The 6th Psoriasis Symposium for Biologics and Systemic Agents

PROGRAM

Apr. 8th(Sat), 2017
Korea University Anam Hospital
Yoo Kwang Sa Hall

Organized by
The Korean Society for Psoriasis
Sponsored by
The Korean Dermatological Association

인사말씀

안녕하십니까?

어느덧 만물이 소생하는 봄이 되었습니다.

제6회 생물학적제제와 전신치료제에 대한 건선 심포지움에 여러분을 초대합니다.

대한건선학회는 2012년 부터 건선을 보다 효과적이고 안전하게 치료하는 데 도움을 드리고자 지속적으로 이 심포지움을 개최해오고 있습니다.

건선이 더 이상 피부에만 국한된 질환이 아니라는 것이 알려진 지 오래되었지만, 아직도 중등증 이상의 건선 환자분들 중 많은 수가 실제로 필요한 수준에 못 미치는 치료를 받고 있다는 사실이 여러 연구를 통하여 잘 알려져 있습니다. 많은 환자분들은 올바르지 않은 의료정보에 부정적인 영향을 받아 전신 제제를 사용하는 치료를 기피하는 경향이 있고, 이러한 분위기 때문에 의료진들도 적극적인 건선치료를 시행하는 데 주저하거나 어려움을 느끼게 됩니다. 그러나 최근 건선 치료의 주된 흐름은 치료목표(treatment goal)를 정하고 이것을 달성시키기 위한 적극적인 치료방법을 강구해 나가는 것입니다. 이렇게 보다 적극적인 치료를 통하여 환자분들의 치료 만족도가 높아질 수 있습니다.

이 심포지움은 여러분께서 이러한 목적을 달성하시는 데 도움이 될 수 있도록 3가지 session으로 구성되어 있습니다.

첫 번째 세션에서는 가장 보편적인 전신 치료약제들과 광선 치료를 사용하는 전통적 전신 치료법에 대하여 심도있는 리뷰를 진행합니다.

두 번째 세션에서는, 최근 점점 더 눈부시게 발전하고 있는 생물학적제제를 사용하는 치료법을 다루게 됩니다.

지금까지 주로 사용되고 있는 TNF 억제제 들과 interleukin-12/23 억제제 뿐만 아니라 최근 새로 개발된 IL-17과 IL-23 억제제들에 대한 최신 지견이 발표될 것입니다. 아울러 생물학적제제를 사용하는 건선치료 시 고려해야 할 여러 가지 중요한 사항들을 함께 살펴보는 시간도 마련되어 있습니다.

세 번째 세션은, 여러 전문가 패널들이 진료현장에서 만나는 다양한 임상증례에 대하여 함께 토론하며 의견을 교환하는 시간을 통해 이 심포지움에 참석하신 여러분께서 진료현장에서 겪는 여러 가지 문제점들을 함께 풀어 나갈 수 있게 하고자 합니다.

끝으로 이 심포지움을 준비하시느라 많은 노력과 수고를 아끼지 않으신, 대한건선학회 학술이사 김병수 교수를 비롯한 임원진과 훌륭한 강의를 해주신 여러 연자님들, 그리고 학회진행에 도움을 주신 고려대 피부과학교실원 여러분께 깊은 감사의 말씀을 드립니다.

2017. 4

대한건선학회 회장 **송 해 준**

Program

12:00-12:30 **Registration**

12:20-12:30 Opening address; Hae-Jun SONG *(President of KSP)*
Congratulatory address; Jee-Ho CHOI *(President of KDA)*

12:30-13:45 **Session 1 The role of conventionals at the age of biologics**
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13:45-15:00 **Session 2 Recent issues on biologics for psoriasis treatment**
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Sang-Woong YOUN *(Seoul National University)*

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Byung-Soo KIM *(Pusan National University)*

S2-3. **What to consider in using biologics for psoriasis** / 22
Dong Hyun KIM *(CHA University)*

Q&A

15:00-15:30 *Coffee break (30min)*

15:30-17:00 **Session 3 Panel discussion about problematic cases on biologics and systemic agents**
Chairs: Jee-Ho CHOI *(Ulsan University)*, Tae-Yoon KIM *(Catholic University)*,
Joo-Heung LEE *(Sungkyunkwan University)*

Panels: Chul-Jong PARK *(Catholic University)*
Sang-Seok KIM *(Hallym University)*
Seong Jin JO *(Seoul National University)*

Session 1
The role of conventionals at the age of biologics

Chairs: professor Jai Il YOUN *(National Medical Center)*
professor Kwang-Joong KIM *(Hallym University)*

S1-1

Methotrexate

Hai-Jin PARK, M.D.

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Methotrexate, as a folic acid antagonist, interferes with purine synthesis and thus inhibits DNA synthesis and cell replication; it also has specific T-cell suppressive activities. Despite the advent of new therapies, methotrexate continues to play a central role as an affordable, gold standard treatment for recalcitrant psoriasis and psoriatic arthritis.

1. Indications

1) moderate to severe psoriasis, erythrodermic psoriasis, generalized pustular psoriasis, palmoplantar pustulosis, psoriatic arthritis
2) Cutaneous T-cell lymphoma, Langerhans cell histiocytosis, lymphomatoid papulosis, pityriasis rubra pilaris, sarcoidosis, pyoderma gangrenosum, systemic sclerosis, dermatomyositis, rheumatoid arthritis, SLE, Crohn's disease, vasculitis

2. Contraindications

Absolute contraindications	Relative contraindications
· Pregnancy and lactation · Marked anemia, leukopenia, thrombocytopenia · Alcoholism · Active peptic ulcers · Severe respiratory failure · Immunodeficiency	· Kidney failure · Elevated liver enzyme levels · Active or past history of hepatitis · Cirrhosis · Interactions with other drugs · Diabetes · Gastric ulcers · Hyperlipidemia · Hypoalbuminemia · Active infectious diseases · Treatment with immunosuppressive drugs · Recent history of vaccination with a live vaccine

3. Dosage

1) Historically, MTX was administered in three doses over 24 hours. However, since the clinical result is the same, a single dose, which is easier and less confusing, is currently recommended. Parenteral administration (IM or SC) is available for patients who cannot tolerate oral MTX.
2) Begin with a test dose of 2.5-7.5 mg followed 5-6 days later with a CBC, platelet count and hepatic profile.

3) The dose may be gradually increased by 2.5 to 5 mg every 2-4 weeks until satisfactory results are obtained.
4) Once disease control has been attained for at least 1-2 months, the MTX can be tapered by 2.5 mg every 1-2 weeks to the lowest dose that still maintains disease control.
5) The usual weekly dose for psoriasis is 10-15 mg.

4. Side effects

1) Common
Hematologic: leukopenia
2) Uncommon
Skin: Photosensitivity, alopecia, oral ulcers
GI: elevated liver enzymes, nausea, vomiting, anorexia, cirrhosis
Hematologic: thrombocytopenia
3) Rare
Skin: necrosis of psoriatic plaques
Hematologic: pancytopenia, lymphoproliferative disorders (primarily in patients with RA)
Infectious disease: infection
Pulmonary: pneumonitis, fibrosis

Table II. Methotrexate: Baseline and follow-up monitoring and dosage

Baseline monitoring
- History and physical examination
- Complete blood cell and platelet counts
- Liver function tests, blood urea nitrogen level, creatinine level
- HIV testing, if at risk

Follow-up monitoring
- Complete blood cell and platelet counts weekly; then every 4 wk
- Liver function tests, blood urea nitrogen level, creatinine level every 4 to 8 wk
- Repeat blood work 7 d after dose escalation

Dosage
- Test dose: 2.5-5.0 mg
- Average dose: 10-15 mg/wk
- Maximum dose: 30 mg/wk
- When improved, taper by 2.5 mg/mo

Modified from Solganick J, Tan MH, Lebwohl M. Psoriasis Forum 1997;3(4):5.

5. Monitoring

1) In patients without risk factors for hepatic fibrosis, liver biopsies may not be indicated or the frequency of liver biopsies may be markedly reduced.
2) Routine monitoring

References

1. Lebwohl M, Ali S. Treatment of psoriasis. Part 2. Systemic therapies. J Am Acad Dermatol 2001;45:649-61
2. Czarnecka-Operacz M, Sadowska-Przytocka A. The possibilities and principles of methotrexate treatment of psoriasis-the updated knowledge. Postepy Dermatol alergol 1014;31:392-400.

S1-2

Cyclosporin

Bong-Seok SHIN, M.D.

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1. Introduction

Psoriasis is a common, chronic immune-mediated inflammatory skin disorder with potential comobidities. Cyclosporin A (CsA), a potent calcineurin inhibitor that acts selectively on T cells, revolutionized the world of immunosuppression upon its discovery in 1970. Since its approval in 1997 by the FDA for the treatment of psoriasis, CsA has been used with great efficacy in the treatment of not only psoriasis but also a wide consortium of dermatological diseases.

However, in the past decade or so, many dermatologists have become increasingly hesitant to use this important drug because of its potent toxicity profile. But, by lately following guideline recommendations, CsA remains an excellent and indispensable tool for the dermatologist treating moderate-to-severe psoriasis

2. Dose of CsA

In dermatological practice, the daily dose of CsA is usually in a therapeutic range of 2.5-5mg/kg. But, the choice of the initial dose is not only dependent on the personal experience of the dermatologist, but also on the cutaneous and general conditions of the patients.

1) Step-down regimen: start at full dosages(5mg/kg/day) until the achievement of remission and then gradually taper the dosage.
2) Step-up regimen: start with daily doses of 2.5-3mg/kg and gradually build up the dose by 0.5-1mg/kg/day every 2-4 weeks in the event of nonresponse, carefully monitoring tolerability.
3) Other regimens:
   Low dosages - In clinical practice, CsA is often used at low dosages, of 3mg/kg/day or less, and sometimes lower than those comprised in the conventional therapeutic range and that, even at low dosages, the effectiveness of CsA is often remarkable in the routine management of psoriasis.
   Fixed dose - Some studies tried to examine the effects of a fixed dose (Body-weight-independent, 100~300mg/day) which can be more practical in clinical setting.

3. Duration of treatment

CsA is generally used for induction of remission with intermittent short courses generally lasting up to 24 weeks, discontinuing the drug after complete remission is achieved. Various attempts have been made to maintain remission in psoriasis patients treated with continuous CsA, such as reduction in daily dose, inter-

mittent CsA dosing, or switching to topical therapy. In case of relapse, patients may undertake a new cycle using the last most effective and best tolerated dose of CsA.

But, in continuous treatment, the US and European guidelines recommend to avoid for more than 1 year and 2 years, respectively.

4. Pulse treatment

1) For induction of remission - In a pilot study, the "4 on/3 off" regimen (4mg/kg/day for 4 consecutive days) was associated with a slower onset of action, but at 6 months differences in efficacy between treatment groups (vs CsA 4mg/kg/day, taken every day for 6 months) appeared unremarkable.
2) For maintenance of response - Psoriasis Relapse Evaluation with Week-End Neoral Treatment (PREWENT) study aimed at evaluating the efficacy and tolerability of week-end CsA microemulsion for reducing relapse rate in patients with chronic plaque psoriasis who had achieved clinical remission following continuous CsA therapy. Time to first relapse was significantly prolonged with CsA versus placebo, and PASI was significantly lower from weeks 4 to 16 in CsA recipients.

5. Combination, rotation, and sequential therapy

Rotational and combination treatments are practical strategies commonly used in clinical setting to reduce the cumulative toxicity of antipsoriasis treatments and to optimize their risk/benefit ratio. But, because of its high and rapid efficacy, CsA rarely needs to be associated with other systemic therapies.

Also, due to its prompt effectiveness and rapid onset of action, CsA is considered an "accelerator" of clinical response, unlike other slow-acting molecules, acitretin, which are instead considered "maintainers". Therefore, CsA can be used first as a clearing agent with subsequent acitretin as maintenance therapy (sequential regimen).

6. Contraindications of cyclosporin

The AAD and the European guidelines differentiate absolute versus relative contraindications.

Absolute contraindication of AAD guideline is abnormal renal function, uncontrolled hypertension, current malignancy, concomitant phototherapy (PUVA or UVB), >200 cummulative PUVA history, concurrent medication of MTX, concomitant coal tar and radiation therapy, hypersensitivity to cyclosporin, live vaccination, and pregnancy. But in European guidelines, >200 cumulative PUVA history, concurrent medication of MTX, and pregnancy are relative contraindications.

7. Cyclosporin in the era of biologics

Combined therapy with systemic biologics is not generally indicated for psoriasis treatment, although it is increasingly used for the treatment of high-need patients with psoriasis.

CsA has been administered as a rescue option, with or without interruption of biologics, in patients experiencing transitory return or severe exacerbations of psoriasis lesions during biological treatment. CsA in association with TNF-alpha inhibitors (etanercept or adalimumab) has been safely and successfully used in a few series. In these experiences, the addition of CsA was capable of inducing a notable benefit on cutaneous lesions as compared to biologics alone or associated with methotrexate.

S1-3

Acitretin

Ga-Young LEE, M.D.

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Acitretin is the pharmacologically active metabolite of etretinate, and is the only oral retinoid currently approved by the FDA for treatment of severe psoriasis. It is unique compared to other systemic therapies for psoriasis such as methotrexate and cyclosporine in that it is not immunosuppressive. It is, therefore, safe for use in psoriasis patients with a history of chronic infection such as HIV, hepatitis B, hepatitis C or malignancy who have a contraindication to systemic immunosuppressive therapy and require systemic therapy because topical therapy is inadequate and they are unable to commit to phototherapy. Acitretin is one of the treatments of choice for pustular psoriasis. Even though acitretin is less effective as a monotherapy for chronic plaque psoriasis, combination therapy with other agents, especially UVB or psoralen plus UVA phototherapy, can enhance efficacy. Because acitretin is not immunosuppressive, it has also been used in combination with biologic therapies. Recently, the successful combination of acitretin with infliximab, adalimumab, etanercept or ustekinumab have reported in refractory psoriasis. Combination of acitretin with toopical agents is possible, but methotrexate with increase hepatotoxicity and cyclosporine with no evidence of increased efficacy are not recommended.

〈Acitetin in teating poriasis〉

1. Indication

1) FDA approved for adults with severe plaque type psoriasis
2) Acitretin monotherapy is recommended in the treatment of hyperkeratotic hand eczema, severe Darier disease, severe congenital ichthyosis, keratoderma, lichen planus, lichen sclerosus, discoid LE, and premalignant and malignant skin lesions

2. Dosing

1) 10-50 mg/d given as a single dose 2) Star
   Lower doses (#25 mg/d) often used to minimize S/E, especially in combination regimens
2) Starting daily dosages between 10 and 25mg and stepwise escalation are generally associated with higher clinical efficacy and lower incidence of adverse events and are safe in both the short-term and long-term treatments of psoriasis.
3) When acitretin is added to UV, light dose should be reduced by 30%-50%

3. Efficacy characteristics

1) Efficacy rate in short-term results not well defined but are high, based on studies of high dosages that are poorly tolerated
2) Acitretin is the least effective systemic therapy as monotherapy
   - Efficacy rates when used in combination with phototherapy are higher
   - Because acitretin is not immunosuppressive, it has also been used in combination with biologic therapies
3) Acitretin appears to provide better efficacy in pustular psoriasis (palmoplantar and generalized von Zumbusch type) than in PV as a single agent treatment.
4) Acitretin is generally thought to be ineffective for psoriatic arthritis

4. Pathomechanism

1) Reduce the proliferative activity
2) Favors the differentiation of epidermal keratinocytes
3) Inhibits keratinocyte production of VEGF,
4) Reduce intraepidermal migration of neutrophils
5) Inhibits IL-6-driven induction of Th17 cells
6) Promote the differentiation of T-regulatory cells

5. Toxicity

1) Cheilitis, Alopecia, Xerosis, pruritus, Xerophthalmia, night blindness, Dry mouth, Paronychia Paresthesias, Headache, Pseudotumor cerebri, Nausea, abdominal pain, Joint pain, Myalgia, HypertriglyceridemiaSide effect
2) Teratogenicity: Small amounts of etretinate can be formed if acitretin is taken simultaneously with alcohol ¡æ Contraception time in pt. receiving acitretin: ~ 2 years (3years in the US)

6. Contraindications

- Women of childbearing potential
- Severely impaired liver or kidney function
- Chronic abnormally elevated blood lipid values

7. Drug interactions

- Etretinate can be formed with concurrent ingestion of acitretin and ethanol
- Acitretin may potentiate glucose-lowering effect of glibenclamide
- May interfere with the contraceptive effect of microdosed progestin minipill180
- Acitretin and methotrexate can both cause hepatotoxicity, therefore they should be combined with caution
- Acitretin may reduce the protein binding of phenytoin
- Acitretin and tetracyclines can both increase intracranial pressure; their combined use should be avoided
- Concomitant administration of vitamin A and other oral retinoids with acitretin should be avoided

8. Baseline monitoring

- History and physical examination
- Lipid profile, CBC count, LFTs, renal function tests
- Pregnancy test if indicated

9. Ongoing monitoring

- LFTs, lipid profile at 2-wk intervals for the first 8 wk, then every 6-12 wk
- CBC count, renal function tests every 3 mo
- Pregnancy test if indicated

10. Cautious use

1) Pregnancy: category X
2) Nursing: mothers receiving acitretin should not breast-feed
3) Pediatric use: the safety and efficacy of acitretin in children with psoriasis is not established; high-dose, long-term oral retinoid use has been associated with ossification of interosseous ligaments and tendons of the extremities, skeletal hyperostoses, decreases in bone mineral density, and premature epiphyseal closure

References

1. Guidelines of care for the management of psoriasis and psoriatic arthritis. Menter A. et al. J Am Acad Dermatol 2009;61:451-485
2. A review of acitretin for the treatment of psoriasis. Lee CS et al. Expert Opin Drug Saf 2009;8:769-779

S1-4

Phototherapy

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Department of Dermatology, Hanyang University College of Medicine

Phototherapy is utilization of ultraviolet radiation and visible light to treat skin diseases, which is considered to be the first line therapy for psoriasis. Broadband ultraviolet-B (BB-UVB), narrowband ultraviolet-B (NB-UVB), psoralen plus ultraviolet-A (PUVA) and targeted phototherapy such as excimer laser are widely used.

The major molecular target for UVB radiation is nuclear DNA which absorbs light, generating pyrimidine dimers and other photoproducts, which ultimately inhibits DNA synthesis. Psoralen from PUVA binds to double strand of DNA and activated when irradiated. Both PUVA and UVB phototherapy affect cytokine production of inflammatory cells, diminishing inflammatory cytokines, shifting the ratio of T-helper lymphocytes, and changing T-cell morphology.

The initial starting dose of NB-UVB is determined according to skin type or minimal erythema dose (MED). Typical regimens for NB-UVB involve dosing 3 times per week for at least 3 months (Table I). The maximum NB-UVB dose that should be administered is 2,000-5,000mJ/cm2 depending on the photoreactive skin type.

Mild pruritus and transient focal erythema after phototherapy occurs frequently. Any area showing erythema with tenderness or blistering should be shielded during subsequent UV exposures. Repeated exposure of the skin to UV radiation can result in cumulative actinic damage ranging from lentigine to theoretically skin cancer. Photosensitizing medications including tetracycline and hydrochlorothizide should be avoided during phototherapy treatment.

<Table I> Dosing guidelines for narrowband ultraviolet B

According to skin type				According to MED	
Skin type	Initial UVB dose	Dose increase	Maximum dose	Initial UVB	50% of UVB
I	130 mJ/cm^2	15 mJ/cm^2	2000 mJ/cm^2	Treatments 1-20	Increase by 10% of initial MED
II	220 mJ/cm^2	25 mJ/cm^2	2000 mJ/cm^2		
III	260 mJ/cm^2	40 mJ/cm^2	3000 mJ/cm^2		
IV	330 mJ/cm^2	45 mJ/cm^2	3000 mJ/cm^2	Treatments >20	Increase as orderd by physician
V	350 mJ/cm^2	60 mJ/cm^2	5000 mJ/cm^2		
VI	400 mJ/cm^2	65 mJ/cm^2	5000 mJ/cm^2		

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1. Anderson KL. A guide to prescribing home phototherapy for patients with psoriasis: the appropriate patient, the type of unit, the treatment regimen, and the potential obstacles. J Am Acad Dermatol. 2015;72:868-78.
2. Lapolla W. A review of phototherapy protocols for psoriasis treatment. J Am Acad Dermatol. 2011;64:936-49.
3. Menter A. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 5. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol. 2010;62:114-35.

Session 2
Recent issues on biologics for psoriasis treatment

Chairs: professor Nack-In KIM *(Kyung Hee University)*
professor Young Chul KYE *(Korea University)*

S2-1

Anti-TNFs and anti-IL-12/23 agents

Sang Woong YOUN, M.D.

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For the moderate-to-severe psoriasis patients who are relatively unresponsive to conventional therapy, psoriasis physicians are now considering psoriasis biologics for the patients to improve their symptoms with high effectiveness and low adverse effects. Anti-TNFs and anti-IL-12/23 biologics are the main two axis of psoriasis biologics under Korean medical insurance situation, physicians are always in trouble selecting the best medication for each patient. When we select appropriate medication for the patient, we should consider several factors like maximum efficacy, high safety, the effect on the quality of life of patients, drug adherence, and medical cost. The long term safety issues of biologics are now becoming clearer that the biologics usually do not increase the patients' health issues when physicians had screened latent tuberculosis before the initiation of biologics.

In this lecture, I will discuss some factors we should consider before selecting biologics for the moderate-to-severe psoriasis patients.

S2-2

Anti-IL-17 agents, and other new ones

Byung-Soo KIM, M.D.

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Psoriasis is a common immune-mediated inflammatory skin disease with dominant epidermal hyperplasia caused by the excessive secretion of inflammatory cytokines. Current advances in an understanding of the complex immunopathogenesis of psoriasis has facilitated the development of several new, more selective biologic agents. Available therapeutic options include biologic drugs such as tumor necrosis factor alpha inhibitors and interleukin 12/23 inhibitor. Further discovery of antibodies targeting IL-17A (ixekizumab and secukinumab) and the IL-17 receptor subunit (brodalumab) have shown higher levels of efficacy in a greater portion of patients.

This presentation will provide a brief review on the immune abnormalities and the role of IL-17 in psoriasis, and to discuss recent data on the efficacy and safety profile of IL-17 inhibitors. In addition, I would like to provide a glimpse of the pipeline of other therapies (IL-23 blockers, small molecule inhibitors) currently in development for psoriasis.

Table 1. Comparison of treatment response of biologic agents and small molecules in psoriasis and psoriatic arthritis (*adapted from Curr Opin Rheumatol. 2016;28(3):204-10*)

Agent	Psoriasis			Psoriatic arthritis					
	Study	N	PASI 75/pbo (%)	Study	N	ACR20/pbo (%)	D/E +/-	Axial +/-	X-ray +/-
Secukinumab	Juncture	676	87/3.3	Future 2	397	54/7	-	ND	ND†
Ixekizumab	Uncover 2	1224	90/48	RHAP	417	60/31	+/-	ND	+
Brodalumab	Amagine 2	1831	86/8	Phase II	168	39/18	-	-	-
Tildrakizumab	Phase IIb	355	74/4	ND	ND	ND	ND	ND	ND
Guselkumab	Phase II	293	81/5	ND	ND	ND	ND	ND	ND
Apremilast	Esteem 1	844	33/5	PALACE 1	504	31/19	-	-	-

Results from phase II and phase III studies in psoriasis and PsA are enumerated in the table. The data are derived from the trials and should not be used to compare agents since the study populations differ. The results for the most responsive cohorts are shown. ACR, American College of Rheumatology 20 response; Axial, response of axial disease to treatment; D/E, dactylitis/enthesitis, only significant changes listed as þ; PASI, Psoriasis Activity Skin Index; pbo, placebo; documented improvement in predefined radiographic endpoints (X-ray).
† Inhibition of radiographic damage was presented in the FUTURE2 trial.

References

1. Mansouri Y, Goldenberg G. New systemic therapies for psoriasis. Cutis. 2015;95(3):155-60.
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3. Ritchlin CT, Krueger JG. New therapies for psoriasis and psoriatic arthritis. Curr Opin Rheumatol. 2016;28(3):204-10.
4. Langley RG, Elewski BE, Lebwohl M, Reich K, Griffiths CE, Papp K, et al. ERASURE Study Group.; FIXTURE Study Group. Secukinumab in plaque psoriasis--results of two phase 3 trials. Secukinumab in plaque psoriasis--results of two phase 3 trials. N Engl J Med. 2014 Jul 24;371(4):326-3.

S2-3

What to consider in using biologics for psoriasis

Dong Hyun KIM, M.D.

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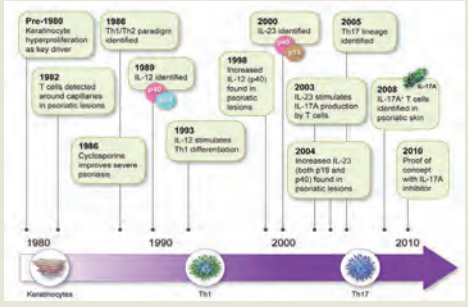
Contents

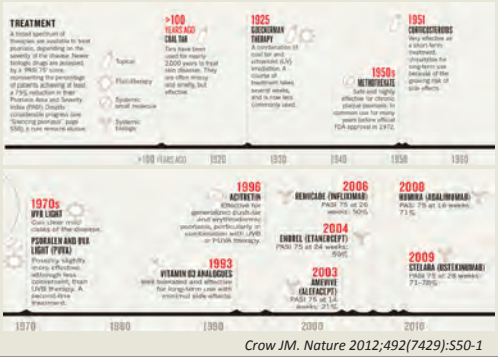
- Biologics approved in psoriasis
- Standards of health insurance coverage for psoriasis
- Screening lab test
- Dose (loading, maintenance)
- Costs for biologics
- Medical records for maintenance
- Adverse events
- Bioloigics switching, Maintenance, Intermittent use

Evolving Concepts in Pathophysiology



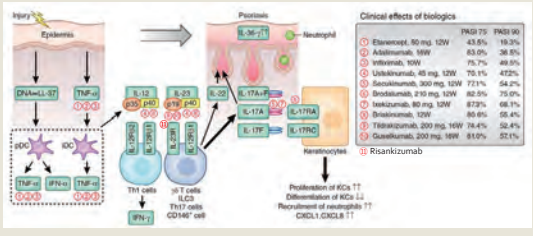
Lynde CW, et al. J Am Acad Dermatol 2014;71:141-50

Progress in Treatment



Crow JM. Nature 2012;492(7429):S50-1

Biologics for Psoriasis



Furue M, Kadono T. J Dermatol 2016;43:4-8

Biologics Approved in Psoriasis

- Anti-T cell Treatment (T cell-dendritic cell interaction)
  - Alefacept (Amevive): 2003 -2011
  - Efalizumab (Raptiva): 2003 -2009 (Progressive multifocal leukoencephalopathy)
- TNF-α inhibitor
  - Etanercept (Enbrel): 2002(PsA), 2004, 2016 (≥ 4 years old)
  - Infliximab (Remicade): 2005 (PsA), 2006
  - Adalimumab (Humira): 2005 (PsA), 2008
  - Golimumab (Simponi): 2009 (PsA)
  - Certolizumab pegol (Cimzia): 2013 (PsA)
- IL-12/23 p40 inhibitor
  - Ustekinumab (Stelara): 2009, 2013 (PsA)
- IL-17 inhibitor
  - Secukinumab (Cosentyx): 2015, 2016(PsA)
  - Ixekizumab (Taltz): 2016
  - Brodalumab (Siliq): 2017

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  - Brodalumab (Siliq) 2017

생물학적제제 허가 및 보험급여 기준 (판상건선)

- 허가기준
  - 6개월 이상 지속되는 만성 중증 판상 건선 환자 (18세 이상 성인)
- 보험기준
  - (가)(나)(다) 또는 (가)(나)(라)를 충족하는 경우
  - (가) ≥ BSA 10
  - (나) ≥ PASI 10
  - (다) MTX나 CsA을 3개월 이상 투여하였음에도 반응이 없거나 부작용 등으로 치료를 지속할 수 없는 경우
  - (라) PUVA 및 NBUVB 치료법으로 3개월 이상 치료하였음에도 반응이 없거나 부작용 등으로 치료를 지속할 수 없는 경우

보건복지부 고시 제2016-223호

생물학적제제 허가 및 보험급여 기준 (건선 관절염)

- 허가기준
  - 두 가지 종류 이상의 DMARDs로, 총 6개월 이상 (각 3개월 이상) 치료하였으나, 치료 효과가 미흡하거나 부작용으로 치료를 중단한 활동성 및 진행성 건선관절염 환자 중 다음에 해당하는 경우
  - 3개 이상의 압통 관절과 3개 이상의 부종 관절
  - 상기 증상이 1개월 간격으로 2회 연속 측정한 결과일때

보건복지부 고시 제2016-223호

Severity of Psoriasis (based on BSA)

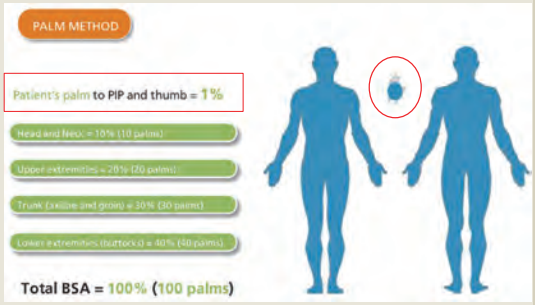
	Mild	Moderate	Severe
AAD	BSA < 5%	5% ≤ BSA < 10%	BSA ≥ 10%
S3	BSA ≤ 10%	BSA > 10%	

- Specific location: Scalp, Nail, Genitalia

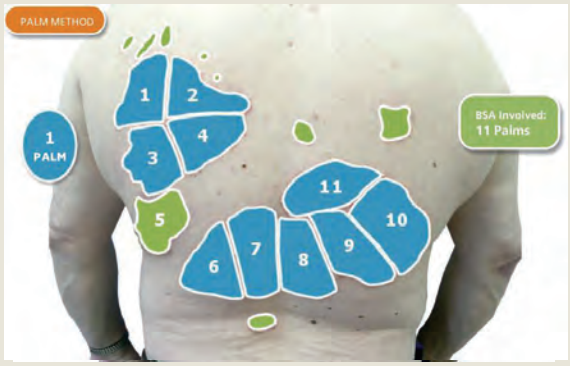
Severity of Psoriasis (based on PASI)

	Mild	Moderate	Severe
BAD			PASI ≥ 10
S3	PASI ≤ 10	PASI > 10	

BSA (Body Surface Area)



http://www.pasitraining.com



http://www.pasitraining.com

PASI (Psoriasis Area Severity Index)

- Gold standard to judge the severity of psoriasis (from 1978)
- PASI: 1) severity of psoriatic lesion and 2) area of involvement
- PASI 75: benchmark endpoint of clinical study drugs
  - The percentage of patients achieving at least a 75% reduction in PASI
- PASI 50: accepted as clinical significant
- PASI 90: represents as high degree of clearing
  - Ex, initial PASI 20
    - → PASI 10 means PASI 50
    - → PASI 5 means PASI 75
    - → PASI 2 means PASI 90

PASI calculation

0.1 (Eh + Ih + Sh) Ah [head]

+

0.2 (Eu + Iu + Su) Au [upper extremities]

+

0.3 (Et + It + St) At [trunk]

+

0.4 (El + Il + Sl) Al [lower extremities]

Severity of Psoriatic Lesions (0-4 scale):
assessed based on three target symptoms:
1) Erythema (E)
2) Induration (thickness) (I)
3) Scaling (S)

0 = none 1 = slight 2 = moderate
3 = severe 4 = very severe

Area of involvement (0-6 scale):
0 = none 1 = < 10%
2 = 10 to < 30% 3 = 30 to < 50%
4 = 50 to < 70% 5 = 70 to < 90%
6 = 90-100%

The worst PASI score

0.1 (4 + 4 + 4) X 6 [head] = 7.2

+

0.2 (4 + 4 + 4) X 6 [upper extremities] = 14.4

+

0.3 (4 + 4 + 4) X 6 [trunk] = 21.6

+

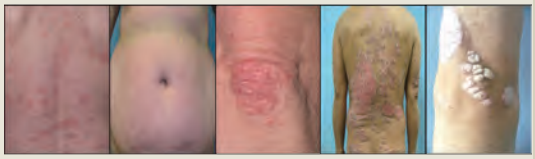
0.4 (4 + 4 + 4) X 6 [lower extremities] = 28.8

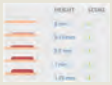
∑ (h + u + t + l) = 72

Erythema

Induration

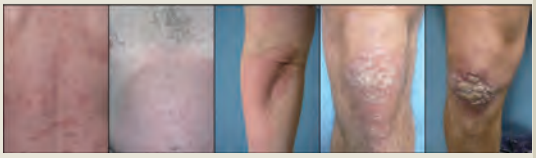
None = 0 (0 mm)	Mild = 1 (0.25 mm)	Moderate = 2 (0.5 mm)	Severe = 3 (1 mm)	Very severe = 4 (1.25 mm)





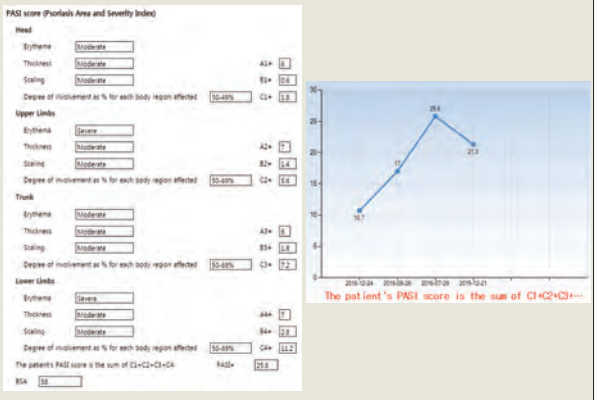
Scaling

None = 0 (no scale)	Mild = 1 (fine scale, partial)	Moderate = 2 (thin scale, entire)	Severe = 3 (thick scale)	Very severe = 4 (very thick scale)



A Psoriasis Area and Severity Index (PASI) is a quantitative rating scale for measuring the severity of psoriatic lesions based on area coverage and plaque appearance. Please complete **all** sections of the table and shade in the affected areas on the body diagrams below.

Plaque characteristic	Rating score	Body region (and weighting factor)			
		Head	Upper Limbs	Trunk	Lower Limbs
Erythema	0 = None 1 = Slight 2 = Moderate 3 = Severe 4 = Very severe				
Thickness					
Scaling					
Add together each of the 3 scores for each of the body regions to give 4 separate sub totals.					
Sub Totals		A1=	A2=	A3=	A4=
Multiply each sub total by amount of body surface area represented by that region i.e. A1 x 0.1 for head, A2 x 0.2 for upper limbs, A3 x 0.3 for trunk, A4 x 0.4 for lower limbs to give a value B1, B2, B3 and B4 for each body region respectively					
		A1 x 0.1 = B1	A2 x 0.2 = B2	A3 x 0.3 = B3	A4 x 0.4 = B4
		B1=	B2=	B3=	B4=
Degree of involvement as % for each body region affected (score each region with score between 0–6)	0 = None 1 = 1–9% 2 = 10–29% 3 = 30–49% 4 = 50–69% 5 = 70–89% 6 = 90–100%				
For each body region multiply sub total B1, B2, B3 and B4 by the score (0–6) of the % of body region involved to give 4 subtotals C1, C2, C3 and C4					
		B1 x score = C1	B2 x score = C2	B3 x score = C3	B4 x score = C4
		C1=	C2=	C3=	C4=
The patient's PASI score is the sum of C1+C2+C3+C4				PASI=	



Pre-treatment work-ups for biologics

- Routine lab test:
  - Complete blood count
  - Routine chemistry
  - Urine analysis
- Serology for HBV/ HCV (and HIV)
- Active and latent tuberculosis infection screening tests

Latent Tuberculosis Infection Screening

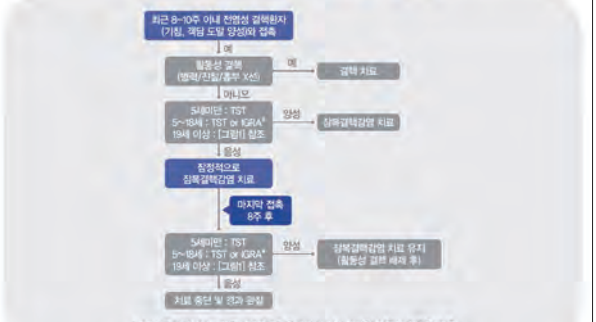
- 과거 결핵치료력, 결핵환자 접촉력
- 결핵의심 증상 [2주 이상의 기침, 객담, 객혈, 흉통, 체중감소, 미열, 야간발한. 쉬피로감, 전신무력감]
- Chest x-ray
- Tuberculin skin test (≥ 10mm) – 단독검사는 권고하지 않음
- Interferon-gamma release assay(IGRA)
  - 검사없이 사용한 생물학적제제 – 삭감
  - Biologics 최초 투여 시 이후에도 생물학적 제제를 투여 받고 있는 환자가 TB screening 을 목적으로 시행할 경우 급여 인정

Korea Center for Disease Control and Prevention. Korean guideline for Tuberculosis. Second Edition, 2014

TNF 길항제 치료 예정자에서 잠복결핵 감염의 진단

- 과거 결핵 치료력(완치 판정) 있는 경우 생물학적제제 바로 사용
- 잠복결핵 – 결핵 예방 치료 시작

TNF 길항제 치료 예정자에서 접촉자 검진



Treatment for Tuberculosis

- 활동성 결핵
  - 생물학적제제 치료는 결핵치료 종료 후 시작하는 것을 권고 (IIIA)
  - 결핵 치료 반응이 양호하고 중증 결핵이 아니며 약제 감수성 결핵인 경우, 2개월 집중치료기 이후 생물학적제제 치료 시작을 고려할 수 있음 (IIIB)
- 잠복결핵 치료
  - 치료 시작 3주 후부터 생물학적제제 치료 시작을 권고 (IIIA)
  - 잠복결핵 치료 시작과 동시에 시작하는 것을 고려할 수 있음 (IIIB)
  - 보험 심사상 최소 3주의 치료 기간을 갖고 생물학적제제 치료를 시작
  - 9H: INH - 5mg/kg/day, 9months (IA)
  - 4R, 3HR – (IIB)

Korea Center for Disease Control and Prevention. Korean guideline for Tuberculosis. Second Edition, 2014

Screening for hepatitis B

Table I. National Psoriasis Foundation interpretation of hepatitis B serologic screening tests before initiation of anti–tumor necrosis factor-alfa therapy* with extension of guidelines to all systemic immunosuppressive drug therapies for psoriasis

HBV infection	HBsAg	HBcAb	HBsAb	HBeAgSt	Abnormal LFTs and/or symptoms	Additional testing	Treatment (and notes†)
Uninfected, nonimmune	–	–	–	–	–	–	Safely treat with ISDT. Consider vaccination before ISDT.
Vaccinated	–	+	–	–	–	–	Safely treat with ISDT. If HBsAb titer <10 mIU/mL, consider booster vaccination before ISDT.
Acute	+	–	+	+	+	–	Defer ISDT.
Chronic	+	–	+	–	+	HBeAg, HBeAb, HBV DNA	Treat with ISDT in consultation with hepatologist. • Chronic active HBV (HBeAg$^+$, HBeAb$^-$, HBV DNA >10^5 copies/mL): seek consultation with hepatologist; antiviral prophylaxis is recommended prior to ISDT. • Chronic inactive HBV (HBeAg$^-$, HBeAb$^+$, HBV DNA <10^5 copies/mL): seek consultation with hepatologist; consider antiviral prophylaxis prior to ISDT.
Resolved	–	+	+	–	–	HBV DNA	Treat with ISDT in consultation with hepatologist.
Occult	–	+	+	–	–	HBV DNA	Treat with ISDT in consultation with hepatologist.

Prior to initiation of ISDT, clinicians should screen patients for other conditions, which may preclude their respective safe treatment. *HBcAb*, Hepatitis B core antibody; *HBcIgM*, hepatitis B core IgM antibody; *HBeAb*, hepatitis B core e antibody; *HBeAg*, hepatitis B core e antigen; *HBsAb*, hepatitis B surface antibody; *HBsAg*, hepatitis B surface antigen; *HBV*, hepatitis B virus; *ISDT*, immunosuppressive drug therapy; *LFT*, liver function test result.

Manalo IF, et al. J Am Acad Dermatol. 2015;73:881-2

Dose, PASI evaluation

- Etanercept (Enbrel)

Treatment
(25mg SQ BIW or 50mg SQ QW or 50mg SQ BIW)
efficacy evaluation at Week 12, then Q6M

- Infliximab (Remicade)

Treatment (5mg/kg IV)
Week 0, 2, 6, then Q8W
efficacy evaluation: Week 22 (before 5th Tx)
,then Q24W

Dose, PASI75 evaluation

- Adalimumab (Humira)

Loading (80mg SQ) Week 0, 1	Treatment (40mg SQ) Week 3(3rd visit), then Q2W efficacy evaluation: week 16 (before 10th Tx) , then Q24W

- Ustekinumab (Stelara)

Loading (45mg SQ < 100kg) Week 0, 4	Treatment (45mg SQ < 100kg) Week 16 (3rd visit), then Q12W efficacy evaluation: week 28 (before 4th Tx) then Q24W

- Secukinumab (Cosentyx)

Loading (300mg SQ) Week 0, 1, 2, 3, 4	Treatment (150mg SQ) Week 8, then Q4W PASI75 evaluation

Cost for Biologics

	Stelara	Humira	Remicade	Enbrel
성분명 용량	Ustekinumab 45mg/90mg	Adalimumab 40mg	Infliximab 100mg	Etanercept 25mg/50mg
약가	45mg: 2,497,492원 (의보수가)	40mg: 414,850원 (의보수가)	100mg: 383,051원 (의보수가)	50mg: 149,439원 (의보수가)
유지치료 주사회수	4회/년	24회/년	6회/년	48회/년
연간 유지요법 비용	9,989,968원 (건강보험 적용 시 본인부담 60%)	9,956,400원 (건강보험 적용 시 본인부담 60%)	6,894,918원 (60Kg 성인 기준, 체중에 따라 변동) (건강보험 적용 시 본인부담 60%)	14,346,144원 (50mg BIW 기준, 용량에 따라 변동) (건강보험 적용 시 본인부담 60%)

2017, 3월 기준

건강보험 본인부담금 상한제

우선 환자가 본인 부담금(60%)을 지불하고
이후 환급 받는 사후 환급 시스템

2017년 본인부담상한액

소득분위	1분위	2~3분위	4~5분위	6~7분위	8분위	9분위	10분위
2014년도	120만원	150만원	200만원	250만원	300만원	400만원	500만원
2015년도	121만원	151만원	202만원	253만원	303만원	405만원	506만원
2016년도	121만원	152만원	203만원	254만원	305만원	407만원	509만원
2017년도	122만원	153만원	205만원	256만원	308만원	411만원	514만원

2017년 본인부담상한액(참조:국민건강보험공단)

Adverse events

- Pruritus
- Upper respiratory infections
- Headache
- Tiredness
- Rash
- Nausea
- Injection site reaction
- Urinary tract infection
- No serious infection

Yiu ZZ, et al. J Invest Dermatol. 2016;136:1584-91

Biologics Switching

- 최초 약효 평가시점 이후에 PASI75를 만족하지 못할 경우 switch 인정
  - 최초 약효 평가 시 PASI 75 달성 실패 : lack of efficacy
  - 최초 평가 이후 follow 기간 중 PASI 75 유지 실패 :loss of efficacy
  - Back switching 보험 인정 안됨
  - Switch 시점 PASI ≥10, BSA ≥10 달성
- PASI 75 달성 기준
  - Switch 시점 의 PASI score 대비 75% 이상 score 감소
  - 교체한 약제는 최소 6개월 투여를 권고
- Switch 시 의무기록 기입 내용
  - PASI score (PASI 75 만족하지 못한 내용)
  - Switch 사유 (Loss of efficacy, lack of efficacy, compliance 개선 등)
  - 주치의 소견서 첨부 필요

Maintenance of efficacy

- Lack of response in long term use
  - Immunogenicity (Anti-drug antibody)
  - Use of an immunomodulatory agent
- Suboptimal dosing, Low serum drug levels
  - Continuous topical therapy
  - Intermittent or episodic therapy (not recommend)
  - Dose tapering (between-dose intervals)
    - Lower BMI and short time to PASI100

Hansel K, et al. Acta Derm Venereol. 2017;97:346-350

휴약을 하였던 환자에게 재투여하는 경우

- 최초 평가 이전 휴약
  - 최초 투약 인정 기준에 해당할 경우 투약 인정
- 최초 평가 이후 지속 투약 중인 환자가 휴약할 경우
  - 휴약 기간이 3개월 미만의 경우 연속 투약으로 인정
  - 휴약 기간이 3개월 이상일 경우
    - 마지막 평가 결과(마지막 투약 시점)와 비교하여 악화 되었을 경우 인정
    - 마지막 평가 결과가 없을 경우 최초 투약 인정 기준에 해당 해야함
    - 휴약 기간이 1년 이상일 경우 최초 투약 인정 기준에 해당 해야함
- 평가 시점에 의학적인 사유로 평가하지 못했을 경우 4주 이내에 평가

보건복지부 행정해석 2011-1-24 시행 내용

수술 전 생물학적제제 휴약

Guidelines	Recommended time lapse since the last administration of each biologic prior to a surgery	Recommended timing of restarting biologics after a surgery	Comments
Consensus Guidelines for the Management of Plaque Psoriasis, 2012 (North America)[1]	At least 1 week IFX: 39 days ADA: 56 days	At least 1 week	Timings decided on four half-lives of each agent. Follow American College of Rheumatology Recommendations[6]
British Association of Dermatologists' guidelines for Biologic interventions for psoriasis, 2009 (UK)[2]	IFX: 4-6 weeks ADA: 6-8 weeks UST: 12 weeks	Can be restarted if there is no evidence of infection or delayed wound healing	Follows British Society for Rheumatology guidelines recommendation
Japanese Dermatological Association of Guideline and safety manual for use of biologic agents in psoriasis, 2013 (Japan)[3]	IFX: 4 weeks ADA: 2 weeks UST: 6 weeks	Can be restarted if there is no evidence of infection or delayed wound healing	Follows Japanese guidelines for the use of TNF-α blockers for rheumatoid arthritis recommendation

Half-lives of each biologics: 8-9 days for infliximab (IFX), 14-19 days for adalimumab (ADA) and 21 days for ustekinumab (UST).

* 4 half-lives of each biologic

Kawakami H, et al. J Dermatol. 2016;43:190-3

임신 시 생물학적제제

- Pregnancy category B
  - Etanercept
  - Infliximab
  - Adalimumab
  - Ustekinumab
  - Secukinumab
- Pregnancy category C
  - Topical corticosteroid
  - Topical calcipotriol
  - Cyclosporin
- Recommend narrow band UVB + topicals

생물학적제제 사용시 예방접종

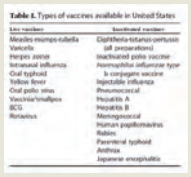


Table I. Types of vaccines available in United States

Live vaccines	Inactivated vaccines
Measles-mumps-rubella	Diphtheria-tetanus-pertussis (all preparations)
Varicella	Inactivated polio vaccine
Herpes zoster	*Haemophilus influenzae* type b conjugate vaccine
Intranasal influenza	Injectable influenza
Oral typhoid	Pneumococcal
Yellow fever	Hepatitis A
Oral polio virus	Hepatitis B
Vaccinia/smallpox	Meningococcal
BCG	Human papillomavirus
Rotavirus	Rabies
	Parenteral typhoid
	Anthrax
	Japanese encephalitis

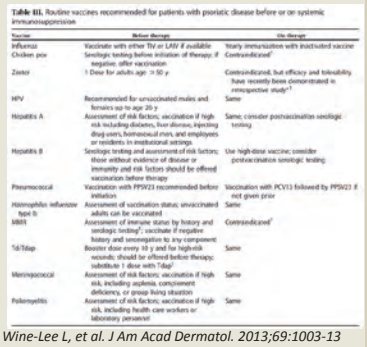


Table III. Routine vaccines recommended for patients with psoriatic disease before or on systemic immunosuppression

Vaccine	Before therapy	On therapy
Influenza	Vaccinate with either TIV or LAIV if available	Yearly immunization with inactivated vaccine
Chicken pox	Serologic testing before initiation of therapy; if negative, offer vaccination	Contraindicated[7]
Zoster	1 Dose for adults age >50 y	Contraindicated, but efficacy and tolerability have recently been demonstrated in retrospective study[7]
HPV	Recommended for unvaccinated males and females up to age 26 y	Same
Hepatitis A	Assessment of risk factors; vaccination if high risk including diabetes, liver disease, injecting drug users, homosexual men, and employees or residents in institutional settings	Same; consider postvaccination serologic testing
Hepatitis B	Serologic testing and assessment of risk factors; those without evidence of disease or immunity and risk factors should be offered vaccination before therapy	Use high-dose vaccine; consider postvaccination serologic testing
Pneumococcal	Vaccination with PPSV23 recommended before initiation	Vaccination with PCV13 followed by PPSV23 if not given prior
Haemophilus influenzae type b	Assessment of vaccination status; unvaccinated adults can be vaccinated	Same
MMR	Assessment of immune status by history and serologic testing[7]; vaccinate if negative history and seronegative to any component	Contraindicated[7]
Td/Tdap	Booster dose every 10 y and for high-risk wounds; should be offered before therapy; substitute 1 dose with Tdap[7]	Same
Meningococcal	Assessment of risk factors; vaccination if high risk, including asplenia, complement deficiency, or group living situation	Same
Poliomyelitis	Assessment of risk factors; vaccination if high risk, including health care workers or laboratory personnel	Same

Wine-Lee L, et al. J Am Acad Dermatol. 2013;69:1003-13

생물학적제제 사용 동의서

- 치료의 배경
- 사용 약물
- 허가사항
- 용법 및 용량
- 투여방법
- 가능한 부작용
- 치료 비용
- 환자 동의서

Microsoft Word 문서

경청해 주셔서 감사합니다.

Session 3
Panel discussion about problematic cases on biologics and systemic agents

Chairs: professor Tae-Yoon KIM *(Catholic University)*
professor Jee-Ho CHOI *(Ulsan University)*
professor Joo-Heung LEE *(Sungkyunkwan University)*

CURRICULUM VITAE

Chul Jong PARK, M.D.

Department of Dermatology, Bucheon St. Mary's Hospital,
The Catholic University of Korea College of Medicine

Present Academic & Hospital Appointments

Professor of Department of Dermatology at Bucheon St. Mary's Hospital,
The Catholic University of Korea College of Medicine

Education

1989	M.D. degree from The Catholic University of Korea College of Medicine
1997	Ph.D. degree from The Catholic University of Korea, Graduate School, Seoul, Korea

Career

1994. 2	Korean Board of Dermatology
2000-2001	Post-doc. at University of Cincinnati, Ohio
2009-	Professor Department of Dermatology, at Bucheon St. Mary's Hospital, The Catholic University of Korea College of Medicine

Membership

Inspector, Korean Society for Psoriasis
Vice-president, Korean Society of Vitiligo
Korean Medical Association
Korean Dermatological Association

CURRICULUM VITAE

Sang Seok KIM, M.D.

Department of Dermatology, Kangdong Sacred Heart Hospital,
Hallym University School of Medicine

Academic Education

1997	B.S. M.D., College of Medicine, Hallym University
2001	M.S. College of Medicine, Hallym University

Appointments and Professional Activities

2002-2003	Clinical Instructor, Department of Dermatology, Kangdong Sacred Heart Hospital, Hallym University
2003	Clinical Visiting Fellow, National Skin Centre, Singapore
2003-2005	Full Time Instructor, Department of Dermatology, Kangdong Sacred Heart Hospital, Hallym University
2006-2012	Assistant Professor, Department of Dermatology, School of Medicine, Hallym University
2006-Present	Director, Department of Dermatology, Kangdong Sacred Heart Hospital, Hallym University
2012-Present	Associate Professor, Department of Dermatology, School of Medicine, Hallym University
2012-2013	Visiting Assistant Professor, Department of Dermatology, Perelman School of Medicine, University of Pennsylvania, USA

Member

2008-2010	Treasurer, the Seoul Regional Society of the Korean Dermatological Association
2011-Present	International member, American Academy of Dermatology
2012-Present	Director, The Korean Society for Skin Cancer
2016-Present	Treasurer, The Korean Society for Photomedicine
2016-Present	Director at Large, The Korean Hair Research Society

CURRICULUM VITAE

Seong Jin JO, M.D.

Department of Dermatology, Seoul National University College of Medicine

Academic Qualifications

2009.2-2012.2	Postgraduate school of Seoul National University, Seoul, Korea Ph.D. of Dermatology
2003.3-2005.2	Postgraduate school of Seoul National University, Seoul, Korea M.S. of Dermatology
2001.2	M.D. in Korea
1997.3-2001.2	Seoul National University College of Medicine, Seoul, Korea B.S.

Current and Previous Positions

2017.3-Present	Department of dermatology, Seoul National University Hospital, Seoul, Korea Clinical associate professor
2012.3-2017.2	Department of dermatology, Seoul National University Hospital, Seoul, Korea Clinical assistant professor
2009.5-2012.2	Department of dermatology, Seoul National University Hospital, Seoul, Korea Fellowship
2006.2-2009.4	Military Service, Republic of Korea
2002.3-2006.2	Residency at the Department of Dermatology, Seoul National University Hospital, Seoul, Korea
2001.3-2002.2	Internship at the Seoul National University Hospital, Seoul, Korea

Memberships and Professional Society

2006-Present	Korean Dermatological Association
2014.06-Present	Board member of Directors, The Korean Hair Research Society.
2014.08-2015.02	Board member in charge of public communication and publishing affairs, The Korean Society for Skin cancer
2015.03-2017.02	Assistant administrator of the planning committee, The Korean Society for Aesthetic and Dermatologic Surgery (KSDS)
2015.03-Present	Director of the education committee, The Korean Society for Psoriasis