

OBJECTIVE:

To report on patient reported experience with a novel medical formula (PKU GOLIKE[®]) and its impact on patient reported satiety.

METHODS:

Patient/caregiver reported outcomes related to satiety with use of PKU GOLIKE collected as part of Registered Dietitian contacts. Response to the question, "Would you say you have felt fuller longer after consuming PKU GOLIKE than with other Medical Formulas?", was collected and documented in the Registered Dietitian assessment. All patients active with this provider's service receiving PKU GOLIKE were included in the assessment. Only PKU GOLIKE patients that opted-in to providing an answer are included in this review.

BACKGROUND:

Phenylketonuria (PKU) is an inherited metabolic disorder caused by a deficiency of the enzyme phenylalanine hydroxylase (PAH). In the United States, one in every 10,000 to 15,000 babies is affected by PKU.

PAH is required for the body to breakdown phenylalanine (Phe), an amino acid found in all protein-containing foods. When PAH is deficient or defective, Phe accumulates in the blood to abnormally high levels. If left untreated, PKU can cause brain damage or even death. When PKU is diagnosed early and treatment is initiated, individuals with PKU can lead very healthy and productive lives.

People who have been diagnosed with PKU require a restrictive diet as first line management; including a low-protein diet and specially formulated low/free phenylalanine synthetic protein medical formulas (protein substitutes). Phenylalanine is a component of all natural protein, both plant and animal sources. To maintain acceptable Phe levels, patients must severely limit the amount of natural protein they consume. Following a restrictive diet creates challenges. One of which is experiencing hunger throughout the day that often results in snacking on foods which may or may not be high in Phe. As a result, patients may overconsume foods (natural and medical) to stave off the feeling of hunger.

Traditional PKU medical formulas routinely consumed by PKU patients consist of free amino acids that do not mimic natural protein digestion and may contain high amounts of sugar. In recent years, developments within the medical formula market have brought alternative product options which more closely resemble natural protein digestion and may help patients feel fuller for longer. For example, glycomacropeptide (GMP) products have been clinically shown to reduce Ghrelin, the hunger hormone, and improve Phe utilization throughout the day. Similarly, a novel medical formula, PKU GOLIKE, that became available in the United States in October 2022, uses a physiomic technology coating that resembles a natural food protein structure. This technology allows for the slow release of amino acids which in turn could be expected to improve patient satiety.

CHART 1:

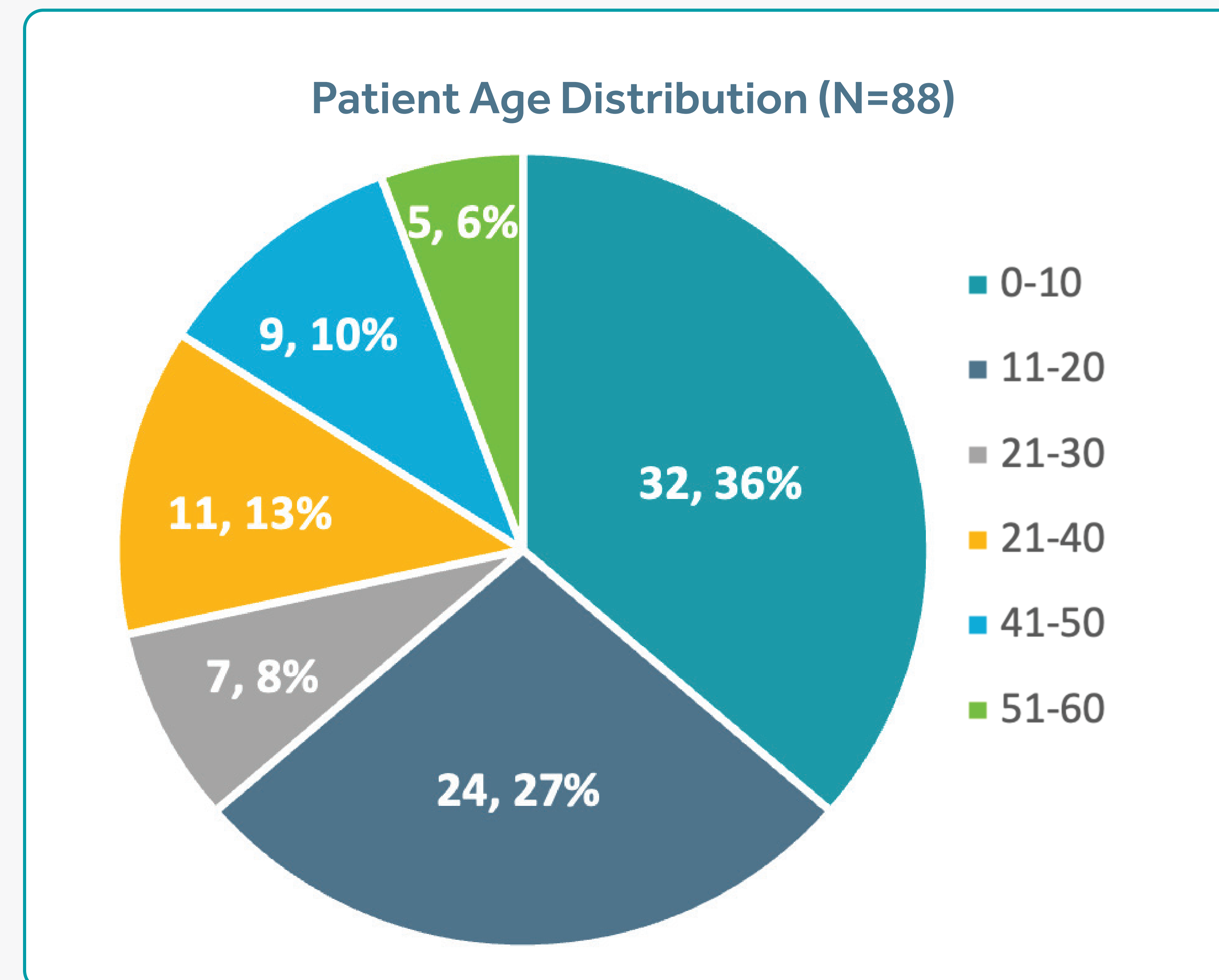


TABLE 1:

PATIENT CHARACTERISTICS (N=88)	
Mean age, years	15.7
Female, n (%)	58 (66)
Mean duration of PKU GOLIKE use, months	3.4

RESULTS:

Between May 2023 and January 2024, 88 patients (or their caregivers) provided a response related to their experience with PKU GOLIKE and its impacts on satiety. Of these respondents, 82% (n=72) reported feeling fuller for longer when using PKU GOLIKE.

CONCLUSIONS:

Optimal management of PKU requires adherence to a natural protein restricted diet which necessitates the use of PKU specific medical formulas in this population. Depending on the medical formula consumed, patients may experience variable feelings of fullness. Protein substitute preparation innovations now make available formulations that are more similar to the physiologic uptake of natural protein, which may impact patient reported satiety. In this review, the majority of respondents reported feeling fuller for longer when consuming PKU GOLIKE when compared to other medical formulas they have used. Limitations to this review include single-question format, patient reported design, and lack of a comparative group not receiving PKU GOLIKE.

DISCLOSURES:

DL, Registered Dietitian, is the operator of Zoia Pharma, LLC, which participates in a Distribution and Services agreement with Relief Therapeutics, Inc. to provide PKU GOLIKE to PKU patients in the USA.

KH, Registered Dietitian, and KCH, PharmD, are employees of Pentec Health, Inc, which has a Distribution and Services agreement with Relief Therapeutics, Inc. to provide PKU GOLIKE to PKU patients in the USA.

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