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ORIGINAL ARTICLE

# Nb-UVB and PUVA therapy in treating early stages of Mycosis Fungoides: A single-center cross-sectional study

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## Abstract

**Introduction:** Mycosis fungoides (MF) and Sezary Syndrome are the most common forms of cutaneous T-cell lymphoma. Early-stage MF is known to have an indolent behavior, and the EORTC guidelines recommend treating patients with skin-directed therapies, such as phototherapy, instead of systemic therapies. Phototherapy is a popular therapeutic option, with two commonly used light sources—PUVA and narrow band-nb UVB. PUVA is less commonly used due to its potential carcinogenic role, but it has systemic effects, while nb-UVB has mostly skin-limited effects. There is ongoing debate regarding the role of UVB light, and in 2021, the Cutaneous Lymphoma Italian Study Group reached a consensus on technical schedules for NB-UVB and PUVA for MF. This study aims to analyze and compare the efficacy of the two phototherapy options in treating early-MF patients.

**Materials and methods:** The study included patients diagnosed with stage IA/B MF in the last 10 years, who had at least 12 months of follow-up data and a minimum of 24 phototherapy sessions (PUVA or nb UVB) and treated with topical steroids apart from phototherapy.

**Results:** Results showed that the two phototherapy options were similarly effective in treating early MF, with no significant differences in clinical response, although PUVA was associated with more adverse effects.

**Conclusions:** The study provides valuable insights into the use of phototherapy in early MF, and the results can be used to guide treatment decisions and improve patient outcomes.

KEYWORDS
cancer, lymphoma, MF, Mycosis Fungoides, nb-UVB, phototherapy, PUVA, skin, T-cell, tumor

## 1 | INTRODUCTION

Mycosis fungoides (MF) and Sezary syndrome are the most common forms of cutaneous T-cell lymphoma.[1–4] It is well-known that early-stage (IA/B and IIA) MF characterized by patches/plaques has an indolent behavior,[1,5,6] so the EORTC guidelines recommend treating patients with skin-directed therapies (SDT) instead of systemic therapies, which are usually reserved for advanced (> stage IIB) ones.[7] One of the therapeutic options is phototherapy which, since its introduction in the late 1970s, became one of the pivotal therapeutic approaches.[8] Currently, two kinds of light sources are commonly used in dermatologic outpatients: one is based on UVA light emission associated with 8-methoxsalen (the so-called PUVA therapy), and the second on the UVB light emission, usually with a peak of emission between 308 and 312 nm (narrow band-nb UVB). PUVA was popular in the 1980s and gradually became less used than nb-UVB due to its potential carcinogenic role on skin cells.[9,10] Nevertheless, there is a difference between PUVA and nb-UVB. The former also exerts a systemic action while the latter presents mainly skin-limited effects.[11,12] Moreover, it has been established that PUVA may increase the risk of non-melanoma skin cancer or melanoma, in some researches it has been demonstrated increased risk, especially if the number of global sessions is more than 250,[13–15] while the role of UVB light is an object of an ongoing debate.[16–18] In 2016 United States Cutaneous Lymphoma Consortium (USCLC) task force proposed its own recommendations[19] fueling the power to a debate on the role of phototherapy in MF/SS and the need for standardization of the treatment in several countries.[20] In 2021, the Cutaneous Lymphoma Italian Study Group[20] reached a consensus on technical schedules of nb-UVB and PUVA for MF owing to the absence of solid evidence on the use of phototherapy in MF/SS. The present study aims to analyze and confront the efficacy of the two different phototherapy uses in treating early MF patients at our outpatient lymphoma division.

## 2 | MATERIALS AND METHODS

All patients diagnosed with stage IA/B MF in the last 10 years (31/12/2011–31/12/2021) were retrieved from the database of the cutaneous lymphoma outpatients of our unit. MF diagnosis and stage were registered following ISCL/EORTC criteria.[19,21] Among retrieved cases, only patients with at least 12 months of follow-up data, at least 24 sessions of phototherapy (PUVA or nb-UVB) and treated only with topical steroids in addition to phototherapy were included. The characteristics of all patients are shown in (Table 1). The number of treatments, the time between phototherapy cycles, total cumulative dose, mSWAT before/after each cycle, response to therapy (in accordance with EORTC/CLTF criteria[22]), and follow-up duration were analyzed. Patients treated with PUVA ingested 8-methoxy psoralen (8-MOP crystalline tablets 10 mg TRADEMARK) at a dose of 0.6 mg/kg 2 h before exposure to UVA rays.[23] All patients underwent to PUVA therapy three times per week. Whole body UVA was given in a Waldmann 6000 cabinet (Waldmann GmbH, Schwenningen, Germany) containing 40 UVA fluorescent tubes. Starting UVA dose and each increase depended on the Fitzpatrick skin phototype. For skin phototype II, the starting dose was 1.0 J/cm$^2$ and increased by 0.5 J/cm$^2$ per session, while in type III phototype was 1.5 J/cm$^2$ and 1 J/cm$^2$ per session. Patients were treated with NB-UVB two or three times weekly in a Waldmann 5000 cabinet incorporating 24,100-W Philips TL-01 fluorescent lamps (311–313 nm). Also, for nb-UVB starting dose and increase per session depending on the skin phototype and for type II was 2 20 mJ/cm$^2$ with an increase in 25 mJ/cm$^2$, while starting dose in skin III patients was 260 mJ/cm$^2$, with an increase of 40 mJ/cm$^2$. Patients were treated with PUVA or nb UVB in case of failure to topical therapy with emollients and/or potent topical steroids or were unwilling to use them and/or complained of itchiness. In case of painful erythema and blisters after a phototherapy session, the next subsequent session was postponed until regression of the erythema. The subsequent irradiation dose was halved. Based on EORTC/ISCL criteria,[22] clinical response was evaluated after 24 phototherapy sessions as follows: complete response CR, 100% clearance of skin lesions; partial response PR, 50%–99% clearance of skin lesions from baseline; stable disease (SD), 25%–50% clearance of skin lesions; and progressive disease (PD), ≥25% increase in skin lesions from baseline.

A descriptive and comparative statistical analysis was conducted with IBM SPSS 26. All quantitative variables, including age and symptom onset, were estimated using measures of central location (mean, median). Qualitative or categorical variables are described as frequencies and proportions. Proportions were compared using Fisher's exact test. A $p$-value of <.05 was considered statistically significant. The first part of the analysis was performed to assess the efficacy of PUVA and nb UVB based on changes in the mSWAT score before and after the selected treatment. The second part of the analysis considered the difference in the number of cycles of PUVA or nb-UVB to assess the clinical response. A third part of the study analyzed the long-time effects of PUVA and nb-UVB treatment based on the interval between a cycle of phototherapy and the following (defined as time to next phototherapy-TTNP). All the patients gave their written consent to the study, which was approved by the local Institutional Review Board (MF.Tox.Isto19).

## 3 | RESULTS

From our records, 115 patients were retrieved. 40 lacking proper follow-up data or treated with less than 24 sessions of phototherapy were ruled out. Of the 75 remaining patients, 60 were in IA and 15 in IB stage, and none underwent a maintenance treatment protocol. Among stage IA patients, 53 underwent nb-UVB, and 7 were treated with PUVA. Among the patients in stage IB, 7 were treated with nb-UVB and 9 with PUVA. The mean age of the patients was 70.73 (standard deviation 13.3) for the nb-UVB

**TABLE 1** Clinical and demographic characteristics of the patients treated with the two phototherapy sources and comparison of the methods, the specifics of the treatments and the clinical outcomes.

| Groups characteristics | Nb-UVB | | PUVA | | Significativity | |
|---|---|---|---|---|---|---|
| Cases | 60 | | 15 | | | |
| Age | Mean = 70.73<br>Std dev 13.321 | | Mean = 55.27<br>Std dev 23.362 | | .001 | |
| F: M ratio | 26: 34 | | 1: 14 | | .007 | |
| Stage at T0 | IA = 53 IB =7 | | IA = 7 IB 9 | | <.001 | |
| mSWAT at T0 | *N* = 49<br>Mean = 7.51<br>std dev = 5.523 | | *N* = 11<br>Mean = 23.00<br>Std dev = 23.277 | | <.001 | |
| Follow-up time (Months) | *N* = 60<br>Mean = 60.13<br>Std dev = 29.983 | | *N* = 12<br>Mean = 55.00<br>Sted dev = 27.116 | | .549 | |
| Analysis | | | | | | |
| Alive/Death (1 = Alive with no disease, 2 = Alive with active disease 3 = Dead) | Alive with no disease activity = 36<br>Alive with active disease = 18<br>Dead = 6 | | Alive with no disease activity = 6<br>Alive with active disease = 8<br>Dead = 1 | | .208 | |
| Cycles number | Cases = 60<br>Mean = 2.17<br>Std dev = 2.109 | | Cases = 15<br>Mean = 1.73<br>Std dev =1.58 | | .459 | |
| Mean Energy per treatment J/cm$^2$ | Cases = 60<br>Mean = 42.1258<br>Std dev = 51.19252 | | Cases = 15<br>Mean = 198.9133<br>Std dev = 211.69278 | | .000 | |
| Mean time to next phototherapy (Months) | Cases = 24<br>Mean = 15.217<br>Std dev = 15.076 | | Cases = 5<br>Mean = 14.660 Std dev = 15.6278 | | .941 | |
| mSWAT after therapy | *N* = 58<br>Mean = 0.190<br>Std dev = 0.8677 | | *N* = 14<br>Mean = 0.750<br>Std dev = 1.5286 | | .004 | |
| Direct Treatment response<br>CR = Complete<br>PR = Partial<br>SD = Stable | Complete =54<br>Partial = 6 | | Complete = 10<br>Partial = 5 | | .037 | |
| Recurrency | No = 43<br>Yes = 17 | | No = 11<br>Yes = 4 | | .587 | |
| Stratified Treatment response<br>CR = Complete<br>PR = Partial<br>SD = Stable | IA<br>RC = 47<br>RP = 6 | IB<br>RC = 7<br>RP = 0 | IA<br>RC = 5<br>RP = 1 | IB<br>RC = 5<br>RP = 4 | IA<br>0.548 | IB<br>0.088 |

arm and 55.27 (standard deviation 23.3) for PUVA ones. The male gender had a slight prevalence in nb-UVB patients (34 vs. 26 female), while only one female was treated with PUVA, apart from 14 males. The median mSWAT score was 7.51 before (std deviation 5.5) and 0.19 (std deviation 0.86) after UVB. Changes in mSWAT score ranged from 23 (std dev 23.77) to 0.75 (std deviation 1.5) after PUVA. 54 patients (90%) showed a CR, 6 (10%) a PR after nb-UVB, while 10 (66.7%) CR and 5 (33.3%) PR were observed after PUVA. A sub-analysis of the response stratified on the stage showed homogeneous response results between the groups, with 47 patients with a RC for nb-UVB and 5 for PUVA (87.2% vs. 80%) in stage IA and 7 and 5 respectively in stage IB (100% vs. 80%). 43 out of 60 (71.7%) patients did not experience a disease relapse after nb-UVB. The same result was observed in 11/15 (73.3%) patients treated with PUVA. In patients with a complete response, approximately 80% maintained a response in an average of two years. Specifically, in the Nb-UVB group only 17 had a disease recurrence and 4 in the PUVA group in an average of 24 months (Figure 1). TTNP was 15.2 months after UVB nb (std deviation 15.07), 14.6 after PUVA (std deviation 15.6). The mean follow-up time was 62 months, mean administered dose was 42.12 J/cm$^2$ (std deviation 51.19 J/cm$^2$) in nb-UVB patients and 198.91 J/cm$^2$ after PUVA (std deviation 211.69 J/cm$^2$). Patients treated with nb-UVB required a mean of 2.17 cycles of phototherapy (std deviation 2.109), while the mean cycles required with PUVA was 1.73 (std deviation 1.58). All the results are listed in (Table 1).

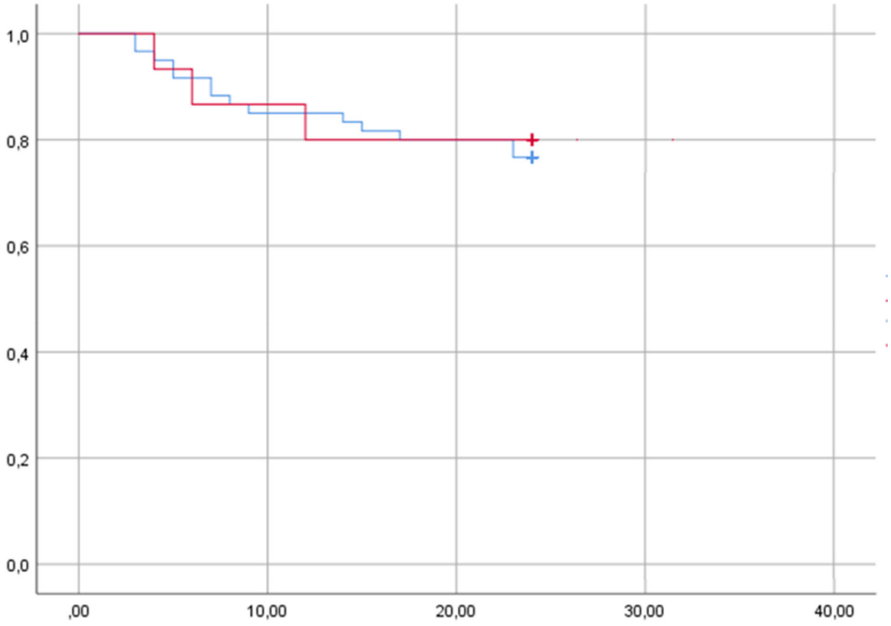


**FIGURE 1** Kaplan–Meyers morbidity recurrences of the two groups. Group 1 (red) has been treated with nb-UVB, while Group 2 (blue) has been with PUVA. We note the fairly overlapping trends in terms of disease recurrence.

## 4 | DISCUSSION

Skin-directed therapies (SDT) are the gold-standard treatment in the early stages of mycosis fungoides. Differences in response to the treatments depend on the selected SDT and the stage of the disease.[7] Since the 70s, one of the most used therapies is phototherapy, consisting of PUVA and nb UVB. PUVA induces neoplastic T lymphocyte death by forming singlet oxygen and directly damaging DNA. T-cell apoptosis is also the molecular mechanism of nb-UVB in MF.[24] Due to the lower risk of skin carcinogenesis, no need for photosensitizer nor total body photoprotection within the 24-h period post-irradiation, its convenience and tolerability, nb-UVB has been increasingly used in the last decades.[25,26] To date, there is no prospective randomized controlled trial comparing the effectiveness of PUVA and NB-UVB. In 2015 a sort of "Copernican revolution" was proposed by USCL.[19] Since the absence of standardization of treatment protocols, the difference between treatment modalities made it unlike analyzing the disease response to the administered treatments. Hence, it is not surprising that, in the literature, the response rate to phototherapy can vary from 65 to 85%.[8,19,27–38] The present study aims to retrospectively analyze early-stage MF patients treated with a homogeneous protocol for PUVA and nb-UVB. Furthermore, patients who underwent systemic treatment (such as bexarotene, acitretin, and systemic steroids) during phototherapy were excluded to limit at most, the possible confounding bias to the response to phototherapy. Our data corroborate literature one on the efficacy of nb-UVB and PUVA.[8,19,27–40] In particular, in our series nb UVB showed a CR rate of 71.7%, similar to what was previously reported.[27–29,32,33,41,42]

Furthermore, the higher number of patients treated with nb-UVB reflects the current trend to prefer nb-UVB to PUVA in early-stage patients for above mentioned reasons. PUVA CR rate was 73.1%, similar to literature data.[19,34–36] The absence of a higher CR rate in PUVA, when compared to nb-UVB in our series, can be due to the small PUVA patient number. However, even if the complete and partial response rates are in percentage terms better in the group treated with nb-UVB than in those treated with PUVA (Table 1) when they are stratified by stage of the disease, emerges no significant differences highlighting that proportionally, the NB-UVB for stages IA seem to have an efficacy comparable to that of PUVA for stages 1B (Table 1). From our data and those in the literature, we can suggest that in IA stages, nb-UVB therapy may be preferred in the first instance instead of PUVA, given the comparable results but with a lower rate of known adverse effects and carcinogenic risk.

We must bear in mind the limitations of this study, among the main ones the group ratio, sample numerosity and its retrospective nature. A prospective and multicentric study, which is under preparation in Italy, may be helpful to empower the current knowledge on phototherapy efficacy in early MF.

### AUTHOR CONTRIBUTION

A.P. contributed to conceptualization and methodology. C.Z. and A.P. contributed to data curation and writing—original draft. C.Z. contributed to formal analysis. C.Z. and G.B. contributed to investigation. F.B. and A.P. contributed to project administration. B.M.P. contributed to resources. C.Z. and B.H. contributed to software. B.M.P. and F.B. contributed to supervision and validation. C.Z. and M.M. contributed to writing—review and editing.

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## CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of Interest.

## DATA AVAILABILITY STATEMENT

Data are available on request from the authors.

## CONSENT TO PUBLICATION

The research was conducted under the approval of the local IRB (MF. Tox.Isto19).

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