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POINT OF VIEW

Biological therapies in near-fatal asthma

Las terapias biológicas en las crisis de asma de riesgo vital

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Patients with life-threatening asthma, or "*near fatal asthma*" (NFA), or critical asthma syndrome (CAS), face a high risk of mortality. Asthmatic patients with severe exacerbations and respiratory failure should be managed in the Intensive Care Unit (ICU) or Intermediate Respiratory Care Unit. This will facilitate the escalation of ventilatory and hemodynamic support.[1,2]

Regular intensive care

The treatment of asthma in the ICU combines pharmacological interventions and ventilatory support measures to reverse bronchospasm, reduce inflammation, and treat respiratory failure.[1,2] According to the Spanish Guide for the Management of Asthma (GEMA 5.5), patients with moderate or severe exacerbations should receive oxygen without delay to maintain an oxygen saturation level above 90% ($\geq$ 95% in pregnant women or patients with heart disease)[2]. Initial treatment includes short-acting beta agonists (SABAs, such as salbutamol) via spacer or nebulizer, with the addition of ipratropium bromide in moderate or severe cases. Systemic corticosteroids (methylprednisolone 40—50 mg/day for 5–7 days, p.o. or i.v.) should be initiated at the earliest possible opportunity.[2]

In severe crises, the administration of inhaled magnesium sulfate, in conjunction with SABA or SABA and ipratropium, has been shown to improve pulmonary function and reduce patient admissions. In cases where other methods have failed, the intravenous route is employed. Controlled oxygen therapy aims to achieve an oxygen saturation $\geq$94%.[2,3] Noninvasive ventilation (NIV) is preferred over invasive ventilation because it has been shown to offer better results and lower mortality.[1] If mechanical ventilation is required, it is essential to adjust the parameters to avoid dynamic hyperinflation (low respiratory rate, prolonged expiratory time, low tidal volume). Additionally, sedation with ketamine or propofol is recommended due to their bronchodilator properties.

HeliOx (a combination of helium and oxygen) is not a standard recommendation, but it may be considered for patients with refractory conditions.[1] Similarly, the use of aminophylline or theophylline is not recommended. Extracorporeal membrane oxygenation (ECMO) is a valuable treatment option for severe, near-fatal asthma cases with

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Table 1 Compassionate use of biologics in patients with life-threatening asthma.

Biological drug	Mechanism of action	Dose	Day of biological drug administration after intubation	Route	Department where used (ICU/ Emergency room)	Sex/Age	OTI + MV	VV ECMO	Time to improvement after administration	Extubation	Parameter improving after administration	Year	Country	Reference
Benralizumab	Anti-IL5R	100 mg single dose	–	sc	Emergency room	158 patients	–	–	–	–	Improved FEV1 and less dyspnea on day 28	2021—2024	UK	Ramakrishnan S, et al. Treating eosinophilic exacerbations of asthma and COPD with benralizumab (ABRA): a double-blind, double-dummy, active placebo-controlled randomised trial. Lancet Respir Med. 2025;13:59-68. doi:10.1016/S2213-2600(24)00299-6
Benralizumab	Anti-IL5R	30 mg single dose	–	sc	NA	Male 52 years	–	–	–	–	Improved FEV1 and PEFR	2019	UK	Ramakrishnan S, et al. The use of benralizumab in the treatment of near-fatal asthma: a new approach. Am J Respir Crit Care Med. 2020 Jun 1;201:1441-1443. doi: 10.1164/rccm.202001-0093LE. PMID: 32023077; PMCID: PMC7258629
Benralizumab	Anti-IL5R	30 mg single dose	+4	sc	ICU	Male 23 years	+	–	4 days	+13 (+9 after Benra)	Normalization of pH and decrease in PIP and Raw on day +4 of Benra administration	2021	Spain	Pérez de Llano et al. Compassionate use of a single dose of benralizumab in a near-fatal asthma exacerbation. J Investig Allergol Clin Immunol. 2021 Jun 22;31:268-270. doi: 10.18176/jiaci.0609. PMID: 32938574

Table 1 (*Continued*)

Biological drug	Mechanism of action	Dose	Day of biological drug administration after intubation	Route	Department where used (ICU/ Emergency room)	Sex/Age	OTI + MV	VV ECMO	Time to improvement after administration	Extubation	Parameter improving after administration	Year	Country	Reference
Benralizumab	Anti-IL5R	30 mg	+17	sc	ICU	Female 64 years *Was already receiving benralizumab every 8 weeks	+ Tracheostomy	–	2 days	NA Tracheostomy	Less need for corticosteroids Resolution of bronchospasm	2022	Netherlands	Kroes JA et al. Administration of benralizumab in a patient with severe asthma admitted to the intensive care unit with COVID-19 pneumonia: case report. Eur J Hosp Pharm. 2022 Jul;29:235-236. doi: 10.1136/ejhpharm-2020-002660. PMID: 33883206; PMCID: PMC9251165
Benralizumab	Anti-IL5R	30 mg	+2	sc	ICU	Female 24 years	+	+	5 days	stop ECMO on day +4 and extubation on day +5 after administering Benra	90% decrease in eosinophil count at 48 h and simultaneous improvement of respiratory failure, with successful weaning from ECMO and OTI	2024	Italy	Montagnolo et al. Successful benralizumab treatment in acute near-fatal asthma with ECMO support: a case report. J Asthma. 2024;61:1790-1793. doi:10.1080/02770903.2024.2375287

Table 1 (*Continued*)

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Benralizumab	Anti-IL5R	30 mg single dose	+7	sc	ICU	Female 48 years	+	+	The following days (NA)	NA	Decrease in peak pressure and respiratory resistance	2025	Netherlands	Conemans L et al. Out of breath, out of options: benralizumab as a last hope in ICU-treated near-fatal eosinophilic asthma: a case series. Respirol Case Rep. 2025 Mar 12;13:e70117. doi: 10.1002/rcr2.70117. PMID: 40078572; PMCID: PMC11903096
Benralizumab	Anti-IL5R	30 mg single dose	+5	sc	ICU	Male 65 years	+	+	NA	Extubation day +18	Decrease in peak pressure and respiratory resistance. Clinical improvement and resolution of atelectasis	2025	Netherlands	Conemans L et al. Out of breath, out of options: benralizumab as a last hope in ICU-treated near-fatal eosinophilic asthma: a case series. Respirol Case Rep. 2025 Mar 12;13:e70117. doi: 10.1002/rcr2.70117. PMID: 40078572; PMCID: PMC11903096

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Benralizumab	Anti-IL5R	30 mg single dose	+7	sc	ICU	Male 62 years	+	+	NA	NA	Decrease in peak pressure and respiratory resistance. Clinical improvement and resolution of atelectasis	2025	Netherlands	Conemans L et al. Out of breath, out of options: benralizumab as a last hope in ICU-treated near-fatal eosinophilic asthma: a case series. Respirol Case Rep. 2025 Mar 12;13:e70117. doi: 10.1002/rcr2.70117. PMID: 40078572; PMCID: PMC11903096

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Benralizumab	Anti-IL5R	30 mg single dose	+5	sc	ICU	Male 61 years	+	–	NA	Extubation day +9	Decrease in peak pressure and respiratory resistance	2025	Netherlands	Gonemans L et al. Out of breath, out of options: benralizumab as a last hope in ICU-treated near-fatal eosinophilic asthma: a case series. Respirol Case Rep. 2025 Mar 12;13:e70117. doi: 10.1002/rcr2.70117. PMID: 40078572; PMCID: PMC11903096
Benralizumab	Anti-IL5R	30 mg Single dose	+2	sc	ICU	Male 52 years	+	–	6 h	Extubation day +2 after administering biological drug	At 6 h after administration, bronchospasm decreased, TV increased, pCO_2 normalized	2025	Japan	Matsuoka S et al. Life-threatening asthma exacerbation successfully treated with benralizumab. Intern Med. 2025 Aug 1;64:2382-2385. doi: 10.2169/internalmedicine.4737-24. Epub 2025 Jan 15. PMID: 39814383; PMCID: PMC12393936

Table 1 (*Continued*)

Biological drug	Mechanism of action	Dose	Day of biological drug administration after intubation	Route	Department where used (ICU/ Emergency room)	Sex/Age	OTI + MV	VV ECMO	Time to improvement after administration	Extubation	Parameter improving after administration	Year	Country	Reference
Benralizumab + Omalizumab	Anti IL5R Anti IgE	30 mg 300 mg	+15 +18, +30	sc sc	ICU	Male 69 years	+	–	NA	Rapid weaning and decannulation tracheostomy	Gradual improvement of ventilatory parameters	2024	Ireland	Coghlan P et al. The use of monoclonal therapy in the treatment of near-fatal asthma complicated by steroid sensitivity: A case report. J Allergy Clin Immunol Pract. 2024 Jul;12:1918-1920.e1. doi: 10.1016/j.jaip.2024.03.042. Epub 2024 Apr 1. PMID: 38570071
Reslizumab	Anti-IL5	3 mg/kg	+3	iv	ICU	Female 53 years	+	–	24 h	Extubation day +2 after administering biological drug	Start of weaning 24 h after drug administration	2019	Austria	Renner et al. Reslizumab in an invasively ventilated patient with acute respiratory failure. J Allergy Clin Immunol Pract. 2019 Nov-Dec;7:2922-2923. doi: 10.1016/j.jaip.2019.05.019. Epub 2019 May 25. PMID: 31136820

Table 1 (*Continued*)

Biological drug	Mechanism of action	Dose	Day of biological drug administration after intubation	Route	Department where used (ICU/ Emergency room)	Sex/Age	OTI + MV	VV ECMO	Time to improvement after administration	Extubation	Parameter improving after administration	Year	Country	Reference
Reslizumab	Anti-IL5	3 mg/kg	+12, +39	iv	ICU	Male 36 years	+ Tracheostomy day +23 of MV	+	2 days	Stop ECMO two days after reslizumab, Stop MV day +20 after drug administration. Decannulation day 40	Improvement of respiratory parameters	2024	Spain	Granda P, et al. Compassionate use of reslizumab in a life-threatening asthma exacerbation. J Investig Allergol Clin Immunol. 2024 Feb 23;34:60-61. doi: 10.18176/jiaci.0920. PMID: 37357596
Tezepelumab	Anti-TSLP	210 mg single dose	+12	sc	ICU	Male, 43 years	+	+	24 h	Stop ECMO day +7 after tezepelumab. OTI for 33 days	Intrinsic PEEP decrease, gas flow reduction	2024	Austria	Grasmuk-Siegla et al. Tezepelumab in a case of severe asthma exacerbation and influenza-pneumonia on VV-ECMO. Respir Med Case Rep. 2024 May 30;50:102057. doi: 10.1016/j.rmcr

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Tezepelumab	Anti-TSLP	210 mg single dose	+4	sc	ICU	Male 38 years	+	+	24 h	Stop ECMO day +4 and extubated 7 days after tezepelumab	Decreased air resistance. Increase in TV	2025	Japan	Nakajima M et al. Compassionate use of tezepelumab in near fatal asthma: A case report and review of the literature. Respir Med Case Rep. 2025 Apr 26;55:102223. doi: 10.1016/j.rmcr.2025.102223. PMID: 40492166; PMCID: PMC12147447
Omalizumab	Anti-IgE	600 mg	+4	sc	ICU	Male 39 years	+	–	< 24 h	Extubation 24 h after drug administration	Decrease in FiO_2. Possibility to start weaning. Resolution of bronchospasm	2023	India	Shanmukhappa et al. Omalizumab rescue therapy in refractory status asthmaticus. J Asthma. 2023 Dec;60:2243-2247. doi: 10.1080/02770903.2023.2233606. PMID: 37427873
Omalizumab	Anti-IgE	600 mg	+8 +22	sc	ICU	Male 41 years	+ Tracheostomy day +7	+	48 h	Tracheostomy day +7. Stop ECMO(two days after drug administration) Stop MV day +15 after administration of drug (total 24 days MV)	Decrease in Ppeak, decrease in $PaCO_2$, decrease in FIO_2	2019	Germany	Milger et al. Omalizumab rescue therapy for refractory status asthmaticus. Ann Intern Med. 2019 Mar 5;170:351-352. doi: 10.7326/L18-0359. Epub 2018 Nov 20. PMID: 30458534

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Biological drug	Mechanism of action	Dose	Day of biological drug administration after intubation	Route	Department where used (ICU/ Emergency room)	Sex/Age	OTI + MV	VV ECMO	Time to improvement after administration	Extubation	Parameter improving after administration	Year	Country	Reference
Omalizumab	Anti-IgE	600 mg	+8	sc	ICU	Female 25 years	+	+	90 minutes	Extubation day +10 (two days after omalizumab administration) At 24 h after treatment, stop ECMO	Increase in TV, stop ECMO gas flow 12 h of treatment	2021	Czech Republic	Benes J et al. Successful treatment of refractory status asthmaticus with omalizumab: a case report. Allergy Asthma Clin Immunol. 2021 Dec 9;17:128. doi: 10.1186/s13223-021-00629-z. PMID: 34886898; PMCID: PMC8656026
Omalizumab	Anti-IgE	600 mg	+3, +6, +7, +10, +11	sc	ICU	Male 41 years	+	–	24 h	Extubation at 14 days (11 days after omalizumab administration)	Decrease in DP, IgE and pCO_2	2022	Germany	Slevogt et al. Rescue therapy for refractory status asthmaticus with updosed omalizumab adjusted for IgE level, body weight and effect. Respir Med Case Rep. 2022 Feb 22;36:101614. doi: 10.1016/j.rmcr.2022.101614. PMID: 35251928; PMCID: PMC8889270

Table 1 (*Continued*)

Biological drug	Mechanism of action	Dose	Day of biological drug administration after intubation	Route	Department where used (ICU/ Emergency room)	Sex/Age	OTI + MV	VV ECMO	Time to improvement after administration	Extubation	Parameter improving after administration	Year	Country	Reference
Mepolizumab	Anti-IL5	100 mg	+7	sc	ICU	Female 43 years	+	–	48 h	Extubation at 15 days (8 days after treatment)	PIP decrease, pH normalization, intrinsic PEEP decrease	2019	Germany	Tello et al. Anti-interleukin-5 therapy (mepolizumab) in life-threatening asthma attack: A case-based discussion. Respir Med Case Rep. 2019 Aug 22;28:100927. doi: 10.1016/j.rmcr.2019.100927. PMID: 31485410; PMCID: PMC6715903
Mepolizumab	Anti-IL5	100 mg	NA	sc	ICU	Female 61 years	+	+	NA	NA	NA	2020	France	Binachon et al. Acute severe asthma requiring invasive mechanical ventilation in the era of modern resuscitation techniques: A 10-year bicentric retrospective study. PLoS One. 2020 Oct 2;15:e0240063. doi: 10.1371/journal.pone.0240063. PMID: 33007018; PMCID: PMC7531794

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Mepolizumab	Anti-IL5	100 mg	+20	sc	ICU	Male 31 years	+	+	48 h	Extubation day +30 (10 days after mepo) Stop ECMO 7 days after treatment	Decrease in intrinsic PEEP, decrease in eosinophil count, disappearance of bronchospasm	2022	France	Barbarot N et al. Treating acute severe eosinophilic asthma with IL-5 inhibitors in ICU. Case Rep Pulmonol. 2022 Aug 21;2022:2180795. doi: 10.1155/2022/2180795. PMID: 36046750; PMCID: PMC9420636
Mepolizumab	Anti-IL 5	100 mg	+4	sc	ICU	Female 25 years	+	–	48 h	Extubation day +11	Normalization of $PaCO_2$, reduction of PIP and auto-PEEP	2023	Portugal	H.C. Rodrigues et al. Mepolizumab in severe asthma exacerbation in a respiratory ICU-a successful off-label use, Pulmonology. 2023; 29:5, 438-440, DOI: 10.1016/j.pulmoe.2023.03.002

DP: driving pressure; ECMO: extracorporeal membrane oxygenation; FEV1: forced expiratory volume in 1 s; OTI: orotracheal intubation; iv: intravenous; NA: not available; PEFR: peak expiratory flow rate; PIP (cmH_2O): peak inspiratory pressure; Raw: airway resistance; sc: subcutaneous; ICU: Intensive Care Unit; MV: mechanical ventilation; TV: tidal volume.

persistent respiratory acidosis where adequate ventilation is not achieved.[3–5]

New treatments: biological therapy

Up to 30% of patients with asthma in the ICU do not recover within five days despite the administration of high doses of corticosteroids and bronchodilators, due to persistent severe obstruction[1,3,4]. Systemic corticosteroid therapy is the mainstay of the management of severe asthma exacerbations.[2] However, biological drugs (biologics) have been shown to improve control in severe asthma, even in refractory cases.[4–10]

A history of admission to the ICU is the main risk factor for recurrence and can be considered an indirect marker of type 2 (T2) inflammation.[4,10] Such patients typically present with corticosteroid-resistant T2 inflammation associated with mucus plugs.[4,10] Anti-T2 biologics act rapidly on this inflammation, reducing plug formation and overcoming corticosteroid resistance. This, in turn, improves the prognosis.[4,10]

In 2021, Bourdin et al.[10] proposed the use of biologics in patients with asthmatic exacerbations admitted to the ICU. In Spain, the available biologics include benralizumab (anti-IL5R), mepolizumab and reslizumab (anti-IL5), dupilumab (anti-IL4R/13), omalizumab (anti-IgE), and tezepelumab (anti-TSLP). These biologics are indicated for severe asthma when conventional treatments fail.[2]

While none of these drugs have an approved indication for acute exacerbations, they have been used successfully through compassionate (off-label) use programs.[2,4–10] The ABRA study (United Kingdom, 2021—2024) is the only clinical trial in this context. The study evaluated a 100 mg subcutaneous dose of benralizumab in 158 adults with eosinophilic exacerbations of asthma or COPD ($\geq$300 eosinophils/μl). The results showed a significant decrease in treatment failures and symptom improvement versus prednisolone alone, with good tolerability.[4] Case reports involving biological treatments (benralizumab, tezepelumab, mepolizumab, omalizumab, and reslizumab) in patients with asthmatic exacerbation admitted to the ICU (intubated with mechanical ventilation and some with VV ECMO) confirm the efficacy of these drugs in acute life-threatening episodes[4–10] (Table 1). Some of the benefits reported after the administration of biologics in these patients were the disappearance of bronchospasm, normalization of pH, a decrease in eosinophil count and immunoglobulin E (IgE) levels, a decrease in peak pressure, respiratory resistance and driving pressure, an increase in patient tidal volume, and the possibility of starting weaning from ECMO and mechanical ventilation, with successful extubation of the patient a few hours/days after drug administration[4–10] (Table 1).

There is an unmet need to improve the management of severe asthma exacerbations in patients admitted to the ICU, based on clinical trials evaluating the efficacy of biological drugs. Currently, there are no studies registered in ClinicalTrials.gov, and the available evidence comes from a small number of cases with heterogeneous treatments and follow-up periods.[4–10] Controlled trials analyzing biomarkers of inflammation and their clinical correlation could determine whether these drugs improve the prognosis of patients with near-fatal asthma. Furthermore, conducting such studies would facilitate the optimization of resources, thus reducing mechanical ventilation and the use of corticosteroids and bronchodilators, and improving hospital stay and clinical outcomes.

Conclusions

Biologics have revolutionized the treatment of severe asthma as adjunctive maintenance therapy. This approach holds the potential to improve patient prognoses, minimize the necessity and dosage of corticosteroids, mitigate adverse effects, and optimize clinical outcomes for patients admitted due to near-fatal asthma exacerbation. However, the evidence on their efficacy and safety in this context is limited and is based on compassionate use. While they are not intended for administration in acute situations, their use in near-fatal asthma exacerbations in the ICU presents an opportunity for patients who have not responded to conventional treatment.

CRediT authorship contribution statement

María Lozano-Espinosa: conceptualization; research; supervision; validation - verification, visualization - preparation, writing - original draft; writing - revision and editing.

Darío Antolín-Amérigo: supervision; validation - verification, visualization - preparation, writing - original draft; writing - revision and editing.

Declaration of Generative AI and AI-assisted technologies in the writing process

There has been no assistance or use of AI for drafting the manuscript, although Open Evidence was used to search for relevant literature.

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Declaration of competing interest

María Lozano Espinosa has no conflicts of interest in relation to this manuscript.

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