

(29.7 ± 23.0 vs. 28.8 ± 25.0 days) and a non-LVP related readmission (25.7 ± 23.6 vs. 24.6 ± 22.9 days) compared to the LVP only group. **Conclusions:** Adjunctive albumin infusion in cirrhotic patients during LVP procedures may result in a longer hospital-free time period post-discharge. Future studies examining the effect of adjunctive albumin infusion in LVP procedures on readmission for cirrhotic-related complications are recommended.

CO20

PREDICTED TIME TO WHEELCHAIR AND VENTILATION EVENTS COMPARING AVALGUCOSIDASE ALFA (AVA) VERSUS (VS) ALGLUCOSIDASE ALFA (ALG) USING A MODEL OF LATE-ONSET POMPE DISEASE (LOPD)

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Objectives: LOPD is associated with progressive loss of muscle and respiratory function, which may require assisted ventilation and/or use of a wheelchair. Preventing or delaying these adverse outcomes is an important treatment goal but evaluating treatment effects on the need for ventilation and wheelchair support is difficult in a clinical trial due to the length of observation and large sample size required. An alternative approach is to simulate treatment effects on these outcomes using existing observational and clinical trial data. **Methods:** A disease model was created using a combination of the results of Phase 2 and 3 studies of AVA, data in the public domain, and Pompe Registry data on ALG. Equations were developed reflecting the relationships between treatment and both forced vital capacity and 6-minute walk test distance, along with eventual need for ventilation and wheelchair use. These were implemented in a DICE (Discretely Integrated Condition Event) individual-level simulation, which was used to predict the proportions of patients requiring future ventilation and/or wheelchair and the average time to those requirements, depending on whether the patient received AVA or ALG. **Results:** When simulated over a lifetime horizon, AVA reduced the cumulative percentage of patients needing non-invasive ventilation by 13.8% (55.6% vs. 69.4%), invasive ventilation by 13.1% (23.3% vs. 36.4%), and wheelchair use by 20.1% (38.0% vs. 58.1%), compared to ALG. Requiring non-invasive ventilation, invasive ventilation, and wheelchair was delayed by a mean of 4.6 years (22.0 vs. 17.4), 5.6 years (36.3 vs. 30.7), and 6.4 years (26.0 vs. 19.6), respectively. **Conclusions:** The findings from simulation suggest that the immediate benefits of AVA vs. ALG will lead to reductions in the need for assisted ventilation and wheelchair use in patients with LOPD. This analysis further supports the overall clinical relevance of AVA in LOPD. Prospective analysis is warranted to confirm these findings.

CO21

VALIDATION OF CROSSOVER ADJUSTMENT OUTCOMES IN A RANDOMIZED CLINICAL TRIAL (RCT) USING REAL-WORLD EVIDENCE (RWE) IN NON-SMALL CELL LUNG CANCER (NSCLC)

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Objectives: In some RCTs crossover is allowed. This might bias estimates of relative treatment effect. Several crossover correction methodologies may be applied, such as the rank-preserving structural failure time model (RPSFTM), inverse probability of censoring weights (IPCW) and the two-stage method. These methods aim to adjust survival for patients who crossover to reflect clinical practice. The aim was to validate the outcomes of crossover methodologies using RWE. **Methods:** In KEYNOTE-024, pembrolizumab was compared to chemotherapy in stage IV NSCLC with PD-L1 tumor proportion score of ≥50%. The chemotherapy arm (n=151) was corrected for crossover using the two-stage method. The RWE study included n=108 stage IV NSCLC patients treated with chemotherapy. Patient characteristics of KEYNOTE-024 and RWE were compared on age, histology, sex and smoking status. Survival after crossover adjustment was compared with overall survival of stage IV NSCLC patients treated with chemotherapy in clinical practice. **Results:** The baseline characteristics between RWE and RCT studies were similar. PD-L1 was ≥50% in KEYNOTE-024, but not reported for RWE. Survival of RWE and RCT crossover-adjusted chemotherapy arms was almost identical up to month 10 of follow-up. After 10 months, survival for the crossover-adjusted chemotherapy arm flattened, whereas survival of chemotherapy in clinical practice did not flatten. Crossover adjusted survival was observed to provide a better prediction of RWE survival, compared to the unadjusted survival. **Conclusions:** Crossover adjusted data overestimated survival compared to clinical practice. Further research is needed to determine the cause, which might be explained by differences between RWE and RCT studies. Potential differences include quality of care, subsequent treatment after crossover, inclusion and exclusion criteria (e.g., PD-L1 status), limited patient numbers in the tail, or methodological issues

regarding the two-stage method. Validation against RWE remains important for prediction of clinically plausible survival.

CO22

USE OF IXEKIZUMAB FOR PSORIATIC ARTHRITIS PATIENTS IN REAL-WORLD CONDITIONS

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Objectives: To describe patients characteristics, treatment patterns, persistence and effectiveness of ixekizumab in psoriatic arthritis (PsA) patients in a real-world setting. **Methods:** Retrospective study conducted in 8 Spanish rheumatology units, including adult patients with PsA who started ixekizumab treatment between January 1, 2019 and December 31, 2020, with a minimum follow-up of 24 weeks until treatment interruption/end of follow-up. Demographic/clinical characteristics, treatment patterns and changes in the Disease Activity in Psoriatic Arthritis (DAPSA) were collected. Continuous data were presented as mean (standard deviation (SD)) and categorical variables as count and percentage. Effectiveness was evaluated by changes from baseline until 12/24 weeks, using paired t-test. Treatment persistence was estimated by Kaplan-Meier method. **Results:** Eighty-nine patients were analyzed: mean age at ixekizumab initiation 51.5 (11.6) years; 55.1% women; mean body mass index 24.1 (4.8) kg/m². Mean time from PsA diagnosis was 10.3 (9.0) years, 55.1% peripheral, 13.6% axial, and 30.3% both. Before starting ixekizumab, 79.8% of patients received at least one conventional synthetic disease-modifying antirheumatic drug (csDMARD; mean, 1.8) and 95.5% had been treated with one or more targeted synthetic or biologic disease-modifying antirheumatic drug (ts/bDMARD; mean, 2.7). The proportion of patients starting ixekizumab in combination with a csDMARD was 37.1% (79% methotrexate). The median persistence was not reached in the study period (mean persistence, 86.9 [95% CI 80.6-93.2] weeks). Treatment persistence rates were 95.5/84.3/68.5% at 24/48/104 weeks. Twenty-one (23.5%) patients discontinued ixekizumab due to loss of effectiveness (21.3%) or adverse events (2.2%). Mean DAPSA score in patients with available information (n=24) at the observed cut-off points decreased significantly from 23.7 (9.8) at baseline to 14.8 (10.3) and 14.3 (7.4) at 12/24 weeks, respectively (p-value 0.005). **Conclusions:** This Spanish cohort of PsA patients treated with ixekizumab had a long-standing and refractory disease. Nevertheless, they showed high treatment persistence and improvements in disease activity after initiating ixekizumab.

CO23

VALIDATING THE RESULTS OF A MATCHING ADJUSTED INDIRECT COMPARISON (MAIC) IN MET EXON 14 (METEX14) SKIPPING NON-SMALL CELL LUNG CANCER (NSCLC)

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Objectives: Tepotinib is approved in multiple countries for METex14 skipping NSCLC based on the Phase II VISION study (NCT02864992). As this study did not contain a control arm, real-world data (RWD) from five pooled sources in patients with METex14 skipping NSCLC were used to estimate the comparative effectiveness of tepotinib against pembrolizumab. However, uncertainty exists in the comparisons due to the non-randomized nature of RWD. This study aimed to confirm the findings of the RWD analysis using published clinical trial data. **Methods:** RWD for pembrolizumab were available for patients with METex14 skipping NSCLC, and published data from KEYNOTE-024 were available for pembrolizumab in NSCLC without EGFR/ALK mutations (wild-type). Tepotinib (treatment-naïve patients from VISION) was compared with pembrolizumab RWD using propensity scoring and with KEYNOTE-024 using MAIC. For validation, pembrolizumab RWD (METex14 skipping) were reweighted for comparison with KEYNOTE-024 (wild-type) to assess differences in pembrolizumab outcomes between wild-type and METex14 populations. **Results:** A benefit was seen for tepotinib when comparing to pembrolizumab using METex14 NSCLC RWD (median investigator progression-free survival [PFS]: 8.5 versus 3.3 months). In the KEYNOTE-024 comparison, a benefit was also observed for tepotinib (median PFS 13.5 versus 8.3 months). Overall survival (OS) results were similar between tepotinib and

pembrolizumab. After accounting for differences in patient characteristics, pembrolizumab RWD presented a poor match in outcomes versus the wild-type population from KEYNOTE-024 (median PFS: 6.2 vs 8.3; median OS: 15.6 vs 26.0 months). **Conclusions:** Multiple datasets with different levels of data access can be leveraged to reduce the inherent uncertainty of indirect comparisons. In this analysis, tepotinib improved PFS compared with pembrolizumab regardless of data source. After adjusting for prognostic characteristics, the pembrolizumab RWD showed poorer outcomes than pembrolizumab clinical trial data, suggesting a negative prognostic impact of METex14 skipping. However, other differences in the data sources limit conclusions.

CO25

EFFICACY OF TARGETED DRUGS FOR THE TREATMENT OF ADULTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS IN THE RUSSIAN FEDERATION: A SYSTEMATIC LITERATURE REVIEW UPDATE

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Objectives: To update the existing systematic review and network meta-analysis comparing the efficacy of targeted drugs in adults with moderate-to-severe plaque psoriasis by adding randomized clinical trials (RCTs) on a new interleukin (IL)-23 inhibitor recently approved in the Russian Federation – risankizumab, and other RCTs published after 2019. **Methods:** We updated our systematic literature search in PubMed/MEDLINE and Embase databases. Evidence synthesis included RCTs evaluating the efficacy of adalimumab (ADA), infliximab (INF), etanercept (ETN), certolizumab pegol (CZP), ixekizumab (IXE), netakimab (NTK), secukinumab (SEC), risankizumab (RIS), guselkumab (GUS), ustekinumab (UST), tofacitinib (TOFA), and apremilast (APR) after 12 weeks of therapy. The Bayesian meta-analyses with meta-regression accounted for high heterogeneity in patient characteristics and significant differences in the placebo response rates. The considered drugs were ranked based on values of surface under the cumulative ranking curve. Additionally, drug class analyses were carried out. **Results:** Twenty-three new RCTs were added to the network. IL-23 inhibitor RIS, recently approved in Russia, has joined the group of the most efficacious drugs, such as IL-17 inhibitors NTK and IXE, as well as IL-23 inhibitor GUS. In terms of PASI 75, RIS and IXE showed superiority compared to tumor necrosis factor- α (TNF α) inhibitors (INF, ADA, ETN), small molecules (TOFA and APR), and IL-12/23 inhibitor UST, while NTK and GUS were characterized by comparable efficacy with INF and outperformed the remaining drugs. There were no statistically significant differences between all the TNF α inhibitors. **Conclusions:** The addition of head-to-head trials and increased statistical power of the network revealed previously unidentified significant differences between treatment options for moderate-to-severe plaque psoriasis.

CO26

TYPES OF THE MOST FREQUENT PROVIDER OF AMBULATORY DIABETES CARE AND ITS IMPACT ON CONTINUITY OF CARE, MEDICAL EXPENSES USING NATIONAL HEALTH INSURANCE DATABASE OF KOREA

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Objectives: Several studies have noted benefits of continuity of care (COC) of most frequent provider (MFP) which the primary provider as the seen most frequently during the study period improved patient compliance, decreased health care cost. This is the large-scale observation study which confirm the types of MFP of ambulatory diabetes care and its impact on continuity of care, medical expense using NHIS Database of Korea. **Methods:** This study identified the types of MFP of ambulatory Diabetes cares and categorized into three types of clinics and hospitals or higher. Moreover, this study categorized clinics into functional primary care, specialized and gray-zone clinics according to the comprehensive care provided by the clinics. Categorizing of the MFP among ambulatory diabetes care, this study investigated types of MFP of ambulatory diabetes cares and their effects on continuity of care, medical expense and health outcomes. **Results:** We conducted a cohort with a study population consisted of 185,911 newly diagnosed diabetes patients in 2014 from the NHIS database. The participants were then categorized into types of MFP (three types of clinics and hospitals or higher) and followed from 1 January 2015 until 31 December 2019. Compared to patients within the functional primary care clinics, those within the other types of MFP had reduced COC (specialized clinics; aOR 0.47, CI 0.45–0.49, grey-zone clinics; aOR 0.76, CI 0.73–0.80, hospitals or higher; aOR 0.89, CI 0.85–0.93). Total medical costs of patients were lowest in within the functional primary care clinics (functional primary care; 74.2, median [IQR], specialized clinics; 156, median [IQR], grey-zone clinics; 76.5, median [IQR]). **Conclusions:** Understanding the types of MFP of ambulatory diabetes care will be useful for developing healthcare programs in terms of achieving the appropriate utilization. This paper shows the results provides empirical evidence for policymakers to develop or strengthen program for regular doctor among diabetes patients.

CO27

EVALUATION OF ANTISEPTICS AND THE MICROBIOLOGICAL ENVIRONMENT REGARDING COMPLICATIONS OF PHLEBITIS CAUSED BY PERIPHERAL CANNULAS

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Objectives: Our aim was to demonstrate which of the different antiseptics is more effective in reducing phlebitis occurrence and to analyse the microbiological environment on the skin surface around the puncture point of the cannula. **Methods:** An experimental, qualitative, quantitative study was performed between July and October of 2021 by collecting samples weekly at the Departments of the University of Pécs Clinical Centre. Patients included in our study gave written consent, had a peripheral cannula for more than 24 hours, and did not receive oncology treatment. We took, cultured microbiological samples from the skin area around the puncture, and kept survey sheet about cannulas as well. Data were analysed with SPSS 25.0, descriptive statistics, correlation analysis, χ^2 test, ANOVA, and independent samples t-test were calculated ($p < 0.05$). **Results:** 70% isopropyl alcohol (according to descriptive statistics) is most effective in preventing phlebitis. There were no differences between antiseptics with different agents, such as: 72.9% ethanol ($n=29$), 70% isopropyl alcohol ($n=3$), octenidine dihydrochloride / phenoxethanol ($n=9$), 2% chlorhexidine digluconate ($n=3$), and the incidence of phlebitis ($p=0.798$). Microorganisms were cultured in 47.2% of skin inoculations ($n=51$). Cannulas placed into the elbow flexions ($n=14$) had significantly more microbes than those in the forearms ($n=55$) and hands ($n=35$) ($p=0.036$). Cannulas were in the vasculature for an average of 86.55 ± 58.00 hours (min=7, max=316). There was no significant difference in the incidence of phlebitis between cannulas used for ≤ 96 hours ($n=30$) and cannulas used for ≥ 97 hours ($n=14$; $p=0.247$). **Conclusions:** During peripheral short cannula usage, Cutasept disinfectant should be preferred if possible, however, other formulations tested could be used as well and areas of elbow flexion should be avoided to prevent phlebitis development. Based on our study, phlebitis as a complication can be traced back to mechanical or chemical causes in addition to microbial infection.

CO29

THE VERY LONG-TERM DURABILITY OF TEVAR FOR TRAUMATIC AORTIC TRANSECTION DETERMINED BY REAL-WORLD EVIDENCE

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Objectives: The young age of many aortic transection patients treated with TEVAR requires long term follow-up to determine the durability of the endoprosthesis over a period of time appropriate to the patients' expected survival. FDA post approval five-year surveillance studies undermined by high rate of patients lost to follow-up, bench testing of graft components limited to ten years, the paucity of long-term outcomes in 2012, prompted a literature search, an ad hoc Real World Evidence summary showing favorable five year TEVAR outcomes, and a case report of a nine year survivor, presented at the 2012 Third Aortic Conference. This abstract reports the results of a search extended to twenty years with results analyzed by ad hoc summing of RWE to realize very long term outcomes of TEVAR for traumatic aortic transection. **Methods:** The author updated the 2011 systematic search and ad hoc summing of TEVAR data to increase the long-term outcomes to twenty years. The iterative process allowed the sample to be refined to explore insights that emerged from the addition of new data. The search found four additional publications with similar data profiles. The new data provided an additional decade of very long-term clinical surveillance of the endograft supported by objective radiologic data of graft integrity and patient-provided health outcome data. **Results:** The pooling of the four newer studies added an additional 197 patients with endoleaks in 6 patients, malapposition problems in 2 patients, and successful re-intervention in 3 patients. During long term clinical and radiologic follow-up surveillance to 20 years, no fatal endograft failures occurred. **Conclusions:** The RWE supports a conclusion that TEVAR used for blunt thoracic aortic transection provides a long-term stable and durable repair of the traumatic aortic injury. The long term stable aortic repair constitutes evidence for strategizing a reduction in radiation follow-up studies.

CO30

THERAPEUTIC ROLE OF MELATONIN IN PEDIATRIC MIGRAINE: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Objectives: The objective of the current study is to compare the efficacy and safety of melatonin in pediatric migraine. **Methods:** Medline® and Embase® databases were searched via Ovid with English language restriction. In addition, references of included studies and clinicaltrials.gov were manually searched for