EXPLORING THE PATIENT PERCEIVED IMPACT OF NON-ALCOHOLIC STEATOHEPATITIS

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INTRODUCTION

• Nonalcoholic steatohepatitis (NASH) is a progressive form of nonalcoholic fatty liver disease (NAFLD), and is characterized by excessive liver fat accumulation, inflammation, fibrosis (progression to advanced liver disease, leading to cirrhosis, liver-related mortality and hepatocellular carcinoma) and to liver disease is currently unapproved.
• The global prevalence of NAFLD is estimated at 24%; although NASH represents only 10-20% of NAFLD cases, it can potentially progress to advanced liver disease, leading to cirrhosis, liver-related mortality and hepatocellular carcinoma and to liver disease is currently unapproved.
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AIM

• The study aimed to explore the impact of NASH on the patient's perspective and to determine the availability of a suitable patient-reported outcome (PRO) measure (PROM) for use in adults with confirmed NASH. Additionally the study aimed to develop a conceptual model for NASH

METHOD

Review of published literature
• A targeted literature review was conducted using MEDLINE and Embase (1946 – 2017) to identify:
  • the humanistic burden of disease in adult patients with diagnosed NASH and confirmed NASH
  • validated PROs developed specifically for this patient population

Review of Grey Literature and Patient-Reported Qualitative Information
• A manual search of grey literature and conference websites was conducted
• Patients blogs and patient groups websites including British Liver Trust and Global Liver were also examined for qualitative information on the patient experiences of living with NASH

Development of a Conceptual Model for NASH
• A review of humanistic burden identified by the patient and grey literature references was synthesized and reviewed by UK and Canadian experts and patient advocacy representatives
• The results were used to develop an initial conceptual model for NASH which was used to determine the suitability of existing PROs for this disease

RESULTS

• Few of the published studies assessed health-related quality of life (HRQoL) of a biopsy-confirmed NASH population only
• Studies presented burden of NAFLD across the spectrum of severity with NASH sometimes reported as a subgroup
• The terms NASH and NAFLD were not always clearly differentiated

TABLE 1. PRO Instruments used in studies involving NASH patients

Results

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Description</th>
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<tr>
<td>SF-36 v2</td>
<td>A 36-item PRO consisting of 8 domains. Scores range from 0 to 100, with lower scores indicating worse HRQoL.</td>
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<tr>
<td>MIEEE</td>
<td>A 30-item instrument developed to assess the impact of chronic liver conditions. Includes 6 domains: abdominal symptoms, fatigue, emotional well-being, social role, physical role, and body image.</td>
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<tr>
<td>CLDQ</td>
<td>A 29-item instrument developed to assess the impact of chronic liver conditions. Includes 6 domains: abdominal symptoms, fatigue, emotional well-being, social role, physical role, and body image.</td>
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<tr>
<td>SF-6D</td>
<td>A 6-item instrument developed to assess the impact of chronic liver conditions. Includes 6 domains: pain, anxiety, depression, physical mobility, self-care, and usual activity.</td>
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<tr>
<td>EQ-5D</td>
<td>A 5-item instrument developed to assess the impact of chronic liver conditions. Includes 5 domains: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression.</td>
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CONCEPTUAL MODEL FOR NASH

• Clinical experts and patient representatives reviewed the findings and confirmed that there were clearly identified areas of impact on the patient experience, reflected in the conceptual model
• The experts confirmed that the conceptual model is applicable to all patients (confirmed or not confirmed) in NASH
• They further highlighted the need for future qualitative work with NASH patients to confirm the above model and initiate the development of a new NASH-specific PRO

DISCUSSION & CONCLUSIONS

• The current review found that patients report other aspects of the disease which are not currently covered by existing PROs
• SF-36 is a generic instrument not validated for NASH and is unlikely to address all issues relevant to NASH patients
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REFERENCES


ACKNOWLEDGEMENTS

• The authors would like to thank the patients who participated in the study and contributed to the development of the conceptual model for NASH
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