L’esperienza clinica in dermatologia col biosimilare in Italia

Paolo Gisondi
Conflict of interest

• I have been a consultant and/or speaker for Abbvie, Celgene, Eli Lilly, Janssen, Leo-pharma, Merck Sharp & Dohme, Novartis, Pfizer and UCB
Chronic Plaque Psoriasis

- Chronic inflammatory disease of the skin with a chronic-relapsing course.
- Characterized by erythematous scaly plaques usually symmetrically distributed in typical areas (elbows and knees, sacral region and scalp).
- It may have a significant impact on quality of life of the patient.
- Immune-mediated pathogenesis in which predisposing genetic factors interact with environmental factors.

Immunopathology of psoriasis

Keratinocyte activation

Inflammatory chemokines, cytokines

Dendritic cell and T cell activation, cytokines

Leucocyte recruitment, angiogenesis

Plaque formation

Trigger/initiation

Dendritic cell

IL-12/IL-23

Tc1, Th1, Th17, Th22

T cell

Mild psoriasis
Moderate psoriasis
Severe psoriasis
Erythrodermic psoriasis
Nail psoriasis
Italian guidelines on the systemic treatments of moderate-to-severe plaque psoriasis

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Abstract

Psoriasis is a common disease, which has a considerable impact on the healthcare system. Therefore, appropriate use of therapeutic resources is very important. Management of psoriasis in daily clinical practice is highly variable because many issues are still debated and not definitely addressed by the evidence-based medicine. Moreover, the different availability and reimbursability of drugs in each country justifies national guidelines. Expert consensus can provide helpful guidelines for optimizing patient care. A total of 20 dermatologists from different areas of Italy and with large experience in the treatment of psoriasis agreed to participate in the guidelines expert panel who aimed to reach consensus on the factors influencing psoriasis severity, the indications for systemic treatments, the parameters to be considered in the choice of treatment, and the factors to be considered in the choice of biological treatment. The recommendations for the use, screening and monitoring of systemic therapies were based on the 2015 S3 European Dermatology Forum/European Academy of Dermatology and Venereology psoriasis guidelines. Recommendations on the treatment of psoriasis in special patient populations were also agreed. The final document was discussed in a meeting moderated by a facilitator with participation of the entire group and adopting a nominal group technique to reach consensus. A statement was regarded as consented when agreement was achieved by at least 75% of the voting experts according to the Delphi procedure.
Topical therapies, conventional treatments, biological agents and small molecule for chronic plaque psoriasis

<table>
<thead>
<tr>
<th>Topical therapies</th>
<th>Conventional treatments</th>
<th>Biological agents</th>
<th>Novel small molecule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corticosteroids</td>
<td>Acitretin</td>
<td>Adalimumab</td>
<td>Apremilast</td>
</tr>
<tr>
<td>Vitamin D3 analogues</td>
<td>Methotrexate</td>
<td>Etanercept</td>
<td></td>
</tr>
<tr>
<td>Calcipotriol plus betamethasone gel</td>
<td>Cyclosporine</td>
<td>Infliximab</td>
<td></td>
</tr>
<tr>
<td>Topical Retinoids (i.e. Tazarotene)</td>
<td>Phototherapy: Nb-UVB (311-313 nm) and PUVA</td>
<td>Ustekinumab</td>
<td></td>
</tr>
<tr>
<td>Topical Immunomodulators (i.e. tacrolimus, pimecrolimus)</td>
<td></td>
<td></td>
<td>Secukinumab</td>
</tr>
<tr>
<td>Keratolytics</td>
<td></td>
<td></td>
<td>Ixekizumab</td>
</tr>
</tbody>
</table>

**SCHEDA PRESCRIZIONE DEI FARMACI BIOLOGICI PE**

Centro prescrittore __________________________
Medico prescrittore (cognome, nome) ______________
Tel. ______________ e-mail ______________

**Compilare in caso di prima**

Il/la Paziente:

1. **Presenta:**
   - □ PASI > 10 e 
   - oppure
   - □ PASI < 10 e
   - □ al viso □ p

2. **Ha fallito un trattamento**

Farmaco (specificare): ___

<table>
<thead>
<tr>
<th>Farmaco prescritto</th>
<th>dose (mg)</th>
<th>frequenza (settimane)</th>
<th>Prima prescrizione</th>
<th>Prosecuzione della cura</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab</td>
<td></td>
<td></td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Etanercept</td>
<td></td>
<td></td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Infliximab</td>
<td></td>
<td></td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Ixekizumab</td>
<td></td>
<td></td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Secukinumab</td>
<td></td>
<td></td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Ustekinumab</td>
<td></td>
<td></td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

**Durata prevista del trattamento** (mesi) ______________

(NOTA BENE:
La validità della scheda di prescrizione cartacea non può superare i 12 mesi dalla data di compilazione.
Per i pazienti già in trattamento, il piano terapeutico dovrà essere redatto all’atto della prima visita specialistica utile).

Data ______________

Timbro e Firma del Medico
Clinical case 1
_Palmoplantar psoriasis requiring systemic therapy_

- Male patient, 42 years age.
- Failure of conventional systemic therapies including acitretin, CsA, MTX.
- Treated with IL-17 inhibitor.
Clinical case 2
Severe psoriasis in patients with comorbidities

- 78 years old patients with arterial hypertension, atrial fibrillation, diabetes, dyslipidemia under treatment. No PsA.
- PASI 35; BSA 80%; DLQI 16
Baseline visit
Psoriasis remission with etanercept that is effective and well tolerated
Clinical remission
MAPP* is a population-based, multinational survey of 3,426 patients from 139,948 screened households and 781 physicians in North America and Europe.

11% of patients with BSA >10% are receiving systemic treatment.
The Under-treatment in italian patients (n=339)

Reasons for not initiating systemic therapy

The limiting factors for initiating therapy were most often long-term safety and tolerability concerns and cost.

Dermatologists (N=391)

The place of anti-TNF biosimilars in the treatment of psoriasis

**Early access**
- Using affordable, high-quality anti-TNF biosimilars can provide earlier access to more effective biologic treatment options

**Optimal access**
- Anti-TNF biosimilars may provide patients with optimal access to best treatment options and may potentially improve treatment continuity

**Equal access**
- Considerable regional variability in biologic prescriptions exists throughout Europe; anti-TNF biosimilars can reduce market access inequality

Principal anti-TNF biosimilars available or in development

**Registered**
- **Infliximab CT-P13 Remsima® Mundipharma**
- **Inflectra® Hospira**

- **Etanercept SB4 Samsung/Biogen Benepali®**

**Phase 3**
- Adalimumab° Sandoz
- Adalimumab Amgen
- Adalimumab Boeringher
- Etanercept* Erelzi® Sandoz
- Etanercept Coherus
- Etanercept Daiichi Sankyo
- Infliximab Samsung/Biogen
- Infliximab Epirus

- Adalimumab Samsung/Biogen
- Adalimumab Biogen
- Etanercept Daewoong
- Etanercept TSH Biopharm
- Etanercept LG life science
- Infliximab Amgen
- Infliximab Nichi-Iko

**Phase 1-2**
- Adalimumab Coherus
- Adalimumab Biocad
- Adalimumab Momenta/Baxter
- Etanercept BioXpress
- Etanercept Protalix
- Adalimumab AET/BioXpress
- Infliximab Biocad

**Preclinical**
- Adalimumab Epirus
- Etanercept Avestaghen

Tested in patients with psoriasis

Registro italiano dei farmaci biosimilari per la psoriasi e la artrite psoriasica

Accedi al registro PsoBiosimilars.it

Nome Utente

Password

Hai dimenticato la password? Recupera

Accesso al 11 maggio 2017
http://psobiosimilars.it/users/login

• http://psobiosimilars.it/users/login
• 33 centri registrati
• 66 utenti abilitati
• 267 casi inseriti
Infliximab biosimilar CT-P13 in the treatment of chronic plaque psoriasis. Data from the Psobiosimilars registry

P. Gisondi,1 L. Bianchi,2 A. Conti,3 P. Dapavo,4 P. Malagoli,5 S. Piaserico,6 F. Savoia,7 F. Prignano8 and G. Girolomoni1

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Infliximab biosimilar CT-P13 in the treatment of chronic plaque psoriasis. *Data from the Psobiosimilars registry*

- **Objective**
  - Investigate effectiveness and safety of infliximab biosimilar CT-P13 in patients with chronic plaque psoriasis (n=204).

- **Methods**
  - Prospective study on patients with psoriasis enrolled in the Psobiosimilar registry, which is a web-based, observational cohort registry designed to assess the long-term effectiveness and safety of biosimilars in Italy (http://www.psobiosimilars.it).
  - Two groups of patients were included: patients who switched from the infliximab originator to the biosimilar CT-P13, and patients naive to the infliximab originator who started CT-P13.
  - Effectiveness was evaluated by measuring the Psoriasis Area and Severity Index (PASI) changes from baseline to 6 months; safety by reporting any adverse events registered during the observational period.

Clinical characteristics of patients treated with the infliximab biosimilar CT-P13

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Switch (n=122)</th>
<th>Naïve (n= 82)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender male N (%)</td>
<td>88 (72.1)</td>
<td>46 (56.1)</td>
<td></td>
</tr>
<tr>
<td>Age (m ± SD)</td>
<td>55.9 ± 11.7</td>
<td>50.8 ± 12.6</td>
<td>0.003</td>
</tr>
<tr>
<td>BMI (m ± SD)</td>
<td>27.7 ± 4.4</td>
<td>28.6 ± 6.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Smokers N (%)</td>
<td>46 (37.7)</td>
<td>33 (40.2)</td>
<td>0.7</td>
</tr>
<tr>
<td>PASI baseline (m ± SD)</td>
<td>2.05 ± 2.8</td>
<td>20.8 ± 9.7</td>
<td>0.0001</td>
</tr>
<tr>
<td>Previous systemic treatments for PsO (m ± SD)</td>
<td>3.2 ± 1.3</td>
<td>3.4 ± 1.5</td>
<td>0.8</td>
</tr>
<tr>
<td>Psoriasis duration, years (m ± SD)</td>
<td>25.5 ± 12.4</td>
<td>18.9 ± 12.3</td>
<td>0.0003</td>
</tr>
<tr>
<td>Duration of previous treatment with IFX originator,</td>
<td>4.9 ± 3.9</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>years (m ± SD)</td>
<td>(range 0-13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Premedication before IFX infusion N (%)</td>
<td>71 (58.2)</td>
<td>38 (46.3)</td>
<td>0.09</td>
</tr>
<tr>
<td>IFX infusion in 1-hour</td>
<td>5 (4.1)</td>
<td>18 (21.9)</td>
<td>0.001</td>
</tr>
</tbody>
</table>
## Comorbidities in patients treated with the infliximab biosimilar CT-P13

<table>
<thead>
<tr>
<th>Condition</th>
<th>Switch (n=122)</th>
<th>Naïve (n= 82)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>PsA N (%)</td>
<td>49 (40.2)</td>
<td>34 (41.4)</td>
<td>0.8</td>
</tr>
<tr>
<td>Peripheral arthritis</td>
<td>24 (49)</td>
<td>16 (47.06)</td>
<td>0.8</td>
</tr>
<tr>
<td>Peripheral arthritis + dactylitis and/or enthesitis</td>
<td>18 (36.7)</td>
<td>12 (35.2)</td>
<td>0.8</td>
</tr>
<tr>
<td>Spondylitis</td>
<td>7 (14.3)</td>
<td>6 (17.6)</td>
<td>0.5</td>
</tr>
<tr>
<td>Diabetes N (%)</td>
<td>12 (9.84)</td>
<td>1 (1.22)</td>
<td>0.01</td>
</tr>
<tr>
<td>Arterial hypertension N (%)</td>
<td>40 (32.7)</td>
<td>28 (34.1)</td>
<td>0.8</td>
</tr>
<tr>
<td>Hypercholesterolemia N (%)</td>
<td>33 (27.05)</td>
<td>16 (19.5)</td>
<td>0.2</td>
</tr>
<tr>
<td>Hypertriglyceridemia N (%)</td>
<td>19 (15.5)</td>
<td>6 (7.3)</td>
<td>0.07</td>
</tr>
<tr>
<td>HBV-related hepatitis N (%)</td>
<td>3 (2.4)</td>
<td>9 (10.9)</td>
<td>0.01</td>
</tr>
<tr>
<td>HCV-related hepatitis N (%)</td>
<td>0</td>
<td>4 (4.8)</td>
<td>0.01</td>
</tr>
<tr>
<td>Latent Tuberculosis N (%)</td>
<td>4 (3.2)</td>
<td>4 (4.8)</td>
<td>0.5</td>
</tr>
<tr>
<td>History of neoplasm N (%)</td>
<td>2 (1.64)</td>
<td>3 (3.66)</td>
<td>0.3</td>
</tr>
</tbody>
</table>

PASI score in patients with psoriasis treated with infliximab biosimilar CT-P13 stratified in switching (open circles and dashed line) and naïve (black squares and continuous line) at baseline, 2, 4 and 6 months.

* P <0.001 vs baseline

## Adverse events in patients exposed to infliximab biosimilar CT-P13 stratified in the groups switch and naïve*

<table>
<thead>
<tr>
<th>Switch (n=122)</th>
<th>Naïve (n=82)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelet number reduction (n=2)</td>
<td>Arthralgia (n=3)</td>
</tr>
<tr>
<td>Herpes zoster</td>
<td>Lipothymia during IFX infusion</td>
</tr>
<tr>
<td>Infusion reaction (rush associated to sweating)</td>
<td>Urticaria</td>
</tr>
<tr>
<td>Arterial hypertension during IFX infusion</td>
<td>Relapse of psoriatic arthritis</td>
</tr>
<tr>
<td>Arterial hypotension during IFX infusion</td>
<td>Liver enzymes increase</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>Worsening of psoriasis</td>
</tr>
<tr>
<td>Upper respiratory infection</td>
<td></td>
</tr>
</tbody>
</table>

*Each adverse event refers to a single case, unless specified.

The infliximab biosimilar in the treatment of moderate to severe plaque psoriasis

Paolo Dapavo, MD, Igor Vujic, MD, Maria Teresa Fierro, MD, Pietro Quaglino, MD, and Martina Sanlorenzo, MD
Turin, Italy, and Vienna, Austria

**Background:** The infliximab originator’s patent recently expired, leading to the production of biosimilar versions of the drug. The biosimilars’ efficacy was not tested on patients with psoriasis but most regulatory authorities approved their use in psoriasis because of an extrapolation of data from studies conducted in other diseases.

**Objective:** We sought to describe the use of the infliximab biosimilar (Remsima; CT-P13) in patients with psoriasis.

**Methods:** Objective (Psoriasis Area and Severity Index) and subjective (visual analog pain scale) measurements of disease activity were collected in 2 cohorts of patients with moderate to severe plaque psoriasis: cohort 1 patients switched from the infliximab originator to the infliximab biosimilar; and cohort 2 patients were infliximab-naïve and started on the infliximab biosimilar.

**Results:** We observed no changes of Psoriasis Area and Severity Index and visual analog pain scale scores in 30 patients who switched from the infliximab originator to the biosimilar. Four of 5 infliximab-naïve patients who started infliximab biosimilar treatment achieved 75% improvement or better from baseline Psoriasis Area and Severity Index score at the end of the induction phase.

**Limitations:** Number of patients and length of follow-up was limited.

**Conclusions:** Patients with psoriasis taking infliximab originator treatment can switch to the infliximab biosimilar without experiencing a significant change in clinical response or additional adverse events. The use of the infliximab biosimilar could reduce the growing pressure on health care budgets. (J Am Acad Dermatol 2016;75:736-9.)
Conclusions
Biosimilars in the therapy of psoriasis

• Cost is a relevant constraint for the biological treatment and biosimilars may represent a very important opportunity for recruiting more patients to biological therapy.

• Psobiosimilars registry is a web-based registry designed to assess the long-term effectiveness and safety of biosimilars for psoriasis in Italy.

• Current evidence indicates that the efficacy and safety of biosimilars and originators is essentially identical.
  - Patients with psoriasis who respond to the infliximab originator can be switched to the biosimilar CT-P13 without experiencing changes in clinical response or additional adverse events including infusion reactions.
Clinical characteristics of patients treated with the etanercept biosimilar SB-4

| Patients treated with the etanercept biosimilar SB-4 included in Psobiosimilar Registry |
|---------------------------------|-----------------|
| Total number of patients        | 24              |
| Gender male N (%)               | 16 (66)         |
| Age (m ± SD)                    | 59.4 ± 12.3 (38-88) |
| BMI (m ± SD)                    | 28.6 ± 4.8      |
| Smokers N (%)                   | 7 (29.1)        |
| Naive N (%)                     | 6 (25)          |
| Switch N (%)                    | 18 (75)         |
| PASI baseline (m ± SD) Naive    | 15.4 ± 5 (10-23.6) |
| PASI baseline (m ± SD) Switch   | 3.1 ± 2.3 (0-6) |
### Patients registered at Psocare Centers: 57,300

<table>
<thead>
<tr>
<th></th>
<th>PLAQUE PSORIASIS</th>
<th>OTHER PSORIASIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Treated</td>
<td>5,000</td>
<td>1,000</td>
</tr>
<tr>
<td>Treated</td>
<td>35,300</td>
<td>3,500</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment with Biologics</th>
<th>Not Treated with Biologics</th>
<th>Treated with Biologics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>23,420</td>
<td>11,880</td>
</tr>
</tbody>
</table>

- Patients with psoriasis in Italy: 1.8 M
- Patients with moderate to severe psoriasis: 350,000

Cost of biologics for psoriasis in Italy in 2014 = €160 M

Source: market research Cegedim, November 2014

Source: AIFA, IMS
The Joint official position of the Italian Society of Rheumatology, Dermatology and Inflammatory Bowel Disease on the use of biosimilars in IMIDs

The use of biosimilars in immune-mediated disease: A joint Italian Society of Rheumatology (SIR), Italian Society of Dermatology (SIDeMaST), and Italian Group of Inflammatory Bowel Disease (IG-IBD) position paper

Gionata Fiorino a,*, Giampiero Girolomoni b, Giovanni Lapadula c, Ambrogio Orlando d, Silvio Danese a, Ignazio Olivieri e,f,*, on behalf of SIR, SIDeMaST, and IG-IBD

ABSTRACT

Biological agents are widely used in rheumatology, dermatology and inflammatory bowel disease. Evidence about their efficacy and safety has been strengthened for all those therapeutic indications over the last decade. 

Biosimilar agents are monoclonal antibodies similar to previously approved biologics. In the European Union, they have been approved for all the indications in the management of immune-mediated inflammatory diseases (IMIDs), although data only in rheumatoid arthritis and ankylosing spondylitis are currently available. Direct evidence on efficacy, safety, and immunogenicity of biosimilars is mandatory in psoriasis, psoriatic arthritis, and inflammatory bowel disease, as well as in children. Based on the current evidence in the literature, we present the joint official position of the Italian Society of Rheumatology, Dermatology and Inflammatory Bowel Disease on the use of biosimilars in IMIDs.

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Psoriasis

- Keratinocyte proliferation & loss of differentiation
- Angiogenesis (vasodilation, increased permeability)
- Inflammation (T cells, DCs, Mø, NK cells, neutrophils)

Normal skin

Histology
Clinical case 2

- Male patients, 18 years age; no comorbidities, no concomitant medications
- Resistance to any topicals, MTX, CsA, acitretin, phototherapy (NA)
- PASI=35; Patients was candidate to IFX 5 mg/Kg/day
Clinical case 2

- At week 12, PASI= 0, i.e. the patients has reached the PASI 100
Biologics treatment provided patients with psoriasis higher satisfaction rates

Psoriasis patients in Nordic countries treated with biologics in 12-month study showed highest satisfaction rates

Psoriasis-related problems rated by patients and mean estimated treatment satisfaction values in different treatment groups (N = 404)

- No or mild problems
- Moderate problems
- Severe or very severe problems
- Treatment satisfaction (0-10)

<table>
<thead>
<tr>
<th>Severity of problem (%) of patients</th>
<th>Topical treatment (n = 185)</th>
<th>Systemic and/or biological treatment &lt;12 months (n = 146)</th>
<th>Biological treatment 12 months (n = 73)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>45</td>
<td>44</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>36</td>
<td>37</td>
<td></td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>19</td>
<td>4</td>
</tr>
<tr>
<td>Treatment satisfaction</td>
<td>5,7</td>
<td>6,5</td>
<td>8,2</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Palmar psoriasis
Psoriasis with knee involvement
Scalp psoriasis
Psoriasis with elbow involvement