Understand the Patient-Perceived Impact of Nonalcoholic Steatohepatitis: Raising the Volume on a Silent Disease


1RTI-Health Solutions, Manchester, United Kingdom; *Novartis Pharma AG, Basel, Switzerland; **RTI-Health Solutions, Research Triangle Park, NC, USA; Global Liver Institute, Washington, DC, USA; British Liver Trust, Bournemouth, United Kingdom; *Virginia Commonwealth University, VA, USA; **Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA; **Institute of Cellular Medicine, Newcastle University, Newcastle upon Tyne, United Kingdom

BACKGROUND
Nonalcoholic steatohepatitis (NASH) is a progressive form of nonalcoholic fatty liver disease (NAFLD), characterized by excessive liver fat accumulation, inflammation, cell injury and fibrosis. Although NASH is often considered an asymptomatic ‘silent’ disease in the early stages, patients with NASH/NAFLD experience significantly higher rates of anxiety, depression and experience lower health-related quality of life (HRQoL) than the general population.2,3 However, no qualitative studies have been published exploring in-depth, the patient-perceived impact of NASH.

OBJECTIVE
This study aimed to identify the symptomatic and HRQoL impact of NASH from the patient perspective via concept elicitation (CE) interviews conducted with patients diagnosed with NASH.

METHODS
Institutional Review Board (IRB) approval was granted for the study by Western IRB (USA). The most common comorbidities present in these patients were obesity (mean BMI: 27 kg/m^2; F0 to F3).

RESULTS
The mean (SD) age of the patients was 55.9 (10.0) years; 78% of the patients were female, 83% were white and 43.5% of the patients were employed. Seven patients (30.4%) had phenotypic-diagnosed NASH and 16 (69.6%) had biopsy-confirmed NASH (Figure 2). The mean (SD) time since NASH diagnosis was 3.2 (1.5) years.

Figure 2. Fibrosis grade in NASH patients obtained from medical records

Impact of NASH on HRQoL – Patient experience:

- Patients reported that NASH impacted on many aspects of their daily life:
  - Activity limitations, work and social life (Figure 5): NASH symptoms, particularly fatigue and cognitive problems, affected patients’ ability to carry out ADLs and iADLs and impacted healthy eating choices, social and work life.

Figure 5. Patient experience – Activity limitations, Work and Social life

- Personal relationships and emotions (Figure 6): Both the experience of NASH symptoms and the daily awareness of living with NASH also had a profound impact on patients’ lives.

Figure 6. Patient experience – Relationships and Emotions

CONCLUSION
- The interviews identified key symptoms experienced by NASH patients such as pain, poor sleep quality and cognitive problems.
- The interviews also provided insight into the negative impact of NASH on patients’ HRQoL in terms of physical functioning, work and social life. NASH also impacted negatively on patients’ emotional life and family/personal relationships.
- Findings from this study challenge the notion that NASH is an asymptomatic condition and supports future patient-centered research initiatives in NASH.
- These findings reinforce the need to develop a NASH-specific patient-reported outcome measure (PROM) in order to better quantify and compare the humanistic burden associated with NASH.
- The development of PROM should follow FDA guidance4.
- The next step will be to generate the content of a NASH-specific PROM based on the output of the CE interview.

REFERENCES

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