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Background

Vedolizumab (VDZ) has proven as an effective medication in adult Inflammatory Bowel Disease (IBD). There has been increased off-label use of VDZ also in children but with very limited published experience. Therefore we aimed to describe the short-term effectiveness and safety of VDZ in children with IBD in the largest pediatric cohort to date.

Methods

Retrospective review of children (2–18 years) treated with VDZ from 17 centers affiliated with the Paediatric IBD Porto group of ESPGHAN. Baseline characteristics and explicit prior and current clinical data were recorded on a standardized REDcap case-report forms. Primary outcome was treatment success at week 14 and last follow-up, defined as steroid-free remission (i.e. wPCDAI<12.5 or PUCAI<10) without the need for new medications or surgical intervention. Safety data were also explicitly recorded.

Results

Of the 55 included children, 33 (60%) had UC/IBDU, and 22 (40%) had Crohn's Disease (CD); [28 (51%) male, mean age at first VDZ dose 14.5±2.8 years, and median disease duration 3.5 years (IQR 1.8–5.1)]. All were previously treated with anti-TNF (27% primary failure, 49% secondary failure, 15% adverse reaction and 9% for other reasons) and 8 (15%) had prior surgical intervention.

Success rates at week 14 were 21% in UC, and only 9% in CD (p=0.24). Median follow-up period was 22 weeks (IQR 14–22) from VDZ initiation (range 6–76). Success rates by last follow-up were 39% in UC and 27% in CD (p=0.36). By the last follow-up 8 (15%) new children required surgery, of whom 6 had colectomy for UC (18% of the entire UC cohort). There were three mild adverse events to VDZ, including pruritis, transient dyspnea and mild periorbital oedema; there were no serious drug-related adverse events. Median fecal calprotectin decreased from 1168mcg/gm (IQR 609–1409) prior to treatment to 412mcg/gm (IQR 54–745) following treatment when available (p=0.013).

Conclusion

In this largest real-life cohort of VDZ use in pediatric refractory IBD to date, VDZ was safe and effective in 21% and 39% of UC at 14 weeks and last follow-up whereas in CD the rates were 9% and 27%. These data thus support previous findings of slow induction rate of VDZ, particularly in CD.