Impaired Fasting Glucose Is Associated With Lower Rates of Sustained Virologic Response (SVR) in Patients With Genotype 1 Chronic Hepatitis C (CHC): Retrospective Analysis of the IDEAL Study


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Abstract

Background/Summary: Impaired fasting glucose is independently associated with reduced likelihood of SVR with current therapy (Meta-HBV, 2009; Allon, 2009). However, the relationship between SVR, fasting blood glucose (FBG) and HbA1c has not been defined.

Methods: 3070 treatment-naive patients (pts) received peginterferon alfa-2b (PEG-IFN) 1a 1.5 µg/kg/week and ribavirin (RBV) based on medical history of diabetes. Among those who underwent pretreatment HbA1c testing, no association between HbA1c level and SVR was apparent; however, pts with HbA1c >8.5% were excluded from treatment.

Results: Baseline FBG levels were correlated with lower SVR rates and higher relapse rates in CHC genotype 1 pts treated with PEG-IFN compared to those with FBG <100mg/dL. IFG was strongly associated with lower SVR and higher relapse rates in CHC genotype 1 pts treated with PEG-IFN compared to those with FBG <100mg/dL. Among those without diabetes, SVR rates were lower with FBG ≥100 mg/dL

Assessments

All patients underwent pretreatment fasting blood glucose (FBG) determination and were categorized by their medical history of diabetes. Patients with a baseline FBG ≥100 mg/dL were defined as having impaired fasting glucose (IFG) compared to those with FBG <100mg/dL. IFG was strongly associated with lower SVR and higher relapse rates in CHC genotype 1 pts treated with PEG-IFN compared to those with FBG <100mg/dL. Among those who underwent HbA1c testing, the SVR rate was significantly lower among pts with HbA1c >8.5% compared to those with HbA1c ≤8.5% (P = 0.02). However, IFG was associated with lower SVR (37% vs. 26%) and higher relapse rates (22% vs. 10%) in these pts. In a subset of pts with IFG, IFG was associated with higher relapse rates (28.7% (880/3068) of patients had baseline FBG ≥100 mg/dL and were considered to have IFG. Among these pts, the SVR rate was significantly lower than in those with FBG <100 mg/dL (26% (83/324)) and those with FBG <100 mg/dL. This was true for all regimens tested in IFG patients with a baseline FBG ≥100 mg/dL and RBV were 50% of those with FBG <100 mg/dL. These data suggest that FBG should be routinely assessed prior to therapy, and randomized trials are needed to determine if improvement in glucose control prior to treatment will lead to improved outcomes.

Conclusions: If IFG is used as a predictor of treatment response, pts with IFG should be treated with alternative regimens. Among pts who underwent HbA1c testing, IFG was associated with lower SVR (37% vs. 26%) and higher relapse rates (22% vs. 10%) in these pts. In a subset of pts with IFG, IFG was associated with higher relapse rates (28.7% (880/3068) of patients had baseline FBG ≥100 mg/dL and were considered to have IFG. Among these pts, the SVR rate was significantly lower than in those with FBG <100 mg/dL (26% (83/324)) and those with FBG <100 mg/dL. This was true for all regimens tested in IFG patients with a baseline FBG ≥100 mg/dL and RBV were 50% of those with FBG <100 mg/dL. These data suggest that FBG should be routinely assessed prior to therapy, and randomized trials are needed to determine if improvement in glucose control prior to treatment will lead to improved outcomes.

Aim

To define the relationship between SVR, fasting blood glucose, and HbA1c in patients receiving peginterferon (PEG-IFN) plus ribavirin in the IDEAL trial

Patients and Methods

Study Design

IDEAL was a phase 2b, randomized, parallel arm trial conducted at 110 academic and community centers in the United States (Figure 1). All patients received 1.5 µg/kg/week IFN-alfa2b and RBV as an oral stabiloid therapy. Patients with a history of diabetes, defined as FBG ≥100 mg/dL, or HbA1c >8.5% prior to treatment were included in the analysis. The frequency of impaired fasting glucose (IFG) was 28.7% (880/3068) of patients had baseline FBG ≥100 mg/dL and were considered to have IFG. Among these pts, the SVR rate was significantly lower than in those with FBG <100 mg/dL (26% (83/324)) and those with FBG <100 mg/dL. This was true for all regimens tested in IFG patients with a baseline FBG ≥100 mg/dL and RBV were 50% of those with FBG <100 mg/dL. These data suggest that FBG should be routinely assessed prior to therapy, and randomized trials are needed to determine if improvement in glucose control prior to treatment will lead to improved outcomes.

Results:

As expected, patients with a history of diabetes had a lower SVR rate and higher relapse rates compared to those without diabetes. The SVR rate was significantly lower among patients with IFG 

Virologic Response

Virologic response rates were comparable in patients with lower and higher levels of HbA1c

Change in HbA1c (% From Baseline)

-8 -7 -6 -5 -4 -3 -2 -1 0 1 2

SVR vs. change in HbA1c

Figure 4. Relationship between hemoglobin concentration and HbA1c at treatment weeks 4 and 12 for patients with values at both time points (n = 1182).

Summary

These data suggest that FBG should be routinely assessed prior to therapy, and randomized trials are needed to determine if improvement in glucose control prior to treatment will lead to improved outcomes.

Acknowledgments

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References


Disclosures

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Figure 5. Relationship between hemoglobin concentration and HbA1c at treatment weeks 4 and 12 for patients with values at both time points (n = 1182).
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Supported by Schering-Plough Corporation, now Merck & Co., Inc., Whitehouse Station, NJ, USA.

Study Design

- IDEAL was a phase 3b, randomized, parallel-arm trial conducted at 118 academic and community hospitals in the United States.
- Treatment-naive, CHC genotype 1 patients (pts) received peginterferon alfa-2a (PEG-IFN) and ribavirin (RBV).
- Pts were categorized by their medical history of diabetes.
- Based on American Diabetes Association (ADA) criteria, pts with FBG ≥116 mg/dL were defined as having impaired fasting glucose (IFG).
- Among pts with FBG ≥116 mg/dL, pts with diabetes were considered to have a history of diabetes.
- Among pts with FBG <116 mg/dL, pts with IFG were categorized in one of three groups: normal, IFG or diabetes.
- Pts with a history of diabetes had SVR rates that were lower than those without a history of diabetes.

Patients and Methods

- ADA criteria were used to define IFG and diabetes.
- FBG and HbA1c levels were measured at baseline and at treatment weeks 4 and 12.
- The frequency of IFG of ≥100 mg/dL was defined as having impaired fasting glucose (IFG).
- Patients with a detectable, <2-log reduction in HCV-RNA at week 12, or with detectable HCV-RNA at week 24 were defined as virologic failure.
- SVR was defined as undetectable HCV-RNA at week 24.

Results

- 3070 treatment-naive patients with chronic hepatitis C, genotype 1 infection, aged 18 to 70 years and weighing 40 to 125 kg were included in the analysis.
- The frequency of IFG of ≥100 mg/dL was defined as having impaired fasting glucose (IFG).
- Pts with a history of diabetes had SVR rates that were lower than those without a history of diabetes.
- Among this subgroup of patients, there was a lower trend in SVR rates in patients with lower HbA1c levels than those without.
- SVR rates were significantly lower among pts with IFG (FBG ≥100 mg/dL) compared with pts with FBG <116 mg/dL (18.5% vs. 36.3%; 95% CI [24.7%, 40.8%]; P = .0003; Figure 1).
- A Pearson correlation coefficient was estimated as 0.44 at treatment week 4.

Virologic Response

- Virologic response was lower in patients with a detectable, <2-log reduction in HCV-RNA at week 12, or with detectable HCV-RNA at week 24.
- SVR was significantly lower among patients with IFG (FBG ≥100 mg/dL) compared with patients with FBG <116 mg/dL (18.5% vs. 36.3%; 95% CI [24.7%, 40.8%]; P = .0003; Figure 1).

Figure 1. IDEAL study design.

Figure 2. Virologic response rates according to baseline fasting blood glucose.

Figure 3. Relationship between hemoglobin concentration and HbA1c at treatment weeks 4 and 12 for patients with values at both time points (n = 1019).

Conclusions

- These data suggest that FBG should be routinely assessed prior to treatment of chronic hepatitis C.
- Randomized trials are needed to determine if improvement in glucose control prior to treatment would improve virologic response.
- Anemia may be associated with a decrease in HbA1c.
- These data suggest that FBG should be routinely assessed prior to treatment of chronic hepatitis C.
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Summary

• Fasting blood glucose (FBG) was strongly associated with lower SVR and higher relapse rates in CHC genotype 1 pts treated with PegIFN/RBV. Among those who underwent testing, no association between HBA1c level and SVR was seen.

Patients

• 3070 treatment-naive patients with chronic hepatitis C genotype 1 infection, aged 18 to 70 years and weighing 45 to 120 kg.

Assessments

• All patients underwent pretreatment fasting blood glucose (FBG) determination and were categorized by their medical history of diabetes. Based on the American Diabetes Association definition, pts with FBG >100 mg/dL were deemed as having impaired fasting glucose (IFG). IFG, or impaired glucose tolerance (IGT), refers to normal FBG levels but impaired glucose response (IGR) at one or both of the subsequent glucose levels: 75 g of glucose (oral glucose tolerance test) at 120 and 180 min, or abnormal glucose response levels were attained in response to the glucose load test.

Results

• Among this subgroup of patients, there was a trend for lower SVR rates in patients with IFG. However, the SVR rate was not associated with HbA1c levels at baseline (P<.06 vs. P=.025).

Conclusions

• Impaired fasting glucose is associated with lower rates of sustained virologic response to PegIFN/RBV in patients with genotypic 1 chronic hepatitis C. This association was independent of patients' medical history of diabetes.

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Background/Aims: Impaired fasting glucose is independently associated with reduced likelihood of SVR with current therapy (PEG-IFN/RBV). Among those who underwent testing, no association between HBA1c level and SVR was observed.

Methods: 3070 treatment-naive patients (pts) received peginterferon (PEG-IFN) alfa-2b or alfa-2a plus ribavirin (RBV). All pts underwent pretreatment Fasting Blood Glucose (FBG) and hemoglobin A1c (HBA1c) testing. Patients with FBG ≥116 mg/dL (IFG) and/or patients with a history of diabetes were excluded. Pts with FBG between 100 and 115 mg/dL did not have HBA1c testing. Virologic response rates were analyzed.

Results: 45% of pts were included in the analysis of FBG (729/1608 pts) and of HBA1c (677/1500 pts). Among those undergoing testing, no association between HBA1c level (≤6% vs >6%) and SVR was observed. HBA1c levels were analyzed by median values of 5, 6, 7, and ≥8% in the pre-treatment assessment visit. Among this subgroup of patients, there was a trend for lower SVR rates in patients with lower HBA1c levels (<6% vs ≥6%; P = .08) (Figure 3).

Conclusions: Impaired fasting glucose and the clinical diagnosis of diabetes were both negatively associated with SVR. HBA1c levels were associated with lower SVR rates in diabetic patients. Among those with impaired glucose control (eg, fingerstick glucose monitoring and/or fructosamine) at baseline, the HBA1c level was strongly associated with lower SVR rates.

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1. Harrison SA. 
3. J. Long is an employee of Merck & Co., Inc. S. Noviello is a former employee and now consultant of Virochem, and Osiris Therapeutics. J. W. King has received research support from Schering-Plough Corporation, now Merck & Co., Inc. F. Nunes, A. Nyberg, S. Oh, P. Pandya, M. P. Pauly, C. Peine, R. Perrillo, G. Poleynard, F. Poordad, A. Post, F. Felizarta, R. Firpi-Morell, S. Flamm, J. Franco, B. Freilich, J. Galati, A. Gibas, E. Godofsky, F. Gordon, G. W. Galler serves as advisor for Schering-Plough and Gilead and speaks for Takeda. J. McCone speaks for Schering-Plough and Roche. L. M. Nyberg has received research and grant support from Schering-Plough, Roche, Vertex, and Zymogenetics, and speaks for Schering-Plough.

Figure 1. IDEAL study design.

Figure 2. Virologic response rates according to baseline fasting blood glucose levels.

Figure 3. Relationship between hemoglobin concentration and HbA1c at treatment weeks 4 and 12 for patients with values at both time points (n = 1014).

Figure 4. Relationship between hemoglobin concentration and HbA1c at treatment weeks 4 and 12 for patients with values at both time points (n = 1014).

Figure 5. Relationship between hemoglobin concentration and HbA1c at treatment weeks 4 and 12 for patients with values at both time points (n = 1014).

Summary

• FBG and the clinical diagnosis of diabetes were each strongly associated with lower SVR and higher failure rate.
• There was no significant association between HBA1c level and SVR; however, patients with HBA1c >8.5% were excluded from treatment.

Conclusions

• These data suggest that FBG should be routinely assessed prior to treatment of chronic hepatitis C.
• Randomized trials are needed to determine if improvement in glucose control prior to treatment will lead to improved virologic response.
• Anemia may be associated with a decrease in HBA1c.
• On-treatment anemia was associated with lower HBA1c levels and higher failure rates.

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Abstract

Background/Aims: Impaired fasting glucose is independently associated with reduced likelihood of SVR with current therapy (2005-2006). However, the relationship between fasting glucose and SVR has not been defined.

Methods: 3070 treatment-naïve patients (pts) received peginterferon α-2b or -2a plus ribavirin (RBV). All pts underwent pretreatment FBC determination and were categorized by their medical history of diabetes. Based on American Diabetes Association definition, pts with FBC ≥150 mg/dL were defined as having impaired fasting glucose (IFG). Hemoglobin (HbA1c) was measured for diabetes cases/controls (mean 9.3% [57.8 mmol/L] vs 6.1% [35.9 mmol/L]). SVR was defined as undetectable HCV-RNA (lower limit of quantitation of 27 IU/mL by Roche Amplicor) at end of treatment (EOT) or 24 weeks post-treatment (Follow-up).

Results: Among those who underwent testing (n = 324), median HbA1c was 6.1% (interquartile range, 5.6%-6.6%). SVR according to baseline FBC for all pts and according to HBA1c for the subset with testing and shown (Table). SVR rate was significantly lower among pts with baseline FBC ≥100 mg/dL compared with those with baseline FBC <100 mg/dL (P = 0.001; Figure 1).

Conclusions: Impaired fasting glucose and the clinical diagnosis of diabetes were each correlated with changes in HbA1c levels at treatment weeks 4 and 12 (n = 103) (Pearson correlation coefficient was estimated as 0.39 at treatment week 4). However, the SVR rate was not associated with HbA1c level (P = 0.05; P = 0.10).

Aim

To define the relationship between FBC, fasting blood glucose, and HbA1c in patients receiving peginterferon (Peg-IFN)-RBV plus ribavirin in the IDEAL trial.

Patients and Methods

Study Design

- IDEAL was a phase 3b, randomized, parallel arm trial conducted at 116 academic and community centers in the United States (Figure 2).
- Peg-IFN-α2b or -2a plus RBV were administered as open-label treatment.
- Patients with a detectable HCV-RNA in basal HCV-RNA at week 24 were discontinued from treatment and were categorized by their medical history of diabetes. Among those who underwent testing, 30.3% (267/880) of patients had baseline FBC ≥100 mg/dL and were considered impaired fasting glucose (IFG).

- 28.7% (236/824) of patients had basal FBC ≥100 mg/dL and were considered to have IFG.

Virologic Response

Virologic response rates were lower in patients with a medical history of diabetes and/or baseline FBC ≥100 mg/dL compared with those with baseline FBC <100 mg/dL (Figure 3).

- SVR EOT Response Relapse

- EOT = end-of-treatment; FBC = fasting blood glucose; SVR = sustained virologic response.

Results

- • SVR EOT Response Relapse
- EOT = end-of-treatment; FBC = fasting blood glucose; SVR = sustained virologic response.

- SVR = sustained virologic response.

- Treatment groups were significantly different in HCV-RNA at treatment weeks 4 and 12 (n = 103) (Pearson correlation coefficient was estimated as 0.44 at treatment week 4). However, the SVR rate was not associated with HbA1c level (P = 0.05; P = 0.10).

Conclusions

- SVR rate was significantly lower among patients with IFG (FBC ≥100 mg/dL) compared with those with FBC <100 mg/dL (P = 0.001; Figure 1).
- Relapse rate was also higher in those with IFG (40% [274/680] vs 22.7% [126/552]; P < 0.001).

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