Efficacy and safety of golimumab in pediatric ulcerative colitis: A Systematic literature review

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Background and objectives

- Ulcerative colitis (UC) is a chronic inflammatory bowel disease that is autoimmune in its origin.
- Tumor necrosis factor-α-antagonist monoclonal antibodies are first-line biologicals used in adult patients with moderate-to-severe UC[1].
- However, Infliximab is the only approved biological therapy for children with UC[1]. With this understanding, golimumab might be another option for pediatric moderate-to-severe UC.
- Hence, this study aimed to evaluate the efficacy and safety of golimumab in pediatric UC patients.

Methodology

- A literature search was conducted in Embase® and MEDLINE® via Ovid to identify English language articles published from database inception to 8th of June 2022 for studies assessing the efficacy and safety of golimumab in pediatric UC patients.
- All the identified studies were screened based on the title/abstracts and followed by full-texts screening against the eligibility criteria (**Table 1**) and data extraction by one reviewer.
- The quality assessment of included study was evaluated using Downs and Black check list.[2]

Table 1: Study eligibility criteria

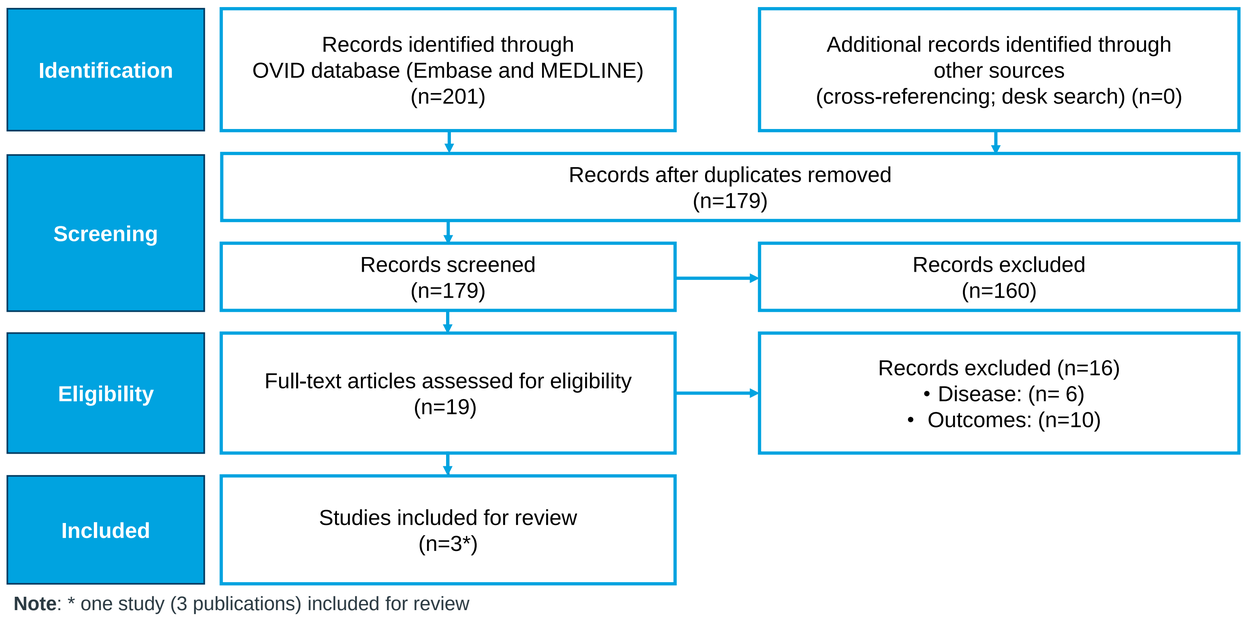
PICOS	Inclusion criteria
Population	Pediatric patients with ulcerative colitis
Intervention/ Comparators	Golimumab
Outcomes	Efficacy and safety
Study design	No restriction

Results

Study Selection:

- After removing duplicates, 179 records were obtained through databases and additional searches.
- One single-arm, phase 1b, multicenter, open-label trial with long-term extension (3 publications) was included for the review (**Figure 1**).
- Of 179 identified studies, one single-arm trial was included with three associated publications. The trial was performed for 126 weeks.
- At week 6, Hyams et al. 2017 reported Mayo clinical response in 21 (60.0%), Mayo clinical remission in 15 (43%), Pediatric Ulcerative Colitis Activity Index (PUCAI) clinical remission in 12 (34%), and mucosal healing in 19 (54%) patients. [3]

Figure 1: PRISMA chart of included studies



Note: * one study (3 publications) included for review

Results

- Of the 21 patients who achieved mayo response, PUCAI remission was observed in 9 (45%), 11 (55%), and 10 (50%) patients at weeks 30, 54, and 110, respectively.[3,4]
- Through week 14, 20 patients entered long-term extension (LTE) and 50% (10/20) of patients were in remission at week 126.[5]
- Adverse events were reported in 33/35 (94.3%) patients through week 14 and 19/20 (95%) patients through week 126 (LTE).[3]
- Frequently reported AEs were UC exacerbation (50%) and headache (35%). Deaths were not reported from weeks 14 through 126.[3,4]
- More detailed efficacy and safety results are presented in **Table 2 and 3**.

Quality Assessment:

- The overall methodological quality of the single-arm trial (PURSUIT PEDS PK study (Hyams et al. 2017; Hyams et al. 2020; Hyams et al. 2018))[3,4,5] was "fair" according to the suggested categorization scheme for the Downs and Black checklist.[2](**Figure 2**).

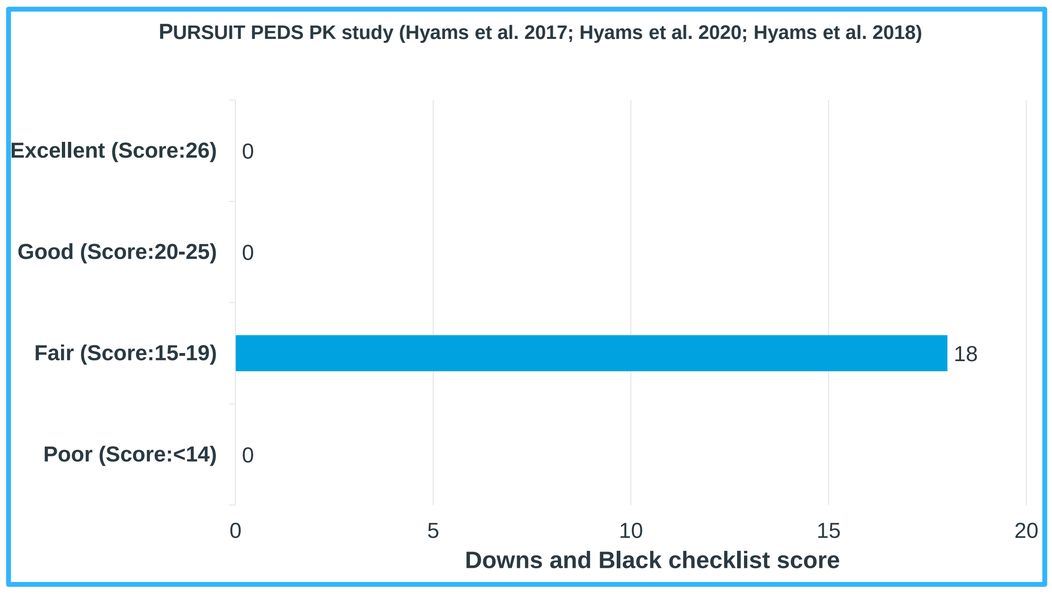
Table 2: Efficacy outcomes

Study name	Timepoint	Sample size (N)	Mayo clinical response n (%)	Mayo clinical remission n (%)	PUCAI clinical remission n (%)	Mucosal healing n (%)
Hyams 2017[3]	Week 6	35	21 (60)	15 (43)	12 (34)	19 (54)
Hyams 2020[4]	Week 30 Week 54 Week 110	20	NR	9 (45) 11 (55) 10 (50)	11 (55) 12 (60) 10 (50)	NR
Hyams 2018[5]	Week 126	20	NR	NR	10 (50)	NR

Table 3: Safety outcomes

Study name	Timepoint	Sample size (N)	AE, Dropout n (%)	Death n (%)	Any AE n (%)	SAE n (%)	UC exacerbation n (%)	Headache n (%)
Hyams 2017[3]	14 Weeks	35	3 (8.6)	0	33 (94.3)	11 (31.4)	13 (37)	9 (26)
Hyams 2020[4]	126 Weeks	20	3 (15.0)	0	19 (95.0)	5 (25.0)	10 (50.0)	7 (35.0)

Figure 2: Quality Assessment



Conclusions

- Golimumab demonstrated continued clinical benefit in pediatric UC patients and an acceptable safety profile.
- Further studies in larger populations are needed to ascertain the therapeutic benefit of golimumab in pediatric UC.

Keywords: AE: Adverse events; SAE: Serious adverse events; UC: Ulcerative colitis; PUCAI: Pediatric Ulcerative Colitis Activity Index

References:

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ISPOR EUROPE 2022 | Clinical Outcomes: Clinical Outcomes Assessment | 9th November 2022