

BRIEF REPORT OPEN ACCESS

Real-World Evidence on Short-Term Weight Changes Following Methylphenidate Use in Pediatric Population: A Retrospective Study Using Common Data Model

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ABSTRACT

In July 2025, the Food and Drug Administration (FDA) warned of significant weight loss among young children receiving stimulants for attention-deficit hyperactivity disorder. However, real-world evidence on the magnitude and prevalence of stimulant-associated weight loss remains limited. This study evaluated short-term weight changes after methylphenidate initiation among youth aged 3–18years using the Medical record Observation and Assessment of drug safety Common Data Model (MOA CDM) in Korea. We

Haeyoung Lee and Eun-Gee Park have contributed equally to this work.

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conducted a retrospective study using electronic health record-based MOA CDM data from January 2008 to December 2024. The cohort included individuals aged 3–18 years with at least one methylphenidate prescription and had available weight measurements. The index date was defined as the first prescription date. Individuals without weight data within 45 days before or 90 days after the index date were excluded. Outcomes included changes in body weight (kg) and weight percentile, and the proportion having a ≥ 10 -percentile decline. Weight percentiles were calculated using the 2017 Korean National Growth Charts for Children and Adolescents. A total of 2087 youths from 17 nationwide hospitals were included; 68.71% were male, and 58.12% were aged 6–10 years. Within 3 months, mean body weight decreased by -0.33 kg (95% confidence interval [CI], -0.44 to -0.22) and mean weight percentile decreased by -2.49 percentiles (95% CI, -2.83 to -2.15). Overall, 21.57% had a ≥ 10 percentile decline, with larger reductions among pre-school-aged children (28.57%). Our findings underscore the importance of growth monitoring during treatment initiation.

1 | Introduction

Attention-deficit hyperactivity disorder (ADHD) medication use among children and adolescents has been increasing for the last decade [1, 2] as the diagnosis of ADHD has become more frequent [1, 3]. Methylphenidate, among ADHD medications, is the most commonly prescribed stimulant for the treatment of ADHD [1, 4]. In a systematic review and network meta-analysis of 133 randomized controlled trials, methylphenidate demonstrated clinical efficacy in improving core ADHD symptoms, including hyperactivity and impulsivity, compared with placebo in pediatric populations [4, 5]. However, methylphenidate may cause weight-related adverse effects, including appetite suppression and subsequent weight loss [6].

Weight-associated adverse events following methylphenidate use among the pediatric population have raised a clinical concern [7] due to their potential impact on growth [8]. Previous studies evaluating weight changes associated with methylphenidate in pediatric populations [7–10] largely relied on a single hospital or small-scale observational studies. In July 2025, the U.S. Food and Drug Administration (FDA) announced a Drug Safety Communication regarding the risk of significant weight loss associated with extended-release stimulant medications, including methylphenidate, in children younger than 6 years old [11, 12]. Based on data from clinical trials, the FDA reported that younger children may have higher systemic drug exposure at equivalent doses compared with other age groups and may be more susceptible to adverse events [11, 12]. However, evidence on the prevalence and magnitude of weight loss with larger populations in clinical settings remains limited.

Given the frequent use of methylphenidate [4, 13] and concerns about treatment-related weight loss during growth [4, 8], large-scale investigations using real-world data (RWD) are needed to quantify weight changes after methylphenidate use among the pediatric population. The objective of this study is to analyze short-term weight changes following methylphenidate use in Korean children and adolescents using Medical record Observation and Assessment for drug safety Common Data Model (MOA CDM).

2 | Methods

2.1 | Data Source and Study Design

We conducted a retrospective cohort study using the MOA CDM database from 2008 to 2024. The MOA CDM is a standardized,

distributed data network derived from de-identified electronic health records (EHRs) of university hospitals (i.e., MOA CDM data partners) [14, 15]. The MOA CDM is composed of both Observational Medical Outcomes Partnership (OMOP) CDM and Sentinel CDM [16]. The Korea Institute of Drug Safety & Risk Management (KIDS), a national organization affiliated with the Korea Ministry of Food and Drug Safety, has coordinate the CDM database since 2018 [14, 15]. In December 2025, the MOA CDM comprised 33 data partners with data on over 47 million individuals nationwide [16]. For this study, we specifically collaborated with 17 MOA CDM data partners. We used data on date of birth, sex, date of prescription, medication use, and body weight measurement (e.g., kg). All individuals who met the pre-defined eligibility criteria were identified and analyzed at each participating institution using the local MOA CDM database. Ethics approval was waived by the Institutional Review Board (IRB) of the KIDS in view of the retrospective nature of the study (IRB number 2025–4). We followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations.

2.2 | Study Cohort

The study cohort included children and adolescents aged 3 to 18 years who received methylphenidate between January 1, 2008 to December 31, 2024. The first date of methylphenidate prescription was defined as the index date. Exclusion criteria contained [1] index date before January 1, 2009, or after September 30, 2024; [2] age younger than 3 years or older than 18 years at the index date; [3] missing information on age or sex; and [4] missing information on body weight measurement during either the pre-index period (-45 to 0 days) or the post-index period ($+1$ to $+90$ days).

2.3 | Exposure and Outcomes Definition

Methylphenidate exposure was identified using the RxNorm and RxNorm Extension vocabularies [17], including the concept “methylphenidate” and its descendant codes. All formulations (i.e., immediate-release, sustained-release, and extended-release) of methylphenidate were included in the analysis.

The outcomes of interest were [1] absolute changes in body weight, [2] changes in weight for age percentile, and [3] the proportion of individuals with a weight trajectory decrease of at

Study Highlights

- What is the current knowledge on the topic?
 - Methylphenidate is associated with weight loss in children, especially in those <6 years of age, which has moved the U.S. Food and Drug Administration to issue a warning about significant weight loss among young children receiving stimulants for attention-deficit hyperactivity disorder (ADHD).
- What question did this study address?
 - This retrospective study in a population of Korean children and adolescents investigated the prevalence and magnitude of short-term weight loss associated with methylphenidate use in the pediatric population using real-world data.
- What does this study add to our knowledge?
 - We have confirmed the extent of weight loss associated to methylphenidate use in a retrospective study of Korean children and adolescents. Our findings indicate that 21.57% of youths aged 3 to 18 experienced a 10-percentile-point weight trajectory change (i.e., ≥ 10 percentile weight loss) within three months of methylphenidate initiation.
- How might this change clinical pharmacology or translational science?
 - Our findings extend existing safety observations by providing real-world evidence on the magnitude of weight trajectory changes after methylphenidate initiation, particularly among younger children, and may help inform age-specific monitoring in routine clinical practice.

least 10 percentile points. The 10 percentile-point threshold was selected based on the recent FDA safety communication defining a decrease of at least 10 percentiles as clinically significant weight loss [11, 12]. When multiple weight measurements were captured within each period, we selected the value closest to the index date for the pre-index period and the lowest value for the post-index period to assess the maximum observed short-term weight reduction. Weight-for-age percentiles were calculated for each individual by sex and age (months) using the 2017 Korean National Growth Charts for Children and Adolescents [18, 19]. The calculation formula is provided in Appendix S1. To evaluate a 10 percentile-point weight trajectory change, individuals with a baseline weight percentile below the 10th percentile were excluded, as a ≥ 10 -percentile decline could not be observable in this group.

2.4 | Statistical Analysis

Baseline demographic characteristics, including age, sex, and index year, were summarized. Changes in body weight were assessed by calculating absolute weight change (kg) between the pre-index and post-index periods. Pre- and post-index body weight measurements were compared stratified by sex

and 1-year age groups. For weight-for-age percentile analyses, pre-index weight percentiles, post-index weight, and changes in weight percentiles were calculated. Comparisons of weight percentiles before and after the index date were conducted by sex and 1-year age groups. The number and proportion (%) of individuals experiencing a 10 percentile-point weight trajectory change were calculated. We performed a meta-analysis of mean differences in body weight between pre- and post-treatment periods across centers. Statistical significance of the pooled estimate was assessed using a Wald test, with a two-sided 95% confidence interval (CI). A pooled estimate whose CI did not include zero was considered statistically significant. A leave-one-out meta-analysis was conducted to assess the robustness of the results.

All statistical analyses were performed independently using R by 17 MOA CDM data partners [20]. The analyses were conducted using the following R packages: 'DBI', 'odbc', 'SqlRender', 'DatabaseConnector', 'dplyr', 'psych', 'reshape2', 'lubridate', 'tidyr', and 'purrr'. Meta-analyses were performed using 'meta'.

3 | Results

3.1 | Characteristics of Analytic Cohort

From 17 MOA CDM data partners, 70,666 individuals receiving methylphenidate during the study period were identified. After excluding individuals who did not meet the pre-defined age range and whose demographic information or body weight measurements were missing, 2087 children and adolescents were included in the final cohort (Figure 1). One reason for exclusions was due to missing valid body weight measurement data during both pre-index and post-index periods ($n = 9344$).

Demographic characteristics of the cohort are described in Table S1. Among 2087 children and adolescents, 1434 (68.71%) were boys, and 653 (31.29%) were girls. The cohort consisted mostly of school-aged children (6–11 years, 58.12%), followed by adolescents aged 12–18 years (40.06%), whereas preschool-aged children (<6 years) accounted for approximately 1.82% of the cohort. The number of new methylphenidate users remained relatively stable from 2009 through 2020, followed by an increase from 2021 to 2023.

3.2 | Weight Changes, Percentiles, and 10-Percentile-Point Trajectory Changes

Mean body weight decreased from 42.09 kg during the pre-index period to 40.57 kg during the post-index period. The mean change in body weight was -0.33 kg (95% CI, -0.44 to -0.22). In sex-stratified analyses, mean body weight decreased by -0.42 kg (95% CI, -0.57 to -0.27) among boys and by -0.48 kg (95% CI, -0.65 to -0.31) among girls. In age-stratified analyses, the largest mean decreases were observed at ages 17 years (-1.60 kg; 95% CI, -2.13 to -1.08) and 18 years (-1.49 kg; 95% CI, -2.00 to -0.98) (Table S2).

Mean weight percentile decreased from 54.47 during the pre-index period to 48.71 during the post-index period (a mean decrease of -2.49 percentile points; 95% CI -2.83 to -2.15). Weight

reductions were observed in both boys (−3.06 percentile points; 95% CI, −3.54 to −2.59) and girls (−2.22 percentile points; 95% CI, −2.74 to −1.71) (Table S3).

Of 2087 individuals in the final cohort, 1785 with a baseline weight percentile >10 were eligible for analysis (Figure 1). Among them, 385 (21.57%) had at least a 10-weight-percentile reduction. The proportion was similar between boys (21.43%) and girls (20.99%). In age-stratified analyses, among children aged four to eight years, the overall proportion was highest at age four (40.00%) and declined to 27.54% by age eight (Figure 2). The leave-one-out sensitivity analysis identified one influential observation. However, the direction and statistical significance of the association remained unchanged (Appendix S2).

4 | Discussion

Our study, leveraging RWD from 17 hospitals in Korea, assessed short-term weight changes following initial methylphenidate treatment in children and adolescents. The results showed overall reductions in body weight and weight percentile, with 21.57% of children and adolescents having a 10-weight-percentile reduction. These patterns were generally consistent across sex and age groups, but were more pronounced among younger children.

Our findings provide real-world evidence (RWE) that extends prior studies and the recent FDA safety communication. The FDA, based on clinical trial data, reported a 10 percentile-point weight trajectory change in preschool-aged children receiving methylphenidate [11, 12]. Consistent with this announcement,

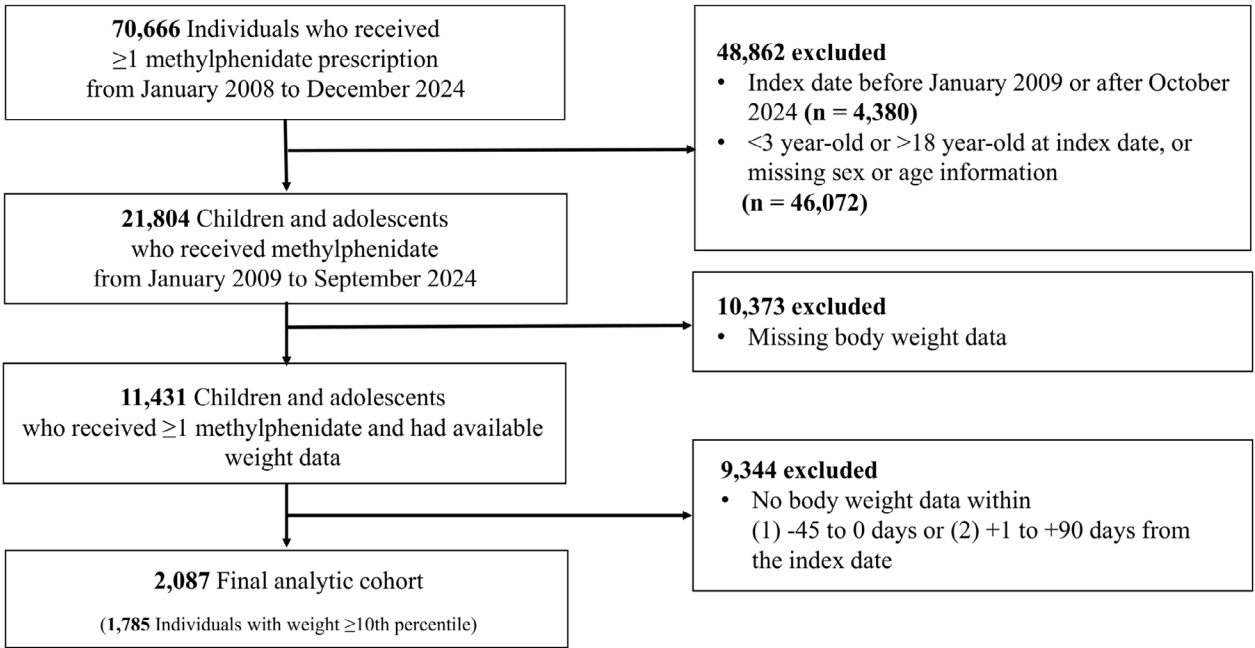


FIGURE 1 | Flow diagram for study cohort selection.

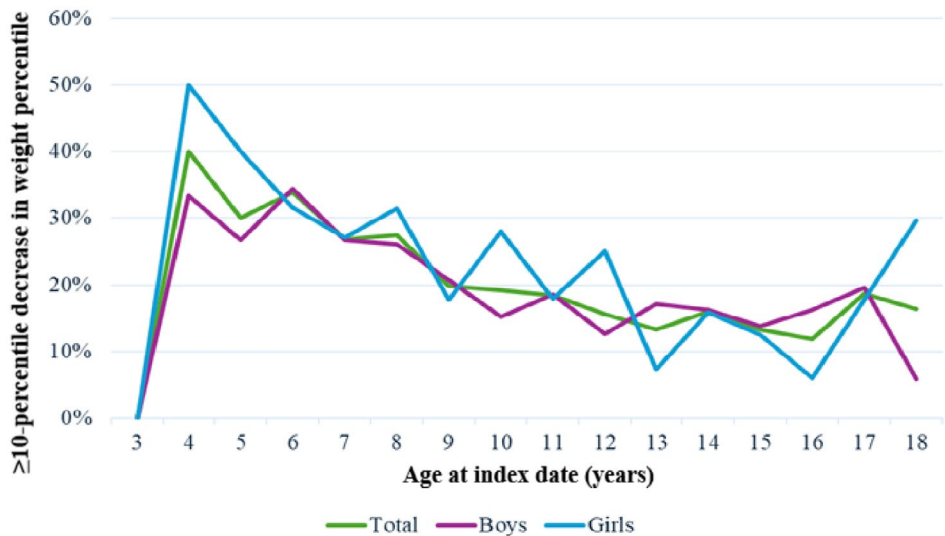


FIGURE 2 | Proportion of children and adolescents with a ≥10-percentile decrease in weight percentile.

we observed more pronounced weight loss among pre-school children compared to other age pediatric groups. In pre-school children, methylphenidate is prescribed off-label [21], and they may be more susceptible to adverse events than older children [21]. However, the small sample size of the pre-school children in our study may limit the generalizability of this finding. Nevertheless, our findings align with previous studies [7–10] demonstrating methylphenidate-related weight loss in pediatric population while offering two key extensions: [1] quantification of weight loss magnitude across a broader age range in areal-world clinical setting and [2] analysis of a large, multicenter cohort that reflects populations beyond those captured in clinical trials.

Our study suggests the importance of surveillance for weight changes in pediatric populations receiving methylphenidate. Appetite suppression and reduced energy intake mediated by dopaminergic pathways may result in methylphenidate-associated weight loss [22]. Prior studies suggest that these effects may be more pronounced in girls [22], indicating that girls may warrant closer monitoring. Ongoing monitoring of nutritional status and body weight is warranted in children and adolescents receiving methylphenidate, particularly during the early phase of treatment.

We observed that 302 individuals in the cohort had a baseline weight below the 10th percentile before initiating methylphenidate treatment. This finding suggests that a subset of pediatric patients may already be vulnerable to weight changes prior to treatment initiation, and even small additional weight reductions in this population may warrant careful clinical monitoring.

A large sample size is the strength of this study. Including more than 2000 children and adolescents from 17 CDM data partners enhanced the generalizability of the findings to clinical practice in Korea. However, some limitations need to be considered. First, a substantial number of individuals were excluded because of missing weight measurements. This missingness was likely driven by EHR data entry practices rather than patient characteristics. Therefore, the missingness was considered to be missing completely at random [23] and was unlikely to introduce bias into the estimates. Second, this study focused on short-term weight changes following methylphenidate initiation and therefore cannot inform long-term weight trajectories. Further studies are needed to evaluate long-term weight trajectories. Third, weight was the sole growth-related outcome investigated; future studies should incorporate other measures, such as height and body mass index, to enable a more comprehensive assessment of growth outcomes. Fourth, because the CDM database integrates EHR data from multiple data partners, data for 2024 may be incomplete for some institutions due to ongoing data collection. Accordingly, the observed decrease in methylphenidate use in 2024 should be interpreted with caution. Fifth, our study did not adjust for potential factors associated with weight change, and future studies may need to address this. Sixth, although pubertal development factors, such as onset of growth spurts and age at menarche, may influence weight changes and ADHD medication use, these data were unavailable in our database and could not be assessed. Seventh, potential differences in weight changes across methylphenidate formulations were not evaluated separately.

In conclusion, our findings indicate that children and adolescents initiating methylphenidate had reductions in both absolute weight and weight percentile. These findings underscore the importance of early weight monitoring after treatment initiation.

Author Contributions

H.L., E.-G.P., H.-J.Y., Y.-G.S., B.K., and S.J.S. wrote the manuscript; H.L., E.-G.P., B.K., and S.J.S. designed the research; H.L. and E.-G.P. performed the research; D.Y.K., C.K., D.W.S., J.S., S.-H.K., D.C., K.K., J.L., Y.K., K.L., H.-K.P., H.J.J., I.Y.C., T.J.A., M.H.M., C.J., S.I., S.W.K., J.Y.L., Y.W.C., Y.-Y.K., and S.J.S. analyzed the data.

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The authors have nothing to report.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The MOA CDM database is available from KIDS and MOA CDM data partners on reasonable request.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Table S1:** Characteristics of the study cohort. **Table S2:** Short-term weight changes (kg) following methylphenidate initiation among youth. **Table S3:** Short-term weight percentile changes following methylphenidate initiation among youth. **Appendix S1:** Calculation of percentiles using the formula (Reference: Korea Centers for Disease Control and Prevention. 2017 *Korean National Growth Charts for Children and Adolescents: User Guideline*. 2017). **Appendix S2:** Leave-one-out meta-analysis for sensitivity analysis of weight change (kg and percentile).