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nal Contribution

ybin combined with phosphatidylcholine and vitamin E in tients with nonalcoholic fatty liver disease: A randomized ntrolled trial

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Abstract

The only currently recommended treatment for nonalcoholic fatty liver disease (NAFLD) is lifestyle modification. Preliminary studies of silybin showed beneficial effects on liver function. Realsil (RA) comprises the silybin phytosome complex (silybin plus phosphatidylcholine) coformulated with vitamin E. We report on a multicenter, phase III, double-blind clinical trial to assess RA in patients with histologically documented NAFLD. Patients were randomized 1:1 to RA or placebo (P) orally twice daily for 12 months. Prespecified primary outcomes were improvement over time in clinical condition, normalization of liver enzyme plasma levels, and improvement of ultrasonographic liver steatosis, homeostatic model assessment (HOMA), and quality of life. Secondary outcomes were improvement in liver histologic score and/or decrease in NAFLD score without worsening of fibrosis and plasma changes in cytokines, ferritin, and liver fibrosis markers. We treated 179 patients with NAFLD; 36 were also HCV positive. Forty-one patients were prematurely withdrawn and 138 patients analyzed per protocol (69 per group). Baseline patient characteristics were generally well balanced between groups, except for steatosis, portal infiltration, and fibrosis. Adverse events (AEs) were generally transient and included diarrhea, dysgeusia, and pruritus; no serious AEs were recorded. Patients receiving RA but not P showed significant improvements in liver enzyme plasma levels, HOMA, and liver histology. Body mass index normalized in 15% of RA patients (2.1% with P). HCV-positive patients in the RA but not the P group showed improvements in fibrogenesis markers. This is the first study to systematically assess silybin in NAFLD patients. Treatment with RA but not P for 12 months was associated with improvement in liver enzymes, insulin resistance, and liver histology, without increases in body weight.

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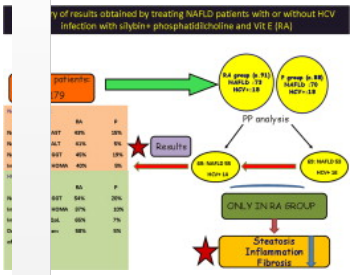
Graphical abstract



Research Highlights

► Currently there is no effective therapy for nonalcoholic fatty liver disease, except for lifestyle modification. ► Realsil treatment for 12 months improves liver enzymes, insulin resistance, and liver histology. ► HCV patients in the Realsil group showed improvements in fibrogenesis markers.

Abbreviations

AE, adverse event; AST, aspartate aminotransferase; ALT, alanine aminotransferase; BMI, body mass index; HCV, hepatitis C virus; HOMA, homeostatic model assessment; IL, interleukin; MMP, matrix metalloproteinase; NAFLD, nonalcoholic fatty liver disease; NAS, NAFLD activity score; NASH, nonalcoholic steatohepatitis; P, placebo; PP, per protocol; SF-36, short form 36; TGF, transforming growth factor; TIMP, tissue inhibitor of metalloproteinase; TNF, tumor necrosis factor; γGT, γ-glutamyltranspeptidase

Keywords

Nonalcoholic fatty liver; Silybin; Hepatoprotectant; Antioxidant; Free radicals

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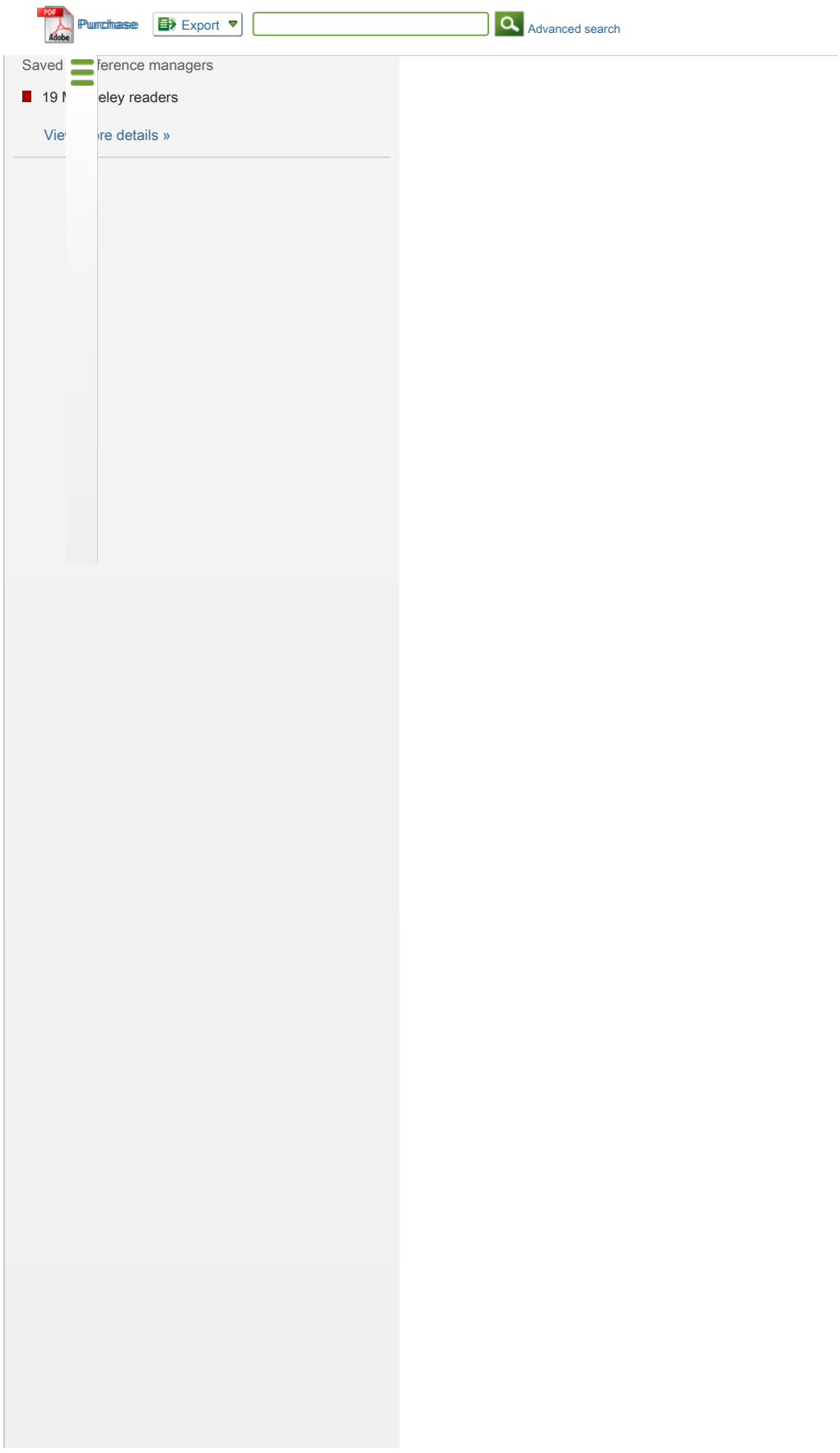
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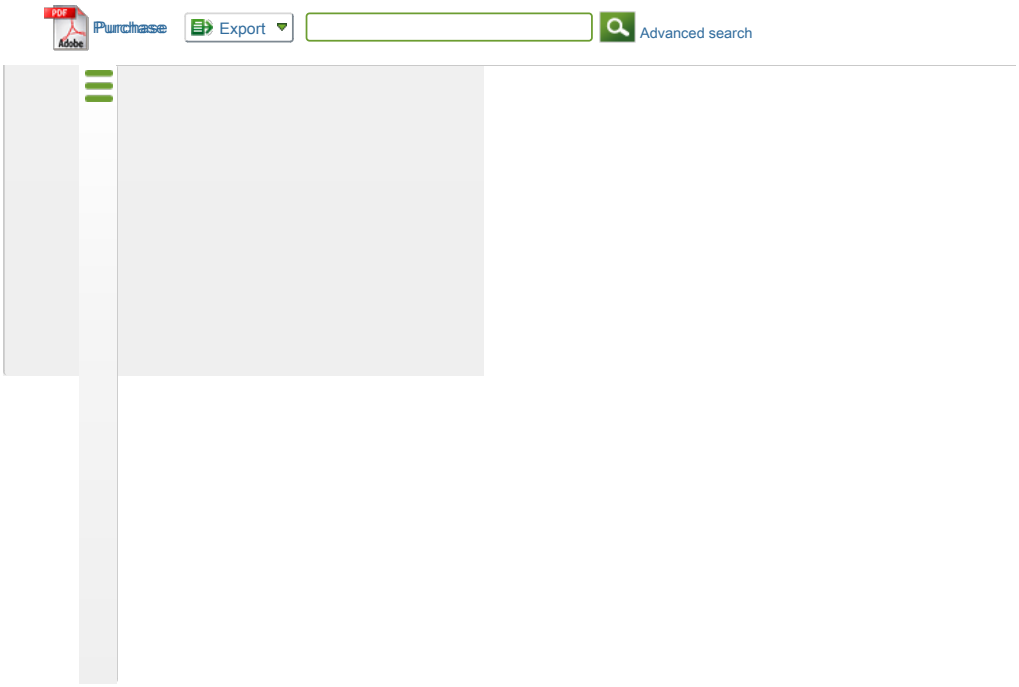
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