A real world evidence perspective on the management of NAFLD patients in Russia

Real-world comorbidities and treatment patterns among patients with nonalcoholic fatty liver disease receiving phosphatidylcholine as adjunctive therapy in Russia.
Maev IV, et al.
BMJ Open Gastro 2019;6:e000307

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METHODOLOGY

- **An observational, multicenter study conducted in the real world[1]*** (Sept 2015 – Sept 2016)
- Main objective: **Management of NAFLD in patients who received EPLs**
- Secondary objectives: EPL safety, compliance to EPL therapy and treatment satisfaction

** Real-life studies provide a **more insightful overview** of daily practice than randomized controlled trials[2]*

- **2,843 newly-diagnosed NAFLD patients** with at least one of the following concomitant diseases (*i.e.,* 'high-risk' patients), **components of the metabolic syndrome:**
  - High blood pressure; T2DM; High serum cholesterol; Overweight/obesity
- Patients received:
  - Possible comorbidity-related medications
  - EPL therapy (Essentiale® Forte N: 300 mg of EPLs) prescribed as an adjunctive treatment to standard care for 24 weeks

Since this was an observational study, no therapeutic or diagnostic intervention was performed in the frame of the study

1. Maev IV, et al. Real-world comorbidities and treatment patterns among patients with nonalcoholic fatty liver disease receiving phosphatidylcholine as adjunctive therapy in Russia. BMJ Open Gastro 2019;6:e000307
2. Harari S. Randomised controlled trials and real-life studies: two answers for one question. Eur Respir Rev 2018; 27:180080
NAFLD: Non-alcoholic fatty liver disease; **T2DM:** Type 2 diabetes mellitus; **EPLs**: Essential phospholipids

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RESULTS

79.6% of NAFLD patients had **at least 2 metabolic comorbidities**

- **Obesity** and **hypercholesterolemia** were the most common comorbidities
- A majority of patients were **asymptomatic**
- **Hepatomegaly** was detected in **64.2%** (1774/2843) of NAFLD patients

Baseline characteristic	Study population (N=2843)
Mean ± SD age (median; IQR), years	48.7±8.6 (50.7; 43.6–55.6)
Male/female, n (%)	1076 (37.8)/1767 (62.2)
Mean ± SD weight (median; IQR), kg	91.0±14.1 (90.0; 82.0–99.5)
Mean ± SD BMI (median; IQR), kg/m2	32.0±4.6 (31.8; 29.2–34.6)
Mean ± SD waist circumference (median; IQR), cm	98.4±12.4 (98.0; 90.0–105.0)
Comorbid condition	
According to the nature of the comorbidity, n (%)*	
Hypertension	1642 (57.8)
Overweight/obesity	2298 (80.8)
Elevated cholesterol	2122 (74.6)
T2DM†	477 (16.8)
According to the number of comorbidities, n (%)	
1	580 (20.4)
2	1112 (39.1)
3	869 (30.6)
4	282 (9.9)

*Patients may have more than one comorbid condition.† In this study, mean ± SD hemoglobin A1c level at baseline was 6.1%±1.4% (this parameter was available in 843 subjects).
BMI: body mass index; **IQR**: interquartile range; **SD**: standard deviation; **T2DM**: type 2 diabetes mellitus.

NAFLD: Non-alcoholic fatty liver disease

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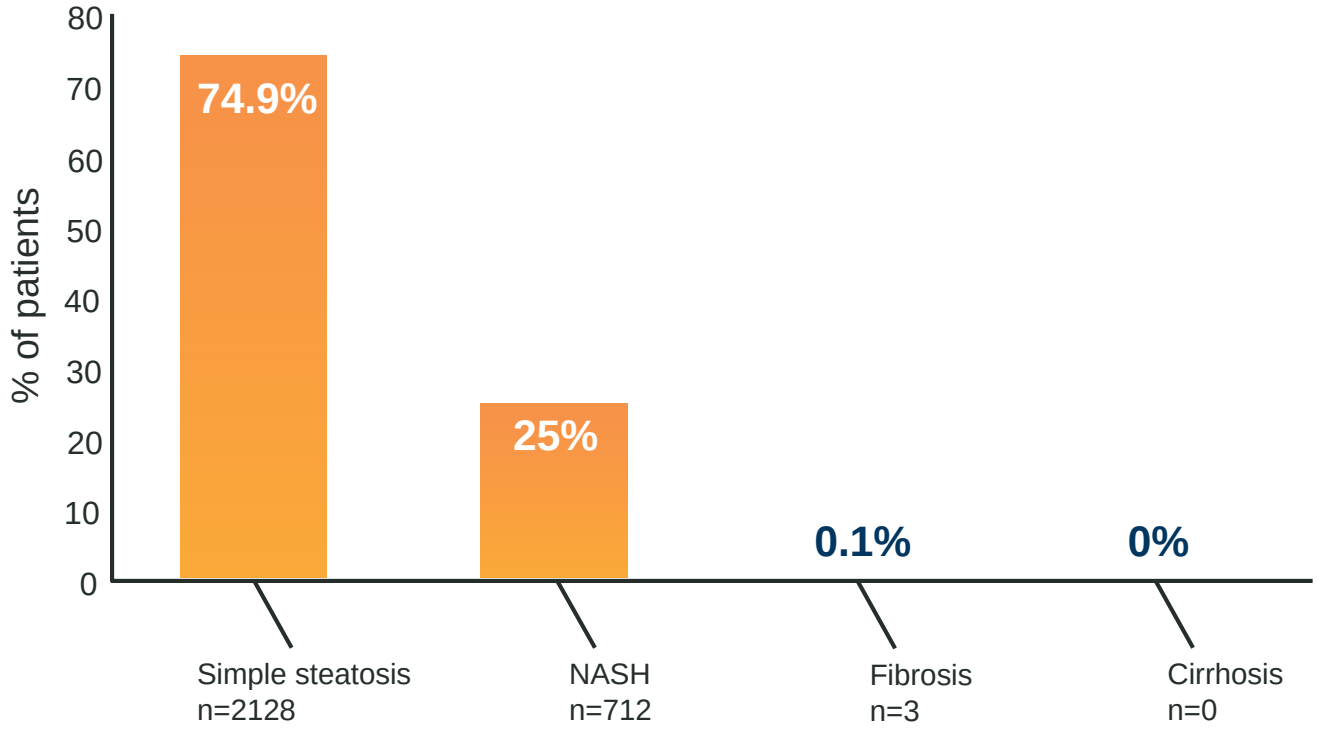
RESULTS

EPLs were **used early** (from simple steatosis) and **maintained long term**

- **Simple steatosis** was the most frequent clinical form of NAFLD in patients who received EPLs

CLINICAL FORMs OF NAFLD (% OF PATIENTS)



NAFLD: Non-alcoholic fatty liver disease; **NASH**: Nonalcoholic steatohepatitis; **EPLs**: Essential phospholipids

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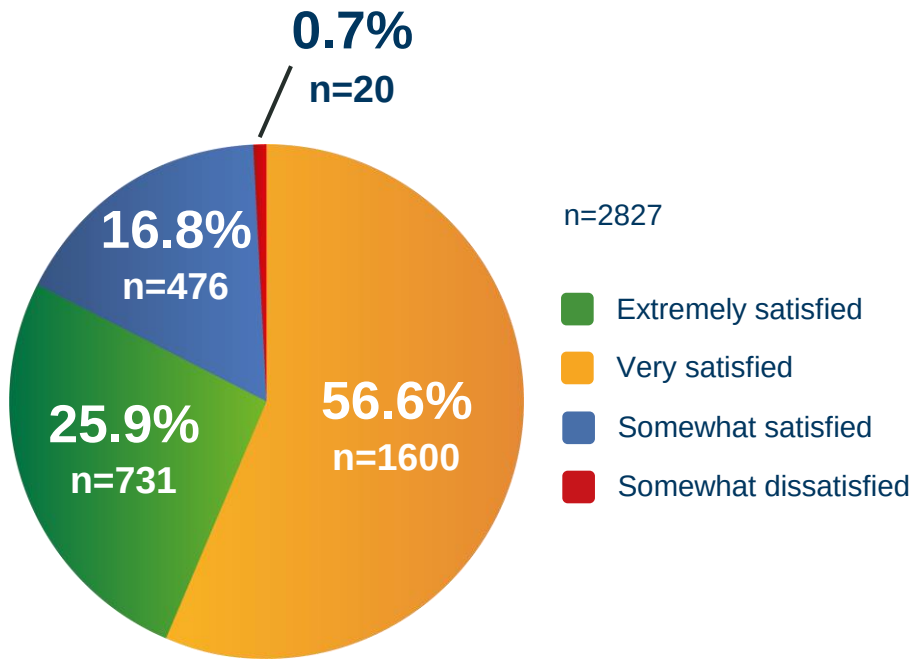
RESULTS

EPLs were associated with a **high-rate compliance** and **high satisfaction** among patients and their physicians

- EPLs showed a **good safety profile,** and **no adverse events/severe adverse events** were reported during the study period

COMPLIANCE AND PATIENT SATISFACTION WITH EPL THERAPY

90.5%
Six-month compliance rate



NAFLD: Non-alcoholic fatty liver disease; **NASH**: Nonalcoholic steatohepatitis; **EPLs**: Essential phospholipids

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CONCLUSION

LIVER PROTECTION WITH EPLs HAS A MAIN ROLE IN THE MANAGEMENT OF NAFLD

Essentiale® with EPLs

The world's number 1 OTC liver & bile remedy*

- **Ultrasonographic improvements[2,3]**
- **Superior ALT and AST reduction[3,4]**
- **Reduction in symptom incidence[5]**

- **In Russia NAFLD patients are heavily burdened by metabolic comorbidities, mainly obesity and hypercholesterolemia[1]**
- **EPLs are used early, and the vast majority of NAFLD patients treated with EPLs have simple steatosis[1]**
- **EPL use is associated with high levels of treatment compliance and satisfaction, and a very good safety profile[1]**

1. Maev IV, et al. Real-world comorbidities and treatment patterns among patients with nonalcoholic fatty liver disease receiving phosphatidylcholine as adjunctive therapy in Russia. BMJ Open Gastro 2019;6:e000307. **2.** Yin D, Kong L. Observation for curative effects of Essentiale® in treatment of fatty liver caused by diabetes mellitus. Med J Qllu 2000;15:277-8. **3.** Sas E, et al. Beneficial influence of polyunsaturated phosphatidylcholine enhances functional liver condition and liver structure in patients with nonalcoholic steatohepatitis. Results of prolonged randomized blinded prospective clinical study. J Hepatol 2013;58:S549-S566. **4.** Liang H. Discussion of treatment of fatty liver using polyene phosphatidyl choline capsules. Chin Med Factory Mine 2006;19(3):207–208. **5.** Dajani A, et al. Essential phospholipids as a supportive adjunct in the management of patients with NAFLD. Arab J Gastroenterol 2015;16: 99–104. * from Nicholas Hall's global OTC database 2018, DB

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