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Hypoglycemia Alert Dogs: Innovative Assistance for People with Type 1 Diabetes

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ABSTRACT

The Indiana Canine Assistance Network (ICAN) previously documented the positive impact of a diabetes alert dog (DAD) on a diabetes patient's quality of life. To our knowledge, no randomized controlled studies were published regarding the ability of DADs to detect hypoglycemia. Our current work aimed to test DADs in 2 controlled trials.

Four service dogs from ICAN previously trained in both basic and advanced obedience and mobility assistance were placed in a hypoglycemia alert training program. The training introduced the dogs to wiped skin and breath samples from patients with type 1 diabetes mellitus, followed by positive reinforcement for successful recognition (alert) of hypoglycemic (low) samples. For the purposes of the current 2 studies, samples were placed in separate cups on a randomization device (Lazy Suzan wheel). One cup contained the low sample, 3 contained euglycemic samples from the same patient, and 3 contained gauze without samples. In both studies, 4 separate wheels, containing samples from 4 separate patients were used and dogs (study 1; n=2, study 2; n=4) replicated the search 2 times/wheel. The placement of the samples was based on a pre-specified randomization scheme.

Sensitivity (proportion of correct alerts) and specificity (proportion of sniffs without alert on normal samples) were calculated after pooling data across all trials in both studies (2 dogs participated in both studies). Overall, the best dog performed at 100% sensitivity / 88% specificity. The dog with the poorest performance was 22% sensitivity / 71% specificity. This variability in dog performance reflects differences in training level and other individual animal characteristics.

Our results demonstrate that DADs are able to identify chemical compounds specific to hypoglycemia and therefore be trained to alert to its presence. We are continuing studies to elucidate best practices for training DADs and ultimately to identify the chemical signature that the dogs are detecting.

BACKGROUND

- For over a decade, the mission of the Indiana Canine Assistance Network (ICAN) has been to train and place assistance dogs with persons with disabilities throughout the state of Indiana.
- Dogs are rigorously trained through a comprehensive, multi-level, positive reinforcement program.
  - Dogs were trained inside correctional facilities using carefully screened male and female offenders trained as handlers.
  - Dogs were taken on furlough outside the correctional facility approximately every 6 weeks to test their skills in everyday situations.
- Anecdotal reports have suggested the ability of dogs to detect hypoglycemia, with recent case studies supporting these anecdotes. To better understand the capabilities of dogs to detect hypoglycemia, the ICAN head trainer and several ICAN volunteers (Eli Lilly and Company employees) began formulating studies with previously trained service dogs.
- The purpose of this study was to determine if ICAN-trained diabetes alert dogs (DADs) could alert to the scent of a low glycemic sample in the presence of normal and blank (control) samples in a controlled environment.

METHODS

Study Objective

- The primary objective of the study was to determine if trained DADs could alert to the scent of a low glycemic sample in the presence of euglycemic (normal) and blank (control) samples.
  - Sensitivity was assessed by the proportion of trials for which the DAD correctly alerted to the low glycemic sample.
  - Specificity was evaluated by the number of sniffs on non-low glycemic samples (i.e., euglycemic and blank samples) without an alert.

METHODS *(continued)*

Study Design

- Two similar studies (Study 1 and 2) were performed.
- Each trained DAD (Study 1, n=2; Study 2, n=4) was tested on the same set of patient samples twice (scent wheel; Study 1, k=4; Study 2, k=4). Each study was conducted with a different set of patients.
  - Each replicate had the same patient samples arranged in the same order, but the scent wheel was rotated to a different orientation.
  - Each replicate lasted a maximum of 30 seconds or until a correct alert by the DAD.

Study Samples and Collection Procedure

- Patients with type 1 diabetes mellitus provided gauze samples containing breath and wiped skin secretion samples during various glycemic states.
  - Low glycemic state: plasma glucose level <70 mg/dL (1 sample)
  - Euglycemic state: plasma glucose level 70 to 130 mg/dL (3 samples)
  - Blank samples: gauze only (no traces of breath or sweat; 3 samples)
- Samples (Table 1) consisted of gauze squares wiped on the skin (back of the neck and forehead) and placed in a plastic zipper bag.
  - Prior to sealing the zipper bag, the patient exhaled into the bag containing the gauze square.

Table 1. Scent Wheel Setup and Sample Blood Glucose Concentrations

	Study 1				Study 2			
Cup	Wheel 1	Wheel 2	Wheel 3	Wheel 4	Wheel 1	Wheel 2	Wheel 3	Wheel 4
1	NR	NR	NR	NR	Low	Blank	Normal	Low
2	NR	NR	Low	Low	Blank	Normal	Blank	Blank
3	NR	NR	NR	NR	Normal	Blank	Low	Normal
4	NR	NR	NR	NR	Normal	Normal	Blank	Blank
5	Low	NR	NR	NR	Blank	Blank	Normal	Normal
6	NR	Low	NR	NR	Normal	Normal	Normal	Blank
7	NR	NR	NR	NR	Blank	Low	Blank	Normal

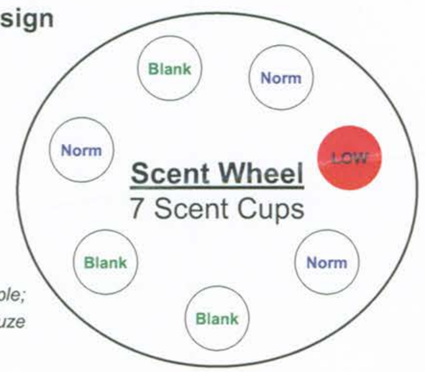
Abbreviation: NR = not recorded.

Note: The location of the Normal and Blank samples was not recorded for Study 1.

Scent Wheel Design

- The scent wheel was designed to use 7 identical cups that hid the sample from sight, but allowed the scent to escape (Figure 1).
- The seven cups included 1 low glycemic (Low), 3 euglycemic (Norm), and 3 gauze only (Blank) samples (Figure 1).
- Each wheel included randomly placed samples from the same patient.
- The scent wheel was placed on the ground and rotated between trials.

Figure 1. Scent Wheel Design



Abbreviations: Norm = Euglycemic sample; Low = Low glycemic sample; Blank = gauze only/no sample.

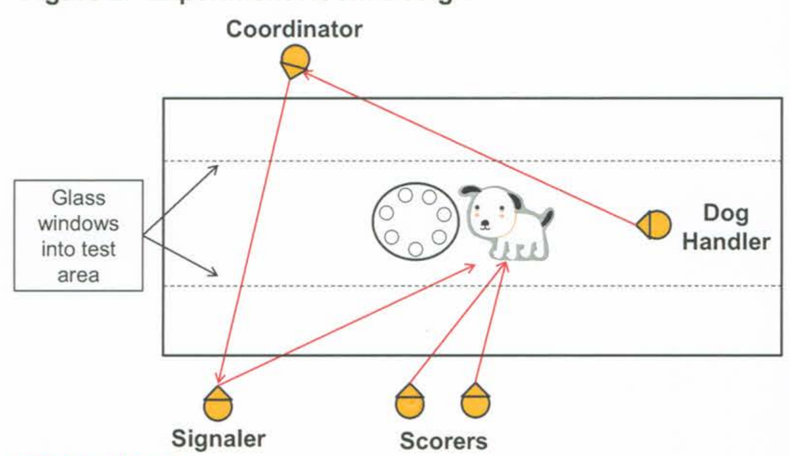
Scent Wheel Cleaning Procedure

- The scent wheel and sample cups were cleaned before each study and between each trial.
  - Sample cups were washed thoroughly with commercially available dish soap prior to the study.
  - Commercially available cleaning wipes were used to ensure scent contamination was not present between trials and samples.

Experiment Room Design and Operation

- The experiment room had 5 individuals and 1 dog per trial. Four individuals were blinded and 1 individual was unblinded to the study (Figure 1),
  - Blinded: 1 Dog handler, 2 scorers, and 1 coordinator
  - Unblinded: Signaler
  - Test Subject: Dog
- Dog Handler (Blinded): led the dog to and from the experiment room and gave the dog a treat for a correct response.
- Scorers (Blinded): Recorded the dog name, time, responses, and sniffs by the dog.
- Coordinator (Blinded): Watched the signaler for a correct response, and told the dog handler to give the dog a treat upon a correct response.
- Signaler (Unblinded): Loaded the scent wheel with the patient samples and placed the scent wheel in the ground. During the study, the signaler notified the coordinator if the response was correct.

Figure 2. Experiment Room Design



RESULTS

Participant DADs

- Study 1 consisted of 2 DADs (Spencer and Pete) and Study 2 consisted of 4 DADs (Spencer, Pete, Hudson, and Sadie).
  - All DADs were Labrador retrievers and less than 2 years of age.
  - DAD training for each dog varied from 3 to 8 months.

Sensitivity Analysis

- One of 7 sample cups (14%) contained the low glycemic sample; therefore, the expected random alert sensitivity level is 14%.
- In Study 1, both DADs displayed a statistically significantly greater ($p<0.05$) sensitivity (75% and 100%) to detect the low glycemic sample than the expected random correct alert (14%; Table 2).
- In Study 2, 3 of 4 DADs displayed a statistically significantly greater ($p<0.05$) sensitivity (44% through 75%) to detect the low glycemic sample than the expected random correct alert.

RESULTS *(continued)*

Table 2. Sensitivity

		Study 1 Sensitivity			Study 2 Sensitivity		
Dog Name		Observed (%)	Expected (%)	P-Value	Observed (%)	Expected (%)	P-Value
DAD 1	Spencer	75	14	<0.001	75	14	<0.001
DAD 2	Pete	100	14	<0.001	44	14	0.029
DAD 3	Hudson	N/A	N/A	N/A	63	14	0.002
DAD 4	Sadie	N/A	NA	N/A	22	14	0.625

Abbreviation: DAD = diabetes alert dog.

Note: One of 7 sample cups (14%) contained the low glycemic sample; therefore, the expected random alert sensitivity level is 14%. P-values are based on a binomial test.

Specificity Analysis

- In Study 1, both DADs were able to determine that a sample was not a low glycemic sample ≥84% of the time.
- In Study 2, the specificity level was between 71% and 86%.

Table 3. Specificity

		Study 1 Specificity	Study 2 Specificity
Dog Name		Observed (%)	Observed (%)
DAD 1	Spencer	84	78
DAD 2	Pete	88	86
DAD 3	Hudson	N/A	86
DAD 4	Sadie	N/A	71

Abbreviation: DAD = diabetes alert dog.

Study Challenges

- During Study 2, a strange odor was noticed in the testing environment which may have impacted the results.
- The study did not use a scent wheel with the absence of a low glycemic sample for the assessment of specificity.
  - The DADs' training could have been compromised by the DADs' expecting a reward every time a scent wheel is present.
- Recording the DADs' sniffs on the scent wheel (non-low glycemic samples for specificity) was difficult due to the speed of the DADs.

CONCLUSIONS

- DADs' sensitivity to detect hypoglycemia is greater than by chance alone.
- Sensitivity results varied by the level of training and due to distractions in the testing environment during Study 2.
- Hypoglycemia samples emanate a smell that is detectable by a DAD.
- This study supports the hypothesis that DADs are able to identify the samples associated with hypoglycemia.

Future Studies and Research

- Studies are needed to determine if the detectable compounds are contained in the breath, skin swab, or both.
- Studies should be conducted to determine which compounds are detected by the DADs.
- Care should be taken in the design of consistent, determinative studies to assess training, repeatability, and real-world scenarios of DADs.

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