

F076 - Late-breaking Research: Clinical Studies/Pediatric

Saturday, February 17 3:30 PM — 5:30 PM

Room 5B

3:30 pm - 3:42 pm

6775 - Gentamicin Therapy Induced Type VII Collagen in Recessive Dystrophic Epidermolysis Bullosa Patients Harboring Nonsense Mutations

/Vadim Lincoln, BA

Objective 1: Optimizing of topical gentamicin dosing

Objective 2: Evaluating the feasibility of micro-needle roller-assisted gentamicin delivery

Objective 3: N/A

Background: Recessive dystrophic epidermolysis bullosa (RDEB) is a life-threatening disease caused by mutations in COL7A1 that encodes for type VII collagen (C7). ~30% of COL7A1 mutations are nonsense and generate premature termination codons (PTC). Our previous clinical trial showed that 0.1% gentamicin topically applied to open wounds and intradermally injected into the closed wounds of 5 RDEB patients induced PTC read-through, produced functional C7, and corrected dermal-epidermal separation. Now, we seek to optimize read-through by increasing topical gentamicin dose to 0.5%. Furthermore, since topical gentamicin is ineffective for closed wounds and intradermal injection is potentially painful, we will assess the efficacy of minimally painful MR2 micro-needle roller-assisted gentamicin delivery into closed wounds. Study Type: Clinical Trial Methods: For topical dose evaluation, multiple open wounds in three patients received gentamicin 0.5%-ointment for 14 days. For micro-needle efficacy evaluation, two patients rolled the device daily for 2 weeks over intact skin or scarred areas that previously blistered and gentamicin 0.5%-ointment was applied. Skin biopsies were examined by immunofluorescence before and at one, three, and five months post-treatment for C7 expression. Wounds were evaluated using photographs taken at zero, one, three, and five months post-treatment. Results: Increasing topical gentamicin dose to 0.5% resulted in correctly localized C7 at levels of 38-50% of normal skin (20% of normal was observed with 0.1%) and was sustained for at least three months. With micro-needling, C7 was readily observed at levels 50-130% of normal in treated areas after 1 month with sustained expression at 5 months. In areas that were previously blistered and scarred, newly restored C7 prevented new blister formation. No untoward side effects were observed. Conclusion: Increased topical gentamicin doses resulted in stronger PTC readthrough and greater C7 expression in open wounds. Micro-needle rolling-assisted gentamicin delivery is an effective, minimally painful delivery option for closed wounds.

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6790 - Crisaborole Ointment Improves Disease Severity as Measured by the Atopic Dermatitis Severity Index (ADSI): Pooled Results From Two Phase 3 Studies /Anna Tallman

Objective 1: Examine the efficacy of crisaborole using the Atopic Dermatitis Severity Index

Objective 2: Compare assessment of atopic dermatitis with ADSI vs ISGA

Objective 3: N/A

Introduction: Crisaborole ointment is a nonsteroidal phosphodiesterase 4 inhibitor for the treatment of mild to moderate atopic dermatitis (AD). In 2 identical Phase 3 clinical studies (NCT02118766; NCT02118792), significantly more crisaborole- than vehicle-treated patients experienced improvement in Investigator's Static Global Assessment (ISGA). This post hoc analysis examined efficacy of crisaborole per the Atopic Dermatitis Severity Index (ADSI).

Type of Study: Phase 3 clinical trials.

Methods: Patients ≥ 2 years with mild to moderate AD according to ISGA were randomized 2:1 (1016:506 patients) to crisaborole:vehicle BID for 28 days. ADSI scores were the sum of pruritus, erythema, exudation, excoriation, and lichenification severity scores (4-point scales: none [0] to severe [3]). ADSI scores were interpreted as clear/almost clear (0 to <2), mild (2 to <6), moderate (6 to <9), severe (9-15).

Results: Although all patients had mild to moderate disease at baseline per ISGA, many had moderate (43%) or severe (34%) disease per ADSI. Mean (SD) baseline ADSI scores were 7.39 (2.37) and 7.29 (2.40) for crisaborole and vehicle arms, respectively. Mean change (95%CI) in ADSI score at day 29 was significantly greater in crisaborole-treated patients (-3.52 [-3.72 to -3.32] vs -2.42 [-2.72 to -2.12];, $P < 0.0001$). Proportion of crisaborole- vs vehicle-treated patients with ADSI score of clear at day 29 was 38% vs 31% for mild disease, 22% vs 15% for moderate disease, and 13% vs 4% for severe disease at baseline.

Conclusions: In this post hoc analysis of 2 Phase 3 studies, crisaborole demonstrated greater improvement in disease severity than vehicle based on ADSI scores.

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6638 - Oral Ivermectin vs. Oral Fluralaner for the Treatment of Scabies /Mohamad Goldust, MD

Objective 1: This study aimed at comparing the efficacy and safety of oral ivermectin vs. oral fluralaner the treatment of scabies.

Objective 2: Efficacy and safety of oral ivermectin for the treatment of scabies

Objective 3: Efficacy and safety of oral fluralaner for the treatment of scabies

Objective: Scabies is a skin infestation caused by a mite known as the *Sarcoptes scabiei*. It is commonly treated with the insecticides but the treatment of choice is still controversial. This study aimed at comparing the efficacy and safety of oral ivermectin vs. oral fluralaner the treatment of scabies. Methods: In this double blind clinical trial study, 242 patients with scabies were enrolled, and randomized into two groups: the first group received a single dose of 200 µg/kg body weight oral ivermectin, and the second group received single dose of oral fluralaner. Treatment was evaluated at intervals of 2 and 4 weeks, and if there was treatment failure at the 2-week follow-up, treatment was repeated. Results: A single dose of ivermectin provided a cure rate of 67.7% at the 2-week follow-up, which increased to 82.6% at the 4-week follow-up after repeating the treatment. Treatment with single dose of oral fluralaner was effective in 71.5% of patients at the 2-week follow-up, which increased to 85.9% at the 4-week follow-up after this treatment was repeated. Conclusion: At the 4-week follow-up, oral ivermectin was as effective as oral fluralaner. Fluralaner is a new and cost-effective antiparasitic drug and as treatment can be given to masses with better compliance with or without supervision.

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6659 - Glycopyrronium Tosylate for the Treatment of Primary Axillary Hyperhidrosis: Pediatric Subgroup Analyses from the ATMOS-1 and ATMOS-2 Phase 3 Randomized Controlled Trials /Adelaide A. Herbert

Objective 1: Hyperhidrosis is largely underdiagnosed and undertreated, particularly in pediatric patients; efficacy and safety data from two replicate phase 3 trials of topical glycopyrronium tosylate (GT; formerly DRM04) were evaluated by age group to better understand the impact of treatment in the pediatric population ($\leq 16y$).

Objective 2: To compare efficacy and safety of topical glycopyrronium tosylate in the pediatric population ($\leq 16y$) versus the older cohort ($>16y$) at Week 4.

Objective 3: N/A

Background: Topical glycopyrronium tosylate (GT; formerly DRM04) is an anticholinergic developed for treatment of primary axillary hyperhidrosis.

Type of Study: ATMOS-1 and ATMOS-2 were randomized, double-blind, vehicle (VEH)-controlled, 4-week phase 3 trials assessing efficacy and safety of GT in patients $\geq 9y$.^[1]

Methods: Pooled efficacy and safety data are shown at Wk4 for patients $\leq 16y$ (pediatrics) vs $>16y$ (older) from post hoc analysis of ATMOS-1 (NCT02530281) and ATMOS-2 (NCT02530294). Patients had primary axillary hyperhidrosis $\geq 6mo$, average Axillary Sweating Daily Diary (ASDD/ASDD-Child [ASDD C]) Item 2 ≥ 4 , sweat production ≥ 50 mg/5 min in each axilla, and HDSS ≥ 3 . Patients were randomized 2:1 to GT 3.75%:VEH.

Results: 463 patients were randomized to GT and 234 to VEH. Of these, 44 were $\leq 16y$ (GT, N=25; VEH, N=19). Baseline demographics and disease characteristics were similar between age groups. Efficacy results were consistent among patients aged $\leq 16y$ vs $>16y$ and the overall population.^[2] Pooled ASDD/ASDD C Item 2 responder rates (≥ 4 -point improvement; pediatric vs older cohort) were 59.9% vs 60.2% for GT- and 13.0% vs 28.8% for VEH-treated patients. Median absolute decreases in sweat production (mg) were -64.2 vs -80.6 for GT- and -53.7 vs -62.0 for VEH-treated patients; 79.9% vs 74.3% GT- and 54.8% vs 53.0% of VEH treated patients had $\geq 50\%$ reduction in sweat production. Mean decrease from Baseline in CDLQI (GT, -8.1; VEH, -1.9) was consistent with DLQI (GT, 8.4; VEH, -4.7). TEAEs were reported for 44.0% vs 56.7% of GT- and 10.5% vs 34.3% of VEH-treated patients. Most were related to anticholinergic activity and were mild, transient, and infrequently led to drug discontinuation.

Conclusions: Topically applied GT was well tolerated and improved disease severity, sweat production, and quality of life, with similar findings in pediatric patients vs the older cohort. TEAEs were similar across age groups and consistent with anticholinergics.

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6722 - Pediatric Malignant Melanoma: A Report from the National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) /Ryan C. Kelm, BS

Objective 1: Assess incidence rate, trends and survival for pediatric MM

Objective 2: Explore MM differences in incidence rates, incidence trends and survival between children and adolescents

Objective 3: Explore pediatric MM gender differences

Introduction Although MM in minors is rare, current incidence rates (IRs) warrant exploration 1-3. We determined the current IRs from the national Surveillance, Epidemiology, and End Results (SEER) cancer database. Type of study Population-based study Methods The SEER database (2000-2014) was searched for data from patients aged 0-19 years, diagnosed with MM, and with known age and malignant behavior. Age-adjusted IR, incidence trends (Annual Percent Change (APC)) and survival were calculated as rates per million. MM cases were detected by using International Classification of Childhood Cancer (ICCC). Results A total of 1,796 cases (218 children, age 0-9 years; 1,578 adolescents, age 10-19) of MM were detected. Although the overall IR for MM was 5 per 1 million, the IR for children (1.3) contrasted with adolescents (8.7). Notably, the IR was significantly higher in females than in males for both children and adolescents, respectively (children = 1.5 F vs 1.0 M and adolescents = 10.2 F vs 7.3 M; $p < 0.05$). IR trends were significantly decreased in adolescents (APC: -4.5; 95%CI -6.2 to -2.7; $p < 0.05$), but not in children (APC: 1.0, 95%CI -2.3 to +4.5). The 5-year survival was higher in adolescent females (97.1%) compared to adolescent males (92.6%). Conclusions The most recent findings from SEER show distinct differences for MM in children vs adolescents, and for females vs males for both children and adolescents, suggesting age and gender differences in the biology of MM. Although pediatric MM is rare, efforts for prevention, and early recognition of pediatric MM is warranted.

REFERENCES

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6589 - Global Skin Disease Burden: An Update from the Global Burden of Disease 2016 Study /Parker Hollingsworth, BS

Objective 1: Use disability-adjusted life-years (DALYs) to compare the mortality and morbidity of diseases, such as those affecting the skin.

Objective 2: Identify which skin conditions examined in the 2016 GBD study have the greatest disease burden.

Objective 3: N/A

Background-- The 2016 Global Burden of Disease (GBD), sponsored by the Bill and Melinda Gates Foundation, is a worldwide collaboration of researchers based at the Institute for Health Metrics and Evaluation. The GBD provides a transparent method of comparing diseases, including skin diseases, through the use of a disability-adjusted life-year (DALY). One DALY is equivalent to one healthy year lost. Study type-- Observational study Methods-- Data for skin diseases was extracted from >10,000 sources, including systematic reviews, cohort studies, disease registries, surveys, and inpatient and outpatient clinic and hospital data. 1 Skin conditions were selected based upon standardized disease definitions, and prevalence. Prevalence estimates, with 95% uncertainty intervals (UIs), were generated using DisMod-MR 2.1, a Bayesian meta-regression tool. Disability-adjusted life-years (DALYs) were determined by adding years of life lost (YLLs) and years lost to disability (YLDs). DALYs for 16 skin conditions were compared across 195 countries, and 23 age categories. Results-- Skin conditions accounted for 60 million DALYS or 2.5% of total DALYS measured across 333 diseases and injuries. In descending order of million total DALYS per skin condition is: Acne vulgaris (15.8), dermatitis (11.2), viral skin diseases (5.9), psoriasis (5.6), urticaria (4), scabies (3.8), fungal skin diseases (3.5), other skin and subcutaneous conditions (3), pyoderma (1.9), melanoma (1.6), keratinocyte carcinoma (1), pruritus (0.71), decubitus ulcer (0.67), cellulitis (0.61), and alopecia areata (0.5). Conclusion-- Skin disease remains a significant cause of disability worldwide, with acne vulgaris resulting in the largest global burden of disease in the 2016 GBD study.

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6730 - Online Care is Equivalent to In-person Care in Managing Psoriasis: A Multi-centered Randomized Controlled Trial /April Armstrong, MD, MPH

Objective 1: Discuss challenges with traditional consultative teledermatology delivery

Objective 2: Compare psoriasis improvements between online versus in-person models of managing psoriasis patients

Objective 3: Discuss dissemination and implications of online care of chronic skin diseases

Background: Many patients with chronic skin diseases lack regular access to dermatology providers and experience poor outcomes. Study Design: We conducted a 12-month, pragmatic, randomized controlled, equivalency trial to evaluate the impact of an innovative online model for psoriasis management as compared to in-person care. Methods: We enrolled 300 adult psoriasis patients across the disease spectrum and randomized them 1:1 to online versus in-person care. The online model enabled patients and PCPs to access dermatologists online directly and asynchronously and fostered multidirectional communication. The primary aim was to determine whether the online model results in equivalent improvements in psoriasis severity as compared to in-person care. Results: The participants were 50% male, 63% white, with mean age 49 (SD14) and baseline BSA 8.5% (SD12%). Over 12 months, the adjusted repeated measures analysis showed that the difference in the average change in PASI (primary outcome) between the online and in-person groups was -0.271 (95% CI -0.853, 0.312). The average change in BSA between the two groups was -0.053% (95% CI -1.584%, 1.477%). Between-group differences in PASI and BSA were within the pre-specified equivalence margins, which demonstrated equivalence between the two interventions. The difference in the average change in Patient Global Assessment (PtGA) between the two groups was -0.111 (95% CI -0.317, 0.096), which exceeded the equivalence margin with the online group showing greater improvement in PtGA. Conclusion: The connected-health online model was equivalent to in-person model in improving psoriasis clinical outcomes.

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6697 - Cytokines Associated with Progression to SCAR and Risk of Death in Hospitalized Cancer Patients with Morbilliform Rash /Alina Markova, MD

Objective 1: To identify hospitalized patients with cancer who are at risk for severe cutaneous adverse reactions

Objective 2: To characterize cytokines associated with progression to severe cutaneous adverse reaction in patients hospitalized with morbilliform rash

Objective 3: To determine cytokines associated with increased risk of death in cancer patients with morbilliform rash

Retrospective review of 49 hospitalized oncology patients to identify clinicoserologic risks for severe cutaneous adverse reactions (SCARs) was performed: 'Complex' morbilliform rash defined as SCAR with systemic organ involvement requiring systemic therapy with prolonged course; 'Simple' morbilliform rash was defined as rash without systemic involvement, or spontaneously resolved systemic involvement, limited course, and not requiring systemic therapy. Results: 'Complex' morbilliform rash (median IL-6=37pg/mL) due to drug/GVHD had significantly higher serum IL-6 than 'simple' rash (16pg/mL; P=0.045). Serum elafin (35.1 vs. 17.0ng/mL; P=0.019) and IL-6 (60 vs 19pg/mL; P=0.015) were statistically significantly higher in cancer patients with morbilliform rash who ultimately died. Elafin, IL-10, TNF- α were not significantly correlated with 'simple' vs. 'complex' rash. IL-10 level correlated with progression to 'complex' rash due to drug ('simple'=20 vs. 'complex'=41 pg/mL; p=0.030). IL-6 was associated with decreased GFR relative to baseline [F(1,41)=5.39; (P=0.025)] with trend for elevated bilirubin (P=0.053). IL-10, TNF- α was not associated with overall mortality, peripheral eosinophilia, hepatic/renal dysfunction, or GVHD. IL-6 was not associated with eosinophilia or GVHD. Elafin had trend for association with GVHD (P=0.052), but not associated with eosinophilia/organ dysfunction. Elevated elafin and IL-6 were statistically associated with higher all-cause mortality in oncology patients with morbilliform rash. At initial dermatology consultation, the pro-inflammatory cytokine IL-6 was statistically significantly elevated in hospitalized oncology patients with morbilliform rash who ultimately developed a complex drug eruption/SCAR. IL-6 may have significant diagnostic value, while serum elafin and IL-6 may have significant prognostic utility in hospitalized patients with cancer who develop morbilliform rash.

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6744 - Prospective Evaluation of ALT-70 and Thermal Imaging for Diagnosing Lower Extremity Cellulitis /David Li, BS

Objective 1: To prospectively examine the performance of ALT-70 and thermal imaging for diagnosing lower extremity cellulitis.

Objective 2: To compare whether the ALT-70 or thermal imaging is superior in diagnosing lower extremity cellulitis within a prospective cohort.

Objective 3: To provide clinical recommendations regarding the application of these two point-of-care modalities in patients with presumed cellulitis.

Background: Cellulitis is a skin and soft tissue infection with many mimickers (aka pseudocellulitis).[1] While dermatology consultation may decrease misdiagnosis rates, widespread implementation is challenging.[2,3] Without a definitive diagnostic tool, current efforts have led to point-of-care modalities to improve diagnostic accuracy, including the ALT-70 model for lower extremity cellulitis and the use of thermal imaging.[4,5] In this study, we evaluate the performance of these two modalities in a prospective cohort. Type of Study: Prospective Cohort Study Methods: We enrolled patients with presumed diagnosis of cellulitis in the emergency department (ED), ED observation unit, or within 24 hours of inpatient admission. Patients requiring antibiotics for abscesses, osteomyelitis, penetrating wounds, bites, or diabetic foot infection, were excluded. Eligible patients were evaluated by a board-certified dermatologist who provided a clinical diagnosis (gold-standard). Patients' ALT-70 scores and skin surface temperatures were also acquired (FLIR ONE iOS Camera).[6] Results: 67 patients with both ALT-70 and thermal imaging data were enrolled. The ALT-70 conferred a sensitivity of 97.8%, specificity of 47.6%, positive predictive value (PPV) of 80.4%, and negative predictive value (NPV) of 90.9% for cellulitis. Thermal imaging had a sensitivity of 87.0%, specificity of 38.1%, PPV of 75.5%, and NPV of 57.1%. Receiver operating characteristic (ROC) curves demonstrated a statistically significance difference between ALT-70 (c-statistic 0.851) and thermal imaging (c-statistic 0.625; $p < 0.01$) in diagnosing cellulitis. Conclusion: ALT-70 is superior to thermal imaging in diagnosing lower extremity cellulitis at a temperature cutoff of 0.47C and may reduce misdiagnosis rates and unnecessary care related to cellulitis.

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