

Saline Spa Water or Combined Water and UV-B for Psoriasis vs Conventional UV-B

Lessons From the Salies de Béarn Randomized Study

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Objective: To study the effects of UV-B therapy and saline spa water given alone or in combination for the treatment of psoriasis.

Design: Randomized, controlled, comparative study with blinded observers.

Setting: Salies de Béarn, saline spa water center located in the southwest of France.

Participants: Seventy-one adult patients with psoriasis with a Psoriasis Area and Severity Index (PASI) score greater than 10.

Intervention: Patients were randomly assigned to 1 of 3 treatments: spa water alone (group A); UV-B 311-nm phototherapy alone (group B); and a combination of the 2 therapies (group C). The 3 groups were treated on a daily basis 5 days a week for a total of 21 days.

Main Outcome Measures: Change in PASI score from baseline as determined by an investigator blinded to ran-

domization; variation in quality of life, adverse effects, and long-term effects (1 year after treatment).

Results: Four patients dropped out because of secondary effects. Efficacy was similar in groups B and C, with changes in PASI of -64% and -55%, respectively at 3 weeks. For group A, change in PASI was -29%, thus showing a minor therapeutic effect of saline spa water alone and poor efficacy compared with groups B and C ($P < .001$). More adverse effects were reported in groups A and C but did not reach significance. Combined saline spa water and UV-B therapy had no sparing effect on UV-B dosages. One year after treatment, no long-term benefit could be attributed specifically to a given regimen, but the patients had overall significantly better PASI scores than at baseline.

Conclusions: Saline spa water alone had a minor therapeutic effect in psoriasis, and the beneficial effect of bathing to enhance phototherapy was not demonstrated.

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THE THERAPEUTIC properties of the Dead Sea area for skin diseases have been known since ancient times¹⁻⁴; *climatotherapy* refers to a combination of sun exposure and bathing in sea water. Similar therapeutic effects have been obtained by bathing in thermal saline water before UV phototherapies in Bad Bentheim in Germany^{5,6} or at the Blue Lagoon in Iceland.⁷ Most types of psoriasis, except generalized pustular psoriasis, respond to treatment; however, the agents responsible for the therapeutic effect of photobalneotherapy with saline water have not been fully elucidated. An important role is attributed to natural or artificial UV radiation,^{4,8-11} but a therapeutic effect of saline water has also been considered.^{3,12,13} Bathing in high concentrations of salt solutions may trigger elution of various chemotactic and proin-

flammatory mediators, including elastase and cytokines, from affected skin,^{14,15} leading to anti-inflammatory effects. In addition, an immunomodulatory effect involving various cells (ie, lymphocytes and Langerhans cells) and cytokines (ie, interleukin 2 and interferon γ) has been shown in vitro during spa therapy.¹⁶

Biochemical effects of the Dead Sea spa therapy have been evidenced by in vivo and in vitro studies.^{17,18} In vivo, significant increases in the serum levels of bromine, rubidium, calcium, and zinc have been shown in psoriatic patients after daily bathing in the Dead Sea for 4 weeks,¹⁹ which may result from penetration of water minerals through psoriatic skin¹⁷; the beneficial effects observed have been attributed to the nonspecific sedative effects of increased bromine serum levels. In vitro studies¹⁸ have shown increased levels of minerals in psoriatic keratinocytes,

PATIENTS AND METHODS

SALIES DE BÉARN SPA WATER

Salies de Béarn is located in the southwest of France; its thermal water is naturally saline (sodium concentration, 250 g/L). The spa water is also magnesium rich (980 mg/L) and contains 26 chemical elements, including bromine and lithium (**Table 1**).

INCLUSION CRITERIA

The study protocol was approved by the ethical committee of Bordeaux University Hospital, Bordeaux, France. After giving informed consent, patients older than 15 years with stable psoriasis vulgaris of more than 1 year's duration and a Psoriasis Area and Severity Index (PASI) score²⁶ of more than 10 were included. No patient undergoing active treatment for psoriasis was accepted, and treatment with other modalities had to be stopped 2 weeks before the start of treatment. Furthermore, patients receiving systemic drugs usually responsible for psoriasis worsening, such as lithium carbonate or β -adrenergic blocking agents, were excluded. Patients with erythrodermic and pustular forms of psoriasis, including palmoplantar pustuloses, were also excluded, as were patients who had contraindications to phototherapy (ie, previous cutaneous carcinoma or photosensitivity) or balneotherapy (ie, serious heart conditions or contagious disease) and pregnant women.

TREATMENT

The patients were treated for a 3-week period on a daily basis 5 days a week and were lodged and fed at the same hotel to avoid environmental biases as much as possible. Patients were randomly assigned to 1 of 3 treatments. Group A received SSW treatment alone, including a 3-minute jet shower to remove scales followed by a 35°C to 37°C 20-minute bath. The jet shower (pressure, 3 bars) was given from a distance of 14 feet; the skin impact area was about 5 cm², and the temperature varied from 32°C to 34°C. Group B received UV-B 311-nm phototherapy alone with the same UV-B lamp (Philips TL 01/100W; Waldman Eclairage, Reichstett, France).²⁷⁻²⁹ Group C received a combination of the treatments in groups A and B. Phototherapy was performed immediately after balneotherapy without allowing the skin to dry.

In groups B and C, UV-B phototherapy was performed according to the following protocol: starting dosage ranging from 0.1 to 0.4 J/cm² according to the

patient's phototype, and treatment 5 days a week with progressive increments of 0.05 to 0.1 J/cm² to a maximum of 1.4 J/cm² for phototype 2 and 3 J/cm² for phototype 5. Only moisturizers and emollients were permitted during the treatment.

ASSESSMENT METHODS

The patients were examined by 1 investigator (C.C., M.-L.L.-B., C.S., or A.T.) 15 days before inclusion to confirm that the condition was stable and to stop psoriasis treatments except moisturizers. In Salies de Béarn, the patients were examined by the same 3 dermatologists (C.C., M.-L.L.-B., and C.S.) during the treatment at days 0, 7, 14, and 21 (end of treatment), and 1 year later. A second investigator (C.C., M.-L.L.-B., or C.S.), blinded for randomization, examined the patient at days 0 and 21. The lesions were photographed before and after the study. The main criterion for judgment was the change in PASI score between days 0 and 21 determined by the blinded investigator. Other end points were the change in body surface involved, the change in quality-of-life index determined on a 10-cm analog scale,³⁰ pruritus, and the occurrence of adverse events. At the last visit, 1 year after completion of treatment, each patient was examined by 1 of the 3 dermatologists, who determined a PASI score. Other assessments included treatment needed in the interim, including hospitalization and work absence.

Serum levels of electrolytes and trace elements (ie, sodium, potassium, calcium, iron, bromine, magnesium, lithium, fluoride, selenium, phosphorus, strontium, and zinc) were determined at baseline and at completion of treatment (day 21) in the same laboratory.

SAMPLE SIZE AND STATISTICAL ANALYSIS

A sample containing 90 patients was selected to ensure 80% power with an error risk of 5% and to detect a difference of 20% in the variation of PASI score between the phototherapy group and the balneotherapy group. Randomization was centrally controlled by the Dermatology Department in Bordeaux. The inclusions started in January 1996, and an intermediary analysis was conducted in April 1996, as 71 patients were included. The results of this analysis showed that additional inclusions could not add sufficient power to change its conclusions, and the trial's investigators decided to stop the inclusions. The statistical analysis was based on the intention-to-treat principle; data were compared with a Kruskal-Wallis test for continuous variables and by a χ^2 test for categorical variables.

which may play a role in cell proliferation and differentiation as is already known for calcium or magnesium in cell culture.²⁰ Recently, selenium-rich spa water has been considered also to be beneficial in psoriatic patients on a clinical basis.²¹

Furthermore, bathing in tap water or salt solutions has been associated with increased photosensitivity of the skin to UV-B irradiation,²²⁻²⁴ which may enhance the efficacy of phototherapy. Most studies of spa photobal- neotherapy in psoriasis have consisted of clinical observations and descriptive rather than well-controlled studies.

Although most patients had psoriasis, heterogeneity in the type of psoriasis, the extent of the dermatosis, and the modality and duration of treatment preclude definitive statements about the comparative efficacy of such a regimen. We report herein a randomized prospective study conducted in Salies de Béarn, a source of natural saline spa water (SSW) with a high mineral content, designed to study the influences of UV-B and SSW in the treatment of psoriasis and the UV-sparing effect of SSW, and to assess the outcome 1 year after completion of treatment.

Table 1. Comparison of the Chemical Composition of Salies de Béarn Spa Water and of the Dead Sea*

Element	Salies de Béarn, mg/L	Dead Sea, mg/kg
Sodium	102 630	23 170
Magnesium	980	10 500
Sulfur (SO ₄)	980	1150
Chlorine	152 140	81 900
Potassium	1370	2620
Calcium	1450	7950
Lithium	9	Unknown
Carbon (CO ₃)	225	245
Fluorine	1	1.27
Silicon	30	Unknown
Phosphorus	0.5	Unknown
Manganese	8	0.27
Iron	32	Unknown
Cobalt	6	0.023
Nickel	80	0.027
Copper	5	0.059
Zinc	30	0.045
Gallium	18	Unknown
Selenium	0.5	0.001
Bromine	160	1590
Rubidium	40	Unknown
Strontium	115	Unknown

*Data from Estoup.²⁵

Table 2. Characteristics of Patients at Inclusion*

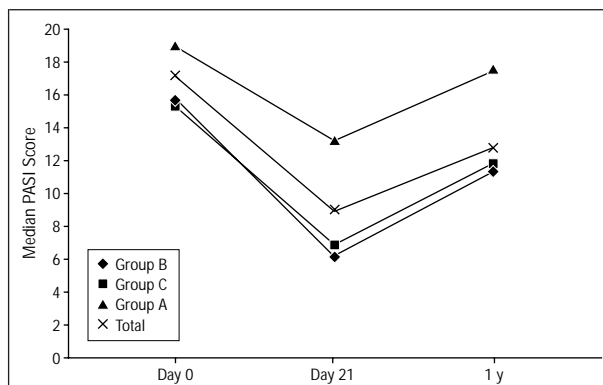
	Group			P
	A (SSW)	B (UV-B)	C (SSW/UV-B)	
No. of patients	22	21	24	...
Phototype, No. (%)				
1	1 (4.5)	0	0	.40
2	1 (4.5)	3 (14.3)	3 (12.5)	
3	11 (50.0)	15 (71.4)	11 (45.8)	
4	7 (31.8)	2 (9.5)	9 (37.5)	
5	2 (9.1)	1 (4.8)	1 (4.2)	
Mean age, y	58.5	48.5	44.5	.08
Median duration of disease, y	22.5	20.5	16.5	.20
PASI score at day 0 (blinded investigator)				
Mean (SD)	21.1 (9.2)	17.5 (7.6)	17.2 (7.9)	.21
Median	19.0	15.7	15.0	

*SSW indicates saline spa water; PASI, Psoriasis Area and Severity Index.

RESULTS

The 71 patients (46 men and 25 women) ranged in age from 19 to 76 years (median, 49 years). The mean duration of psoriasis was 21 years (range, 4-50 years), and the mean PASI score was 19.5 ± 7.9. Four patients dropped out early and were excluded from the statistical analysis: 3 had rapidly occurring adverse effects (skin irritation with SSW) and 1 had contracted a pulmonary infection.

Data for the 67 remaining patients are summarized in **Table 2**. All group characteristics were similar for age, sex, skin type, former treatment modalities, duration of disease, PASI score, quality-of-life index, and pruritus.



Change in Psoriasis Area and Severity Index (PASI) score in the 3 treatment groups and in the whole study sample at day 0, day 21, and 1 year. Group A (saline spa water) had 22, 22, and 15 patients, respectively, at the 3 times; group B (UV-B), 21, 21, and 15 patients; and group C (saline spa water and UV-B), 24, 24, and 10 patients.

Table 3. Efficacy of Treatment and Secondary Effects*

	Group			P
	A (SSW)	B (UV-B)	C (SSW/UV-B)	
No. of patients at day 0	22	21	24	...
Change in PASI at day 21, %†	-29	-64	-55	<.001
Change in quality-of-life index at day 21, %†	+10	-50	-60	.01
Mean total UV-B dose, J/cm ²	...	12.5	11.8	.80
Secondary effects, No. (%) of patients‡	8 (36)	7 (33)	12 (50)	.47
No. of patients at 1 y	15	15	10	...
Change in PASI at 1 y, %§	-14	-34	-21	.80

*SSW indicates saline spa water; PASI, Psoriasis Area and Severity Index.

†(Day 21 - day 0)/day 0.

‡Itching and burning in most cases.

§(Day 365 - day 0)/day 0.

Efficacy was similar in groups B and C, with a change in PASI of -64% and -55%, respectively, at 3 weeks. For group A, the change in PASI was -29%, indicating less efficacy than in groups B and C ($P < .001$) (**Figure** and **Table 3**). This figure correlated well with unblinded PASI scores and global physician evaluation, as well as quality-of-life index. Treatment with SSW had no sparing effect on UV-B doses (Table 3); the total UV-B dose was 12.5 J/cm² in group B and 11.8 J/cm² in group C ($P = .80$).

More adverse effects, consisting mostly of itching and skin burning, were reported in groups A and C but overall did not reach statistical significance. Electrolyte blood measurements at days 0 and 21 showed no significant differences between treatment groups (data not shown).

Only 40 patients (60% of those included) could be reexamined 1 year after their stay in Salies de Béarn (Table 3). In the 3 groups, the PASI score was slightly improved when compared with the PASI score at inclusion (day 0). No long-term benefit could be assigned specifically to SSW therapy; however, no reexamined patient required major psoriasis treatment, such as cyclosporine or methotrexate, or needed to stop work. Four patients received phototherapy.

Until now the absence of clinical studies conducted according to good methodologic standards in the field of spa water and psoriasis has precluded definitive conclusions about efficacy. We present the first prospective randomized study, to our knowledge, in the setting of a spa center (Salies de Béarn). This study examined patients with severe psoriasis with a PASI score greater than 10 and a mean duration of disease of 20 years. Patients were enrolled during a short period (3 months) and randomly assigned, avoiding heterogeneity in the 3 groups, and investigators were trained together before the study to compute PASI scores to ensure homogeneity in the results. Moreover, the main criterion for judgment was the improvement of the PASI score, determined by an investigator who was blinded for randomization. This design was especially helpful to assess more objectively the 2 groups of patients treated with phototherapy.

This study showed that SSW alone had a minor therapeutic effect in psoriasis. Furthermore, no adjuvant effects of salted water on UV therapies could be detected within the rigid framework of the study design. The 29% improvement in psoriasis found in group A may have resulted from a wide variety of factors such as stress reduction, associated emollient therapy, or the natural course of the dermatosis. However, environmental conditions were the same for the 3 groups.

Moreover, 2 recent studies suggest a constant but minor role of salted water in improving psoriasis as was observed with Salies de Béarn SSW. A prospective, double-blind, controlled study¹³ evaluated the therapeutic effect of Dead Sea salts in patients with psoriasis. Twenty-five patients with psoriasis vulgaris were randomly allocated to 2 groups treated with either Dead Sea salt baths (13 patients) or common salt baths (12 patients); the mean percentage reduction in the PASI score after 3 weeks of treatment was mildly higher in patients treated with Dead Sea salts compared with those treated with common salts (34.8% and 27%, respectively). Another prospective study conducted in the Dead Sea area by Even-Paz et al⁹ disclosed that sun exposure was the main factor producing beneficial results for psoriasis in Dead Sea spa therapy. The study included 81 patients allocated to 1 of the following groups: Dead Sea water bathing only (15 patients), sun exposure only (34 patients), and sun exposure combined with Dead Sea water bathing (32 patients); the mean percentage reduction in the PASI score was 28.4% in patients who only bathed in the Dead Sea water. Overall, these studies seem to indicate that psoriasis improvement with SSW cannot exceed 30%; this effect may be caused by the local properties of spa water on psoriatic skin^{14-16,18} rather than by systemic diffusion of electrolytes through damaged skin.^{17,19} Indeed, no increase in serum levels of electrolytes or trace elements was evidenced in our study.

Some authors²²⁻²⁴ have demonstrated that skin sensitivity to UV-B irradiation is increased by bathing in salted water. However, increased photosensitivity does not mean increased therapeutic index, and when broadband UV-B lamps (280-320 nm) are used to treat patients with psoriasis, erythema can be considered a bothersome second-

ary effect.³¹ In this prospective randomized study, the beneficial effect of bathing in saline water to enhance the therapeutic efficacy of phototherapy was not demonstrated. In a study of 81 psoriatic patients treated either by bathing, climatotherapy, or the combination of both regimens, Even-Paz et al⁹ found a mild beneficial effect of Dead Sea bathing; there was an 83% improvement in PASI score for the combined regimen vs 73% for climatotherapy alone. In an open comparative study performed in Iceland,⁷ bathing in a thermal lagoon (Blue Lagoon) combined with UV-B treatment was more effective than UV-B treatment only (mean PASI score in the bathing group decreased from 20.8 to 2.8 and from 16.7 to 6.9 in the UV-B control group after 4 weeks of treatment). However, 2 major criticisms can be made for both studies^{7,9}: first, patients were not assessed by an investigator blinded from randomization, and second, no statistical comparison was performed to prove a significant difference between the 2 treatment groups.

Surprisingly, we have not found mention in the literature of the irritating effect of saline water on psoriatic skin. In our study, more adverse effects, consisting mainly of pruritus or skin burning, were reported in patients who were given spa therapy even when salinity was increased progressively. This may explain the slightly worse results of combined therapy when compared with phototherapy alone; balneotherapy, and especially jet shower, included in our initial design to remove hyperkeratotic lesions and scales, may have aggravated skin inflammation and/or induced the Koebner phenomenon. Exposure modalities to SSW before UV irradiation have to be adjusted before a definitive statement can be made on combined therapies.

A large spectrum of variables must be integrated into the therapeutic guidelines of psoriasis, and a nondogmatic approach is necessary to determine what is the most appropriate regimen in a given patient with such a chronic disease (in our study, the mean duration of the disease at inclusion was more than 20 years). Despite the absence of long-term major therapeutic efficacy, alone or combined with phototherapy, balneotherapy may have its place in psoriasis treatment. Even if its therapeutic effects are limited, balneotherapy may be proposed as an alternative therapy or may be used in cases of contraindications to phototherapy or systemic treatments, such as retinoids, cyclosporine, or methotrexate. Furthermore, skin care is essential in psoriasis, and during spa therapy, the patient may benefit from associated local treatments difficult to apply at home (ie, tars or keratolytic topical medications). Finally, many patients with psoriasis feel isolated and complain of absence of compassion from their dermatologist or general practitioner, a finding that was reported at some "meet the investigators" sessions organized at the end of treatments in Salies; during spa therapy, more attention is given that may contribute to improvement of the skin disorder.

Our long-term data were available for only 60% of the participants of the study, because some patients were recruited from other regions of France and were not able to travel a long distance for the last visit. However, the overall data at 1 year are rather encouraging in terms of treatment needs, including hospitalization, and work dis-

continuation. In the future, the exact place of balneotherapy or photobalneo-therapy in the treatment of psoriasis has to be specified by more studies in spa centers, which should include several relevant outcome variables, including determination of cost-effectiveness and long-term quality of life and psychological status, as compared with conventional therapies.³²

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