

Patient perspectives on pruritus in intrahepatic cholestasis of pregnancy: a multinational survey

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Introduction

- Cholestatic pruritus is one of the disease-defining symptoms of intrahepatic cholestasis of pregnancy (ICP)^{1,2}.
- In severe refractory cases, pruritus can lead to iatrogenic delivery with significant perinatal morbidity associated with prematurity³.
- In a large double-blind randomised controlled trial, up to 11% of participants with ICP were electively delivered for severe maternal symptoms⁴.
- Current therapies offer minimal effectiveness for cholestatic pruritus associated with ICP, which for many women may not be worthwhile⁵.

Aim

- To characterize the severity of cholestatic pruritus, the impact on quality of life, and the effectiveness of available treatments from the patient's perspective.

Methods

- A 30-question web-based survey was distributed to international participants via an ICP patient support group; key questions are outlined in Table 1.
- Participants were asked to assess itch severity and sleep disturbance using a numerical rating scale (NRS) of 0–10 (0, none; 10, most severe).
- Anonymized responses were collected between August 25 and September 10, 2020.
- Results were tabulated and percentages are presented based on non-missing data.

Figure 1: Distribution of worst itch severity

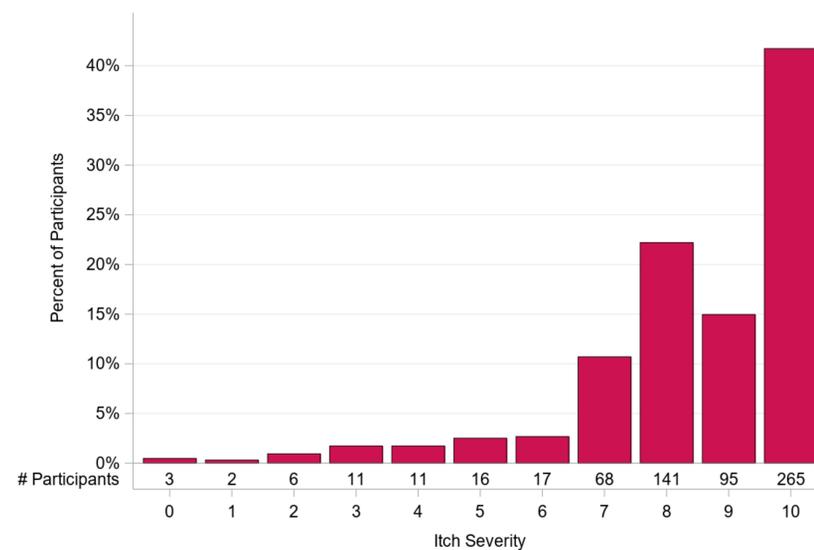


Figure 2: Itch and sleep disturbance severity

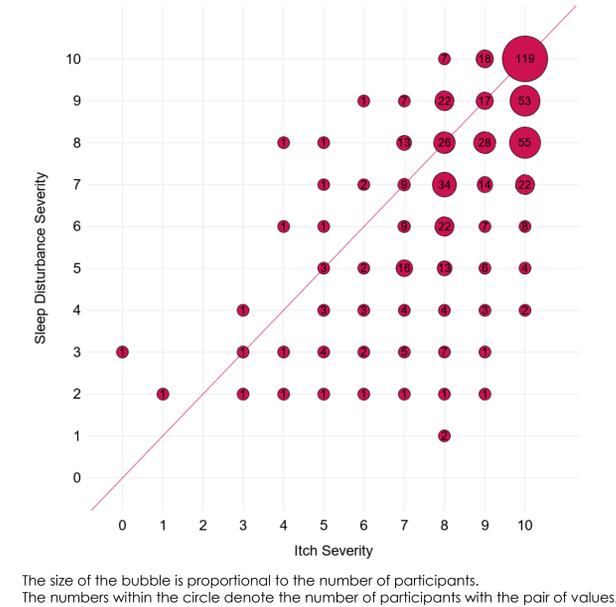


Table 2: Most common medications taken to treat pruritus symptoms and outcome

Medication	Reported Use	Participants, n (%)		
		w/ No Impact	w/ Partial Resolution	w/ Full Resolution
UDCA	523 (76.0%)	243 (47.0%)	237 (45.8%)	37 (7.2%)
Antihistamines	319 (46.4%)	227 (74.7%)	75 (24.7%)	2 (0.7%)
Creams/ointments	258 (37.5%)	111 (45.1%)	135 (54.9%)	0

Note: Percentages for impact (no impact, partial and full resolution) are based out of those who reported use and impact. No impact also includes responses of "Not sure" and "N/A".

Results

- Of 688 women who responded, 352 (51.2%) lived in the UK, 162 (23.5%) in the US, 54 (7.8%) in Australia, 19 (2.8%) in Canada, 10 (1.5%) in New Zealand, 8 (1.2%) in Ireland; 51 (7.4%) did not provide a nationality, and 32 (4.7%) were from 19 other countries
- Median worst itch reported for the most recent ICP pregnancy was 9 on an NRS (0 for "no itch", 10 for "worst itch you can possibly imagine")
 - 90% reported a worst itch of ≥ 7 and 42% reported a 10 (Figure 1)
- 77% reported itching symptoms were worse at night; 94% reported itch-related sleep disturbances, with median degree of disturbance reported being 8 out of 10
 - Itch severity was associated with a higher degree of reported sleep disturbance (Figure 2)
- 93% reported that itch made their fatigue "somewhat worse" (30%) or "much worse" (63%)
- 75% reported that itch was associated with mood changes, including but not limited to increased anxiety, feelings of hopelessness and/or irritability
- 59% reported that itch led to disruption of day-to-day responsibilities and routines, 44% of whom reported that the disruption lasted > 30 days
- 33% reported missing school or work during an episode of itching
- 71% were **NOT** asked about itch by their prenatal care providers; 89% of providers did investigate further once the participant confirmed presence of pruritus
 - 81% ordered lab/blood tests
 - 31% recommended medications
 - 58% of participants reported taking ≥ 2 medications for itch and 29% took ≥ 3 medications
 - Most common medications were UDCA (76%), antihistamines (46%), topical creams or ointments (38%); in the majority of cases, these medications achieved only partial resolution or had no impact on itch
 - <5% were referred to another doctor

Conclusions

- This international survey underscores the debilitating effects of pruritus in ICP.
- A large proportion of participants experienced a substantial impact on quality of life, most of which was not elicited by their prenatal care providers.
- A majority reported taking ≥ 2 medications for itch, most without knowledge of their providers.
- Consistent with prior studies, most participants reported either partial or no resolution of ICP-associated pruritus with existing therapies.
- These data highlight the high unmet need for development of safe and effective therapies for patients with ICP.

Table 1. Selected survey questions

Itch Survey Questions	
	In which country do you currently live?
Itch manifestation and severity	Did your antenatal or prenatal care provider ask you about itching, or mention it to you as a symptom to report to them?
	If you mentioned being itchy to your provider, did he/she investigate your symptoms further?
	If YES, what was done?
	Which of the following medications are you taking, or have you taken in the past to treat your ICP itch?
	Please indicate how well the medication reduced your itch.
Itching and Quality of Life	When you have experienced itching, is it/was it worse at certain times during the day?
	If YES, at what time of the day is/was it the worst?
	How would you rate the worst itch you experienced during most recent pregnancy?
	Has your itch caused a disturbance in your sleep?
	If YES, please rate to what degree
	Is your sleep disturbance associated with your itch severity?
	Please complete the following sentence: My itching makes my fatigue level:
Has your itch contributed to changes in your fatigue level?	
Has your itch been associated with mood changes (such as but not limited to increased anxiety, feelings of hopelessness and/or irritability)?	
During an episode of itching, have you had to miss school or work?	
Has an episode of itching disrupted your day-to-day responsibilities and/or routines?	
If YES, how long did your itching disrupt your day-to-day responsibilities and/or routines?	

