

Omalizumab outcomes for up to 6 years in pediatric patients with severe persistent allergic asthma

Antonio Nieto García¹, Teresa Garriga-Baraut², Ana María Plaza³, María Nieto Cid¹, Javier Torres-Borrego⁴, Mar Folque⁵, Jaime Lozano³, Montserrat Bosque⁶, Laura Moreno-Galarraga⁷, Miguel Tortajada⁸, Cristina Rivas Juesas⁹, María Penín Antón¹⁰, María Araceli Caballero-Rabasco¹¹, Mirella Gaboli¹², Alejandro López Neyra¹³, Juan Navarro Morón¹⁴, Andrea Freixa², Laura Valdesoro Navarrete¹⁵, Esther Ballester Asensio⁸, Verónica Sanz Santiago¹⁶, Raquel Romero¹⁷, Álvaro Gimeno Díaz de Atauri¹⁸, Alfredo Valenzuela Soria¹⁹, Mercedes Sánchez Mateos²⁰, José Batllés Garrido²¹, Anselmo Andrés Martín²², Elena Campos Alonso²³, Carmen Aragón Fernández²⁴, Elena Vázquez Rodríguez²⁵, Luz Martínez Pardo²⁶, Genoveva del Río Camacho²⁷, and Ángel Mazón Ramos¹

¹Hospital Universitari i Politècnic La Fe

²Hospital Universitari Vall d'Hebron

³Hospital Sant Joan de Deu

⁴ Reina Sofía Children's University Hospital. Pediatrics Clinical Management Unit.

⁵Hospital Sant Joan de Déu, Universitat de Barcelona

⁶Pediatric Allergology and Pneumology Unit, Hospital de Sabadell, Barcelona, Spain.
Universitat Autònoma de Barcelona (UAB)

⁷Complejo Hospitalario de Navarra

⁸Hospital Universitario Doctor Peset

⁹Hospital de Sagunto

¹⁰Hospital Universitario Príncipe de Asturias

¹¹Hospital del Mar

¹²Hospital Universitario Virgen del Rocío

¹³Hospital Universitario Ramón y Cajal

¹⁴Hospital Costa del Sol

¹⁵Consorcio Corporacion Sanitaria Parc Tauli

¹⁶Hospital Infantil Universitario Niño Jesús

¹⁷Hospital Universitario San Cecilio

¹⁸Hospital Universitario 12 de Octubre

¹⁹Hospital Universitario Virgen de las Nieves

²⁰Hospital Universitario Puerta del Hierro Majadahonda

²¹Hospital Universitario Torrecárdenas

²²Hospital Universitario Virgen Macarena

²³Hospital Público Comarcal de La Merced

²⁴Hospital Universitario de Jerez de la Frontera

²⁵Hospital Universitario Nuestra Señora de Valme

²⁶Complejo Hospitalario de Jaén

²⁷Hospital Universitario Fundación Jiménez Díaz

October 29, 2020

Abstract

Background: Various studies have assessed omalizumab outcomes in the clinical practice setting but follow-up and/or number of patients included were limited. We aim to describe the long-term outcomes of pediatric patients with severe persistent allergic asthma receiving omalizumab in the largest real-life cohort reported to date. **Methods:** ANCHORS was a multicenter, observational, retrospective cohort study conducted in 25 Pediatric Allergy and Pulmonology units in Spain. We collected data of patients <18 years and initiating omalizumab between 2006-2018, from the year prior to omalizumab initiation to discontinuation or last available follow-up. The primary outcome was the evolution of the annual number of moderate-to-severe exacerbations compared to the baseline period. **Results:** Of the 484 patients included, 101 (20.9%) reached six years of treatment. The mean \pm standard deviation number of exacerbations decreased during the first year of treatment (7.9 ± 6.6 to 1.1 ± 2.0 , $p<0.001$) and remained likewise for up to six years. The other clinical parameters assessed also improved significantly during the first year and stabilized or continued to improve thereafter. The percentage of patients experiencing adverse events was consistently low, and the main reason for discontinuation was good disease evolution. **Conclusion:** In this large, long-term, observational study, moderate-to-severe exacerbations decreased significantly from the first year of treatment with omalizumab. The beneficial effect was maintained in the long-term, along with a good safety profile. Our results position omalizumab as an effective long-term treatment in pediatric patients with severe persistent allergic asthma.

Title

Omalizumab outcomes for up to 6 years in pediatric patients with severe persistent allergic asthma

Authors

Antonio Nieto García, MD, PhD¹; Teresa Garriga-Baraut, MD, PhD²; Ana M^a Plaza Martín, MD, PhD³; María Nieto Cid, MD^{1,4}; Javier Torres Borrego, MD, PhD⁵; María del Mar Folqué Giménez, MD³; Jaime Lozano Blasco, MD³; Montse Bosque García, MD, PhD⁶; Laura Moreno-Galarraga, MD, PhD⁷; Miguel Tortajada-Girbés, MD, PhD⁸; Cristina Rivas Juesas, MD, PhD⁹; María Penín Antón, MD¹⁰; María Araceli Caballero-Rabasco, MD¹¹; Mirella Gaboli, MD, PhD¹²; Alejandro López Neyra, MD¹³; Juan Navarro Morón, MD¹⁴; Andrea Freixa, MD²; Laura Valdesoro Navarrete, MD, PhD⁶; Esther Ballester Asensio, MD⁸; Verónica Sanz Santiago, MD¹⁵; Raquel Romero García, MD¹⁶; Álvaro Gimeno Díaz de Atauri, MD¹⁷; Alfredo Valenzuela Soria, MD¹⁸; Mercedes Sánchez Mateos, MD¹⁹; José Batllés Garrido, MD²⁰; Anselmo Andrés Martín, MD²¹; Elena Campos Alonso, MD²²; Carmen Aragón Fernández, MD²³; Elena Vázquez Rodríguez, MD²⁴; Luz Martínez Pardo, MD²⁵; Genoveva del Río Camacho, MD, PhD²⁶; Ángel Mazón Ramos, MD, PhD¹

¹ Pediatric Pulmonology and Allergy Unit. Hospital Universitari i Politècnic La Fe, Health Research Institute La Fe, Valencia, Spain

² Pediatric Allergy Unit. Hospital Universitario Vall d'Hebron, Barcelona, Spain

³ Allergy and Clinical Immunology Department. Hospital Materno-infantil Sant Joan de Déu, Barcelona, Spain

⁴ Now with Allergy Service. Hospital Universitario de La Plana, Villarreal, Spain

⁵ Pediatric Allergy and Pulmonology Unit. Hospital Universitario Reina Sofía, Córdoba, Spain

⁶ Pediatric Allergy and Pulmonology Unit. Hospital de Sabadell – Corporació Universitaria Parc Taulí, Sabadell, Spain

⁷ Pediatrics Service. Complejo Hospitalario de Navarra, Pamplona, Spain

- ⁸ Pediatric Allergy Unit. Hospital Universitario Doctor Peset, Valencia, Spain
- ⁹ Pediatric Pulmonology and Allergy Unit. Hospital de Sagunto, Sagunto, Spain
- ¹⁰ Pediatrics Service. Hospital Universitario Príncipe de Asturias, Alcalá de Henares, Spain
- ¹¹ Pediatric Pulmonology and Allergy Unit. Hospital del Mar, Barcelona, Spain
- ¹² Pediatric Pulmonology and Allergy Unit. Hospital Universitario Virgen del Rocío, Sevilla, Spain
- ¹³ Pediatric Pulmonology Unit. Hospital Universitario Ramón y Cajal, Madrid, Spain
- ¹⁴ Pediatrics Service. Hospital Costa del Sol, Marbella, Spain
- ¹⁵ Pediatric Pulmonology Unit. Hospital Universitario Infantil Niño Jesús, Madrid, Spain
- ¹⁶ Pediatric Pulmonology and Allergy Unit. Hospital Universitario Clínico San Cecilio, Granada, Spain
- ¹⁷ Pediatric Pulmonology and Allergy Unit. Hospital Universitario 12 de Octubre, Madrid, Spain
- ¹⁸ Pediatric Pulmonology Unit. Hospital Universitario Virgen de las Nieves, Granada, Spain
- ¹⁹ Pediatric Pulmonology Unit. Hospital Universitario Puerta de Hierro, Majadahonda, Spain
- ²⁰ Pediatric Pulmonology and Allergy Unit. Hospital Universitario Torrecárdenas, Almería, Spain
- ²¹ Pediatric Pulmonology Unit. Hospital Universitario Virgen Macarena, Sevilla, Spain
- ²² Pediatrics Service. Hospital Público Comarcal de La Merced, Osuna, Spain
- ²³ Pediatrics Service. Hospital Universitario de Jerez de la Frontera, Jerez de la Frontera, Spain
- ²⁴ Pediatric Pulmonology Unit. Hospital Universitario Nuestra Señora de Valme, Sevilla, Spain
- ²⁵ Pediatric Pulmonology Unit. Complejo Hospitalario de Jaén, Jaén, Spain
- ²⁶ Pediatrics Service. Hospital Universitario Fundación Jiménez Díaz, Madrid, Spain

Running title: Six years of omalizumab in pediatric asthma

Corresponding author

Antonio Nieto García

Unidad de Alergia y Neumología Pediátrica
Hospital Universitari i Politècnic La Fe
Av. Fernando Abril Martorell, nº 106
46026 Valencia (Spain)
nieto_ant@gva.es

Manuscript word count: 2561

Number of tables and figures: 6

Hosted file

HLF1001_Manuscript_FINAL_20201023.pdf available at <https://authorea.com/users/371147/articles/489598-omalizumab-outcomes-for-up-to-6-years-in-pediatric-patients-with-severe-persistent-allergic-asthma>

Hosted file

Figure 1.pdf available at <https://authorea.com/users/371147/articles/489598-omalizumab-outcomes-for-up-to-6-years-in-pediatric-patients-with-severe-persistent-allergic-asthma>

Hosted file

Figure 2.pdf available at <https://authorea.com/users/371147/articles/489598-omalizumab-outcomes-for-up-to-6-years-in-pediatric-patients-with-severe-persistent-allergic-asthma>

Hosted file

Figure 3.pdf available at <https://authorea.com/users/371147/articles/489598-omalizumab-outcomes-for-up-to-6-years-in-pediatric-patients-with-severe-persistent-allergic-asthma>

Hosted file

Figure 4.pdf available at <https://authorea.com/users/371147/articles/489598-omalizumab-outcomes-for-up-to-6-years-in-pediatric-patients-with-severe-persistent-allergic-asthma>

Hosted file

Figure 5.pdf available at <https://authorea.com/users/371147/articles/489598-omalizumab-outcomes-for-up-to-6-years-in-pediatric-patients-with-severe-persistent-allergic-asthma>