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Differential Biliary Adverse Event Signals Among Glp-1 Receptor Agonists: A FAERS Disproportionality Analysis

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Abstract

Background: Biliary adverse events (AEs) have been reported with glucagon-like peptide-1 receptor agonists (GLP-1RAs), but within-class differences remain unclear.

Methods: We conducted a disproportionality analysis of FAERS comparing biliary outcomes (cholelithiasis, cholecystitis, biliary colic, bile duct stone, and cholangitis) across semaglutide, tirzepatide, liraglutide, exenatide, and dulaglutide; semaglutide was used as the reference agent. Proportional reporting ratios (PRR), reporting odds ratios (ROR), 95% confidence intervals, and Fisher exact tests were calculated. Subgroup analyses and sensitivity analyses were performed.

Results: After deduplication, 3,460 reports were analyzed: semaglutide 1,797, tirzepatide 1,363, liraglutide 1,033, exenatide 999, and dulaglutide 574. Compared with semaglutide, exenatide (PRR 0.39 (0.23–0.65) p<0.001) and tirzepatide (PRR 0.58 (0.39–0.84), p= 0.004) showed lower reporting for **bile duct stone,** while dulaglutide (PRR 0.50 (0.30–0.82), p=0.003) and exenatide (PRR 0.30 (0.19–0.47), p<0.001) showed lower reporting for **biliary colic**(PRR 0.30 and 0.50). Dulaglutide showed higher reporting for **cholangitis** (PRR 1.65 (1.05–2.60), p=0.045). Exenatide (PRR 1.12 (1.08–1.16), p<0.001), liraglutide (PRR 1.07 (1.03–1.12), p<0.001), and tirzepatide (PRR 1.05 (1.01–1.09), p=0.018) showed higher reporting for **cholecystitis**. Exenatide (PRR 1.33 (1.23–1.44), p<0.001), liraglutide (PRR 1.21 (1.11–1.31), p<0.001) and tirzepatide (PRR 1.15 (1.06–1.25), p<0.001) also showed higher reporting for **cholelithiasis**. Subgroup findings were consistent with heterogeneity mainly observed for bile duct stone and biliary colic. Sensitivity analyses were largely concordant, although rarer outcomes lost significance.

Conclusions: Biliary AE reporting varies across GLP-1RAs, highlighting agent-specific differences within class and the need for individualized prescribing and counseling.

Introduction

Glucagon-like peptide-1 receptor agonists (GLP-1RAs) are a cornerstone in the management of type 2 diabetes mellitus and obesity due to their demonstrated efficacy in glycemic control, weight reduction and lowering risk of cardiovascular diseases[1]. Concurrent to the increase in the prescription and use of these agents, attention has shifted to evaluate safety concerns, including gallbladder-related adverse events.

Biliary complications such as cholelithiasis, cholecystitis, biliary colic and biliary cancer have been reported in GLP-1RA users in randomized controlled trials and observational studies[2–5].

Semaglutide is now one of the most widely prescribed GLP-1RAs for both diabetes and obesity and represents the most extensively studied GLP-1RA in clinical practice[6]. Several trials and studies have identified the effects of GLP-1RAs on the biliary system, however there is limited evidence available when comparing within class differences in biliary related adverse events in semaglutide versus other GLP-1RA agents[2,4,7] Given its widespread use, it serves as an important reference point and prompts

further evaluation about whether these biliary adverse events (AE) differ across agents. Using semaglutide as the reference agent therefore provides a stable anchor to evaluate within-class differences and allows interpretation of biliary AEs in the context of current prescribing patterns.

The FDA Adverse Event Reporting System (FAERS) is a useful system for detecting real-world safety signals for medications, as it stores and allows analysis of post-marketing adverse event reports submitted to the FDA[8]. Given the growing clinical use of GLP-1RAs and the evolving literature linking them to biliary complications, it is essential to evaluate and compare biliary adverse events across individual agents to help guide physicians in having informed risk-benefit discussions with patients. Therefore, in this study, we conducted a FAERS-based disproportionality analysis to assess relative reporting of biliary adverse events among individual GLP-1RAs, comparing semaglutide with dulaglutide, exenatide, liraglutide, and tirzepatide.

Methods

We conducted a retrospective analysis using data from the FDA Adverse Event Reporting System (FAERS), a publicly available database that collects post-marketing adverse event reports submitted by healthcare professionals, manufacturers, and consumers[8]. FAERS data from January 1st, 2005, to February 17th, 2026, was included.

The analysis focused on GLP-1 receptor agonists approved for the treatment of type 2 diabetes mellitus and obesity. We evaluated dulaglutide, exenatide, liraglutide, and tirzepatide, and used semaglutide as the reference agent given its widespread clinical use. Biliary adverse events were grouped into the following clinically relevant categories; cholelithiasis, cholecystitis, biliary colic, bile duct stone and cholangitis. Reports listing one of the study drugs and containing one of the mentioned biliary adverse events were included in the analysis. ADRs are categorized using standardized medical terminology from the Medical Dictionary for Regulatory Activities (MedDRA). Deduplication of reports was performed by conditional formatting for variables including patient age, sex, active drug ingredient, country, date of report and drug reactions.

A disproportionality analysis was performed using Proportional Reporting Ratios (PRRs) to assess the relative reporting frequency of biliary adverse events associated with each GLP-1 receptor agonist compared with semaglutide. For each adverse event category, PRRs were calculated by comparing the proportion of reports for a given event among users of an individual GLP-1RA with the proportion of the same adverse event reported among semaglutide users. Additionally, Reporting Odds Ratios (RORs) was performed on the same data to validate the findings. We used the standard error of the log-PRR to calculate 95% confidence intervals (CIs). A 2-sided Fisher exact p test was used to determine statistical significance, with $p < 0.05$ considered significant.

We performed a sub-group analysis on the deduplicated data on age, sex and indication for use. Unknown values were excluded from the analysis. Breslow–Day heterogeneity tests were used to detect

heterogeneity across strata with $p < 0.05$ considered a signal for heterogeneity.

To assess robustness of results, we performed a sensitivity analysis. We repeated the disproportionality analysis by (i) excluding reports with unknown indication for use, (ii) restricting to U.S. reports geographically.

This study did not require Institutional Review Board (IRB) approval, as it utilized the publicly available, open-access FAERS database, which does not contain any identifiable health information. We adhered to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist in preparing our report[9]. **(Supplementary material table 1)**

Results

There were 27 duplicates reports of cholecystitis, 14 of cholelithiasis, 1 each of bile duct stone and biliary colic and 0 of cholangitis removed from the analysis. **(Table 2)**

We analyzed a total of 3,460 de-duplicated adverse event reports across 5 biliary conditions for five GLP-1RA drugs. Of these, semaglutide accounted for 1797 reports, tirzepatide 1363, liraglutide 1033, exenatide 999 and dulaglutide 574. **(Table 1)** Semaglutide was used as the reference drug.

We stratified the data based on reporter type, route and indication for use. 3219 (93.3%) reports were from manufacturers, 103 (3%) from healthcare providers, 102 (2.9%) from patients and 36 (1%) unknown. There were 3162 (91.4%) reports of injection use, 81(2.3 %) of oral, 20 (0.6%) of mixed and 197(5.7%) unknown. 1448 (41.8%) reports of use for type 2 diabetes, 835 (24.1%) for obesity, 122 (3.5%) for both and 1055 (30.5%) unknown.

Data was also stratified based on age and sex, the most common age group for GLP-1RA ADR reports was 45-64 years (1153 reports, 33.3%) followed by 18-44 years (653 reports, 18.9%). Females had a higher number of ADR reports as compared to males (2094, [60.5%]vs 1129 [32.6%] reports).

For **bile duct stone,** exenatide (PRR 0.39 (0.23–0.65), ROR 0.37 (0.22–0.63), $p<0.001$) and tirzepatide (PRR 0.58 (0.39–0.84), ROR 0.56 (0.37–0.83), $p= 0.004$) showed significantly lower reporting compared to semaglutide. Dulaglutide (PRR 0.81 (0.49–1.34), ROR 0.80 (0.47–1.37), $p=0.518$) and liraglutide (PRR 0.75 (0.51–1.10), ROR 0.73 (0.48–1.10), $p=0.136$) showed no significant differences.

For **biliary colic**, dulaglutide (PRR 0.50 (0.30–0.82), ROR 0.46 (0.27–0.79), $p=0.003$) and exenatide (PRR 0.30 (0.19–0.47), ROR 0.27 (0.17–0.44), $p<0.001$) demonstrated significantly lower relative reporting compared to semaglutide. Tirzepatide (PRR 0.89 (0.69–1.15), ROR 0.88 (0.66–1.17), $p=0.383$) and Liraglutide (PRR 0.87 (0.65–1.16), ROR 0.85 (0.62–1.18), $p=0.376$) showed no significant differences.

For **cholangitis,** dulaglutide (PRR 1.65 (1.05–2.60), ROR 1.71 (1.04–2.81), $p=0.045$) showed significantly higher reporting relative to semaglutide. Tirzepatide (PRR 1.24 (0.87–1.78), ROR 1.26 (0.86–1.84),

p=0.240), Liraglutide (PRR 0.82 (0.52–1.29), ROR 0.81 (0.51–1.30), p=0.416) and Exenatide (PRR 0.99 (0.65–1.52), ROR 0.99 (0.63–1.56), p=1.000) showed no significant differences.

For **cholecystitis**, exenatide (PRR 1.12 (1.08–1.16), ROR 2.39 (1.71–3.33), p<0.001), liraglutide (PRR 1.07 (1.03–1.12), ROR 1.60 (1.20–2.14), p<0.001), and tirzepatide (PRR 1.05 (1.01–1.09), ROR 1.36 (1.06–1.74), p=0.018) all demonstrated significantly higher PRRs compared to semaglutide. Dulaglutide (PRR 1.01 (0.95–1.07), ROR 1.06 [0.75–1.51], p=0.792) showed no significant differences.

For **cholelithiasis**, exenatide (PRR 1.33 (1.23–1.44), ROR 2.12 (1.71–2.63), p<0.001), liraglutide (PRR 1.21 (1.11–1.31), ROR 1.58 (1.28–1.94), p<0.001) and tirzepatide (PRR 1.15 (1.06–1.25), ROR 1.39 (1.15–1.67), p<0.001) demonstrated significantly higher reporting relative to semaglutide. Dulaglutide (PRR 1.03 (0.91–1.16), ROR 1.06 (0.81–1.38), p=0.684) showed no significant differences.

(Table 3)

In the subgroup sex-stratified analysis, for cholelithiasis and cholecystitis, ADR reporting was consistent across age and sex groups. However, for bile duct stone, exenatide and liraglutide demonstrated significant heterogeneity by sex with lower reporting in males (p=0.014 and p=0.031, respectively). **(Table 4) (supplementary material table 2)**

In the age-stratified analysis, exenatide and liraglutide demonstrated heterogeneity for bile duct stone with significantly lower reporting in individuals ≥65 years (p=0.049 and p=0.027, respectively). Exenatide also demonstrated heterogeneity in biliary colic reporting with lower reporting in <65 age group (p=0.005). **(Table 5) (supplementary material table 2)**

In the indication for use stratified analysis (Type 2 diabetes vs obesity vs both), most strata did not demonstrate heterogeneity (p>0.05), however, for cholelithiasis, tirzepatide showed higher reporting for obesity as compared to semaglutide (p=0.05**) (supplementary material table 2)**

We performed sensitivity analysis, by excluding reports with unknown indication for use and restricting to U.S. reports geographically. There was largely no change in the signals of outcomes. However, certain signals particularly for rarer outcomes (e.g., bile duct stone and cholangitis) lost statistical significance likely due to reduced power. **(supplementary material table 3)**

Discussion

In our FAERS-based disproportionality analysis, we observed that biliary adverse events are not consistent across all individual GLP-1RAs. Specifically, dulaglutide and exenatide had lower relative reporting of biliary colic and bile duct stone; exenatide, liraglutide, and tirzepatide had higher relative reporting of cholecystitis. Similarly, dulaglutide demonstrated higher relative reporting of cholangitis, and exenatide, liraglutide and tirzepatide showed higher relative reporting of cholelithiasis. These results

align with recent studies showing similar variability across individual GLP-1RAs rather than the same pattern across all agents[4,7,10].

Several biologically plausible mechanisms have been proposed to explain the association between GLP-1RAs and biliary AEs. These mechanisms primarily focus on the effects of GLP-1 signaling on gallbladder physiology. GLP-1RAs reduce cholecystokinin (CCK) secretion, leading to decreased gallbladder emptying, impaired motility, and prolonged bile stasis. These physiological changes increase the risk for gallstone formation and biliary inflammation[7,11]. A systematic review and meta-analysis evaluating GLP-1RA-associated biliary complications reported that the risk of adverse events increases with higher doses and longer duration of therapy[2]. Another contributing factor is weight loss induced by GLP-1RAs, as rapid weight reduction is an established risk factor for gallstone disease due to increased bile cholesterol supersaturation and gallbladder hypomotility[2,4,12].

Our analysis demonstrated a strong signal for semaglutide and biliary colic/bile duct stone. This parallels with the findings seen in multiple systematic reviews and pharmacovigilance analyses showing a similar association[13–15]. Cholecystitis and cholelithiasis had higher relative reporting with tirzepatide, exenatide and liraglutide. This is consistent with prior clinical trials[16]. This is also supported by findings of Gameil et al which also showed a higher clinically significant risk with liraglutide compared to semaglutide and dulaglutide[7] and a randomized controlled trial by Lundgren et al., which showed a higher incidence of cholelithiasis with liraglutide compared to placebo[17].

The higher cholangitis signal observed for dulaglutide (vs semaglutide) should be interpreted cautiously. Cholangitis typically occurs in the setting of biliary obstruction and may be influenced by factors not well captured in FAERS (previous ERCP, anatomic abnormalities, malignancy).

For tirzepatide, systematic reviews and meta-analyses of RCTs have reported increased risk of gallbladder and biliary outcomes including cholelithiasis supporting biologic plausibility for a post-marketing signal[5,18]. Although tirzepatide is slightly different from traditional GLP-1RAs due to its dual GIP and GLP-1 receptor agonism, current evidence does not suggest that this alters the risk of biliary events significantly compared to other GLP-1RAs. Multiple systematic reviews and meta-analyses have shown that the magnitude and pattern of biliary complications observed with tirzepatide fall within the range that is reported for GLP1-RAs[18,19]. This supports the interpretation that tirzepatide-associated biliary events are part of a broader incretin class effect instead of its dual GIP/GLP-1 receptor agonism. Our findings, which show comparable relative reporting patterns between tirzepatide and long-acting GLP-1RAs, are also consistent with this interpretation.

While FAERS remains an important post-marketing surveillance dataset, it is important to highlight that our study had a few limitations. Firstly, the FAERS database is a voluntary reporting database that can be subject to underreporting or incomplete reports. Secondly, the database does not include patient factors (co-morbidities, BMI, concurrent medication use or lab abnormalities) that could potentially lead to confounding. However, our within-class comparator approach (drug vs the remainder of the GLP-1RA

class) aided to partially reduce confounding within the class level, while still allowing detection of drug-specific patterns. Thirdly, the database lacks crucial information on drug dosage, frequency and duration. Lastly, disproportionality reporting, including PRR and ROR is best suited for signal detection rather than measurement of incidence of adverse events[20,21].

Despite these, there is consistency noted between our findings and previous trials and studies, which strengthens the credibility of the patterns observed in our study. Our results suggest that biliary AE risks should not be generalized across GLP-1RAs and should be evaluated on an agent-specific basis.

In this comprehensive FAERS-based analysis, we observed notable variability in biliary AE reporting across individual GLP-1 receptor agonists. While semaglutide showed higher relative reporting for some biliary outcomes, dulaglutide, exenatide, liraglutide and tirzepatide demonstrated contrasting findings, therefore identifying that biliary AEs are not uniform among all agents. Findings vary based on multiple factors including individual pharmacologic profiles, treatment duration and dose intensity. As the use of GLP-1RAs increases for diabetes, obesity and cardiovascular problems, understanding these differences is important. Further prospective and comparative studies are warranted to clarify these mechanisms and determine how they make meaningful differences in patient care.

Declarations

Author Contributions (per ICMJE criteria): Alvina, Huda Jaffar, Chidera N Onwuzo, and Abdelkader Chaarcontributed to the conception and drafting of the manuscript and preparation of the tables and figures with the data. Mohamed Eisa provided critical revisions and supervision. All authors meet ICMJE authorship criteria and approve the final manuscript.

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Tables

Tables 1 to 5 are available in the supplementary files section

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