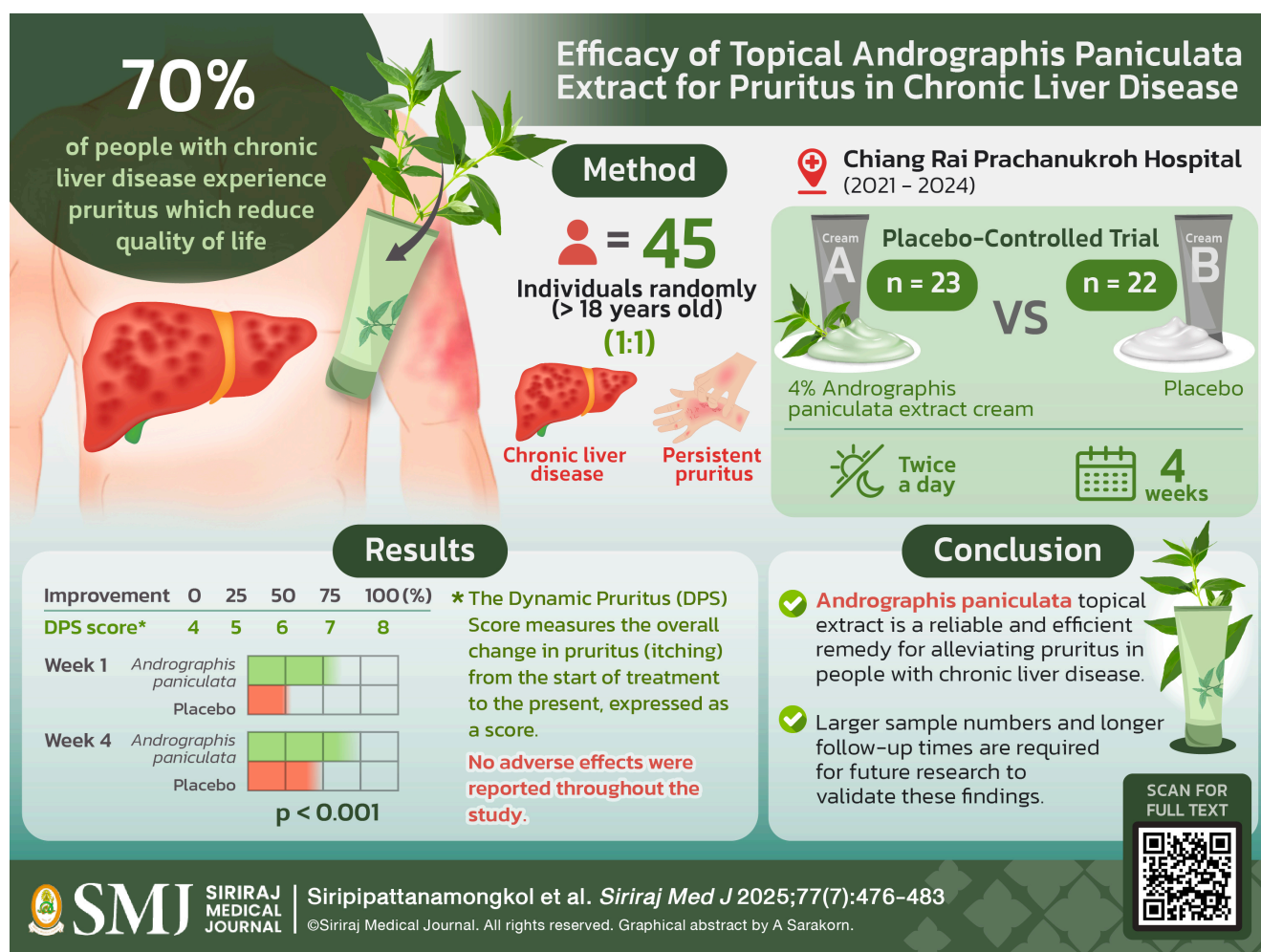


Efficacy of Topical *Andrographis Paniculata* Extract for Pruritus in Chronic Liver Disease: A Randomized, Placebo-Controlled Trial

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ABSTRACT

Objective: Assessing the effectiveness of topical extract from *Andrographis paniculata*, which has anti-inflammatory properties, in reducing pruritus in individuals with chronic liver disease.

Materials and Methods: At Chiang Rai Prachanukroh Hospital, a randomized, placebo-controlled trial was carried out from 2021 to 2024. Forty-five individuals with chronic liver disease and persistent pruritus who were at least eighteen years old were randomly assigned (1:1) to receive 4% extract cream from *Andrographis paniculata* or a placebo, which was applied twice a day for four weeks. The dynamic pruritus score (DPS), which was used to measure pruritus severity at baseline, week 1, and week 4, was the main outcome. The dermatology life quality index (DLQI) was used to measure the quality of life as the secondary outcome.

Results: The *Andrographis paniculata* extract significantly improved the pruritus severity compared to placebo, with DPS scores of 6.31 ± 0.41 at week 1 and 6.82 ± 0.40 at week 4 versus 5.01 ± 0.24 and 5.59 ± 0.35 , respectively ($p < 0.001$). However, there was no significant difference in DLQI scores between treatments. There were no adverse effects reported, and one participant in the treatment arm withdrew due to logistical issues.

Conclusion: *Andrographis paniculata* topical extract is a reliable and efficient remedy for alleviating pruritus in individuals with chronic liver disease. However, larger sample numbers and longer follow-up times are required for future research to validate these findings and evaluate the impact on quality of life.

Keywords: *Andrographis paniculata*; pruritus; quality of life; chronic liver disease; topical treatment (Siriraj Med J 2025; 77: 476-483)

INTRODUCTION

Up to 70% of people with chronic liver disease, especially those with cholestatic liver disease, experience pruritus, a common and upsetting symptom.¹ It may significantly lower the patient's standard of living, with some patients experiencing such intense itching that it leads to depression or even suicidal ideation.^{2,3} Despite its prevalence, little is known about how it develops in chronic liver disease. While bile acids were historically implicated as the primary culprits due to their toxic effects on skin and nerve endings^{3,4}, recent studies have found lysophosphatidic acid and its precursor enzyme, autotaxin, as key mediators of itching. Elevated levels of these substances correlate with pruritus severity and decrease with symptom improvement.⁵⁻⁸

Current treatments for pruritus in chronic liver disease are limited and often inadequate. While addressing the underlying cause, such as removing bile duct obstructions, can alleviate symptoms, numerous cholestatic conditions, including progressive familial intrahepatic cholestasis, primary biliary cirrhosis, and primary sclerosing cholangitis, are incurable.^{9,10} Available pharmacological options, such as cholestyramine, rifampicin, naloxone, and sertraline, are taken orally and associated with significant side effects, some of which can be severe or life-threatening.¹¹⁻¹⁵ These drawbacks highlight how urgently safer and more efficient treatments are needed to control itching in this patient group.

Andrographis paniculata, a traditional medicinal herb, has garnered attention for its potent anti-inflammatory properties.¹⁶⁻²³ The cytokines TNF- α , IL-1 β , and IL-6 that are linked to itching and inflammation are inhibited by its active ingredients, which include andrographolide and related diterpenes.¹⁶⁻¹⁹ Preclinical studies have proved the herb's efficacy in reducing inflammation in animal models^{20,21}, and studies on humans have demonstrated potential in reducing the symptoms of diseases such as upper respiratory infections and rheumatoid arthritis.^{22,23} Although evidence specific to dermatological applications is limited, *Andrographis paniculata*'s immunomodulatory and anti-inflammatory properties point to its potential as a pruritus treatment.

The purpose of this study was to assess *Andrographis paniculata*'s effectiveness as a topical remedy for pruritus in individuals suffering from chronic liver disease. It is anticipated that this novel, complementary approach will improve the quality of life for individuals suffering from this debilitating symptom due to its anti-inflammatory properties and potential to alleviate itching.

MATERIALS AND METHODS**Study population and design**

This randomised, placebo-controlled study was conducted at Chiang Rai Prachanukroh Hospital, Thailand, from 2021 to 2024. All participants provided written informed consent before enrolling in the study, and the

research protocol was registered with the Thai Clinical Trial Registry (TCTR20250206011) after being approved by the Chiang Rai Prachanukroh Hospital's Research Ethics Committee (approval number: EC CRH 125/63In).

The following were the requirements for inclusion: 18 years of age or older, with a diagnosis of cholestatic or chronic liver disease, and a history of widespread itching that lasts longer than two weeks. The exclusion criteria included: a known allergy to *Andrographis paniculata*; the use of topical steroids within the past 2 weeks; impaired consciousness due to hepatic encephalopathy or other conditions; life expectancy of fewer than 4 weeks; pregnancy or breastfeeding; blood pressure below 90/60 mmHg; low platelet count ($<50,000/\text{mm}^3$) or abnormal blood clotting (INR >1.5); or an underlying skin diseases (e.g., atopic dermatitis, psoriasis, dermatophytosis, candidiasis, or chronic skin infections).

All participants continued to receive standard treatments for pruritus, including antihistamines, ursodeoxycholic acid, and moisturising cream throughout the study period.

Participants were randomly assigned in equal proportions using a computer-generated block randomization method to receive either a 4% *Andrographis paniculata* extract cream or a placebo moisturizing cream. The creams were packaged in identical 30 g white tubes labelled as "Drug A" or "Drug B" with the active cream being light green while the placebo was white, ensuring visual similarity. Researchers, outcome assessors, and participants were blinded to treatment assignments throughout the study.

Active Treatment: The 4% *Andrographis paniculata* extract cream was prepared by SBU Corporation and contained standardised concentrations of active compounds including andrographolide and related diterpenes.

Placebo: The placebo cream was a moisturising cream with identical appearance, texture, and packaging to the active treatment but lacked the active ingredients.

Participants were instructed to apply the assigned cream to the affected area twice daily for four weeks (total dose: 360 g of cream). Compliance was checked through self-reporting and tube weight measurements at follow-up visits.

Pruritus Severity

The primary outcome was the change in pruritus severity assessed using the dynamic pruritus score (DPS) at baseline, 1 week, and 4 weeks after treatment initiation. The DPS is a validated tool that captures fluctuations in pruritus intensity over time by incorporating both peak

and average itch severity, providing a comprehensive evaluation of symptom changes.²⁵

The DLQI, or Dermatology Life Quality Index

The variance in quality of life, as measured by the DLQI in Thai at the same intervals, was the secondary result. Higher scores indicate a greater loss in quality of life. The DLQI is a well-known 10-item questionnaire that assesses how skin disorders affect patients' everyday activities, emotional health, and social interactions.²⁶⁻²⁹

Analysis of statistics

Using a 5% alpha error, we determined that each group should initially consist of 19 participants to ensure there is an 80% chance of detecting a 50% difference in pruritus severity between the groups. Considering an expected dropout rate of 15%, the final sample size for each group will be adjusted to 22 individuals. Descriptive statistics were used to summarize the baseline clinical and demographic features. Depending on the data distribution, continuous variables are either provided as mean \pm standard deviation (SD) or median (interquartile range, IQR). The Student's t-test or the Wilcoxon rank-sum test are used for analysis. Frequencies and percentages are used to compare categorical variables using the chi-square or Fisher's exact test. Repeated-measures ANOVA or appropriate non-parametric techniques were used to evaluate changes in DPS and DLQI scores over time. Stata Version 14 and the intention-to-treat (ITT) method were used for all statistical computations, and a $p < 0.05$ was deemed statistically significant.

RESULTS

Study population

Initially, 63 patients were assessed for eligibility, of which, 18 patients were excluded, with 12 not meeting the inclusion criteria, 5 were unable to adhere to the follow-up protocol, and 1 declined to take part (Fig 1). Consequently, 45 patients were enrolled and randomised into two groups: the *Andrographis paniculata* topical treatment ($n=23$) or placebo ($n=22$). One participant in the treatment group dropped out due to logistical challenges, resulting in a final cohort of 44 patients ($n=22$ in each group) completing the study.

Baseline characteristics

Table 1 summarizes the baseline characteristics of the patients and reveals no significant differences between the groups. With comparable Child-Turcotte-Pugh scores in both groups, the causes of chronic liver disease (such as viral or alcoholic hepatitis) and the presence of

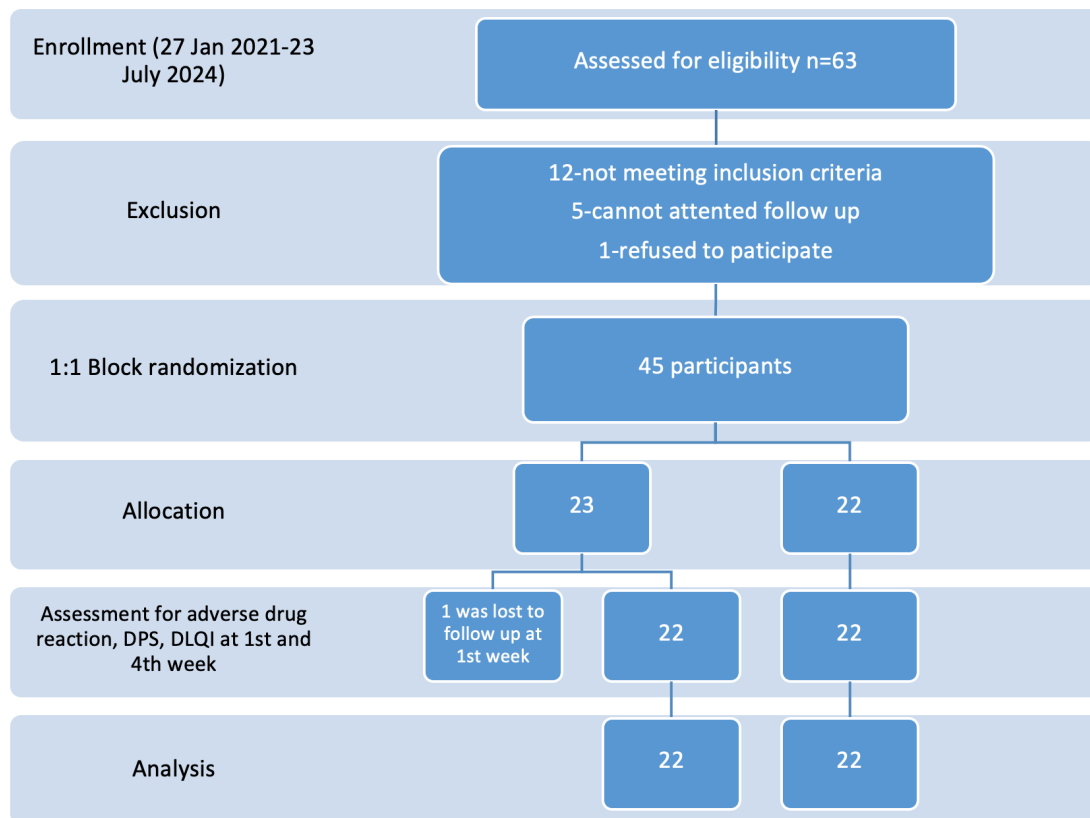


Fig 1. Study flowchart

Abbreviations: DPS: Dynamic pruritus score, DLQI: Dermatology Life Quality Index

comorbidities (such as diabetes, hypertension, or chronic kidney disease) were likewise equally distributed.

Overall, the mean duration of pruritus was 5.12 ± 7.60 weeks with a shorter duration in the treatment group (3.39 ± 2.10 weeks) compared to the placebo (7.00 ± 10.46 weeks), although this difference was not statistically significant ($p = 0.112$). At the outset, both groups experienced moderate quality of life impairment, with DLQI scores of 9.74 in the treatment group and 7.45 in the placebo group ($p = 0.289$).

Effects of *Andrographis paniculata* compared to placebo

Participants treated with *Andrographis paniculata* showed significant improvement in pruritus severity compared to the placebo group (Table 2). At week 1, the mean DPS was 6.31 for the treatment group versus 5.04 for the placebo group. By week 4, the mean DPS increased to 6.82 in the treatment group compared to 5.59 in the placebo group ($p < 0.001$).

Over the course of the trial, both groups demonstrated improvements in quality of life as measured by the DLQI, with the treatment group showing a trend of more noticeable improvement, however there was no statistical significance (Table 2). The treatment group's

baseline DLQI scores were 9.74 ± 1.64 , while the placebo group's were 7.45 ± 1.33 . Despite ongoing progress, the treatment group did not vary significantly from the placebo group ($p = 0.096$).

Side effects

Both creams were well-tolerated by all participants with no adverse effects reported throughout the study period.

DISCUSSION

This randomised, placebo-controlled study is the first to evaluate the efficacy of topical *Andrographis paniculata* extract cream for relieving itching in patients with chronic liver disease, showing that *Andrographis paniculata* significantly reduced pruritus severity, as measured by the DPS, compared to placebo. However, this was not accompanied by any considerable improvement in their quality of life. These findings suggest that *Andrographis paniculata* is a safe and effective adjunctive treatment for pruritus in this patient population.

The anti-pruritic effects of *Andrographis paniculata* observed align with its known anti-inflammatory and immunomodulatory properties. The herb contains

TABLE 1. Participant's baseline characteristics.

Characteristic	<i>Andrographis paniculata</i> extract (N=23)	Placebo (N=22)	p-value
Age	58.95 ± 11.77	57.40 ± 10.45	0.644
Male, (n, %)	14 (60.87)	9(40.91)	0.149
BMI	23.22 ± 3.36	24.51 ± 4.00	0.249
Cause of chronic liver disease/cholestasis, n (%)			
Alcoholic hepatitis	7 (30.43)	9(40.91)	0.779
PBC/autoimmune hepatitis	4 (17.39)	3(13.64)	
Cholangiocarcinoma	3 (13.04)	1(4.55)	
Bile duct stone	1 (4.35)	0 (0)	
Viral hepatitis	7 (30.43)	6 (27.27)	
Drug-induced liver injury	0 (0)	1 (4.55)	
MASH with cirrhosis	0 (0)	1 (4.55)	
Idiopathic	1(4.35)	0 (0)	
Hypertension, n (%)	4 (17.39)	8 (36.36)	0.135
Diabetes, n (%)	3 (13.04)	5 (22.73)	0.324
Hyperlipidemia, n (%)	1 (4.35)	1 (4.55)	0.744
Chronic kidney disease, n (%)	3 (13.04)	4 (18.18)	0.474
HIV infection, n (%)	1 (4.35)	0 (0)	0.511
Atopic dermatitis, n (%)	1 (4.35)	0 (0)	0.511
Duration of pruritus (week)	3.39 ± 2.10	7.00 ± 10.46	0.112
Total bilirubin (mg/dL)	8.04 ± 8.57	5.07 ± 6.21	0.192
Albumin (g/dL)	3.41 ± 0.62	3.19 ± 0.61	0.214
Alkaline phosphatase (U/L)	199.37 ± 128.28	239.23 ± 163.61	0.367
Absolute eosinophil count (cell/mm ³)	238.09 ± 193.23	640.87 ± 1353.26	0.164
Child Turcotte Pugh score status, n (%)			0.930
Class A	10 (43.48)	8 (36.36)	
Class B	5 (21.74)	6 (27.27)	
Class C	8 (34.78)	8 (36.36)	
Dermatology Life Quality Index at baseline	9.74 ± 7.88	7.45 ± 6.25	0.289

Data is presented as mean ± standard deviation

Abbreviations: BMI, body mass index; HIV, human immunodeficiency virus; MASH, metabolic associated steatohepatitis; PBC, primary biliary cirrhosis; SD, standard deviation

TABLE 2. A comparison of the clinical outcomes of *Andrographis paniculata* extract vs placebo using the dynamic pruritus score and dermatology life quality index.

Outcome assessment	Andrographis paniculata extract (N=23)	Placebo (N=22)	Change in mean (95%CI)	p-value
Dynamic pruritus score (DPS)**				<0.001*
At baseline	reference	reference		
At first week	6.31 ± 0.41	5.04 ± 0.24	-1.27(-2.28,-0.32)	0.010*
At fourth week	6.82 ± 0.40	5.59 ± 0.35	-1.23(-2.31,0.15)	0.027*
Within-group p	<0.001*	<0.001*		
Dermatology Life Quality Index (DLQI)***				0.096
At baseline	9.74±1.64	7.45±1.33	-2.28(-6.57,2.00)	0.289
At first week	4.30 ± 1.23	5.32 ± 1.18	1.01(-2.50,4.46)	0.555
At fourth week	3.52 ± 1.27	4.5 ± 1.32	0.98(-2.71,4.67)	0.596
Within-group p	<0.001*	<0.001*		

Data is presented as mean ± standard error

*Shows statistically significant difference

** The Dynamic Pruritus Score measures the overall change in pruritus (itching) from the start of treatment to the present, expressed as a score. Scoring 4 indicates no change from the baseline, while scores of 5, 6, 7, and 8 represent 25%, 50%, 75%, and 100% improvement, respectively. Since the scoring is based on changes relative to the baseline, the baseline scores themselves are not displayed.

*** Dermatology Life Quality Index, a higher score means more worsening impact on quality of life

active compounds such as andrographolide and dehydroandrographolide, which inhibit pro-inflammatory cytokines such as TNF- α , IL-1 β , and IL-6, and deactivate histamine release and mast cell activity^{16-20,24} to alleviate itching. Previous study had also proved the effectiveness of *Andrographis paniculata* in reducing itching in end-stage renal disease patients³⁰, supporting its potential utility across different conditions characterised by chronic itching.

The significant reduction in itching severity due to the topical administration of the *Andrographis paniculata* extract underscores its therapeutic potential. However, the DLQI scores did not significantly improve, possibly due to the small sample size restricting the statistical power needed to find a subtle improvement in the quality of life. Furthermore, patients with advanced liver disease often experience systemic symptoms such as fatigue and malnutrition, which may overshadow dermatologic improvements and limit the sensitivity of the DLQI in capturing the full impact of pruritus relief.²⁶⁻²⁹

This study's rigorous randomised, placebo-controlled design and use of standardised end measures (DLQI and

DPS) are two of its many strong points. Additionally, the absence of adverse effects highlights the safety of topical *Andrographis paniculata* extract in this population. However, it is not without its limitations, such as the small sample size and the short treatment duration (four weeks) may have constrained the ability to detect significant changes in quality of life or long-term effects. Furthermore, the use of pre-existing anti-pruritic medications may have introduced confounding variables. To verify these results and investigate the processes behind *Andrographis paniculata*'s anti-pruritic benefits, future studies should employ larger sample numbers, longer follow-up times, and stricter management of concurrent drugs.

This study has important clinical implications. Pruritus in chronic liver disease is difficult to manage with few safe and effective treatments. Topical *Andrographis paniculata* extract shows promise as a well-tolerated, effective therapy for reducing itching. Moreover, its inclusion in Thailand's National List of Essential Medicines for other uses supports its safety and potential for wider clinical application.³¹

In conclusion, the *Andrographis paniculata* topical extract is a reliable and efficient remedy for alleviating pruritus in individuals with chronic liver disease. Its strong anti-pruritic effects and favourable safety profile make it a valuable adjunctive therapy. More research is necessary to confirm these findings, investigate the mechanisms of action, and assess the long-term benefits in larger and more diverse patient groups.

Data Availability Statement

Due to the regulations of the Institutional Review Board (IRB) at Chiang Rai Prachaukroh Hospital and the privacy rules of the Health Insurance Portability and Accountability Act (HIPAA), the datasets generated and analysed during the current study are not publicly available. However, they can be accessed upon reasonable request from the corresponding author.

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DECLARATIONS

Grants and Funding Information

This research received no grant or funding support.

Conflict of Interest

The *Andrographis paniculata* extract cream and placebo used in this study were manufactured by SBU Corporation Co., Ltd. The researcher has no financial interest or shareholder position in the company.

Registration Number of Clinical Trial

Thai Clinical Trial Registry (TCTR20250206011).

Author Contributions

Conceptualization and methodology, CS, VT, PS, NC; Formal analysis, PS, NC; Investigation; CS, VT; Visualization and writing – original draft, CS; Writing – review and editing, CS; All authors have read and agreed to the final version of the manuscript.

Use of Artificial Intelligence

AI was used to assist with translation from Thai to English in some parts of introduction and first part of discussion.

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