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# Cross-Sectional Analysis of Adverse Dermatologic Events Reported to the FDA After Use of GLP-1 Agonists

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## INTRODUCTION

The use of injectable Glucagon-Like Peptide-1 Receptor (GLP-1) agonists including semaglutide, liraglutide, and tirzepatide has increased significantly after receiving FDA approval for the indication of weight loss.[1-3] While characteristic buccal lipodystrophy following rapid weight loss secondary to these medications has been reported,[4] there is a paucity in the literature regarding other dermatologic side effects upon which physicians can counsel. This study investigates the emergence of dermatologic adverse events reported to the FDA after usage of GLP-1 agonists.

The FDA Adverse Event Reporting System (FAERS) Public Dashboard was queried on 1/8/2024 for all reported dermatologic adverse events after usage of GLP-1 agonists approved for weight loss, specifically semaglutide, liraglutide, and tirzepatide. Frequencies of reported reactions within the "Skin and Subcutaneous Tissue" sub-category were collected. Difference of proportion analysis was completed for the top 5 reported adverse events among each GLP-1 agonist.

There were 80,482 adverse events reported at the time of data collection, of which 4,896 (6.08%) were dermatologic. Liraglutide was the most reported culprit (45.85%), followed by semaglutide (40.18%) and tirzepatide (14.22%). There was an 186% increase in reported dermatologic events from 2022 to 2023, mirroring the time of widespread commercial availability. The majority of reported adverse events were consumer-reported (60.33% of reported events) from women (65.01%) within the Unite States (88.44%). Among the cohort, the top reported reactions were "rash" (21.79%), "pruritus" (17.95%), "alopecia" (13.97%), "urticaria" (11.09%), and "hyperhidrosis" (10.76%). Each GLP-1 agonist experienced the same top 5 reactions in different combinations (Table 1) demonstrating the difference of proportion analysis for each reaction by medication. Pairwise comparisons of reaction by medication can be seen in (Figure 1). Events of alopecia and urticaria were reported more frequently among users of tirzepatide, however, all other reactions were more common among liraglutide and semaglutide. There were only 5 reports for "lipodystrophy acquired" and "lipoatrophy" combined.

Post-market surveillance of GLP-1 agonists is imperative as this drug class gains mainstream popularity. Systematic reviews of the literature suggest adverse events are mainly gastrointestinal, secondary to the medications' mechanism of action.[5,6] While statistical significance is difficult to ascertain given the nature of reporting to the FAERS database, a clinical significance of greater than 5% difference was noted for certain adverse events per medication studied. Further research is necessary to determine the potential causality of the reported adverse events, but this study provides preliminary context for prescribers as they counsel patients on possible adverse events when starting GLP-1 agonists.

**TABLE 1.**

**Difference of Proportions for Reported Dermatologic Outcomes Among Users of GLP-1 Agonists**

| | Liraglutide | Semaglutide | Tirzepatide | *P*-Value |
|---|---|---|---|---|
| Rash | 23.1% | 21.8% | 17.7% | 0.011 |
| Pruritus | 18.6% | 18.9% | 12.9% | 0.001 |
| Hyperhidrosis | 12.8% | 10% | 6% | <0.001 |
| Urticaria | 12.8% | 7.7% | 14.9% | <0.001 |
| Alopecia | 11.8% | 13.3% | 22.7% | <0.001 |

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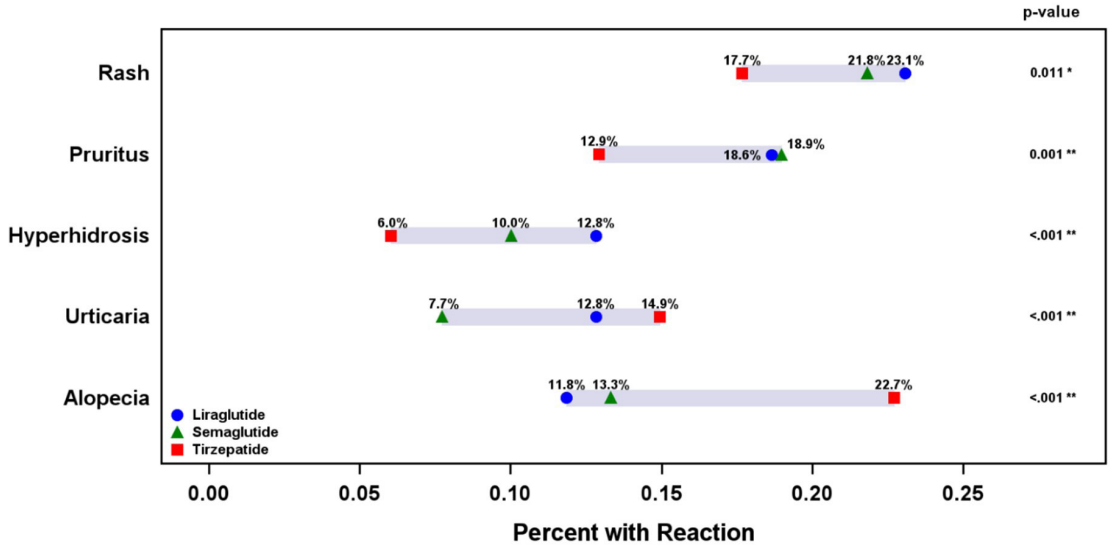
**FIGURE 1.** Percent of top 5 reported adverse events among users of GLP-1 agonists indicated for weight loss.




## DISCLOSURES

There are no conflicts of interest to disclose in relation to the creation of this manuscript.

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