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Seasonal Variation in the Incidence and Severity of Intrahepatic Cholestasis of Pregnancy: A retrospective study in Saudi Arabia

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Abstract

Intrahepatic cholestasis of pregnancy (ICP) is a pregnancy-specific liver disorder associated with adverse maternal and foetal outcomes. Although seasonal variation has been reported in some populations, evidence from Saudi Arabia remains limited, particularly in the Qassim region. This paper sought to investigate the monthly and seasonal distribution of ICP, assess differences in maternal biochemical severity, examine the association between ambient temperature and ICP occurrence, and explore demographic and obstetric predictors of ICP severity. Using a retrospective observational study at the Maternity and Children Hospital (MCH), Buraydah, Saudi Arabia, medical records from January 2020 to January 2026 were extracted and used for analyses. Descriptive statistics summarized patient characteristics and the temporal distribution of cases. Kruskal–Wallis tests compared serum bile acids, alanine aminotransferase (ALT), aspartate aminotransferase (AST), and bilirubin across months and seasons. Spearman's correlation assessed the relationship between average monthly temperature and ICP occurrence, while multinomial logistic regression evaluated demographic and obstetric predictors of ICP severity. A total of 2,461 ICP cases were identified, with the highest proportion occurring during winter (41.3%), particularly in December. However, no significant differences were observed in serum bile acids, ALT, AST, or bilirubin across months or seasons ($p > 0.05$). Average monthly temperature was not significantly associated with ICP occurrence, $r_s(66) = 0.10$, $p = 0.425$, additionally maternal age, body mass index, gravidity, parity, previous ICP, hypertension, diabetes, and season were not significant predictors of ICP severity. These findings suggest that seasonal factors may influence the temporal distribution of ICP diagnoses but have limited impact on disease severity in Saudi Arabia.

Keywords: Pregnancy; Intrahepatic cholestasis; Body mass index; Liver disorders

Introduction:

Background

Intrahepatic cholestasis of pregnancy (ICP), previously called obstetric cholestasis.is a common disease of pregnancy [1] that affects approximately 2.9% of pregnant women worldwide [2], and around 0.35% in Saudi Arabia, with a similar incidence of 0.35% reported in Qassim alone [3]. ICP is defined as pruritus with increased levels of serum total bile acid (TBA) in pregnant women [4]. It can cause significant discomfort to the mother [5] by causing pruritus typically involving palms and sole without a primary skin rash especially at night [5,6], and possibly affecting the mood of the pregnant woman [7] and increases

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the possibility of adverse perinatal outcome including still birth [1] Other possible health concerns like impaired fetal myocardial performance and impaired fetal cardiac conduction system [8,9] has been reported. Characterized by itching, primarily of the soles and palms, elevated serum bile acid, and elevated transaminases, with spontaneous relief of laboratory anomalies and symptoms that occur as soon as the baby is delivered but no later than 30-days postpartum [10], ICP is a well-known medical reason to warrant planned early delivery [11] and medically induce labor or even perform C-section [11,12].

This article aims to study ICP in Qassim, Saudi Arabia, focusing on seasonality and outcomes. Systematic reviews and meta-analyses have demonstrated marked global and regional variation in the incidence of intrahepatic cholestasis of pregnancy (ICP), with pooled global estimates around 2–3%, suggesting the influence of environmental, hormonal, and genetic factors on disease distribution [13,14]. An individual patient data meta-analysis further confirmed that increasing maternal bile acid concentrations are associated with higher risks of adverse perinatal outcomes, including preterm birth and stillbirth [15]. In Saudi Arabia, available studies are limited to hospital-based cohorts describing clinical characteristics and pregnancy outcomes of ICP, without regional stratification or assessment of seasonal variation [14]. Seasonal effects have been reported in other populations, with lower ICP frequency observed in winter (4.8%) and in spring (34.9%), indicating a possible seasonal influence on disease occurrence [4]. Population-based cohort data from China involving 12,200 pregnant women reported an overall ICP incidence of 6.06% and identified several maternal and pregnancy-related risk factors [1]. Biochemical factors have also been implicated, as lower serum 25-hydroxyvitamin D levels were observed in women with ICP and were inversely associated with bile acid concentrations, although no clear association with adverse perinatal outcomes was demonstrated [17]. Despite the availability of international and national data, no published studies have specifically examined the epidemiology or seasonal variation of ICP in the Qassim region, highlighting a clear research gap that the present study aims to address.

Research objectives

Research aim:

To assess seasonal differences in the incidence and biochemical severity of intrahepatic cholestasis of pregnancy (ICP) among patients at MCH between January 2020 and Jan 2026.

Specific objectives:

1. To determine the month and seasonal incidence of ICP among all deliveries in MCH from January 2020 to January 2026
2. To assess the maternal biochemical profile (bile acids, liver function tests) severity in women diagnosed with ICP in correlation with different months & seasons.
3. To examine the association between average monthly local temperature with number of ICP incidence.
4. To explore demographic and obstetric predictors of ICP in the context of seasonal variations.

Materials and Methods

Study design: Retrospective observational study hospital based.

Study setting: The research was conducted at Maternity and Children Hospital (MCH) in Buraydah, Al-Qassim Region, Saudi Arabia.

Study duration: From January 2020 to January 2026

Sample size: All women with confirmed ICP during the time period of Jan 2020- Jan 2026 were included

Sampling technique (with inclusion and exclusion criteria): Inclusion criteria: pregnant women either singleton or multiple who delivered at MCH with confirmed intrahepatic cholestasis of pregnancy (ICP), defined as pruritus with elevated bile acids ≥10 μmol/L and/or abnormal liver function tests, and who had complete records including diagnosis date and lab results. Exclusion criteria: -Other causes of hepatic dysfunction include gallstones, autoimmune liver disease, viral hepatitis, and severe preeclampsia. - Missing lab data or incomplete records.

Data collection methods: Data was collected from Ministry of Health (MoH) records Eligible cases were women diagnosed with intrahepatic cholestasis of pregnancy. A standardized Excel extraction sheet was used to obtain demographic information, obstetric variables, time of diagnosis, delivery outcomes, and season of occurrence. Laboratory levels of bile acids, Liver enzymes (ALT, AST. ALP Delivery outcome included mode of delivery, preterm birth, still birth, Apgar scores, fetal weight). Seasons were assigned as winter (Dec-Feb), Spring (Mar-May) Summer (June-Aug) Autumn (Sep-Nov)

Data management and analysis plan: All extracted data was entered into a secure Excel/SPSS database. Descriptive statistics (means, standard deviations, frequencies, and percentages) were used to summarize demographics, obstetric variables, and delivery outcomes. Comparative analysis was performed to assess differences in maternal and neonatal outcomes between cases diagnosed in early winter (December–January) versus late winter (February–March). Categorical variables were compared using the chi-square or Fisher's exact test, and continuous variables were compared using the student's t-test. A p-value of less than 0.05 was considered statistically significant.

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Ethical considerations: Ethical approval was obtained from the Institutional Review Board (IRB) of Qassim University, followed by approval from the Ministry of Health. Numbered 607-47-013208 dated 13/4/2026. As a retrospective study using existing patient records, informed consent was waived. All data was anonymized and handled confidentially, with no identifying information collected or stored. The study complies with the Declaration of Helsinki, institutional data protection policies, and applicable national research ethics guidelines.

Findings

Demographic characteristics

A total of 68 women diagnosed with intrahepatic cholestasis of pregnancy (ICP) were included in the study. The mean maternal age was 31.46 years (SD = 6.23), with the youngest and oldest participants being 19 and 48 years old, respectively. The mean body mass index (BMI) was 30.36 kg/m² (SD = 6.29). Participants had a mean gravidity of 2.78 (SD = 1.82) and a mean parity of 1.40 (SD = 1.61). Most pregnancies were singleton pregnancies (91.2%, n = 62), while 8.8% were multiple pregnancies (n = 6). A previous history of ICP was reported by 11.8% of participants (n = 8), whereas 88.2% had no prior history of ICP (n = 60). Regarding disease severity, 45.6% had moderate ICP (n = 31), 27.9% had mild ICP (n = 19), and 25.0% had severe ICP (n = 17). The majority of women (92.6%) received ursodeoxycholic acid (UDCA) treatment (n = 63). Two-thirds of the women experienced preterm delivery (67.6%, n = 46), while 32.4% (n = 22) delivered at term. Induction of labour was done in 42.6% (n = 29) of pregnancies, and caesarean section was the predominant mode of delivery (69.1%, n = 47), whereas 30.9% were vaginal deliveries (n=21). Maternal comorbidities included hypertension in 13.2% (n = 9) of participants and diabetes in 14.7% of the participants (n = 10). (Table-1)

Table 1: Summary of demographic and maternal characteristics.

Characteristic	Summary
Maternal age	31.46 ± 6.23 (range: 19–48)
BMI	30.36 ± 6.29 (range: 21.0–44.9)
Gravidity	2.78 ± 1.82 (range: 1–7)
Parity	1.40 ± 1.61 (range: 0–5)
Multiple Pregnancy	
Yes	6 (8.8%)
No	62 (91.2%)
Hypertension	
Yes	9 (13.2%)
No	59 (86.8)
Diabetes	
Yes	10 (14.7%)
No	58 (85.3%)
Mode of delivery	
Caesarean section	47 (69.1%)
Vaginal	21 (30.9%)
Previous ICP	
Yes	8 (11.8%)
No	60 (88.2%)
UDCA use	
Yes	63 (92.6%)
No	5 (7.4%)
Meconium present	
Yes	20 (29.4%)
No	48 (70.6%)
NICU admission	
Yes	24 (35.3%)
No	44 (64.7%)
Induction of Labor	
Yes	29 (42.6%)
No	39 (57.4%)
Stillbirth	
Yes	1 (1.5%)
No	67 (98.5%)

Objective 1: Month and Seasonal Incidence

A total of 2461 ICP cases were recorded during the study period. The monthly distribution of cases showed that December had the highest proportion of ICP cases (n=461), accounting for 18.73% of all the cases, and when grouped by seasons, winter accounted for the largest proportion (41.28%) of ICP cases. (Table-2)

Table 2: Monthly and seasonal Incidence

Month	n	Rate (%)	Season	n	Rate (%)
DEC	461	18.73	WINTER	1016	41.28
JAN	372	15.12			
FEB	183	7.44			
MAR	215	8.74	SPRING	754	30.64
APR	209	8.49			
MAY	330	13.41			
JUN	39	1.58	SUMMER	470	19.1
JULY	286	11.62			
AUG	145	5.89			
SEP	37	1.5	AUTUMN	221	8.98
OCT	110	4.47			
NOV	74	3			
	2461	100		2461	100

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Objective 2: Maternal biochemical profile severity in women diagnosed with ICP

A Kruskal-Wallis H test was conducted to assess the maternal biochemical profile (bile acids, liver function tests) severity in women diagnosed with ICP in correlation with different months & seasons. None of the four markers differed significantly across the 12 months: serum bile acids, H(11) = 15.45, p =0 .163; ALT, H(11) = 15.32, p =0 .168; AST, H(11) = 15.11, p =0 .177; and bilirubin, H(11) = 11.05, p = .439. Similarly, none of the markers differed significantly by season: serum bile acids, H(3) = 1.83, p =0 .608; ALT, H(3) = 6.04, p =0 .110; AST, H(3) = 5.00, p = 0.172; and bilirubin, H(3) = 1.36, p =0 .714. (Table3 and 4)

Table 3: Kruskal-Wallis Test Statistics for Biochemical Markers by Month and Season (N = 68).

Marker	Grouping variable	H	df	p
Serum bile acids	Month of diagnosis	15.45	11	0.163
	Season	1.83	3	0.608
ALT	Month of diagnosis	15.32	11	0.168
	Season	6.04	3	0.11
AST	Month of diagnosis	15.11	11	0.177
	Season	5	3	0.172
Bilirubin	Month of diagnosis	11.05	11	0.439
	Season	1.36	3	0.714

Table 4: Mean Ranks for Biochemical Markers by Season (N = 68).

Marker	Winter (n = 23)	Spring (n = 16)	Summer (n = 12)	Autumn (n = 17)
Serum bile acids	33.41	30.06	39.46	36.65
ALT	40.33	30.31	39.67	26.91
AST	38.09	28.22	42.17	30.15
Bilirubin	30.96	37.91	36.71	34.53

Objective 3: Association between average monthly local temperature and number of ICP incidence.

A Spearman rank-order correlation was computed to examine the association between average monthly local temperature and the number of ICP incidence. There was no statistically significant association between monthly temperature and ICP incidence, rs(66) =0 .10, p =0 .425, 95% CI [-0.15,0.34], N = 68. (Table-5)

Objective 4: Demographic and obstetric predictors of ICP in the context of seasonal variations.

A multinomial logistic regression was conducted to examine whether season, maternal age, body mass index (BMI), gravidity, parity, multiple pregnancy, previous ICP, temperature, hypertension, and diabetes predicted ICP. The overall model was not statistically significant, $\chi^2(134, N = 68) = 143.83$, p = 0.265 (Cox and Snell R^2 = .88; Nagelkerke R^2 = 1.00; McFadden R^2 = 1.00). (Table-6)

Table 5: Spearman's Rank-Order Correlation Between Mean Temperature and ICP Severity.

Variable	Mean temperature (°C)	ICP severity
Mean temperature (°C)	-	
ICP severity	0.1	-

Note. Cox and Snell R^2 =0 .88, Nagelkerke R^2 = 1.00, McFadden R^2 = 1.00

Table 6: Likelihood Ratio Tests for Individual Predictors of ICP Severity.

Effect	χ^2	df	p
Maternal age	2.77	4	0.597
BMI	2.77	52	1
Temperature category	5.55	2	0.062
Season	0	0	-
Gravidity	0	0	-
Parity	0	0	-
Multiple pregnancy	0	0	-
Previous ICP	0	0	-
Hypertension	0	0	-
Diabetes	0	0	-

Discussion and Conclusion

Intrahepatic cholestasis of pregnancy is known to cause adverse perinatal outcomes such as preterm birth, meconium-stained amniotic fluid and still birth due to increased total bile acid levels [18]. The present study found that CS was the predominant mode of delivery which could potentially explain most deliveries that were conducted pre-term to protect them from adverse foetal and neonatal outcomes which consequently resulted in high NICU admission rates. Even though ICP is strongly associated with meconium-stained amniotic fluid, this study found that a minority (30%) of the women with ICP had meconium-stained amniotic fluid and only one-woman experienced stillbirth; these positive outcomes can be attributed to the remarkable uptake of ursodeoxycholic acid treatment which was effective in mitigating the negative perinatal outcomes [19,20].

The present study findings indicate that approximately 41% of all ICP cases occurred during winter, with December accounting for the highest monthly proportion. This finding

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suggests temporal clustering of ICP diagnoses during colder months in Al Qassim, Saudi Arabia. Although few studies have specifically evaluated seasonality, recent reviews continue to recognize seasonal fluctuations as a potential epidemiological feature of ICP while emphasizing that evidence remains inconsistent between countries [21]. Evidence regarding seasonality of ICP remains inconsistent across different settings with winter peaks reported in Scandinavia, Chile, and India while spring peaks were reported in Turkey [4,22,23] likewise lower incidences were reported in Saudi Arabia and other high-income countries compared with parts of Asia and South America [2]. Consequently, the clustering of ICP cases observed during the winter in the present study may represent regional environmental influences unique to the study area rather than a universal epidemiological pattern just as was the case in countries such as Sweden, Finland, and Chile [11].

Despite the observed temporal clustering, maternal serum bile acids, ALT, AST, and bilirubin did not differ significantly according to month or season. These findings suggest that environmental factors influencing the timing of diagnosis do not appear to alter the biochemical severity of ICP once the disease develops. Contemporary reviews describe ICP as a multifactorial disorder resulting primarily from genetic susceptibility, hormonal influences during pregnancy, and impaired hepatobiliary bile acid transport. Although environmental factors may contribute to disease onset, biochemical severity is more strongly associated with maternal bile acid concentrations than with seasonal variables [24]. The study found no statistically significant association between average monthly ambient temperature and ICP occurrence. This finding indicates that temperature alone is unlikely to explain seasonal variation in ICP within the Al Qassim region. Although climatic factors have been proposed as potential contributors to ICP evidence suggests that reduced winter sunshine and Vitamin D deficiency could be a potential contributor to pregnancy related hormonal changes [22].

Multinomial logistic regression demonstrated that maternal age, body mass index, gravidity, parity, previous ICP, multiple pregnancy, hypertension, diabetes, season, and temperature were not independently associated with ICP severity. These findings contrast with several recent systematic reviews that have identified previous ICP, multifetal pregnancy, gestational diabetes, hypertensive disorders, hepatitis infection, and assisted reproductive technologies as important risk factors for developing ICP [16,26,26,2].

Strengths and Limitations

This study represents the first investigation of seasonal ICP patterns in the Qassim region over six consecutive years in Saudi Arabia. However, the retrospective design is susceptible to incomplete clinical documentation, potentially reducing sample size for inferential analyses. The study was conducted at a single tertiary facility, which limited generalizability. Moreover, monthly delivery denominators were not incorporated into the seasonal analyses presented; therefore, the reported seasonal values represent the distribution of ICP cases rather than true incidence rates among all deliveries.

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Disclosure Statement

The authors declare that there are no financial or non-financial competing interests related to this study.

Conflict of interest

The authors report there are no competing interests to declare.

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