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# ACUTE LIVER FAILURE IN PEOPLE CONSUMING FAT BURNERS: A SYSTEMATIC REVIEW

Gastroenterology

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## ABSTRACT

**Background** The modern sedentary lifestyle has increased obesity rates due to decreased physical activity. Seeking effortless weight loss, many people use fat burners, claiming to reduce weight. However, excessive use poses risks like palpitations, anxiety, hepatotoxicity and liver failure. Studies are reporting that fat burners caused Acute Liver Failure (ALF) in many cases. The lack of regulations from the Food and Drug Administration (FDA) regarding these products has contributed to their widespread consumption and increased risk of liver diseases. This review aimed to attain a better understanding of available fat burners and document the cases of ALF caused by the consumption of these products. **Methods** Electronic databases were systematically searched for relevant articles. Selection and screening were performed based on inclusion and exclusion criteria. The case reports and series included in the final list of the studies were assessed using the CARE guidelines. **Results** This review included 33 studies that showed commonly used products were Hydroxycut, Garcinia Cambogia, Herbalife, Green tea extracts, Oxylite Pro etc. The patients presented with symptoms of nausea, fatigue, jaundice and vomiting. More females (73%) were reported with ALF and mean age of 37 years. Most of the patients (56%) showed improvement in symptoms of ALF after discontinuation of the product. **Conclusion** Despite numerous reports worldwide, evidence establishing a direct link between fat burners and ALF remains inadequate. Larger trials analyzing ingredients are crucial to fill these evidential gaps.

## KEYWORDS

Hepatic failure, Acute Hepatic Failure, Weight loss supplements, Dietary supplements, Herbal supplements.

## INTRODUCTION

It is a concerning statistic that the overweight population of the world has nearly tripled in the last five decades. According to a report of World Health Organisation (WHO), 39% of adults were overweight and 13% were obese in the year 2016 worldwide (*Obesity and Overweight*, n.d.). Because of a sedentary lifestyle, people have less time to spend on physical exercise, therefore they tend to look for convenient ways to reduce weight with lesser efforts. The seemingly effective solution is the use of dietary supplements and fat burners (Gavrić et al., 2018; Jakopin, 2019). These are dietary products that claim to reduce body weight by increasing the basal metabolic rate (Abdelmageed & Xiao, 2017; Popovic et al., 2018). Fat burners are supposed to work through three mechanisms- thermogenesis, lipolysis and appetite suppression. Major ingredients in the fat burners are caffeine, green tea extracts/ Epigallocatechin-3-galate (EGCG), L-Carnitine, Conjugated linoleic acid (CLA), and Garcinia cambogia (Hydro citric acid).

### Adverse effects of Fat burners

The consumption of fat burners may demonstrate benefits up to a certain dose but beyond that, they may lead to harmful effects such as heart palpitations, seizures, anxiety, depression, mood swings, bradycardia, insomnia, muscle contractions, hepatotoxicity, and even liver failure (Abdelmageed & Xiao, 2017; El-Zayat et al., 2019; Jakopin, 2019; Jędrejko et al., 2021). There are studies reporting that fat burners caused ALF and hepatic toxicity (Chitturi & Farrell, 2008; Molinari et al., 2006).

### The Burden of usage of fat burners

These supplements are most commonly used by young adults of age 18-24 years (Jakopin, 2019), corporate employees and athletes as they claim to improve performance because of their thermogenic effects (Abdelmageed & Xiao, 2017). Data showed that women consume more fat burners than men (Jędrejko et al., 2021). The products are easily available in the market, however, these lack regulation from the Food and Drug Administration (FDA) (Hannabass & Olsen, 2016). It was reported that around 15% of adults in the US have consumed weight loss supplements at some point in their lifetime, with more women (21%) than men (10%) reporting its use (*Office of Dietary Supplements - Dietary Supplements for Weight Loss*, n.d.).

### Acute Liver Failure

ALF is defined as the development of severe acute liver injury along with encephalopathy and impaired synthetic function (International Normalized Ratio (INR) of 1.5) in patients without preexisting liver disease and within the duration of 26 weeks (Shah et al., 2022; Sundaram et al., 2019). Globally the two main causes of ALF are viral hepatitis (90%) and drug-induced hepatitis (50%) (Acharya, 2021; Shah et al., 2022). There are other causes, such as Wilson's disease, cancer, and weight loss supplements. There are case reports published supporting the fact that consumption of fat burners has caused ALF, and hepatotoxicity (Durazo et al., 2004; Ferreira et al., 2020; Gavrić et al., 2018).

The clinical symptoms of patients are fatigue, loss of appetite, nausea, diarrhea, jaundice, and vomiting. The treatment of ALF should be specific and according to the etiology with liver transplantation being the extreme prognostic option (Shah et al., 2022). In case the person has consumed fat burners, the supplements should be discontinued first. By ceasing their consumption, the person can get back to normal along with other medications (Molinari et al., 2006).

### Burden of ALF

A report published in The Lancet, estimates that the incidence of ALF in the USA is 1 case per million people per year and around 2000-3000 cases are reported in the country every year. The burden is much higher in low and middle-income countries than in high-income countries (Vento & Cainelli, 2020). There was a survey conducted on 3500 American adults who tried to lose weight in the past one year and around 1/3$^{rd}$ of the participants had consumed dietary supplements at least once to reduce weight (Ferreira et al., 2020).

### Rationale

The demand for fat burners rises due to their promised quick weight loss, projecting a 7.0% Compound Annual Growth Rate (CAGR) in the global fat burn supplement market (2018-2023). However, users overlook potential adverse effects. Fat burners are linked to an increased risk of ALF, with reported cases globally (Durazo et al., 2004; Popovic et al., 2018; Yellapu et al., 2011). Yet, comprehensive systematic data on all ALF cases from fat burners is limited. Due to the absence of Randomised Control Trials (RCTs) and detailed liver impact information, this review includes case reports and series to address this gap.

### AIM

To attain a better understanding of all the available fat-burning products used globally and document the case reports/series of ALF caused by the consumption of fat burners.

### OBJECTIVES

1. To synthesize information on all the ingredients/products being used in fat-burning supplements via systematic review.
2. To document the reported cases of ALF caused by fat burners.

## METHODS

We adhered to the guidelines for conducting a systematic review as suggested in the Cochrane RevMan Handbook for systematic reviews.

### Eligibility criteria

### Inclusion criteria

All types of study designs like case series, case reports, observational studies, RCTs, systematic reviews, and meta-analysis that report ALF due to consumption of fat burners.

Other specifications of studies included are:

1. ALF due to consumption of all kinds of available fat burners even if they are banned by the FDA.
2. English language.
3. Global studies.
4. Conducted till December 2021

### Exclusion criteria

1. The studies that reported ALF due to other causes such as hepatitis and drug-induced.
2. The studies reporting any other disease caused by the consumption of fat burners.

### Information sources

1) Freely accessible electronic databases- PubMed, Google Scholar, Cochrane etc.
2) Journals of Hepatology
3) Relevant reports of national and international organizations

### Data Collection And Analysis

### Selection of studies and data extraction:

The primary reviewer selected studies using a search strategy. After screening, eligible studies underwent abstract review. The primary author screened selected abstracts for full articles. Studies not meeting criteria were excluded. The data was extracted from the final list of selected studies, information was extracted and entered in excel sheet.

### Assessment of methodological quality

The case reports and series were assessed for the methodological quality using the CARE guidelines. The case reports that follow the checklist were considered for review. For case control study, STROBE checklist and for narrative review, SANRA checklist was used.

## RESULTS

While searching electronic databases for relevant articles, 324 records were identified and 259 were removed after screening for title and abstract. After review and discussion of 65 articles, 18 of them were removed since they did not satisfy the criteria. Further, 14 articles were excluded due to partial information. Finally, 33 articles (31 case reports/case series, 1 case control study and 1 narrative review) were included in the study. PRISMA chart of selected studies is presented in Fig.1.

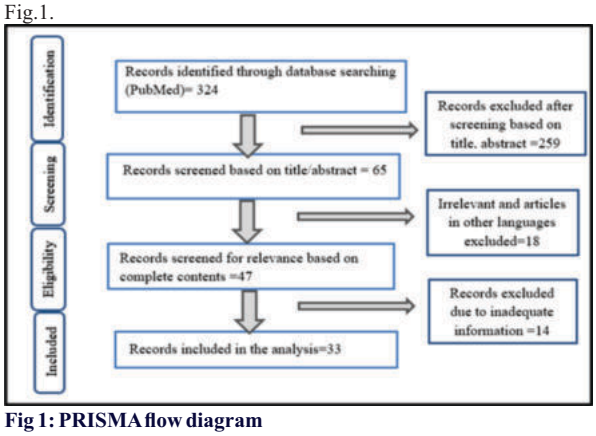


**Fig 1: PRISMA flow diagram**

### Study Setting and Population Characteristics

These studies were conducted in various countries including USA, Brazil, India, Japan, Canada, Singapore and Hawaii. Case reports/series included in our review had 75 participants. It was reported that around 3/4$^{th}$ of the participants (73%) were females and 27% were male. The mean age of the participants was 37 years, ranging between 16 to 66 years. Around 30% of the patients received liver transplant and 8% died.

The Case-Control Study (Vuppalanchi et al., 2022) had 22 cases of liver injury after consuming Herbal Dietary Supplements (HDS) containing G Cambogia. Their median age was 35 years and half of the participants were females. Half of the patients had history of alcohol consumption. Similarly, the narrative review reported 21 cases of hepatotoxicity on consuming products containing G. Cambogia. The mean age of patients was 36 years and 2/3$^{rd}$ were females (Zheng et al., 2016).

### Fat burners consumed in included studies

The results from the case reports/series showed 21% of patients were using Hydroxycut for weight loss. Fourteen percent had products with G. Cambogia. About 10% of patients reported using Slimquik and Lipokintex each. Various other fat burners (45%) used were Herbalife, OxyElite Pro, and products containing green tea extracts, caffeine, usnic acid and heavy metals. The case control study had cases that consumed HDS containing G Cambogia and the controls had consumed HDS containing green tea (Vuppalanchi et al., 2022).

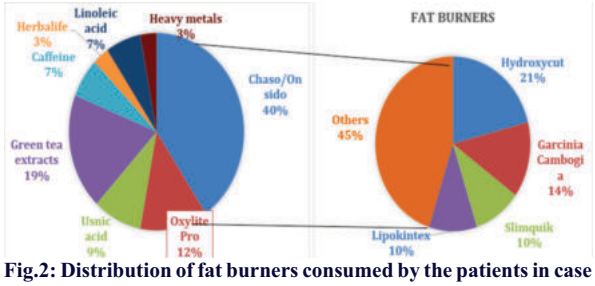


**Fig.2: Distribution of fat burners consumed by the patients in case reports**

### Primary outcome

Out of 75 patients reported in case reports/series, 30 patients (40%) reported ALF after the consumption of weight loss supplements. However, 14% of patients were diagnosed with hepatoxicity, and rest had other liver diseases.

As reported in narrative review (Zheng et al., 2016), almost half of the patients (43%) were diagnosed with hepatitis, 29% had ALF, rest cases reported hepatotoxicity (14%) and other liver diseases (14%).

### Clinical characteristics of patients with liver failure

The common signs and symptoms were jaundice (37%:28/75 patients), nausea (37%:28/75 patients), fatigue (30%:23/75 patients), abdominal pain and vomiting (17 patients each) and loss of appetite. Mostly patients had no medical history but few reported hypertension and diabetes.

However, out of the total cases reported in the case-control study, 3/4$^{th}$ had jaundice, 68% had nausea, half had abdomen pain and itching each, and few had fever and rashes (Vuppalanchi et al., 2022). The patients included in narrative review had fatigue and nausea (52% each), jaundice (32%), and vomiting.

### Blood Investigations

Common blood tests conducted were total bilirubin, Aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), albumin levels and INR. Blood investigations report of most of patients showed higher levels. Normal range taken for total bilirubin was 1.2 mg/dl (Ozeki et al., 2018), AST- 54 U/L, ALT- 57 U/L (Siddiqui et al., 2019) and ALP- 140 U/L. Mean AST, ALT and ALP levels of patients reported in case reports/series was 1092U/L, 1508 U/L and 188U/L respectively. The median of total bilirubin was reported as 9mg/dL (IQR-2.8, 15.8).

However, in the case control study, the mean AST, ALT, ALP and bilirubin levels of 22 patients reported was 1679 U/L, 1975 U/L, 170 U/L and 9.3 mg/dl respectively.

### Treatment

It was reported that all patients were hospitalized after diagnosis of ALF. However, after receiving the treatment, 4% of them died. More than half of the patients (56%) showed improved signs after discontinuation of fat burners and 1/4$^{th}$ underwent liver transplantation. Only 5% of the patients were treated with N-acetyl cysteine and 10% were treated using other regimens such as antibiotics, vitamins etc.

**Quality of Identified Studies:**
The CARE checklist assessed case reports/series quality, while STROBE and SANRA checklists evaluated case control studies and narrative reviews, respectively, shown in table 1. Cohen's kappa statistic indicated high agreement (κ=0.89, 0.8-1.0 range). CARE checklist scores ranged from 12.5 to 22.5, out of 30. Most studies scored over 15, except two case reports (de Ataide et al., 2018; Philips et al., 2019). Few mentioned patient consent, none discussed patient perspective. Clinical findings, diagnostics, and treatments were mostly detailed, but strengths, limitations were inadequately addressed.

**Table 1: Score results for quality assessment.**

| CARE Score Results (Case Reports) | | | | | | |
|---|---|---|---|---|---|---|
| Author | Year | YES | NS | NO | NA | Total Score |
| Cyriac Abby Philips | 2018 | 13 | 2 | 12 | 3 | 14 |
| Y Radha Krishna | 2011 | 16 | 3 | 6 | 5 | 17.5 |
| Gustavo de Sousa Arantes Ferreiraa | 2020 | 21 | 2 | 4 | 3 | 22 |
| Richards JR | 2020 | 20 | 4 | 4 | 2 | 22 |
| de Ataide EC | 2018 | 9 | 7 | 11 | 3 | 12.5 |
| Victor Ferreira | 2020 | 15 | 5 | 6 | 4 | 17.5 |
| Rebecca Corey | 2015 | 14 | 5 | 8 | 3 | 16.5 |
| Muhammad Nadeem Yousaf | 2019 | 21 | 0 | 6 | 3 | 21 |
| Neelam Khetpal | 2020 | 16 | 2 | 6 | 6 | 17 |
| Keri E Lunsford | 2016 | 18 | 2 | 5 | 5 | 19 |
| Shreena S Patel | 2013 | 22 | 1 | 4 | 3 | 22.5 |
| Durazo FA | 2004 | 15 | 5 | 4 | 6 | 17.5 |
| Philips CA | 2018 | 16 | 3 | 7 | 4 | 17.5 |
| Akshay Sharma | 2018 | 13 | 8 | 5 | 4 | 17 |
| Michele Molinari | 2006 | 15 | 5 | 8 | 2 | 17.5 |
| Whitsett M | 2014 | 13 | 6 | 6 | 5 | 16 |
| James L Araujo | 2015 | 19 | 3 | 3 | 5 | 20.5 |
| Rita Nortadas | 2012 | 18 | 1 | 6 | 5 | 18.5 |
| Haimowitz S | 2010 | 14 | 2 | 9 | 5 | 15 |
| Sharma T | 2010 | 17 | 2 | 6 | 5 | 18 |
| Atsushi Takahashi | 2006 | 15 | 3 | 8 | 4 | 16.5 |
| CARE Score Results (Case Series) | | | | | | |
| Giada Crescioli | 2018 | 15 | 4 | 4 | 7 | 17 |
| Gavrić A | 2017 | 18 | 5 | 3 | 4 | 20.5 |
| Masayuki Adachi | 2003 | 17 | 3 | 5 | 5 | 18.5 |
| Dara L | 2008 | 16 | 4 | 3 | 7 | 18 |
| Zheng EX | 2016 | 16 | 3 | 7 | 4 | 17.5 |
| Fong TL | 2010 | 20 | 1 | 4 | 5 | 20.5 |
| Kawata K | 2003 | 14 | 4 | 6 | 6 | 16 |
| Sanchez W | 2006 | 18 | 1 | 6 | 5 | 18.5 |
| Favreau JT | 2002 | 12 | 6 | 6 | 6 | 15 |
| Teschke R | 2016 | 14 | 5 | 6 | 5 | 16.5 |
| STROBE Score Results (case control study) | | | | | | |
| Raj Vuppalanchi | 2021 | 15 | 3 | 9 | 6 | 16.5 |
| SANRA Score Results (narrative review) | | | | | | |
| Andueza N | 2021 | 6 | 0 | 0 | 6 | |

**DISCUSSION:**
In the globalized world, rising obesity rates accompany a decline in physical activity, driving increased reliance on fat burners for weight loss. These readily available products lack FDA regulation, leading to their widespread use and leading to reports of hepatotoxicity, liver failure, anxiety, and palpitations.

This systematic review aims to comprehensively evaluate the global usage and impacts of weight loss supplements, specifically documenting cases of ALF associated with fat burner consumption. Despite their popularity, users often remain unaware of potential adverse effects, necessitating research to highlight fat burners' role in ALF development.

Among 33 studies reviewed (31 case reports/series, one case control study, and one narrative review), 118 ALF cases were linked to fat burner consumption. These cases involved various fat burners like Hydroxycut, G Cambogia, Herbalife, and green tea extracts, displaying similar symptoms of fatigue, abdominal pain, jaundice, and nausea (Andueza et al., 2021). Discontinuation of supplement use often resulted in patient recovery without treatment, although some cases showed unexpected outcomes.

For instance, a study (Haimowitz et al., 2015) detailed liver toxicity due to Hydroxycut, yet discontinuation failed to improve the condition, revealing an underlying genetic cause. Other narrative reviews on HDS hepatotoxicity highlighted multiple reasons of use, including anxiety disorders, menopausal disorders, joint pain, arthritis, dermatitis, and weight loss. Results indicated a predominantly female population affected by HDS-hepatotoxicity cases (Bessone et al., 2022).

Similarly, a Latin American systematic review reported 23 HDS hepatotoxicity cases, with 52% linked to weight loss use. Predominantly, these cases were characterized by jaundice in females, averaging 44 years of age (Santos et al., 2021). This review's strength lies in its global reach, yet limitations arise from the reliance on lower-level evidence—primarily case reports/series—as well as challenges in identifying specific culprit ingredients and determining safe dosage due to varying consumption levels among patients. Additionally, medical history factors such as alcoholism or diabetes may impact disease onset.

**CONCLUSION:**
It is concluded from the review that the consumption of fat burners might lead to ALF that is supported by the evidence narrated above. Although the number of cases reported worldwide are less, but there is strong evidence in support of this. Since there are limitations of the review conducted, there is a need to conduct more evidence-based studies that are higher in the hierarchy, to prove the dose response relationship and establish causal relationship between the consumption of fat burners and ALF. Also, it is important to conduct reviews with larger group of sample population with longer duration of follow up timeline

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