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CHANGES IN ELASTOGRAPHY PARAMETERS IN PATIENTS WITH HEPATITIS C AFTER THE USE OF TRADITIONAL FOLK REMEDIES

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Abstract: Background*:* Hepatitis C virus (HCV) infection often leads to progressive liver fibrosis, which can be non-invasively assessed by elastography. Despite the availability of direct-acting antivirals (DAAs), interest in complementary and alternative therapies remains high in many regions. *Objective:* This study aimed to evaluate the effects of selected traditional folk remedies on liver stiffness as measured by transient elastography in patients with chronic HCV infection. *Methods:* A prospective, single-center study was conducted on 80 adult patients with chronic HCV. Patients in the intervention group (n=40) received a standardized regimen of herbal extracts (based on commonly used folk remedies), while the control group (n=40) received no additional herbal therapy. All patients were on standard antiviral therapy. Liver elastography (FibroScan®) was performed at baseline and at 12 weeks post-intervention. Biochemical markers (ALT, AST) and patient-reported outcomes were also recorded.
Results: Compared with controls, the intervention group demonstrated a modest but statistically significant reduction in liver stiffness values (mean difference -1.2 kPa, p=0.03). Improvements in serum ALT and AST levels were also observed, although these did not reach statistical significance (p>0.05). No serious adverse events were reported, and overall tolerability was high. *Conclusion:* The addition of certain traditional folk remedies to standard antiviral therapy may contribute to mild improvements in liver elasticity in patients with chronic HCV. Further large-scale, randomized controlled trials are needed to confirm these findings and elucidate mechanisms of action.

Keywords: folk medicine, traditional remedies, herbal therapy, milk thistle, antiviral activity, liver health.

Introduction

Hepatitis C virus (HCV) remains a major global health challenge. Despite the availability of highly effective direct-acting antivirals (DAAs), there is growing interest in integrative approaches that combine modern treatment strategies with traditional or alternative medicine. This interest is particularly notable in regions where herbal remedies have been used historically and continue to be a part of cultural health practices.

Liver fibrosis progression in HCV can be non-invasively monitored by transient elastography (commonly measured via FibroScan®), which quantifies liver stiffness. While antiviral therapy can effectively reduce viral load and eventually cure HCV, lingering inflammation or fibrosis may persist, leading some practitioners and patients to explore additional interventions to address hepatic injury.

Traditional folk remedies for liver disease vary across cultures. Many of these formulations include hepatoprotective herbs (such as milk thistle, licorice root, turmeric, and other botanicals) that have antioxidant, anti-inflammatory, or antiviral properties [7]. Although anecdotal evidence and small-scale studies suggest potential benefits, rigorous scientific data remain limited.

The purpose of this study was to investigate whether a standardized combination of common folk remedies, used adjunctively with standard antiviral therapy, could yield measurable improvements in liver stiffness and associated biochemical markers in patients with chronic HCV infection [8].

Methods

Study Design and Setting

This was a prospective, single-center study conducted at a tertiary care hospital's hepatology department. Ethics approval was obtained from the Institutional Review Board (IRB) prior to study initiation. All patients provided written informed consent.

Patient Selection

- **Inclusion Criteria:**

1. Age ≥18 years
2. Confirmed chronic HCV infection (positive HCV RNA for more than six months)
3. Compensated liver disease (Child-Pugh Class A)
4. Undergoing or eligible to undergo standard DAA therapy

- **Exclusion Criteria:**

1. Co-infection with hepatitis B or HIV
2. Decompensated cirrhosis (Child-Pugh Class B or C)
3. Prior use of any investigational herbal or alternative therapy specifically targeting HCV within 3 months before enrollment
4. Any significant comorbidity that would interfere with the study (e.g., advanced renal disease, active malignancy)

A total of 80 patients were enrolled. Using simple randomization, they were assigned to one of two groups (1:1 ratio):

1. **Intervention Group (n=40)**: Received a standardized folk remedy regimen in addition to standard DAA therapy.
2. **Control Group (n=40)**: Received standard DAA therapy only.

Intervention: Traditional Folk Remedies

The standardized herbal regimen was chosen based on a survey of local folk medicine practices and existing literature on hepatoprotective botanicals [9]. The final combination included:

- **Milk Thistle (Silybum marianum)** extract (standardized to 70–80% silymarin), 140 mg twice daily
- **Licorice Root (Glycyrrhiza glabra)** extract, 250 mg once daily
- **Turmeric (Curcuma longa)** extract (standardized to 95% curcuminoids), 500 mg once daily

The herbs were administered orally for 12 weeks. All preparations were provided by a reputable manufacturer specializing in standardized herbal supplements to minimize variability in active ingredients.

Antiviral Therapy

All patients received a standard 12-week course of direct-acting antivirals appropriate for their HCV genotype (e.g., sofosbuvir/ledipasvir or glecaprevir/pibrentasvir). The choice of regimen was guided by the treating physician according to standard-of-care protocols.

Data Collection and Outcome Measures

1. Baseline Assessments:

- Demographic data (age, sex, body mass index)
- Medical history (duration of HCV infection, prior treatments)
- Laboratory tests (ALT, AST, bilirubin, INR, albumin)
- HCV viral load (HCV RNA, log IU/mL)
- Liver elastography (FibroScan®), reported in kilopascals (kPa)

2. Follow-Up and Final Assessments (Week 12):

- Repetition of laboratory tests
- HCV viral load
- Liver elastography

Primary Outcome:

- Change in liver stiffness (kPa) as measured by transient elastography from baseline to Week 12.

Secondary Outcomes:

- Changes in ALT and AST levels
- Rate of virological response (undetectable HCV RNA at Week 12)
- Safety and tolerability (adverse events, patient-reported outcomes)

Statistical Analysis

Data were analyzed using SPSS (version 26.0). Continuous variables are presented as mean ± standard deviation (SD) or median (IQR) when appropriate, and categorical variables as frequencies (%). Between-group comparisons were made using the independent samples t-test (or Mann-Whitney U test, if non-parametric) for continuous variables, and Chi-square test for categorical variables. A p-value of <0.05 was considered statistically significant.

Results

Baseline Characteristics

Of the 80 patients enrolled (40 intervention, 40 control), 70 (87.5%) completed the study (3 patients in each group were lost to follow-up, primarily due to relocation or personal reasons, and 2 patients in the intervention group discontinued the herbal regimen due to mild gastrointestinal discomfort).

Baseline demographic, clinical, and laboratory characteristics were comparable between the two groups (Table 1). The mean (SD) age was 45.8 (±10.3) years in the intervention group and 44.3 (±9.8) years in the control group. Both groups had a near-equal distribution of males and females. Mean baseline liver stiffness values were similar (10.4 ± 2.1 kPa in the intervention group vs. 10.6 ± 2.3 kPa in the control group, $p = 0.54$).

Primary Outcome: Changes in Liver Stiffness

At Week 12, the intervention group demonstrated a mean reduction in liver stiffness of 2.1 kPa (from 10.4 ± 2.1 kPa to 8.3 ± 2.0 kPa), whereas the control group had a mean reduction of 0.9 kPa (from 10.6 ± 2.3 kPa to 9.7 ± 2.2 kPa). The between-group difference in stiffness reduction was -1.2 kPa (95% CI: -2.3 to -0.1, $p = 0.03$), favoring the intervention group.

Secondary Outcomes

1. Biochemical Markers

- **ALT:** Decreased from a mean of 65 ± 15 U/L to 45 ± 10 U/L in the intervention group vs. 62 ± 17 U/L to 50 ± 14 U/L in the control group ($p > 0.05$).
- **AST:** Decreased from a mean of 60 ± 13 U/L to 42 ± 9 U/L in the intervention group vs. 58 ± 14 U/L to 45 ± 11 U/L in the control group ($p > 0.05$).

While both ALT and AST levels improved in both groups, the differences did not reach statistical significance between groups. However, numerical trends supported the potential beneficial effect of the herbal supplements.

2. Virological Response

At Week 12, an undetectable HCV RNA (SVR12) was achieved in 92% of patients in the intervention group and 90% of patients in the control group ($p = 0.76$), indicating that the addition of the herbal regimen did not negatively influence antiviral efficacy.

3. Safety and Tolerability

No serious adverse events were reported. Mild gastrointestinal discomfort occurred in 2 patients in the intervention group, leading to discontinuation of the herbal regimen. No allergic reactions or significant changes in renal function, hemoglobin, or other labs were noted. Patients in both groups reported comparable compliance with DAA regimens.

Discussion

This study provides preliminary evidence that a combination of milk thistle, licorice root, and turmeric extracts, used as an adjunct to standard DAA therapy, may confer additional benefits in reducing liver stiffness among patients with chronic HCV. The modest yet statistically significant improvement in elastography values could suggest a synergistic effect of these botanicals on reducing liver inflammation or fibrosis progression.

Potential mechanisms include:

1. **Antioxidant Activity:** Silymarin (milk thistle) and curcuminoids (turmeric) have well-documented antioxidant properties, which may help mitigate oxidative stress in hepatocytes.

2. **Anti-Inflammatory Effects:** Licorice root contains glycyrrhizin, known to exert anti-inflammatory and immunomodulatory effects.

3. **Antifibrotic Action:** Reduced hepatic stellate cell activation has been reported with silymarin and curcumin in various in vitro and in vivo studies, potentially slowing fibrotic changes.

Although the reduction in aminotransferases (ALT, AST) did not reach statistical significance, the numerical trends favored the intervention group. Moreover, there was no negative impact on virological response, supporting the safety of combining these supplements with standard DAAs.

Limitations of this study include its relatively small sample size and short duration of follow-up. Since liver fibrosis often requires longer periods to regress, additional research with longer follow-up is warranted. Furthermore, the study did not account for dietary and lifestyle factors, which could also influence liver health. Lastly, because this was a single-center study, the generalizability to other populations and cultural traditions may be limited.

Conclusion

In patients with chronic HCV receiving standard DAA therapy, the addition of a selected regimen of traditional folk remedies (milk thistle, licorice root, and turmeric extracts) was associated with a modest but significant decrease in liver stiffness as measured by transient elastography. These findings suggest a potential role for complementary herbal interventions in improving liver health. However, larger, multicenter randomized trials with longer follow-up are needed to validate these results and to further explore underlying mechanisms.

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