Development and Validation of a Claims-based Algorithm for Moderate-to-Severe Atopic Dermatitis Using U.S. Real-World Data

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Introduction

- Real-world data (RWD) sources, such as insurance claims data, provide the opportunity to draw on the experience of thousands of patients treated in routine clinical practice to better understand the relationships between exposures and outcomes
- Conducting studies on atopic dermatitis (AD) using such data is challenging because it is an episodic condition with a heterogenous clinical presentation
- There are ICD-10 diagnosis (Dx) codes for AD (ICD-10: L20*), but the codes do not specify disease severity;-consequently, the potential for misclassification of AD diagnosis and severity is high
- The objective of the study was to develop and validate a claims-based algorithm for moderate-to-severe AD (MTS-AD) using medical records among individuals seeking clinical care in the US

Methods

Patients ≥ 12 years of age with ≥ 1 AD Dx → Candidate claims-based algorithms applied → Random sample of medical records procured → AD expert adjudicates medical records → Calculate PPV of candidate algorithms

- The study protocol was approved by an Institutional Review Board, and all data access conformed to applicable Health Insurance Portability and Accountability Act policies.
- Patients age ≥ 12 years within the Optum Research Database with at least one AD Dx code (ICD-10: L20*) from March 2017 to November 2019 were selected (source population)
- Claims-based algorithms were applied to identify patients with MTS-AD. **Algorithms were based on number of AD Dx, number and types of AD therapies, and specialty of the treating provider**
- Among patients who met one or more candidate algorithms for MTS-AD, a subset was randomly selected for medical record review
- Medical records from a random sample of patients from the AD source population were reviewed to assess the sensitivity of each candidate algorithm
- Medical records were adjudicated by a dermatologist with expertise in AD diagnosis and treatment to confirm the presence of MTS-AD
- Using the adjudicated results from medical records as the "gold standard", the positive predictive value (PPV) of each candidate algorithm was calculated and compared to a pre-specified threshold of ≥ 70%

Results

- 278 medical records were sought and 200 were adjudicated, including 100 records among patients meeting a candidate algorithm for MTS-AD and 100 records among patients in the random sample
- PPV of algorithms which included ≥ 1 AD Dx as one of the criteria ranged from 38-100% (Table 1); the subset of algorithms (1 and 2) with PPVs that met or exceeded the threshold of 70% identified only six patients
- Revised algorithms that required ≥ 2 AD diagnoses as a criterion had PPVs ranging from 57-100% (Table 1)
- The final algorithm selected for MTS-AD had a **PPV of 76% (95% CI: 53% - 90%)** (Table 1, Figure 1) and a sensitivity of 35% (95% CI: 21% - 52%)
- The prevalence of MTS-AD in the AD source population per the final algorithm was 9.1%

Results cont.

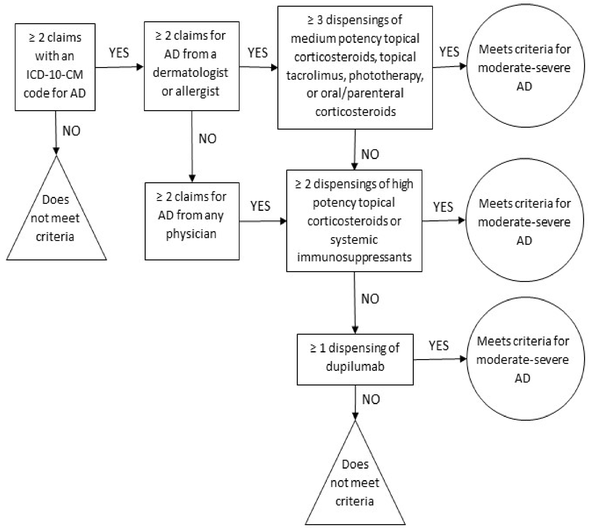

Figure 1. RWE claims-based algorithm to identify MTS-AD

Table 1. Candidate algorithms and their PPV

Algorithm	Algorithms with ≥ 1 AD Dx as a criterion PPV (95% CI)	Algorithms with ≥ 2 AD Dx as a criterion PPV (95% CI)
1- Specialist Dx with ≥ 1 Dupilumab Rx	100% (57%-100%)	100% (57%-100%)
2- Other physician Dx with ≥ 1 Dupilumab Rx	83% (44%-97%)	83% (44%-97%)
3a- Specialist Dx with ≥ 2 Rx from Drug Group 1	54% (29%-77%)	86% (49% - 97%)
3b- Specialist Dx with 1 Rx from Drug Group 1	47% (32%-63%)	60% (36% - 80%)
4a- Other physician Dx with ≥ 2 Rx from Drug Group 1	53% (31%-74%)	78% (45% - 94%)
4b- Other physician Dx with 1 Rx from Drug Group 1	38% (26%-51%)	57% (37% - 76%)
5a- Specialist Dx with ≥ 3 Rx from Drug Group 2	57% (37%-74%)	77% (50% - 92%)
5b- Specialist Dx with 2 Rx from Drug Group 2	51% (36%-67%)	68% (46% - 85%)
6a- Other physician Dx with ≥ 3 Rx from Drug Group 2	45% (29%-62%)	63% (41% - 81%)
6b- Other physician Dx with 2 Rx from Drug Group 2	39% (26%-53%)	59% (41% - 75%)
Final Algorithm (1,2,3a, 4a, 5a)	53% (37% - 69%)	**76% (53% - 90%)**

Dx: Diagnosis; **Rx:** Dispensing claim; **Specialist:** Dermatologist or Allergist; **Drug Group 1:** High potency topical steroids* or Immunosuppressants**; **Drug Group 2:** Medium potency topical steroid***, Topical tacrolimus, Phototherapy, or Oral or parenteral corticosteroids
*Including amcinonide (0.1%), betamethasone dipropionate (0.05%), betamethasone valerate (0.1%), clobetasol propionate (0.05%), desoximetasone (0.25%), diflorasone diacetate (0.05%), fluocinonide (0.05%), halcinonide (0.1%), halobetasol propionate (0.05%), mometasone furoate (0.1%); ** Including azathioprine, cyclosporine, methotrexate, or mycophenolate; *** Including betamethasone valerate (0.1%), desoximetasone (0.05%), flucinolone acetonide (0.025%), hydrocortisone butyrate, hydrocortisone valerate, mometasone furoate, prednicarbate, triamcinolone acetonide (0.1%).

Conclusion

- A claims-based algorithm for identifying patients with MTS-AD was successfully developed and validated using RWD from a U.S. claims database.
- **This validated MTS-AD algorithm is available for use in future studies within administrative databases, including those seeking to evaluate the safety or effectiveness of AD therapies in the post-marketing setting.**

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