Maintenance therapy with CL Gel Among Patients with Mycosis Fungoides-type Cutaneous T-cell Lymphoma (MF-CTCL): A Real-World Evidence Study

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BACKGROUND

- Mycosis fungoides (MF) is a form of non-Hodgkin cutaneous T cell lymphoma (CTCL) that comprises 50% of all CTCL cases.[1]
- Chlormethine gel (CL; mechlorethamine) was the first skin-directed therapy (SDT) purposely developed to treat MF and is approved in several worldwide countries including United States (US) where it is approved as topical treatment for stage IA and IB MF in patients who received prior SDT, and European Union (EU) where the drug is indicated for the topical treatment of MF in adult patients.[2,3,4,5]
- It has been previously reported that the alternative treatment schedules may benefit patients by improving tolerability and response to treatment. Post-hoc analyses of the PROVe study provide an opportunity to examine the use of CL gel in a real-world setting.[6]

OBJECTIVE

- To report partial response (PR) and real-world patterns of maintenance use of CL gel post PR in MF-CTCL patients.

METHODS

- The PROVe study was a US-based prospective observational non-interventional study assessing outcomes, adverse events, treatment patterns, and quality of life in patients diagnosed with MF-CTCL and treated with CL gel. [2]
- Information on patient demographics, medical history, clinical characteristics, ongoing treatments for MF-CTCL, and response were collected for patients from 46 centers between March 2015 and October 2018. Patients were prospectively followed up to 2 years.
- Partial response (PR) was defined as either 50% reduction in affected body surface area (BSA) or through clinician assessment, at any time from CL gel initiation.
- Maintenance therapy was defined as continuing treatment with CL gel after achieving PR.
- Among patients with PR, deepening response was defined as either 10% additional reduction in affected BSA or achieving complete response (CR) as per clinician assessment.

RESULTS

Table 1: Patient Demographics and Clinical Characteristics

Patient characteristic	Overall (n=298)	
Age		
Mean (SD)	61.1	13.4
Median (Q1-Q3)	62	55.0-71.0
Sex n, %		
Female	119	39.9%
Male	179	60.1%
Stage n, %		
Stage IA/IB	206	69.1%
Stage II or higher	50	16.8%
Unknown	42	14.1%
Race/Ethnicity n, %		
Asian	11	3.7%
Black	45	15.1%
Hispanic or Latino	29	9.7%
Native Hawaiian or other Pacific Islander	2	0.7%
Not disclosed	6	2.0%
Unknown or two or more races/ethnicities	2	0.7%
White	203	68.1%
Duration of MF-CTCL in years Mean (SD)	4.8	6.5
Prior skin directed treatment n, (%)	231	77.2%
Prior systemic therapy n, (%)	90	30.2%

- Approximately 70% of patients had Stage IA/IB MF-CTCL with a duration of 4.8 years at CL gel initiation.

Table 2: CL Gel Schedule

CL gel schedule	Overall (n=298)	
CL gel schedule at initiation n, %		
Daily	182	61.1%
5 times per week	5	1.7%
Every second day	72	24.2%
Every third day	30	10.1%
1 time per week	3	1.0%
Less frequently/Unknown	6	2.0%
CL gel frequency decreased anytime n, %	77	25.8%
CL gel frequency increased anytime n, %	52	17.5%
CL gel interruption (<3 months) n, %	91	30.5%
CL gel discontinuation (≥ 3 months) n, %	38	12.8%
CL gel duration (days) median (Q1-Q3) n, %	624.5	363.0 - 846.0
CL gel duration categories (days) n, %		
0-30	2	0.7%
31-90	13	4.4%
91-180	16	5.4%
181-360	43	14.4%
>360	224	75.2%

- 182 (61%) of the patients initiated CL gel daily and 116 (29%) patients initiated less than daily schedule.
- Median duration for CL gel treatment was 624 days (i.e., 1.7 years).
- A total of 224 (75%) patients achieved PR following CL gel initiation and during study period.

Table 3: CL Gel Schedule Pre- and Post-PR

Pre- and post-PR schedule for CL gel	Patients with PR (n=222)	
Schedule/Intensity Immediately Pre-PR n, %		
Daily	135	60.8%
5 times per week	5	2.2%
Every second day	49	22.1%
Every third day	25	11.1%
1 time per week	3	1.3%
Less frequently/Unknown	5	2.2%
Schedule Changes Pre-PR n, %		
Stable	179	80.6%
1 switch in schedule	36	16.2%
>1 switch in schedule	7	3.1%
Increased in Pre-PR period	15	6.9%
Decreased in Pre-PR period	30	13.5%
Maintenance Schedule/Intensity Post-PR n, %		
No maintenance therapy post-PR	19	8.6%
Same as Pre-PR	153	68.9%
Increased from Pre-PR	24	10.8%
Decreased from Pre-PR	29	13.1%

- 61% were on daily CL gel schedule immediately prior to their PR
- 81% patients did not change their CL gel schedule prior to their PR
- 13% reduced their CL gel schedule in the post-PR period as compared to their schedule prior to PR.

LIMITATIONS

- As this was an observational study of real-world clinical practice, the length of follow-up and number of visits for each patient varied. Therefore, evaluation of responses cannot be standardized for all patients in the study.
- Assessment of any outcomes depend on the completeness of data on routine frequency of assessment for response. Since actual % BSA were missing for several patients at CL gel initiation, data based on clinician assessment was also used to identify patients with partial response.

CONCLUSIONS

- 75% of the patients received maintenance therapy with CL gel in combination with other therapies and continued with the same schedule after PR.
- The study results suggest that continuing maintenance therapy and adjusting CL gel dosing schedule may contribute to deepen treatment responses.

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