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RESEARCH ARTICLE

Treatment of plaque-type psoriasis with the 308 nm excimer laser in combination with dithranol or calcipotriol

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Abstract

Purpose: The combination of excimer laser and topical treatment has not been studied in clinical trials. This within-patient comparison study evaluates the response rates of plaque-type psoriasis after treatment with topical only (dithranol or calcipotriol), laser only, and combination therapy with topical medication and laser.

Materials and methods: A total of 61 patients with psoriatic plaques located at symmetric body areas (PASI $\geq$ 6) were screened, 59 were enrolled, 54 completed treatment and 45 completed the 6 months follow-up. Treatments with the excimer laser were performed twice weekly until resolution or a maximum of 15 treatments. Each ointment was applied on one of the test lesions, which had to be at least 10 cm apart from each other. Efficacy was rated with a modified PASI score.

Results: At the end of the treatment phase only one patient in both topical therapy regimens met the criteria of partial clearance (modified PASI $\leq$ 2). The combined therapies resulted in 23 cases of partial clearance in both treatment arms. Four areas treated with calcipotriol, respectively six areas treated with dithranol resulted in total clearance at the end of the treatment phase. The average reduction of modified PASI scores was higher in combination than in topical treatment alone (49.8% calcipotriol + excimer versus 22.9% calcipotriol, 49.7% dithranol + excimer versus 26.8% dithranol). After six months there was a total clearance of 30.5% dithranol + excimer.

Conclusions: Treatment of plaque-type psoriasis with laser in combination with topical treatment is a safe and effective therapy. The best long-term results can be obtained by the application of dithranol and excimer laser.

Keywords: *Calcipotriol, dithranol, excimer laser, psoriasis*

Introduction

Psoriasis is a common, genetically determined hyperproliferative and inflammatory skin disorder. Plaque psoriasis is the most common type and characterised by well-demarcated red skin-covered plaques with silvery scale. It is predominantly found on the extensor surfaces like knees and elbows.

Topical treatment for psoriasis is well established. Dithranol has been successfully used to treat psoriasis since 1916. With the influence of air, light and ions, the radical anthraline is formed which leads to a characteristic brown pigmentation and to skin irritation. The latter is discussed to be responsible for the mode of action.

Also, vitamin D analogues have proved to be effective in treatment of plaque-type psoriasis. The mode of action of vitamin D is best known for its role in the regulation of calcium and bone metabolism. The effects of the biologically active form of vitamin D, 1,25-dihydroxyvitamin D3 ($1,25(OH)_2D_3$), are mediated by binding to a specific intracellular vitamin D receptor, which is present in most tissues including the skin where it is responsible for immunologic modulation and regulates the growth and differentiation of epidermal cells. The pathology of psoriasis reflects the underlying immune-mediated inflammation and cellular hyperproliferation [1, 2]. The latter causes the effectiveness of the biologically

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active vitamin D analogue calcipotriol in the topical treatment of psoriasis [2].

About 20% of all psoriasis patients require phototherapy (alone or in combination with systemic treatment) due to their severity of the disease [3]. In recent years, excimer laser treatment has been reported to be effective in mild or moderate plaque-type psoriasis affecting 10% or less of the patient's body area [4, 5]. The therapeutic effect in psoriasis is related to the induction of T-cell apoptosis [6, 7]. The wave length of 308 nm is close to the antipsoriatic spectrum of the narrow-band UVB phototherapy. Advantages of the use of excimer lasers and reasons for the decision for the study design are discussed later on.

We conducted a within-patient trial, in which all treatment modalities are carried out in one patient. We compared the effectiveness of either excimer laser in combination with calcipotriol or dithranol.

Methods

Study design and participants

This was a single-centre, prospective, within-patient comparison study (study design which applies all treatment modalities in one subject). It was approved by the local ethics committee of the Medical Faculty of Leipzig (169/2004) and was conducted according to principles of the Declaration of Helsinki and the good clinical practice guidelines of the European Community [8–10]. All patients gave their informed consent before enrolment in the study. The study end-points were response and the total sign score (rating scales of erythema, induration and scaling each on the 5-point modified PASI score, [11]). The outcome after 8 weeks or the resolution of the psoriasis lesions were considered to be the overall result. The active phase of the study was performed between December 2005 and 2007 in patients at our institution. Adults over 18 years were eligible for the study if they suffered from plaque-type psoriasis, preferably on symmetric parts of their integument. Inclusion criteria for enrolment in the study were as follows: female and male patients (>18 years) with clinically stable psoriasis and PASI score 1.2 or higher in all plaques (total PASI $\geq$ 6). The test lesions (calcipotriol and dithranol treatment area) had to be at least 10 cm apart from each other. All patients had to have given their informed consent.

Exclusion criteria were as follows:

1. Under 18 years of age, pregnancy or lactation.
2. Patients suffering from pustular psoriasis or erythroderma or acute bacterial, viral (e.g. labial or genital herpes) or fungal infections of the skin, systemic therapy for psoriasis in the past 4 weeks, all local treatments in the last 2 weeks.
3. Malignancies (last 4 years), radiotherapy, systemic therapies with cytostatic or immunosuppressive agents in the past 4 weeks.
4. Patients with clinically relevant gastrointestinal disease, liver or kidney dysfunction, unstable diabetes or other non-stable metabolic or endocrine disorder, unstable ischaemic heart disease, uncontrolled hypertension, tachycardia, bradycardia or arrhythmia as well as TIA or apoplexia.
5. Patients taking medication which could provoke phototoxic reactions like antibiotics, tricyclic antidepressants, beta-blockers, sulphonamides or carbamazepine.

Disease scoring

Before and during the biweekly treatment regimen, psoriatic skin lesions of all patients were scored by one out of two physicians in a non-blinded procedure. Each patient's modified PASI (PSI) [11] score was determined separately for all four treatment areas (calcipotriol, calcipotriol and excimer, dithranol, dithranol and excimer). After the treatment phase, follow-ups were performed after 4 and 6 months and modified PASI scored again.

Local treatment was applied daily, calcipotriol twice daily, in the mornings and evenings, dithranol once daily in the morning without regard of laser treatment which took place twice weekly.

On one study area, the plaques were treated with daily short-term applications of dithranol (Micanol® 3%) for 5 to 200 (mean: 50) min and rinsed off afterwards. This therapy was accompanied by application of salicylic acid 5% at night during the whole duration of the study. The combination with phototherapy is well-established [12, 13]. Calcipotriol 3% ointment was applied twice daily for eight weeks on the other study area. The time interval between ointment application and 308 nm Excimer laser treatment was from 2 to 12 h.

The treatments with the 308 nm excimer laser TALOS (WaveLight, Erlangen, Germany) were performed on both study areas, the dithranol and the calcipotriol site twice weekly at the distal 50% of the plaques at a dose of 2 MED and adjusted depending on response until clearing-up or up to a maximum of 15 treatments [14]. Figure 1 shows one of the treatment areas. Ointment was applied on the whole lesion, whereas only the distal half of the plaque was treated with the Excimer-laser.

Clinical response

The psoriasis severity index (PSI) as a score with the components erythema, induration and scaling was used for rating the psoriasis plaques [11].

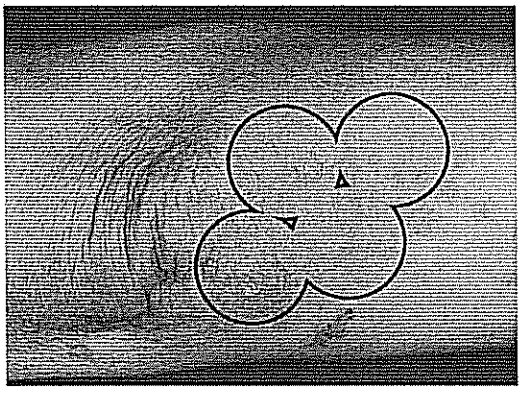

Figure 1. Treated areas: ointment was applied to the whole lesion, whereas the excimer laser was placed only in the distal half of the lesions.

Partial clearance was defined as PSI ≤ 2, total clearance as PSI $= 0$. Minimum value was 0, maximum score 12.

Partial response was defined in the study protocol as scoring of the modified PASI score, PSI ≤ 2. PSI evaluates erythema, induration and desquamation (value 0 (minimum) to 12 (maximum)). Total clearance meant PSI $= 0$.

Primary end-point was the evaluation of resolution of psoriasis plaques after combined therapy with excimer laser with dithranol or calcipotriol versus local treatment alone.

Statistical analyses

Power analysis. Sample-size was estimated based on the publication of Berth-Jones et al. [15]. This study reports on 478 patients in a multi-centre trial comparing calcipotriol to dithranol treatment with a significant difference favouring calcipotriol. In 43% of the patients calcipotriol did better, in 17% worse, in 40% equal to dithranol. The duration of the trial was planned according to the publication of Koo in 1999 [16]. A possible drop-out rate of 10% was calculated. The number of patients needed was 80 with a power of 97%. With 72 patients finishing the study, the power still remained 95%.

Data analysis. A patient was evaluable if the modified PASI score before and after treatment was documented. The chi-squared test, respectively the Wilcoxon rank sum test was carried out to compare the modified PASI scores between the ointment treatment alone (dithranol or calcipotriol) and local treatment in combination with excimer laser therapy (either dithranol and excimer laser or calcipotriol and excimer laser).

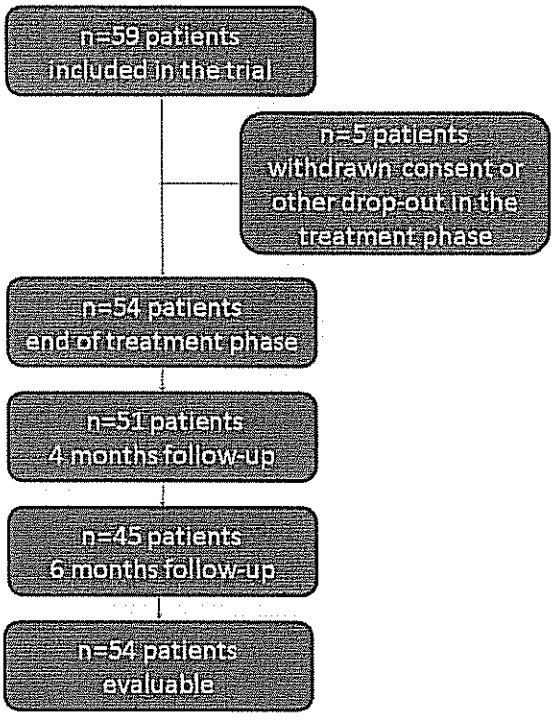

Figure 2. Study patients from screening to analysis.

Results

A total of 59 patients with plaque-type psoriasis (PASI ≥ 6) were enrolled in this trial; 54 (38 men and 16 women) were evaluable. Average age was 45.6 ± 10.7 years (minimum 23, maximum 77), skin types were as follows: type I: $n = 5$, type II: $n = 21$, type III: $n = 31$, type IV: $n = 2$.

The medium total dose of UV radiation was 20.2 ± 7.29 J/cm^2 (minimum 4.25, maximum 59.59 J/cm^2). MED: 0.1: $n = 8$, 0.15: $n = 16$. 0.22: $n = 18$, 0.3: $n =$ n 6, 0.4: $n = 6$. Compliance with the study protocol was sufficiently good: 5 drop-outs until visit 16 (week 8, second treatment), three patients until visit 17 (follow-up after 4 months) and six patients terminated prematurely at visit 18 (follow-up after 6 months, see Figure 2). Drop-out reasons were the new manifestation of pustular psoriasis in one case, one patient withdrew consent. All others were lost to follow-up.

After the treatment period of 8 weeks, topical ointments alone only led to partial response. Specifically, calcipotriol treatment only resulted in one partial clearance, in all other patients there was no change (Figure 3, Tables I and II). Dithranol ointment as the only therapy also resulted in limited reduction of the disease. No total clearance occurred under topical treatment alone without laser application.

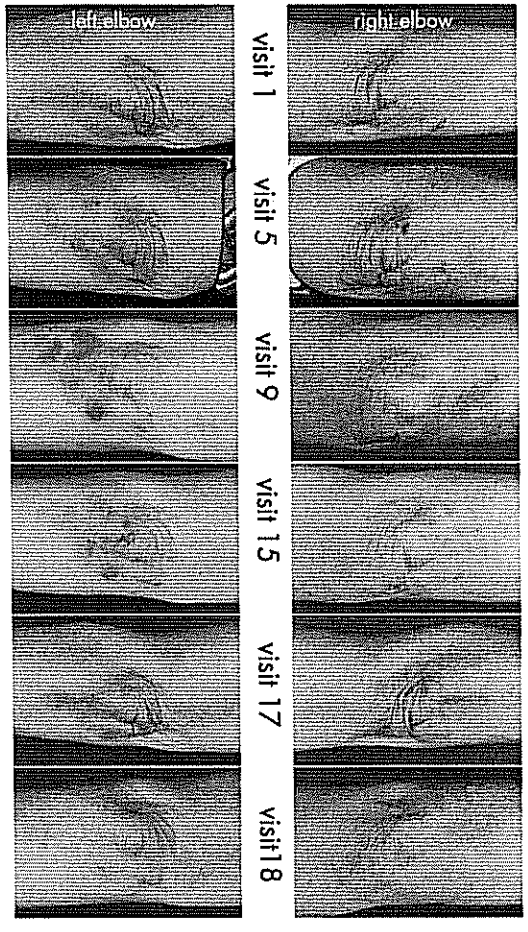

Figure 3. Treatment response over time. Left elbow: local treatment with calcipotriol, distant parts in combination with excimer laser. Visible benefits from the combined therapy regimen could be recorded from the first laser sessions on, rated as partial clearance from visit 5–17. Due to increasing erythema in visit 18 the total score was above 2. Right elbow: local treatment with dithranol, distant parts in combination with excimer laser. Also quick response to the combination therapy, rated as partial clearance from visit 5–16 and as total clearance at the follow-up visits. The overall scores of local treatment alone were between 8–5.

The combination of dithranol or calcipotriol with excimer laser therapy was significantly more effective than each topical regimen alone (Table I). Excimer laser therapy in combination with either calcipotriol or dithranol led to a partial response in 38.9% of the participants directly after the treatment phase. In addition, the total response rates of the combined treatment protocols were higher at the follow-up after 6 months compared to the study visit directly after the end of treatment (Table II). The Wilcoxon rank sum test and the chi-squared test showed strong significance for the superiority of the combined ointment and laser therapy at the end of the treatment phase ($p < 0.0001$). The combination of dithranol with the excimer laser treatment even resulted in a slightly significant better clinical response (62.22% reduction of modified PASI score, $p = 0.124$) compared to the other treatment modalities (see Figure 3).

Discussion

The treatment design of this hypothesis-driven study was based on a rational approach. Excimer laser has been proved to be effective in psoriasis. This implies that a comparison to no treatment is not ethical. It is well known that UVB in combination with calcipotriol is highly effective in psoriasis. The assumption was an efficacy of a combination of excimer laser with the most effective local treatment dithranol. The comparison to calcipotriol was chosen because UVB plus calcipotriol has been shown to be effective [2]. This led to the study hypothesis: H_0: Laser + Dithranol/Vit D3 = Dithranol/Vit D3, H_1: Laser + Dithranol/Vit D3 ≠ Dithranol/Vit D3, which hypothesised that combination therapy would be more efficacious than topical therapy alone.

In this study, the addition of excimer laser therapy to conventional local treatment with standard formulations of calcipotriol or dithranol improved the overall treatment effect in patients with plaque-type psoriasis. Moreover, our study proved that these combination treatments are effective in terms of relapse-free interval.

A trial which compared calcipotriol ointment with short-contact dithranol showed that the effect was significant in favour of calcipotriol at 2 weeks ($P < 0.001$), and remained so at subsequent assessments [15]. In our study, topical treatments alone resulted only in partial responses. This may be caused by the duration of the local treatment, which provokes a decrease of compliance by time [17]. Whereas calcipotriol has become a mainstay in the routine outpatient treatment of psoriasis not requiring a day-care setting, dithranol treatment, being difficult as a routine outpatient therapy, has increased efficacy and improved tolerability if the treatment is carried out in a day-care setting [18]. Storbeck et al., however, reported that the addition of dithranol to phototherapy in psoriasis provided a substantial additional therapeutic effect [3].

In 2003, Hofmann et al. published a trial where the effect of calcitriol versus dithranol in combination with narrow-band ultraviolet B in psoriasis was evaluated. Combination of narrow-band UVB (311 nm) therapy and calcitriol or dithranol were equally effective for the treatment of psoriasis. However, patients preferred calcitriol rather than dithranol when both quality of life and treatment acceptability were assessed [19]. In our trial,

Table I. Treatment response.

Treatment	Response		Visit 16 (week 8, 2nd Tx)	Visit 17 (follow-up after 4 months)	Visit 18 (follow-up after 6 months)
Calcipotriol, no laser	Partial clearance	abs.	1	2	3
		rel.	1.7%	3.4%	5.1%
	Total clearance	abs.	0	2	5
		rel.	0%	3.4%	8.5%
Calcipotriol and laser	Partial clearance	abs.	23	12	8
		rel.	38.9%	20.3%	13.6%
	Total clearance	abs.	4	11	13
		rel.	6.8%	18.6%	22.0%
Dithranol, no laser	Partial clearance	abs.	1	1	3
		rel.	1.7%	1.7%	5.1%
	Total clearance	abs.	0	1	2
		rel.	0%	1.7%	3.4%
Dithranol and laser	Partial clearance	abs.	23	11	5
		rel.	38.9%	18.6%	8.5%
	Total clearance	abs.	6	4	18
		rel.	10.2%	23.7%	30.5%

Table II. Reduction of modified PASI.

Study arm/visit	Calcipotriol, no laser	Calcipotriol and laser	Dithranol, no laser	Dithranol and laser
Week 8, 2nd Tx	22.5%	60.6%	20.9%	62.2%
Follow-up after 4 months	25.8%	54.3%	25.3%	54.2%
Visit 18 Follow-up after 6 months	26.8%	49.7%	22.9%	49.8%

dithranol was slightly, but not significantly, more effective than calcitriol ($p = 0.11$).

In previous studies it has been shown that the 308 nm excimer laser as monotherapy is effective and safe for the treatment of psoriasis [4, 5, 20]. It is more effective in macular than in chronic plaque-type psoriasis [21–24] and in combination with psoralen UVA treatment (PUVA)[25, 26]. The enhanced efficacy of the excimer laser is referred to a higher intensity of UV light delivered to plaques, and the penetration into the dermis, where it may induce T cell apoptosis [7]. And third: the difference in the delivery of UVB light may result in cell death and skin immune system suppression more effectively than traditional UVB [27].

The advantage of application of the excimer laser is the lower total light exposure as well as the assumed lower photo-cancerogenicity, because the healthy parts of the skin are not exposed in this accurate and exact therapy. In addition, fewer treatment sessions (5 to 15) are necessary, of shorter duration than conventional light therapies for psoriasis. Though the effective wave-length of light in psoriasis treatment is 304 to 314 nm, excimer laser therapy leads to quicker clearance of psoriasis plaques and therefore to lower cumulative UVB dosage [28, 29].

Excimer laser therapy is well established and available for psoriasis patients in departments of dermatology in hospitals as well as in dermatology practices. In terms of treatment costs, Marchetti et al. developed a disease-intervention-model from the payer perspective to evaluate the cost effectiveness of treatments for psoriasis [30]. Whereas excimer laser is more expensive per phototherapy treatment (US$151.56 versus $58.86 UVB), the cost per treatment regimen is lower, $909.36 versus $1412.64 for UVB. Due to fewer consultations during the treatment phase, lower resources are calculated for excimer laser therapy (one visit, $92.70) versus three visits during UVB treatment ($184.96) [30].

Moreover, we were able to show that response rates of the combined treatment protocols were higher at the follow-up after 6 months compared to the study visit directly after the end of treatment which might be the result of long-lasting suppression of inflammation.

The application of dithranol takes place once daily but requires high patient compliance and a

comprehension of the mode of application of dithranol which needs to be intensified over time before being removed. Towels could receive brownish stains from the dithranol. The application is quite complicated and not as easy as the use of calcipotriol which is applied twice daily but not rinsed off.

The combination with excimer laser therapy is uncomplicated and simple, but requires time to visit the treatment centre to receive 5 to 15 laser sessions of 5 to 15 min duration and therefore has impact on the patient's lifestyle [31]. However, a piggy-back study investigating the quality of life outcomes of calcipotriol ointment against that of short-contact dithranol cream showed no statistical significance in improvement of quality of life [32].

Although the within-patient study design has numerous advantages as, for example, the comparison of treatments in the same skin condition and compliance, the key limitation of this study consist of the extended treatment modalities for the patients, because they need to apply both calcipotriol and dithranol on different treatment areas. Therefore the compliance of the patients had to be extremely good.

Despite limitations, the positive effects of the combined excimer laser and topical therapy are predominant and favour a combined treatment strategy of local treatment combined with excimer laser in plaque-type psoriasis if indicated.

Conclusion

In summary, treatment of plaque-type psoriasis with the excimer laser in combination with topical dithranol or calcipotriol is a safe and effective therapy according to our results from a pilot study in a single centre site. The best long-term results can be obtained by the application of dithranol and excimer laser light. These results need to be confirmed in multi-centre trials.

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