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RESEARCH

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Effect of continuous inhaled corticosteroids on glycated hemoglobin in asthmatic children: a pilot study

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Abstract

Background Asthma is a prevalent chronic disease with significant impact on patients, families, and communities. Inhaled corticosteroids (ICS) are the mainstay of treatment for persistent and uncontrolled asthma. However, concerns remain about the potential adverse effects of ICS, including HbA1c level. This study aims to evaluate the influence of ICS on Hemoglobin A1c (HbA1c) levels in children with bronchial asthma.

Methods This prospective cohort study included 48 pediatric asthma patients aged 2 to 15 years who had been using ICS for at least 6 months. Comprehensive clinical assessments and measurements of HbA1c levels were conducted at the start of recruitment and after 6 months of ICS use. The types and doses of ICS used followed the guidelines provided by the Global Initiative for Asthma (GINA).

Results The initial HbA1c levels ranged from 4.46 to 6.11, with a mean of 5.32 ± 0.35. Three patients (6.3%) had persistent prediabetes status after 6 months. There was no significant relationship between glycemic status and the characteristics of ICS. The duration of ICS therapy and the doses used did not significantly affect HbA1c levels. A weak positive correlation was observed between initial and subsequent HbA1c levels.

Conclusion The study found no significant difference in HbA1c levels among asthmatic children using ICS after six months of treatment. Additionally, there was no significant difference in HbA1c levels between patients using different types of ICS. Regular monitoring of HbA1c levels is recommended, particularly for children on high doses or prolonged use of inhaled Fluticasone.

Keywords Asthma, Inhaled corticosteroids, Glycemic control, Hemoglobin A1c

Background

Asthma represents a significant and prevalent chronic disease, often characterized by its substantial impact on patients, their families, and the broader community. This condition is primarily known for causing respiratory symptoms, activity limitations, and acute exacerbations, sometimes necessitating urgent healthcare interventions and potentially resulting in fatal outcomes [1]. Asthma is fundamentally an immunologically mediated disease. The abnormal immune response triggered by various inhaled environmental agents and irritants sets off a cascade of events. These events include increased mucus secretion, airway constriction, heightened airway responsiveness, culminating in the manifestation of asthma symptoms [2].

Inhaled corticosteroids (ICS) serve as the cornerstone of daily controller treatment for persistent and uncontrolled asthma. Extensive clinical research has

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demonstrated the efficacy of ICS in diminishing exacerbation risks among both children and adult asthma patients. These medications not only reduce hospitalization and asthma-related mortality rates but also enhance asthma symptom management and overall quality of life. ICS contribute to improved lung function, increased airway responsiveness, and reduced airway inflammation and remodeling. In pediatric populations, ICS effectively ameliorate both daytime and nighttime symptoms, bolster lung function, lessen exacerbation risks, and decrease the necessity for rescue medications [3].

HbA1c, or glycated hemoglobin, is a widely used indicator for assessing glycemic control in pediatrics. It provides valuable information about a child's average blood glucose levels over a period of time, typically 2–3 months [4]. The American Diabetes Association (ADA) recommends using HbA1c as a diagnostic tool for diabetes in pediatrics, with a diagnostic threshold of 6.5% or higher [5].

Several studies have indicated that prolonged exposure to corticosteroids, even inhaled forms, may induce hyperglycemia or other alterations in carbohydrate metabolism [6]. This is particularly concerning in pediatric populations where long-term metabolic changes can have significant developmental and health implications [7]. However, there is a lack of consensus regarding the clinical significance of these changes, especially in relation to HbA1c levels, and the potential long-term outcomes for asthmatic children.

Therefore, the focus of this study is to evaluate the influence of ICS on Hemoglobin A1c (HbA1c) level in children with bronchial asthma who are under ICS treatment.

Methods

Study design

This prospective cohort study was conducted at the Pediatric Department and Outpatient Clinic of Cairo University Children Hospitals from July 2022 to July 2023. The study adhered to the ethical guidelines and received approval from the Departmental Ethical Committee at the Faculty of Medicine, Cairo University.

Subjects

The study included 48 pediatric asthma patients from the aforementioned hospital settings. These patients were selected based on their adherence to the Global Initiative for Asthma (GINA) guidelines (2019) [8], ensuring a range of asthma severity and control levels.

Inclusion criteria were non-diabetic asthmatic children aged between 2 to 15 years, using inhaled corticosteroids (ICS).

Exclusion criteria included children who had received systemic corticosteroids, those with hemoglobinopathies, children on aspirin therapy, non-compliant to ICS, or presenting with clinical pallor or splenomegaly. Informed consent was obtained from the legal guardians of each patient after a thorough explanation of the study objectives.

Methodology

Participants underwent a comprehensive history taking and clinical assessment based on the standard sheet of the allergy clinic at Children's Hospital, Cairo University. This assessment included personal data, location (urban or rural), detailed history of present illness, past medical history, family history, and perinatal history. A thorough clinical examination was conducted, focusing on anthropometric measures, vital signs, and various systems, particularly the respiratory system.

HbA1c levels were assessed twice, initially and then after 6 months of ICS use, to observe any changes due to the medication. The types and doses of ICS used were as per the guidelines provided in GINA 2019 [8] for children older than 5 years.

Laboratory methods

Blood samples were collected under aseptic conditions using sterile vacutainers containing ethylene diamine tetraacetic acid (EDTA). HbA1c levels were measured using the ADAMS™ A1c Lite (HA-8380 V) Automatic Glycohemoglobin Analyzer. The interpretation of HbA1c values followed the American Diabetes Association (ADA) guidelines (2021) [5], categorizing them as normal, prediabetes, or diabetes based on specific percentage ranges.

Statistical methods

Data analysis was performed using the Statistical Package for the Social Sciences (SPSS), version 22 (IBM Corp., Armonk, NY, USA). Categorical data were represented as numbers and percentages, while numerical data were analyzed for normality and expressed as mean ± standard deviation or median with interquartile range, as appropriate. Various statistical tests, including Chi-Square, Paired T-test, Fisher Exact test, independent T-test, and Mann-Whitney U test, were utilized to compare the data. Pearson and Spearman's rank correlations were used to explore associations between HbA1c levels and variables such as age, BMI, dose, and duration of ICS. A p-value of less than 0.05 was considered statistically significant.

Results

This cohort study included 48 children with bronchial asthma who were on inhaled corticosteroids (ICS). The sociodemographic characteristics of the studied patients. Their age ranged from 2 to 13- years old, with a mean age of 6.1 ± 2.8. Males outnumbered females (56.3% versus 43.7%, respectively). More than half (54.2%) were from rural areas, while 45.8% were from urban. Their BMI ranged from 12.8 to 31.2, with a median of 16.5 (IQR: 15.2 to 17.8). Out of 48 studied patients, 10 (10.8%) patients had allergic rhinitis, and only one patient (2.1%) had eczema. Moreover, 5 (10.4%) and 17 (35.4%) patients recorded a family history of allergic rhinitis and asthma, respectively. All patients (100%) did not have a family history of DM (Table 1).

The first serum HbA1c levels drawn at the start of recruitment ranged from 4.46 to 6.11, with a mean of 5.32 ± 0.35, and it was found that patients with normal glycemic status (93.8%) were significantly higher than the Children with prediabetes state (6.2%), ($p < 0.001$). The second evaluation of serum HbA1c six months later revealed levels between 4.15 to 6.18, with a mean of 5.19 ± 0.44, with persistent prediabetes status in the same 3 (6.3%) patients.

There was no significant relationship between the glycemic status and the characteristics of ICS (All $p > 0.05$). Two (66.6%) of children with prediabtes state were using fluticasone, and 1 (33.3%) was on a beclomethasone inhaler. On the other hand, most children with normal glycemic status (73.3%) were on beclomethasone. Two (66.6%) of children with prediabtes state were on a high-dose ICS, and 1 (33.3%) was on a low dose, while most normal glycemic status children were on a low dose (71.1%). The medians of the ICS dose were equal in both glycemic status categories (200 each). Furthermore, the median duration of ICS therapy was non-significantly longer in children with prediabtes state than in normal glycemic-status children (24 versus 10 months, respectively). After six months, the median duration of ICS therapy was also non-significantly longer in children with prediabtes state than in normal glycemic-status children (30 versus 16 months, respectively). Two (66.6%) of children with prediabtes state were using salmeterol beta-agonist drugs, and 1 (33.3%) was using salbutamol, while most normal glycemic status children were on salbutamol (80%). All (100%) of the Children with prediabetes state reported controlled asthma, while 40 (88.9%) of the normal glycemic children documented asthma control (Table 2).

Regarding the comparison of the first HbA1c levels according to the dose and duration of ICS intake. Among patients on a high dose ICS, the means of HbA1c levels in the ≤ 12 months (5.42 ± 0.22) and > 12 months (5.37 ± 0.09) duration were comparable with no significant difference ($p = 0.752$). Similar results of non-significantly different means of HbA1c levels according to the duration were found among patients on a medium dose and a low dose ICS (Table 3).

According to comparison of the second HbA1c levels drawn after 6 months of follow-up according to the dose and duration of ICS intake. Among patients on a high dose ICS, the means of HbA1c levels in the ≤ 12 months (5.16 ± 0.49) and > 12 months (5.10 ± 0.56) duration were comparable with no significant difference ($p = 0.858$). Similar results of non-significantly different means of HbA1c levels according to the duration were found among patients on a medium dose and a low dose ICS (Table 4).

There was a significant positive weak correlation between the first and the second HbA1c levels ($r = 0.382$, $p = 0.007$). Otherwise, there were no significant correlations between both HbA1c levels and the age, BMI, dose, or duration of ICS (all $p > 0.05$) (Table 5).

Table 1 Sociodemographic characteristics of the studied patients

		Cases ($n = 48$)
Age (years)	Minimum- Maximum	2.0-13.0
	Mean ± SD	6.1 ± 2.8
Sex, N %	Female	21 (43.7%)
	Male	27 (56.3%)
Residence, N %	Rural	26 (54.2%)
	Urban	22 (45.8%)
Weight (Kg)	Minimum- Maximum	11.0-53.0
	Median (IQR)	21.0 (17.0-26.5)
Height (meter)	Minimum- Maximum	0.84-1.62
	Mean ± SD	1.16 ± 0.17
BMI	Minimum- Maximum	12.8-31.2
	Median (IQR)	16.5 (15.2-17.8)

SD standard deviation, *IQR* interquartile range

Discussion

The relationship between systemic corticosteroids and their impact on HbA1c level, particularly the risk of diabetes development or worsening in pre-existing cases, has been well-documented [9]. This association naturally extends to concerns about the effects of Inhaled Corticosteroids (ICS), especially considering their pivotal role in managing asthma. Our study aimed to investigate the impact of chronic ICS use on glycemic status in asthmatic children.

We included 48 children aged 2-13 years with asthma but without a history of Diabetes Mellitus, all of whom

Table 2 The current associations between the occurrance of prediabetes and the characteristics of the ICS drugs

		Cases ($n=48$)					
		Normal 45 (93.8%)		**Prediabetes 3 (6.2%)**		**Test statistic**	***P*-Value**
Type of ICS	Beclomethasone	33	73.3%	1	33.3%	3.529[a]	0.232
	Fluticasone	11	24.4%	2	66.7%		
	Fluticasone + beclomethasone	1	2.2%	0			
Estimate of ICS daily dose	High	10	22.2%	2	66.7%	2.934[a]	0.318
	low	32	71.1%	1	33.3%		
	Medium	3	6.7%	0			
Dose of ICS	Median (IQR)	200.0 (200.0-200.0)		200.0 (200.0-500.0)		1.723[b]	0.211
	Mean rank	23.32		34.0			
Duration of ICS at first level (months)	Median (IQR)	10.0 (3.0-24.0)		24.0 (3.0-40.0)		0.706[b]	0.515
	Mean rank	24.13		30.0			
Duration of ICS at the second level (months)	Median (IQR)	16 (9-30.0)		30 (9-46.0)		0.706[b]	0.515
	Mean rank	24.13		30.0			
B-agonist used	Salbutamol	36	80.0%	1	33.3%	3.467[a]	0.127
	Salmeterol	9	20.0%	2	66.7%		
Asthma control	Controlled	40	88.9%	3	100.0%	1.397[a]	1.00
	Not controlled	1	2.2%	0			
	Partially controlled	4	8.9%	0			

IQR interquartile range

[a] Fisher Exact test

[b] Mann-Whitney U test

Table 3 Comparison of the first HbA1c levels according to the dose and duration of ICS intake

		The first HbA1c levels		**t**	***P*-Value**
High ICS dose	**≤ 12 months**	Mean ± SD	5.42 ± .22	0.324	0.752
	> 12 months	Mean ± SD	5.37 ± .09		
Medium ICS dose	**≤ 12 months**	Mean ± SD	4.95 ± 0.64	-0.831	0.559
	> 12 months	Mean ± SD	5.60 ± .37		
Low ICS dose	**≤ 12 months**	Mean ± SD	5.35 ± .31	0.783	0.439
	> 12 months	Mean ± SD	5.25 ± .42		

Table 4 Comparison of the second HbA1c levels according to the dose and duration of ICS intake

		The second HbA1c levels		**t**	***P*-Value**
High ICS dose	**≤ 12 months**	**Mean ± SD**	5.16 ± .49	0.183	0.858
	> 12 months	**Mean ± SD**	5.10 ± .56		
Medium ICS dose	**≤ 12 months**	**Mean ± SD**	5.45 ± .12	-0.238	0.851
	> 12 months	**Mean ± SD**	5.48 ± .09		
Low ICS dose	**≤ 12 months**	**Mean ± SD**	5.14 ± .31	-0.378	0.708
	> 12 months	**Mean ± SD**	5.21 ± .50		

Table 5 Correlations between HbA1c levels and age, BMI, dose and the duration of ICS

	The first HbA1c levels		**HbA1c levels after 6 months**	
	r coefficient	***P*-Value**	**r coefficient**	***P*-Value**
Age	0.119	0.422	0.017	0.907
BMI	0.226	0.123	0.084	0.570
Dose of ICS	0.129	0.387	-0.020	0.896
Duration of ICS	-0.104	0.482	0.233	0.111
HA1c levels after 6 months	0.382	0.007*	NA	NA

NA not applicable

* Significant at $p < 0.05$

had been using ICS for at least six months. The study group's mean age was 6.1 ± 2.8 years, with a slight male predominance (56.3%) and a roughly equal distribution between rural (54.2%) and urban (45.8%) areas. This demographic spread is consistent with previous studies, such as those by Sánchez-Lerma et al. [10] and Chen et al. [11], which noted gender differences in asthma prevalence and the potential influences of androgens and estrogens on atopic diseases.

The higher prevalence of asthma in rural participants aligns with findings from studies like Abd Elmoneim et al. [12] and Al-Gewely et al. [13], possibly reflecting disparities in healthcare access. A notable 35.4% of our subjects had a family history of asthma, supporting the established link between genetics and asthma risk, as highlighted by Paaso et al. [14] and Jain and Bhat [15]. Additionally, 45.8% of our cases had a general family history of atopy, but none had a family history of diabetes.

Concerning comorbidities, 10% of our patients had allergic rhinitis, and 2.1% had eczema. These findings echo the works of Leynaert et al. [16] and Galli et al. [17], which suggest a high association between asthma, allergic rhinitis, and eczema due to shared pathophysiological pathways.

All participants were on ICS, with Beclomethasone being the most commonly used (70.8%), followed by Fluticasone (27.1%). The doses varied, with 25.0% on high doses, 6.3% on medium doses, and the majority (68.8%) on low doses.

We assessed glycemic status using glycosylated hemoglobin (HbA1c) levels, a reliable indicator of average blood glucose concentration over 2–3 months. This approach aligns with research by Selvin et al. [18], which classify HbA1c levels in the range of 5.7-6.4% as indicative of a very high risk for developing diabetes.

In our study, initial HbA1c levels ranged from 4.46 to 6.11, with a mean of 5.32 ± 0.35. The majority (93.8%) had normal glycemic status, and 6.3% were in a prediabetic state. A follow-up after six months showed a mean HbA1c of 5.19 ± 0.44, with the same 6.3% remaining in prediabetes. This stability suggests a negligible impact of ICS on HbA1c level, a conclusion supported by studies like Bindusha et al. [19] and Divya [20].

However, our findings contrast with those of Yucel et al. [21] and Daniel & Jose [22], who observed higher HbA1c levels in children on low-dose ICS. Sankaravadivelu et al. [23] and Wani et al. [24] also reported increased HbA1c levels in patients on higher doses of ICS, although no cases reached levels indicative of steroid-induced diabetes.

This discrepancy may be attributed to individual genetic predispositions to insulin resistance, as suggested by Rahman et al. [25]. In our study, the 6.3% of patients with prediabetes were predominantly male, with one child exhibiting a high BMI. Two of these children were on high-dose Fluticasone, while one was on a lower dose of Beclomethasone.

Interestingly, we found no significant relationship between glycemic status and the characteristics of ICS (dose, duration, type). This aligns with findings Rahman et al. [25] and Yucel et al. [21], who reported no significant correlation between cumulative ICS doses, duration of usage, and HbA1c levels.

Our study revealed a weak positive correlation between the initial and follow-up HbA1c levels ($r = 0.382$, $p = 0.007$), indicating some degree of consistency over time. However, there were no significant correlations between HbA1c levels and age, BMI, dose, or duration of ICS use.

Evaluating HbA1c levels according to ICS dose and duration also yielded non-significant differences. These results are consistent across high, medium, and low doses, and irrespective of the duration of ICS use, suggesting that neither the intensity nor the length of ICS therapy significantly influences HbA1c level in asthmatic children.

Our study contributes to the ongoing debate about the metabolic effects of ICS in children with asthma. While some studies suggest a potential impact on HbA1c level, particularly at higher doses, our findings largely indicate a minimal effect, even over extended periods of use. However, the presence of a subset of patients exhibiting prediabetic HbA1c levels indicates the need for careful monitoring, especially in those with other risk factors like high BMI or higher doses of ICS.

The study presents several limitations. Primarily, the small sample size and short duration of six months limit the ability to extrapolate the findings to longer periods and larger populations. Additionally, the focus solely on asthmatic children restricts the applicability of the findings to broader demographics, and the absence of long-term effect analysis leaves a critical area of impact unexplored. Also, the range of dosages categorized as high, medium, and low might not capture the nuanced variations in patient response to ICS therapy. Not to forget mentioning the fact that the impact of ICS on glycemic control in this study is somewhat biased by not reporting the baseline HbA1c before starting steroid inhalation therapy. This information would have provided a baseline measurement of HbA1c levels in the study participants and would have allowed for a more comprehensive analysis of the impact of ICS on HbA1c levels. Without this baseline measurement, it is challenging to determine the specific changes in HbA1c levels that occurred as a result of the six months of ICS use. An example of this was the three children with the prediabetic status who might have developed this status before the study, but after starting ICS.

Conclusion

The study concluded that there is no statistically significant difference in HbA1c levels among asthmatic patients using inhaled corticosteroids (Fluticasone and Beclomethasone) after six months of treatment.

Additionally, it found no significant difference in HbA1c levels between patients using Beclomethasone and those using Fluticasone. A weak positive correlation was observed between initial and subsequent HbA1c levels, but there was no significant correlation between these levels and factors like age, BMI, dosage, or duration of treatment. Based on these findings, our study suggests studying the effects of different inhaled corticosteroids on HbA1c levels, as well as monitoring the glycemic status of asthmatic children before and during corticosteroid treatment. Regular follow-up of HbA1c is particularly recommended for children on high doses or prolonged use of inhaled Fluticasone. This study is considered an exploratory study that needs to be followed by larger studies with bigger sample size and narrower age range. We advocate for future research that employs alternative methods of glycemic control assessment, beyond HbA1c, in asthmatic patients undergoing treatment with inhaled corticosteroids.

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Authors' contributions
EF contributed in design of the work, data acquisition, drafted the manuscript, MA contributed in design of the work, revised the manuscript and approved it with her revision, MB contributed in design of the work, KK contributed in idea of study, design of the work, interpretation of data.

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Availability of data and materials
All data used during the current study are available from corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
The study was conducted in accordance with the declaration of Helsiniki for studies including human participants and was approved by the institutional research ethics committees at Faculty of Medicine, Cairo University (Approval code: MS-104-2022). Written informed consent was obtained from the parents. Participants' data have been anonymized.

Consent for publication
Written informed consent was obtained from the parents. Participants' data have been anonymized.

Competing interests
Not applicable.

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