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# Incidence and Demographic Characteristics of Type 1 Diabetes Mellitus in Children from Bihor County, Romania, 2014–2024: A Descriptive Single-Centre Study

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## Highlights

### What are the main findings?

- A descriptive analysis of 172 children with newly diagnosed type 1 diabetes mellitus (T1DM) at the only pediatric diabetes centre in Bihor County showed 11–23 new cases per year over 2014–2024, with no statistically significant temporal trend in recorded case numbers (Poisson regression $p = 0.185$); while the rural/urban distribution of cases (45.3% vs. 54.7%) did not differ significantly from the rural share of the county's general (all-ages) population in the 2021 census (52.7% rural, $p = 0.054$), a non-age-matched comparison that should be interpreted cautiously.
- The approximate crude incidence (14.9–18.8 per 100,000 children/year, assuming a population of 83,000–105,000 children aged 0–17 years) is indicative only and is not directly comparable with national estimates for children aged 0–14 years (11.0 in 2015; 13.3 in 2020); INSP-CNSSP registry data, which cover all forms of diabetes and children in active follow-up, provide context only and cannot confirm trends in pediatric T1DM incidence or prevalence.

### What are the implications of the main findings?

- These single-centre, descriptive findings do not by themselves establish a higher local incidence or burden of pediatric T1DM; they support dedicated local epidemiological monitoring, with multi-source case ascertainment and inclusion of the county in national childhood diabetes registries.
- Residence-based access to diagnosis at this single, Oradea-based centre remains a plausible but unconfirmed factor; the rural/urban comparison does not show that access to diagnosis is similar for rural and urban children; this question would benefit from dedicated analysis of distance to the centre and diagnostic delay by residence.

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## Abstract

**Background/Objectives**: Type 1 diabetes mellitus (T1DM) is a common chronic disease of childhood, with a rising incidence worldwide, across Europe, and in Romania.

This retrospective, descriptive, single-centre study aimed to describe the demographic features, the temporal distribution and the approximate incidence of T1DM in children diagnosed in Bihor County, Romania. **Methods**: Of 174 children with newly diagnosed T1DM at Emergency Clinical County Hospital Bihor (2014–2024), 172 residing in Bihor County were analysed (two were excluded because they resided outside the county; none was excluded for missing data) for sex, age at onset, residence, and year and month of onset. The incidence was approximated using an assumed pediatric population (83,000–105,000 children aged 0–17 years), and the findings were set against official administrative registry data (INSP-CNSSP) for Bihor County and Romania. **Results**: The sex ratio was close to unity (47.1% girls; 95% confidence interval (CI) 39.8–54.5%). The rural share of cases (45.3%) did not differ significantly from the rural share of the county's general all-ages population in the 2021 census (52.7%; $p = 0.054$), a non-age-matched comparison that should be interpreted cautiously. Mean age at onset was 9.2 ± 4.5 years (girls 9.7 ± 4.3, boys 8.7 ± 4.6 years; $p = 0.135$); the largest proportion of cases (37.8%) was observed at ages 10–14 years. The annual number of recorded new cases ranged from 11 to 23 without a statistically significant temporal trend (Poisson regression of case counts, without population offset, $p = 0.185$; rate ratio 1.27 for 2019–2024 versus 2014–2018, 95% CI 0.93–1.76, $p = 0.126$). The approximate crude incidence was 14.9–18.8 cases per 100,000 children/year (point estimate 16.6); this is an indicative estimate that is not directly comparable with national estimates for children aged 0–14 years. Administrative registry data (INSP-CNSSP), which cover all forms of diabetes and children in active follow-up, showed an increase in the number of children aged 0–14 years in follow-up from 32 (2012) to 187 (2021) and prevalence above the national average, but cannot confirm trends in pediatric T1DM incidence or prevalence. **Conclusions**: This descriptive single-centre series broadly followed national and European patterns in sex ratio, age distribution and seasonality, with a relatively stable number of recorded annual cases. Given the single-centre case ascertainment and approximate denominators, the findings should not be regarded as population-based incidence estimates or as evidence of a higher local incidence or burden of T1DM; confirmation through multi-source case ascertainment or registry linkage is needed.

**Keywords:** type 1 diabetes mellitus; incidence; prevalence; pediatric epidemiology; Bihor County

## 1. Introduction

Substantial variation in the incidence of type 1 diabetes mellitus exists across geographic regions and population groups, reflecting a growing epidemiological burden concentrated mainly among children and adolescents. Globally, this condition remains one of the most frequently diagnosed chronic diseases in childhood, with its annual incidence continuing to rise.

Registry-based studies such as the DIAMOND project and the multicentre EURODIAB study have documented a sustained increase in the incidence of childhood T1DM in most regions of the world, with notable variation by geographic area [1,2]. The International Diabetes Federation estimated that more than 1.2 million children and adolescents (up to 19 years of age) were living with T1DM worldwide in 2021 [3]. More recent analyses based on the IDF Diabetes Atlas (10th edition) have updated the global estimates of the incidence of T1DM in children and adolescents [4] and, through modelling, of the prevalence and burden of T1DM in all age groups in 2021 [5].

Romania has been included in these epidemiological monitoring efforts through the National Registry of Childhood Diabetes, coordinated since 1996 by the Romanian National

Organisation for the Protection of Children and Adolescents with Diabetes (ONROCAD). Registry data show an increase in T1DM incidence in children under 15 years, from approximately 4.7 new cases per 100,000 children per year in 1996 to approximately 11 new cases per 100,000 children per year in 2015 [6], with a higher incidence reported in the literature for the 10–14 year age group compared with younger children [7], and a further, documented increase of 16.9% in incidence during the first year of the COVID-19 pandemic [8]; a 2023 meta-analysis of studies from several countries likewise found a higher incidence of type 1 diabetes in children during the pandemic [9].

Bihor County, located in north-western Romania, has a pediatric care network centralised mainly in the municipality of Oradea. Analysing the incidence and demographic distribution of cases treated locally can provide useful information for planning early-diagnosis resources, while relating these data to the national administrative registry allows a more rigorous framing of the results within a verifiable population context.

The aim of this descriptive study was to describe the demographic characteristics (sex, age at onset, and area of residence), the temporal distribution, and the estimated crude incidence of T1DM in children newly diagnosed at Emergency Clinical County Hospital Bihor, and to relate these data to the officially reported diabetes prevalence and incidence data for the county.

## 2. Materials and Methods

A retrospective, observational, descriptive study was carried out based on the clinical records of children admitted with newly diagnosed T1DM at Emergency Clinical County Hospital Bihor, in Oradea, Romania, between 2014 and 2024. A total of 174 children were identified; two were excluded because their locality of residence lay outside Bihor County, and 172 children resident in the county were analysed. No patient was excluded because of missing data: sex, month and year of onset, area of residence, and age at onset were available for all 172 patients.

### *2.1. Inclusion and Exclusion Criteria*

Inclusion criteria:

- Children and adolescents (0–17 years) newly diagnosed with type 1 diabetes mellitus at Emergency Clinical County Hospital Bihor, Diabetes, Nutrition and Metabolic Diseases Department, in Oradea, Bihor County, during the study period (2014–2024), with a diagnosis of T1DM established according to international guidelines (e.g., ISPAD/ADA).

Exclusion criteria:

- Patients diagnosed with forms of diabetes mellitus other than type 1 (e.g., type 2, monogenic/MODY, or secondary/steroid-induced diabetes).
- Patients initially diagnosed and treated in another county or centre and referred to the Diabetes, Nutrition and Metabolic Diseases Department of the Emergency Clinical County Hospital Bihor, Oradea, only for subsequent follow-up (i.e., not newly diagnosed locally).
- Patients whose locality of residence at the time of diagnosis lies outside Bihor County, even if newly diagnosed and treated at this centre, since the incidence and prevalence estimates in this study are specifically referenced to the county's own pediatric population.

### *2.2. Diagnostic Criteria and Exclusion of Other Types of Diabetes*

The diagnosis of T1DM was established by the treating pediatric diabetologists according to international guidelines (ISPAD/ADA) [10], on the basis of the clinical presentation (polyuria, polydipsia, weight loss, frequently with ketosis or diabetic ketoacidosis), hy-

perglycemia meeting the diagnostic criteria for diabetes, and the acute or subacute onset; insulin treatment was started at diagnosis in all cases, but insulin use alone was not taken as evidence of T1DM, in line with ISPAD guidance. Type 2 diabetes and monogenic diabetes (MODY) were excluded mainly on clinical grounds, i.e., the abrupt onset, the clinical phenotype (absence of obesity and of features of insulin resistance such as acanthosis nigricans), the personal and family history, and the insulin requirement from onset. Diabetes-related autoantibodies (e.g., GADA, IA-2A, ZnT8A) and C-peptide are not measured routinely at our institution; they are performed only in selected cases with an atypical presentation (for example, overweight or obese children, a gradual or mild onset, a strong multigenerational family history of diabetes suggestive of monogenic diabetes, or onset in early infancy), and these results were therefore not systematically available for the cohort, although current ISPAD guidance identifies diabetes-related autoantibodies as the means of confirming autoimmune T1DM [10]. Consequently, some misclassification (e.g., autoantibody-negative T1DM or undiagnosed monogenic diabetes) cannot be entirely excluded (see Section Limitations of the Study).

### *2.3. Case Ascertainment and Population Denominators*

Cases were identified from a single source, the admission records of the Diabetes, Nutrition and Metabolic Diseases Department of Emergency Clinical County Hospital Bihor. This is the only department in Bihor County with a pediatric diabetes service and inpatient pediatric beds for this specialty, and all children with newly diagnosed T1DM in the county are managed at this centre; no other institution in the county was therefore expected to diagnose and treat new-onset pediatric T1DM. No other hospital sources, private clinics, or regional or national diabetes registries (e.g., ONROCAD) were available for cross-checking, and a formal capture-recapture analysis was not possible. Children from Bihor County who were diagnosed and treated at centres outside the county could therefore not be identified (see Section Limitations of the Study). The population at risk was approximated from the 2021 census total population of Bihor County [11] and an assumed share of children aged 0–17 years of 15–19% of the total population, giving an estimated pediatric population of 83,000–105,000 children; because reliable annual, age-specific denominators were not available, a single constant denominator (midpoint 94,000) was used for the whole period, and annual population-adjusted rates were not calculated. Because complete county-wide coverage cannot be formally confirmed, the study is presented as a single-centre series and not as a population-based incidence study.

For each patient, the following were extracted from the medical records: sex, month and year of disease onset, locality and area of residence (urban/rural), and age at onset. Locality of residence was additionally used to verify that each patient resided within Bihor County at the time of diagnosis, using geographic point-in-polygon matching against official administrative boundaries. Data were centralised and processed statistically using descriptive methods: absolute and relative frequencies for categorical variables (sex, area of residence, age group) and central tendency and dispersion indicators (mean, ±standard deviation (SD), median with interquartile range (IQR), and range) for age at onset, with a comparison of age at onset between sexes by Welch's *t*-test (and the Mann–Whitney U test as a sensitivity analysis). Additionally, a chi-square goodness-of-fit test was used to assess the uniformity of the seasonal distribution of onset, a one-sample proportion test (with exact binomial confirmation) was used to compare the cohort's rural/urban distribution against the county's general population structure, and an exact (chi-square-based) Poisson 95% confidence interval was calculated for the estimated crude incidence rate. The annual number of cases was examined in two complementary ways: an exact Poisson rate-ratio test comparing the 2014–2018 and 2019–2024 periods (with a supplementary comparison

restricted to the 2019–2022 window) expressed as an incidence rate ratio (IRR; assuming a constant population at risk) with its 95% confidence interval, and a Poisson regression of the annual case count on calendar year, to test for a continuous linear trend across the full study period (without a population offset, because annual population denominators were not available; this analysis therefore tests for a trend in the recorded number of cases and not in the incidence rate, and, with a constant denominator, an offset would not change the estimated trend); a 95% Wilson score confidence interval was calculated for the sex distribution. All statistical analyses, calculations, graphs and figures were produced using Python 3.14 and its libraries: calculations were done using Pandas version 3.0.1, SciPy version 1.18.1, Statsmodels version 0.14.6 and GeoPandas version 1.1.4; graphs and figures were generated using Matplotlib version 3.10.8. The reporting of this retrospective observational study was guided, where applicable, by the general STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) recommendations for observational studies.

To contextualise the results, cohort data were related to the estimated pediatric population of Bihor County [11] and compared with official diabetes incidence and prevalence data published by the National Institute of Public Health—National Centre for Statistics in Public Health (INSP-CNSSP) for Bihor County and for Romania [12].

## 3. Results

Over the period analysed, 174 children with newly diagnosed T1DM were identified, of whom 172 resided in Bihor County and were included in the analysis; two were excluded because their locality of residence lay outside the county. No patient was excluded because of missing data: sex, area of residence, age at onset, and month and year of onset were available for all 172 patients, so that the incidence estimates and all demographic analyses are based on the same 172 patients.

### *3.1. Distribution by Sex and Area of Residence*

Of the 172 patients, 81 (47.1%, 95% CI 39.8–54.5%) were female and 91 (52.9%) were male (F:M ratio ≈ 0.89:1); the confidence interval is compatible with a true sex ratio close to unity. Seventy-eight children (45.3%) came from rural areas, and 94 (54.7%) from urban areas (Table 1).

**Table 1.** Baseline characteristics of the 172 children with newly diagnosed T1DM in Bihor County, 2014–2024. SD, standard deviation; IQR, interquartile range; CI, confidence interval (Wilson method for proportions).

| Characteristic | Value ($N = 172$) |
|---|---|
| Girls, *n* (%) | 81 (47.1; 95% CI 39.8–54.5) |
| Boys, *n* (%) | 91 (52.9) |
| Rural residence, *n* (%) | 78 (45.3; 95% CI 38.1–52.8) |
| Urban residence, *n* (%) | 94 (54.7) |
| Age at onset, mean ± SD (years) | 9.2 ± 4.5 |
| Age at onset in girls/boys, mean ± SD (years) | 9.7 ± 4.3/8.7 ± 4.6 (Welch $p = 0.135$) |
| Age at onset, median (IQR; range) (years) | 10.0 (5.0–13.0; 0.75–17.0) |
| Age group 0–4 years, *n* (%) | 32 (18.6) |
| Age group 5–9 years, *n* (%) | 53 (30.8) |
| Age group 10–14 years, *n* (%) | 65 (37.8) |
| Age group 15–17 years, *n* (%) | 22 (12.8) |

Figure 1 shows the location of Bihor County within Central and Eastern Europe (panel A) and the geographic distribution of the cases across the county's administrative units (panel B), illustrating the marked concentration of cases in Oradea alongside a wide dispersion of cases, mostly one to three per unit, across many rural communes.

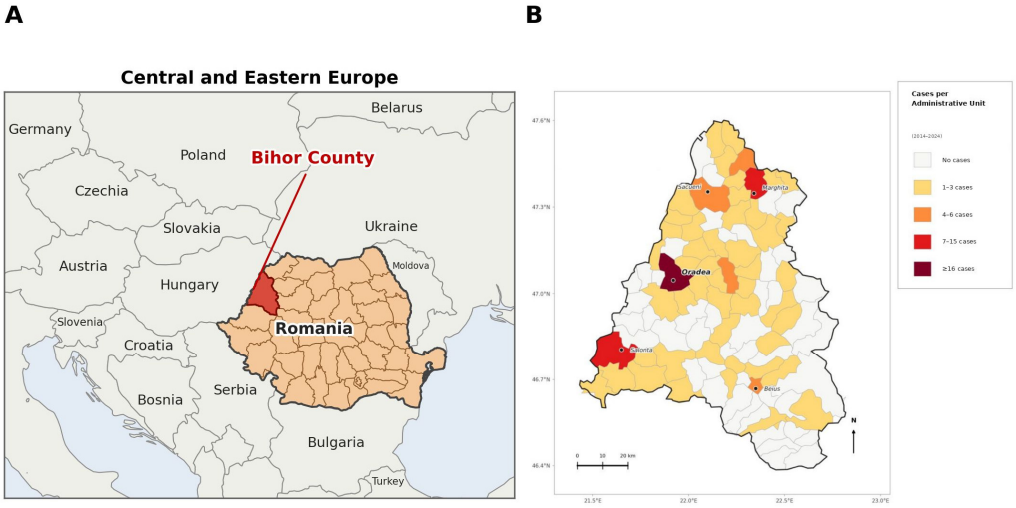



**Figure 1.** Location of Bihor County in Central and Eastern Europe (**A**) and geographic distribution of the 172 cases by administrative unit of residence (**B**).

### *3.2. Age at Onset*

The mean age at T1DM onset was 9.2 ± 4.5 years (mean ± SD; median 10.0 years, IQR 5.0–13.0; range 0.75–17.0 years, i.e., from 9 months to 17 years). The distribution by age group showed the highest frequency of onset in the 10–14 year age group (65 children, 37.8%), followed by the 5–9 year age group (53 children, 30.8%); onset before the age of 5 years accounted for 32 cases (18.6%), and onset in late adolescence (15–17 years) for 22 cases (12.8%) (Table 1, Figure 2A). These percentages describe the distribution of cases and not age-specific incidence, since age-specific population denominators were not available. Age groups were defined using standard integer-year boundaries (e.g., the 5–9 year group includes ages 5.0 up to but not including 10.0 years); the last group (15–17 years) spans only three years of age, compared with five years for the younger groups, which may somewhat underestimate its relative share of cases; in addition, patients approaching the transition to adult diabetes care at this age could result in some under-ascertainment of cases at the upper end of this group. The mean age at onset was slightly higher in girls (9.7 ± 4.3 years) than in boys (8.7 ± 4.6 years), but the difference was not statistically significant (Welch's *t*-test $p = 0.135$; Mann–Whitney U test $p = 0.156$), and the distributions largely overlapped (Figure 2B).

### *3.3. Annual Trend in New Cases*

The number of new cases ranged from a minimum of 11 cases (2016 and 2017; 6.4% of the total each) to a maximum of 23 cases (2019; 13.4%), fluctuating within a comparatively narrow band across the study period (Figure 3). The 2014–2018 period accounted for 68 cases (39.5%; mean 13.6 cases/year) and the 2019–2024 period for 104 cases (60.5%; mean 17.3 cases/year), which corresponds to an incidence rate ratio (IRR) of 1.27 (95% CI 0.93–1.76, exact Poisson rate-ratio test $p = 0.126$); restricting the comparison to the 2019–2022 window used in earlier pandemic-focused analyses gives a similar, likewise non-significant result (IRR 1.27, 95% CI 0.89–1.80, $p = 0.170$). A complementary Poisson regression of the annual case count on calendar year, using all 11 years of data, found no statistically

significant linear trend in the recorded number of cases (average change of approximately +3.3% per year, 95% CI −1.5% to +8.3%, $p = 0.185$); as no population offset could be used (annual denominators were unavailable), this analysis describes changes in recorded case numbers and not in incidence rates. Taken together, these two independent approaches indicate that the annual number of new cases has not shown a statistically significant increase over 2014–2024; the year-to-year fluctuation observed (for example, the rise from 11 cases in 2017 to 20 in 2018) most likely reflects the small annual case counts typical of a single-centre pediatric cohort. Annual counts are presented as absolute numbers and as percentages of the total (Figure 3); annual population-adjusted incidence rates were not calculated because reliable year-specific denominators for the pediatric population of the county were not available, and the use of a single constant denominator would only rescale, and not change, the relative year-to-year pattern shown by the counts.

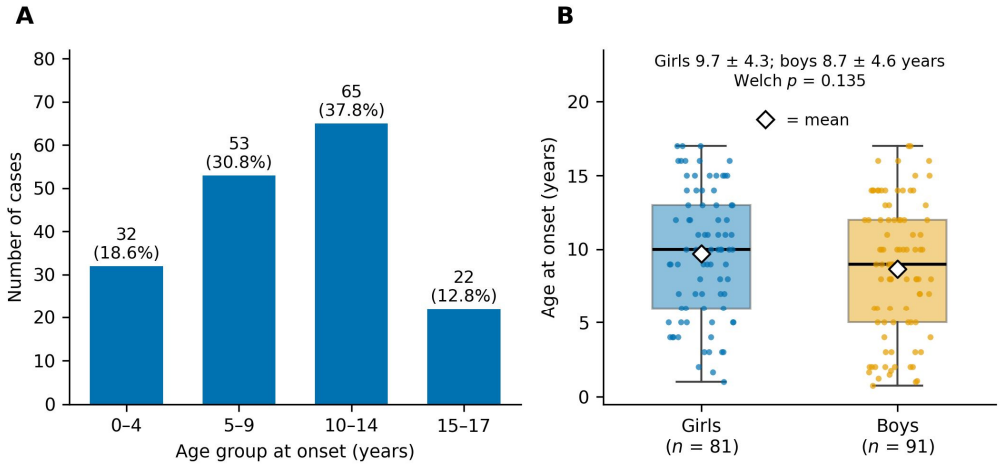



**Figure 2.** Age at onset of T1DM. (**A**) Distribution of cases by age group, with the number and percentage of cases; (**B**) box plot of age at onset by sex (box, interquartile range; line, median; diamond, mean; dots, individual patients).

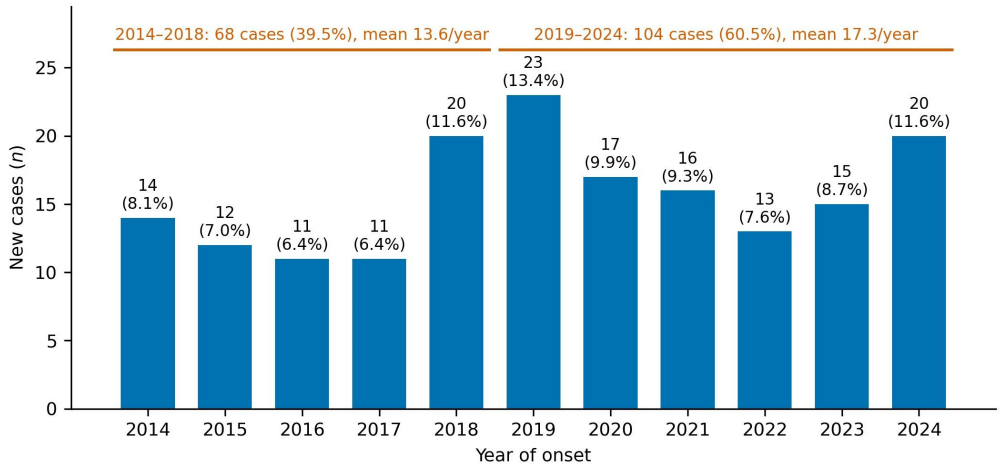



**Figure 3.** New cases of type 1 diabetes mellitus per year, 2014–2024, shown as number of cases and percentage of the total ($N = 172$); dashed lines indicate the mean annual number of cases in 2014–2018 and 2019–2024.

### *3.4. Seasonal Variation of Onset*

The exact month of onset was recorded for all 172 patients. The monthly distribution showed the highest number of new cases recorded in January (19 cases), followed by

November (18 cases) and March, September and December (17 cases each), and a marked decrease over the summer months, particularly June (9 cases) (Figure 4A).

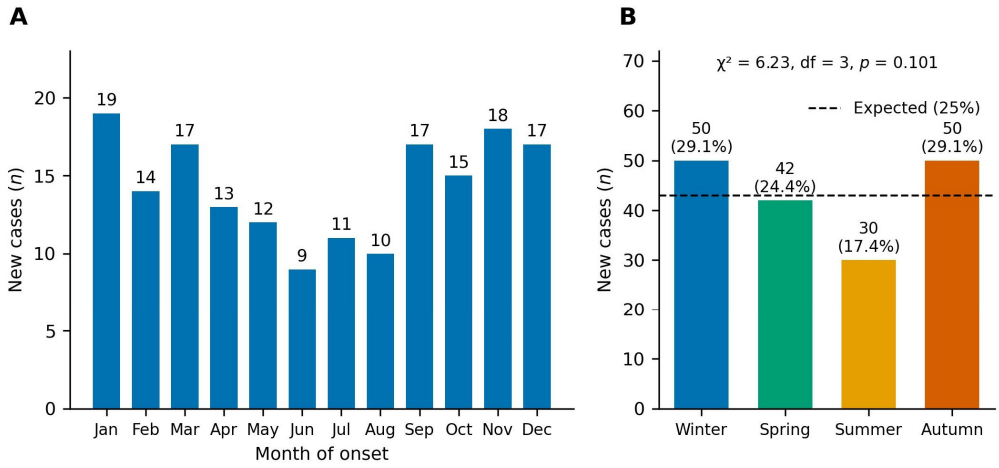



**Figure 4.** Seasonality of T1DM onset. (**A**) Monthly distribution of cases; (**B**) observed seasonal distribution (number and percentage of cases) compared with a uniform distribution (dashed line), with the chi-square goodness-of-fit test result.

Grouping by season showed a broadly similar pattern: 50 cases (29.1%) had onset in winter (December–February), 42 (24.4%) in spring (March–May), 50 (29.1%) in autumn (September–November), and 30 (17.4%) in summer (June–August). Descriptively, winter and autumn accounted for the largest, and equal, shares of cases, together comprising well over half of the cohort (58.1%), while summer remained the period with the lowest frequency of new-onset cases. A chi-square goodness-of-fit test comparing this observed seasonal distribution with an equal, 25%-per-season distribution yielded $\chi^2 = 6.23$ (df = 3, $p = 0.101$) (Figure 4B); with the full 172-patient cohort, this result does not support a statistically significant departure from a uniform seasonal distribution, although the numerically lower frequency of onset in summer remains directionally consistent with the pattern of reduced summer incidence reported in the national registry [6].

This descriptive seasonal pattern, with a numerically lower frequency of onset in the summer months, is directionally consistent with classic observations from the European registry literature, also reported by the Romanian national registry [6]. Such seasonality is generally attributed to a possible interaction between seasonal exposure to respiratory viral infections (which could act as a trigger or accelerator of autoimmune beta-cell destruction in genetically susceptible individuals) and the seasonal variation in cutaneous vitamin D synthesis, with lower levels in autumn and winter months, a hypothesis that is under active investigation, but still inconclusive, in the current literature, including a recent regional study from south-eastern Romania that documented a significant association, at the time of diagnosis, between vitamin D deficiency and T1DM in children [13].

### *3.5. Incidence and Prevalence—Methodological Considerations*

According to the 2021 Population and Housing Census, Bihor County had a total population of 551,297 inhabitants [11]. The pediatric population (0–17 years) was assumed to represent approximately 15–19% of the total population (an assumption, not a census-published figure), which would correspond, for Bihor County, to an approximate estimate of 83,000–105,000 children and adolescents. Relating the 172 new cases identified over the 11 years analysed (2014–2024) to this estimated population yields an approximate mean crude incidence of 14.9–18.8 new cases per 100,000 children per year (point estimate 16.63 per 100,000/year at the midpoint population of 94,000, Poisson 95% CI 14.24 to 19.31,

calculated using the exact (chi-square-based) Poisson confidence interval method, reflecting case-count sampling variability only, and not the additional, likely larger, uncertainty arising from the 83,000–105,000 population denominator range discussed below), a value of a similar order to, or somewhat above, the national ONROCAD figures for children aged 0–14 years (11.0 per 100,000 in 2015 [6]; 11.4 in 2019 and 13.3 in 2020 [8]), although this comparison is not like-for-like (see below). This estimate should be interpreted with caution: the actual population at risk in the county varies from year to year (including due to methodological differences between the usual-resident population, used by the census and by INSP-CNSSP for rate calculations, and the higher domicile-registered population), and the cohort studied originates from a single centre, so the calculated value represents an approximate, indicative estimate rather than a rigorously calculated incidence rate based on an exact, independently verified population denominator for each year of the interval.

These estimates rest on a single source of case ascertainment (Section 2.3) and on an approximate, constant population denominator. Children from the county who were diagnosed and treated outside it, if any, would not have been captured, so that the true incidence may be higher than estimated, whereas the uncertainty of the denominator (83,000–105,000 children) may bias the estimate in either direction. No eligible patient was excluded because of incomplete demographic records, so missing data did not contribute to any underestimation. The national estimates cited above refer to children aged 0–14 years, whereas our cohort covers ages 0–17 years (150 of the 172 patients, 87.2%, were aged 0–14 years at onset) and a different period (2014–2024). Age-specific county population data (0–14 and 15–17 years) by year were not available to us, so an estimate restricted to ages 0–14 years or matched by period could not be calculated reliably. The local rate is therefore presented as approximate and indicative; no conclusion that it exceeds the national incidence is drawn, and the findings should be regarded as a single-centre series rather than as definitive population-based incidence estimates.

The current prevalence of T1DM in the county's pediatric population could not be calculated directly from the clinical cohort data analysed, since the database used included only new (incident) cases, without a complete, updated record of all patients under 18 currently in active follow-up. Aggregate data on the number of children with diabetes mellitus (all clinical forms) in active follow-up in Bihor County are nonetheless available from the INSP-CNSSP administrative registry and are presented below.

### *3.6. National and Regional Context: Data from the INSP-CNSSP Administrative Registry*

Romania's National Institute of Public Health, through the National Centre for Statistics in Public Health (INSP-CNSSP), publishes an annual aggregate record of all diabetes mellitus cases reported by nutrition, diabetes and metabolic disease outpatient clinics nationwide, broken down by county, area of residence, sex and age group [12]. Although this administrative registry covers all clinical forms of diabetes (type 1, type 2 and other forms) across all age groups, and the reported cases represent patients in active follow-up (not necessarily new diagnoses made in that particular year), the published data for Bihor County provide a useful population-level frame of reference for the cohort analysed in this study.

According to this report, the total number of diabetes cases in active follow-up at nutrition clinics in Bihor County rose from 29,738 in 2012 to 39,870 in 2021, and the prevalence rate climbed from 5166.8 to 7175.4 cases per 100,000 inhabitants over the same interval, values consistently above the national average (4150.2 and 6561.7 per 100,000, respectively, in the same two years) [12]. In children aged 0–14, the number of diabetes cases in active follow-up in Bihor County increased nearly six-fold over the interval covered by the INSP-CNSSP report, from 32 cases in 2012 to 187 cases in 2021 (Table 2), while the number

of new cases reported annually in this age group ranged between 7 (2012) and 21 (2014 and 2020), without a clear year-on-year linear trend, but with a visibly higher average in the second half of the interval compared with the first [12]. Relating the Bihor County figures to the national total for the same age group (0–14 years) shows that the county consistently accounted for a modest and relatively stable share of Romania's new pediatric diabetes mellitus cases throughout the decade, averaging approximately 3.6% per year (range 2.4–6.0%), broadly proportionate to the county's share of the national population, without a distinct upward or downward trend relative to the rest of the country.

**Table 2.** Diabetes mellitus in children aged 0–14 in Bihor County, 2012–2021 (all clinical forms; source: INSP-CNSSP) [12].

| Year | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 |
|---|---|---|---|---|---|---|---|---|---|---|
| Children 0–14 in active follow-up | 32 | 35 | 63 | 91 | 107 | 116 | 134 | 147 | 164 | 187 |
| Children 0–14, new cases | 7 | 11 | 21 | 19 | 16 | 14 | 20 | 16 | 21 | 18 |

This trend, although it cannot be compared case-by-case with the cohort of 172 T1DM patients analysed in the present study (partially different populations, in terms of definition and time interval, and, in the case of the INSP-CNSSP registry, including all clinical forms of diabetes rather than type 1 exclusively), shows, at population level, a sustained increase in the number of children with diabetes mellitus in active follow-up in Bihor County over the past decade; this reflects the cumulative growth of an active-follow-up caseload over time and is not directly comparable to the annual number of new diagnoses examined in our own cohort, where no statistically significant temporal trend was found. It should be noted that, in three of the nine year-to-year intervals shown in Table 2 (2013–2014, 2014–2015, and 2020–2021), the increase in the number of children in active follow-up exceeds the number of new cases reported for that year, which cannot be explained by new diagnoses alone in a closed cohort; this may reflect administrative corrections, catch-up reporting of previously under-registered cases, or in-migration of already-diagnosed patients into the county. This discrepancy is a recognised limitation of administrative registry data of this kind and should be taken into account when interpreting the absolute figures in Table 2. In addition, because these registry data include all forms of diabetes and describe children in active follow-up rather than new diagnoses, they cannot be used to confirm or refute trends in the incidence or prevalence of pediatric T1DM, and they are presented only as contextual information.

Internationally, according to the same source, Romania sits below the European Union average both for diabetes mortality (8.8 deaths per 100,000 inhabitants, versus 11.3 in the EU and 15.0 across the WHO European region) and for overall disease prevalence (3.9%, versus 5.5% in the EU) [12]. This favourable position at the aggregate, national level does not, however, rule out substantial regional variation, such as that observed for Bihor County, where diabetes prevalence rates were consistently above the national average throughout the entire decade analysed. Expressed as a compound annual growth rate (CAGR), the county's overall (all-ages) diabetes prevalence rate grew by approximately 3.7% per year between 2012 and 2021 (from 5166.8 to 7175.4 per 100,000), a pace slightly slower than the compound annual growth rate of the national prevalence rate over the same interval (approximately 5.2% per year, from 4150.2 to 6561.7 per 100,000). This indicates that, although Bihor County's prevalence rate remained consistently above the national average in absolute terms throughout the decade, its relative rate of increase was, if anything, marginally below the national pace, rather than substantially exceeding it. A regional com-

parison, using the same INSP-CNSSP source, shows that Bihor County's 2021 prevalence rate (7175.4 per 100,000) also exceeded the mean prevalence rate reported for Macroregiunea 1 (which statistically groups the Nord-Vest and Centru development regions together in this source; 6436.7 per 100,000 in 2021), indicating that the county's elevated disease burden is not solely a reflection of demographic or environmental factors shared across this broader macro-region, but appears to be at least partly a county-specific pattern. The INSP-CNSSP source does not report prevalence separately for the Nord-Vest development region alone, so a direct comparison restricted to Nord-Vest could not be made. This CAGR comparison should not be confused with the much steeper growth in the raw number of children aged 0–14 in active follow-up (32 to 187 cases, a 21.7% per year increase in absolute headcount): unlike the prevalence rate, this raw count is not adjusted for the size of the underlying population and therefore cannot be directly compared with the national prevalence-rate CAGR. It should also be noted that the compound annual growth rate (CAGR), a simple geometric-mean measure commonly used in economic and financial contexts, was used here as a direct, readily interpretable approximation of the trend; this differs from the Estimated Annual Percentage Change (EAPC) more commonly reported in epidemiological trend analyses (including in reference [6], which used Poisson regression to estimate its annual rate of increase), and the two measures are not numerically identical, though they are typically of similar magnitude for gradually changing trends.

## 4. Discussion

The present study provides a descriptive analysis of the demographic characteristics and the estimated incidence of pediatric T1DM at a single centre in Bihor County, set against both national registry-type data and official INSP-CNSSP prevalence data. Given the single-source case ascertainment and the approximate population denominators, the findings are presented as descriptive estimates rather than as definitive population-based incidence rates.

The sex ratio close to unity (47.1% girls versus 52.9% boys; 95% CI for girls 39.8–54.5%) observed in the study cohort is consistent with the international literature, which shows that T1DM generally does not display a marked predilection for either sex at pediatric age [1,10], and with the Romanian registry, in which mean incidence in boys (7.3 per 100,000) and girls (7.1) did not differ significantly ($p = 0.53$) [6]; a slight male excess was reported in an earlier national analysis ($p = 0.038$) [7]. The confidence interval of our estimate is compatible with both findings.

The largest proportion of cases was observed at ages 10–14 years (37.8%), followed by 5–9 years (30.8%) and 0–4 years (18.6%). This describes the distribution of cases and not age-specific incidence, since age-specific denominators were unavailable and the 15–17 year group spans three years rather than five; the ordering is nevertheless in line with the national registries, which reported the highest mean incidence at ages 10–14 years (9.1 versus 7.6 at ages 5–9 and 4.5 at ages 0–4 per 100,000 in the ONROCAD registry [6]; 9.6 versus 4.8 at ages 0–4 in the analysis of Șerban et al. [7]).

The proportion of cases from rural areas (45.3%) was somewhat lower than, but not statistically distinguishable from, the rural share of the county's general population (52.7%, according to the 2021 census); a one-sample test comparing the cohort's rural proportion against the county's rural population share found no statistically significant difference at the conventional threshold ($z = -1.93$, $p = 0.054$; exact binomial $p = 0.056$); 95% Wilson CI for the rural share of cases 38.1–52.8%). It should be noted that the 52.7% reference figure reflects the rural share of the county's general (all-ages) population, since a pediatric-specific rural/urban breakdown was not available from the 2021 census source used, so some difference between the pediatric and general population distributions cannot be

excluded. Given the centralised location of the Pediatric Diabetes Department in Oradea, the county's largest urban centre, a modest excess of urban cases (54.7% of the cohort, versus an estimated 47.3% urban share of the general population) might in principle be expected from geographic proximity; however, the absence of a statistically significant difference means that residence-based access to diagnosis cannot be confirmed as a major differentiator on the basis of this single-centre cohort alone. The $p$-value lies close to the conventional threshold, and this comparison should therefore not be over-interpreted in either direction; a dedicated analysis with a larger, ideally multicentre or regional sample, and with data on distance to the centre and diagnostic delay, would be needed to clarify it. Moreover, the comparison uses the rural share of the general population in the 2021 census, whereas the cohort comprises children aged 0–17 years diagnosed over 2014–2024; since a pediatric, period-matched comparison was unavailable, the finding should be interpreted cautiously, and it does not show that access to diagnosis is similar for rural and urban children.

The annual number of new cases observed over 2014–2024 did not show a statistically significant increase in recorded case numbers, whether assessed by comparing discrete periods (IRR 1.27, 95% CI 0.93–1.76, $p = 0.126$, for 2019–2024 versus 2014–2018; IRR 1.27, 95% CI 0.89–1.80, $p = 0.170$, when restricted to the 2019–2022 window) or by a continuous Poisson regression across all 11 years ($p = 0.185$). The national ONROCAD registry reported a rise in incidence in children aged 0–14 years from 11.4 per 100,000 in 2019 to 13.3 in 2020 (+16.9%), with 57.8% of the new cases of 2020 diagnosed in the second half of the year [8]; in our cohort, the number of new cases was 23 in 2019, 17 in 2020 and 16 in 2021, and 7 of the 17 cases of 2020 (41.2%) had onset between July and December, so that no comparable signal was observed; the absence of a comparable signal in this cohort may reflect the relatively small annual case numbers at a single centre, genuine local stability in the number of new cases, or both, and should not be taken to contradict the national-level finding, which was based on a much larger sample. INSP-CNSSP registry data for Bihor County, showing a nearly six-fold increase in the number of children aged 0–14 with diabetes mellitus in active follow-up between 2012 and 2021 [12], reflect the cumulative growth of an active-follow-up caseload over a full decade and are not directly comparable to the annual new-case trend examined in our cohort; this registry-level increase is therefore not necessarily in tension with the stable annual number of recorded cases observed here.

Our findings can also be compared more directly with the Romanian registry studies. The national ONROCAD registry (1996–2015; 5422 children aged 0–14 years) reported regional variability, with the highest mean incidence in Transylvania (7.9 per 100,000), followed by Muntenia (7.0) and Moldavia (6.5) [6]; Bihor County lies in north-western Romania, but county-level estimates were not reported, so our single-centre data cannot be placed precisely within this regional pattern. The monthly distribution of our cases (highest in January, lowest in June) mirrors the seasonality described nationally, with a peak in January and a low in June [6], although in our cohort the chi-square test did not reach significance ($p = 0.101$), probably because of the limited sample size. The age distribution (largest proportion of cases at 10–14 years) and the sex distribution (47.1% girls, with no significant difference in age at onset between sexes) were in line with the national findings summarised above [6,7]. For the COVID-19 period, the national registry reported an increase in incidence from 11.4 to 13.3 per 100,000 between 2019 and 2020 [8], a pattern not seen in the number of cases in our cohort (23 in 2019 and 17 in 2020), as discussed above. In contrast, a 2023 meta-analysis reported a higher incidence of type 1 diabetes in children during the first year of the pandemic (pooled incidence rate ratio 1.14) and during months 13–24 (1.27) [9], and a single-centre cohort from Bucharest reported a 30.1% increase in newly diagnosed T1DM cases between March 2019–February 2020 and March 2020–February 2021 [14]; the small annual numbers in our single-centre series limit

any comparison. In south-eastern Romania, a regional study documented a significant association between vitamin D deficiency and T1DM in children at diagnosis [13]; vitamin D status was not assessed in our cohort.

The estimated mean crude incidence for the study cohort (approximately 14.9–18.8 new cases per 100,000 children per year; point estimate 16.63, Poisson 95% CI 14.24 to 19.31) is an approximate figure that depends on the assumed pediatric population (83,000–105,000 children aged 0–17 years) and on single-centre case ascertainment. It is not directly comparable with the national ONROCAD estimates, which refer to children aged 0–14 years and to other years (11.0 per 100,000 in 2015 [6]; 11.4 in 2019 and 13.3 in 2020 [8]); because age-specific denominators were unavailable, a comparable estimate could not be calculated. We therefore do not conclude that the incidence in Bihor County exceeds the national incidence: the local estimate is of a similar order to, or somewhat above, the recent national figures, and this should be confirmed in a study with multi-source case ascertainment and population data matched by age and period. The diabetes prevalence rates (all clinical forms, all ages) officially reported for Bihor County by INSP-CNSSP were consistently above the national average throughout the 2012–2021 decade [12], and a 2024 press release by the Romanian Society for Diabetes, Nutrition and Metabolic Diseases, based on National Health Insurance House (CNAS) records, identified Bihor County as one of only two Romanian counties (alongside Satu Mare) where over 10% of the general population has diagnosed diabetes mellitus (14.8% in Bihor) [15]. These figures concern all forms of diabetes, predominantly in adults, derive from different sources, years and reference populations, and cannot be used to infer the burden of pediatric T1DM; they are cited only as context.

Comparison with other Central and Eastern European (CEE) countries places the estimated crude incidence of our cohort (16.6 per 100,000 children/year, ages 0–17 years) within the range reported for the region, although differences in age range, study period and ascertainment methods limit direct comparison (Table 3). In Hungary, the prospective national registry (children aged 0–14 years, 1989–2009; ascertainment above 96% by capture-recapture) recorded an average incidence of 12.5 per 100,000 per year, rising from 7.7 in 1989 to 18.2 in 2009, with a mean annual increase of 4.4% [16]. In Serbia, a nationwide multicentre study covering 15 regional pediatric diabetes centres (2007–2017) reported an incidence of 14.28 per 100,000 in children aged 0–14 years, with an average yearly increase of 5.9% [17]. In Austria, the nationwide registry documented a steep rise in the incidence of T1DM in children younger than 15 years between 1989 and 2011, followed by a plateau in 2011–2020 and an all-time high of 28.7 per 100,000 in 2021 [18]. In Northwestern Turkey, a prospective study of children younger than 18 years (2013–2015) found a crude incidence of 8.99 per 100,000 per year, stable over the three study years, a mean age at diagnosis of $9.2 \pm 4.2$ years (very similar to the $9.2 \pm 4.5$ years in our cohort), and a significant increase in diagnoses in autumn and winter [19]. In the Masovian Voivodeship, Poland (2381 children younger than 18 years, 2015–2023), diagnoses peaked in February and were lowest in June, with more diagnoses in autumn-winter than in spring-summer (54% vs. 46%) [20]. A Bulgarian study covering 1982–1998 documented significant urban/rural differences in the incidence of T1DM among children [21], a point relevant to the rural/urban distribution of cases observed here, which we could not examine in terms of incidence rates because pediatric rural/urban denominators were not available. Our estimate is thus of a similar order as the recent figures from Hungary and Serbia, higher than that from Northwestern Turkey, and lower than the recent Austrian figure; like the Northwestern Turkish study, and unlike the steadily rising trends in Hungary and Serbia, we found no statistically significant temporal trend in the annual number of new cases, which may reflect the small annual counts at a single centre, genuine local stability, or both. At the European level, a

recent meta-analysis of studies in children aged 0–14 years reported a pooled incidence that rose from 10.85 per 100,000 person-years in 1994–2003 to 20.96 in 2013–2022, with the Eastern European region rising from 8.97 to 15.34 and Romania from 5.60 to 10.51 [22], and the EURODIAB centres (26 centres in 22 countries, 1989–2013) showed a pooled annual increase of 3.4% (95% CI 2.8–3.9%) [23]. All of these comparisons are limited by differences in age range (0–17 years in our cohort versus mostly 0–14 years), study period and case ascertainment (population-based registries, some with capture-recapture validation, versus a single-centre hospital series).

**Table 3.** Comparison of the present study's findings with previously published Romanian and Central and Eastern European data on the incidence of type 1 diabetes mellitus in children. Comparisons are limited by differences in age range, study period and case ascertainment.

| Study | Population/Region | Study Period | Age Group | Crude Incidence (per 100,000/Year) | Reported Trend |
|---|---|---|---|---|---|
| Present study | Bihor County (single centre) | 2014–2024 | 0–17 years | 14.9–18.8 (point estimate 16.63) | No significant trend in recorded case numbers (Poisson $p = 0.185$); IRR 1.27 (2019–2024 vs. 2014–2018), $p = 0.126$ |
| Vlad et al. [6] | Romania (national, ONROCAD registry) | 1996–2015 | 0–14 years | 4.7 (1996) to 11.0 (2015); mean 7.2 (95% CI 7.0–7.4) | Continuous increase, +5.1%/year |
| Serban et al. [7] | Romania (national) | 2002–2011 | 0–17 years | 9.6 (10–14 years) vs. 4.8 (0–4 years) | Increasing incidence; highest in 10–14 year age group |
| Vlad et al. [8] | Romania (national, ONROCAD registry) | 2019–2020 | 0–14 years | 11.4 (2019) to 13.3 (2020) | +16.9% during first COVID-19 pandemic year |
| Gyürüs et al. [16] | Hungary (national registry) | 1989–2009 | 0–14 years | 12.5 (7.7 in 1989 to 18.2 in 2009) | Linear increase, +4.4%/year |
| Vukovic et al. [17] | Serbia (national, 15 regional centres) | 2007–2017 | 0–14 years | 14.28 (age-standardised) | Increase of 5.9%/year |
| Nagl et al. [18] | Austria (national registry) | 1989–2021 | <15 years | 28.7 in 2021 | Steep rise to 2011, plateau 2011–2020, highest value in 2021 |
| Poyrazoğlu et al. [19] | Northwestern Turkey | 2013–2015 | 0–17 years | 8.99 | Stable over 2013–2015 ($p = 0.95$) |
| Tzaneva et al. [21] | Eastern Bulgaria | 1982–1998 | Children | - | Significant urban/rural differences |
| Ruiz-Grao et al. [22] | Europe (meta-analysis of 75 studies, 32 countries) | 1994–2022 | 0–14 years | 10.85 (1994–2003) to 20.96 (2013–2022); Eastern Europe 8.97 to 15.34; Romania 5.60 to 10.51 | Increasing in most countries |
| Patterson et al. [23] | Europe (EURODIAB, 26 centres in 22 countries) | 1989–2013 | 0–14 years | - | Pooled increase of 3.4%/year (95% CI 2.8–3.9%) |

*Limitations of the Study*

This study has a retrospective, descriptive design based on single-centre data and should be regarded as a single-centre series rather than as a population-based incidence study. Case ascertainment relied on a single source, the admission records of the only pediatric diabetes department in the county, and could not be cross-checked against other institutions or diabetes registries (e.g., ONROCAD); children from Bihor County who were diagnosed and treated outside the county, if any, would not have been captured, which could lead to an underestimation of the incidence, and, because the cohort was compiled retrospectively from hospital records, the consistency of ascertainment

across the study years could not be formally verified. No eligible patient was excluded because of incomplete demographic records, so such exclusions did not affect the estimates. Incidence was estimated against an approximate pediatric population denominator (83,000–105,000 children aged 0–17 years), derived from the 2021 census total and the national proportion of children, rather than annual, age-specific county population data; consequently, annual population-adjusted rates could not be calculated, the Poisson regression and the period comparison describe trends in recorded case numbers and not in incidence rates (no population offset was used), and the local estimate cannot be compared like-for-like with national estimates that refer to children aged 0–14 years and to other years. All incidence and prevalence figures reported here are crude (unadjusted) rates, and age-standardised incidence rates could not be calculated because detailed, single-year-of-age population breakdowns were not available for Bihor County across the full study interval. The age-group percentages describe the distribution of cases and not age-specific incidence, and the 15–17 year group spans three years rather than five. The rural/urban comparison used the rural share of the general (all-ages) population in the 2021 census and is therefore not age- or period-matched. The diagnosis of T1DM was established clinically according to international guidelines, and autoantibodies and C-peptide were measured only in selected cases, so that some misclassification (e.g., autoantibody-negative T1DM or monogenic diabetes) cannot be excluded. The comparison with the INSP-CNSSP administrative registry data should be interpreted with additional caution, since that registry includes all clinical forms of diabetes, not type 1 exclusively, and reports cases in active follow-up at a given point in time, not necessarily new diagnoses made in the reporting year; for this reason the two data sets are complementary and cannot be used to confirm or validate the T1DM findings of this cohort. Being a single-centre study, the results cannot be directly generalised to the whole country, but should be interpreted in conjunction with existing national and regional registry data [6–8,12]. Data on the rate and severity of diabetic ketoacidosis (DKA) at disease onset were not collected in the source medical records and could therefore not be reported; this represents a further limitation, since DKA frequency at onset is a recognised indicator of diagnostic delay and disease severity in pediatric T1DM. As general national context only (not specific to Bihor County, to pediatric patients, or to type 1 diabetes alone), the INSP-CNSSP report indicates that diabetic ketoacidosis, with or without coma, was consistently the most frequent acute complication among all hospitalised diabetes patients nationally throughout 2012–2021, accounting for the large majority of acute-complication discharges each year [12]; this figure should not be extrapolated to the present pediatric cohort.

## 5. Conclusions

The descriptive analysis of a cohort of 172 children with newly diagnosed T1DM at Emergency Clinical County Hospital Bihor, Diabetes, Nutrition and Metabolic Diseases Department, in Oradea, revealed a sex ratio close to unity, a rural share of cases not significantly different from that of the county's general population (a cautious, non-age-matched comparison), a mean age at onset of 9.2 ± 4.5 years, and the largest proportion of cases at ages 10–14 years. The recorded number of new cases fluctuated between 11 and 23 over the period analysed (2014–2024) without a statistically significant temporal trend, whether assessed by period comparison or by Poisson regression of case counts. The approximate crude incidence (14.9–18.8 per 100,000 children/year) is indicative only and is not directly comparable with national estimates for children aged 0–14 years, so this single-centre series does not by itself establish a higher local incidence.

Official INSP-CNSSP registry data, which cover all forms of diabetes and children in active follow-up rather than new T1DM diagnoses, provide contextual information only

(an increase in the number of children with diabetes in follow-up and diabetes prevalence above the national average); they cannot confirm trends in pediatric T1DM incidence or prevalence, nor validate the findings of this cohort. These results support the need for more rigorous local epidemiological monitoring, through multi-source case ascertainment and the integration of Bihor County data into national childhood diabetes registries.

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**Institutional Review Board Statement:** The study was approved by the Ethics Committee of the Clinical County Emergency Hospital Bihor (app. no.: 5074; app. date: 13 February 2025) and the Ethics Council of the Bihor County Emergency Clinical Hospital (app. no.: 3977; app. date: 6 February 2025) and followed the ethical standards laid out in the 1975 Declaration of Helsinki.

**Informed Consent Statement:** Given the retrospective nature and full anonymization of the collected data, the need for informed consent was waived.

**Data Availability Statement:** The database supporting the findings of this study is available from the corresponding author at reasonable request due to privacy and ethical restrictions regarding sensitive medical data from pediatric patients.

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

## Abbreviations

The following abbreviations are used in this manuscript:

| | |
|---|---|
| ADA | American Diabetes Association |
| CAGR | Compound Annual Growth Rate |
| CEE | Central and Eastern Europe |
| CI | Confidence Interval |
| CNAS | Casa Națională de Asigurări de Sănătate (National Health Insurance House) |
| COVID-19 | Coronavirus Disease 2019 |
| DIAMOND | Diabetes Mondiale (WHO Multinational Project for Childhood Diabetes) |
| DKA | Diabetic Ketoacidosis |
| EAPC | Estimated Annual Percentage Change |
| EU | European Union |
| EURODIAB | Europe and Diabetes (Study Group) |
| GADA | Glutamic Acid Decarboxylase Autoantibodies |
| IA-2A | Islet Antigen-2 Autoantibodies |
| INSP-CNSSP | Institutul Național de Sănătate Publică—Centrul Național de Statistică și Informatică în Sănătate Publică (National Institute of Public Health—National Centre for Statistics in Public Health) |
| IQR | Interquartile Range |
| IRR | Incidence Rate Ratio |
| ISPAD | International Society for Pediatric and Adolescent Diabetes |
| MODY | Maturity-Onset Diabetes of the Young |
| ONROCAD | Organizația Națională Română pentru Copiii și Adolescenții cu Diabet (Romanian National Organisation for the Protection of Children and Adolescents with Diabetes) |
| SD | Standard Deviation |
| STROBE | Strengthening the Reporting of Observational studies in Epidemiology |
| T1DM | Type 1 Diabetes Mellitus |
| WHO | World Health Organization |
| ZnT8A | Zinc Transporter 8 Autoantibodies |

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