1. IPC-sponsored clinical trial demonstrates that kids with psoriasis are more likely to be overweight. Does obesity drive the degree of the skin involvement?


**Summary**

Reported is an IPC-sponsored international, multicenter, cross-sectional study of 409 children with psoriasis. The study was designed to investigate the relationship between excess and central adiposity and the severity of the psoriasis. Matched controls (205 children without psoriasis) were used as comparators. Psoriasis severity was separated into two classes: mild, with a worst Physician's Global Assessment (PGA) score ≤3 with body surface area ≤10%, and severe, with worst PGA ≥3 with body surface area >10%. Excess adiposity (body mass index ≥85th percentile) occurred in 37.9% of children with psoriasis (n = 155) vs 20.5% of controls (n = 42), but did not differ significantly by severity. The odds ratio (95% CI) of obesity (body mass index ≥95th percentile) overall in children with psoriasis vs controls was 4.29 (1.96-9.39) and was higher with severe (4.92; 2.20-10.99) than with mild (3.60; 1.56-8.30) psoriasis, particularly in the United States (7.60; 2.47-23.34, and 4.72; 1.43-15.56, respectively). Waist circumference above the 90th percentile
A Letter from the President

Dear Colleagues,

On behalf of the International Psoriasis Council (IPC) and this issue’s co-editors, Professor Peter Foley of St. Vincent Hospital (Melbourne) in Fitzroy, Australia, and Dr. Gladys Aires Martins of Hospital Universitário de Brasilia, Brazil, I am honored to introduce the June 2013 issue of IPC’s Psoriasis Review.

In this issue, as usual, IPC presents the semi-annual, top-five clinical and research articles from the latter half of 2012. To qualify, manuscripts had to be published either in print or electronically (Epub) between July 1 and December 31, 2012. IPC councilors selected 20 candidate articles and then voted for those they deemed the most compelling contributions to the literature. As affirmation of IPC’s research agenda, I am proud to announce that our councilors selected a publication that resulted from an IPC-sponsored clinical trial evaluating pediatric psoriasis and body mass index. Professor Amy Paller at the Northwestern University Feinberg School of Medicine led the study. It was no small undertaking for such a small organization as IPC to even consider taking on a global clinical trial destined to recruit more than 600 patients from as far afield as Chile, Canada and Malaysia. I recall the intensity and stress of the logistical and financial challenges discussed among the IPC board members. The moral of this story is, “If you can dream it, you can do it!” The resultant manuscript, published in Archives of Dermatology, enhances our understanding of the psoriasis condition. It proposes that dermatologists follow evidence and is now scaling even greater heights with its more recent venture into completing the genetic map of psoriasis. This project, recently initiated in laboratories in London, Kiel, Germany, and Ann Arbor, Michigan, involves the analysis of more than 20,000 genetic samples. As supported by the abundance of literature now focused on genome-wide association study (GWAS) scans and identification of single nucleotide polymorphisms (SNPs) related to psoriasis, our vocabulary is being enhanced by this foray into genetics. The phenomenon is represented by two articles that were also selected in our top five. The first study, by Lu and colleagues, focuses on genome-wide association study (GWAS) scans and identification of single nucleotide polymorphisms (SNPs) related to psoriasis, our vocabulary is being enhanced by this foray into genetics. The phenomenon is represented by two articles that were also selected in our top five. The first study, by Lu and colleagues, focuses on the identification of genetic elements (SNPs) that are shared between psoriasis and conditions that predispose to increased risk for dyslipidemia, hypertension, and coronary artery disease.

The second study, by Tsoi and colleagues, contributes 15 novel susceptibility loci associated with psoriasis, thus contributing to our knowledge of the genetic architecture of psoriasis. The remaining articles focus on the therapeutic interventions and the magnitude of their impact on conditions beyond psoriasis (eg, myocardial infarction) over the long term and important considerations for this chronic systemic inflammatory condition. I hope you’ll find our summaries of these important contributions to the literature to be helpful and informative.

I am also pleased to report the success of IPC’s workshop with world-renowned experts at the May 7 International Investigative Dermatology Congress in Edinburgh, Scotland. Titled “Stratifying Psoriasis: Methods and Clinical Utility,” the program was co-chaired by Dr. Catherine Smith of St John’s Institute of Dermatology in London and Professor Errol Prens of the Erasmus University Department of Immunology in Rotterdam. A summary of the meeting appears on page 18.

This issue also includes a review of the clinical and scientific advances from the 71st American Academy of Dermatology Congress in Miami Beach, Florida, by a future leader in psoriasis research, Dr. Mahir Patel, who is completing a two-year clinical research fellowship focusing on psoriasis under the supervision of Dr. Alan Menter at Baylor University Medical Center-Dallas.

In 2013, IPC will maintain an aggressive agenda designed to make a significant impact on psoriasis care. Within the past year, IPC has sponsored “Meet the Experts” programs in Huntington Beach, California; Prague, Czech Republic; Durban, South Africa; and Buenos Aires, Argentina. In addition, IPC hosted a symposium at the 3rd World Congress of Psoriasis and Psoriatic Arthritis in Stockholm, Sweden, and a “Mechanisms of Disease” workshop at the 42nd Annual ESDR meeting in Venice, Italy. See “Upcoming Events” on the cover page for information about this year’s “Meet the Expert” sessions.

We hope this newsletter is informative and that the knowledge, experience and insights of our faculty are valuable to you in treating your patients who are living with psoriasis and/or psoriatic arthritis.

For additional copies of IPC’s Psoriasis Review, or to learn more about IPC, please visit www.psoriasiscouncil.org.

Sincerely,

Professor Peter van de Kerkhof, MD, PhD
President, International Psoriasis Council
occurred in 9.3% of the control (n = 19), 14.0% of the mild psoriasis (n = 27), and 21.2% of the severe psoriasis (n = 43) participants internationally; this incidence was highest in the United States (12.0% [n = 13], 20.8% [16], and 31.1% [32], respectively). Waist-to-height ratio was higher in psoriatic (0.48) vs control (0.46) children but was unaffected by psoriasis severity. Children with severe psoriasis at its worst, but mild at enrollment, showed no significant difference in excess or central adiposity from children whose psoriasis remained severe.

COMMENTARY Of interest is the increasing incidence of psoriasis in children, which has more than doubled since the early 1970s, coincident with an obesity epidemic in western civilizations. Current research indicates that children who have psoriasis are about as twice as likely to have excess adiposity and increased central adiposity, regardless of psoriasis severity, than children without psoriasis. In the U.S., those with severe psoriasis were seven times more likely to be obese versus children without the diagnosis. Given the association of psoriasis systemic inflammation with increased metabolic risks, there is a requirement for early monitoring and lifestyle modification. While the research delivers evidence of a link, it does not explain a cause-and-effect relationship. Principal investigator Dr. Amy Paller (Northwestern University Feinberg School of Medicine) has stated that the findings were not a surprise, since the body mass index of the group of kids with psoriasis was much higher. But in speculating which condition drives the other, one hypothesis centers on high body mass being the central stimulator of metabolic disease, of which psoriasis is one component. The findings propose that dermatologists need to have a more holistic approach when treating children with psoriasis and must factor in any weight issues before determining a course of therapy. IPC plans to continue a research path toward better elucidating the relationship between psoriasis and metabolic and cardiovascular comorbidities.
2. Genetic variants enriched in psoriasis pre-dispose for multiple cardiovascular and metabolic comorbidities


Summary

This study delivers a potential explanation for the increased association between psoriasis and various cardiovascular and metabolic comorbidities in at least a subset of genetically defined patients. Various databases and expert input were utilized to identify genetic polymorphisms that had been statistically associated with coronary artery disease (CAD), hypertension, body mass index (BMI), hyperlipidemia (cholesterol & triglyceride levels) and type 2 diabetes mellitus. These polymorphisms were then “crossed” with four different genome-wide associated scans from various psoriasis cohorts that were represented by more than 11,000 individuals from the US, Sweden, and UK. Statistical procedures were utilized to ensure the relevance of each genetic association with psoriasis resulting in 80% power to detect genetic variants with OR=1.2 at a 95% confidence level. The results illuminated seven single-nucleotide polymorphisms (SNPs) that were found to be associated with psoriasis, as well as increased risk for dyslipidemia (rs2247056, rs3177928, rs492602, and rs181362), increased blood pressure (rs805303, rs653178, and rs3184504) or increased risk for CAD (rs3184504). Three of the SNPs (rs2247056, rs3177928, and rs805303) were found to be located in the HLA gene region on chromosome 6, HLA-C*06:02 which is known to be associated with psoriasis. However, four non-HLA SNPs were identified to be in or near the genes for FUT2, UBE2L3, and SH2B3. FUT2 encodes an alpha-(1,2) fucosyltransferase that determines the secretor status of blood group antigens on epithelial cells and in bodily secretions. UBE2L3 encodes an ubiquitin-conjugating enzyme involved in cell proliferation and immune function.

SH2B3 encodes an adaptor protein that has pleiotropic signaling roles in regulating lymphocyte differentiation, induction of VCAM-1 and E-selectin on endothelial cells by tumor necrosis factor-α.

COMMENTARY The results validate the accumulating data identifying an association between psoriasis and various cardiovascular-related comorbidities. Furthermore, the data demonstrate shared genetic elements between psoriasis and these conditions that predispose to increased risk for dyslipidemia, hypertension, and CAD. The function of the identified genes may provide insight into the genetic and phenotypic connection between psoriasis and these comorbid conditions. FUT2 has been recently associated with susceptibility to psoriasis and Crohn’s disease, type 1 diabetes and norovirus infection, implying an important immunologic role. UBE2L3 is known to be involved in immune cell proliferation and is associated with susceptibility to other immune-mediated conditions such as celiac disease, rheumatoid arthritis, Crohn’s disease, and systemic lupus erythematosus. Similarly, SH2B3 has an impact on tumor necrosis factor-α function and thrombus formation potentially explaining its dual role in susceptibility to multiple autoimmune diseases and endothelium-related cardiovascular diseases. Further evaluation is required to define the relationship (ie, causative or augmenting) between these SNPs in patients with psoriasis or subsets thereof and the respective cardiovascular co-morbidities.
3. TNF-inhibitor therapy statistically reduces the risk for myocardial infarction in patients with psoriasis


**Summary**

Wu and colleagues performed a retrospective cohort study spanning six years between 2004 and 2010 to investigate the impact of anti-TNF therapy on myocardial infarction (MI). The cohort included patients that had received diagnoses of psoriasis or psoriatic arthritis. That the study was performed within the Kaiser Permanente Southern California (KPSC) health plan is meaningful to the validity of the outcomes. KPSC is a large integrated health maintenance organization that has served approximately 3.2 million members during each of the past 10 years. Members receive most of their health care at KPSC-owned facilities, including prescription drug benefits at KPSC pharmacies. Collectively this integrated system facilitates a comprehensive health care database across the KPSC clinic and hospital systems. The study population included a total of 8,845 patients composed of 1,673 patients who received a TNF-inhibitor for at least two months (TNF-inhibitor cohort), 2,097 who were TNF-inhibitor naive and received other systemic agents or phototherapy (oral/phototherapy cohort), and 5,075 who were not treated with TNF-inhibitors, other systemic therapies, or phototherapy (topical cohort). The collective cohort was observed for a median of 4.3 years (interquartile range, 2.9, 5.5 years), translating into 42,424 patient-years of follow-up. The entire cohort experienced 221 episodes (2.5%) of incident MI, for an overall rate of 5.21 per 1,000 patient-years. The incident rates of MI for the TNF-inhibitor, oral/phototherapy, and topical cohorts were 3.05, 3.85, and 6.73 per 1,000 patient-years, respectively (P < .001). After adjusting for MI risk factors, the TNF-inhibitor cohort had a 50% lower hazard of MI compared with the topical cohort (adjusted hazard ratio, 0.50; 95% CI, 0.32-0.79). Patients in the oral/phototherapy cohort had a 46% lower risk of MI compared with the topical cohort (HR, 0.54; 95% CI, 0.38-0.77).

**COMMENTARY** While there is an increasing body of literature associating psoriasis with various metabolic and cardiovascular comorbidities, the impact of any therapeutic regime on this relationship has not been fully investigated to date. Theorizing that chronic systemic inflammation is the root cause of psoriasis and the associated comorbidities, it follows that treatment strategies targeted to reduce such systemic inflammation should hypothetically result in preferred clinical outcomes. To that end, the current study calculated statistically significant reductions in MI risk and incident rate in patients treated with TNF-inhibitors as compared to those treated with topical agents. Additionally, the use of TNF-inhibitors for psoriasis was associated with a non–statistically significant lower MI incident rate compared to treatment with oral agents/phototherapy, which themselves may have anti-inflammatory effects. Oral agents included cyclosporine, acitretin, and methotrexate; phototherapy included broad-band ultraviolet light B (UV-B), narrow-band UV-B, or psoralen–UV-A. The data expand prior observations from the CORRONA rheumatoid arthritis database, which similarly documented a reduced risk for cardiovascular events (including MI) in patients treated with TNF antagonists. Future research in this area is needed to better define the potential of TNF therapy in reducing the risk of major adverse cardiovascular events in patients with systemic inflammatory conditions.
4. Charting the genetic architecture of psoriasis: new genes enter the mix


Summary

Recently, many contributions to the literature have identified new genetic loci associated with psoriasis. These loci tend to appear in specific areas of the chromosome, most notably within genes linked to TH17 cell function. In order to both validate and extend these prior observations, Tsoi et al helped to design a customized single-nucleotide polymorphism (SNP) array, the immunochip. The immunochip contains 196,524 variants resulting primarily from prior genetic analysis of databases across 12 different immune-mediated inflammatory diseases, including psoriasis. The immunochip permits deeper replication and fine-mapping of genome-wide significant loci and enhances the power to better evaluate the contribution of less significant SNPs. The immunochip was used to analyze five different genetic databases from the European Union and US containing a combined 10,588 patients with psoriasis and 22,806 controls. The efforts resulted in the identification of 15 new susceptibility loci, increasing to 36 the number associated with psoriasis in European individuals. As well, five independent signals were revealed within previously known loci. The data make an important contribution to our evolving knowledge of the genetic basis of psoriasis and, hopefully, form the foundation of superior therapeutic strategies and health outcomes for patients.

COMMENTARY

The preponderance of genetic determinants found in psoriasis and related immune-mediated inflammatory disorders emphasize the importance of the skin to innate and acquired host defense. The new loci identified by Tsoi et al were found to be associated with genes involved in regulating T-cell function (eg, RUNX3, TAGAP, and STAT3), interferon-mediated antiviral responses (DDX58), macrophage activation (ZC3H12C) and nuclear factor (NF)-kB signaling (CARD14 and CARM1). These findings are in keeping with recent advances in psoriasis pathogenesis which span both the adaptive and innate compartments of the immune system. As a consequence of these findings, the cumulative number of significant loci implicated in psoriasis patients with European ancestry has expanded to 36. Interpreting how variants of these genes function together to affect psoriasis is imperative to attaining a full comprehension of the condition and its associated comorbidities.
5. Ustekinumab as a long-term solution to combat psoriasis: a 5-year assessment of safety and effectiveness


Summary

To determine if biological therapies are appropriate as maintenance treatments for psoriasis, studies over longer-term time horizons are required. In this report, Kimball et al report on 517 ustekinumab patients followed for five years to demonstrate a stable clinical response and safety profile that is conducive to the chronic management of the condition. Patients were initially randomized to either placebo or ustekinumab (45 mg or 90 mg) at weeks 0 and 4 and every 12 weeks thereafter; placebo patients crossed over to ustekinumab at week 12. Additionally, partial responders were permitted to adjust their dosing interval to every eight weeks. Clinical response through week 244 was evaluated using the Psoriasis Area and Severity Index (PASI) in the overall trial population. Safety endpoints were evaluated through week 264. The results indicated that initial clinical response was generally maintained through week 244, with a PASI 75 achieved in 63.4% and 72.0% patients receiving the 45 mg and 90 mg doses, respectively. Immunogenicity rates remained low through year 5, with antibodies to ustekinumab detected in only 5.2% of patients. The extended trial was calculated to span 3,104 patient-years of follow-up, with rates of overall adverse events (AEs), serious AEs, serious infections, malignancies and major adverse cardiovascular events that were generally consistent over time and comparable between doses. Notably, the cumulative rates of overall AEs, AEs leading to discontinuation, SAEs, infections, malignancies and MACE (major adverse cardiac event) were generally comparable between patients receiving ustekinumab 45 and 90 mg, suggesting no dose effect. There were 32 serious infections reported in 30 patients, 14 reports of non-melanoma skin cancers and 15 reports of other malignancies. As well, there were 10 cases of MACE (eight in the 45-mg group and two in the 90-mg group) that occurred in patients with at least three established cardiovascular risk factors. Thus, through five years of continuous treatment, ustekinumab maintained a stable effectiveness and safety profile in patients with psoriasis that were consistent with the observations seen in the shorter-term clinical trials.

COMMENTARY

Experiments such as this are important to defining the true potential of therapies in consistently treating the chronic systemic inflammation that is psoriasis. This long-term extension is different from the traditional registries, which report outcomes of an actual-use setting. Nevertheless, the controlled environment affords the potential to collect more robust data through the five-year course of study. Thus, results from these types of analyses will help dermatologists determine the likelihood of treatment success in patients with psoriasis who may be candidates for biologic therapies such as ustekinumab. For example, it is notable that a high proportion of patients maintained skin clearance with PASI 90 responses of 39.7% and 49% for the 45-mg and 90-mg dose groups, respectively. Concomitant with such clinical responses, improvements in health-related quality of life as measured by the DLQI were also consistently maintained through the five-year trial evaluation period. The results confirm that ustekinumab is an effective and well-tolerated therapeutic regimen that is appropriate for long-term management of patients with moderate-to-severe psoriasis.
Psoriasis and psoriatic arthritis were significant topics of discussion at the 2013 American Academy of Dermatology Annual Meeting in Miami Beach, Fla., in March. Renowned speakers, both nationally and internationally, presented the results of various studies related to the treatment of these conditions.

Psoriatic arthritis

Among the studies discussed were PSUMMIT I and II, which were randomized, double blind, placebo-controlled trials that focused on the effects of IL-12/23 blockade on psoriatic arthritis. PSUMMIT I was a 108-week study consisting of 615 patients with psoriatic arthritis randomized to 45 or 90 mg ustekinumab or placebo at weeks 0 and 4, followed by q12w thereafter. The primary endpoint, the percentage of patients achieving an ACR20 at week 24, was achieved in 49.5%, 42.4%, and 22.5% in the 90-mg, 40-mg, and placebo arms, respectively.

PSUMMIT II was a 60-week trial that included patients naïve to TNF blockers and also those who had previously been exposed to anti-TNF agents. Subjects were again randomized to 45 or 90 mg ustekinumab or placebo. ACR20 at week 24 was 43.8%, 43.7%, and 20.2%, respectively, in the ustekinumab 90-mg and 45-mg dosages, compared to placebo. Thus, primary endpoints of ACR20 at week 24 were met in both studies, regardless of previous anti-TNF exposure. Ustekinumab showed a safety profile similar to those seen in previous clinical studies. Also, the result on ACR20 of ustekinumab in psoriatic arthritis was approximately 25% less than seen with three TNF-α agents (adalimumab, etanercept, infliximab) at this time point in prior similarly designed studies.

The efficacy of agents targeting the IL-17 pathway is being studied in multiple clinical trials for plaque psoriasis. However, to date, little is known regarding targeting IL-17 for psoriatic arthritis. A proof-of-concept, 6-week, multicenter, double blind, randomized, placebo-controlled trial examined the effect of anti-IL-17A antibody secukinumab on psoriatic arthritis. An ACR20 response rate at week 6 was achieved in 39% of patients on secukinumab versus 23% on placebo, with a tendency for TNF-α-naïve patients to show a better response. Neither result was considered statistically significant. A larger cohort of patients treated for a much longer period of time will be needed to establish a more definitive relationship between secukinumab and psoriatic arthritis, in addition to further studies utilizing other IL-17 targeting agents.

The effect of the investigative agent apremilast, a PDE4 inhibitor, on psoriatic arthritis was also reviewed. ACR20 response at week 12 was 43%, 35%, and 10% in 20 mg twice a day, 40 mg twice a day, and placebo groups, respectively. Diarrhea, nausea, and headache were the most commonly reported adverse events.
A REPORT FROM THE 71ST AAD ANNUAL MEETING

Abatacept is an antibody to CTLA-4, which inhibits T-cell activation by competitively inhibiting the binding of CTLA-4 to CD80 or CD86. It is currently approved for rheumatoid arthritis and juvenile inflammatory arthritis, with phase I studies having shown moderate efficacy in plaque psoriasis. A study of 10 mg/kg/30-min IV infusion of patients with psoriatic arthritis on days 1, 15, 29, and every 28 days showed an ACR20 response of 48% at 169 days compared to 19% in the placebo arm.

An emphasis was also placed on the sixth section of the American Academy of Dermatology 2011 “guidelines of care for the management of psoriasis and psoriatic arthritis,” which recommends that treatment should be guided by the presence or absence of psoriatic arthritis. If a patient with psoriasis does in fact have joint disease and has failed NSAIDs (nonsteroidal anti-inflammatory drugs), methotrexate, and/or a TNF inhibitor should be considered as first-line treatment. Ustekinumab should be considered in the event TNF inhibitors are contraindicated or if patients have failed to respond.

Topical therapy

A review of topical treatments in psoriasis was presented, noting that the vast majority of patients with psoriasis are treated topically. Patient adherence is a limiting factor for topical treatment. Thus, patient preference of a vehicle should always be considered in choosing a topical therapy. This is particularly true for patients with scalp psoriasis, who often have poor adherence due to dislike for certain vehicles on their scalp. Overall, patient adherence is critical for success of topical therapy and should be emphasized through patient education and counseling.

Topical agents in development for psoriasis were discussed, an area that has been largely overlooked compared to investigative biologic agents. New classes of topical agents being studied are nerve growth receptor blockers, janus kinase inhibitors, MEK1/MEKK1 inhibitors, corticosteroid receptor agonists, Rose Bengal plus ambient light, phosphodiesterase 4 inhibitors, STAT inhibitors, and pan-selectin antagonists. Presenters paid considerable attention to topical agents inhibiting the JAK/STAT pathway. Advantages offered over our current topical corticosteroids include lack of HPA axis suppression or cutaneous atrophy. Current topical JAK inhibitors under development include tofacitinib, ASP015K, and INCB018424.

In a phase IIa, multicenter, randomized, double blind, vehicle-controlled trial, 71 patients were randomized to 2% tofacitinib or placebo utilizing two different vehicle ointments administered twice daily for four weeks (Ports, 2013). Results showed topical tofacitinib was well tolerated and efficacious. Adverse event of stinging was reported but was similar across all groups. The agent INCB018424, a JAK 1 and 2 inhibitor, was also examined in a proof-of-concept study (Punwani, 2012). Twenty-nine patients were randomized to 0.5% or 1.0% INCB018424 once daily, or 1.5% twice daily, vehicle or two active comparators, 0.005% calcipotriene or 0.05% betamethasone dipropionate cream, for 28 days. Results showed 1% and 1.5% cream improved lesion thickness, erythema, and scaling as well as reduced lesion area compared to placebo. Few adverse events were reported.

Phototherapy

It is accepted that narrow-band ultraviolet light B (NB-UVB) is more effective than broad-band UVB, although less efficacious but safer than PUVA therapy (ultraviolet light A plus the light sensitizing agent psoralen). Therefore, many dermatologists consider it to be a first-line treatment option.

A systematic review of 29 randomized controlled trials was performed to determine the efficacy of PUVA versus NB-UVB, including three trials directly comparing the two (Archier, 2012). Results suggested PUVA is a more effective treatment; however, given its long-term carcinogenic risk and more cumbersome administration, dermatologists prefer NB-UVB phototherapy as first-line treatment. Carcinogenic risks of PUVA therapy and NB-UVB therapy were assessed in chronic plaque psoriasis patients via a systematic literature review that included 49 published studies in both European and U.S. centers (Archier, 2012).
The review found an increased risk of skin cancers following PUVA in both geographic areas, with higher risk in the U.S. population. However, more prospective trials for psoriasis patients treated with NB-UVB are necessary for more conclusive assessment of its carcinogenic risk.

A review of phototherapy in combination with systemic and biologic agents was also presented. Results showed treatment with etanercept plus NB-UVB phototherapy was more effective at week 6 than treatment with etanercept monotherapy at a clinical, histological and immunological level (Gambichler, 2011).

**Systemic therapy**

Methotrexate continues to be the most widely used systemic agent worldwide for long-term treatment of moderate to severe plaque psoriasis. Double blind, placebo-controlled trials for its use in chronic plaque psoriasis show a Psoriasis Area Severity Index (PASI) 75 response of 40%, which is apparent between 12 and 16 weeks. The RESTORE1 trial directly compared efficacy of infliximab to methotrexate with a primary endpoint of PASI 75 compared to methotrexate-treated patients (78% versus 42%, respectively).

A clinical pharmacogenetic model was utilized to predict response of methotrexate monotherapy in 75 rheumatoid arthritis patients who had failed DMARDs (Fransen, 2012). Risk scores for non response were calculated at six months in patients receiving methotrexate monotherapy by utilizing four clinical factors and four polymorphism genes: MTHFD1, AMPD1, ITPA, and ATIC. At six months, there were 25 responders and 50 nonresponders. The pharmacogenetic prediction model categorized 75% of patients into predicted responders and predicted non-responders based on calculated risk scores. Negative predictive value was determined to be 81%, whereas positive predictive value was determined to be 47%. Therefore, based on this study, the pharmacogenetic model has the potential to predict non response to methotrexate monotherapy.

A 21-patient prospective observational cohort studied the possibility of utilizing weekend cyclosporine therapy (5 mg/kg on two weekend days) after achieving clearance, rather than traditional maintenance doses (2-3 mg/kg daily) (Fernandes, 2013). Results showed similar PASI 75 responses at 32 weeks: 80% of the weekend therapy and 75% of the continuous therapy group. There were four adverse events reported in the continuous therapy compared to one in the weekend therapy cohort; however, they were not statistically significant. These results suggest weekend therapy may be a potential option for maintenance dosing in psoriasis patients who have responded well to cyclosporine.

Efficacy of low-dose versus high-dose acitretin was compared for the treatment of psoriasis in two eight-week, double blind, randomized, placebo-controlled trials followed by a 16-week open label extension (Haushalter, 2012). Patients were randomized to placebo, 10 mg, 25 mg, 50 mg, or 75 mg acitretin in the double blind phase with potential dose adjustment during the open label extension. High-dose treatment was defined as 50 mg/day and low-dose as 25 mg/day, with primary endpoints being investigator static global assessment and reduction in body surface area (BSA). At 24 weeks, low-dose acitretin therapy resulted in treatment success in 47% of cases compared to 29%-33% in other treatment arms. Low-dose acitretin therapy also resulted in the greatest improvement in BSA, 73% compared to 28%-54% in the other treatment groups. This study reinforces the concept of initiating acitretin therapy at a low dose while maintaining clinical efficacy.

**Biologic therapy**

Also discussed at the meeting was the long-term five-year safety of ustekinumab for moderate to severe psoriasis. Safety data were compiled from four clinical studies utilizing ustekinumab for psoriasis treatment and included 3,117 patients who received at least one dose of ustekinumab, 1,482 patients treated for at least four years, and 838 patients treated for at least five
years (Papp, 2013). Rates of adverse events and serious adverse events, with particular attention to infection, non-melanoma skin cancers, other malignancies, and major cardiovascular events were analyzed. Adverse events were comparable between the 45 mg and 90 mg-dose groups. Rates of adverse events were comparable with other approved biologics and rates of overall mortality and other malignancies were comparable with those expected in the general U.S. population (Papp). No significant increase or decrease in MACE (major adverse cardiac events) was noted.

Erythrodermic psoriasis

Safety and efficacy of biologic treatment in erythrodermic psoriasis have not been extensively reported. A multicenter retrospective study utilizing the French Psoriasis Group included 28 patients with erythrodermic psoriasis (>90% BSA) comprising 42 total flares on biologic treatment for three and/or six months (Viguier, 2012). Biologic treatments consisted of infliximab, adalimumab, etanercept, ustekinumab, or efalizumab. Forty-eight percent, 50%, and 40% of flares achieved 75% improvement in BSA or PASI at 12-14 weeks after treatment with infliximab, adalimumab, and etanercept patients, respectively. Twelve serious adverse events were reported, including seven bacterial infections. Biologic treatment was discontinued in 19% of cases due to safety concerns. Only one-third of patients were on the same biologic therapy after one year, suggesting biologic use may show overall short-term efficacy while long-term treatment is hampered by lack of efficacy and side effects.

Nail psoriasis

Nail psoriasis is often overlooked but results in significant quality-of-life impairment for patients. Several randomized controlled trials and case studies with nail psoriasis severity index (NAPSI) as an outcome measure suggest biologic treatments including adalimumab, briakinumab, etanercept, golimumab, infliximab and ustekinumab all improve NAPSI scores (Jemec, 2012). These improvements tend to mirror improvements in skin psoriasis and psoriatic arthritis.

Acute generalized pustular psoriasis

A national, multicenter, retrospective study was conducted among patients with acute generalized pustular psoriasis seen in a French university hospital dermatology department and initiated on anti-TNF treatment (Viguier, 2012). Eleven patients were entered into the study. Anti-TNF agents showed rapid response, particularly infliximab. Five patients discontinued therapy due to adverse events.

A study reviewing 15 patients with moderate to severe generalized pustular psoriasis evaluated response after selectively depleting myeloid lineage leukocytes via the administration of adsorptive granulocyte and monocyte apheresis (GMA) over five sessions (once weekly for five weeks) (Ikeda, 2013). After five sessions, 12 patients were considered responders, based on initial GPP severity scores. The study concluded that GMA was safe and effective and suggested granulocytes/monocytes play a major role in the pathogenesis of generalized pustular psoriasis.

Pustular psoriasis

The National Psoriasis Foundation (NPF) consensus on treatment options for pustular psoriasis was presented (Robinson, 2012). Currently, literature is weak for pustular psoriasis with more extensive studies needed. The NPF consensus recommends that treatment options should be guided by both extent of involvement and severity of disease. Acitretin, cyclosporine, methotrexate, and infliximab were considered by the foundation to be first-line treatments, with adalimumab, etanercept, and PUVA second-line treatments.

Weight gain and psoriasis

Published reports have shown that therapy with anti-TNF agents can lead to weight gain; however, there is no evidence to support such findings in patients treated with ustekinumab. In a prospective, multicenter study, effects of ustekinumab (n=79) and infliximab (n=83) on BMI in
chronic plaque psoriasis patients were directly compared (Gisondi, 2013). After seven months of treatments, patients on infliximab demonstrated a statistically significant increase in BMI (2.1% ± 4.5) compared with ustekinumab-treated patients (0.1% ± 3.3 kg). The study thus demonstrated that, unlike infliximab treatment, ustekinumab treatment does not result in an increase in BMI and is potentially a factor to be considered before initiating biologic therapy (Gisondi).

Waning efficacy of anti-TNF therapy is a commonly reported occurrence in patients, partially explained through immunogenicity and the development of anti-drug antibodies. Seventeen studies—one randomized controlled trial and 16 observational studies totaling 865 patients—of treatment indications for rheumatoid arthritis, spondyloarthritis, psoriasis, and inflammatory bowel disease were conducted in a meta-analysis to assess for anti-drug antibodies and alterations in response rates (Garces, 2012). Anti-drug antibodies to adalimumab and infliximab reduced drug response by 68%, an effect that could be attenuated by concomitant methotrexate. No antibodies were found to etanercept. Therefore, addition of concomitant immunosuppressant medication can potentially curb immunogenicity and improve response.

Dissatisfaction with treatment remains a common problem in patients with moderate to severe disease, yet remains poorly understood. Reasons for discontinuation of therapy were investigated in 1,095 patients with moderate to severe psoriasis (Yeung, 2013). Common reasons reported included cost related to co-payments with phototherapy, side effects of methotrexate, and loss of efficacy with anti-TNF therapy.

Discrepancies often occur between response rates reported in clinical trials and those seen in clinical practice. A retrospective review of 36 consecutive patients treated with ustekinumab from a Barcelona referral center found that overall response was better in patients weighing less than 100 kg (Ruiz Salas, 2012). It also found that biologic-naïve patients achieved better PASI 75 response at 24 weeks compared to previous biologic exposure (85% versus 50%, respectively).

Practical data with anti-TNF–α agents were reported in a retrospective study of a large U.S. claims database, which included 2,534 patients initiated on etanercept and 1,919 initiated on adalimumab (Bonafede, 2013). The data concluded that 46.4% and 56.8% remained on etanercept and adalimumab, respectively, for at least 12 months, 49% and 56.3% were discontinued, 23.8% and 22.4% restarted, and 14.9% and 11.3% switched therapies within 12 months. Thus, there were frequent treatment modifications within 12 months of starting etanercept or adalimumab.

Retreatment data after discontinuation of adalimumab were presented through analysis of REVEAL, a 52-week trial for moderate to severe psoriasis (Papp, 2013). Continuous treatment with adalimumab, 40 mg every other week, was compared to patients receiving retreatment after an interruption period. PASI 75 response rates were 84%, 84%, and 86% at weeks 0, 12, and 24 for the continuous treatment group compared to 40%, 71%, and 79% in the retreatment group. Response to retreatment was highest for patients who had maintained at least a PASI 50 response when entering the retreatment phase. Both groups experienced similar rates of adverse events.

Safety data

In a British Society for Rheumatology Biologics Register study, the authors compared a cohort of 11,881 anti-TNF-treated rheumatoid arthritis patients with a cohort of 3,673 rheumatoid arthritis patients treated with non-biological DMARDs (disease-modifying anti-rheumatic drugs) (Galloway, 2013). The study reported a statistically significant increase in the risk of shingles in anti-TNF-treated patients, whereas no statistically significant increase in the risk of skin and soft tissue infections was observed.

While there is an established increased incidence of serious infections with anti-TNF therapy, it has not been determined whether variability exists among the
different agents. A Dutch Rheumatoid Arthritis Monitoring (DREAM) registry was used to examine this relationship from the time of first serious infection up to five years (van Dartel, 2012). Results showed that the risk of serious infections was similar among rheumatoid arthritis patients treated with adalimumab or infliximab, while the risk was lower in rheumatoid arthritis patients treated with etanercept.

TNF-α therapy associated with cancer risk was further explored in the Safety Assessment of Biological Therapeutics that utilized data from four sources for a total of about 40,000 patients with rheumatoid arthritis, inflammatory bowel disease, psoriasis, and psoriatic arthritis. The assessment compared anti-TNF therapy to disease-specific alternative therapy (Haynes, 2013). Results showed short-term cancer risk was not elevated among those treated with anti-TNF agents compared to alternative therapies.

Comorbidities

Traditional stepwise treatment for psoriasis includes over-the-counter emollients, more potent topical therapies, phototherapy, and, ultimately, systemic treatment. An emerging paradigm allows utilizing the growing armamentarium of biologic treatments in addition to systemic and phototherapy once a patient has failed topical treatments. The agent selected for treatment should be considered with respect to the multiple comorbidities and risk factors associated with psoriasis. Physicians should create a mental “grid” when approaching treatment options and be cognizant of the following factors when selecting treatment: pregnancy, liver function enzymes, diabetes, hypertension, skin cancer, amount of alcohol consumption, dyslipidemia, medications, and cardiovascular disease.

Mehta et al demonstrated further evidence that psoriasis is a systemic disease in a 2011 study of six patients with moderate to severe disease. The study utilized [18F]-fluorodeoxyglucose positron emission tomography-computed tomography (FDG-PET/CT) to detect inflammation. Results demonstrated numerous foci of inflammation, including skin, liver, joints, tendons, and the ascending and descending aorta.

The meeting also included a presentation of the most recent data regarding the association between biologic agents and major adverse cardiovascular events (MACEs). Bigby provided a counterargument to a study titled “Association between biologic therapies for chronic plaque psoriasis and cardiovascular events: a meta-analysis of randomized controlled trials,” which was published in the August 24, 2011, issue of the Journal of the American Medical Association. The study, by Ryan et al, suggested that the association of IL-12/23 inhibitors and major cardiovascular events was a concern but was statistically insignificant and underpowered, and would need to be studied further. Bigby’s counterargument suggested that the rate of MACEs in the IL-12/23 population studied in the original article by Ryan et al was 0.012, ie, 10 times the background rate of the placebo-controlled group in the 22 trials. Thus, the number to harm was found to be 83, a difference that cannot be excluded. Using a different statistical analysis, a similar study by Tzellos et al looked at the incidence of MACEs during the placebo-controlled phase of randomized monotherapy trials of IL-12/23 agents for psoriasis, excluding those for psoriatic arthritis (Tzellos, 2013). Compared to placebo, there was a significant difference in the rate of MACEs observed in patients receiving IL-12/23 inhibiting agents. Therefore, this association of IL-12/23 agents and MACEs is still under significant debate and further investigation through registry studies will be essential to draw more definitive conclusions.

Evidence is becoming more convincing that TNF-α inhibitors reduce the incidence of cardiovascular disease in patients with rheumatoid arthritis as well as those with psoriasis. The CORRONA registry featured 10,156 rheumatoid arthritis patients followed from 2001-06 and assessed for myocardial infarction (MI), transient ischemic attack (TIA)/strokes, and cardiovascular-related deaths. The report concluded that TNF blockers decrease cardiovascular risk,
methotrexate had no effect, and prednisone increased cardiovascular risk (Greenberg, 2011). Similarly, a 2012 study performed by Wu et al within the Kaiser Permanente Southern California health plan showed that treatment with TNF inhibitors significantly reduced the incidence of MI compared to patients treated with topical therapies by 48%. A clinical review of this study is on page 5 of this issue.

Pregnancy and psoriasis

Pregnant women are routinely excluded from prospective clinical trials. Thus, limited data are available regarding treatment options for psoriasis in this select population. Pregnant females may experience new onset disease and flares of psoriasis during their pregnancy but with increased frequency in the immediate post-partum period. Although methotrexate and acitretin have demonstrated known harm to the fetus, there have been too few studies of other biologics such as adalimumab, etanercept, infliximab, and ustekinumab to determine an effect on pregnant psoriasis patients (Bae, 2012). Current registries do not provide sufficient information. According to the National Psoriasis Foundation, topical emollients and low-to-moderate-potency topical steroids are first-line therapy for pregnant women; narrow-band ultraviolet B phototherapy is a second-line agent (Bae). TNF inhibitors and cyclosporine may also be used cautiously as needed. Cyclosporine must be discontinued prior to childbirth as it is excreted in breast milk.

In a 2010 study by Bandoli et al, 170 pregnant women with psoriasis were compared to pregnant controls. Of the 170 patients with psoriasis, 128 patients were treated with biologics during pregnancy. Data showed an increase in obesity and smoking in pregnant women with psoriasis as well as a significantly reduced incidence of prenatal vitamin supplementation compared to non-psoriasis pregnant patients. Overall, preventive care was emphasized, including prenatal screening, dietary and exercise counseling, guidance regarding alcohol and smoking usage, and folic acid supplementation.

A case report of a 22-year-old woman with a long-standing history of recalcitrant pustular psoriasis and psoriatic arthritis was presented (Andrulonis, 2012). She was treated with ustekinumab during pregnancy, experienced no complications and gave birth to a healthy infant.

Yang et al explored the controversy over the effect of psoriasis on birth weight in a 2011 study of 1,463 pregnant women with psoriasis. In the study, 44.1% of the subjects were defined as having severe disease, compared to 11,704 controls. A 1.4 times increase risk of low birth weight in patients with more severe disease compared to controls was noted. There was no increase in risk reported for mild disease.

Elderly and psoriasis

The elderly population is growing at a rapid rate, with psoriasis remaining one of the most prevalent dermatologic conditions in this population. Challenges to treatment are immunosenescence and comorbid conditions and, as a result, a reluctance of healthcare providers to initiate systemic therapy (Wong, 2012). Long-term efficacy and safety in 89 elderly (>65) patients treated continuously with TNF inhibitors, etanercept and adalimumab were evaluated retrospectively (Esposito, 2012). Results demonstrated persistence of response as well as adherence to treatment and a good safety profile.

The association between vaccination for herpes zoster and the incidence of herpes zoster infection in elderly patients (>60) on TNF treatment with various immune-mediated diseases was studied within and beyond 42 days of vaccination. Of 633 patients on TNF inhibitors, no increase in risk of zoster or varicella occurred within 42 days. The study actually showed a reduction of herpes zoster by 47% over a median of two-year follow-up (Zhang, 2012).

Pediatric psoriasis

Further research on the risk of obesity in pediatric patients with psoriasis was performed through a cross-sectional analysis of 409 patients aged five to 17 in North and South America, Europe, and Asia, under the auspices of the IPC. This 2012 study by Paller and colleagues is described in a clinical review on page 1 of this issue.
A REPORT FROM THE 71ST AAD ANNUAL MEETING

A study of 20 patients with psoriasis, ranging in age from eight to 17, showed further evidence linking metabolic syndrome and psoriasis in pediatric patients. The study’s subjects were compared with age- and sex-matched children who had acne vulgaris, warts, or benign nevi. Thirty percent of the pediatric patients with psoriasis demonstrated evidence of metabolic syndrome compared to only 5% in the control group (Au, 2012).

References


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IPC News

IPC Councilors

New Councilors Appointed

Earlier this year, the IPC Board of Directors appointed three new councilors. IPC councilors serve in an advisory capacity and lend their global expertise on psoriasis research, treatment, and education to support all IPC programs, events, and initiatives. They provide expert opinion on current psoriasis therapeutic and research-related issues, participate in roundtable conferences, contribute manuscripts to top-tier journals and make presentations before congresses around the world. The new councilors are:

**Professor Lone Skov – Copenhagen, Denmark**
Professor, Consultant, Department of Dermato-Allergology, Gentofte Hospital
Faculty of Health Sciences, University of Copenhagen, Denmark

In addition to her current positions, Dr. Skov’s distinguished career includes serving as daily leader of the outpatient clinic at Gentofte Hospital’s Department of Dermatology and Venereology. She led the effort to organize theoretical education in dermatology in Denmark and has served as head of the hospital’s Department of Dermatology and Venereology. She received her medical degree from the University of Copenhagen’s medical school and completed her PhD thesis at the same university. Her specialty is dermatovenereology. She has served as a teacher and lecturer in dermatology and venereology, published 88 papers in peer-reviewed journals and three book chapters and has served as a reviewer for a number of scientific and medical journals.

**Linda Stein Gold, MD – Detroit, United States**
Director of Dermatology Clinical Research, Division Head of Dermatology
Henry Ford Health System, Detroit and West Bloomfield, Michigan, USA

Before serving in her present positions, Dr. Stein Gold was senior staff physician and associate director of dermatology research for the Henry Ford Health System. She completed her medical degree at the University of Pennsylvania School of Medicine in Philadelphia, followed by an internship in the Department of Internal Medicine at the Hospital of the University of Pennsylvania and a residency in dermatology at Henry Ford Hospital in Detroit. Stein Gold has been an investigator in numerous clinical studies and is a frequent regional and national lecturer on dermatology topics, including psoriasis, alopecia, viral infections, atopic dermatitis, and fungal infections. An expert in the area of topical therapies, she has published several papers on and is frequently invited to speak on this topic.

**Jashin J. Wu, MD – Los Angeles, United States**
Associate Program Director, Director of Dermatology Research
Kaiser Permanente Los Angeles Medical Center

Jashin J. Wu attended Northwestern University Medical School, completed his internship at Internal Medicine, Baylor College of Medicine, and his residency in dermatology at the University of California, Irvine. Dr. Wu’s interests include psoriasis, clinical research, and “academic dermatology.” Dr. Wu has conducted more than 35 clinical trials and has written more than 125 book chapters or PubMed journal articles that have been published or are in press or submitted. His work has been published in prestigious journals, including New England Journal of Medicine (NEJM), Journal of the American Medical Association (JAMA), JAMA Dermatology, Journal of the American Academy of Dermatology (JAAD), and British Journal of Dermatology.
IPC NEWS

Education and Outreach

Meet the Experts programs

Punta del Este, Uruguay

The 31st Annual Meeting of LatinAmerican Dermatologists (RADLA) took place the weekend of April 26, 2013. IPC, in partnership with SOLAPSO (Sociedad Latinoamericana de Psoriasis), presented “Meet the Experts: Case Based Learning Discussion.” IPC Board Member Alan Menter, MD, Texas, and IPC Councilors Edgardo Chouela, MD, Argentina, and Ricardo Romiti, MD, Brazil, each made presentations along with SOLAPSO president Nélida Raimondo, MD, Argentina, and Néstor Macedo, MD, Uruguay. Each presented a challenging psoriasis case for discussion among one another and invited the participation of the audience.

Paris, France

On July 4, 2013, IPC will hold a “Meet the Experts: Case-Based Learning Discussion” at the 4th Psoriasis International Network Conference in Paris. IPC Board Member Wolfram Sterry, MD, Germany, will serve as program chair. Faculty will include IPC Councilors Nick Reynolds, MD, Great Britain; Wayne Gulliver, MD, Canada; and Colin Theng, MD, Singapore.

Hong Kong, China

Also scheduled for July is the 9th Asian Dermatological Congress in Hong Kong. IPC will sponsor its “Meet the Experts: Case-Based Learning Discussion” as part of the program. IPC Board Member and Christopher Griffiths, MD, Great Britain, will serve as program chair. IPC Board Member, Alan Menter, MD, United States, will participate as one of the faculty presenters, as will IPC Councilor Vermén Verrallo-Rowell, MD, Philippines, and Steven Loo, MD, Hong Kong.

Treatment

The British Journal of Dermatology recently accepted an IPC manuscript for publication


Virtual Evidence-Based Psoriasis Course Starting in Columbia

Responding to the need to provide a high-quality virtual course that offers in-depth analysis of the pathophysiology, immunology and therapy of psoriasis, the Colombian Association of Dermatology (ASOCOLDERMA) and the Colombian Psoriasis and Psoriatic Arthritis Group (COLPSOR) are moving forward with the first psoriasis evidence-based course in Columbia. Primarily a resource to offer degrees of certification to Columbian dermatologists, the program aims to eventually be received as a resource for physicians throughout Latin America. IPC has endorsed the program as an important educational resource for the region.
Research

IPC Symposium: “Stratifying Psoriasis: Methods & Clinical Utility”

On May 7, 2013, IPC sponsored a satellite symposium at the International Investigative Dermatology (IID) Congress in Edinburgh, United Kingdom. The objective was to identify mechanisms by which psoriasis populations can be subdivided, with a view to delineating susceptibility to disease and better responses to treatment. More than 130 participants attended the symposium, which was led by Catherine Smith (St John’s Institute of Dermatology, London) and Errol Prens (Erasmus University, Rotterdam), who also made presentations on “Why Stratify Psoriasis?” and “Immunological Biomarkers of Treatment Response,” respectively. Also making podium presentations were J.T. Elder (University of Michigan, United States) “Genetic Approaches to Stratification;” Gertjan Wolbink (Sanquin Blood Supply, the Netherlands) “TNFi Immunogenicity;” James Krueger (Rockefeller University, United States) “Advances in Tissue Transcriptomics;” and Mike Barnes (William Harvey Research Institute, United Kingdom) who highlighted methods of integrating data to support stratification. A summary publication of the symposium is currently in development.

Dr. James T. Elder, University of Michigan researcher, was a presenter at the May IPC symposium in Edinburgh.

IPC’s Genetics Project: “Towards Completing the Genetic Map of Psoriasis”

IPC continues its aggressive clinical study, which is designed to genetically type rare, protein-altering variants in more than 10,000 psoriasis cases and 10,000 controls. The information might help clarify the genetic architecture of psoriasis, resulting in better targeted therapies and the development of markers to monitor disease progression and drug responsiveness. IPC continues to raise sponsorship funds for the project, which currently is being performed by investigators from the genetic research laboratories of Professors J.T. Elder and Goncalo Abecasis (University of Michigan, U.S.); Jonathan Barker and Richard Trembath (King’s College, London, UK) and Andre Franke (Christian-Albrechts University, Kiel, Germany). The international collaboration is expected to lay the groundwork for innovative approaches to treatment strategies, as well as to define the therapeutic response to treatments in specific psoriasis patients by building a bridge between the genotype and phenotype of the disease. A summary manuscript related to the project has been published: “The quest for psoriasis susceptibility genes in the post-genomewide association studies era: charting the road ahead,” Capon & Barker 2012, Br J Dermatol, Jun;166(6):1173-1175.
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Our vision is to improve scientific knowledge and bring the best care to all patients with psoriasis.

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EDITOR DISCLOSURES

Dr. Gladys Aires Martins, Brasília, Brazil

Dr. Aires Martins has been associated with the pharmaceutical companies Janssen-Cilag, Leo Pharma, Pfizer, and Abbott, serving as an advisory board member, consultant and speaker, and as a participant in clinical trials.

Associate Professor Peter Foley, Fitzroy, Australia

Associate Professor Foley has served as a member of national, regional and global medical advisory boards, investigator, speaker, consultant and/or received educational and travel grants from Amgen, AbbVie, BMS, Celgene, CSL, Eli Lilly, Galderma, GSK/Stiefel, Janssen, Leo, Merck, Novartis, Pfizer, and Roche.