A Novel Bedwetting Alarm Utilizing Real Time Heart Rate Analysis and Artificial Intelligence: Preliminary Outcomes

smart. safe. dry.

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BACKGROUND:

Current treatments for enuresis involve either drug therapy or the use of enuresis alarms which depend on negative reinforcement as a means of providing operant conditioning. Drug therapy is no more effective than alarm therapy but can be associated with potential life threatening complications if misused or applied inappropriately. Bedwetting alarms (BWA) have been in use since the 1930's with little innovation in the field or improvement in efficacy for the patient. These bedwetting alarm systems rely on a moisture sensor to detect the presence of excess moisture and are generally difficult to use, prone to breakage, unreliable, and are not kid-friendly.

Alarm systems are varied; some will incorporate a moisture sensor pad on the bed while others use a sensor attached to the clothes which will be activated when urine closes the circuit and activates the alarm. Such systems, however, only trigger upon the release of substantial amounts of urine, providing notice in some cases only after substantial urination has occurred. Thus, any remedial actions taken in response to an alarm can only occur after urination begins, and individuals and caregivers are relegated to only responding after involuntary urination occurs.

Some of today's "hi-tech" alarm systems rely on large sensors attached to an individual's undergarments and relay data by a wired or wireless connection. The large sensors can be uncomfortable for a user, can detach or be inadvertently removed during sleep, and can require placement at locations distant from the source of the urination. Wired connections can hinder a user's ability to sleep and can cause potential tangling hazards. Existing sensors using wireless connections require large batteries and circuitry to last throughout the night and are prone to erroneous sensing of moisture.

A NOVEL BEDWETTING ALARM:

Unlike current enuretic alarms, GOGO Band® is an intelligent predictive alarm, which is vastly different than standard reactive "dumb" alarms that are on the market today.

The GOGO Band System includes a wearable biometric and heart rate monitor, moisture sensor, bedside tablet PC, and an App that is downloaded to the parent's phone. GOGO Band utilizes real time heart rate variability (HRV) analysis and applied machine learning and artificial intelligence (AI) to create an alarm that can wake the patient from sleep prior to wetting. Reactive alarms only respond after the wetting event has occurred, thereby limiting the ability for the patient to learn what their bladder filling status was prior to the accident. The predictive GOGO Band alarm responds prior to the wetting event, giving the patient the ability to actually learn the sensation of their bladder filling status before having an accident.

A recent analysis of the GOGO Band efficacy data was conducted. Our data includes no Personally Identifiable Information and is HIPPA compliant. The GOGO Band System has three modes of operation: Training, Predictive, and Weaning. During the Training mode patient specific HRV parameters were collected and used to build a proprietary predictive alerting model.

The Training Mode duration typically lasts from 10-21 days of system use and depends on the enuretic severity of the patient. In the Predictive Mode the patient experienced treatment during which the patient specific AI model prevised that an impending urination event was about to occur. Patients remained in the Predictive Mode for 30 days of system use before they entered the Weaning Mode. In this mode weeklong levels of varying non-alarming weaning protocols were used to test if patients could sense their bladder filling status and remain dry. Patients with more than two wet nights per week in a Weaning Mode level would move back to a lower alarm suppression level. Conversely, patients who were dry would move up to a higher alarm suppression level.

Only patients that used the system for more than 30 days were included in this analysis. All data analysis was done with SPSS and xlstat.

RESULTS:

A total of 40 subjects that have used the system for more than 30 nights is included in this analysis. Gender mix was 33 males (82.5%) and 7 females (17.5%). The mean age of the subjects is 10.6 yrs. Subjects wet the bed an average of 6.2 nights per week prior to treatment. The system's ability to capture wetting events and time stamp them allows us to track the actual number of wetting events per night that occur as seen in the chart below. Children can wet up to 4 times per night as per this chart.

Number of wetting event per night:	Frequency	Percent
0	274	64.5
1	124	29.2
2	20	4.7
3	6	1.4
4	1	10.2
Total	**425**	**100**

Severity and number of accidents per night had no impact on the ability to achieve dryness with the GOGO Band System in logistical regression analysis.

The data was also segregated based on compliance since it became clear during the analysis that compliant patients achieved better results than non-compliant patients.

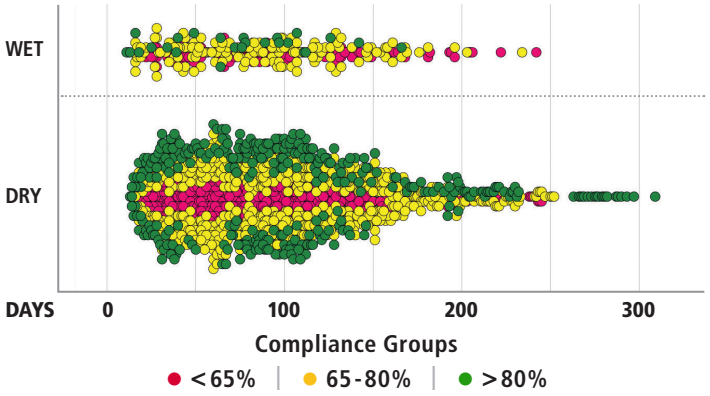
Mode	% Dry with <65% Compliance	% Dry with 65-80% Compliance	% Dry with >80% Compliance	Total Nights
Training	17.6[a]	[a]71.6	10.8[a]	251
Predictive	80.2[a]	78.6[a]	93.8[b]	760
Weaning	80.6[a]	86.8[b]	92.9[c]	1460
TOTAL	80.4[a]	81.9[a]	92.1[b]	2451

Each different letter superscript in each row denotes a statistically different outcome ($p<0.05$).

From the table above it is evident that patients who used the system consistently are more successful in remaining dry with dry night rates of 93%. Unfortunately, our deidentified data does not allow us to identify traditional cure rates. In many cases the patients who were successful on the system would self-exit prior to completion and data acquisition would cease. Unfortunately, we have no method at this time to confirm whether self-exit was due to success or perceived failure.

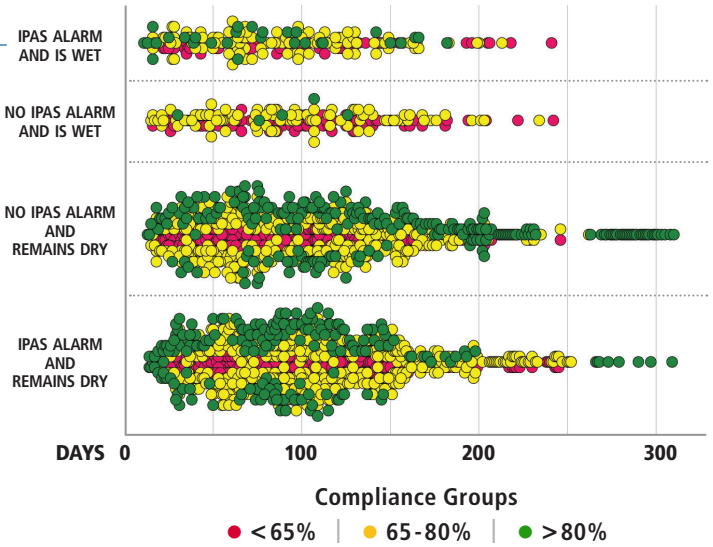
IPAS Alarm is the system notification that a urination event is imminent. In some cases the IPAS is suppressed, thereby no audible alarm is produced as part of the learning and or weaning algorithms. Lack of an alarm does not imply failure of the system to recognize the need to urinate.

Scatter Plot of All Wet and Dry Events During Predictive and Weaning Modes Exclusive of Suppressed IPAS Alarm



The above graph depicts the degree of predictive alarming and the patient's ability to stay dry. It is clear that the high >80% compliance patients (green) have less alarming events indicating that the system is just not randomly alarming but a true physiological change is occurring. The patients with 65-80% compliance (yellow) and <65% compliance (red) have consistent numbers of predictive alarming events for as long as 300 days. The marked reduction in alarms in the high compliance group prove that the alarm system is just not functioning randomly, but the machine learning algorithm has learned to sense when an accident is impending and in the high compliance group the physiological changes have led to a change in bladder-brain processing that allows for the patient to sleep through the night and not wet themselves. A confounder of the data is that even with the extended time use by these groups, we postulate that with non-consistent use there is little opportunity to change the patient's underlying physiological mechanisms that cause nocturnal enuresis. Therefore, these lower compliant patients continue to remain dry with the assistance of the alarm unlike the high compliance group which over time did not need the alarm to remain dry.

Grouped Scatter of Dry and Wet for All Predictive and Weaning Mode Nights



In the above graph (previous page) we see the relationship between the compliance groups, intelligent predictive alarm system (IPAS) state and whether the patient stays dry or wets. The IPAS is not activated either because the alarms were suppressed as part of the treatment protocol or the system did not recognize an event. What is clear from this graph is that the need to alarm is reduced after 150 days in the high compliance group (green) with more patients remaining dry even when there is no alarm. More striking is that after about 175 days all high compliance patients no longer wet themselves without an IPAS alarm. This implies a change in the patients processing of bladder information and ability to arouse from sleep. These findings support the assumption that dryness is occurring not due simply to a continued waking of the patient by random alarming but by changes in the arousal or Brain-Bladder interactions.

A Cox Proportional Hazards model was conducted to determine whether compliant days had a significant effect on the hazard of dry nights. The results of the model were significant based on an alpha of 0.05, LL = 612.61, df = 1, $p < .001$, indicating compliant days was able to adequately predict the hazard of dry nights. The coefficient for compliant days was significant indicating that at any particular time, a one-unit increase in compliant days will reduce the hazard of dry nights by a factor of 0.88.

Cox Proportional Hazards Regression Coefficients for Compliant Days:

Variable	*B*	*SE*	95% CI	*z*	*p*	*HR*
Compliant Days	-0.13	0.01	[-0.14, -0.11]	-16.21	< .001	0.88

SUMMARY:

We have developed a new biometric, artificial intelligence, and machine learning-powered wearable bedwetting alarm that uses Pavlovian, or classical conditional training, to increase the effectiveness of enuresis alarm treatment.

The non-intelligent alarms on the market today rely on a form of operant conditioning which in many cases relies on negative reinforcement i.e. waking the child up to change the bed or do their laundry. Additionally, the fact that the patient wakes up after the bladder has been emptied provides no opportunity for the child to learn what physiological signals they can use in an effort to learn to stay dry.

Our alarm is capable of waking the patient prior to an accident giving the child the ability to process and internalize the feeling of bladder fullness or in some cases to remember what they were dreaming at that moment allowing them to associate this to learn how to achieve dryness. What was a striking revelation in our data analysis is that the high compliance patients over time had a reduction in the number of predictive nighttime alarms indicating that there were ongoing changes in the brain-autonomic axis processing of the patient concerning bladder fullness. As we continue to increase the amount of our data acquisition, we will be better equipped to analyze this heart rate data and more deeply understand this learning process.

At the present time, the GOGO Band® System is best suited for patients and parents that are willing to work together to achieve an outcome: dryness at night. In patients where their parents do not or will not get up to a ringing alarm, or if the child is not able to get up on their own with a ringing alarm the system is still marginally better than a reactive dumb alarm. We presently do not have data on nocturnal enuretics with ADHD nor can we categorize our patients into monosymptomatic or non-monosymptomatic nocturnal enuretics to provide further guidance in who is a good candidate for treatment. What we can say is that non monosymptomatic patients should be identified and treated for the underlying bowel and bladder dysfunction as in all nocturnal enuresis protocols.

These preliminary findings indicate that the GOGO Band System is more effective than the current reactive "dumb alarms." The data also suggests that it may be more effective in compliant patients than medications. In several instances in patients who were refractory to medications they achieved complete dryness using the system. At the present time we have no direct comparator studies to definitively compare the alarm to medication, but we expect to perform future studies. Our findings indicate that the GOGO Band System is a better solution than standard non-intelligent reactive bedwetting alarms. The addition of HRV and AI based algorithms produce a smart, predictive alarm that yields results that surpass other alarms and possibly even medications.

Dr. Israel Franco, MD is a board-certified Pediatric Urologist with over 30 years of experience and leads Yale University's Children's Bladder and Continence Center which is actively engaged in leading-edge research in the field of urinary incontinence and dysfunctional voiding. He received his medical degree from Albert Einstein College and his fellowship from Children's Memorial Hospital in Chicago. Dr. Franco is regularly invited to speak at national and international academic meetings in the field of pediatric incontinence. Dr. Franco was an early innovator in laparoscopic techniques in pediatric urology and has brought to the forefront the role that underlying neuropsychiatric issues play in pediatric incontinence. Dr. Franco is the CSO of GOGO Band and long term Board Member and Treasurer of the International Children's Continence Society (ICCS) which plays a vital role in the education of physicians and nurses in the care of children's urinary and bowel continence issues. Dr. Franco has published over 90 articles in peer reviewed journals, contributed 19 chapters for textbooks, and has been a Castle-Connolly Top Doctor since 2014.