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Screening for Liver Fibrosis in Patients with Type 2 Diabetes Mellitus in Brazzaville: Value of Vibration-Controlled Transient Elastography (FibroScan®)

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Abstract

Objective: This paper aims to determine the frequency of non-alcoholic fatty liver disease (NAFLD) and the severity of liver fibrosis assessed by vibration-controlled transient elastography (VCTE) in patients with type 2 diabetes mellitus in Brazzaville. **Population and Method:** This was a cross-sectional and analytical study that took place from April 1, 2021, to October 30, 2021, a period of 7 months. The outpatient department for metabolic and endocrine diseases at the Brazzaville University Hospital served as the setting for patient recruitment. The liver fibrosis assessment was performed at the Suza Clinic. We included all consenting patients with type 2 diabetes, aged at least 18 years. Patients with known chronic liver disease of any cause and patients reporting risky alcohol consumption (>30 g/day for men and >20 g/day for women) were not included. Hepatic steatosis and fibrosis were assessed by VCTE (FibroScan®) with controlled attenuation parameter (CAP). The variables studied were sociodemographic, clinical, and paraclinical. Statistical analyses were performed using SPSS 25 software. **Results:** In our study, we included 50 type 2 diabetic patients. Men represented 36% (n = 18) and women 64% (n = 32). The mean age of the patients was 56.08 +/− 10.48 years, with a range of 27 to 80 years. The mean duration of type 2 diabetes was 5.38 +/− 5.73 years, with a range of 0 to 21 years. Metabolic syndrome, obesity, and dyslipidemia were noted in 58%, 62%, and 48% of cases, respectively. Glycated hemoglobin was

elevated in 72% of cases. Fatty liver disease (NAFLD) was detected in 44 patients, representing a frequency of 88%. Among the 44 patients with fatty liver disease, seven patients were at stage S1 (15.9%), eighteen patients at stage S2 (40.9%), and nineteen patients at stage S3 (43.2%). Among them, 26 patients (59.1%) had no or mild fibrosis (F0 - F1), 8 (18.2%) had F2, 7 (15.9%) had F3 and 3 (6.8%) had F4 fibrosis. Significant fibrosis (≥F2) was found in 18 patients (40.9%) and advanced fibrosis (F3 - F4) in 10 patients (22.7%). **Conclusion:** NAFLD is very frequent in patients with type 2 diabetes in Brazzaville, and more than one in five patients with NAFLD has advanced fibrosis. Systematic screening by VCTE should be considered in this population.

Keywords

Screening, Liver Fibrosis, Vibration-Controlled Transient Elastography, NAFLD, Type 2 Diabetes, Brazzaville

1. Introduction

Non-alcoholic fatty liver disease (NAFLD) covers a broad spectrum of liver damage ranging from simple steatosis to non-alcoholic steatohepatitis, which is the aggressive form likely to lead to liver fibrosis [1]. It is common in type 2 diabetic patients. Its prevalence in type 2 diabetic patients is estimated at approximately 55 to 75% depending on the studies and diagnostic methods used [2] [3]. In this population, it is twice as common as in the general population [4]. Several studies have demonstrated that type 2 diabetes (T2D) is an independent factor in the progression of simple steatosis to non-alcoholic steatohepatitis and advanced fibrosis. This would increase the risk of progression to cirrhosis, hepatocellular carcinoma and mortality from liver disease [4] [5]. Type 2 diabetes mellitus also represents an independent factor for the initiation and progression of simple steatosis to the form with hepatic fibrosis or steatohepatitis or NASH (Non-alcoholic steatohepatitis), with the potential to progress to cirrhosis and hepatocellular carcinoma [2]-[4]. The objective of this study was to determine the frequency of NAFLD and the severity of liver fibrosis assessed by VCTE in patients with type 2 diabetes in Brazzaville.

2. Patients and Methods

This was a cross-sectional and analytical study, conducted from April 1, 2021, to October 30, 2021, a period of 7 months. The outpatient department for metabolic and endocrine diseases at the Brazzaville University Hospital served as the setting for patient recruitment. Liver fibrosis assessment was performed at the Suza Clinic. We included all consenting patients with type 2 diabetes, aged at least 18 years. Patients were not included if they had type 1 diabetes; known liver disease (viral, alcoholic, drug-induced or autoimmune hepatitis, primary biliary cholangitis, primary sclerosing cholangitis, haemochromatosis, alpha-1 antitrypsin defi-

ciency, Wilson disease or hepatocellular carcinoma); risky alcohol consumption (>30 g/day for men and >20 g/day for women); treatment with potentially steatogenic drugs (corticosteroids, tamoxifen, calcium channel blockers, amiodarone, oestrogens, tetracyclines or antiretroviral drugs); ascites; alanine aminotransferase ≥ 5 times the upper limit of normal; clinical signs of hypothyroidism; or pregnancy. Patients who withdrew their informed consent or who had biological cholestasis were excluded. Hepatic steatosis and fibrosis were assessed by VCTE (FibroScan®), as detailed below. The variables studied were sociodemographic, clinical and paraclinical.

Ethical considerations: The study was approved by the Health Sciences Research Ethics Committee (Comité d'Éthique de la Recherche en Sciences de la Santé, CERSSA), Brazzaville, Republic of the Congo (ethical clearance decision No. 371/MESRSIT/IRSSA/CERSSA). Administrative authorisations were obtained from the Faculty of Health Sciences of Marien Ngouabi University. All participants received an information sheet written in French and translated into the national languages (Lingala and Kituba), and written informed consent was obtained from each participant before inclusion. Data were anonymised and coded.

Recruitment: All patients with type 2 diabetes seen during the study period who met the inclusion criteria were invited to participate (exhaustive sampling). Participation was voluntary; some eligible patients declined to participate or did not attend the scheduled elastography appointment, and their number was not recorded. Fifty patients were finally included, and all of them underwent VCTE with CAP.

Diagnosis of NAFLD and exclusion of other liver diseases: NAFLD was defined as hepatic steatosis on VCTE (CAP ≥ 215 dB/m) in the absence of risky alcohol consumption and of any other known cause of chronic liver disease or steatogenic treatment (non-inclusion criteria above). Viral hepatitis B and C and other liver diseases were excluded on the basis of the medical history and the patients' medical records; systematic serological testing for hepatitis B and C was not performed.

Vibration-controlled transient elastography: VCTE with CAP was performed with a FibroScan® Mini 430 device (Echosens, Paris, France) after at least 2 hours of fasting. Patients were placed in the supine position with the right arm in abduction, and the probe was positioned in an intercostal space over the right lobe of the liver. The M probe was used in patients with a body mass index (BMI) < 30 kg/m^2 and the XL probe in those with a BMI ≥ 30 kg/m^2. Liver stiffness (kPa) was the median of 10 valid measurements obtained at a depth of 25 to 65 mm; examinations were considered reliable when the success rate was >60% and the interquartile range/median ratio was <30%. Steatosis was graded according to CAP values: S0, <215 dB/m; S1, 215 - 252 dB/m; S2, 253 - 296 dB/m; S3, >296 dB/m. Fibrosis was staged according to liver stiffness: F0 - F1, <7 kPa; F2, 7 - 8.5 kPa; F3, 8.5 - 10.5 kPa; F4, >10.5 kPa. Significant fibrosis was defined as ≥ F2 and advanced fibrosis as F3 - F4. VCTE with CAP has been validated for the non-invasive assessment of steatosis [6] and fibrosis [7] in NAFLD.

Definitions: Overweight and obesity were defined according to the WHO classification as a BMI of 25 - 29.9 kg/m^2 and ≥30 kg/m^2, respectively. Abdominal obesity was defined as a waist circumference ≥ 94 cm in men and ≥ 80 cm in women [8]. Metabolic syndrome was defined according to the International Diabetes Federation criteria, *i.e.* abdominal obesity plus at least two of the following: triglycerides >1.5 g/L, fasting blood glucose >1.0 g/L, HDL cholesterol <0.40 g/L in men or <0.50 g/L in women, and blood pressure > 130/85 mmHg [8]. Dyslipidemia was defined as LDL cholesterol >1.6 g/L and/or triglycerides >1.5 g/L and/or HDL cholesterol <0.40 g/L in men or <0.50 g/L in women and/or current lipid-lowering treatment. Glycated haemoglobin (HbA1c) was considered elevated when >7% [9]. Hypertension was defined as known hypertension, current antihypertensive treatment or blood pressure ≥140/90 mmHg.

Statistical analysis: Data were entered into CsPro 7.2 software, synchronised with a Dropbox server, exported to Excel 2013 and analysed with SPSS 25 software. Qualitative variables were presented as numbers and percentages, and quantitative variables as means ± standard deviations. Proportions were compared between men and women using Pearson's chi-square test, or Fisher's exact test when an expected count was <5. The significance threshold was set at 5%.

3. Results

In our study, we included 50 patients with type 2 diabetes. Men represented 36% (n = 18) and women 64% (n = 32), with a sex ratio of 0.56 in favor of women. The mean age of the patients was 56.08 +/− 10.48 years, with a range of 27 to 80 years. The most represented age range was 50 to 59 years. The mean duration of type 2 diabetes was 5.38 +/− 5.73 years, with a range of 0 to 21 years. The general characteristics of type 2 diabetic patients by sex are shown in Table 1, and the associated comorbidities in Table 2.

Table 1. Distribution of patients by sex according to the characteristics of type 2 diabetes.

	Total		Male		Female		P
	N	%	N	%	N	%	
Stroke Complications							1.000
Yes	3	6	1	33.3	2	66.7	
No	47	94	17	36.2	30	63.8	
HbA1C							0.533
Normal	14	28	6	42.9	8	57.1	
High	36	72	12	33.3	24	66.7	
Oral Anti-Diabetic (OAD)							1.000
Yes	45	90	16	35.6	29	64.4	
No	5	10	2	40	3	60	

Continued

Insulin							0.463
Yes	10	20	5	50	5	50	
No	40	80	13	32.5	27	67.5	
OAD+ insulin							0.654
Yes	6	12	3	50	3	50	
No	44	88	15	34.1	29	65.9	
Sports activity							**0.050**
Yes	5	10	4	80	1	20	
No	45	90	14	31.1	31	68.9	

Table 2. Distribution of patients by sex according to comorbidities associated with type 2 diabetes.

	Total		Male		Female		P
	N	%	N	%	N	%	
Metabolic Syndrome							0.551
Yes	29	58	9	31	20	69	
No	21	42	9	42.9	12	57.1	
Hypertension							0.880
Yes	34	68	12	35.3	22	64.7	
No	16	32	6	37.5	10	62.5	
Body Mass Index							0.405
Normal	7	14	3	42.9	4	57.1	
Overweight	12	24	6	50	6	50	
Obesity	31	62	9	29	22	71	
Waist Circumference							**0.007**
Normal	13	26	9	69.2	4	30.8	
Elevated	37	74	9	24.3	28	75.7	
Dyslipidemia							0.111
Yes	24	48	8	33.3	16	66.7	
No	26	52	8	30.8	18	69.2	

During our study, fatty liver disease (NAFLD) was detected in 44 diabetic patients, representing a frequency of 88%. Among the 44 patients with fatty liver

disease, seven patients were in stage S1 (15.9%), eighteen patients in stage S2 (40.9%), and nineteen patients in stage S3 (43.2%).

Liver stiffness was assessed by VCTE in all patients; the results are reported for the 44 patients with NAFLD. Twenty-six patients (59.1%) had no or mild fibrosis (F0 - F1), 8 (18.2%) had F2, 7 (15.9%) had F3 and 3 (6.8%) had F4 fibrosis. Significant fibrosis (≥F2) was found in 18 patients (40.9%) and advanced fibrosis (F3 - F4) in 10 patients (22.7%).

4. Discussion

In our study, the mean age of the study population was 56.08 +/− 10.48 years with extremes of 27 and 80 years. Hue A et al reported a mean age of 58.5 +/− 11.5 years in their series [10]. Indeed, type 2 diabetes is a chronic condition with an average age of onset around fifty. In our series, the mean duration of type 2 diabetes was 5.4 +/− 5.7 years with extremes of 0 and 21 years. Our results are superimposable with data from the literature which found a mean duration of diabetes of less than 10 years [11] [12].

The presence and severity of liver fibrosis have a prognostic value in type 2 diabetic patients with NAFLD. This justifies the interest of an assessment which is recommended by several authors throughout the literature [13] [14]. In our study, 40.9% of the patients with NAFLD had significant fibrosis (≥F2) and 22.7% had advanced fibrosis. This shows the importance of the association of type 2 diabetes and NAFLD. Indeed, several studies have demonstrated that type 2 diabetes is an independent risk factor for the progression of NAFLD to NASH and advanced fibrosis [4] [5]. Advanced fibrosis is the most important prognostic factor in NAFLD and is associated with mortality and complications of hepatic causes [15].

In our sample, the prevalence of advanced fibrosis was 22.7%. Our results are close to the data in the literature, which reports a prevalence varying between 7 and 20% depending on the studies and the diagnostic modalities used [16]. Monitoring the progression of fibrosis is also necessary at variable time intervals [14]. Abdominal obesity and poor glycaemic control have been reported as factors associated with fibrosis in patients with type 2 diabetes: Halloul *et al.* assessed liver fibrosis using Fibroscan® in type 2 diabetic patients and identified abdominal obesity and uncontrolled diabetes as independent factors accelerating the progression of NAFLD to liver fibrosis [17]. In our study, the small number of patients with advanced fibrosis (n = 10) did not allow a reliable analysis of the factors associated with fibrosis; this question should be addressed in larger studies.

Limitations: This study has several limitations. It was a single-centre study with a small sample size. Participation was voluntary, which may have introduced a selection bias: some eligible patients declined to participate or did not attend the elastography appointment, and their number was not recorded. Viral hepatitis was excluded on the basis of the medical history without systematic serological testing. Liver biopsy was not performed, and the CAP and liver stiffness cut-offs used have not been validated in sub-Saharan African populations. Finally, the

cross-sectional design does not allow conclusions to be drawn on the progression of fibrosis.

5. Conclusion

Our study shows a high frequency of NAFLD (88%) in patients with type 2 diabetes in Brazzaville. Among patients with NAFLD, 40.9% had significant fibrosis and 22.7% advanced fibrosis on VCTE. These findings support systematic screening for NAFLD and liver fibrosis by VCTE in patients with type 2 diabetes in our setting.

Author Contributions

DF collected the data and performed the initial analysis as part of her medical doctoral thesis. JRI designed and supervised the study. JFMM drafted and revised the manuscript. CMAA, NA, FEMO, MGI, RM, NAIN, RSN, MNM, AMO and BIAI contributed to patient recruitment, data interpretation and/or critical revision of the manuscript. All authors read and approved the final version of the manuscript.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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