Dermatology research with the Observational Health Data Sciences and Informatics (OHDSI) network

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The Observational Health Data Sciences and Informatics (OHDSI) network enables access to billions of de-identified, standardized health records and built-in analytics software for observational health research. We review dermatology uses of OHDSI. The OHDSI collaborative network has been a successful model for the leveraged use of the vast, rich store of data available from the Observational Medical Outcomes Partnership, a public-private partnership between the FDA, pharmaceutical entities, and healthcare providers. Instrumental to OHDSI is the Common Data Model (CDM), which establishes transformation conventions into a single standardized data format, supporting large scale analytics across heterogeneous data partners. Similarly, a standard vocabulary exists, enabling interoperability between systems, facilitating homogeneity and data transparency, and supporting high-quality research. OHDSI studies may be conducted as a single project, grouped into a common CDM, or as a larger, open, collaborative effort to enhance the ease and speed of observational studies. Its scale lends increased power and reproducibility and characterizes the generalizability of clinical trials to real-world populations; it improves accuracy of estimations and predictions, facilitating the study of rare exposures, diseases, and outcomes. Various applications of OHDSI are represented in the literature, particularly in adverse event reporting, heritability estimation, adherence to treatment, and characterization of previously unknown conditions. Together, these results illustrate the potential of OHDSI in dermatology: its adoption would facilitate examination of treatment patterns that lack best practice guidelines, improve the dermatologic knowledge base, and ultimately, patient outcomes. Bibliometric analysis revealed increasing numbers of dermatology-based OHDSI papers in PubMed — from 2 papers in 2014 to 25 papers in 2020, with topics including prediction modeling, pharmacovigilance, and prognostic studies.

The problematic use of change scores in dermatology clinical trials

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Change scores are common, but important underlying assumptions, such as stable disease at baseline and outcome changes linearly with an approximate slope of one, are necessary for use and interpretation. Likewise, transformations like dichotomized endpoints and percentage change from baseline present unique problems. To assess change score use, we queried all 2015-2019 clinical trials from JADA, Dermatology, BID, JID, JAAD, and JAND summarized change score use, and evaluated underlying assumptions. Seventy-four trials used pre-post baseline scores, 25 used percentage change from baseline, 93 used dichotomized change points to highlight certain study-discussed outcome linearities (13.6%). Eighty-two trials used outcomes for patient selection (32.3%). Seven (8.5%) used a pre-selection score for baseline and 16 (19.5%) had a run-in time prior to baseline scoring. Twenty-two studies (15.4%) plotted mean outcome values over time and an additional 39 studies (32.2%) plotted various change scores. Forty-four (33.9%) scores appeared linear, but only 5 (4.40%) had a slope of approximately 1. The FDA often mandates change score outcomes for medication approval. Accordingly, industry-funded trials were more likely to use change scores (OR from logistic regression 3.32, 1.89-5.83). Use of change scores is common. Model assumptions are infrequently met or discussed. Many robust approaches to pre-post outcomes are available. Dichotomization is particularly troublesome and leads to loss of data and bias. We recommend the elimination of change score usage when possible, as more robust and easily interpretable models exit. Also, we recommend discussion of FDA endpoint requirements with policymakers.

Polypoid melanoma is associated with aggressive histopathological characteristics and poor clinical prognosis compared to non-polypoid nodular melanoma

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Polypoid melanoma is a rare subtype of melanoma characterized by pedunculated exophytic growth. These tumors tend to have a thick Breslow depth, but it is unknown if the prognosis of this subtype is worse compared to other variants of melanoma. A retrospective review was performed of 37 polypoid melanomas and compared to 264 non-polypoid exophytic melanomas. Each case was independently re-evaluated by board-certified dermatopathologists for the following histopathologic parameters including Breslow depth, mitosis rate, ulceration, and angiolymphatic invasion. Basic demographic data and clinical characteristics were collected from electronic medical record data and compared, including clinical stage at diagnosis, locoregional and distant disease at presentation, Breslow depth, and ulceration among other characteristics. Patients with polypoid melanoma had an average age younger than patients with nodular melanoma. Histopathologic review revealed that polypoid tumors had a significantly higher mean Breslow depth and had a higher frequency of angiolymphatic invasion than nodular melanomas. Analysis of clinical outcomes by log-rank test showed a higher risk of distant recurrence and worse overall survival in polypoid compared to nodular melanomas. Multivariate analysis showed an association of polypoid subtype with higher risk of recurrence and worse overall survival. The results of this study support the hypothesis that polypoid melanoma is associated with a higher frequency of aggressive histopathological characteristics and poor clinical prognosis compared to non-polypoid nodular melanoma.

Geographic variations in cutaneous melanoma in the Russian Federation

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Cutaneous melanoma (CM) incidence has been increasing around the world. The goal of this study was to describe geographic incidence and mortality trends in Russia between 2001 and 2017. Oncological data from the Moscow Oncology Research Institute was gathered for the years 2001-2017, geographic information system (GIS) was used to map incident cases, and descriptive analyses were performed. International Classification of Diseases for Oncology (ICD) C43 code (comprising C43.0-C.43.9) was used to identify CM cases. Associations between ethnicity, geographic latitude/longitude, and CM incidence/mortality rates were studied. Routine methods of descriptive epidemiology were used to study incidence and mortality rates by age groups, years, and jurisdictions (i.e., Federal Districts and Federal Subjects of Russia). In total, 141,597 patients were diagnosed with melanoma in Russia over the period 2001-2017, of whom 62% were women. The overall age-standardized incidence and mortality rates were 4.27/100,000 and 1.62/100,000, respectively. A consistent annual increase in both age-standardized incidence and mortality rates was observed. Geographic mapping revealed north-to-south gradient corresponding with increasing UV exposure and east-to-west gradients due to darker skin phenotype in the east and generally colder climates. As the study was fully descriptive, retrospective, and based on official statistical reports, detailed characteristics of clinical forms, anatomic sites, Breslow depth, and treatments could not be analyzed. This study outlined the burden of melanoma in the Russian Federation, and the trends were similar to those observed in countries with similar latitudes and skin phenotype. The importance of the skin color gradient and recreational/cultural practices were some of the most important risk factors highlighted in this study for the development of melanoma in Russia.

Significant disparities in prognosis and survival in Black cutaneous lymphoma patients emphasize the need for more focused study and care

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Cutaneous lymphomas (CLs) are a rare type of non-Hodgkin lymphoma that consist of a diverse group of B- and T-cell subtypes, most of which are mycosis fungoides (MF) and Sézary syndrome (SS). While some CL subtypes are indolent, others may be aggressive and associated with decreased survival. Previous studies have shown worse outcomes and poorer survival for Black patients with MF/SS; however, this data is sparse, and racial/ethnic disparities in prognosis across CL subtypes have not been well elucidated. We present a prospective center study of 51 patients examining racial/ethnic variance in prognostic features and survival among all subtypes of CL. Our population was comprised of 10.4% Asian, 8.1% Black, 20.4% Hispanic, 59.7% white, and 1.4% of unknown race/ethnicity; 46.2% female and 53.7% male; and 16 distinct subtypes of CL. We found that Black CL patients had worse overall survival (p<0.0001) when compared to all other racial/ethnic groups. We affirmed that Black MF/SS patients had worse outcomes and demonstrated that this held true regardless of stage (p<0.0001). Additionally, we showed that, in the MF/SS population, Black patients had a higher rate of development of folliculotropism and/or large cell transformation, which are aggressive features that may portend a poor prognosis. Racial/ethnic disparities in CL have a tangible impact on the lives of Black patients with increased morbidity and mortality. Further studies are requisite to investigate the mechanisms, whether intrinsic and/or extrinsic, behind these inequities as to better guide treatment and ancillary care for the improvement of outcomes for the Black CL population.

Qualitative study of pain experiences among patients with hidradenitis suppurativa

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Hidradenitis suppurativa (HS) is an inflammatory skin disease with recurrent painful, malodorous abscesses at intertriginous sites. Pain, which is the most burdensome symptom of HS, is more highly correlated with reduction in quality of life (QoL) than is disease severity. Evidence guiding HS pain management is lacking, and individuals living with HS are at increased risk of chronic opioid use. This study employed a grounded theory approach to elucidate pain experiences as well as attitudes regarding opioid use among patients with HS. We gathered quantitative data from patient reported outcomes and disease characteristics and qualitative data from semi-structured interviews. Interviews were conducted with English-speaking patients 18 years of age with confirmed HS diagnosis and average Numeric Rating Scale (NRS) pain score of ≥2 over the preceding week. Data collection continued until thematic saturation was reached, requiring a total of 21 interviews. Mean age was 36.9 years, 48% of participants were female, and 71% were non-Hispanic. Almost all (96%) participants had Hurley Stage II or III disease. Mean NRS score for pain over the preceding week was 5.24 (SD: 3.2), and 62% of patients had Dermatology Life Quality Index (DLQI) scores ≥8 (indicating a very to extremely large impact of HS on QoL). Thematic qualitative data analysis yielded four preliminary domains: pain character, pain impact, pain management, and exacerbating/alleviating factors. Participants described their pain using terms associated with both noxious and neuropathic pain character. Within the pain character domain, neuropathic factors had a greater impact on patients with HS. Future research should focus on understanding the role of pain in diverse patient populations and the associated mechanisms, challenges, and activities. Characterizing pain experiences in HS is a critical next step to informing the development of interventions that will improve QoL, reduce opioid use, and strengthen the patient-physician relationship.