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ORIGINAL ARTICLE

Low- Dose hypofractionated total skin electron beam therapy in mycosis fungoides—a single institutional experience

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ABSTRACT

Background: The most prevalent form of cutaneous T-cell lymphoma, known as mycosis fungoides (MF), typically has an indolent course with slowly progressive lesions. The most effective skin-directed therapy for MF is thought to be total skin electron beam therapy (TSEBT). TSEBT, as a single modality, can effectively provide adequate disease control without causing significant cumulative toxicities. A high overall response is attained with acceptable toxicity using Cd-TSEBT of 30-36 Gy. Several studies have investigated the effects of lowering the overall TSEBT dose and shortening the duration of the treatment course with a satisfactory clinical response and reduction of radiation-related toxicities. **Aim:** By using a low-dose hypofractionated course of TSEBT in patients with MF, we conducted a single-institutional trial to assess disease response and toxicity. **Methods:** This prospective study included 17 patients with a histologically confirmed diagnosis of MF stage Ib to III illness, who had at least one prior therapy that had failed, and were treated at Ayady Almostakbal Hospital, Alexandria, Egypt. The patients were treated with hypofractionated TSET using 2.5 Gy over 10 fractions twice weekly to a total dose of 25 Gy. **Results:** The overall response rate was 94.1%, with a partial response rate of 29.4% and a complete response rate of 64.7% and one patient lost follow-up without completing a course of radiotherapy. The most frequent side effects associated with treatment were erythema and fatigue. The adverse events were nearly equally distributed between grade 1 and 2 toxicities. **Conclusion:** Low-dose hypofractionated TSBET provides a good treatment modality for patients with MF with a satisfactory response rate and an acceptable toxicity profile.

Key words: mycosis fungoides, hypofractionation, radiation, toxicity

INTRODUCTION

Cutaneous T-cell lymphomas (CTCL) are a heterogeneous group of non-Hodgkin's lymphomas that primarily affect the skin but progress to involve lymph nodes, blood and visceral organs in advanced stages [1]. The most common type of cutaneous T-cell lymphoma is mycosis fungoides (MF) that usually has an indolent course with slowly progressive lesions. Although the majority of patients presented with early-stage disease, MF is regarded as incurable disease that require lifelong treatment [2].

The most effective skin-directed treatment for MF is total skin electron beam therapy (TSEBT) [3]. Without major cumulative toxicities, TSEBT as a single modality can effectively provide adequate disease control. Even at low irradiation doses , the neoplastic T-cells in MF are particularly radio-sensitive, exhibiting significant levels of response [4,5].

Furthermore, radiotherapy has the benefit of treating wide areas of disease while accessing deeper layers of the skin at the same time. TSEBT offers a relatively uniform dose distribution to the whole skin with minimal serious long-term complications [6]. TSEBT has been approved for the treatment of Sezary syndrome and in refractory stage IA and stage IB-IV of MF as well. Multiple large and multi-institutional studies have been

confirmed the efficiency of conventional dose-TSEBT (cd-TSEBT) [7-11].

Cd-TSEBT of 30–36 Gy achieves a high overall response (OR) ranged from 94.7–100% with acceptable toxicity. Induction of sustained complete response in MF is particularly challenging. Despite receiving cd-TSEBT, many patients relapse within the first two years. Theoretically, in certain patients with disease relapse, TSEBT can be successfully repeated particularly in those who had a good initial response [12,13]. However the accompanying cumulative toxicities limit its re-use following disease relapse.

More recent research has therefore have investigated the impact of reducing the total TSEBT dose and shortening the overall treatment time. Low dose TSBT (ld-TSEBT) has a satisfactory clinical response with reduction of radiation-related toxicities [14,15]. The advantage of using the therapy more frequently throughout the patient's lifetime is provided by ld-TSEBT . The use of systemic radiosensitizers may be also allowed by lower doses of radiation [15]. The International Lymphoma Radiation Oncology Group (ILROG) suggests hypo-fractionated TSEBT as a suitable option for patients with MF to reduce the overall treatment duration [16].

Accordingly, due to significant busy radiation centers and poor patients' ambulatory status during COVID 19 pandemic, we carried out a single-institutional study to assess disease response, and toxicity utilizing low-dose hypo-fractionated course of TSEBT in patients with mycosis fungoides.

METHODS

This prospective study was conducted on 17 MF patients who presented to cancer management and research department, Medial Research Institute, Alexandria University, and received radiotherapy at Ayady Almostakbal Hospital (Ayady 4040), Alexandria, Egypt. Patients were enrolled in the study from April 2020 till September 2021, and followed up till February 2022. The study was authorized by the Research Ethical Committee of Medial Research Institute, Alexandria University. The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans (IORG#:IORG0008812).

Ayady Almostakbal center is considered the main referral center for total skin electron radiation allover Egypt and consistent with ILROG suggestion of using hypofractioned protocols as valid option in TSET as measure to decrease patient exposure during COVID 19 pandemic [16].

Patients who had a histologically confirmed diagnosis of MF stage Ib to stage III disease, were 18 years of age or older, and had an Eastern Cooperative Oncology Group performance status of 0 to 2 were enrolled in this study. All participants completed informed consent.

Patients who had visceral or significant blood involvement or who previously treated with TSEBT were excluded from the study. During the course of treatment, topical steroids or any other MF agent therapy was discontinued. Clinical staging was detected according to TNM staging at presentation [17]. During the duration of treatment, topical prednisone or any other MF agent therapy was discontinued.

TSEBT was administered using the Stanford 6-dual field technique which entail treated patient in 6 standing positions at 60-degree difference (anterior, right posterior oblique, left posterior oblique, posterior, right anterior oblique, left anterior oblique) [3]. At every angle, 2 fields upper and lower were given using thin polycarbonate scattering plate at 210 cm from isocenter. 12 fields were treated daily with 6-MeV electron energy linear accelerator. Most of patients hadn't used eye shield due to frequent falling. In order to compensate for underdosing in areas like axilla and planter surface , supplement radiotherapy fields were received to compensate for underdosing . Fraction size was 2.5 Gy over 10 fractions delivered twice weekly to total does of 25 Gy. To limit scatter from the floor ,patients treated in upright position while standing up on the platform.

The Physician's Global Assessment (PGA) approach, which was employed in the T-cell lymphoma trial, was used to assess the response to treatment [18].

The response was evaluated weekly during the treatment course. Complete response (CR) was defined as complete disappearance of all visible skin lesions, whereas, partial response (PR) was defined as clearance of 50% to 99% skin lesions from baseline without emergence of new lesions. Progressive disease was considered when ≥25% increase in skin lesions from baseline occurs. Disease recurrence inside the radiation field or regional lymph nodes, as well as distant metastases, has been reported also as signs of disease progression.

Baseline clinical examination was carried out before start of radiation and was repeated

weekly during treatment course. Toxicities during RT course were recorded according to Common Terminology Criteria for Adverse Events (CTCAE) version 5 [19].

Patients were followed every week during radiotherapy and every month after there.

Statistical analyses

SPSS version 17 (SPSS Inc., Chicago, IL, USA) was used to conduct the statistical analyses though using the statistical software package. By using Chi-square test, categorical variables were compared between different groups. For three or more groups of data, a one-way ANOVA was used. Statistical significance was set at $P \leq 0.05$.

RESULTS

The current study included seventeen patients diagnosed with MF and treated with low-dose hypofractionated TSEBT at our institution.

Clinicopathological data among studied patients are represented in table (1).The age of the patients ranged between 25 and 72 years old ,with a median age of 48 years , 9 of patient population were (53%) males. The majority of the patients (94 %) had Eastern Cooperative Oncology Group performance status (EGOC) 0 or 1 before start of radiotherapy. Stage IIb and T3 (41.2%) disease were commonly encountered among the studied patients. 15 patients out of 17 completed hypo-fractionated TSEBT course in 10 fractions with 2.5 Gy fraction size delivered twice weekly to total does of 25 Gy with one patient required additional 2 fractions to achieve a complete response according to discretion of physician .The other patient stopped treatment after the 7th fraction of radiotherapy, however not achieving any response before lost follow up. Median time of follow up was 29 weeks.

Clinical response

The overall response rate was 94.1% where 11 patients (64.7%) achieved complete response, 5 patients had (29.4%) partial response and one (5.9%) one patient lost follow up before completing course of treatment (Table2).

The median time for complete response was 13 weeks; whereas 8.5 weeks was the median time for partial response.

At 3 months, there was 0% cumulative disease progression incidence, and at 9 months, there was 17.6%. Out of 17 studied patients, all 3 progressed Patients (17.6%) received subsequent courses of radiotherapy.

We also studied the association between the clinicopathological parameters and the response and the results summarized in table 3.

Patient age didn't affect probability of complete response and the difference between patients grouped below 45 and above 45 was not significant (p= is 0.12)

Also, gender and performance status did not impact complete response rate with p value equal to 0.77 and 0.1835 respectively

Although Stage 3 was linked to a lower percentage of complete responses, there was no statistically significant difference (p=0.074).Same was for T stage of tumor as patients with T4 associated with low probability of reaching complete response but again the difference between T4 and T2 and T3 didn't reach statistical significance.

Toxicity

Side effect of treatment were recorded according to CTCAE version 5, the most frequent adverse reactions (AEs) associated with treatment were erythema and fatigue. The adverse events were nearly equally distributed between grade 1 and 2 toxicities. Few patients developed finger swelling and skin pain (3 and 4 respectively). Only one patient had grade 4 diffuse moist desquamation required hospitalization. All AEs were reversible, managed by medical treatment or resolved without treatment (Table 4). Figure 1and 2 are examples of two cases included in the current study.

Tables 1: Clinicopathological data among studied patients (n = 17)

Variable	No.	%
Age		
Median	48	
Mean	50 ±6.5	
Sex		
Male	9	53%
Female	8	47%
EGOC		
0	8	47%

Variable	No.	%
1	8	47%
2	1	6%
tumor stage		
Ib	6	35.3%
IIB	7	41.2%
III	4	23.5%
T-stage		
T2	6	35.3%
T3	7	41.2%
T4	4	23.5%

Table 2: Distribution of the studied cases according to response (n = 17)

Response data	No	%
Complete response	11	64.7
Partial response	5	29.4
Can't assessed	1	5.9
Median time to partial response	8.5 weeks	
Median time to complete response	13 weeks Range (8 - 17 weeks)	

Table 3: Association between response and clinicopathological data

Variable	Response						P
	CR (n = 11)		PR (n = 5)		Not assessed (n = 1)		
	No.	%	No.	%	No.	%	
Age							0.12
<45	6	54.5	1	20			
≥45	5	45.5	4	80	1	100	
Sex							0.77
Male	7	63.6	1	20	1	100	
Female	4	36.4	4	80			
EGOC							0.1835
0	7	63.6	1	20			
1	4	36.4	3	60	1	100	
2			1	20			
Tumor stage							0.074
Ib	5	45.5			1	100	
IIB	5	45.5	2	40			
III	1	9	3	60			
T-stage							0.074
T2	5	45.5			1	100	
T3	5	45.5	2	40			
T4	1	9	3	60			

Table 4: Adverse effects of TSEBT among the studied patients

Adverse event	All grades		G1	G2	Any G4
	No.	%			
Erythema	12	70.6%	4 (33.3%)	8(66.7%)	
Pruritis	7	41.2%	2(28.6%)	5(71.4%)	

Adverse event	All grades		G1	G2	Any G4
Skin pain	4	23.5%	3 (75%)	1(25%)	
Finger swelling	3	17.6%	2(66.7%)	1(33.3%)	
Fatigue	12	70.6%	9 (75%)	3 (25%)	
Desquamation	11	64.7%	5 (45.5%)	5 (45.5%)	1 (9%)
Dry eye	6	35.3%	2 (33.3%)	4 (66.7%)	

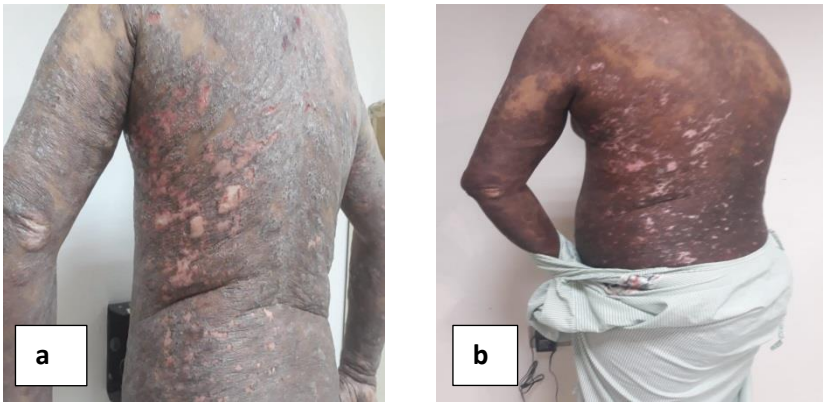

Figure 1: 47-years old male with **a** plaques over the back before start of radiotherapy **b** patches at the end of treatment

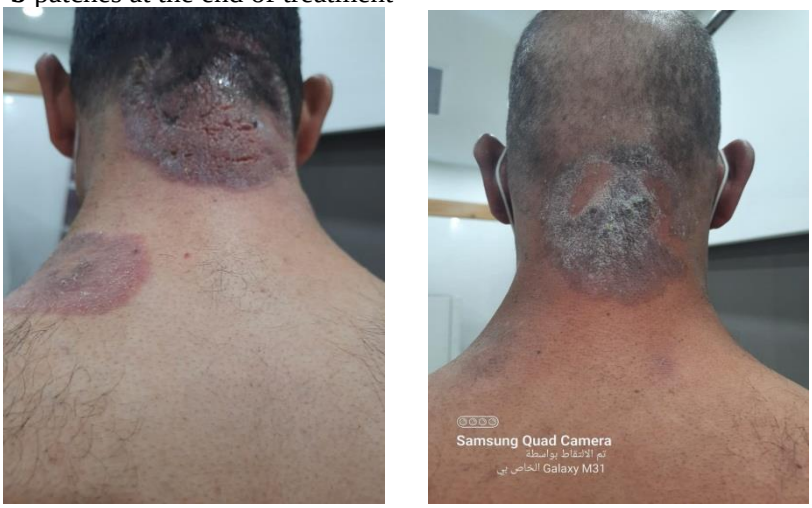

Figure 2: 50-years old male **a** before start of radiotherapy **b at** the end of treatment

DISCUSSION

Conventional fractionated TSEBT is approved as an effective modality for MF/SS, with an overall response rate reaching 96% and complete response rates ranging between 60% and 95%, using 30–36 Gy TSEBT delivered over 5 to 10 weeks [20,21].

Despite of these satisfactory results with cd TSEBT, achieving a sustained CR in MF/SS is particularly challenging, beside significant risk of severe toxicities that limit its use upon disease recurrence. Low-dose TSEBT (12 Gy) delivered in 8 - 12 fractions has the potential to decrease the treatment burden for MF patients. Stanford and the UK Cutaneous Lymphoma Group have reported positive outcomes, with response rates ranging from 87% to 88 [22,23].

Moreover, Hoppe et al showed a response rate of 88%, and a complete response rate of 27% in a pooled analysis of phase 2 clinical trials including 33 MF patients treated with low-dose total skin electron beam radiation therapy (12 Gy /1 Gy per fraction over 3 weeks) [22] .

Recently, the feasibility of Low-dose hypofractionated TSEBT was proved in a retrospective study with acceptable toxicities [24].

During the pandemic of COVID-19, we conducted this prospective study to evaluate the efficacy of low hypofractinated TSEBT in patients with MC .We aimed to define a valid alternative to reduce the risk of infection and the number of patients' visits.

In the current study the radiation course completed in 10 fractions with fraction size of 2.5Gy twice weekly to total does of 25 Gy . The response rate was 94% with 64.7% of patients achieved a complete rate and 29.4% achieved partial response. This was in agreement with Jeans et al, who demonstrated a 100% response rate, but with lower complete response rate (57.4%) [25] .

On the contrary, the rate of complete response in our study is lower than other complete response rates reported in hypo-fractionated series, including a complete response rate of 83% reported by Le Bourgeois et al using 30 Gy in 12 fractions [26] and a complete response rate of 90% in patients treated with 4 Gy weekly for 4 to 6 fractions, according to Nisce et al. [27].

Although hypofractionation was employed in these studies, the overall dose was larger, resulting in a higher CR than in the current study.

Our results were similar to other studies using low-dose TSEBT not using hypofractionation. After providing 10 Gy in 10 fractions over 2.5 weeks, Kamstrup et al observed a 57 percent complete response rate [28], while Rivers et al reported a 25% complete response rate after delivery of ≤12 Gy over 3 weeks [29].

In our study, adverse events were tolerable, mostly grade 1and 2 and only one patient had grade 4 AEs. The most frequent adverse reactions (AEs) associated with treatment were erythema and fatigue. Few patients developed finger swelling and skin pain. Similarly, Jeans et al reported that the most frequent acute radiation-induced AEs were grade 1 or 2 and included pruritus, diffuse erythema, desquamation and acute fatigue. Also they did not report acute grade 3 toxicity, although opposite to our finding, treatment-related alopecia and nail ridging were reported in 41%and 17% of cases respectively [25].

Variation in AEs attributed in difference in patients' characteristics and fractionation schedule. The limitations of the current study are: small number of the patients, heterogeneity of the studied patients especially regarding the stage and the Modified Severity Weighted Assessment Tool was not recorded .Future studies with lager number of patients and with TSEBT combination with other agents could increase the CR rate and the response duration.

CONCLUSION

For patients with MC, low-dose hypo-fractionated total skin electron beam therapy offers an effective treatment option with a satisfactory response rate and a tolerable toxicity profile. Low-dose hypo-fractionated TSEBT provides a shorter treatment course, improved patient compliance, and more important the ability to repeat the therapy several times over the patient's lifetime. When prolonged courses of radiation therapy need to be avoided during health system emergencies, this is a suitable alternative that should be taken into account.

Conflicts of interest:

The authors declare that no conflict of interest

Fund information: None declared

Authors' contributions: AM and HG: made substantial contribution to the design of the work, enrollment of the patients, analysis and interpretation of the data, drafting and revised the work

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