



## Liver diseases in Lebanon

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### Main Information

**Primary registry identifying number**

LBCTR2020074524

**Protocol number**

BIO-2018-0009

**MOH registration number**

**Study registered at the country of origin**

Yes

**Study registered at the country of origin: Specify**

**Type of registration**

Retrospective

**Type of registration: Justify**

LBCTR was not established at time of study

**Date of registration in national regulatory agency**

15/07/2020

**Primary sponsor**

PI initiated

**Primary sponsor: Country of origin**

Lebanon

**Date of registration in primary registry**

17/07/2020

**Date of registration in national regulatory agency**

15/07/2020

**Public title**

Liver diseases in Lebanon

**Acronym**

**Scientific title**

Spectrum of Liver diseases in Lebanon: a retrospective cohort study

**Acronym**

**Brief summary of the study: English**



Liver diseases is a worldwide etiology causing high morbidity and mortality. Fibroscan is a quick, painless examination performed in clinic or at the patient's bedside. It is used to evaluate liver status for patients with suspected liver disease prognosis. This study aims at describing the spectrum of liver diseases among patients performing Fibroscan at a tertiary care center in Lebanon.

**Methods:**

This is a retrospective data collection study on patients who underwent Fibroscan at the American University of Beirut hepatobiliary unit between 2015 and 2018. Medical charts of all patients were reviewed. Data were collected and analyzed using SPSS 25 software.

**Results:**

A total of 620 patients presented to the hepatobiliary unit for Fibroscan, of which 419 (67.5%) were males. The mean age was  $47.8 \pm 13.4$  (range 18-84). 362 (58.3%) had NAFLD, 89 (14.3%) had Hepatitis-B, 69 (11.1%) had Hepatitis-C, 48 (7.7%) had ALD, 20 (3.3%) had DILI, and 13 (2.9%) had autoimmune hepatitis. 190 (30.6%) were overweight (BMI over 25), 128 (20.6%) had diabetes. Liver stiffness corresponding to the diagnosis of F4 liver fibrosis stage on Fibroscan was mostly reported in 6 (46.5%) autoimmune hepatitis, 101 (27.9%) NAFLD, and 18 (26.1%) HCV patients. 141 (45.5%) patients who had one or more metabolic risk factors suffered from severe stage steatosis compared with 78 (28.9%) who had not any risk factors with P-value 0.04.

**Conclusions:** Based on our sample, NAFLD is emerging as a predominant etiology of CLD, followed by, HBV, and HCV. This is the first study that reports CLD status in Lebanon, further studies that describe the prevalence and incidence of the disease at a larger scale are needed.

**Brief summary of the study: Arabic**

هو فحص سريع وغير مؤلم يتم إجراؤه في العيادة أو بجوار Fibroscan. أمراض الكبد هي مسببات عالمية تسبب الأمراض والوفيات العالية سرير المريض. يتم استخدامه لتقييم حالة الكبد للمرضى الذين يشتبه في تشخيصهم لأمراض الكبد. تهدف هذه الدراسة إلى وصف طيف أمراض الكبد بين المرضى الذين يؤدون الفبروسكان في مركز رعاية جامعية في لبنان.

**طرق:**

و2015 هذه دراسة جمع البيانات بأثر رجعي عن المرضى الذين خضعوا ليفبروسكان في وحدة الكبد في الجامعة الأمريكية في بيروت بين عامي 2015 و2018. تم مراجعة المخططات الطبية لجميع المرضى. تم جمع البيانات وتحليلها باستخدام برنامج SPSS 25.

**النتائج:**

13.4 ± 47.8 % من الذكور. كان متوسط العمر 67.5 (419) مريضاً إلى الوحدة الكبدية الصفراوية فيبروسكان ، منهم 620 قدم ما مجموعه C ، مصاب بالتهاب الكبد (11.1%) ، 69 ، B ، مصاب بالتهاب الكبد (14.3%) ، 89 ، NAFLD ، مصاب بـ3.3% (362) ، 18-84 (نطاق) ، 48 (7.7%) ، كان يعاني من التهاب الكبد المناعي 2.9 (13 و ، DILI ، مصاب بـ3.3% (20) مصاب بمرض تصلب العصبي المتعدد ، (7.7%) ، مصابون بالسكري. تم الإبلاغ عن تصلب الكبد 20.6 (128) ، 25% ، يعانون من زيادة الوزن (مؤشر كتلة الجسم فوق 30.6 (190) الذاتي. (27.9%) (101) من التهاب الكبد المناعي الذاتي ، 46.5 (6) على الليفوسكان في الغالب في F4 المقابل لتشخيص مرحلة تليف الكبد (45.5%) ممن لديهم عامل أو أكثر من عوامل الخطر الأيضية من تتكس 45.5 مريضاً (141) عانى HCV. من مرضى 26.1 (18) ، NAFLD ، (P 0.04) لم يكن لديهم أي عوامل خطر ذات قيمة 28.9 (78) واحد في المرحلة مقارنة بـ هذه هي الدراسة الأولى التي تشير إلى حالة HCV و HBV يليه ، CLD كمسببات سائدة لـ NAFLD الاستنتاجات: بناءً على نموذجنا ، يظهر في لبنان ، وهناك حاجة إلى مزيد من الدراسات التي تصف انتشار وانتشار المرض على نطاق أوسع CLD.

**Health conditions/problem studied: Specify**

liver diseases

**Interventions: Specify**

none no research intervention was done

**Key inclusion and exclusion criteria: Inclusion criteria**

all adults who presented for fibroscan at AUBMC hepatobiliary unit تمت 2016 and 2018

**Key inclusion and exclusion criteria: Gender**

Both

**Key inclusion and exclusion criteria: Specify gender**

**Key inclusion and exclusion criteria: Age minimum**

18

**Key inclusion and exclusion criteria: Age maximum**

99

**Key inclusion and exclusion criteria: Exclusion criteria**

age less than 18

**Type of study**



Observational

**Type of intervention**

N/A

**Type of intervention: Specify type**

N/A

**Trial scope**

N/A

**Trial scope: Specify scope**

N/A

**Study design: Allocation**

N/A

**Study design: Masking**

N/A

**Study design: Control**

N/A

**Study phase**

N/A

**Study design: Purpose**

N/A

**Study design: Specify purpose**

N/A

**Study design: Assignment**

N/A

**Study design: Specify assignment**

N/A

**IMP has market authorization**

**IMP has market authorization: Specify**

**Name of IMP**

**Year of authorization**

**Month of authorization**

**Type of IMP**

**Pharmaceutical class**

**Therapeutic indication**

**Therapeutic benefit**

**Study model**

Cohort

**Study model: Explain model**

liver disease

**Study model: Specify model**

N/A

**Time perspective**

Retrospective

**Time perspective: Explain time perspective**

we collected all data from the date of fibroscan machine availability at AUBMC

**Time perspective: Specify perspective**

N/A

**Target follow-up duration**

0

**Target follow-up duration: Unit**

NA



|   |  |
|---|--|
| <b>Number of groups/cohorts</b><br>1            |  |
| <b>Biospecimen retention</b><br>None retained   | <b>Biospecimen description</b><br>NA   |
| <b>Target sample size</b><br>470                | <b>Actual enrollment target size</b>   |
| <b>Date of first enrollment: Type</b><br>Actual | <b>Date of first enrollment: Date</b><br>01/01/2016                          |
| <b>Date of study closure: Type</b><br>Actual    | <b>Date of study closure: Date</b><br>31/12/2019                             |
| <b>Recruitment status</b><br>Complete           | <b>Recruitment status: Specify</b>   |
| <b>Date of completion</b>                       |  |
| <b>IPD sharing statement plan</b><br>No         | <b>IPD sharing statement description</b><br>data will be shared upon request |
| <b>Additional data URL</b>                      |  |
| <b>Admin comments</b>                           |  |
| <b>Trial status</b><br>Approved                 |  |

## Secondary Identifying Numbers

| Full name of issuing authority | Secondary identifying number |
|--------------------------------|------------------------------|
| NA                             | NA                           |



## Sources of Monetary or Material Support

Name

NA

## Secondary Sponsors

Name

NA

## Contact for Public/Scientific Queries

| Contact type | Contact full name | Address | Country | Telephone | Email           | Affiliation |
|--------------|-------------------|---------|---------|-----------|-----------------|-------------|
| Public       | Rola jaafar       | beirut  | Lebanon | 01350000  | rj29@aub.edu.lb | AUBMC       |
| Scientific   | walid faraj       | beirut  | Lebanon | 01350000  | wf07@aub.edu.lb | AUBMC       |

## Centers/Hospitals Involved in the Study

| Center/Hospital name | Name of principles investigator | Principles investigator speciality | Ethical approval |
|----------------------|---------------------------------|------------------------------------|------------------|
| AUBMC                | Walid Faraj                     | General Surgeon                    | Approved         |

## Ethics Review

| Ethics approval obtained                     | Approval date | Contact name    | Contact email   | Contact phone |
|--|---------------|-----------------|-----------------|---------------|
| American University of Beirut Medical Center | 15/05/2017    | Dana Fakhredine | df17@aub.edu.lb | 01350000      |

## Countries of Recruitment

Name

Lebanon



## Health Conditions or Problems Studied

| Condition     | Code                               | Keyword  |
|---------------|------------------------------------|----------|
| liver disease | Liver disease, unspecified (K76.9) | fibrosis |

## Interventions

| Intervention | Description                | Keyword   |
|--------------|----------------------------|-----------|
| none         | no interventions were made | fibroscan |

## Primary Outcomes

| Name                      | Time Points     | Measure            |
|---------------------------|-----------------|--------------------|
| NAFLD percentage          | at time of test | number of patients |
| alcoholic fatty liver     | at time of test | number of patients |
| Hep A, B and C infections | at time of test | number of patients |

## Key Secondary Outcomes

| Name  | Time Points     | Measure            |
|---|-----------------|--------------------|
| risk factors associated with liver etiology | at time of test | number of patients |



## Trial Results

**Summary results**

**Study results globally**

**Date of posting of results summaries**

**Date of first journal publication of results**

**Results URL link**

**Baseline characteristics**

**Participant flow**

**Adverse events**

**Outcome measures**

**URL to protocol files**