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Infliximab Therapy for Plaque Psoriasis: The UCL Experience

Pierre-Dominique Ghislain
Dermatology Department, UCL (Université Catholique de Louvain), Brussels
Belgium

1. Introduction

Psoriasis is a disease with frequently severe impairment of quality of life. Traditional therapies (topical treatments, UV, cyclosporine, acitretin, methotrexate...) are widely used but are not always sufficient, and may be poorly tolerated or contra-indicated. Among biologicals, firsts on the European dermatological market were etanercept and infliximab. Alefacept use was restricted to the United States of America. Byafter, adalimumab and ustekinumab were launched.

Among all these biotherapies, infliximab is considered a little bit different : known to be one of the most efficient, infliximab treatment requires a mode of administration quite repulsive for some practitioners. It is an intravenous drug, needing a medicalized center of care with good experience and equipment. Infliximab is also known to induce some adverse event, particularly infusion hypersensitivity.

To verify these sentences, we intended to examine our patient cohort treated by infliximab in our Dermatology Unit, with a retrospective study of the first 50 patients beginning infliximab therapy in our Department (excluding patients in phase II or III clinical trials).

Aims :

- to evaluate the proportion of noticeable adverse events, and particularly the therapy discontinuation for adverse events.
- to evaluate in 'real life' the dose and frequency of treatments
- to evaluate the clinical relapses (loss of drug efficacy) and the medical attitude towards this
- to evaluate the reasons for therapy drop-out and/or drug switches
- to evaluate the patient point of view and wishes : drug holidays ? Continuous treatment : good or bad concept for patient psychology ?
- to evaluate the number of temporarily-discontinued treatments and the consequence for re-introduction : adverse event ? Systematic prevention ?

Limitations :

- a retrospective study with 50 patients allows only some observations with no medical evidence

- no comparison is possible
- real life context induces more drop-outs, drug switches and lost to follow-up than controlled clinical studies

2. Retrospective study

2.1 Patients and methods

This is a retrospective study. We revised the list of patients affected with moderate and severe psoriasis and treated with infliximab in our Department since April 2006. Only the first 50 patients were kept, in order to ensure a sufficient trial and analysis period (one year minimum). Four patients were excluded, who were initially treated in the Department but subsequently received follow-up in another hospital. 46 patient files were analyzable in total. Of these, the PASI follow-up data were complete for 41 patients. Analysis of the files was carried out respecting privacy laws, according to the procedures in force for retrospective analyses.

2.2 Results

- Patients were 13 women and 33 men.
- Age range was 19 to 72 years.
- As prior treatment for psoriasis, all patients but 2 (44/46) previously received PUVA therapy and cyclosporine and methotrexate, according to Belgian regulations for the prescription of biological therapy. Two patients did not receive cyclosporine: one due to an absolute renal contra-indication and another who had begun biological therapy in a country where prior treatment with cyclosporine was not required.
- Concerning biological therapy, 15 patients began infliximab as first-line treatment (biotherapy naive patients). 31 took infliximab as second- or third-line treatment.
- The average length of infliximab therapy on day of analysis was 604 days (14 - 1666)
- Best results obtained were PASI 100 (19 patients), PASI 90 (6), PASI 75 (6), PASI 50 (4), PASI <50 (6). Among the 19 patients who achieved PASI 100, 4 had a complete relapse, and 6 a partial relapse. 9 maintained a complete response. Of the patients scoring between 50 and 99%, 8 completely relapsed, and 3 partially.
- As significant adverse events, we noticed 2 cases of arthritis and atypical lupus, 2 typical lupus syndromes, 2 true anaphylactic reactions. We did not see any significant infection. The lupus syndromes required hospitalization and took six months to disappear.
- In clinical follow-up, we did not notice any global tendency to weight loss or gain and no change in blood pressure.
- In the serie, we have one death, by suicide, deemed to be unrelated to the treatment
- Infliximab was used in monotherapy in 41 cases; 5 in combination with methotrexate
- Dosage was secondarily adapted in 8 cases (3 increases in frequency due to insufficient response, 5 dose reductions due to complete and sustained clinical response)
- Temporary interruption and subsequent reintroduction were observed in 10 cases: for non-compliance (2), personal choice (1), intercurrent illness (1), waiting to settle social security (1), extended trip (1), clinical trial (1), temporary treatment switch (3). The reintroduction was accompanied by manifestations of hypersensitivity in one case only.

3. Discussion

3.1 Population

Our patients' demographic data is unremarkable: average weight, alcohol and tobacco habits, comorbidity, and concurrent medication appear to be similar to the general population of psoriasis patients. Only the sex ratio would seem to be non-standard: there are significantly less women than men in our series (13 vs 33). Even if it is not consistent with the general psoriasis sex ratio, it is in accordance with other infliximab case series.

For legal, and social security reimbursement reasons, we do not prescribe infliximab to children and adolescents; our youngest patient is aged 19 years. Subject to a safeguarded general condition, we did not set an upper limit; the oldest patient was aged 72.

3.2 Prior systemic treatment

Prior treatments received for psoriasis are stereotypical: before authorizing biological therapy, Belgian regulations require patients to have tried three therapeutic channels: PUVA therapy, cyclosporine, and methotrexate. It is noted that this refers to PUVA therapy proper, and not just UVB treatment. For cyclosporine, a 'minimum of 2 months of therapy' is stipulated, 'at a minimum of 2.5 mg/kg.day'. For methotrexate, a minimum of 3 months is required, at 15 mg minimum per week. Infringements to either requirement can be made only in the case of documented intolerance or absolute contra-indication.

Among the 46 patients, one was Argentinian and had been able to begin biological therapy in his country without going through the three prior steps; the Belgian authorities therefore authorized him to take infliximab immediately. Another patient had mild renal insufficiency and unstable blood pressure despite the treatment, which was deemed sufficient to certify contra-indication to cyclosporine. The remaining 44 patients all received the three standard treatments, in some cases also UVB, acitretin, or spa treatments. None received fumaric acid (not used in Belgium). Reasons for discontinuing prior treatments included the absence of sufficient clinical results, or an intolerance to the treatment, as well as the prevention of side effects after reaching an excessive cumulative dose. Note: one of the patients had renal insufficiency induced by prolonged cyclosporine therapy.

3.3 Choice of biological therapy

No regulations lay down the use of a specific first-line biological therapy. It would no doubt be logical to begin with a TNF inhibitor, before considering an anti-interleukin, such as ustekinumab, however no objective data exists to support this affirmation. This rationale lies merely in a lack of experience and appraisal with ustekinumab, as opposed to the years of experience with TNF inhibitors, infliximab in particular. There is no way to choose one product over another among TNF inhibitors. Suggestions to begin with etanercept are based on certain data emerging from records, but these are not sufficiently back-up. In the end, the choice of first-line biological therapy currently depends on the habits of the prescriber and discussions with the patient.

In our case series, 15 patients have received infliximab as first-line treatment. The choice was laid out by presenting the patient with the different options, along with their known

advantages and disadvantages. Many patients appreciate the simplicity of infliximab's dosage schedule: half a day in hospital every eight weeks seems much easier than more regular injections at home. Patients often say: "at least, with the drip, I can forget about psoriasis and its treatment completely for two whole months". Patients do not have to go to the pharmacy on a regular basis, keep boxes in the family refrigerator, or have a nurse repeatedly visit their house (figure 1).



Fig. 1. Infusion in specialized unit

On the other hand, some patients fear the hospital environment and prefer treatments they can manage independently. This explains the figure of 31 patients who began infliximab as second- or third-line treatment. Of these patients, the majority had begun with etanercept, with a clinical response deemed insufficient. Some had begun with adalimumab, with a subsequent secondary clinical relapse. Some patients used these two products before beginning infliximab. One patient had received ustekinumab, with a good clinical result, but the development of a paradoxical eczematous reaction.

When we compared the response to infliximab in biotherapy naive and non-naive patients, we found no significant difference, contrary to our expectations. The two groups have the same numbers of complete responses and there is no difference in the subsequent relapse rate.

3.4 Duration of treatment

The average duration of treatment (stopped on the day of database analysis) is 604 days, with extremes of 14 and 1666 days. This duration is long enough to draw conclusions, at least partial ones. The 14-day duration corresponds to a treatment stopped due to side effects.

3.5 Efficacy of infliximab

Clinical response is often excellent. Primary response must be distinguished from more long-term response. Primary response is immediate efficacy, generally deemed at 10 weeks for infliximab. The more long-term response is the persistence of efficacy, without relapse; there is no defined timeframe for measuring this. We will therefore talk about a 1-year or 2-year response, etc. For this study, we analyzed the long-term response according to the clinical practice at the time of file analysis, so 1 to 4 years after the beginning of treatment.



Fig. 2. W0, baseline

A review of the literature indicates excellent clinical response rates to infliximab after 10 weeks: around 80% at PASI 75 (Chaudhari et al., 2001). In other words: four patients out of five achieve a three-quarter response at minimum (reduce their initial PASI by 75% minimum). In our series, this was true for 31 out of 41 assessable patients, so 76%. 19 patients (46%) had a complete response (total clearance of lesions) (table 1). 6 patients achieved a PASI reduction of between 90 and 99%. 6 others reduced their PASI by a

percentage between 75 and 89%. Just 4 remained with an improvement of 'only' between 50 and 74%. 6 patients are considered to have a primary resistance to treatment as they have never obtained a 50% reduction in their initial severity. These six patients cannot be distinguished from the others on the basis of age, sex, comorbidity, or prior treatments received. No characteristics predictive of response emerged from our series.



Fig. 3. W10, complete response

| PASI improvement | Initial clinical response | | | | |
|--------------------|---------------------------|--------|--------|--------|-------|
| | 100% | 90-99% | 75-89% | 50-74% | < 50% |
| Number of patients | 19 | 6 | 6 | 4 | 6 |
| %, of patients | (46%) | (15%) | (15%) | (10%) | (15%) |

Table 1. Clinical response at 10-12 weeks

Although the initial clinical response is therefore very good, there are concerns about its persistence in the medium and long term. Indeed, in our series there were numerous relapses: of the 35 responders, 12 (34%) experimented complete relapse, and 9 partial losses of efficacy (26%) (table 2). By relapse, we mean relatively rapid or gradual return to initial clinical severity. Each case must be confirmed in time in order to exclude spontaneous fluctuations of the illness. True relapses rarely pose diagnostic problems, and justify treatment abandonment. In contrast, for partial loss of efficacy, the absence of external factors must first be verified. In our series, several patients experienced periods of aggravation, which should be seen in relation to increased alcohol consumption; hygienic, dietary, and psychosomatic care improved several cases. The use of contributory drugs should also be systematically researched.



Fig. 4. W46, partial relapse

| Response evolution | Clinical response upon completion (after 1 to 4 years) | | |
|--------------------------------|--|--------------|------------------|
| | Stable | Partial loss | Complete relapse |
| Initial responders 100% (19) | 9 (47%) | 6 (32%) | 4 (21%) |
| Initial responders 50-99% (16) | 5 (31%) | 3 (19%) | 8 (50%) |
| Total (35 pat.) | 14 (40%) | 9 (26%) | 12 (34%) |

Table 2. Clinical response at long-term

Our series shows more relapses than the literature initially reported, but the latter was often based on short observation time periods, or a more frequent combination with methotrexate. However, the most recent publications are in line with our observations. Thus, a Brazilian series demonstrates numbers similar to ours: 32% maintain efficacy, 44% partially recur, 17% completely relapse, and another 6% of patients had a relapse corrected by infusion every six weeks (Duarte et al., 2011). In a series of 120 patients, 93% of patients had an initial response achieving at least PASI 90, however 87% required a higher frequency of treatment than the normal regimen of 5 mg/kg every 8 weeks (Kamili et al., 2011).

In our series, complete relapses occurred most commonly after between 8 and 12 months of treatment; partial relapses could appear up to three years after the start. The responders are highly satisfied and intend to continue treatment, with an improvement in quality of life consistently nearing 100%. We should note that 9 out of 35 patients (26%) maintain a complete clinical response throughout!

An interesting observation is the difference for the long-term result between complete and partial initial responders. Among complete initial responders, half patients maintain the response, and 21% have a complete relapse. In comparison, among partial initial responders, 31% have a stable efficacy, and 50% have a complete relapse.

3.6 Infliximab and methotrexate

We commonly propose infliximab in monotherapy. It is the most common method for treating plaque psoriasis, in contrast to other indications, where combination with methotrexate is systematic. The aim is therefore both to increase treatment efficacy, and to prevent the formation of neutralizing anti-drug antibodies (Poulhalon et al., 2007). The question of more frequently combining infliximab and methotrexate in dermatology has already been raised but never resolved. In our series, 4 patients take methotrexate in parallel with infliximab; they began it after around four months on infliximab, to compensate for insufficient efficacy. 1 other patient began infliximab immediately in parallel with methotrexate.

3.7 Practical attitude in case of relapse

In case of partial relapse, after removing the aggravating factors mentioned above, we usually suggest continuing treatment, this time in combination with methotrexate. The dosage of the latter is in line with usual regulations, adapted to the patient's weight (between 55 and 135 kg, for the present four patients). The medical practice is initially to diminish the dosage relative to methotrexate taken alone, but the clinical facts then dictate the procedure to follow. Tolerance posed no particular problems for three patients. The fourth patient experiences biological perturbations in the liver, which require frequent dose reductions; gastroenterology results are reassuring and allow treatment to be continued, which is furthermore essential due to the severity of the psoriasis and its impact on the patient's life.

We did not try to combine infliximab with other treatments for psoriasis.

Another option would have been to adapt the dosage of infliximab; an increase in frequency has demonstrated success (an infusion every 6 weeks instead of every 8) (Duarte et al., 2011). In Belgium, this is impossible in common practice due to Social Security reimbursement regulations.

If relapse is complete, a combination with methotrexate is not sufficient and the continuation of infliximab is not justified. It could even be deleterious, by analogy with other observations (Korswagen et al., 2011). Among patients with relapse (complete or partial, severe and resistant), 16 were treated with ustekinumab: after a minimum of 10 months, 5 responses at 100%, 7 satisfactory responses (50-99%), and 4 failures were observed. Please note: a naive patient of biological therapy for whom infliximab has never produced a significant improvement (primary non-responder), has then responded optimally to adalimumab.

4. Adaptation of dosage

The official dosage is 5 mg/kg, every eight weeks, after the induction phase. We adapted it in 8 cases. For 3 patients, we increased the frequency of infusions to 1x/6 weeks to try and

respond to the loss of efficacy observed. For two of them, response improved temporarily, however the dosage frequency would have had to be increased more, which was not possible. In contrast, for 5 patients, the dose had to be reduced; the clinical response had been complete and stable for 18 months, and these patients questioned the usefulness of continuing the treatment, at least at the initial dosage. Four patients out of the five thus continued their treatment at a reduced dose, without loss of efficacy. In practice, a reduction to 4, and then 3 mg/kg was suggested to them.

4.1 Medical follow-up

The medical follow-up we propose follows English guidelines (Smith et al., 2009): essentially clinical and anamnestic, it is also based on a blood sampling every six months and particular monitoring for tuberculosis risk. For our patients, we have not observed a tendency for weight gain or loss, nor change in blood pressure.

4.2 Adverse events

Few adverse events were observed, but these were occasionally severe.

One death by suicide, of a 30 year old man. The patient had been depressed for a long time, with a first suicide attempt long before the infliximab treatment. The psychological follow-up was good, but the patient was unable to cope with a failed love affair. The doctor considered this suicide as unrelated to the infliximab treatment. Similarly, a 67 year old patient reported an aggravated impotence problem since the first infliximab infusions. He decided to stop the treatment, which left the effect on erectile function unclear. He had reported the same problem during methotrexate treatment, with recovery after discontinuation. Urological examination results were normal.

Overall, we did not observe any significant infection. Specifically, we did not note any opportunistic infection or any tuberculosis. There were no severe infections to justify a deferral of the infliximab infusion, and anti-infective treatment did not need to be increased in any case.

One patient suspended their treatment during cardiac surgery on the mitral valve (condition pre-existing the infliximab treatment).

For six patients, the obligation to discontinue treatment was more acute (see table 3).

The two cases of induced lupus were severe and required hospitalization. Remission was slow. The first patient had already been treated with infliximab, with an excellent initial clinical response but a relapse after one year. The treatment was stopped for 9 months, but the administration of adalimumab was not conclusive, and the patient wished to try infliximab again. Ten days after the first re-introduced infusion, the patient experienced joint pain and swelling, with rapidly-progressive functional disability leading to an incapacity to move, and hospitalization. The second patient, on methotrexate from the start, developed signs of articular lupus from the 9th month of infliximab treatment, with seroconversion. After the 11-month infusion, the seizure was acute, incapacitating, requiring hospitalization and the use of corticosteroids, and then even thalidomide. It was possible to discontinue the latter after six months.

| | Age | Sex | Prior biotherapies | Time to onset | Description | Severity | Treatment | Evolution |
|---|-----|-----|------------------------|-----------------------------------|-------------------------|----------|--|-------------------------------------|
| 1 | 43 | F | Infliximab, Adalimumab | 1st infusion after a 9-month stop | Lupus syndrome | Severe | Discontinuation of infliximab | Complete resolution |
| 2 | 36 | F | Etanercept | 9 months | Lupus | Severe | Discontinuation of infliximab | Complete resolution |
| 3 | 40 | M | Adalimumab | 1st infusion | Arthralgia, ailments | Severe | Discontinuation of infliximab | Complete resolution |
| 4 | 39 | M | Etanercept | 15 months | Inflammatory joint pain | Moderate | Discontinuation of infliximab | Complete resolution |
| 5 | 41 | F | Infliximab, Etanercept | 2nd infusion after 2-year stop | Anaphylactic shock | Severe | Prevention for following infusions and progressive desensitization | Good tolerance; reduced efficacy |
| 6 | 63 | M | Etanercept, Adalimumab | 4th infusion | Anaphylactic reaction | Moderate | Prevention for following infusions | Good tolerance but clinical relapse |

Table 3. Observed adverse events

For patient 3 (see table), resistant to adalimumab from the start, adverse effects arose from the first infliximab infusion: chest pain with normal tracing on the ECG, unremarkable blood pressure and pulse. The second infusion had to be stopped (faintness) and resumed the following week, with premedication. On the following three days, the patient had to visit the emergency department for incapacitating inflammatory joint pain. The patient was off work for 24 hours. The clinical result was good (PASI reduced to 80%). The third infusion gave rise to the same joint pains, increased, diffused, with headaches. The treatment was discontinued and replaced with ustekinumab, with no tolerance problem.

Patient 4, who was resistant to etanercept, initially showed an excellent response to infliximab (98% PASI improvement). After around 10 months, the recurrence preceding each infusion came earlier and earlier. The treatment was discontinued after 17 months, after it had lost all effect and inflammatory, atypical joint pain had developed for several days and then weeks following the last two infusions, despite the use of methotrexate (begun very late).

For patients 5 and 6, the anaphylactic reactions were true. For the first patient, the shock arose on the 2nd infusion after treatment reintroduction. The patient had participated in the Centocor EXPRESS clinical trial (C0168T38) in 2003 and 2004. The treatment had been stopped for 2 years, with use of etanercept. The infliximab treatment could be restarted after the anaphylactic shock, with systematic preventive measures, progressively reduced, but without the possibility of complete cessation. Clinical efficacy was reduced: less complete response, and period of 8 weeks between two infusions became too long. This justified the discontinuation of infliximab 4½ years later. The reaction was less severe for the second patient. The treatment was also continued, with prevention, but a clinical relapse appeared, which became complete six months later (no improvement after infusion). This patient currently has a partial response to ustekinumab.

4.3 Drug holidays

10 patients experienced temporary interruptions to treatment. The reasons varied widely.

Two patients were not compliant: they forgot appointments on several occasions and canceled due to 'lack of time'. Several times, this led to delays of up to three months. This did not affect tolerance for either patient, but one of the two had an insufficient clinical response. The doctor therefore suggested a treatment more in line with their lifestyle.

One patient personally chose to have a drug holiday; he was able to restart treatment successfully and without adverse events, after recurrence of psoriasis.

One patient (already mentioned above) had to interrupt infliximab for nearly six months due to repeated heart surgery.

One patient interrupted treatment for several months, as his Social Security status was unsettled, and he was no longer allowed to claim his treatment fees.

One patient had to go on an extended trip abroad.

One patient interrupted treatment for a clinical drug trial.

Several patients who had received infliximab therapy for several years recently expressed interest in switching to a biological therapy administered subcutaneously, which they had heard about and considered easier to manage. However, the beginning of treatment is often difficult (partial recurrence following the discontinuation of infliximab), and efficacy of the new treatment is not always immediate. Three patients experienced the change badly and tolerated the beginning of the recurrence poorly. Despite medical explanations and the concern for avoiding drug 'shopping', they returned to their prior infliximab treatment. The reintroduction was accompanied by manifestations of hypersensitivity in one case only.

4.4 Adherence to treatment

Infliximab treatment usually involves strong adherence by the patient. When efficacy is maintained in the long-term, the patient is especially grateful for this invariability. All patients consider not having to undergo treatment at home as being very positive. The

inconvenience of hospitalized infusion is deemed negligible by most patients. For many, this aspect of full care is even deemed to be positive. One possible problem, in psychological terms, is that the infusions take place in hospitals which treat other ambulatory patients, in particular patients undergoing cancer chemotherapy. This co-existence can be difficult to experience for some patients affected with psoriasis. It is easier to manage in large hospitals, which can organize their wards accordingly.

4.5 Quality of life

We did not have systematically evaluate a score of quality of life. Thus, no analysis is possible. Only one patient has stopped the treatment because considered too heavy to manage. Four patients complain about the need of hospital infusion. All others were satisfied by the treatment.

As for other psoriasis treatments, erythematous scars occurring after initial improvement may be of transitory bad perception by the patient (figure 5).

The major problem is to psychologically and medically manage losses of clinical response. But for patients with a sustained complete response, the dermatological quality of life is perfect.



Fig. 5. W6, PASI75 response with erythematous sequelae

5. Conclusion

From this series of 50 patients treated by infliximab, we can confirm the efficacy of the product: PASI 100 (46%), PASI 90-99 (15%), PASI 75-89 (15%), PASI 50-74 (10%). In around half the cases, this efficacy is reduced over time (26%), or completely lost (34%); it is maintained in 40% of cases. In this study, we have a tendency for a more sustained response among complete initial responders in comparison with partial initial responders (47 vs 31%).

We always present infliximab to new patients as the most effective therapy in principle, warning them however about this risk of efficacy loss. The concurrent use of methotrexate could be considered, having proved its worth in indications other than plaque psoriasis (Kamili et al., 2011). Patient satisfaction is increased, despite the need for infusions in specialized and equipped centers. The occurrence of hypersensitivity reactions during infusion must be monitored and the risk of arthritic and lupus reactions must be known.

6. Conflict of interest

The author has participated in clinical trials, given lectures, and participated in expert panels funded by Schering-Plough/Merck. He has also served as consultant for Schering-Plough/Merck.

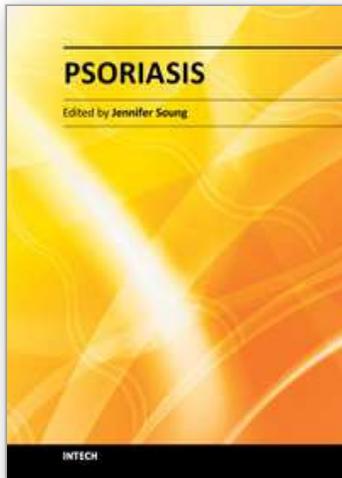
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We hope you enjoy and find the information provided in this book useful in your research or practice. We urge that you continue to keep abreast of the new developments in psoriasis and share your knowledge so that we may advance treatment and cures of psoriasis.

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University Campus STeP Ri
Slavka Krautzeka 83/A
51000 Rijeka, Croatia
Phone: +385 (51) 770 447
Fax: +385 (51) 686 166
www.intechopen.com

InTech China

Unit 405, Office Block, Hotel Equatorial Shanghai
No.65, Yan An Road (West), Shanghai, 200040, China
中国上海市延安西路65号上海国际贵都大饭店办公楼405单元
Phone: +86-21-62489820
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