Specific nutritional modification can improve Fatty Liver

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Content

Background

Since 2005, a team of medical doctors and naturopaths have studied the effect of dietary changes, as well as the use of a specific liver formula LIVATONE PLUS to assist patients in the reduction of fatty liver and symptoms of liver dysfunction. The head researcher was Dr Sandra Cabot McRae MBBS, DRCOG.

This need for information regarding the reduction of fatty liver is a result of the rising number of people being affected by it, together with the limitations of medications for this type of liver injury. Our team noticed the escalation of fatty liver in their patients who often presented for seemingly unrelated conditions. This provided the inspiration to do a clinical study in patients with fatty liver.

The Medical Observer Journal of Australia in July 2004 published an article titled ***Non-alcoholic fatty liver disease is the new epidemic of liver disease facing the Western world***. Well it has been gradually creeping upon us, but in reality, it has been an epidemic for at least a decade now!

Back in the 1980s fatty liver was mainly seen in alcoholics and rarely in children. Today fatty liver is now recognised as ***the most common cause of abnormal liver function tests*** in the USA, UK and Australia. Around 20-25% (or 1 in 4-5 persons) in the general population in Australia and the USA has fatty liver disease.

Fatty liver occurs when fat accumulation is more than 5% of the liver weight. Fatty liver is most commonly caused by incorrect diet, obesity, alcoholism and diabetes. Other causes can include malnutrition (especially protein deficiency), congenital metabolic disorders, excessive use or toxicity of orthodox medications (such as corticosteroids, paracetamol, valproic acid, tetracycline, salicylates or synthetic oestrogens) or systemic illnesses with fever.

Aim of Clinical Study

The aim of this study was to illustrate the result of a specific liver supplement and dietary regime over a 6-month period on liver tests and symptoms that indicated fatty liver.

Hypothesis

That nutritional medicine and supplementation can result in:

- An improvement in liver function.
- A reduction in clinical symptomatology.
- A reduction in obesity – This was going to be challenging as 50% of participants could be classified as obese by their BMI and furthermore, it is traditionally thought that those with a fatty liver find it more difficult to lose weight.
- A reduction in the amount of the fatty infiltration of the liver.
- Improvement in the quality of life and general health.

Because this study period was conducted over a relatively short time (6 months for each patient), we were not expecting to completely reverse the condition of fatty liver, which is generally thought to take many years to develop. We do not claim that damage to the liver will always be completely reversed by the program outlined in our study.

Study Design

This study was designed as an investigative initial clinical study. It was not placebo-controlled, randomised or double blinded.

Participant Recruitment and Selection

Participants were recruited by replying to advertisements placed on health websites, by word-of-mouth and from patients in our various medical clinics. Applicants were asked to complete a questionnaire, which was consequently analyzed and compared with a set of predetermined selection criteria. Participants' suitability was determined according to this.

Applicants needed to fit into the following selection criteria:

- Had a previous medical diagnosis of Fatty Liver.
- Had a positive ultrasound confirming the diagnosis of Fatty Liver.
- Did not have advanced cirrhosis of the liver or liver failure indicated by symptomatology and/or pathology.
- Did not have other pre-existing, serious medical conditions such as kidney failure, heart failure, cancer, psychotic illness etc.
- Was a non-smoker at time of application.
- Did not drink more than 7 alcoholic beverages per week at time of application.
- Did not use recreational drugs at time of application.
- Was not taking orthodox medication (or was willing to stop medication after discussion with their doctor), which may exert hepatotoxic effects (e.g. statins and long-term antibiotics).
- Was willing to terminate the use of all dietary supplements known to have any effect on liver function.
- Was motivated and enthusiastic to follow the program and willing to comply with various demands of study executives.
- Was willing to have specific tests required such as blood tests and abdominal ultrasound.
- Must have completed and signed a consent form.

Once the applicants were deemed suitable, they were required to attend one of our medical clinics for an initial consultation with Dr Sandra Cabot McRae or Dr Evgenia Nisman or Dr Marissa Stevenson Wong and later with several naturopaths. Successful applicants were continually accepted up until the study completion in 2016. In total from 2005 until 2016, we were able to recruit and follow over a 6 month period, 66 subjects who fitted the criteria.

Supplement Protocol

Participants were instructed to take 2 capsules twice daily of a specialized liver tonic called LivaTone Plus. These were provided to the participants at no charge for the duration of the study period of 6-months.

No other nutritional/ herbal supplements were permitted to be taken during the study period. Orthodox medications prescribed to participants before the commencement of the study by their pre-existing medical practitioner, were permitted to be continued during the study, provided they did not have known hepatotoxic activity.

Dietary & Lifestyle Protocol

Participants had to carry out some basic dietary modifications suggested by the research team. The dietary protocol for participants was similar to that outlined in the book ***"The Liver Cleansing Diet."*** In this program, carbohydrate intake is limited and the importance of eating complete protein and fresh vegetables on a regular basis is emphasised.

- All participants were permitted to have a maximum of 4 alcoholic beverages weekly.
- Complete exclusion of smoking and recreational drug use was implemented.
- Exercise was strongly encouraged; however, it was not a fundamental modification.

Compliance

Because this program involved commitment from its participants, it was imperative to ensure enough contact (at least weekly) was maintained between participants and the study's management team, in order to ensure compliance was maintained.

As a result, it was necessary for all participants to attend weekly 'follow-up consultations' at our Clinics and/or by phone or skype with one of our in-house practitioners. In addition, participants were required to complete a daily diet diary for the duration of the study, which was reviewed at their follow-up consultations.

Patients were provided with supplies of LivaTone Plus supplements, plus a diet book, so as to make their compliance as easy as possible.

Study Method

Monitoring of specific tests known to be indicative of, or associated with, the liver damage caused by fatty liver was organised at accredited pathology laboratories. In some cases, these measurements may also predict the degree of fatty infiltration of the liver. These tests were done at the commencement and conclusion of the 6-month study period.

The tests included:

- Abdominal ultrasound scan
- Liver function enzymes
- Lipid studies
- Fasting blood glucose and insulin

Clinical history was taken at the commencement, conclusion and every 2 weeks over the study period. These included:

- Fatigue levels
- Digestive discomfort
- Mental and physical well-being
- Room for individuality of presentation was allowed with one symptom possibly related to liver dysfunction being monitored throughout the length of the program
- Body weight
- Body Mass Index
- Waist circumference

Discontinuation of the Study

From 2005 to 2016, 83 subjects were recruited, but 17 dropped out because of hardship, emotional issues, inability to change their diet or lack of compliance with taking the Livatone Plus regularly.

Considering the demands this study required off the participants, the overall abandon rate was surprisingly low. This could be attributed to the level of compliance assurance measures undertaken such as the daily diet diaries, and the level of support the participants received. It may have also been attributed to the significant improvements in fatigue levels, overall well-being and other concerning symptoms.

Of the 83 initial participants, 66 completed the program. Therefore, the overall abandon rate was approx. 20%.

It should be noted that during the course of this clinical study, no patients experienced significant side-effects from the treatment protocol.

Considerations

During the course of this investigative observation study, certain unavoidable problems were presented, which should be considered when the results are being viewed and conclusions made. Fatty liver is generally considered to be a chronic problem, with most of the participants commencing to develop it many years before the study.

We did try to recruit 100 study participants but found this difficult for unknown reasons. Diagnosis of fatty liver is often overlooked, even though it affects around 25% of the general population, this low detection rate has allowed for the unnecessary progression of the condition.

As a result of the comparatively short time-frame (6-months) this study was conducted over, huge changes in liver pathology were not expected. In addition, because of the prolonged length of time fatty liver had presumably developed over, difficulty was experienced in evaluating initial clinical symptoms because the participants had developed them very slowly.

As a result, clinical measurements were, in many cases, not quantitatively significant, however, qualitative description revealed there were significant benefits found.

Abdominal ultrasound scans were used to detect the presence or absence of increased echogenicity caused by fatty infiltration of the liver. An abdominal ultrasound scan is able to detect the presence of fatty liver and grade it as mild, moderate or extensive.

Results

Symptom 1:

Fatigue - was measured on a scale of 1 – 10.

A value of 10 describes a severe degree of fatigue that affects all aspects of the patients' life.

- Overall, 83 % of participants had fatigue levels, which had reduced significantly (on average by one third)
- 17% of participants did not experience any improvement in fatigue.
- There was a general reduction in degree of fatigue by 35%.

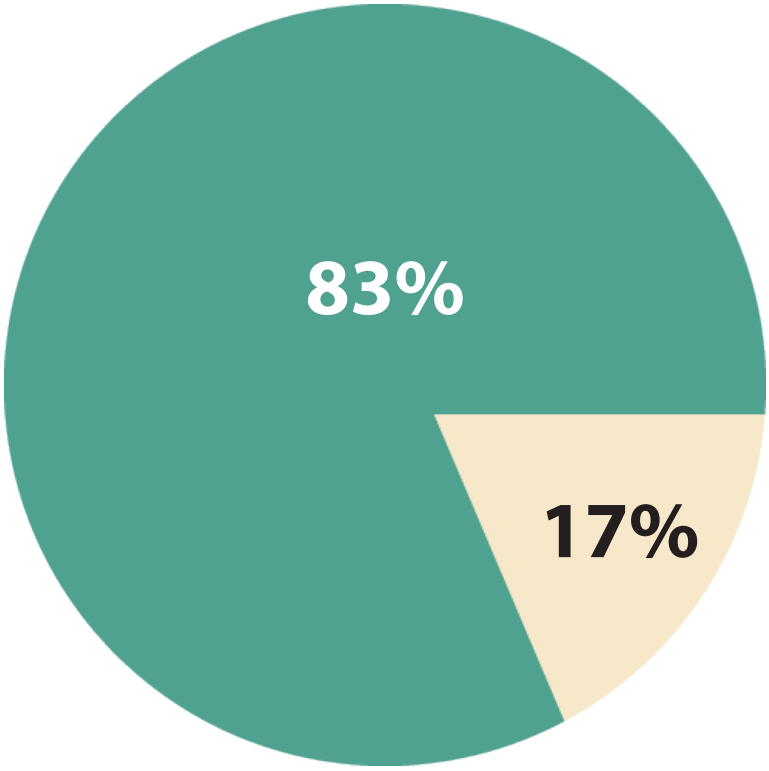

Chart 1: FATIGUE

Fatigue levels reduced significantly

No improvement

Symptom 2:

Digestive Discomfort - was measured on a weekly basis.

That is, the participant was asked how many days over the previous week they had experienced digestive discomfort. Digestive discomfort may encompass symptoms such as bloating, nausea, reflux, constipation, diarrhea, excessive flatulence or burping, abdominal cramping or halitosis.

89% of the participants received significant reductions in digestive discomfort. In fact, on average, participants had a 70% improvement in their digestive symptoms.

Chart 2: DIGESTIVE DISCOMFORT

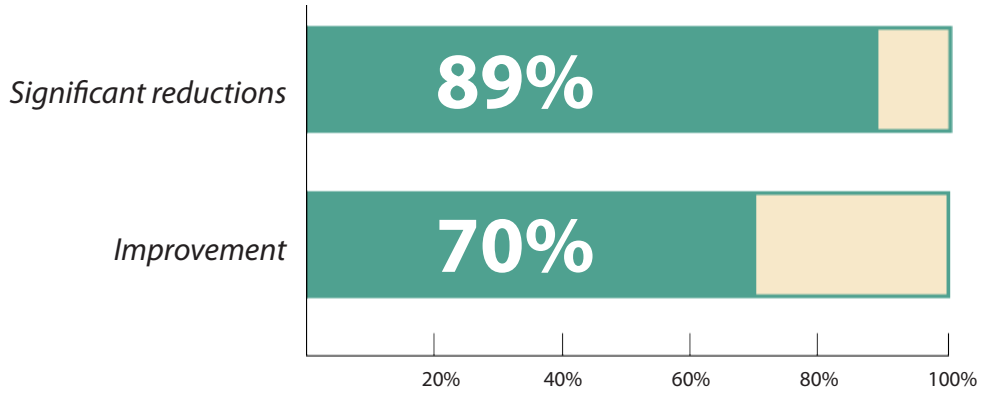

Chart 2 illustrates the degree of change in digestive symptoms found from the commencement of the study period to the conclusion.

Symptom 3:

Well-being - was measured on a sliding scale of 1 -10.

The value of 10 represents a feeling of extreme mental and physical wellness.

Positive mental and physical wellness describes a feeling that the participants diagnosis with fatty liver was not impacting on their well-being either mentally or physically.

On average, mental and physical well-being had improved over the 6 months by 43%.

Chart 3: WELL-BEING

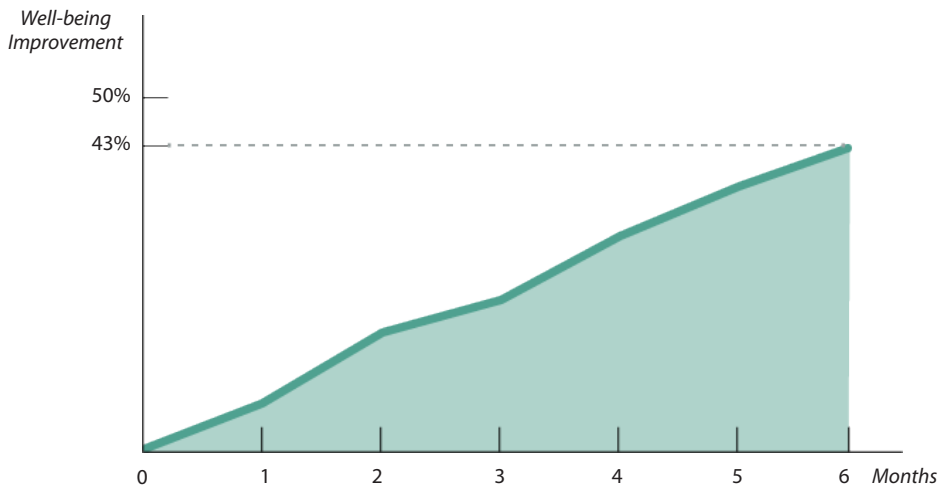

Chart 3 represents the participants' overall feeling of mental and physical well-being from the commencement of the study period to the conclusion.

Symptom 4:

Individual symptoms possibly related to liver dysfunction

Because this clinical study was designed to acknowledge individual presentations of the same disease process, this symptom allowed for uniqueness of presentation. Participants were asked to describe their most troubling symptoms at their initial consultation.

Any symptom that the study executives attributed to compromised liver function was then monitored as symptom 4 throughout the length of the program. This was measured on a daily basis per week i.e. the participant was asked how many days over the previous week they had experienced their particular individual symptom.

- 23% of patients experienced a significant reduction in constipation
- 17% experienced that their halitosis disappeared or reduced to non-worrying levels
- 24% found their sleep quality improved
- 11% found their red itchy eyes disappeared
- 18% found that pruritis or itchy skin resolved
- 31% resolved their GERD
- 24% resolved their abdominal bloating

Chart 4: INDIVIDUAL SYMPTOMS

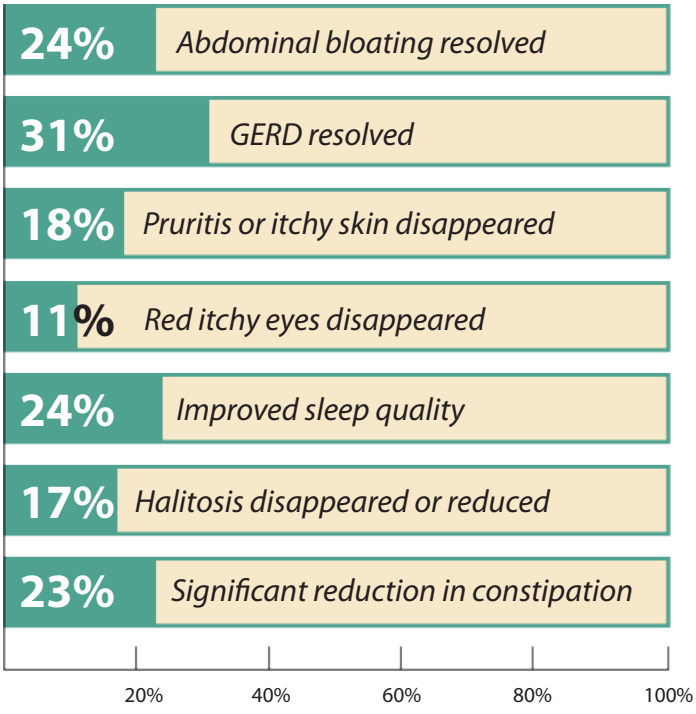

Chart 4 illustrates the changes noted in the frequency that participants experienced their individual symptom.

Weight

Weight gain and/or inability to lose weight, is a sign which is commonly associated with the development of fatty liver. Furthermore, weight gain and/or diabetes is further accelerated by the progression of fatty liver.

Weight loss is a great predictor of a reduction in the degree of fatty infiltration. Interestingly we found that many of the study subjects had battled for years with excess weight and had tried many different diets, as well as weight loss drugs, but did not get good initial results. It was only when we showed them how to improve their liver function that early and sustained weight loss occurred.

Our hypothesis is that a fatty liver has a disturbed fat metabolism and is storing fat due to multiple factors such as high insulin and leptin levels and excess inflammation in hepatocytes caused by build up of triglycerides within them. If we reduce liver inflammation, the fat-metabolism function of hepatocytes is improved and this explains weight loss without any increase in exercise or calorie restriction.

Of all the 66 study participants:

- 64% were overweight, 18% with a BMI over 30 and 46% with a BMI over 25
- 89% of the overweight participants experienced a significant weight loss with the average weight loss over 6 months being 7.5 kg.

Body Mass Index (BMI)

Body mass index describes an individual's body weight compared with their height. It is useful in determining whether one fits into the normal healthy weight range or not.

BMI brackets are as follows:

- Underweight = < 18.5 Normal = 18.5 – 24.9
- Overweight = 25 – 29.9 Obese = > 30
- 92% of all participants had a reduction of their BMI. The average reduction for overweight participants' BMI was 12.0%.

Abdominal Ultrasound

Abdominal ultrasounds are an effective tool in determining the presence or absence of fatty liver. 83% of participants' abdominal ultrasounds showed some degree of reduction of fatty infiltration.

Chart 5: ABDOMINAL ULTRASOUND CHANGES

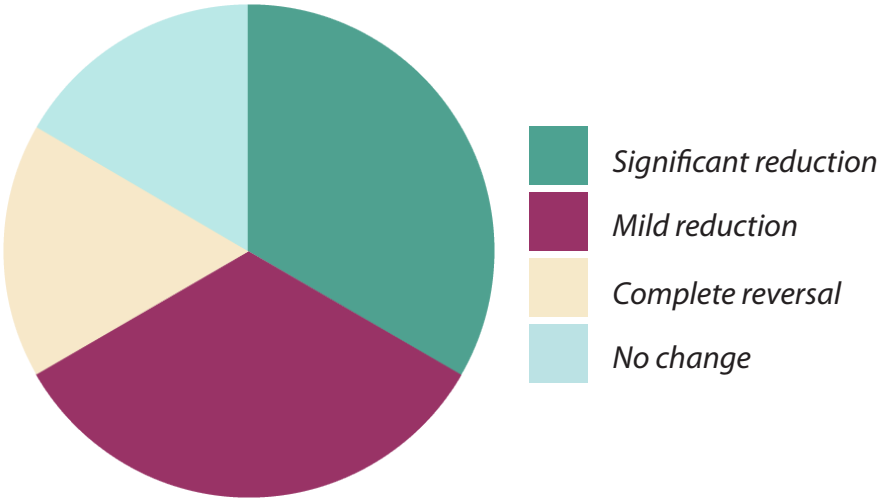

Chart 5 illustrates the degree of change noticed in participants' abdominal ultrasounds.

Pathology Tests

Pathology tests were chosen to evaluate liver function, fat and sugar metabolism. Fatty liver may or may not cause abnormal liver function tests, however, an elevation of liver enzymes is indicative of liver inflammation. Fatty liver is often associated with an abnormal lipid profile and impaired glucose tolerance and insulin resistance.

The table below shows the average levels of pathology parameters tested at the commencement and conclusion of the study and the average change over the period of the 6 month study.

Pathology Test	Reference Range	Average level at commencement	Average level at conclusion	Average Difference
ALT (U/L)	0 – 40	54	28	– 26
AST (U/L)	0 – 40	34	23	– 11
GGT (U/L)	0 – 45	49	30	– 19
ALP (U/L)	30 – 115	94	64	– 30
Total Cholesterol (mmol/L)	3.9 – 5.5	5.7	5.3	- 0.4
HDL (mmol/L)	0.8 – 1.7	1.2	1.4	+ 0.2
LDL (mmol/L)	1.7 – 3.5	3.3	3.0	- 0.30
Triglycerides (mmol/L)	0.5 – 1.7	1.8	1.2	-0.6
Fasting Blood Sugar (mmol/L)	3.6 – 6.0	5.52	5.38	– 0.14
Fasting Insulin (mU/L)	0 – 20.0	15.68	11.18	– 4.5

Conclusion

This clinical study has provided evidence to indicate that liver injury caused by fatty liver, and fatty infiltration in itself, may be significantly reduced, when effective dietary and supplemental modifications, in particular LivaTone Plus, are implemented.

Considering that:

- At present, there is no orthodox medical treatment, apart from weight loss, that is proven to effectively treat or manage fatty liver or its consequences.
- Fatty liver is associated with diseases such as obesity and diabetes.
- Fatty liver, and especially the more insidious form of fatty liver, known as Non-Alcoholic-Steatorrhoeic Hepatosis (NASH), may progress to severe liver disease.

There is an urgent need for proven, effective complementary medical protocols that cause no harm. Nutritional medicine is increasingly recognized by many health workers as being an extremely useful tool in achieving a reduction in morbidity and mortality rates for the epidemic of degenerative diseases and obesity now facing the developed world.

Although this study was not double blind, randomised or placebo controlled and involved a small sample of people, we consider the treatment outlined in this observation study to be effective in reducing fatty infiltration of the liver and enhancing weight loss.

Furthermore, throughout this observation study, no noteworthy side-effects were observed.