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Ultra Rapid Lispro (URLi) Showed Greater Reduction in Postprandial Glucose (PPG) vs Humalog® in Children, Adolescents, and Adult Patients with Type 1 Diabetes (T1D)

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Background/Introduction:

URLi is a novel insulin lispro formulation developed to more closely match physiological insulin secretion.

Methods:

This 2-site, randomized, 2-period crossover, double-blind study evaluated the pharmacokinetics and glucodynamics during a liquid test meal, after a single 0.2 U/kg SC dose of URLi or Humalog in 13 children, 14 adolescents, 15 adults with T1D.

Results:

Onset of insulin appearance was faster with URLi vs Humalog in children (1.1 vs 6.5 min; $p=0.0002$), adolescents (1.9 vs 6.4 min; $p=0.001$), and adults (0.9 vs 4.8 min; $p=0.004$). Early exposure (AUC_{0-15min}) was greater with URLi vs Humalog: 7-fold ($p<0.0001$) in children, 4 fold ($p=0.0003$) in adolescents, 5-fold ($p<0.0001$) in adults; late exposure (AUC_{3-7h}) was reduced by 58% ($p<0.0001$) in children, 40% ($p=0.013$) in adolescents, 37% ($p=0.021$) in adults. Total exposure was similar in URLi and Humalog. At 1h, URLi reduced PPG by 42 mg/dL ($p=0.008$) in children, 19 mg/dL ($p=0.195$) in adolescents, 34 mg/dL ($p=0.018$) in adults, vs Humalog. At 2h, URLi reduced the PPG by 32 mg/dL ($p=0.11$) in children, 39 mg/dL ($p=0.051$) in adolescents and was not statistically different in adults, vs Humalog. URLi was well tolerated in all age groups.

Conclusion:

In summary, URLi accelerated insulin lispro absorption, reduced late exposure and early PPG following a test meal vs Humalog in children, adolescents, and adults with T1D.