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Utilization Patterns of Total Serum Bile Acid Testing in a Nationwide Referral Laboratory in Korea

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Abstract

Background/Objectives: Total serum bile acid (TSBA) testing supports evaluation and monitoring of cholestatic disorders. However, its real-world utilization and result distributions remain poorly characterized in Korea. We therefore assessed nationwide patterns using retrospective referral laboratory data. **Methods**: We retrospectively analyzed serum TSBA test results from specimens referred nationwide to a large referral clinical laboratory in Korea between 16 June 2025, and 30 May 2026. Initial TSBA concentrations were categorized as <10, 10–<40, 40–<100, and ≥100 μmol/L. Test utilization, follow-up patterns, pediatric and obstetric subgroups, and factors associated with elevated initial TSBA concentrations were evaluated. National utilization trends were assessed using Health Insurance Review and Assessment Service (HIRA) claims data. **Results**: During the approximately 1-year study period, 13,072 TSBA records from 11,543 subjects were included. Initial TSBA concentrations were <10 μmol/L in 81.0%, 10–<40 μmol/L in 14.3%, 40–<100 μmol/L in 2.7%, and ≥100 μmol/L in 2.1%. Follow-up testing was performed in 9.8%. Among children aged < 10 years, 22.4% had initial TSBA concentrations ≥ 100 μmol/L. In the obstetric hospital female subgroup, 94.7% had initial TSBA concentrations < 10 μmol/L. Test orders from infants and those originating from university hospitals were associated with higher odds of elevated initial TSBA concentrations across all predefined cutoffs. HIRA claims data showed increasing national utilization, including among pediatric populations and women aged 20–49 years. **Conclusions**: This study describes TSBA testing utilization patterns and result distributions across different referral settings using data from a large nationwide referral laboratory in Korea.

Keywords: test utilization; total bile acid; cholestasis; maternal and child health; Korea

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1. Introduction

Total serum bile acids (TSBA) are sensitive biochemical markers of impaired bile acid homeostasis and cholestasis and are increasingly used for the diagnosis, risk stratification, and therapeutic monitoring of hepatobiliary disorders [1,2]. TSBA measurement has long been incorporated into clinical practice for the evaluation of intrahepatic cholestasis of pregnancy (ICP), in which elevated bile acid concentrations are associated with adverse fetal outcomes [3–8]. Accordingly, several international guidelines recommend TSBA as a primary biochemical test for the diagnosis of ICP and for risk stratification using clinically

relevant thresholds, including ≥10 or ≥19 μmol/L for diagnosis and ≥40 and ≥100 μmol/L for predicting fetal complications and guiding obstetric management [3–8].

Beyond pregnancy-associated cholestasis, TSBA measurement has gained increasing clinical importance in pediatric cholestatic liver diseases [9–13]. Recent international guidelines recommend TSBA assessment in disorders such as progressive familial intrahepatic cholestasis (PFIC), Alagille syndrome (ALGS), biliary atresia, and other inherited cholestatic disorders, in which serum bile acid concentrations reflect disease severity and treatment response [9–13]. The recent approval of ileal bile acid transporter (IBAT) inhibitors, including odevixibat and maralixibat, by the U.S. Food and Drug Administration (FDA) has further expanded the clinical role of TSBA testing [9–16]. In patients receiving these targeted therapies, reductions in TSBA concentrations are regarded as important pharmacodynamic biomarkers and are incorporated into clinical trials and therapeutic response assessments together with improvements in pruritus and liver biochemistry [9–17].

Meanwhile, in Korea, according to Ministry of Health and Welfare Notification No. 2025-169, reimbursement for oral odevixibat, an IBAT inhibitor, is approved for patients aged 3 months or older who have been diagnosed with PFIC and meet both of the following criteria: a serum bile acid concentration of ≥100 μmol/L and a Clinical Global Impression of Severity (CGIS) score of ≥2 [9–11,17]. Continuation of reimbursement is permitted when the TSBA concentration has decreased by ≥30% from baseline at the 6-month assessment after treatment initiation [17]. Even if the TSBA concentration has not decreased by ≥30% from baseline, reimbursement may still be continued if pruritus has improved, defined as a mean monthly CGIS score of ≤1 or a decrease of ≥1 point from baseline [17]. Documentation of TSBA test results is mandatory for reimbursement approval [17].

Characterizing test utilization patterns helps clinical laboratories understand how tests are used in practice and provides baseline information for quality improvement and future assessment of appropriate test use [18–20]. Test utilization patterns refer to the observable characteristics of how TSBA testing is used in routine clinical practice, including test-ordering frequency, patient demographics, requesting institution type, initial and repeated testing, and the distribution of reported results [18–20]. Characterizing these patterns is relevant to laboratory medicine because it provides baseline information on how a test is incorporated into clinical practice and may support subsequent evaluation of testing practices, quality improvement, and appropriateness [18–20]. Despite the expanding clinical indications and growing therapeutic relevance of TSBA measurement, information regarding the real-world utilization of TSBA testing remains limited. In particular, little is known about utilization patterns of TSBA testing in Korea, including the clinical departments requesting the test, patient demographics, and the distribution of measured TSBA concentrations. Furthermore, although multiple guideline-recommended TSBA thresholds are used in clinical decision-making, the prevalence of specimens exceeding these clinically relevant cutoffs has not been systematically investigated in routine laboratory practice in Korea.

Therefore, the present study aimed to characterize the real-world utilization patterns and result distribution of TSBA testing in Korea using a large retrospective referral laboratory dataset. The primary research question was: How is TSBA testing utilized in routine clinical practice in Korea, and how are the resulting concentrations distributed across patient and referral settings? In addition, we evaluated the prevalence of specimens meeting guideline-recommended TSBA cutoffs to provide practical information for clinical laboratories regarding result interpretation, expected positivity rates, and the potential clinical relevance of TSBA testing in routine practice. Since Korea operates a nationwide single-payer National Health Insurance system, and claims data from the Health Insurance Review and Assessment Service (HIRA) provide information regarding the overall national

volume of reimbursed TSBA testing [21]. Therefore, we compared the number of tests in our dataset with the national claims volume to help readers understand the approximate contribution and representativeness of our data relative to TSBA testing performed in Korea. This comparison was not intended to imply that health insurance policy itself was an outcome or objective of the study.

2. Materials and Methods

2.1. Study Design

This retrospective observational study analyzed TSBA test results generated at a clinical laboratory over a 1-year period, from 16 June 2025, to 30 May 2026. GC Labs is a large referral clinical laboratory that provides TSBA testing services to local clinics, general hospitals, pediatric hospitals, obstetric hospitals, university hospitals, military hospitals, public health centers, and other clinical laboratories nationwide [19,20]. GC Labs is a nationwide referral clinical laboratory that receives specimens from approximately 5000 healthcare institutions, offers approximately 5000 test items, and performs approximately 100 million laboratory tests annually [22].

2.2. Data Source and Study Population

The inclusion criteria were all routine clinical TSBA test results from patient specimens referred nationwide to GC Labs during the study period, including both initial and repeated measurements. The exclusion criteria were non-clinical tests, including those performed for quality control, research, method evaluation, or other purposes identified by separate order codes. Test records lacking information on age or sex were excluded. In addition, duplicate test results generated on the same day for the same subject were excluded when no additional specimen-related information was available to determine whether the results represented distinct specimens, as such duplication could potentially compromise data reliability.

2.3. Laboratory Measurements

TSBA concentrations were measured using the Total Bile Acids 5th Generation enzymatic colorimetric assay (Randox Laboratories, Crumlin, UK), in accordance with the manufacturer's instructions [23]. Measurements were performed on a DxC 700 AU analyzer (Beckman Coulter, Brea, CA, USA) from 16 June 2025, to 24 October 2025, and on a cobas c702 analyzer (Roche Diagnostics, Mannheim, Germany) from 25 October 2025, to 30 May 2026 [23–25]. Because the same reagent was used on two different analyzers during the study period, comparability between the DxC 700 AU and cobas 8000 c702 analyzers was verified using 47 residual clinical serum specimens [26]. Method comparison showed excellent agreement, with a correlation coefficient (R) of 0.9999, a slope of 0.962 (95% CI, 0.957–0.966), and an intercept of 0.36 μmol/L (95% CI, 0.10–0.63). The Passing–Bablok regression equation was c702 analyzer = 0.077 + 0.967 × DxC 700 AU analyzer, corresponding to estimated biases of −0.25 μmol/L (−2.5%), −1.24 μmol/L (−3.1%), and −3.21 μmol/L (−3.2%) at 10, 40, and 100 μmol/L, respectively. The mean difference was −1.07 μmol/L (−2.85%), indicating lower concentrations on the cobas 8000 c702 analyzer than on the DxC 700 AU analyzer. This difference was within the total allowable error criterion of 4 μmol/L or 10%, proposed as a professional opinion by the Royal College of Pathologists of Australasia Quality Assurance Programs [25–27].

2.4. Definition and Analytical Variables

TSBA concentrations were categorized into four clinically relevant groups: <10 μmol/L, 10–<40 μmol/L, 40–<100 μmol/L, and ≥100 μmol/L, which are presented in international clinical guidelines [3–11]. Elevated initial TSBA concentrations were additionally evaluated

using three binary cutoffs: ≥10 μmol/L, ≥40 μmol/L, and ≥100 μmol/L [3–11]. These thresholds were selected because they correspond to clinically relevant concentrations reported in guidelines for ICP and in the reimbursement criteria for treatment with oral odevixibat, an IBAT inhibitor [3–11,17]. A concentration of approximately 10 μmol/L has historically been used as a threshold for elevated TSBA and as a diagnostic threshold for ICP in some guidance when accompanied by compatible clinical features [3–11]. Concentrations of ≥40 μmol/L are associated with an increased risk of adverse pregnancy outcomes, whereas concentrations of ≥100 μmol/L identify a substantially higher-risk group, particularly with respect to stillbirth [3–11,17]. These cutoffs were used in the present study as clinically relevant concentration thresholds rather than as diagnostic categories for individual patients.

Age at initial testing was grouped as follows: <1, 1–9, 10–19, 20–29, 30–39, 40–49, 50–59, 60–69, and ≥70 years. Infants aged < 1 year were analyzed separately because neonatal and infantile cholestatic liver diseases represent a distinct clinical context in which TSBA testing may be particularly relevant, whereas the remaining age categories were selected to allow interpretable comparisons across childhood and adulthood while maintaining adequate sample sizes [9].

To analyze intraindividual changes in patients who had multiple TSBA measurements during the study period, the first available result was defined as the initial TSBA concentration. Subject-level analyses were performed using one record per subject based on the initial test, whereas follow-up analyses incorporated serial measurements when available. Intraindividual changes were assessed according to whether the change exceeded 30%, in accordance with the Korean reimbursement criteria for treatment with the IBAT inhibitor odevixibat [17].

Two clinically relevant subgroups were evaluated. Female subjects whose tests were requested by obstetric hospitals were evaluated as a potential population relevant to pregnancy-related cholestatic disorders, while pediatric subjects were evaluated as a potential population relevant to pediatric cholestatic liver diseases and IBAT inhibitor therapy [8–17]. Female subjects whose tests were requested by obstetric hospitals were regarded as the obstetric subgroup. The pediatric subgroup included subjects younger than 10 years at initial testing. For pediatric subjects, additional analyses focused on those who had TSBA concentrations ≥ 100 μmol/L at least once during the study period, considering the potential relevance of markedly elevated TSBA concentrations in pediatric cholestatic disorders [17]. For pediatric subjects who had at least one TSBA concentration ≥ 100 μmol/L, the first measurement meeting this threshold was defined as the index measurement. Follow-up change was then calculated from the index measurement to the last available measurement after the index test. A decrease of ≥30% was additionally evaluated [17].

2.5. National Claims Data

To assess the national utilization of TSBA testing in Korea, we additionally reviewed publicly available healthcare claims statistics from the Healthcare Bigdata Hub of the Health Insurance Review and Assessment Service (HIRA) [21]. The Korean Electronic Data Interchange (EDI) code D1900, corresponding to bile acid testing, was used to retrieve annual test utilization data. Because reimbursement claims are adjudicated in the year following the year of service, the most recent complete national claims data available at the time of analysis were those available as of October 2025 [21]. We reviewed annual utilization trends as well as age- and sex-stratified data in 10-year age groups. Because the claims database did not provide information on pregnancy status or exact pediatric age subgroups below 10 years, women aged 20–49 years were used as a proxy group for

women of reproductive age in the analysis of utilization patterns potentially related to obstetric indications.

2.6. Statistical Analysis

Continuous variables were summarized as the mean ± standard deviation or median with interquartile range, as appropriate. Categorical variables were summarized as counts and percentages. The distribution of initial TSBA categories was assessed overall and according to sex, age group, and institution type. Multivariable Firth-penalized logistic regression analyses were performed to identify factors associated with elevated initial TSBA concentrations at each cutoff: ≥10 μmol/L, ≥40 μmol/L, and ≥100 μmol/L. The independent variables included age group, sex, and institution type. The 20–29-year age group, male sex, and general hospital institution type were used as the reference categories. Firth penalized logistic regression was additionally performed to reduce potential estimation bias associated with small subgroup sizes and sparse events. Potential multicollinearity among the independent variables was assessed using generalized variance inflation factors (GVIFs), adjusted for the degrees of freedom of categorical predictors. The primary objective of this study was descriptive rather than analytical, as the lack of detailed clinical information limited further investigation and interpretation of potential interactions among age, sex, and referral settings in relation to TSBA testing patterns. Adjusted odds ratios (ORs), 95% confidence intervals (CIs), and *p*-values were calculated. All statistical analyses were performed using MedCalc Statistical Software version 23.5.2 (MedCalc Software Ltd., Ostend, Belgium; https://www.medcalc.org; 2026) and R software version 4.5.2 (R Foundation for Statistical Computing, Vienna, Austria). A p-value < 0.05 was considered statistically significant. Generative artificial intelligence was used in part to assist with editing the R code for statistical analysis. The authors reviewed and verified all code, analyses, and outputs and take full responsibility for the content of this manuscript.

3. Results

3.1. Study Population

A total of 13,072 TSBA test records from 11,543 subjects were included in the analysis. All specimens were serum samples (Table 1). The median age at initial testing was 65.8 years (interquartile range [IQR], 48.5–79.5 years), and the mean age was 61.9 ± 22.0 years. The study population included 5625 males (48.7%) and 5918 females (51.3%). Most subjects were referred from general hospitals (10,461 subjects, 90.6%). The median initial TSBA concentration was 4.2 μmol/L (IQR, 2.2–8.0 μmol/L), and the mean initial TSBA concentration was 12.2 ± 37.8 μmol/L. The maximum observed initial TSBA concentration was 674.3 μmol/L. Overall, 9345 subjects (81.0%) had initial TSBA concentrations < 10 μmol/L, 1647 (14.3%) had concentrations of 10–<40 μmol/L, 309 (2.7%) had concentrations of 40–<100 μmol/L, and 242 (2.1%) had concentrations ≥ 100 μmol/L. A total of 1135 subjects (9.8%) underwent follow-up TSBA testing during the study period.

The prevalence of elevated initial TSBA concentrations differed substantially by institution type (Figure 1). Among institution types, pediatric hospitals showed the highest proportions of elevated TSBA concentrations, across all predefined cutoffs of 10, 40, and 100 μmol/L, followed by university hospitals. The corresponding proportions were 50.0% (2/4), 50.0% (2/4), and 50.0% (2/4) in pediatric hospitals and 49.3% (185/375), 28.5% (107/375), and 14.9% (56/375) in university hospitals, respectively.

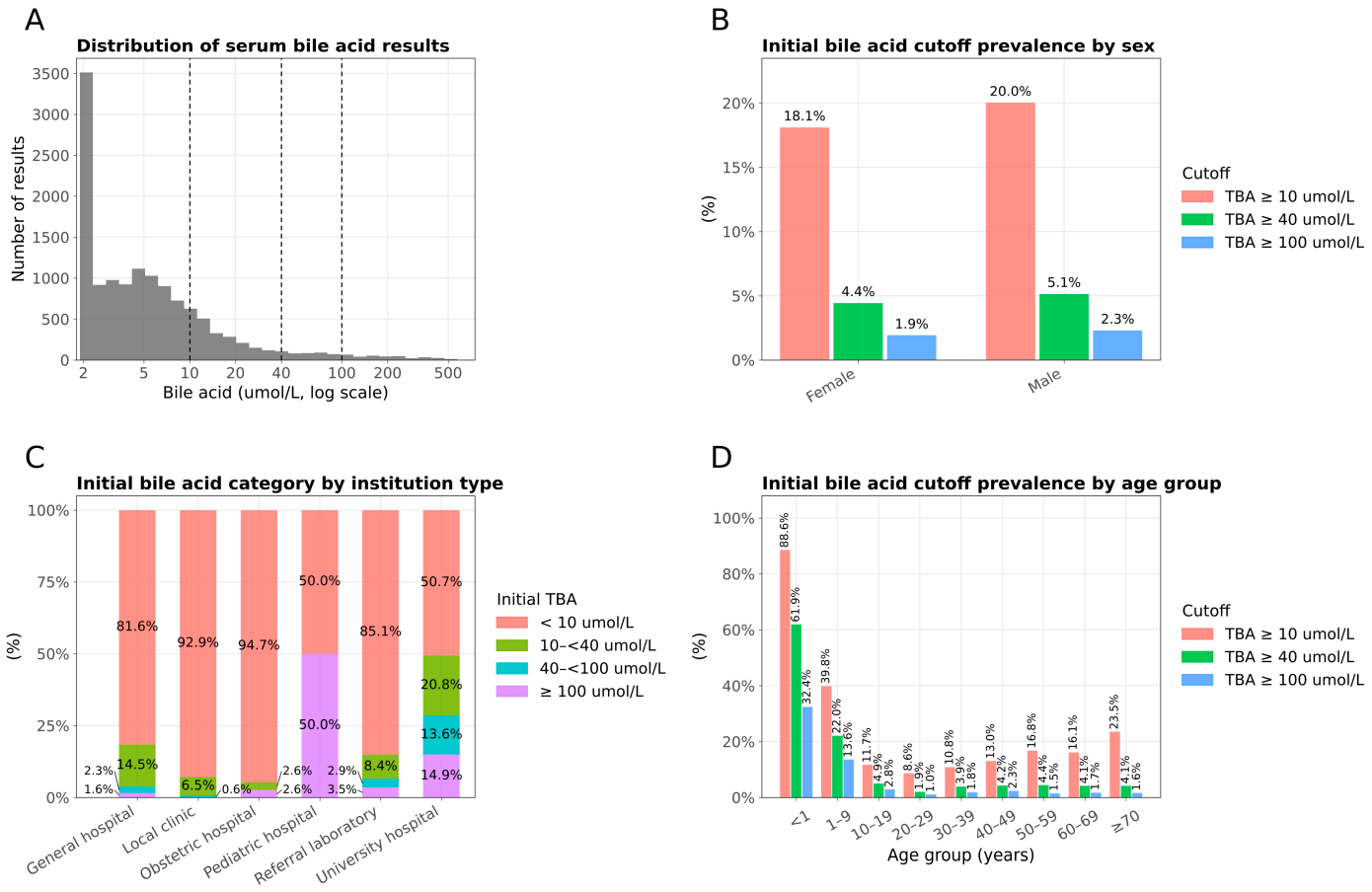


Figure 1. Distribution of total serum bile acid (TSBA) concentrations and prevalence of elevated total bile acid according to predefined cutoffs. (**A**) Distribution of initial TSBA concentrations. (**B**) Prevalence of elevated TSBA using cutoff values of 10, 40, and 100 µmol/L. (**C**) Distribution of initial TSBA concentration categories according to requesting institution type. (**D**) Distribution of initial TSBA concentration categories according to age group. The predefined cutoffs were used to classify subjects into clinically relevant TSBA concentration categories of <10, 10–<40, 40–<100, and ≥100 µmol/L.

Table 1. Baseline characteristics of 11,543 study subjects.

Characteristics	Results
Age, years	65.8 [48.5–79.5]
<1 years	105 (0.9%)
1~9 years	118 (1.0%)
10~19 years	386 (3.3%)
20~29 years	672 (5.8%)
30~39 years	765 (6.6%)
40~49 years	1036 (9.0%)
50~59 years	1556 (13.5%)
60~69 years	2001 (17.3%)
≥70 years	4904 (42.5%)
Sex	
Male	5625 (48.7)
Female	5918 (51.3)

Table 1. *Cont.*

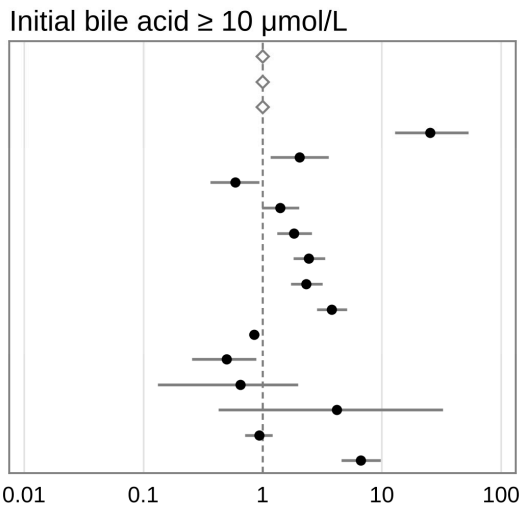
Characteristics	Results
Institution type	
General hospital	10,461 (90.6%)
Referral laboratory	511 (4.4%)
University hospital	375 (3.2%)
Local clinic	154 (1.3%)
Obstetric hospital	38 (0.3%)
Pediatric hospital	4 (0.0%)
Bile acid, μmol/L	4.2 [2.2–8.4]
<10 μmol/L	9345 (81.0%)
10–<40 μmol/L	1647 (14.3%)
40–<100 μmol/L	309 (2.7%)
≥100 μmol/L	242 (2.1%)
Number of measurements	
Once	10,408 (90.2)
Multiple	1135 (9.8)
Age, years	65.8 [48.5–79.5]
<1 years	105 (0.9%)
1~9 years	118 (1.0%)
10~19 years	386 (3.3%)
20~29 years	672 (5.8%)
30~39 years	765 (6.6%)
40~49 years	1036 (9.0%)
50~59 years	1556 (13.5%)
60~69 years	2001 (17.3%)
≥70 years	4904 (42.5%)

Values are presented as *n* (%) for categorical variables and as medians [interquartile ranges] for continuous variables.

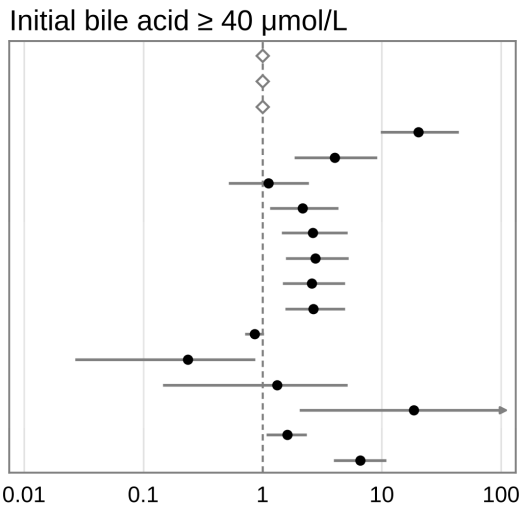
3.2. Multiple Logistic Regression Analysis

In the multivariable Firth penalized logistic regression analysis adjusted for age group, sex, and institution type, younger pediatric age groups showed markedly higher odds of elevated initial TSBA concentrations (Figure 2). Compared with the 20–29-year reference group, subjects aged < 1 year had significantly higher odds of initial bile acid concentrations ≥ 10 μmol/L (adjusted OR, 25.32; 95% CI, 12.87–53.06; $p < 0.001$), ≥40 μmol/L (adjusted OR, 20.26; 95% CI, 9.81–44.09; $p < 0.001$), and ≥100 μmol/L (adjusted OR, 13.05; 95% CI, 5.19–36.26; $p < 0.001$). Compared with general hospitals, university hospitals were associated with significantly higher odds of elevated initial bile acid concentrations across all three cutoffs: ≥10 μmol/L (adjusted OR, 6.67; 95% CI, 4.59–9.75; $p < 0.001$), ≥40 μmol/L (adjusted OR, 6.58; 95% CI, 3.94–10.93; $p < 0.001$), and ≥100 μmol/L (adjusted OR, 4.62; 95% CI, 2.31–9.19; $p < 0.001$). For the ≥100 μmol/L cutoff, no events occurred among subjects from local clinics (0/154). However, Firth penalized logistic regression enabled estimation of the adjusted OR despite the absence of events in this subgroup, and the resulting estimate is presented in Figure 2. The degree-of-freedom-adjusted GVIFs ranged from 1.010 to 1.075, indicating no substantial multicollinearity among sex, age group, and institution type.

Variable	Adjusted OR (95% CI)	*p*-value
Age 20–29 years	Reference	
Male sex	Reference	
Institution type-General hospital	Reference	
Age <1 years	25.32 (12.87–53.06)	< 0.001
Age 1–9 years	2.04 (1.17–3.57)	0.013
Age 10–19 years	0.59 (0.36–0.94)	0.027
Age 30–39 years	1.41 (0.99–2.03)	0.060
Age 40–49 years	1.84 (1.33–2.58)	< 0.001
Age 50–59 years	2.44 (1.81–3.35)	< 0.001
Age 60–69 years	2.33 (1.73–3.18)	< 0.001
Age ≥ 70 years	3.78 (2.86–5.09)	< 0.001
Female sex	0.85 (0.77–0.94)	0.001
Institution type-Local clinic	0.50 (0.26–0.88)	0.015
Institution type-Obstetric hospital	0.65 (0.13–1.98)	0.493
Institution type-Pediatric hospital	4.21 (0.42–32.56)	0.199
Institution type-Referral laboratory	0.94 (0.71–1.21)	0.629
Institution type-University hospital	6.67 (4.59–9.75)	< 0.001



Variable	Adjusted OR (95% CI)	*p*-value
Age 20–29 years	Reference	
Male sex	Reference	
Institution type-General hospital	Reference	
Age <1 years	20.26 (9.81–44.09)	< 0.001
Age 1–9 years	4.03 (1.85–9.11)	< 0.001
Age 10–19 years	1.11 (0.52–2.44)	0.781
Age 30–39 years	2.17 (1.15–4.33)	0.016
Age 40–49 years	2.65 (1.45–5.14)	0.001
Age 50–59 years	2.76 (1.56–5.26)	< 0.001
Age 60–69 years	2.59 (1.48–4.89)	< 0.001
Age ≥ 70 years	2.65 (1.55–4.92)	< 0.001
Female sex	0.85 (0.71–1.02)	0.088
Institution type-Local clinic	0.24 (0.03–0.86)	0.025
Institution type-Obstetric hospital	1.32 (0.15–5.17)	0.755
Institution type-Pediatric hospital	18.49 (2.04–145.57)	0.012
Institution type-Referral laboratory	1.62 (1.08–2.35)	0.021
Institution type-University hospital	6.58 (3.94–10.93)	< 0.001



Variable	Adjusted OR (95% CI)	*p*-value
Age 20–29 years	Reference	
Male sex	Reference	
Institution type-General hospital	Reference	
Age <1 years	13.05 (5.19–36.26)	< 0.001
Age 1–9 years	5.36 (1.96–15.80)	< 0.001
Age 10–19 years	1.45 (0.54–4.10)	0.463
Age 30–39 years	1.75 (0.73–4.53)	0.212
Age 40–49 years	2.47 (1.13–6.09)	0.023
Age 50–59 years	1.58 (0.72–3.92)	0.266
Age 60–69 years	1.88 (0.89–4.53)	0.103
Age ≥ 70 years	1.77 (0.88–4.17)	0.117
Female sex	0.83 (0.64–1.09)	0.177
Institution type-Local clinic	0.16 (<0.01–1.12)	0.072
Institution type-Obstetric hospital	2.85 (0.31–11.71)	0.289
Institution type-Pediatric hospital	38.73 (4.56–296.86)	0.002
Institution type-Referral laboratory	2.02 (1.16–3.33)	0.015
Institution type-University hospital	4.62 (2.31–9.19)	< 0.001

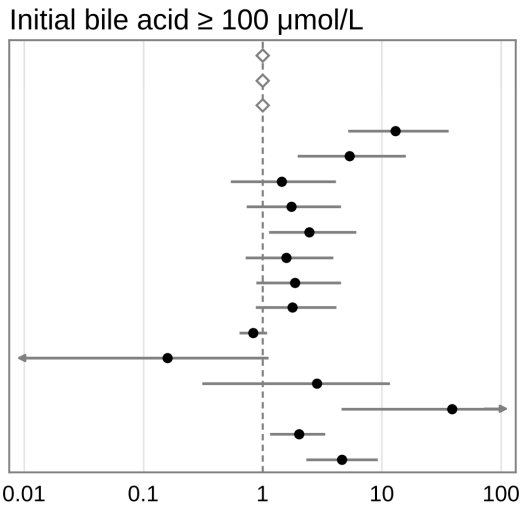


Figure 2. Multivariable Firth penalized logistic regression analysis of factors associated with elevated initial serum total bile acid concentrations. Forest plots show adjusted odds ratios and 95% confidence intervals for factors associated with elevated initial TSBA concentrations at each cutoff value. Open diamonds indicate the reference categories (odds ratio = 1), and filled circles indicate the adjusted odds ratios, with horizontal lines representing the 95% confidence intervals. Arrows indicate confidence intervals extending beyond the plotting range.

3.3. Obstetric Hospital Female Subgroup

Considering the major clinical indications for TSBA testing, female subjects whose specimens were requested by obstetric hospitals were examined as a potential obstetric population in which intrahepatic cholestasis of pregnancy may be clinically relevant. Their demographic, testing, and TSBA result characteristics are summarized in Table 2. The obstetric hospital female subgroup included 38 subjects. The median age was 34.5 years (IQR, 31.4–37.1 years), and the mean age was 34.6 ± 4.1 years. The median initial TSBA concentration was 3.1 μmol/L (IQR, 2.4–5.4 μmol/L). Most subjects in this subgroup had initial TSBA concentrations < 10 μmol/L (36/38, 94.7%). One subject (2.6%) had an initial bile acid concentration of 10–<40 μmol/L, and one subject (2.6%) had an initial bile acid concentration ≥100 μmol/L. Two subjects in the obstetric hospital female subgroup underwent follow-up testing. Among these subjects, the median absolute change from the initial to the last bile acid concentration was −1.0 μmol/L. One of the two subjects showed a decrease of ≥30% from the initial concentration.

Table 2. Characteristics of subgroups (obstetric hospital female patients and pediatric patients age < 10 years).

Characteristics	Obstetric Hospital Female	Pediatric Age < 10 Years
Number of subjects	38	223
Age, years, median [IQR]	34.5 [31.4–37.1]	1.3 [0.2–5.4]
Age, years, mean ± SD	34.6 ± 4.1	2.9 ± 3.2
Number of tests per subject, median [IQR]	1.0 [1.0–1.0]	1.0 [1.0–2.0]
Subjects with follow-up testing, *n* (%)	2 (5.3%)	58 (26.0%)
Initial bile acid < 10 μmol/L, *n* (%)	36 (94.7%)	83 (37.2%)
Initial bile acid 10–<40 μmol/L, *n* (%)	1 (2.6%)	49 (22.0%)
Initial bile acid 40–<100 μmol/L, *n* (%)	0 (0.0%)	41 (18.4%)
Initial bile acid ≥ 100 μmol/L, *n* (%)	1 (2.6%)	50 (22.4%)
Ever bile acid ≥ 100 μmol/L, *n* (%)	1 (2.6%)	54 (24.2%)
Last vs. initial change, μmol/L, median [IQR]	−1.0 [−5.6 to 3.6] *	−14.5 [−43.5–3.4]
Last vs. initial change, %, median [IQR]	63.3 [−44.8 to 171.4] *	−24.6 [−62.6–39.7]
Decrease ≥30% from initial to last, *n* (%)	1 (50.0%)	27 (46.6%)

IQR, interquartile range; SD, standard deviation. * For the two subjects with follow-up testing in the obstetric hospital subgroup, changes are presented as median [range].

3.4. Pediatric Subgroup

To explore the pediatric population in relation to laboratory-based criteria relevant to ileal bile acid transporter inhibitor therapy, including odevixibat, we descriptively examined the proportion of pediatric subjects whose TSBA concentrations and serial changes met the predefined concentration and follow-up criteria. The characteristics of this subgroup are summarized in Table 3. The pediatric subgroup included 223 subjects younger than 10 years. The median age was 1.3 years (IQR, 0.2–5.4 years), and the mean age was 2.9 ± 3.2 years. The subgroup included 118 males (52.9%) and 105 females (47.1%). The median initial TSBA concentration was 22.2 μmol/L (IQR, 6.4–91.2 μmol/L), and the mean initial TSBA concentration was 70.2 ± 106.4 μmol/L. In the pediatric subgroup, 50 (22.4%) had concentrations ≥ 100 μmol/L.

Overall, 54 pediatric subjects (24.2%) had TSBA concentrations ≥ 100 μmol/L at least once during the study period. Among the 54 pediatric subjects who had at least one TSBA concentration ≥ 100 μmol/L, 25 subjects (46.3%) had follow-up measurements after the first result ≥ 100 μmol/L. In these followed subjects, the median index TSBA concentration was 163.7 μmol/L, and the median last TSBA concentration was 115.4 μmol/L. The median percentage change from the first result ≥100 μmol/L to the last available result was −35.8%, and 14 of 25 subjects (56.0%) showed a decrease of ≥30% (Figure 3).

Table 3. Characteristics of pediatric patients aged < 10 years who had multiple bile acid measurements.

Characteristic	Value
Pediatric subjects with ever bile acid ≥ 100 µmol/L	54
Follow-up after ever bile acid ≥ 100 µmol/L, *n* (%)	25 (46.3%)
Index bile acid among followed subjects, µmol/L, median [IQR]	163.7 [121.0–247.0]
Last bile acid after index among followed subjects, µmol/L, median [IQR]	115.4 [70.5–187.8]
Change after first ≥100 µmol/L, µmol/L, median [IQR]	−93.3 [−114.8 to −15.8]
Change after first ≥100 µmol/L, %, median [IQR]	−35.8 [−74.1 to −13.1]
Decrease ≥30% after first ≥100 µmol/L, *n* (%)	14 (56.0%)

IQR, interquartile range.

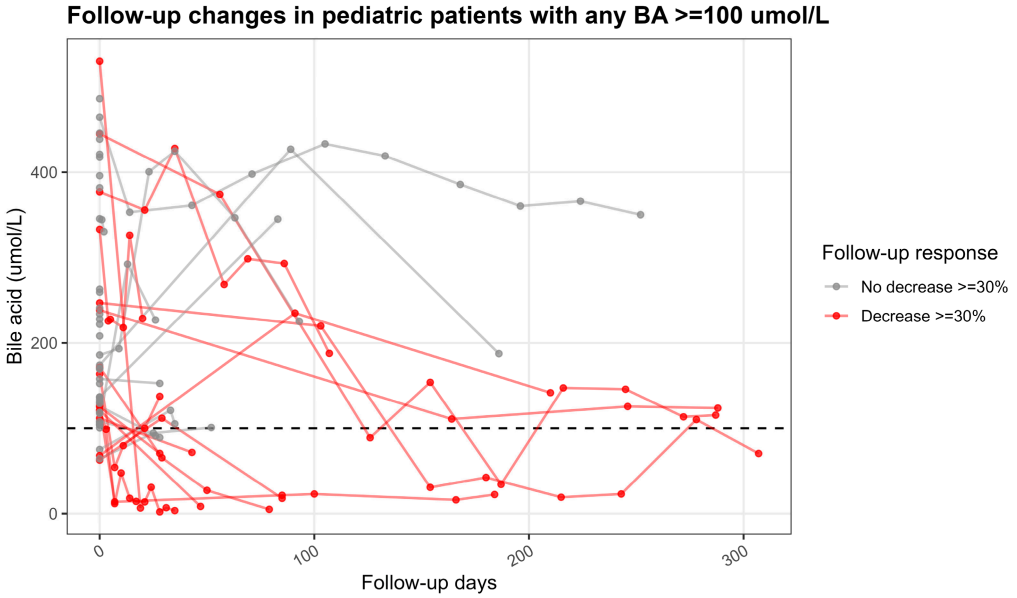


Figure 3. Longitudinal changes in serum total bile acid concentrations among pediatric patients with follow-up measurements. Serial TSBA concentrations are shown for pediatric patients who underwent follow-up testing. Each line represents an individual patient. Red lines indicate pediatric patients with follow-up measurements who showed a decrease of ≥30% from the initial TSBA concentration, regardless of whether the initial concentration was ≥100 µmol/L. The dashed line indicates the cutoff of 100 µmol/L. This approach was used to visualize relative intraindividual changes based on percentage change.

3.5. National Utilization Based on HIRA Claims Data

Analysis of national HIRA claims data for EDI code D1900 showed that the utilization of bile acid testing in Korea has increased since 2022 (Figure 4). This increasing trend was observed in the overall population and remained evident after stratification by sex and 10-year age group. Because the claims data did not provide pregnancy status or exact pediatric age subgroups below 10 years, women aged 20–49 years were analyzed as a proxy group for women of reproductive age. Utilization also increased in this group, suggesting that bile acid testing has increased nationally across clinically relevant demographic groups.

From June to December 2025, the HIRA database recorded 10,639 patients undergoing bile acid testing nationwide, while the GC Labs dataset included 7712 patients and 8476 test records between 16 June and 31 December 2025, corresponding to a descriptive patient-count ratio of 72.5% (7712/10,639).

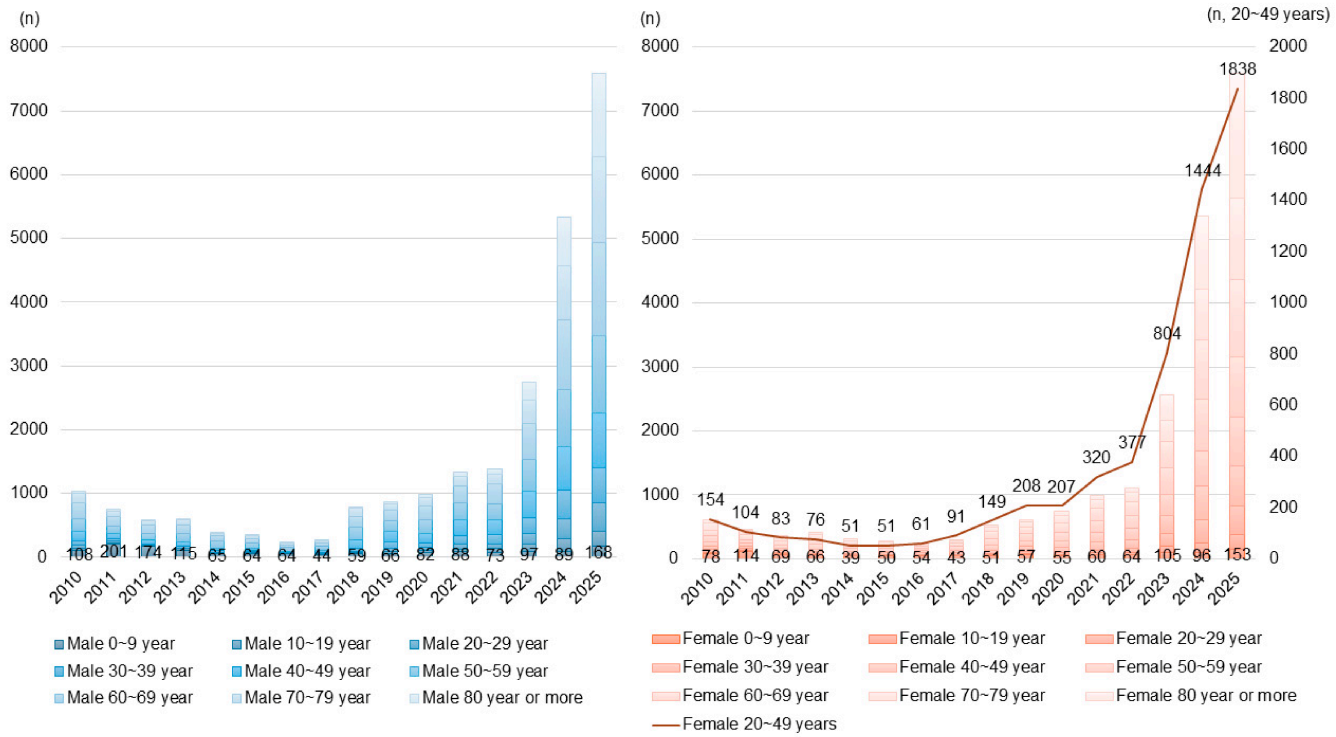


Figure 4. Age- and sex-specific distribution of patients undergoing serum total bile acid testing based on the Korean Health Insurance Review and Assessment Service (HIRA) claims database. The figure shows the annual number of patients who underwent serum total bile acid testing according to age group and sex. Numbers within the bars represent the number of patients aged < 10 years, and numbers on the line graph represent the number of female patients aged 20–49 years.

4. Discussion

In this 1-year retrospective study, we characterized the real-world utilization of TSBA testing using laboratory data from a large clinical referral laboratory in Korea and complementary national claims data. Most subjects had low initial TSBA concentrations, whereas a small but clinically important subset showed marked elevation. Initial TSBA concentrations were <10 μmol/L in 81.0% of subjects and ≥100 μmol/L in 2.1%, indicating that testing might be used across a broad range of clinical contexts, from screening or monitoring to evaluation of clinically significant cholestatic abnormalities [3–17].

Pediatric subjects showed particularly distinctive findings. Infants younger than 1 year had markedly higher odds of TSBA elevation across all cutoffs, and among children younger than 10 years, 22.4% had initial TSBA concentrations ≥ 100 μmol/L and 24.2% reached this level at least once during the study period. These findings may support the clinical importance of TSBA testing in pediatric cholestatic liver diseases and severe bile acid metabolism disorders [9–16,28]. Among pediatric subjects with TSBA concentrations ≥ 100 μmol/L, approximately half underwent follow-up testing. In those with follow-up measurements, the median percentage change was −35.8%, and more than half showed a decrease of ≥30%, suggesting a potential role for serial TSBA testing in monitoring disease course or treatment response [9–17]. However, because clinical diagnoses, treatment information, liver function tests, medication history, and genetic data were not available, causal interpretation was not possible. Alternative explanations, including biological variability, regression to the mean, and selection bias among patients undergoing repeat testing, should also be considered when interpreting these exploratory findings [27].

Institution type was also associated with TSBA elevation. University hospitals and referral laboratories showed higher odds of clinically significant TSBA elevation, probably

reflecting referral of complex hepatobiliary, pediatric, transplant-related, or rare disease cases. In contrast, most women referred from obstetric hospitals had TSBA concentrations <10 μmol/L, suggesting that testing in obstetric settings was mainly used for screening or evaluation of suspected intrahepatic cholestasis of pregnancy. These findings highlight the heterogeneous clinical settings in which TSBA testing is used. However, the clinical interpretations of these findings should be regarded as hypotheses for future investigation rather than definitive conclusions supported by the present data.

In addition, although Firth penalized logistic regression was performed to reduce potential estimation bias associated with sparse data, the extremely small sample sizes in certain institution categories, particularly pediatric hospitals (n = 4) and obstetric hospitals (n = 38), may still lead to imprecise estimates. Furthermore, although the adjusted GVIFs were low (1.010–1.075), suggesting no substantial multicollinearity, age and institution type were associated in certain referral settings. Therefore, these findings should be interpreted with caution, considering the potential influence of age–institution associations and small subgroup sizes on the regression estimates.

The national HIRA claims data provided increasing national use of TSBA testing since 2022, including in pediatric age groups and women of reproductive age. However, because claims data contain information on test utilization but not measured TSBA concentrations, they cannot be used to estimate the prevalence of specimens exceeding clinically relevant cutoffs. This limitation underscores the value of laboratory-based datasets, which include actual test results and may allow assessment of result distributions and positivity rates.

In Korea, progressive familial intrahepatic cholestasis and intrahepatic cholestasis of pregnancy are not separately monitored as distinct disease entities in national statistics based on the Korean Standard Classification of Diseases [21,29,30]. Therefore, the exact national prevalence of these diseases is difficult to determine using administrative diagnostic codes alone. In this context, TSBA test utilization by age and sex may provide indirect information on populations undergoing evaluation or monitoring for bile acid-related disorders. Although the GC Labs dataset and HIRA claims data covered different time periods, comparison with national utilization data suggests that TSBA testing in Korea is highly centralized. This indicates that TSBA testing functions as a low-volume but clinically important specialized laboratory test rather than a broadly distributed routine assay [31,32]. Although the GC Labs dataset accounted for approximately 72.5% of the national patient count during the partially overlapping study periods, potential referral bias and laboratory-specific testing practices should be considered, as these findings may not fully represent TSBA testing patterns across all healthcare settings in Korea.

This centralization has practical implications. Centralized testing may support efficient maintenance of analytical expertise, quality control, and test availability for low-volume assays. However, recent changes in the Korean referral laboratory reimbursement system may create challenges in maintaining sustainable access to rare-disease-related tests such as TSBA measurement [31–35]. As new therapies for bile acid-related rare diseases become available and laboratory monitoring becomes increasingly important for treatment selection and response assessment, appropriate support may be needed to ensure continued access to clinically essential but low-volume centralized laboratory tests.

Analytical interpretation of TSBA results also requires caution. TSBA comprises a heterogeneous group of bile acid species, including primary and secondary bile acids and their glycine- and taurine-conjugated forms [1]. Unlike many routine clinical chemistry analytes, TSBA lacks an internationally recognized higher-order reference measurement system, including commutable reference materials and a standardized calibration hierarchy [33–38]. In addition, commercially available enzymatic assays may differ in calibrator value assignment, substrate specificity, reagent formulation, and response to individual

bile acid species [24–37]. Therefore, TSBA results obtained using different analytical systems should not be considered directly interchangeable. In the present study, a method comparison study was performed to support comparability across the analyzer transition, and therefore the use of two analytical systems was unlikely to have materially affected the main findings. Nevertheless, caution is warranted when interpreting TSBA results across different analytical methods, because results from different systems may not be directly interchangeable.

Several limitations should be acknowledged. First, this was a retrospective laboratory database study, and detailed clinical information was unavailable. Therefore, the clinical indications for testing, underlying diagnoses, pregnancy status, treatment history, liver function tests, and clinical outcomes could not be assessed. Second, institution type was based on the requesting institution category and may not fully reflect the clinical context or referral pathway. Third, some institution-type categories had small sample sizes or sparse events, limiting the stability of regression estimates for certain outcomes. Fourth, follow-up intervals and repeat testing were not standardized, reflecting real-world practice rather than a predefined protocol. Finally, this study was based on data from a single clinical laboratory, which may limit generalizability to other healthcare systems or testing environments.

Despite these limitations, this study has several strengths. It analyzed a large real-world dataset including more than 11,000 subjects and more than 13,000 TSBA test records. In addition, the study evaluated not only overall result distribution but also utilization patterns, clinically relevant cutoffs, follow-up testing, key subgroups, and adjusted associations using multiple logistic regression. The use of national claims data further provided broader context for interpreting laboratory-based findings.

5. Conclusions

In conclusion, this study provides real-world evidence on how TSBA testing is utilized in Korea and how results are distributed across different patient and referral settings. TSBA testing in this real-world laboratory dataset was performed across diverse age groups and institution types. Most subjects showed low initial concentrations, but a clinically meaningful subset had marked elevation. Pediatric age, especially infancy, and university hospital referral were strongly associated with elevated initial TSBA concentrations. Complementary national claims data showed increasing utilization of bile acid testing in Korea, although claims data could not provide specimen-level results. Together, these findings may suggest that TSBA testing in Korea is a centralized, low-volume but clinically important laboratory test. However, these clinical interpretations cannot be confirmed with the available data and should be presented as hypotheses for future investigation rather than as evidence-based conclusions.

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Data Availability Statement: The datasets generated and analyzed during the current study are available from the corresponding authors on reasonable request. The de-identified health insurance claims data that support the findings of this study are available from the Health Insurance Review and Assessment Service (HIRA).

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Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

ALGS	Alagille syndrome
CGIS	Clinical Global Impression of Severity
CI	Confidence Interval
EDI	Electronic Data Interchange
U.S. FDA	United States of America Food and Drug Administration
HIRA	Health Insurance Review and Assessment Service
IBAT	Ileal bile acid transporter
ICP	Intrahepatic cholestasis of pregnancy
IQR	Interquartile range
OR	Odds ratio
PFIC	Progressive familial intrahepatic cholestasis
TSBA	Total serum bile acid

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