3种新型生物制剂治疗克罗恩病的疗效及安全性研究Δ

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摘　要　目的　比较英夫利西单抗（IFX）、乌司奴单抗（UST）及维得利珠单抗（VDZ）治疗活动期克罗恩病（CD）的疗效及安全性。**方法**　以2020年1月—2023年12月于中国科学技术大学附属第一医院（安徽省立医院）确诊并起始接受上述任一生物制剂治疗的活动期CD患者为对象，根据其治疗方案的不同分为IFX组（34例）、UST组（37例）、VDZ组（15例）。3组患者均接受IFX、UST或VDZ诱导及维持缓解治疗，且至少治疗12个月。比较3组患者诱导期结束后（治疗第9周）及维持期（治疗第12个月）的CD活动指数（CDAI）评分及其较基线的变化值（ΔCDAI）、临床缓解率、临床应答率、营养指标[体重指数（BMI）、血清白蛋白（ALB）、血红蛋白（HGB）]、炎症指标[C反应蛋白（CRP）、红细胞沉降率（ESR）]，并比较其用药1年的累积临床缓解率和不良事件（AE）发生情况。**结果**　3组患者上述各基线指标比较，差异均无统计学意义（$P>0.05$）。3组患者诱导期结束后和维持期的CDAI评分均较基线显著降低，IFX组患者在上述时间点的CDAI评分均显著低于同期UST组、VDZ组（$P<0.05$），且其维持期ΔCDAI的绝对值显著高于同期VDZ组（$P<0.05$）。IFX组患者在维持期的临床缓解率均显著高于同期UST组、VDZ组，其临床应答率显著高于同期VDZ组（$P<0.05$）。IFX组患者在诱导期结束后及维持期的ALB、HGB、CRP、ESR水平以及UST组患者在诱导期结束后的CRP、ESR水平均较基线显著改善，且IFX组ALB、HGB水平显著高于同期UST组、VDZ组（$P<0.05$）。3组患者的累积临床缓解率差异明显（$P<0.05$），其中IFX组患者获得缓解的速度更快、比例更高。IFX组、UST组、VDZ组患者的AE发生率（14.71%、8.11%、20.00%）的差异无统计学意义（$P>0.05$），IFX组AE以输注反应为主（8.82%）。**结论**　与UST和VDZ相比，IFX具有更高的维持期临床缓解率，可更有效地改善活动期CD患者的营养状态并持续减轻机体炎症反应，但临床需注意该药所致输注反应等AE的发生风险。

关键词　英夫利西单抗；乌司奴单抗；维得利珠单抗；克罗恩病；疗效；安全性

Study on the efficacy and safety of 3 kinds of novel biologics in the treatment of Crohn's disease

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ABSTRACT　OBJECTIVE To compare the efficacy and safety of infliximab (IFX), ustekinumab (UST) and vedolizumab (VDZ) in the treatment of active Crohn's disease (CD). **METHODS** The patients with active CD who were diagnosed and initially received any of the aforementioned biologics at the First Affiliated Hospital of the USTC (Anhui Provincial Hospital) from January 2020 to December 2023 were selected as the study subjects. They were divided into the IFX group (34 cases), the UST group (37 cases), and the VDZ group (15 cases) based on their treatment regimens. Patients in all three groups received induction and maintenance therapy with IFX, UST or VDZ for at least 12 months. The CD Activity Index (CDAI) scores and their changes from baseline (ΔCDAI), clinical remission rates, clinical response rates, nutritional indicators [body mass index (BMI), albumin (ALB), hemoglobin (HGB)], and inflammatory markers [C-reactive protein (CRP), erythrocyte sedimentation rate (ESR)] of three groups after the induction phase (9th week of treatment) and during the maintenance phase (12th month of treatment) were compared. Additionally, the cumulative clinical remission rates at 1 year of treatment and the incidence of adverse events (AEs) were compared. **RESULTS** There were no statistically significant differences in the aforementioned baseline indicators among the three groups ($P>0.05$). In all three groups, the CDAI scores were significantly lower after the induction phase and during the maintenance phase, compared to the baseline

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