003 A single-arm, open-label phase III clinical trial of autologous fibroblast transplantation for facial contour deformities; long-term follow up
S Shahreay, A Bajouri and N Aghdami
Regenerative Medicine, Royan, Tehran, Iran and the University of Tehran, Tehran, Iran

Fibroblast cells and collagen fibrils are decreased during skin aging and also destructed following acne scars. Recently, autologous fibroblast transplantation has emerged as a novel treatment for regeneration of facial contour deformities. Our objective was to evaluate the safety, efficacy and durability of autologous fibroblast transplantation in patients with wrinkles and acne scar. This single-arm, open-label, phase III clinical trial was studied during 2010 to 2015. Patients aged 15–65 years old with an evaluator’s assessment score of more than 2/7, underwent three injections of autologous cultured fibroblasts in 4–6 week intervals and followed up for 2, 6, 12 and 36 months. Collagen type I and vimentin expression, Collagen 1 gene expression and Cytogenetic analysis were assessed before transplantation. Safety and efficacy were evaluated based on comparisons of the baseline and follow up evaluations and patient assessment scores. 57 patients (37 wrinkle, 20 acne Scar) with 168 treatment sites (112 wrinkle, 36 acne Scar) received the treatment and met the follow up sessions. Patients did not report any serious adverse events during the study. 120 sites (90.1%) of wrinkles and 31 sites (86.1%) of acne scars had at least 1-grade improvement. 6 months average improvements of wrinkle and acne scar treatment demonstrated 2 out 7. 56.1% of wrinkle sites and 63.9% of acne scar sites were responders. Long-term follow up sessions showed sustained efficacy and accompanied with patient satisfaction. Autologous fibroblast transplantation could be an efficacious and long-term rejuvenation modality with negligible side effects.

004 Increased relapses and complications in pemphigus patients treated by the same physicians in a public safety net versus a private university healthcare system
O Lai, M Kasperkiewicz2, A Belfach1, L J2, S Groszen1 and D Woodley1 1 Dermatology, University of Southern California, Los Angeles, CA, 2 Pharmacy, University of Southern California, Los Angeles, CA

Access to healthcare and its relationship with socioeconomic status has been documented for different diseases. However, very few studies have been performed on comparing these systems, i.e., a county-funded safety net hospital system (Safety Net System) and a private university healthcare system. The aim of this study was to determine whether any patient care disparities existed between patients with pemphigus, a severe mucocutaneous autoimmune blistering disease requiring on-going immunosuppression, are treated by the same physicians in different healthcare systems, which vary widely in terms of incentives for doctors, affect the care of patients with complex diseases is lacking. The aim of this study was to determine whether any patient care disparities existed when patients with pemphigus, a severe mucocutaneous autoimmune blistering disease requiring on-going immunosuppression, are treated by the same physicians in different healthcare systems, i.e., a county-funded safety net hospital system (Safety Net System) and a private university healthcare system. We performed a retrospective chart review study of 65 patients with pemphigus vulgaris and folliculitis who were managed in the Safety Net System (n=34) and Private System (n=31) between July 2001 and May 2015. Patients in the two systems did not differ considerably with regards to applied treatments and achievement of different diseases. The results of this study showed that the Safety Net System patients were more frequently treated with systemic steroids and less frequently with other systemic immunosuppressive agents and treatment was less well-tolerated. Higher relapse rate was observed in the Safety Net System patients. The adverse events were more frequently severe and occurred at a shorter median time interval in the Safety Net System patients. The safety and quality of care was not as good as in the private system. Our results emphasize the need for further research on the factors that influence the access to Quality of Care in safety net versus private systems.

005 Humanized anti-interleukin-31 receptor A antibody nemolizumab (CIM331) suppresses pruritus and improves eczema in patients with moderate-to-severe atopic dermatitis
K Kabashima1, M Funue2, J Hanin3, G Fulka4, J Mlynczak5, A Wolfenberg6, R Galus7, R Nihratz2, K Etholi2 and T Ruzicka1
1 Kyushu University Hospital, Fukuoka, Japan, 2 Oregon Health and Science University, Portland, OR, 3 Jagiellonian University, Cracow, Poland, 4 Dermatology Clinic, Academic Health, Rzeszów, Poland, 5 Ludwig-Maximilian University, Munich, Germany, 6 Medical University of Warsaw, Warsaw, Poland, 7 Chugai Pharmaceutical Co. Ltd., Tokyo, Japan

We reported efficacy and safety of nemolizumab (CIM331), a humanized anti-IL-31 receptor A (anti-IL-31 RA) antibody, in adult patients with moderate-to-severe atopic dermatitis (AD), who were not controlled with topical treatments. In this 12-week, randomized, double-blind, placebo (pbo)-controlled, multinational Phase II study, patients received nemolizumab (0.1, 0.5, 2.0 mg/kg every 4 weeks (Q4W), or 2.0 mg/kg Q4W) or pbo Q4W subcutaneously. Primary endpoint was improvement from baseline (BL) in pruritus visual analogue scale (VAS) at Week 12. Secondary endpoints included changes in EASI, SCORAD, VAS, and patient Global Assessment of Disease Severity (GI) from BL to Week 12. The study was conducted in 29 sites in 17 countries. Efficacy and safety were evaluated. Mean change from BL to Week 12 was −4.46 ± 0.5 mg/kg nemolizumab and −20.9 ± pbo (p = 0.0247).

006 Therapeutic response guided dosing strategy to optimize long-term adalimumab treatment in patients with hidradenitis suppurativa: integrated results from the PIONEER phase 3 trials W Gulliver, MM Okun, A Martorell, Z Geng, X Huang, O Tang, DA Williams and TG
1 Memorial University of Newfoundland - Faculty of Medicine, St John’s, NL, Canada, 2 AbbVie, North Chicago, IL and 3 Hospital of Matnes, Valencia, Spain

Adalimumab (40 mg/week (ADAw)) dosing is appropriate in clinical or immunological remission of patients with moderate to severe hidradenitis suppurativa (HS). This post hoc analysis identified patients for whom long-term treatment with 40 mg ADAw had the most beneficial risk-benefit ratio based on integrated data from the PIONEER I & II phase-3 trials of ADA for patients with HS. Each study had 2 placebo (pbo)-controlled, double-blind periods. 12-week Period A: 1:1 randomization to 40 mg ADAw or pbo. 24-week Period B: at week 12 of both studies, patients were re-randomized 1:1:1 to 40 mg ADAw (ew/ew), ADA every-other-week (ew/oe), or pbo (ew/pbo). Data from Period B of both studies were integrated. The efficacy endpoint was Hidradenitis Suppurativa Clinical Response (HSCR), defined as ≥50% reduction in total abscess and inflammatory nodule (AN) count with no increase in Epidemic Disease Activity Index (EDA) at the end of Period B. Patient lamina were applied to search for the subpopulations of interest; the final subpopulation was proposed by comparing cross-validation performance of these candidate methods via a rigorous statistical framework. The resulting Period B subpopulation included 2 sets of patients: HSCR Responders (those who achieved HSCR at week 12) plus Partial Responders (those who did not achieve HSCR but reached at least a 25% reduction in AN count [AN25] at week 12); this subpopulation was named the PRR Population. The HSCR rate at the end of Clinical Period B in patients who were HSCR responders (HSR) and PRR Population was 75% and 52%, respectively. Patients in the HSR Population (HSR Population, patients who did not reach a least AN25 at week 12). The majority of HS patients who demonstrated at least partial response to ADA treatment by week 12 showed clinical response when treated with ADA with week.