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SYSTEMATIC REVIEW OF CURRENTLY AVAILABLE THERAPIES FOR CROHN'S DISEASE AND ULCERATIVE COLITIS

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Objectives: To conduct a systematic review and meta-analysis regarding the efficacy and safety of some biologics for inflammatory bowel disease (IBD), specifically, adalimumab (ADA), golimumab (GLM), infliximab (IFX), ustekinumab (UST), vedolizumab (VDZ), and the janus kinase (JAK) inhibitor, tofacitinib (TOFA). **Methods:** A literature search of the databases PubMed/Medline, The Cochrane Library, European Medicines Agency, International Clinical Trials Registry Platform and Science Direct, for randomized controlled trials on the above-mentioned drugs vs. placebo (PLB), was conducted and data relating to clinical remission, clinical response, adverse events (AE), serious adverse events (SAE), discontinuation due to AEs, infections and serious infections were extracted. **Results:** The literature search resulted in 1397 studies, 17 of which met the inclusion criteria. The meta-analysis included 7 comparisons (2 for ADA, IFX and UST, 1 for TOFA), but GLM and VDZ data could not be compared. The estimated RD (Risk Difference) values for clinical remission and clinical response favored: ADA over PLB with 40 mg/very week and 40 mg/very other week doses ($p < 0.00001$), IFX over PLB for 5 mg and 10 mg doses ($p < 0.00001$) for 8 and 30 weeks of therapy, TOFA over PLB ($p < 0.00001$), UST 130 mg over PLB for 3, 6 and 8 weeks of therapy ($p = 0.02, p = 0.0002, p < 0.0001$ and $p = 0.001, p < 0.00001, p < 0.00001$, respectively) and UST 6 mg/kg over PLB for 3, 6 and 8 weeks of therapy ($p < 0.0001$). For all comparisons, the estimated RD, were not statistically significant for incidence of AE and SAE, discontinuation due to AE and incidence of serious infections. The studies included in the meta-analysis were characterized as having a low to unclear risk of bias. **Conclusions:** Based on clinical remission and clinical response data, the results of the meta-analysis suggest that the biologics ADA, IFX, UST, and the JAK inhibitor, TOFA, are more effective than PLB for IBD therapy, but safety data are inconclusive.



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RATES OF DISEASE-RELATED HOSPITALIZATION AND COLECTOMY IN REAL-WORLD PATIENTS WITH ULCERATIVE COLITIS ON ANTI-TNF AGENTS: EVIDENCE FROM A SYSTEMATIC REVIEW

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Objectives: Anti-TNF agents (ATAs) are generally the first-line biological therapy in ulcerative colitis (UC) patients who have failed treatment with corticosteroids and/or immunomodulators. Patients with non-response/loss of response with ATAs undergo treatment switch or colectomy/surgery. We assessed the rates of UC-related hospitalization and colectomy among patients on ATAs in real-world UC patients. **Methods:** A systematic literature review was conducted using comprehensive searches in Embase and Medline databases to identify real-world studies published in English during 2005–January 2022. Studies were included if conducted in biological-naïve UC patients who initiated ATAs, had ≥ 50 patients, and published as full manuscripts. Exclusion criteria were mixed population, < 50 patients, conference abstracts and non-English articles. **Results:** Of the 2593 records retrieved from literature, 29 were included providing 27 unique studies. These studies were from Europe (number of studies [n]=15), Korea (n=5), Canada (n=3), US, and Japan (n=2 each). The study design was retrospective (n=19) and prospective observational (n=7). Studies had variations in age (median, 26–45 years), gender ratio (male, 46–64%), disease duration (median, 3–8 years), and baseline concomitant medications (steroids, 42–89%; immunomodulators, 13–78%; 5-ASA, 31–97%). Studies assessed at least one of the following ATAs: infliximab-originate (n=18), adalimumab (n=6), golimumab (n=2), infliximab-biosimilar (n=2), and ATAs as group (n=5). The follow-up duration ranged from 10 weeks to 5.8 years. UC-related hospitalization was reported in seven studies, with 7–32% of patients being hospitalized in these studies. All studies reported UC-related colectomy, with rates of colectomy/surgery varied between 0% and 42% of patients. Colectomy rates by individual ATA were 1–42% (infliximab), 0–8% (adalimumab), and 1–8% (golimumab). Four studies comparing infliximab and adalimumab showed no significant difference in colectomy rates. **Conclusions:** This review revealed that a considerable proportion of biologics-naïve UC patients in real-world clinical practice undergo colectomy/surgery while on/after treatment with ATAs, whereas data on UC-related hospitalization is limited in literature.



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TEPOTINIB COMPARED WITH CHEMOIMMUNOTHERAPY IN FIRST-LINE NON-SMALL CELL LUNG CANCER (NSCLC): MATCHING ADJUSTED INDIRECT COMPARISON (MAIC) OF VISION IN MET EXON 14 (METEX14) SKIPPING NSCLC AND KEYNOTE-189 IN WILD-TYPE NSCLC

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Objectives: Tepotinib is approved in multiple countries for METex14 skipping NSCLC based on the single-arm Phase II VISION trial (NCT02864992). Prior to approval, patients with this oncogenic driver were treated first-line with chemo-immunotherapy (C+IO), but no study is available for C+IO in patients with METex14 skipping. Therefore, a MAIC was conducted to understand comparative effectiveness. **Methods:** The MAIC (implemented using the R 'maic' package) reweighted patient-level data from the VISION February 2021 cut-off in treatment-naïve METex14 skipping patients to match published patient characteristics in the protocol-specified final analysis from KEYNOTE-189 (pembrolizumab + platinum doublet-chemotherapy in non-squamous, wild-type NSCLC). Studies were matched on age, sex, ECOG, smoking history, histology, and disease stage. Patient characteristics, progression-free survival (PFS) and overall survival (OS) were compared between adjusted-VISION and KEYNOTE-189. **Results:** Differences were observed at baseline between VISION and KEYNOTE-189 populations, including age (median 73.8 vs 65.0 years), ECOG-0 (27.7% vs 45.1%), and smoking history (54% vs 88%). These differences were resolved after matching, reducing the VISION effective sample size (148 to 38.7). Unweighted median (m) PFS was identical between studies, C+IO 11.9 months (95% CI: 8.4, 10.9) vs. tepotinib 11.9 months (95% CI: 7.1–12.4). After weighting, tepotinib was favored (mPFS 14.6 months; 95% CI: 10.1, not reached), with a weighted Cox proportional hazard ratio of 0.67 (95% CI: 0.42, 1.07; $p = 0.091$). Consistent OS results were observed (mOS: C+IO 22.3 months vs tepotinib 23.6 months). **Conclusions:** Following population balancing based on patient characteristics, tepotinib appeared to have a greater PFS than C+IO. However, uncertainty exists due to differences in patient characteristics between METex14 skipping and wild-type NSCLC and the lack of matching on PD-L1 or METex14 skipping. Previous studies suggest METex14 skipping is a negative prognostic factor for IO treatments, so the advantage of tepotinib compared with C+IO could be greater in this population.

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THE RELATIONSHIP BETWEEN ASTHMA CONTROL QUESTIONNAIRE SCORES AND EXACERBATION RISK, RESOURCE UTILIZATION, AND UTILITY VALUES: AN ANALYSIS FROM THE CAPTAIN TRIAL

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Objectives: Poor control of day-to-day asthma symptoms has been associated with increased exacerbation risk and reduced health-related quality of life. Our objective was to quantify the relationship between Asthma Control Questionnaire (ACQ) scores and exacerbation rates, healthcare resource utilization (HCRU), and utility values in adults with moderate-to-severe asthma using data from a phase 3 asthma trial (CAPTAIN) for use in economic modeling analyses. **Methods:** CAPTAIN was a 24- to 52-week, phase 3, randomized controlled trial in adults (≥ 18 years) with inadequately controlled asthma (ACQ-6 ≥ 1.5) despite medium- to high-dose inhaled corticosteroid/long-acting beta-agonist maintenance therapy. We used patient-level data from the CAPTAIN intention-to-treat population regardless of treatment assignment (N=2,436). Negative binomial models were estimated for moderate and severe exacerbation rates using time-varying ACQ-7 score, prestudy inhaled corticosteroid dose, and severe exacerbation history as covariates. Poisson models were estimated for unscheduled HCRU rates (physician, urgent care, and emergency department visits) using time-varying ACQ-7 score as a covariate. For the utility analysis, Asthma Quality of Life Questionnaire (AQLQ) responses were mapped onto Asthma Quality of Life-5 Dimensions (AQL-5D) responses, to which a published time trade-off valuation was applied, and a fractional polynomial model for AQL-5D utility values was estimated using time-varying ACQ-7 as a covariate. **Results:** In our analysis, each 1-point increase in ACQ-7 score was associated with 34.3% and 52.4% increases in annualized moderate and severe exacerbation rates, respectively, and 34.1%, 41.2%, and 89.0% increases in annualized physician, urgent care, and emergency department visit rates, respectively. Utility values from the AQLQ/AQL-5D analysis ranged from 0.982 to 0.540 across the ACQ-7 range (0.14–4.71) observed at baseline. **Conclusions:** This study quantifies the relationship between poorer symptom control (measured by ACQ-7) and worse exacerbation, HCRU, and utility outcomes in a moderate-to-severe asthma population. Our results may support future economic evaluations in asthma. **Funding:** GSK (206918, HO-17-17257)



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REAL-WORLD (RW) USE OF CLADRIBINE TABLETS IN PORTUGAL: A TWO-YEAR UPDATE OF A COHORT DATABASE

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Objectives: To present a two-year update on RW data available from a patient registry of patients with multiple sclerosis (MS) being treated with cladribine tablets in Portugal. **Methods:** Anonymized data was retrieved from a patient support program database of MS patients currently being treated with cladribine tablets in Portugal. Data was checked for missing values and descriptive analysis was run for the available information using STATA17. For all parameters missing data was censored,

