Effect of subcutaneous semaglutide on quality of life in patients with non-alcoholic steatohepatitis

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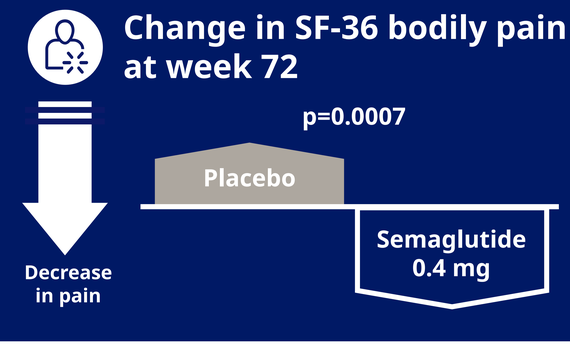
Semaglutide improves quality of life in patients with non-alcoholic steatohepatitis



Aim

- Although often considered to be asymptomatic,[1] non-alcoholic steatohepatitis (NASH) can have a detrimental effect on health-related quality of life (HRQoL).[2,3]
- In a phase 2 trial, treatment with the glucagon-like peptide-1 receptor agonist semaglutide resulted in significantly more patients achieving NASH resolution without worsening of fibrosis compared with placebo, as well as improvements in glycaemic control, fibrosis biomarkers and body weight.[4]
- Here, we report the effects of semaglutide on patient-reported outcomes of HRQoL in this trial.

Methods

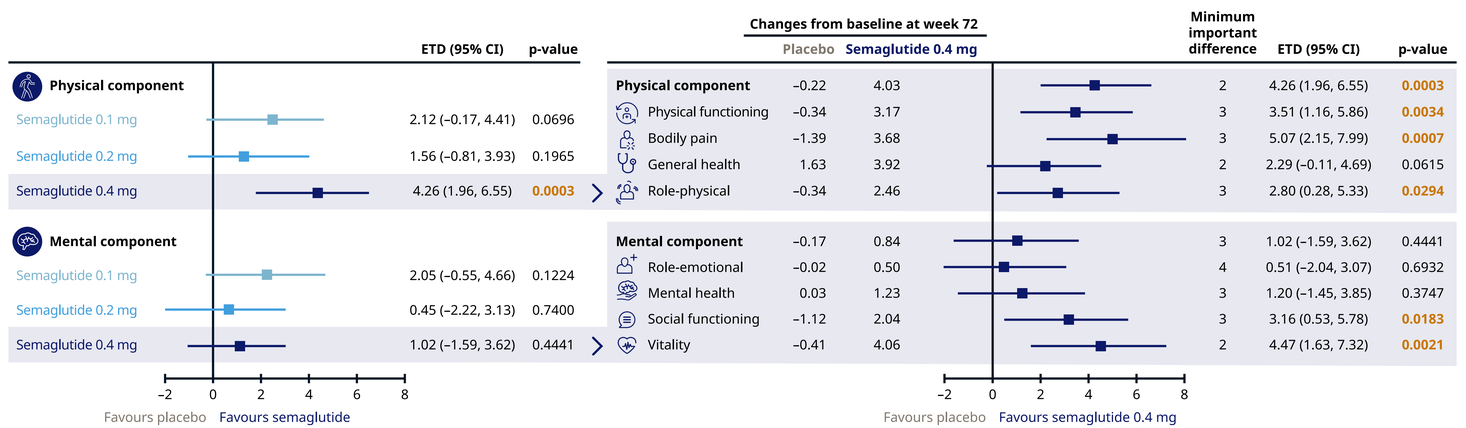
- This was a double-blind, placebo-controlled trial that randomised patients with biopsy-confirmed NASH and fibrosis stage (F) 1–3 to once-daily subcutaneous semaglutide 0.1, 0.2 or 0.4 mg, or placebo for 72 weeks.
- Changes from baseline in Short Form-36 (SF-36) physical and mental component summary scores and individual sub-domains were assessed at week 72.

Key results

- A total of 320 patients were randomised to semaglutide 0.1 mg (n=80), 0.2 mg (n=78), 0.4 mg (n=82) or placebo (n=80).
- At 72 weeks, physical component summary scores were significantly improved with semaglutide 0.4 mg vs placebo (**Figure 1**). No significant differences in physical and mental components were observed between semaglutide 0.1 or 0.2 mg and placebo.
- Treatment with semaglutide 0.4 mg was associated with significantly greater improvements than placebo in the domains of bodily pain, physical functioning, role limitations due to physical health problems, social functioning and vitality (**Figure 1**).
- Numerically greater but non-significant improvements were also seen in other domains.
- Improvements in physical component summary scores were significantly greater in patients with NASH resolution than without (mean [SD] change from baseline in all patients pooled: 3.0 [6.7] vs 1.2 [6.6]; p=0.014).
- There were no significant correlations observed between changes in SF-36 domains and NASH resolution or with changes in body weight, enhanced liver fibrosis (ELF) score or liver stiffness assessed by FibroScan.

Figure 1: Changes in Short Form-36 component summary and individual domain scores

Key results



Data for all randomised patients during the in-trial period, analysed using an ANCOVA model with missing data derived by multiple imputation from placebo group. Data for semaglutide 0.1 mg and 0.2 mg doses not shown (ETD vs placebo all non-significant, except social functioning for 0.1 mg dose, p=0.0022). *MIDs are defined as the smallest difference in score which patients perceive as beneficial, are from the SF-36 Manual and Interpretation Guide and refer to mean group differences rather than responder definitions for individuals.
ANCOVA, analysis of covariance; CI, confidence interval; ETD, estimated treatment difference; MID, minimum important difference; SF-36, Short Form-36.

Conclusions

- Treatment with once-daily subcutaneous semaglutide has a clinically important effect on HRQoL in patients with NASH and stage F1–3 fibrosis.
- Increased focus on and better understanding of patient-centred outcomes are needed in future research of treatments for NASH.

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(1) Doward LC, et al. *Patient* 2020 Dec 18. doi: 10.1007/s40271-020-00485-w; **(2)** Balp MM, et al. *JHEP Rep*. 2019;1:154–61; **(3)** Younossi ZM, et al. *Am J Gastroenterol.* 2019;114:1636–41; **(4)** Newsome PN, et al. *N Engl J Med.* 2021;384:1113–24.

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