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±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 المراضة 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:
هذه دراسة جمع البيانات بأثر رجعي عن المرضى الذين خضعوا لليبروسكان في وحدة الكبد في الجامعة الأمريكية في بيروت بين عامي 2015و 2018. تمت مراجعة المخططات الطبية لجميع المرضى. تم جمع البيانات وتحليلها باستخدام برنامج SPSS 25.
النتائج:
كان متوسط العمر 67.5 (419 ٪) من الذكور. 47.8 ± 13.4 مريضا إلى الوحدة الكبدية الصفراوية فيبروسكان ، منهم 620قدم ما مجموعه 69 (11.1٪) مصاب بالتهاب الكبد C ، 89 (14.3٪) مصاب بالتهاب الكبد B - مصاب بـ 58.3 (362) NAFLD ٪). 84-18(نطاق 48 (7.7٪) كان يعاني من التهاب الكبد المناعي2.9 (13و ٪) مصاب بـ 3.3 (20مصاب بمرض التصلب العصبي المتعدد ، DILI ٪) مصابون بالسكري. تم الإبلاغ عن تصلب الكبد20.6 (128) ، 25٪) يعانون من زيادة الوزن (مؤشر كتلة الجسم فوق 30.6 (190الذاتي. (27.9٪) 101 من التهاب الكبد المناعي الذاتي ، 46.5 (6على الليفوسكان في الغالب في F4 المقابل لتشخيص مرحلة تليف الكبد NAFLD ، 18) و 26.1 ٪) من مرضى HCV. عانى (141 ٪) ممن لديهم عامل أو أكثر من عوامل الخطر الأيضية من تنكس45.5 مريضاً 28.9 (78حاد في المرحلة مقارنة بـ P 0.04 ٪) لم يكن لديهم أي عوامل خطر ذات قيمة.
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 between 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

Number of groups/cohorts
1

Biospecimen retention
None retained

Biospecimen description
NA

Target sample size
470

Actual enrollment target size

Date of first enrollment: Type
Actual

Date of first enrollment: Date
01/01/2016

Date of study closure: Type
Actual

Date of study closure: Date
31/12/2019

Recruitment status
Complete

Recruitment status: Specify

Date of completion

IPD sharing statement plan
No

IPD sharing statement description
data will be shared upon request

Additional data URL

Admin comments

Trial status
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