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NEEDLE-FREE NASAL DELIVERY OF GLUCAGON IS SUPERIOR TO INJECTABLE DELIVERY IN SIMULATED HYPOGLYCEMIA RESCUE

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ABSTRACT

Objective: This study evaluated the ease of use of needle-free nasal glucagon (NG) devices versus injectable glucagon (Glucagon Emergency Kit – GEK) in treating a simulated severe hypoglycemia (SH) episode.

Methods: The caregiver arm included 16 adult persons with diabetes (PWD) and their caregivers. The PWDs were taught how to use one of the devices and they, in turn, instructed their caregivers. The acquaintance arm had 15 adults who were not trained on device use. Acquaintances were shown the device before the simulation. During the simulation, each caregiver and acquaintance treated a manikin representing a PWD with SH using both GEK and NG devices at different time-points.

Results: Fifteen of 16 caregivers and 14 of 15 acquaintances administered a full dose of NG (average time 16 seconds and 26 seconds, respectively).

Eight of 16 caregivers injected glucagon (GEK, average time 1 minute 53 seconds); of which 2 gave the full dose. Failures included injection of diluent only (n=4), insulin injection (n=3), and bent needle (n=1).

Three of 15 acquaintances injected glucagon (GEK, average time 2 minutes 24 seconds); none gave the full dose. Failures included injection of diluent only (n=9), insulin injection (n=1), refusal to inject (n=1) and injection with empty syringe (n=1).

Conclusions: During simulated SH, caregivers and acquaintances used GEK with low success rates and numerous errors; however, they administered NG successfully and in less time. This suggests that NG delivery is easier and faster for non-medical people and use of a different route of administration for glucagon may reduce the risk of accidental insulin injection.

BACKGROUND AND AIM

Injecting glucagon to treat an episode of severe hypoglycemia (SH) can be stressful and error-prone for caregivers of persons with diabetes (PWDs).[1]

We evaluated the ability of trained caregivers and untrained acquaintances in treating a simulated episode of SH with a novel needle-free nasal glucagon (NG) device, under development, compared to a commercially available injectable glucagon (Glucagon Emergency Kit, GEK).

MATERIALS AND METHODS

Trained Caregiver Arm

- Sixteen adult insulin-using PWDs (median age 57 years, median years with diabetes 15) and their caregivers (median age – 54 years)
- PWDs were taught how to use 1 of the devices in random order. PWDs then instructed their caregivers, replicating real-life transfer of information
- One week later, caregivers were asked to treat a manikin during a simulated episode of SH. The procedure was repeated with the other device

Untrained Acquaintance Arm

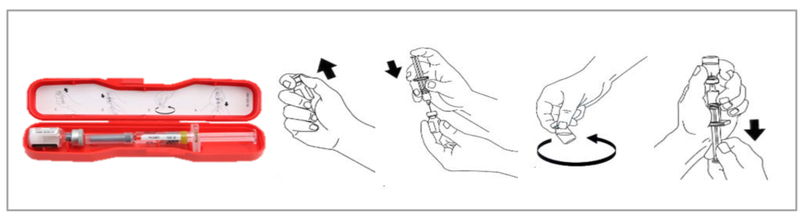
- Fifteen adult volunteers, who were not associated with PWDs and who said they were willing to assist someone in distress (median age 40 years)
- Volunteers were not trained on device use; the device was only shown to them before the simulation
- They treated 2 episodes of SH with GEK and NG at different time points, with a delay of about 10 minutes between each simulation

Severe Hypoglycemia Simulation

- A fully clothed adult manikin represented a PWD in the simulation
- Participants were told
  - The manikin was having an episode of SH and that they had to administer the rescue glucagon as quickly as possible
  - To find the glucagon rescue kit in PWD's backpack. The backpack also contained personal effects and a diabetes supply pouch (glucose meter and strips, alcohol swabs, lancing device, and insulin vial and syringe)
- Sound effects and distractions created a sense of urgency

Nasal Glucagon (NG)

Injectable Glucagon (Glucagon Emergency Kit - GEK)



RESULTS: TRAINED CAREGIVERS

- Fifteen of 16 caregivers delivered full dose with NG (average time 16 sec)
- One caregiver who failed to fully depress the plunger on the NG also failed to inject GEK
- Only 2 of 16 caregivers delivered a full dose with GEK and 6 gave a partial dose (average time 1 min 53 sec); 8 failed to deliver any glucagon
- Failures included injection of diluent only and bent needles
- Two caregivers used insulin due to form factor confusion with glucagon

16	Number of participants	16	
(94%) 15	Delivered full dose	2 (12.5%)	
(0%) 0 --	Delivered partial dose (min, max of full dose)	6 (37.5%) (3%, 85%)	
(6%) 1	Delivered no dose	8 (50%)	
0 min 16 sec* (2 sec, 56 sec)	Avg. time to deliver dose # (min, max)	1 min 53 sec (1 min 6 sec, 2 min 45 sec)	
0	Used insulin due to form factor confusion with glucagon+	2 (12.5%)	

RESULTS: UNTRAINED ACQUAINTANCES

- Fourteen of 15 acquaintances delivered a full dose with NG (average time 26 sec)
- One acquaintance who failed to fully depress the plunger on NG also failed to inject GEK
- None of the acquaintances administered a full dose of GEK; 3 gave a partial dose (average time 2 min 24 sec); 12 failed to deliver any glucagon
- Failures included injection of diluent only, refusal to attempt to inject, and injection with an empty syringe
- One acquaintance used insulin due to form factor confusion with glucagon

15	Number of participants	15	
(93%) 14	Delivered full dose	0 (0%)	
(0%) 0 --	Delivered partial dose (min, max of full dose)	3 (20%) (36%, 56%)	
(7%) 1	Delivered no dose	12 (80%)	
0 min 26 sec** (10 sec, 47 sec)	Avg. time to deliver dose # (min, max)	2 min 24 sec (1 min 18 sec, 3 min 56 sec)	
0	Used insulin due to form factor confusion with glucagon+	1 (7%)	

Notes: Each caregiver treated a manikin with both NG and GEK; each acquaintance treated a manikin with both NG and GEK. Full dose of NG is delivered when plunger is fully depressed; full dose for GEK is defined as at least 90% of the targeted 1mg dose.
#Includes only those in each group who administered glucagon, regardless of percentage of dose delivered; does not include those who failed to administer any glucagon
**p<0.001; **Too few administrations of GEK to permit meaningful statistical comparison.*
+Two caregivers (GEK) and 1 acquaintance (GEK) injected insulin instead of glucagon because they confused injectable insulin and glucagon due to the similar form factor.

CONCLUSIONS

- Needle-free nasal delivery of glucagon is faster and has a higher success rate than the injectable glucagon kit for non-medical caregivers of people with diabetes in a severe hypoglycemia simulation
- Untrained acquaintances were able to deliver nasal glucagon successfully, at a similar rate as trained caregivers, highlighting the simplicity, intuitiveness, and ease of use of the needle-free nasal glucagon delivery system
- Glucagon delivery using a different route and device form than those used for insulin may reduce the risk of confusion and accidental delivery of insulin

Implications

- These data indicate that needle-free nasal glucagon is easy to use for third party caregivers compared with injectable glucagon
- The high rate of failure with the injectable glucagon kit suggests a need for a glucagon delivery system that is easy to teach and use
- The risk of potential confusion observed with injectable glucagon, due to form factor, supports the need for a novel approach to glucagon delivery that is different from insulin delivery

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References:

1. Harris G et al. *Practical Diabetes* Int 2001;18:22-25