

# Concomitant Use of Steroids or Phototherapy with Chlormethine 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.<sup>1</sup>
- 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.<sup>2,3,4,5</sup>
- A previous study reported that topical steroids and phototherapy were commonly used concomitantly with CL gel by MF-CTCL patients<sup>2</sup> but additional post-hoc analyses were required to understand the use of these concomitant therapies in a real-world setting.

## OBJECTIVE

- To determine treatment patterns regarding concomitant use of chlormethine gel with topical steroids, and phototherapy, including possible overlap with chlormethine gel and duration.

## 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.<sup>2</sup>
- Information on patient demographics, medical history, clinical characteristics, ongoing treatments for MF-CTCL, and response was collected for patients from 46 centers between March 2015 and October 2018. Patients were prospectively followed up to 2 years.
- In this study, treatment start and stop dates for topical steroids and phototherapy were analysed in relation to CL gel therapy initiation to assess concomitant medication sequence and duration of overlap.
- Baseline characteristics at CL gel initiation and concomitant medication use patterns were reported using descriptive statistics.

### REFERENCES

1. Yumeen S, Girardi M. Yale J Biol Med. 2020;93(1):111-121.  
2. Kim EJ, Geskin L, Guitart J, et al. J Am Acad Dermatol. 2020.  
3. Geskin LJ, Bagot M, Hodak E, Kim EJ. Dermatol Ther (Heidelb). 2021;11(4):1085-1106.  
4. VALCHLOR (mechlorethamine) gel Prescribing Information; revised 01/2020  
5. Ledaga 160 micrograms/g gel Summary of Product Characteristics; revision date 25/02/2021

## 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%

- Prior to CL gel initiation, 77% and 30% patients had received skin directed treatment or systemic therapy, respectively.

Figure 1. Steroid Use by MF-CTCL Patients and Overlap with Chlormethine Gel Treatment

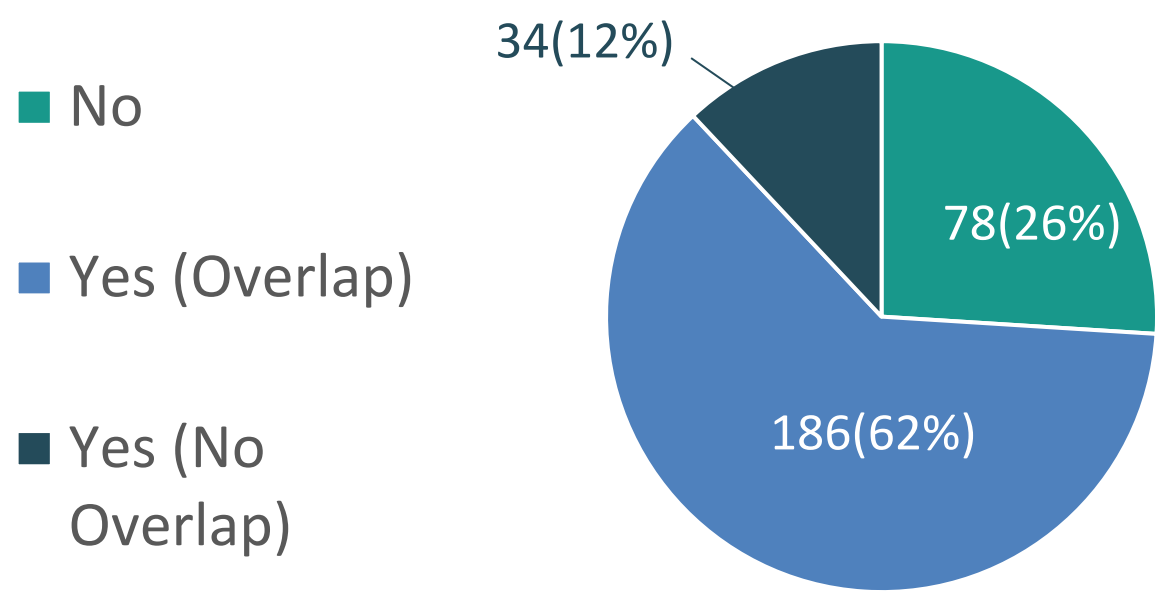
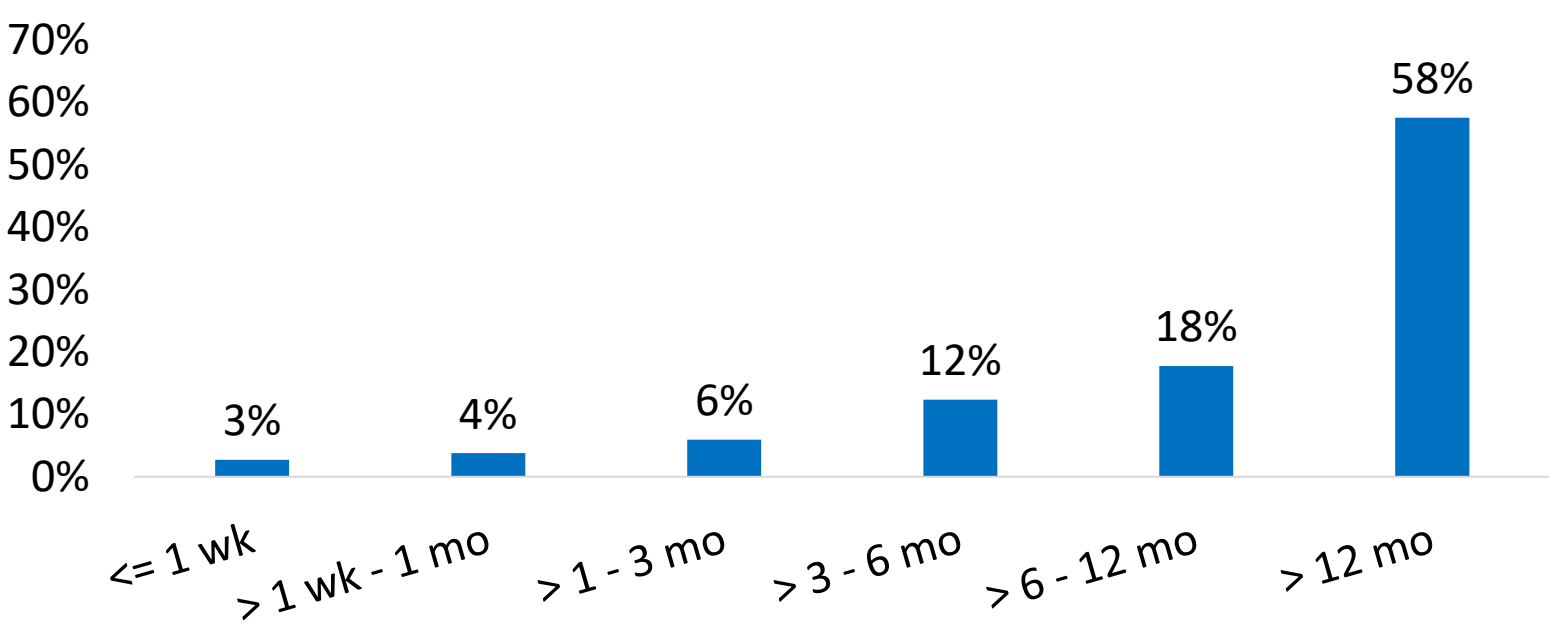


Table 2: Number of Patients with Concomitant Steroids with Respect to Chlormethine Gel Initiation							
Steroid start (with respect to chlormethine gel start)	Patients using both topical steroids and chlormethine gel with respect to days from chlormethine gel initiation						
	Day 0	Day 1	Day 2-21	Day 22-42	Day 43-180	Days >180	Total
Before CL gel initiation	138	128	123	119	126	115	138
CL gel day 1		14	14	14	14	11	14
CL gel day 2-21			2	2	2	1	2
CL gel day 22-42				6	6	3	6
CL gel day 43-180					12	10	12
CL gel day >180						14	14
Total		142	139	141	159	154	186

Figure 3. Duration of overlap for Chlormethine Gel and Topical Steroids



- 186 (62%) had concomitant use of steroid with CL gel.
  - Of these, 58% used both steroids and CL gel for more than a year.

Figure 2. Phototherapy Use by MF-CTCL Patients and Overlap with Chlormethine Gel Treatment

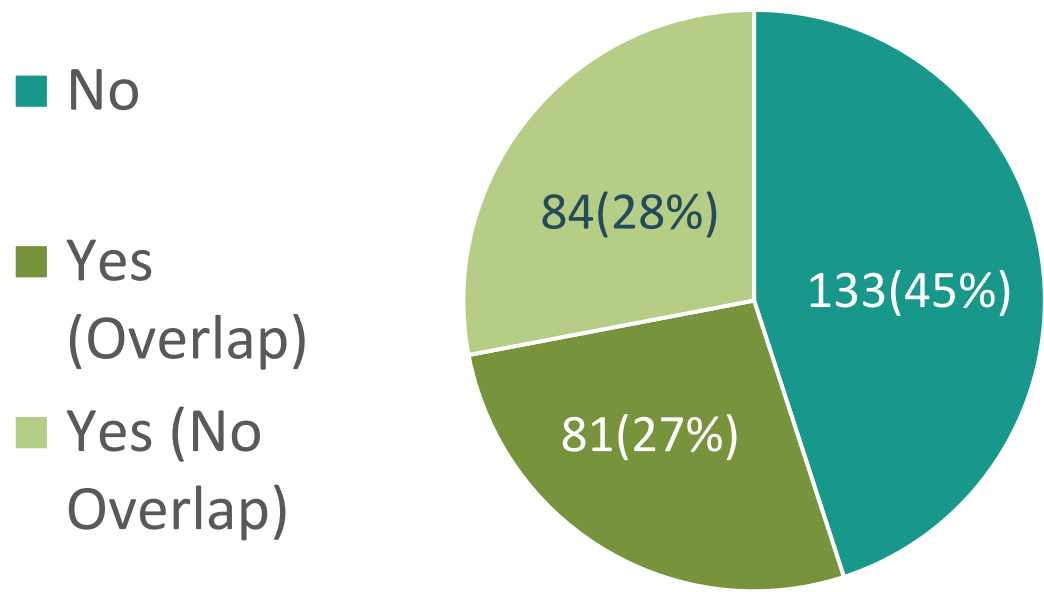
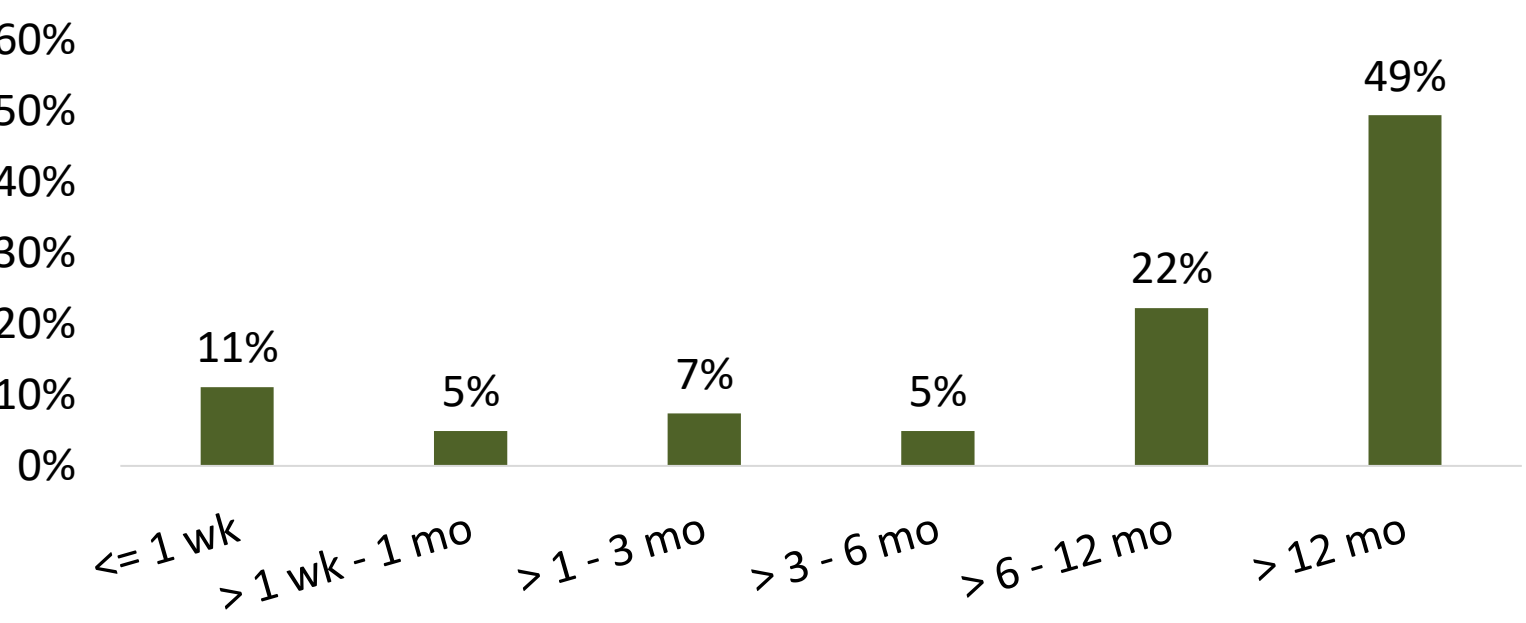


Table 3: Number of Patients with Concomitant Phototherapy with Respect to Chlormethine Gel Initiation							
Phototherapy start (with respect to chlormethine gel start)	Patients using both phototherapy and chlormethine gel with respect to days from chlormethine gel initiation						
	Day 0	Day 1	Day 2-21	Day 22-42	Day 43-180	Days >180	Total
Before CL gel initiation	67	58	51	49	46	56	67
CL gel day 1		0	0	0	0	0	0
CL gel day 2-21			1	1	1	1	1
CL gel day 22-42				0	0	0	0
CL gel day 43-180					4	4	4
CL gel day >180						9	9
Total		58	52	50	51	70	81

Figure 4. Duration of overlap for Chlormethine Gel and Phototherapy



- 81 (27%) had overlapping use of phototherapy with chlormethine gel.
  - Of these, 49% used both phototherapy and CL gel for more than a year.

## LIMITATIONS

- The length of follow-up and number of visits for each patient varied and therefore, assessments were not carried out at pre-defined intervals.
- The frequency or changes in dosing schedules were not evaluated for concomitant medications in relation to changes in chlormethine gel schedule.
- Due to the observational nature of the study, possible missing data (~ 5%) on treatment start and stop dates may affect the assessment of duration of exposure.

## CONCLUSIONS

- For patients with concomitant therapies, the majority started steroids or phototherapy and then added CL gel and used for more than a year.
- These observations suggest that in real life settings, combination treatments with CL gel are standard practice.
- Considering the lack of systemic absorption after CL gel application, physicians may expect improved outcomes with an acceptable tolerability profile.

### FUNDING

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