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Outcomes at a metabolic health clinic: A medical audit

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Background: A low proportion of Americans are deemed metabolically healthy by the Centers for Disease Control and Prevention. There is a need for different approaches to addressing metabolic health in the United States, with therapeutic carbohydrate reduction being one potential intervention.

Aim: To quantify the change across follow-up in outcomes (haemoglobin A1c [HbA1c], triglycerides [TGs], high-density lipoprotein cholesterol [HDL-c], high-sensitivity C-reactive protein [hsCRP] and Homeostatic Model Assessment of Insulin Resistance [HOMA-IR] scores) at a metabolic health clinic implementing a very low carbohydrate approach to eating.

Setting: The study took place at the CHI Metabolic Health Clinic in Elkhorn, Nebraska.

Methods: A cohort of 414 patients with 1234 observations was used in this study. Patient-level data included all available lab values recorded across a minimum of an 8-month follow-up. To account for variable patient follow-up time, frequency and the correlation of repeated observations by individual patients, separate linear mixed models with random intercepts were estimated for each metabolic outcome. Additional sub-analysis was conducted among patients with high baseline HbA1C (values of 5.7% or 39 mmol/mol or greater).

Results: All five of the lab values tracked in this study had positive expected changes regarding their effect on health outcomes. The overall patient population experienced expected decreases in HbA1c, TGs, hsCRP and HOMA-IR scores while increasing HDL-c levels. Among patients with a high initial HbA1c, the positive changes of HbA1c, HDL-c and hsCRP were more pronounced.

Discussion: All laboratory values tracked in this clinic moved in a positive direction regarding their effects on health outcomes. This is consistent with the previous evidence presented on implementation of therapeutic carbohydrate reduction in clinical practice.

Conclusion: Clinics advocating for a therapeutic carbohydrate reduction play a valuable role in the management of metabolic dysfunction.

Keywords: metabolic health; insulin resistance; very low carbohydrate diet; diabetes; HbA1c; HOMA-IR; lipids; CRP.

Background

The Centers for Disease Control and Prevention finds that only 12.2% of Americans are metabolically healthy, demonstrating the need for patient metabolic care.[1] Unlike many other areas of medicine, metabolic health is defined not by the presence of disease, but by the absence of metabolic risk factors – reflecting a fundamentally preventive orientation in medical practice. Because of this, interventions that address modifiable lifestyle behaviours, particularly diet and nutrition, warrant central attention in advancing metabolic health outcomes.

The CHI Metabolic Health Clinic in Elkhorn, Nebraska, is part of a large multispeciality clinic organisation and focuses on lifestyle factors that contribute to metabolic dysfunction. Physicians in the clinic see adults and children with obesity, weight gain, pre-diabetes, type 2 diabetes, hyperlipidaemia, hypertension, gout, Polycystic Ovary Syndrome (PCOS) or other metabolic dysfunctions. This metabolic clinic focuses on implementing changes to diet, exercise and sleep to care for these patients. Physical activity and nutritional intake together are crucial principles in metabolism that are both addressed; however, this clinic places its greatest emphasis on nutrition. Concerning diet in particular, the physicians focus on therapeutic carbohydrate reduction with a whole food, optimal animal-based protein intake to maximise nutrient density and reverse insulin resistance. Consistent with this, the primary clinic intervention focuses on a very low carbohydrate diet (VLCD), classified as less than 50 g of total carbohydrates[2] per day. A VLCD has been shown

Note: Additional supporting information may be found in the online version of this article as Online Appendix 1 and Online Appendix 2.

in clinical practice to improve cardiovascular risk factors, restore proper glucose control and even reverse type 2 diabetes.[3,4] This retrospective single-cohort study aims to show the outcomes at the CHI Metabolic Health Clinic in Elkhorn, Nebraska, on patient blood markers of metabolic health over an 8-month period.

Methods

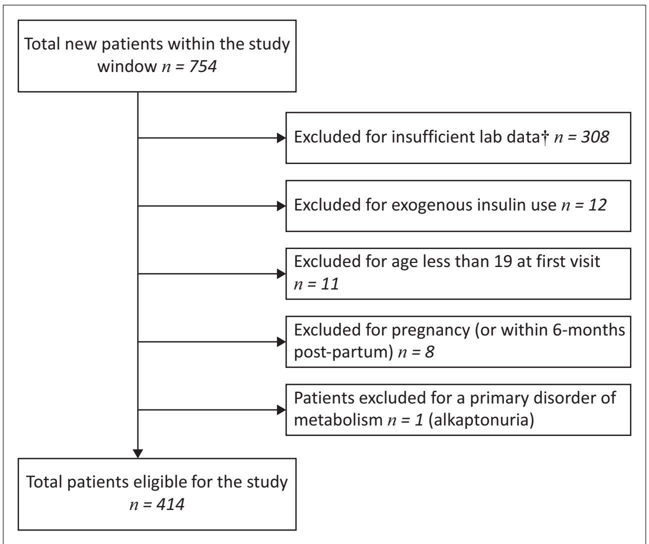
Patient selection and inclusion

This audit evaluated patients treated in the clinic from 01 January 2024 to 21 May 2025, with an initial visit restricted to dates occurring before 21 September 2024, to ensure a minimum available follow-up of 8 months. Figure 1 displays the patient selection process, highlighting the exclusion criteria.

Two physicians were responsible for patient interaction and implementation of the dietary intervention. All patients of any age (>18 years) were included in the study, provided they met all inclusion criteria. For all included patients, all laboratory values within the study period were collected, provided they were ordered after establishing care at the clinic of interest. Patients were not excluded based on a history of mental health or eating disorders.

Metabolic clinic function

At the initial visit, patients are scheduled for a 1-h consultation designed to address their chief complaints, review current dietary habits and discuss the VLCD implementation. Patients are given a food questionnaire to assess their current eating patterns (see Online Appendix 1), which guides the physicians in how they want to implement lifestyle changes for each individual patient. The first steps include examining what the patient's nutrition currently looks like, specifically their carbohydrate intake. It is advised that patients decrease their overall carbohydrate intake. There is a nutritional difference in whole food carbohydrates, such as vegetables and fruit, and processed carbohydrates, such as breads and cereals. Individuals could be healthy at a higher carbohydrate intake than recommended in this clinic; however, because of the patient population often presenting with signs of metabolic dysregulation, carbohydrates from all sources are recommended to be reduced. Initial advice is to include more meat and egg consumption, as this increases protein intake in place of carbohydrate sources. Patients are also advised to avoid sugar-sweetened beverages if they are currently a part of their diet. These dietary discussions are tailored to each patient; however, these are readily accessible changes that are addressed with most patients.



†, Insufficient lab data defined as lack of any laboratory value at two separate time points, or patient not fasted for labs that required fasting.

FIGURE 1: Flowchart of patient selection process.

Laboratory values are also often obtained; high-density lipoprotein cholesterol (HDL-c), triglycerides (TGs), haemoglobin A1c (HbA1c), high-sensitivity C-reactive protein (hsCRP), fasting glucose and insulin being the most common as they indicate common signs of metabolic dysregulation (see Online Appendix 2).[5,6,7,8,9,10,11,12,13] After the initial consultation, a clinic-standard 2-month follow-up is recommended with repeat labs drawn for any abnormal values. Because of this recommendation, patients may not have each laboratory value tested at every visit.

Statistical analysis

Descriptive statistics are reported as median with minimum and maximum or as mean and standard deviation for continuous variables depending on the data distribution. Categorical variables are presented as frequency and per cent. To account for variable patient follow-up time, frequency and the correlation of such repeated observations by individual patients, we estimated metabolic outcomes using separate linear mixed models with random intercepts. Additionally, patient age, and sex, as well as their separate two-way interactions with time, were estimated to evaluate the difference in change over the length of follow-up (up to 500 days after the first appointment). Finally, these models were re-estimated using a separate patient subset consisting of those with high initial HbA1C (values of 5.7% or greater). Alpha of 0.05 was used to determine statistical significance throughout.

Ethical considerations

This study was deemed exempt as secondary research for which consent is not required. The investigators conducted the review in a manner in which the identity of the participants cannot readily be ascertained. The principal investigator did not directly contact the participants, and all identifying information was coded and recycled after data analysis (Federal regulatory statute 45CFR46.104[d]). All procedures were approved by the local institutional review board (InfoEd record# 2005485).

Results

In total, 414 patients with 1234 observations (median = 3 observations per patient, [Min:2, Max:6]) were included in the analysis. Patients were primarily female (80%), with a mean age of 49 (standard deviation [s.d.] = 13.5). The median follow-up time was 173 days from initial appointment (interquartile range [IQR] 123, 196). Table 1 presents the unadjusted and adjusted follow-up coefficients by metabolic outcome for all patients (top) and for the sub-analysis of patients with high initial HbA1c (> 5.7%). Across all adjusted models, there were no statistically significant interaction effects between follow-up time and patient sex. Adjusted models with a statistically significant interaction effect between follow-up time and patient age are excluded from the table and instead discussed here.

Haemoglobin A1c

Evaluating the change in HbA1c levels over time, overall unadjusted results estimate a small statistically significant decrease in HbA1c (−0.126% per 180 days, $p < 0.0001$). Additionally, age was positively associated with HbA1c (0.120% per 10-year increase, $p < 0.0001$).

Among patients with a high HbA1c baseline value, a statistically significant interaction was observed between age and follow-up days, suggesting that the rate of decrease was lower for older patients (interaction $p = 0.0274$, Figure 2).

TABLE 1: Estimated follow-up effect.

Lab value	Unadjusted	*p*-value	Adjusted	*p*-value
HbA1c	-0.126	< 0.0001	-0.124	< 0.0001
TGs	-8.316	0.0226	-8.262	0.0235
HDL-c†	2.466	< 0.0001	-	-
hsCRP	-0.918	0.0357	-0.900	0.0464
HOMA-IR	-0.558	0.0042	-0.553	0.0049
High Initial HbA1C				
HbA1c†	-0.360	< 0.0001	-	-
TGs	-8.226	0.3251	-8.028	0.3377
HDL-c	3.618	< 0.0001	2.160	< 0.0001
hsCRP	-2.106	< 0.0001	-2.142	0.0012
HOMA-IR†	-0.396	0.3681	-	-

Note: Unadjusted and adjusted estimates of follow-up time (presented as 180-day follow-up) on metabolic outcomes covariates are age and biological sex: †, Includes significant interaction (age x days).

HbA1c, haemoglobin A1c; TG, triglycerides; HDL-c, high-density lipoprotein cholesterol; hsCRP, high-sensitivity C-reactive protein; HOMA-IR, homeostatic model assessment of insulin resistance.

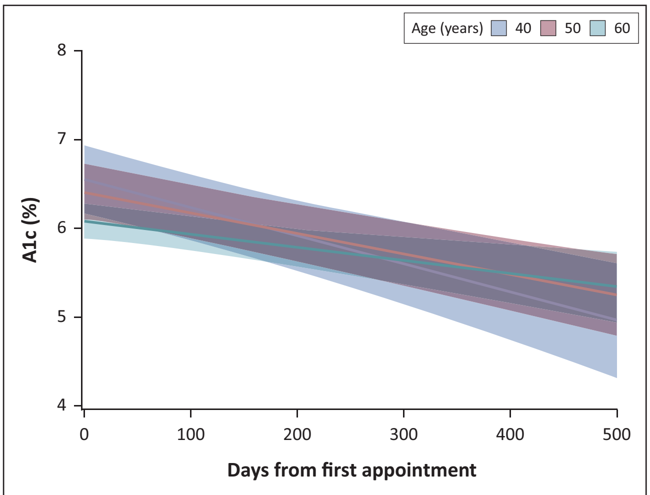


FIGURE 2: High initial haemoglobin A1c: haemoglobin A1c by age across follow-up.

Figure 2 shows the interaction between age (presented at 40 years, 50 years, and 60 years) and follow-up days within patients with a high HbA1c baseline value. For ease of interpretation, sex is excluded from the figure.

Triglycerides

Evaluating the change in TG levels over time, overall adjusted results estimate a small statistically significant decrease (−8.262 mg/dL per 180 days, $p = 0.0235$). No other predictors were statistically significant. Within patients with a high HbA1c baseline value, no predictors were statistically significant, and no significant interactions were observed.

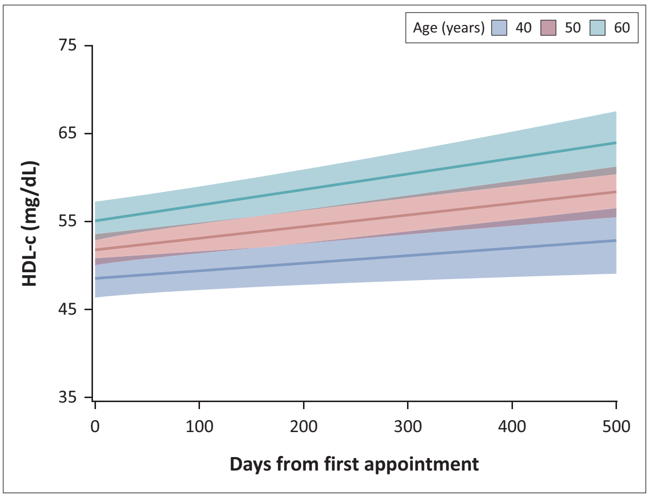
High-density lipoprotein cholesterol

Evaluating the change in HDL-c levels over time, overall unadjusted results demonstrate a statistically significant increase in HDL-c (2.466 mg/dL per 180 days, $p < 0.0001$). Additionally, overall adjusted results demonstrated a statistically significant interaction between age and follow-up days, suggesting that the rate of increase associated with follow-up time may be driven by patient age (interaction $p = 0.0347$, Figure 3). Within patients with a high HbA1c baseline value, age (4.21 mg/dL per 10-year increase, $p = 0.0215$) and follow-up (3.618 mg/dL per 180 days, $p < 0.001$) but not sex (female 8.87 mg/dL higher, $p = 0.0555$) were significantly associated with HDL-c.

Figure 3 shows the interaction between age (presented at 40 years, 50 years, and 60 years) and follow-up days for the total patient sample. For ease of interpretation, sex is excluded from the figure.

High-sensitivity C-reactive protein

Evaluating the change in hsCRP levels over time, overall adjusted results demonstrate a statistically significant decrease in hsCRP (−2.106 mg/L per 180 days, $p < 0.0001$). Additionally, age was a statistically significant negative predictor (−0.75 mg/L per 10-year increase, $p = 0.0008$).



HDL-c, high-density lipoprotein cholesterol.

FIGURE 3: Overall high-density lipoprotein cholesterol by age across follow-up.

Overall, neither age nor sex demonstrated a significant interaction with follow-up time. Results among high HbA1c baseline patients mirrored the overall findings.

HOMA-IR

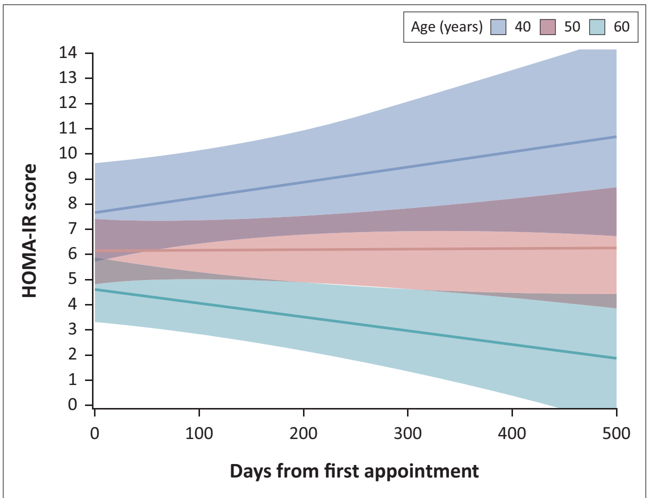
Evaluating the change in Homeostatic Model Assessment of Insulin Resistance (HOMA-IR) levels over time, overall adjusted results demonstrate a statistically significant decrease in HOMA-IR (−0.553 per 180 days, $p < 0.0001$). Additionally, age was a statistically significant negative predictor (−0.55 per 10-year increase, $p = 0.0001$). Within patients with a high HbA1c baseline value, there was a statistically significant interaction between age and follow-up, suggesting a divergence in HOMA-IR by age, with older patients demonstrating a greater decrease and younger patients demonstrating a potential increase (interaction $p = 0.0209$, Figure 4).

Figure 4 shows the interaction between age (presented at 40 years, 50 years, and 60 years) and follow-up days within patients with a high HbA1c baseline value. For ease of interpretation, sex is excluded from the figure.

Discussion

In this study, we retrospectively reviewed patients in a metabolic health clinic that focused on implementing a VLCD. This study provides a real, clinical example of patient changes over time. We present the outcomes of the five blood markers as a representation of patient metabolic health over time.

All five of the lab values tracked in this study had positive expected changes regarding their effect on health outcomes. The overall patient population experienced expected decreases in HbA1c, TGs, hsCRP and HOMA-IR scores while increasing HDL-c levels. This is consistent with the previous evidence presented on the implementation of a VLCD in clinical practice. We discuss each of the laboratory values and the clinical relevance of their changes in the section further.



HOMA-IR, homeostatic model assessment of insulin resistance.

FIGURE 4: High initial HbA1c: HOMA-IR by age across follow-up.

Interpreting lab values

Both the full cohort and the high HbA1c group had a small expected decrease in TGs. The changes in the high HbA1c group were not great enough for statistical significance, however. The results require clinical interpretation to determine whether these small changes have any clinical benefit for the patient population. Given the evidence of risk associated with high TGs, small decreases may be clinically relevant.

The full cohort increased their HDL-c significantly in the study. The overall cohort showed a 10.2% expected 1-year increase in HDL-c from the initial mean. Comparatively, nicotinic acid, an approved medication for dyslipidaemia, may improve HDL-c by 10% – 30%. Nicotinic acid, however, reports side effects including cutaneous flushing, hepatotoxicity, insulin resistance and hyperuricaemia.[14] This clinic is obtaining increases in the same range as medical intervention while avoiding the side effect profile. The high HbA1c group showed a larger 1-year increase of 14% from the initial, indicating further benefit in patients who are experiencing hyperglycaemia.

The expected reductions in hsCRP of the full cohort were 23.6% from initial, while the high HbA1c group had an expected decrease of 51.5%. Reductions in hsCRP on a long-term scale show that a focus on a VLCD may reduce systemic inflammation and thus reduce risk for future health complications. Given that hsCRP is a predictor of disease and may play a role in the disease process itself, any reductions can be viewed as beneficial.[15]

The high HbA1c group had a significant expected reduction in their HbA1c. Metformin glycinate, when used as monotherapy, reduces HbA1c in diabetic patients by around 1%.[16] This clinic showed expected 1-year reductions like that of metformin (0.7%), the first-line treatment for glycaemic control in patients with type 2 diabetes. The patients in this clinic were not drug naïve, meaning they likely experienced pharmacologic benefits for their HbA1c before establishing care at the clinic. This indicates that care in a metabolic clinic, with a focus on a VLCD, may be a beneficial long-term addition to pharmacologic intervention for glycaemic control in pre-diabetic and diabetic patients.

Insulin resistance is the hallmark of type 2 diabetes, and the high HbA1c cohort had a 15% expected 1-year reduction in their HOMA-IR scores. By improving insulin sensitivity overall, this clinic is providing a long-term improvement for patients with diabetes. The expected changes in HOMA-IR were confounded by age. Older patients showed a larger benefit to their insulin sensitivity; however, younger patients showed a potential decline. Despite this, the overall decrease in HOMA-IR, signifying decreased insulin resistance, remained.

Commentary

Patients with hyperlipidaemia, elevated HbA1c or insulin resistance likely presented to the clinic having already been prescribed the first-line medication for their disease state. Therefore, many patients had seen changes in HbA1c, lipids and other values directly because of their medications, leaving less room for improvement from other modalities. We argue that if this clinic (specifically, implementation of a VLCD) were their first-line treatment, before pharmacologic intervention, the expected changes may be even larger. Although not directly analysed in this study, the physicians do appreciate the ability to de-prescribe medications for their patients as metabolic parameters improve. The success of therapeutic carbohydrate reduction could be further supported by the de-prescription as a patient's lifestyle improves. Further research is required to measure the impact of therapeutic carbohydrate reduction in medication-naïve patients, as well as properly analyse the rates of de-prescription in this clinic.

Clinical audits of this nature provide patient data from real healthcare strategies. Not only do these studies create the opportunity for quality improvement, but they can also reassure larger healthcare institutions that individual clinics are seeing positive outcomes in patients. This audit provides data that align with previous research on VLCDs, showing improved cardiovascular risk factors, insulin sensitivity and improved glucose markers.[3,4] By continuing to show the success of this implementation in clinical practice, we can encourage increased recommendations of a VLCD for the management of metabolic health.

Limitations

This study has potential limitations. Firstly, conclusions about the positive effects in this study cannot be causally attributed to a VLCD itself because of the lack of a control group, random assignment or ability to measure compliance of patients to the diet. However, it is important to note that the focus of this metabolic health clinic is a VLCD, which differs significantly from many primary care models. Future research is needed to compare the results of this clinic to those of others that do not implement a VLCD. This would allow for a direct comparison of varying approaches to care.

Secondly, the limitation is the limited number of covariates. This study examined age and biological sex; however, body composition and body mass index could also be crucial components of a patient's initial lab values and their progression over time. Lean versus obese individuals may show varying levels of change over time. Another limitation arises from this, in that this study does not control for weight loss over time. Therapeutic carbohydrate reduction in this clinic may drive weight loss, and the laboratory benefits in this clinic could be attributed to weight loss. Future research is needed to examine weight loss in this clinic and the associated biomarker changes.

As previously mentioned, this clinic does encourage lifestyle changes outside of solely nutrition, such as increases in physical activity and sleep. We acknowledge that these are crucial components of overall health, and real improvements may be attributed to patients changing these lifestyle habits upon presentation to the clinic. The focus of this research is on the nutritional aspects of lifestyle change, as this is the main focus of the providers and is discussed at the greatest length at each patient visit. We argue that therapeutic carbohydrate reduction is the largest driver of metabolic change in this patient population.

This study did not exclude patients with a medical history of mental health or eating disorders. This study was not designed with the intention of evaluating therapeutic carbohydrate reductions' role specific to patients with these past diagnoses. Therefore, no conclusions can be drawn regarding the safety or effectiveness of this intervention in these groups.

Thirdly, we did not control for medication usage outside of exogenous insulin. Patients may have been on medication (such as metformin or atorvastatin) before coming to the clinic and may have started new medications while visiting the clinic. This creates another variable to which changes could be contributed to.

Conclusion

Increasingly high obesity rates paired with a staggeringly low proportion of metabolically healthy individuals in the United States pave the way for different methods to address metabolic health in the clinic. The CHI Metabolic Health Clinic in Elkhorn, Nebraska, is pairing a VLCD with current pharmaceutical strategies to improve markers of metabolic health, as evidenced by the data in this study. This research aligns with the previous work on therapeutic carbohydrate reduction as a modality to improve metabolic outcomes.[3,4] We advocate for the use of a VLCD in the clinical setting to assist patients with their metabolic health, especially in the context of insulin resistance. We argue that clinics such as this one have a significant role in healthcare. Focusing on lifestyle factors to prevent and reverse disease allows for a long-term solution to the current health issues we see in the United States. These types of clinics give a sustainable method to make a change for our population's health and can be used in conjunction with the current strategies to treat metabolic dysfunction.

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Competing interests

The authors declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article.

CRediT authorship contribution

Casey D. Trapp: Conceptualisation, Data curation, Funding acquisition, Investigation, Methodology, Project administration, Supervision, Validation, Visualisation, Writing – original draft, Writing – review & editing. Karen Miller: Resources, Writing – review & editing. Paula Walters: Resources, Writing – review & editing. Alexander Hall: Formal analysis, Software, Writing – review & editing. All authors reviewed the article,

contributed to the discussion of results, approved the final version for submission and publication and take responsibility for the integrity of its findings.

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Data availability

The data that support the findings of this study are not openly available because of patient confidentiality, as chart review of active patients was used for data obtainment. The data is available from the corresponding author, Casey D. Trapp, upon reasonable request.

Disclaimer

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