

BACKGROUND MEDIA INFORMATION

Alcohol-related liver disease: A grave concern for

One of the functions of the liver is to break down alcohol so that it can be removed from the body.¹ Alcohol can damage or even destroy liver cells and, although the liver can regenerate and repair itself, drinking more alcohol than the liver is able to process can lead to serious damage and loss of function.¹ Alcoholic liver disease or alcohol-related liver disease (ALD) is damage to the liver caused by excessive alcohol consumption, resulting in serious and life-threatening complications.²

Europe is the heaviest drinking region in the world in terms of the prevalence of alcohol consumption; therefore, ALD is an important issue for Europe to address.³

Types of alcohol-related liver disease

ALD is a complex disease that encompasses a spectrum of conditions, including:³

- Simple steatosis (accumulation of fat in the liver)
- Alcoholic fatty liver disease (or alcoholic steatohepatitis)
- Alcoholic hepatitis (inflammation of the liver)
- Cirrhosis (scarring of the liver)
- Liver cancer

While many people who consume more than 60 grams of alcohol a day (equivalent to half a bottle of wine or more than a litre of beer) will develop steatosis, only a minority will go on to develop the more serious condition of alcoholic fatty liver disease and between 10 to 20% will develop cirrhosis.³ Specific genetic factors have been shown to influence the risk of developing liver disease linked to alcohol consumption.³

The consequences of ALD can be grave. Severe alcoholic hepatitis is life-threatening, and people who develop cirrhosis and fail to stop drinking are 50% more likely to die in the next five years.²

Burden of disease

- In 2010, liver cirrhosis as a result of ALD, was responsible for 493,300 deaths (156,900 female and 336,400 male deaths) worldwide⁴
- Alcohol-attributed liver cancer is responsible for 80,600 deaths, with approximately four times as many deaths in men compared to women⁴
- ALD is the most prevalent cause of advanced liver disease in Europe³
- Alcohol consumption is responsible for 3.8% of global mortality and 4.6% of disability-adjusted life-years (DALYs) lost due to premature death. The attributable burden in Europe, with 6.5% of all deaths and 11.6% of DALYs attributable to alcohol, is the highest proportion of total ill health and premature deaths due to alcohol of all WHO regions³
- Europe shows particularly large gender differences in alcohol-related burden: deaths attributable to alcohol are 11% for men, yet only 1.8% for women³
- Young people account for a disproportionate amount of alcohol-related burden, with over 10% and 25% of alcohol-related deaths in female and male youths respectively³
- Trends in liver cirrhosis mortality over the past 30 years vary throughout Europe:³
 - About half the European countries (including Austria, France, Germany, Italy, Portugal, Spain, Hungary and Romania) have experienced sharp declines in liver cirrhosis mortality
 - Other countries such as Finland, Ireland, the United Kingdom and a large number of Eastern European countries have increasing rates

Risk factors

Intake of alcohol is the biggest risk factor for ALD:¹

- Risk increases significantly for men who drink more than 40 grams of alcohol a day for more than ten years
- The development of cirrhosis in men is usually associated with consumption of more than 80 grams of alcohol a day for more than ten years
- Men who drink in excess of 230 grams of alcohol a day for 20 years have approximately a 50% risk of developing liver cirrhosis

However, not all chronic alcohol abusers develop liver disease and factors beyond alcohol intake, such as gender, genetic factors and nutrition, are thought to be involved:¹

- Women are more susceptible to ALD than men, even when body size is taken into account
- ALD often runs in families and therefore genetic causes play a part in its development
- Both obesity and a diet that is high in unsaturated fat are risk factors for ALD
- Other factors, such as infection with the Hepatitis C virus, also play a part in ALD risk

Management of alcoholic liver disease

- Abstinence from alcohol is a critical goal for patients as it improves the clinical outcomes of all stages of ALD³
- First-line therapy for severe alcoholic steatohepatitis includes corticosteroids³
- The first complication of alcoholic cirrhosis is typically ascites, which is an abnormal accumulation of fluid in the abdominal cavity. Other complications include jaundice, variceal bleeding, and hepatic encephalopathy and these patients are particularly prone to bacterial infections³
- EASL recommends screening for liver cancer in patients with liver cirrhosis, as well as alcohol-induced damage in organs including the heart, kidney, nervous system and pancreas⁴
- A liver transplant may be considered for patients who have liver failure that has not improved after both treatment and long-term alcohol abstinence³
- The most cost-effective policies to reduce alcohol-related harm are those that affect the availability of alcohol, either through pricing, hours and places of sale, or minimum age purchase laws³

EASL is taking action to address ALD in Europe

EASL is involved in a range of public affairs initiatives aimed at raising awareness among European decision makers about the need to tackle liver disease in a comprehensive manner. In November 2017, EASL was a partner in the fifth Awareness Week on Alcohol-Related Harm (AWARH), which brought together leading European medical and patient organisations to identify policy gaps relating to alcohol at both European and national levels.

EASL and the American Association for the Study of Liver Diseases (AASLD) hosted a joint monothematic conference on ALD from 30 September – 1 October 2017, in London, UK. The meeting brought together scientists, clinicians, regulatory agencies and pharmaceutical companies interested in ALD to define new directions, discuss trial design, and evaluate clinical end-points in ALD and alcoholic hepatitis.

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Fast facts about liver disease

Liver, or hepatic, disease comprises a wide range of complex conditions that affect the liver.

- Liver diseases are extremely costly in terms of human suffering, doctor/hospital visits, and premature loss of productivity¹
- Approximately 29 million people in the European (EU) region suffer from a chronic liver condition²
- The most common causes of liver disease worldwide are chronic Hepatitis B and C virus, alcohol, and non-alcoholic steatohepatitis associated with obesity and metabolic syndrome¹

Cirrhosis

Cirrhosis is the late, symptomatic stage of chronic liver disease which occurs when scar tissue (fibrosis) largely replaces healthy liver tissue, compromising the function of the organ and predisposing to liver cancer.⁴

- Complications of cirrhosis are serious and include, among others, the accumulation of fluid in the abdominal cavity (ascites), jaundice, gastrointestinal bleeding (rupture of gastroesophageal varices), severe bacterial infections, and hepatic encephalopathy
- It is estimated that in 2013, liver cirrhosis resulted in 170,000 deaths in Europe¹
- Chronic liver diseases induce cirrhosis in approximately 633,000 patients per year globally.³⁴
- The complications of cirrhosis are the leading cause of adult liver transplants in Europe with 67,208 carried out between 1988 and 2015⁶

Liver cancer

Liver cancer is a frequent tumour that starts in the main types of liver cells. The most common primary liver cancer is hepatocellular carcinoma (HCC), which starts in the hepatocytes.⁷

- Worldwide, liver cancer is the sixth most common cancer⁸
 - In 2012, 63,500 new cases of liver cancer were diagnosed in Europe⁸
- Liver cancer is the second most common cause of cancer death worldwide, preceded only by lung cancer. There were 788,000 deaths due to liver cancer in 2015⁹
- HCC is one of the most serious outcomes of cirrhosis and is responsible for 90% of cases of primary liver cancer²
- Non-alcoholic fatty liver disease (NAFLD) associated with HCC is rapidly increasing¹⁰

Viral Hepatitis

Viral hepatitis is caused by viruses that infect and damage liver tissue. Some of these viral infections can become chronic and lead to cirrhosis. Viral hepatitis kills 1.4 million people worldwide each year.¹¹

Hepatitis A

Hepatitis A is caused by the Hepatitis A virus. It is most commonly spread by eating food contaminated by the stools of an infected person and can result in mild to severe illness.¹²

- Globally, there are an estimated 1.4 million cases of Hepatitis A every year¹³
- Hepatitis A infection does not cause chronic liver disease and is rarely fatal, but it can cause debilitating symptoms and acute liver failure, which is associated with high mortality¹²

Hepatitis B

Hepatitis B is transmitted through contact with infected blood or other bodily fluids, and can result in acute or chronic liver disease, ranging in severity from a mild condition lasting a few weeks to a serious, lifelong illness progressing to cirrhosis and HCC.¹⁴

- Sexual contact is the most common way of transmitting Hepatitis B
- A highly effective vaccine against Hepatitis B virus is available and protects from transmission
- Approximately one third of the world's population has serological evidence of past or present infection with Hepatitis B¹⁵
- An estimated 257 million people worldwide have Hepatitis B¹⁴
- In 2015, 887,000 deaths occurred worldwide due to complications of Hepatitis B, including cirrhosis and liver cancer.¹⁴

Hepatitis C

Hepatitis C is transmitted through contact with infected blood or other bodily fluids, and can result in acute or chronic disease, ranging in severity from a mild condition lasting a few weeks to a serious, lifelong illness.¹⁷

- Hepatitis C is found worldwide, through the most affected regions are Central and East Asia and North Africa¹⁷
- The number of people chronically infected with the Hepatitis C virus worldwide is estimated to be about 71 million, but most are unaware of their infection¹⁸
- Approximately 399,000 people die each year from Hepatitis C-related liver diseases¹⁷
- Currently, no vaccine is available against the Hepatitis C virus

Hepatitis D

Hepatitis D is caused by the hepatitis delta virus, and is transmitted through contact with infected blood or other bodily fluids. This form of hepatitis only occurs in people who are also infected with Hepatitis B.¹⁹

- Hepatitis D is present worldwide and current estimates suggest that 15 million people have been exposed to the hepatitis delta virus and Hepatitis B virus²⁰
- Hepatitis D occurs more commonly in areas such as the Mediterranean, Middle East, Pakistan, Central and Northern Asia, Japan, Taiwan, Greenland and parts of Africa (mainly the horn of Africa and West Africa), the Amazon Basin and certain areas of the Pacific. Prevalence is low in North America and Northern Europe, South Africa, and Eastern Asia⁹
- The majority of patients infected with the Hepatitis D virus have a progressive disease which over time eventually evolves into cirrhosis²⁰

Hepatitis E

Hepatitis E is caused by the Hepatitis E virus and is mainly transmitted via contaminated water or raw swine meat.²¹

- Hepatitis E is found worldwide, but the prevalence is highest in areas that are resource-poor with water contamination issues²¹
- It is usually self-limiting but (like Hepatitis A) it may develop into acute liver failure²¹
- Every year there are an estimated 20 million Hepatitis E infections, over three million symptomatic cases of Hepatitis E and 44,000 Hepatitis E-related deaths²¹

Alcoholic liver disease (ALD)

Alcoholic liver disease or alcohol-related liver disease is damage to the liver caused by excessive alcohol consumption, resulting in serious and life-threatening complications.³⁴

- Europe is the heaviest drinking region in the world in terms of the prevalence of alcohol consumption; therefore, ALD is an important issue for Europe to address²³
- It is also the most common cause of cirrhosis in the West and in Europe, and one of the ten most common causes of death^{23,24}

Non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH)

NAFLD is a condition in which fat builds up in the liver. It is often associated with obesity and diabetes. In some people NAFLD can progress to non-alcohol related steatohepatitis (NASH), a more aggressive form that can lead to cirrhosis, which can seriously impair the liver's ability to function, and to primary liver cancer.²⁵

- NAFLD is the most common liver disorder in Western countries²⁶
- NAFLD affects approximately 20-30% of the population worldwide²⁷
 - As many as 52 million people in the EU may suffer from some form of NAFLD²⁷
- Between 10 and 30% of patients with NAFLD have NASH that can progress to cirrhosis²⁸

Autoimmune, cholestatic and drug-induced liver diseases

Liver diseases that affect bile secretion are termed 'cholestatic' and they can be caused by drugs, genetic defects, developmental disorders and autoimmune damage of the bile ducts. Autoimmune liver diseases may also affect the liver cells (autoimmune hepatitis).

Autoimmune and cholestatic liver disease

- Autoimmune and cholestatic liver diseases are relatively rare compared with viral hepatitis and fatty liver disease, but are associated with a significant societal and economic burden¹
- The diseases account for 10% of liver transplants performed in Europe over the last 20 years¹
- Despite recent advances in understanding of the diseases and available treatments, there remain significant areas of unmet clinical need in each of the autoimmune liver diseases²⁹

Drug-induced liver disease

- Drug-induced liver injury is the most common cause of acute liver failure in Western countries³⁰

Liver transplant

A liver transplant is a surgical procedure to remove a diseased liver and replace it with a healthy liver from a donor.³²

- It is estimated that over 27,000 liver transplants were conducted globally in 2015³³
- More than 9,500 liver transplants were performed in Europe in 2015³³
- In terms of survival post transplantation, 88% of people are alive after one year, around 75% live at least five years, and many people live for 20 years or more³²

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Non-alcoholic fatty liver disease and non-alcoholic steatohepatitis: A major public health problem

Non-alcoholic fatty liver disease (NAFLD) is a condition in which fat builds up in the liver. In some cases, this accumulation of fat can cause inflammation of the liver and eventually lead to permanent scarring (cirrhosis), which can seriously impair the liver's ability to function.¹

Unlike alcoholic fatty liver disease (alcoholic steatohepatitis), NAFLD occurs in people who drink no alcohol or drink only in moderation.¹ NAFLD is, however, closely associated with obesity and diabetes.^{1,2} The consequences of the condition can be grave and NAFLD represents a major public health problem.²

Diagnosing NAFLD

A healthy liver contains very little or no fat. NAFLD occurs in people who do not drink a significant amount of alcohol (20 grams per day for men and 10 grams per day for women) and who do not have a viral infection or other specific cause of liver disease.² NAFLD is diagnosed when accumulation of fat in the organ exceeds 5% of hepatocytes (the cells that make up the majority of the liver).²

NAFLD is sometimes called a silent disease as even in its late stages it may cause no symptoms and may only be diagnosed after liver function tests have revealed an abnormality.

In Europe, NAFLD and NASH coded as cause of death are most common in Ireland, Hungary, Luxembourg and the United Kingdom.

The stages of NAFLD: From simple fatty liver to irreversible cirrhosis

NAFLD can progress from steatosis, to non-alcoholic steatohepatitis (NASH) and then to cirrhosis, hepatocellular carcinoma (HCC) and end-stage liver disease (ESLD).^{2,3} In its early stages, NAFLD can be treated through diet and lifestyle changes, such as losing weight.⁴

NAFLD-related HCC accounted for 4-22%% of all HCC recorded cases.³

Risk factors

The major risk factors for NAFLD are central obesity, obesity, arterial hypertension and insulin resistance.⁵ More than 70% of patients with type 2 diabetes also have NAFLD.²

Obesity and diabetes are on the rise around the world.⁶ The World Health Organization estimates that in 2016 more than 1.9 billion adults (18 years and older) were overweight and, of these, over 650 million were obese.⁷ Furthermore, in 2016, 41 million children under the age of five were overweight or obese.⁷ Obesity has more than doubled since 1980 and is expected to continue to rise.⁷

Obesity triggers inflammatory pathways in the brain and adipose tissue, resulting in the disruption of insulin levels.⁸ Over time, fats accumulate in the liver (as well as muscles and blood vessels), which exacerbate systemic insulin resistance.⁸

Guidelines on NAFLD published in 2016 by European Association for the Study of the Liver (EASL), European Association for the Study of Diabetes (EASD) and European Association for the Study of Obesity (EASO), state that NAFLD is the most common liver disorder in Western countries.⁴

- The prevalence of NAFLD in Western countries is estimated to be between 17 and 46% of the general population⁴
- In Europe, prevalence of NASH is estimated to be up to 5%⁹

The heavy toll of NAFLD

NAFLD increases the risk of overall mortality and of mortality related to cardiovascular disease and liver disease.² Effective treatment options in NAFLD include; weight reduction, dietary changes and physical activity.⁴

NAFLD may also place significant strain on healthcare services. In Germany, France, Italy, and the UK alone, there are approximately 52 million people with NAFLD with an annual cost of about €35 billion.

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Viral hepatitis: A significant threat to health in Europe

Viral hepatitis is inflammation of the liver caused by a viral infection. There are five main types of hepatitis viruses, known as Hepatitis A, B, C, D and E viruses. While Hepatitis A and E are usually contracted by consuming food or water contaminated with the virus, Hepatitis B, C and D are transmitted through contact with infected blood or other bodily fluids.¹ Hepatitis B and C can also be transmitted through sexual contact or passed from mother to child.¹

Although the five hepatitis viruses and their impact on the human body differ, all can pose a threat to the health of the liver.

Viral hepatitis kills 1.34 million people worldwide each year.¹

Hepatitis B and C are responsible for 96% of the world's hepatitis mortality.¹

Focus on Hepatitis C

Background on Hepatitis C

The Hepatitis C virus was first isolated and discovered in 1989.² By the 25th anniversary of its discovery, the joint research efforts of scientists around the world had led to the identification of a breakthrough cure.² These advances in Hepatitis C, from discovery to cure, represent some of the most exciting discoveries in both liver disease and medicine.²

The Hepatitis C virus is blood-borne.³ There is no vaccine for Hepatitis C as yet, and prevention is only possible through avoiding contact with contaminated blood.⁴ The Hepatitis C virus can cause two types of infection: acute and chronic.³

Acute Hepatitis C³

In acute infections, the immune system clears the virus from the body without any treatment. An acute infection is rarely life-threatening. Between 15 and 45% of people who contract acute Hepatitis C will spontaneously clear the infection within six months of acquiring it.

Chronic Hepatitis C³

Chronic Hepatitis C occurs when the body does not spontaneously clear the virus. This is the case for 60–80% of people who contract acute Hepatitis C. Around 15 to 30% of people with chronic Hepatitis C will go on to develop liver cirrhosis within 20 years.

Epidemiology of Hepatitis C

Hepatitis C causes about 399 000 deaths per year worldwide.³ The number of people chronically infected with the Hepatitis C virus worldwide is estimated to be about 71 million.³

Treatment for Hepatitis C

Chronic Hepatitis C can be treated with antiviral therapy to stop the virus from multiplying inside the body, thereby preventing liver damage. Cure rates for Hepatitis C with novel therapies can now reach up to 95% for the majority of patient groups.³ These exciting drugs, many of which are still being investigated, are called direct acting antivirals (DAAs).³ They directly and specifically target the Hepatitis C virus in many specific stages of its lifecycle.

There are different strains (genotypes) of the virus and some respond better to treatment than others.³ This means that patient management can still pose complex challenges alongside wider patient

concerns such as response to previous treatments and the stage of liver disease, which need to be considered. Screening and early diagnosis can increase the chance of successful treatment.³

Focus on Hepatitis B

Background on Hepatitis B⁴

Hepatitis B is a potentially life-threatening liver infection caused by the Hepatitis B virus. It is a major global health problem. It can cause both acute and chronic infection and puts people at high risk of death from cirrhosis and liver cancer.

A vaccine against Hepatitis B has been available since 1982. The vaccine is 95% effective in preventing infection, the development of chronic disease and liver cancer due to Hepatitis B.

Chronic Hepatitis B⁴

Chronic Hepatitis B is a leading cause of cirrhosis of the liver and liver cancer worldwide. Children infected with the virus before the age of five are most likely to develop the chronic form of the infection.

Epidemiology of Hepatitis B

Approximately one third of the world's population has serological evidence of past or present infection with Hepatitis B.⁵ Over 250 million people worldwide are living with Hepatitis B infection.⁴

Treatment of Hepatitis B

Current treatments for chronic Hepatitis B are safe and effective but at the moment can only suppress the virus replication, i.e. they cannot eradicate it or cure the patient.⁶ Hepatitis B, however, can be prevented by vaccination and the WHO recommends that all infants receive the Hepatitis B vaccine as soon as possible after birth.⁶

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