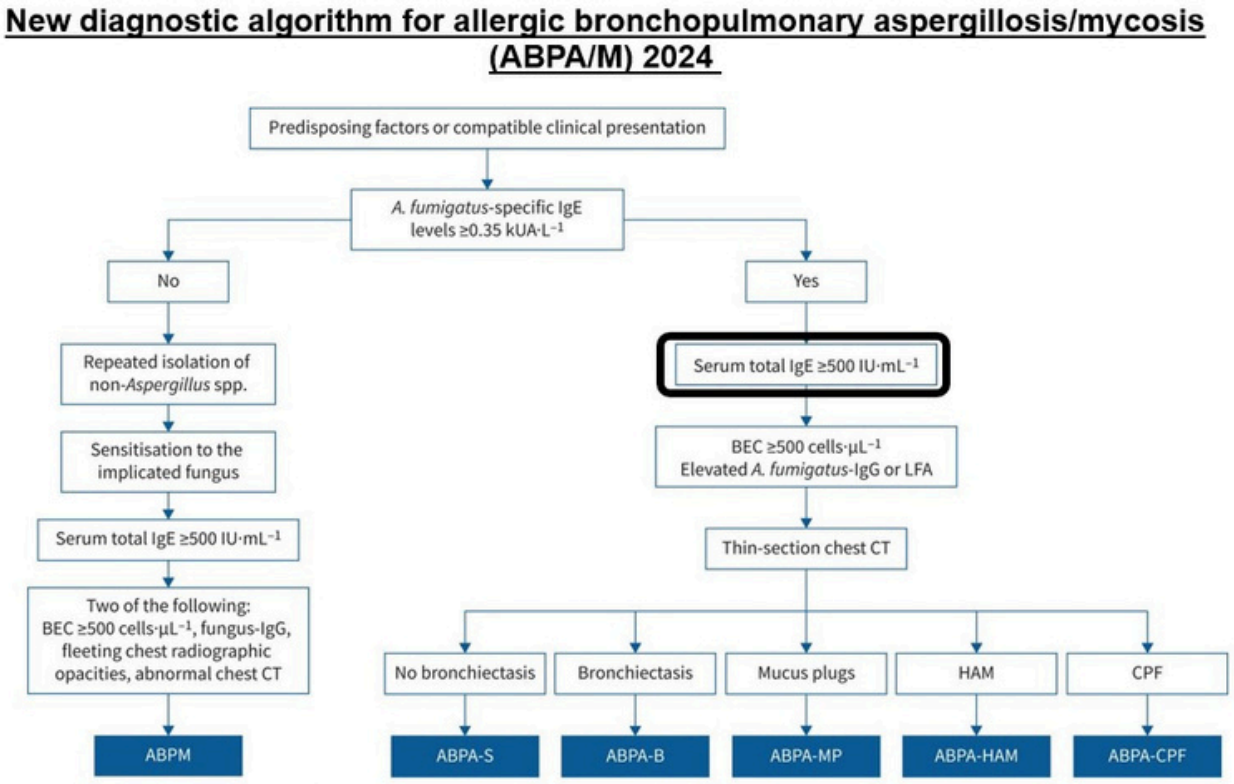


Fig. 1 The figure shows an example of the technique [6] and summarizes pathophysiological determinants, technical aspects, and potential clinical applications of capillary refill time in critically ill patients [1]

New Diagnostic Algorithm for Allergic Bronchopulmonary Aspergillosis/Mycosis 2024



Diagnostic algorithm for allergic bronchopulmonary aspergillosis/mycosis (ABPA/M). Occasionally, patients may present with imaging features of consolidation, centrilobular nodules (with a tree-in-bud appearance), atelectasis and mosaic attenuation. *A. fumigatus*: *Aspergillus fumigatus*; LFA: lateral flow assay; CT: computed tomography; BEC: blood eosinophil count; ABPA-S: serological ABPA; ABPA-B: ABPA with bronchiectasis; ABPA-MP: ABPA with mucus plugging; ABPA-HAM: ABPA with high-attenuation mucus; ABPA-CPF: ABPA with chronic pleuropulmonary fibrosis.

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Figure 3 from **Revised ISHAM-ABPA working group clinical practice guidelines for diagnosing, classifying and treating allergic bronchopulmonary aspergillosis/mycoses**

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