

P2307

**PATTERNS OF PHARMACOLOGIC CARE FOR PSORIASIS:
RESULTS FROM A LARGE-SCALE, RETROSPECTIVE CLAIMS DATABASE**

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Supported by funding from Stiefel Laboratories, Inc.

BACKGROUND

EPIDEMIOLOGY OF PSORIASIS

An estimated 1.5 million Americans suffer from moderate-to-severe psoriasis, a chronic autoimmune disorder that is characterized by epidermal hyperproliferation. Current evidence indicates that the immune system and inflammatory mechanisms, in particular T lymphocytes and inflammatory cytokines, are of major importance in the pathogenesis of psoriasis.

PHARMACOLOGIC TREATMENT FOR PSORIASIS

According to the National Psoriasis Foundation, the goals of treatment for psoriasis are to:

- Gain rapid control over the disease
- Decrease body surface involvement
- Decrease erythema, scaling, and the thickness of individual plaques
- Maintain the patient in long-term remission and avoid relapse
- Avoid adverse effects as much as possible
- Improve the patient's quality of life

Pharmacologic treatment currently includes oral systemics (acitretin, cyclosporine, methotrexate) and biologics (adalimumab, alefacept, etanercept, and infliximab).

Table 1 shows the recommended dosages for these medications.

BACKGROUND

TABLE 1 – RECOMMENDED DOSAGES FOR PHARMACOLOGIC TREATMENTS FOR MODERATE-TO-SEVERE PLAQUE PSORIASIS

Medication	Recommended Dosage Per Package Insert	Maximum Dosage
ORAL SYSTEMICS		
Acitretin ¹	25-50 mg/day	Not stated
Cyclosporine ²	2.5-4.0 mg/kg/day* (216-345 mg/day for men; 185-296 mg/day for women)§	4.0 mg/kg/day
Methotrexate ³	7.5-25 mg/week	30 mg/week
BIOLOGICS		
Adalimumab ⁴	80 mg SC followed by 40 mg SC EOW	Not stated
Alefacept ⁵	7.5 mg/week (IV bolus) or 15 mg/week IM	Not stated
Etanercept ⁶	50 mg twice weekly for 3 months then 50 mg/week thereafter†	Not Stated
Infliximab ⁷	5 mg/kg IV at week 0, 2, & 6; then every 8 weeks	Not stated

*Dosages < 2.5 mg/kg/day also may be effective in some patients.

§ Assumes average adult male and female weight of 86.3 kg and 74 kg, respectively.

† Starting doses of 25-50 mg/week have also been effective.

1. Soriatane [package insert]. Coral Gables, FL: Stiefel Laboratories, Inc.; 2007.

2. Neoral [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2005.

3. TREXALL [package insert]. Pomona, NY: Duramed Pharmaceuticals, Inc.; 2005.

4. HUMIRA [package insert]. North Chicago, IL: Abbott Laboratories; 2008.

5. AMEVIVE [package insert]. Cambridge, MA: Biogen, Inc.; 2003.

6. ENBREL [package insert]. Thousand Oaks, CA: Immunex Corporation; 2006.

7. REMICADE [package insert]. Malvern, PA: Centocor, Inc.; 2007.

OBJECTIVE AND METHODS

OBJECTIVE

Although the number of treatments for moderate-to-severe psoriasis is burgeoning, and clinical trials have examined the efficacy and safety of various doses of pharmacological treatments, to our knowledge, no study has reported dosing patterns of these medications within a “real world” healthcare setting. Given the array of currently available treatments and those in development, as a first step toward guiding clinical decision making, it will be important to understand how these medications are being used in practice as well as their relative comparative effectiveness.

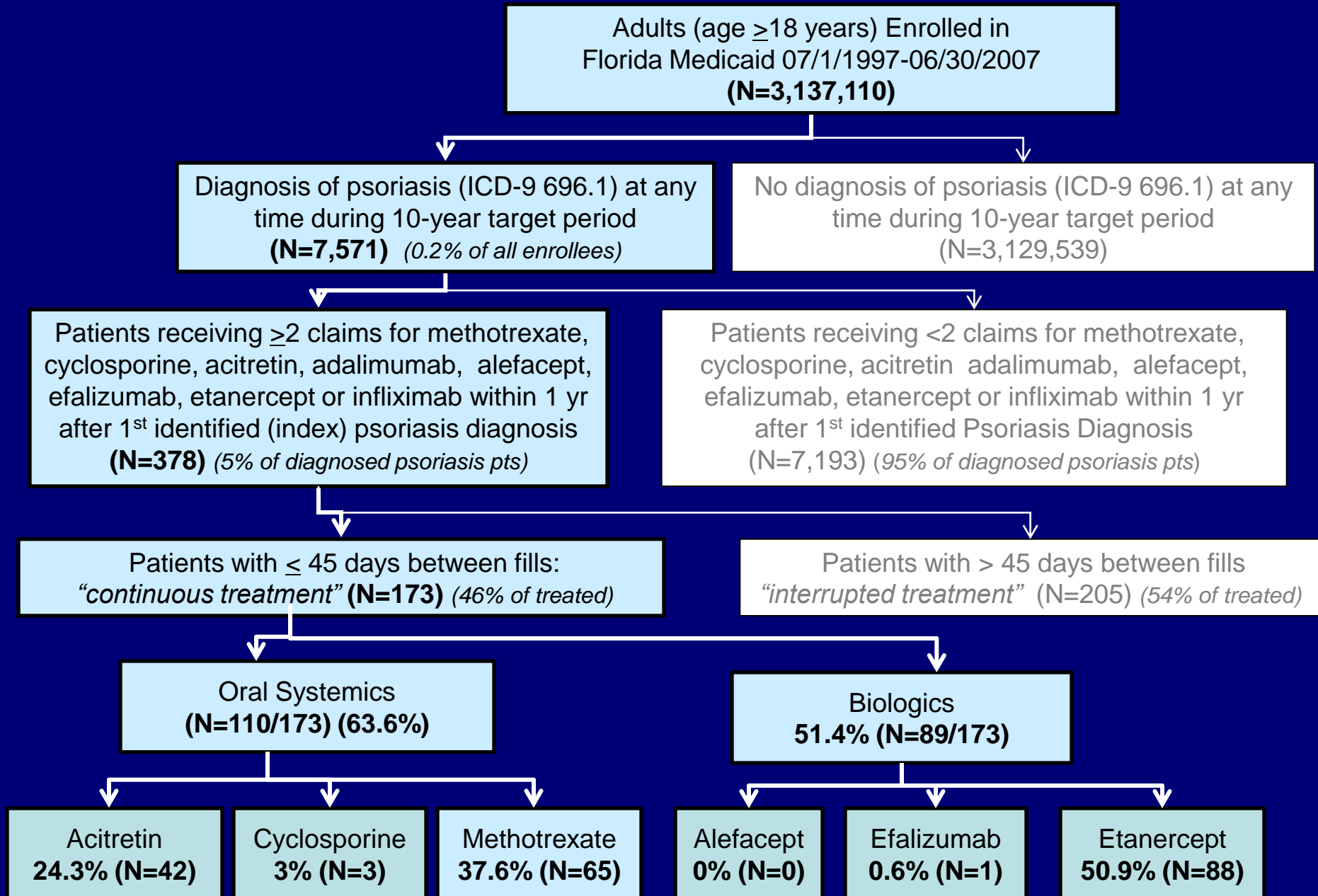
The main objective of the study was to characterize the dosing patterns of pharmacologic treatments for moderate-to-severe psoriasis in a clinical setting.

METHODS

Florida Medicaid provides health services to over 2 million low income state residents. Computerized administrative health care claims data are patient de-identified and HIPAA compliant. Claims records include: patient demographics, diagnoses for which health care was sought (ICD-9); health care procedures (CPT); dates of service; and medication (NDC), dose, and number of days supplied for prescriptions filled.

Using 10 years (7/1/1997 to 6/30/2007) of Florida Medicaid administrative health care claims, we identified Florida Medicaid-enrolled adults (age ≥ 18 years) who filed at least one psoriasis-associated claim (ICD-9 696.1) during the 10-year study period, and who subsequently filled at least 2 of the same prescriptions for targeted treatment of moderate-to-severe psoriasis within 45 days in the year following their first documented psoriasis diagnosis (“index diagnosis”). Targeted treatments included the following medications that were FDA approved for moderate-to-severe psoriasis as of 6/30/2006: oral systemics (acitretin, cyclosporine, methotrexate) and biologics (alefacept, etanercept, infliximab). At the time study data were collected, adalimumab was not marketed. Efalizumab was removed from the market in 2009 and is not included in the dosing analyses.

FIGURE 1 - PATIENT SELECTION



RESULTS

TABLE 2 – PATIENT DEMOGRAPHICS BY TREATMENT GROUP

Age at First Psoriasis Diagnosis by Gender and Medication

	All Patients (N=173)		Acitretin (N=42)		Cyclosporine (N=3)		Methotrexate (N=65)		Efalizumab (N=1)		Etanercept (N=88)	
	F	M	F	M	F	M	F	M	F	M	F	M
Age (yrs)	117 (68%)	56 (32%)	18 (43%)	24 (57%)	3 (100%)	-	51 (78%)	14 (22%)	1 (100%)	-	66 (75%)	22 (25%)
18-29	11 (9.4%)	9 (16.1%)		4 (16.7%)		-	4 (7.8%)	2 (14.3%)	-	-	7 (10.6%)	3 (13.6%)
30-39	26 (22.2%)	8 (14.3%)	4 (22.2%)	1 (4.2%)	1 (33.0%)	-	11 (21.6%)	2 (14.3%)	1 (100%)	-	15 (22.7%)	6 (27.3%)
40-49	15 (12.8)	7 (12.5%)	2 (11.1%)	4 (16.7%)	-	-	9 (17.6%)	2 (14.3%)	-	-	8 (12.1%)	1 (4.5%)
50-59	40 (34.2%)	19 (33.9%)	9 (50.0%)	7 (29.2%)	2 (67.0%)	-	14 (27.5%)	6 (42.9%)	-	-	22 (33.3%)	8 (36.4%)
60-69	16 (13.7%)	9 (16.1%)	-	7 (29.2%)	-	-	9 (17.6%)	1 (7.1%)	-	-	10 (15.1%)	2 (9.1%)
70+	9 (7.7%)	4 (7.1%)	3 (16.7%)	1 (4.2%)	-	-	4 (7.8%)	1 (7.1%)	-	-	4 (6.1%)	2 (9.1%)

RESULTS

TABLE 3 – AVERAGE DOSE IN THE YEAR FOLLOWING INDEX DIAGNOSIS

Treatment	N	Dosing Frequency	Mean (mg)	SD	Median (mg)	Min (mg)	Max (mg)
Acitretin	42	Daily	26.6	11	25.0	10.0	60.0
Cyclosporine	3	Daily	130.0 ^a	61	100.0	89.0	200.0
Methotrexate	65	Weekly	17.5	14.7	14.7	4.2	105
Adalimumab	0	EOW ^b	-	-	-	-	-
Alefacept	0	Weekly	-	-	-	-	-
Etanercept	88	Weekly	67.2	26.6	49.7	23.8	175
Infliximab	0	Q 8 wks ^c	-	-	-	-	-

a. Equivalent to 1.5 and 1.7 mg/kg/day for average U.S. males and females, respectively.

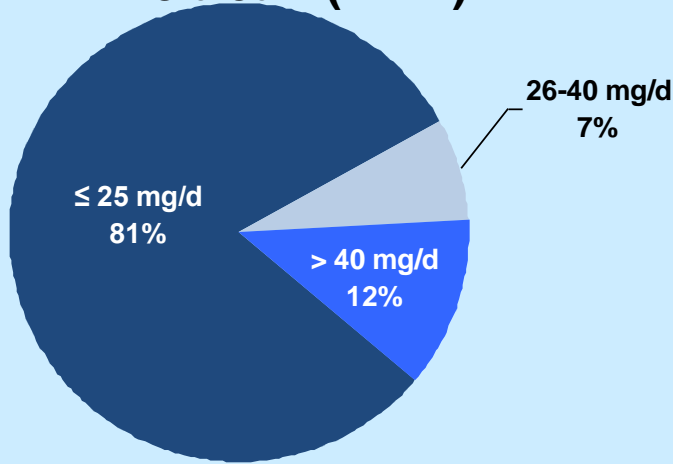
b. EOW = every other week.

c. q 8 wk = every 8 weeks.

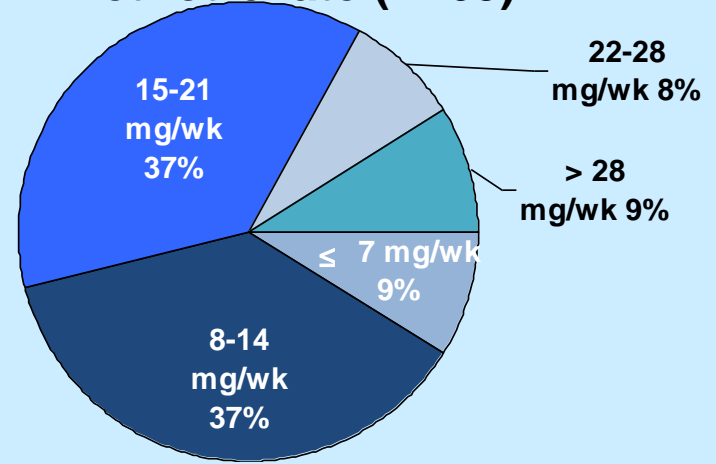
RESULTS

FIGURE 2 – FREQUENCY DISTRIBUTION OF AVERAGE DOSES*

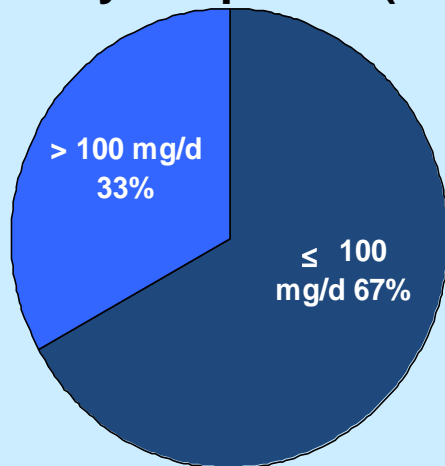
Acitretin (n=42)



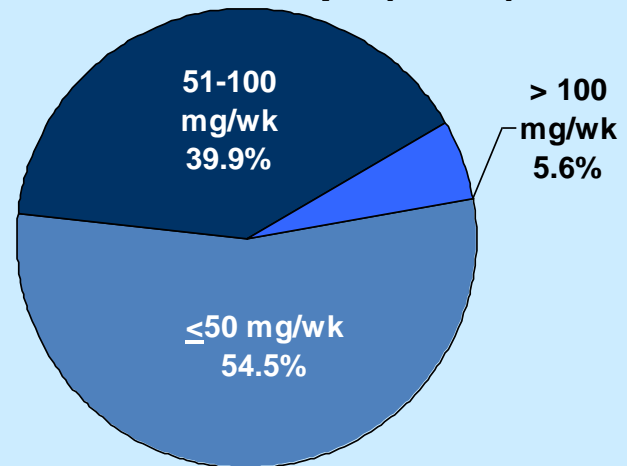
Methotrexate (n=65)



Cyclosporine (n=3)



Etanercept (n=88)



*Insufficient data were available for alefacept and infliximab; adalimumab was not marketed at the time study data were collected.

DISCUSSION

Results indicate that the majority of patients receiving the oral systemics acitretin (81%) and cyclosporine (67%) are using the lower recommended dosage levels (≤ 25 mg/day for acitretin and < 2.5 mg/kg/day cyclosporine). Although it is possible that these lower doses may reflect patients' poor tolerability of higher doses, it is more likely that these patients achieved an effective response at the lower dose level. In contrast, 17% of patients on methotrexate and almost half of those receiving etanercept (45%) were taking a dose higher than the recommended upper limit, possibly increasing patients' risk for adverse events.

CONCLUSION

Given concerns about the safety of long-term use of traditional oral systemic and biologic medications for moderate-to-severe psoriasis,^{1,2} it is important to understand how these medications are being used in actual clinical practice. Long-term "real world" studies that relate dosing patterns and clinical outcomes for the growing number of medications available for the treatment of psoriasis are needed to determine whether many patients can be effectively and safely maintained on low dose levels of medications.

1. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis Section . Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol*. 2009.
2. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008;58(5):826-850.

ADDITIONAL INFORMATION

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