Preventing Sudden Cardiac Death Utilizing Wearable External Cardiac Defibrillators
The OSUMC Experience

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Background:

-Sudden cardiac death (SCD) is a known complication of congestive heart failure.
Up to 40% of patients die due to arrhythmias, predominately ventricular tachycardia (VT) or ventricular fibrillation (VF).
-Multitude trials have demonstrated a mortality benefit with implantable cardiac defibrillator (ICD) placement for primary prevention[1,2,3].
-Large scale trials evaluating the mortality benefit of wearable external cardiac defibrillators (WCDs) are in progress. Most notably, the on-going WEARIT-II registry will enroll 2000 patients in the United States and 1000 in Europe and Isreal.
-Recently, an analysis of 882 patients enrolled in the United States arm of the registry demonstrated a 1.13% absolute mortality benefit[4]. To date no studies stratify which patients would benefit the most based on risk factors or type of cardiomyopathy.

Objective:

-To perform a retrospective analysis of all patients to whom WCDs were prescribed to determine if a significant mortality benefit was conferred to patients and to determine which subset of the population based on risk factors would benefit most from WCD therapy.

Methods:

-Profiles of all patients prescribed WCDs at OSUMC from 12/1/2010 to 1/1/2013 were compiled.
-The patients were subdivided into subsets of ischemic and non-ischemic cardiomyopathy.
-Additional risk factors including hypertension, depressed renal function, diabetes, anemia, dyslipidemia, and current history of smoking were also evaluated.
-The data was then analyzed to determine overall conferred mortality benefit defined as an appropriate ICD firing. Also, risk factors were analyzed to see if a pattern of higher mortality benefit was evident in any subset of the population.

Results:

-A total of 50 patients were treated with WCDs. Two patients received appropriate shocks conferring an overall mortality benefit of 4%.
-Further analysis demonstrated a 3.3% mortality benefit in the ischemic cardiomyopathy group compared to a 5% benefit in the nonischemic cardiomyopathy group.

Table 1

	Ischemic Cardiomyopathy (N=30)	Non-Ischemic Cardiomyopathy (N=20)
Median Age	56.5	58.5
Age Range	33-79	35-67
Male Gender (%)	90	70
Diabetes Mellitus (%)	60	50
Current Smoker (%)	43	55
Hypercholesterolemia (%)	83	60
Hypertension (%)	87	80
Anemia (%)	63	25
Creatinine Clearance <60 ml/min (%)	27	15
Triple Vessel Disease (%)	73	0
Prior PCI (%)	13	0
Prior Bypass Surgery (%)	10	0
History of Cerebrovascular Disease (%)	13	0
History of Peripheral Vascular Disease (%)	17	0

Figure 1

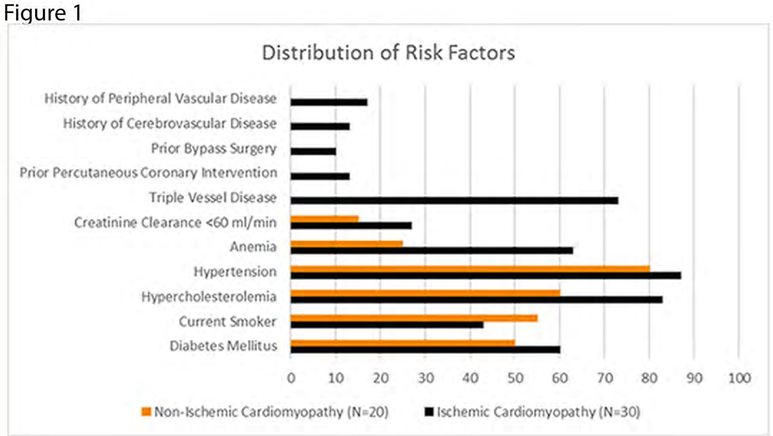


Figure 2

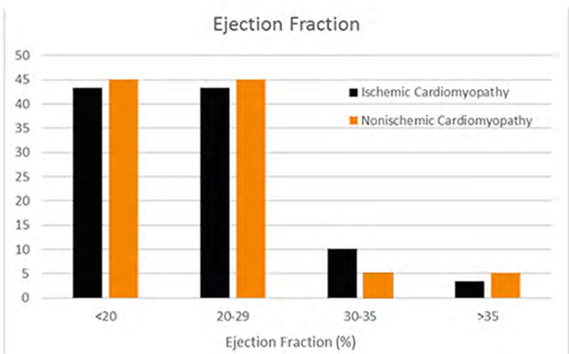
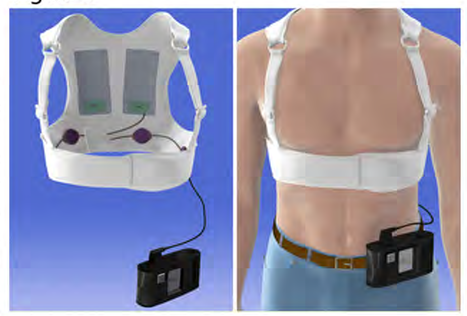


Table 2

Two Shock Events		
	Ischemic Cardiomyopathy	Non-Ischemic Cardiomyopathy
Age	47	62
Ejection Fraction (%)	15-20%	20%
Diabetes	No	Yes
Hypertension	Yes	Yes
Creatinine Clearance	>90 ml/min	<60 ml/min
Triple Vessels Disease	Yes	No
Hypercholesterolemia	Yes	No
HIV	Yes	No
Bypass Surgery	Yes	No

Figure 3



Conclusion:

-At OSUMC our data revealed 20 cases of decompensated nonischemic cardiomyopathy, and 30 cases of ischemic cardiomyopathy that were treated with a WCD. Overall two patients received appropriate defibrillations for VT/VF, one in each arm.
-Based on our results it appears the greatest survival benefit with WCD therapy may be conferred to the nonischemic group. Our findings demonstrate that WCD therapy confers a significant mortality benefit in appropriately selected patients.
-Additionally, the true mortality benefit of WCD may be underestimated in our study. In the MADIT trial, a survival benefit became evident 18 months after infarction. Similarly, long term follow up of our patients may demonstrate an even greater mortality benefit of WCD therapy[5].
-In the interim life saving WCD therapy should be offered to all patients with an ejection fraction of less than 35% until either their EF improves or an ICD is implanted.

Discussion:

-The sample size of this study is too small to establish an algorithm based on risk factors that would make WCD therapy more cost effective . Hence, further follow up and large prospective studies are needed to achieve this goal.

Disclosures: There are no conflicts of interest among any of the authors.

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Comparison of Microbial Populations on Infant Pacifiers verses Their Oral Swab: What Are We Putting in Our Kids Mouths?!

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Abstract

Previous studies have shown that used infant pacifiers (IP) like other oral devices become contaminated with a wide variety of microorganisms. These studies did not delineate the location verses the type of microorganisms. The purpose of this study is to describe the variation in types of microorganisms found from different sites on the pacifier and a swab of the buccal mucosa. Eleven (11) used IP were collected for this study. In addition, swabs were made of the buccal mucosa from the same IP donors and were compared with buccal swabs from 30 medical student volunteers. The IP were evaluated using previously published procedures to isolate, numerate, and identify microorganisms found on the pacifiers and swabs. There were substantial differences between the microorganisms found on swabs from infants verses medical students. In addition, the results showed significant differences between microflora isolated from the swab and the IP. Different parts of the IP revealed significant differences in microflora, specifically with regards to *Staphylococcus* verses *Streptococcus* and *Bacillus* verses *Corynebacter*. These results may have important clinical application.

Background

Humans have been putting oral devices into their mouth since before recorded history. Precursors of pacifiers and wind musical instruments have been found in archeological digs from Neolithic period (10-20 thousand years ago)[1,2]. The Etruscans were making and using dentures about 700 BCE[3]. Athletic mouth guards came along much later in the 1890's[4]. Obviously the value in the use of these oral devices has long been recognized but their potential health hazards have not. For example, it is only recently that the possibility that pacifiers use might interfere with breast feeding, or contribute to ear infections, or interfere with speech development or cause dental development have come to light. The question of the effect of the use of oral devices on the microbiology of the oral cavity and its potential relationship to oral and systemic health has not been deeply explored.

Introduction

The earliest evidence suggests that IP have been used since the Neolithic period of history[1]. Early forms of IP were made from cloth , ivory, or stone. The use of rubber or plastic was not common until the mid 19th century. In western countries, it has been estimated that 75-85% of infants will use IP sometime during their early childhood[2]. These same authors found an association between IP use and Acute Otitis Media (AOM). Sexton and Natale reviewed the positive benefits of IP use and found an analgesic effect, a shortening of hospital stay, and a possible prevention of Sudden Infant Death Syndrome (SIDS)[3]. When these researchers looked at the negative aspects on dental health and microbial contamination, they suggested IP use might lead to oral and systemic infections. Similarly, North Stone *et al* found a positive correlation between IP use and the incidence of colic and AOM[8]. The purpose of the present study is to isolate, quantify, and identify the microorganisms from various sites of used IP and to compare these findings to buccal swabs from the same subjects.

Methods

IP: Eleven (11) used, de-identified IP were collected from both well babies and infants reporting AOM and/or colic symptoms. The IP were placed in sterile plastic zip-lock bags; a buccal swab was made; and all samples were immediately transported to the Forensic Pathology/Microbiology Laboratory, OSU-CHS for processing. De-identified buccal swabs were made on 30 medical student volunteers and served as controls for the IP subjects.

Microbial Sampling:
Each IP and its corresponding swab was given a unique specimen number, photographed, and weighed. Nipples and shields were sectioned aseptically and touched to media (Blood Agar Plate [BAP], Sabaroud's Dextrose Agar [Sab]) (Fig. 1 and 2). The swabs were rolled directly onto separate media (BAP and Sab).

Colony Forming Units (CFU/g) Determination:
After touching to plates, the nipples and shields were aseptically minced into small pieces, approximately 0.5cm^2. One gram (1.0g) of the resultant material was placed in 10mL of sterile water and vortexed for one minute. The swab was placed in 10mL of sterile water and vortexed for 1 minute. The CFU/g were determined by the method of Miles and Misra[5]. Each sample was diluted to a series of six 1:10 dilutions; plated in triplicate on BAP; and incubated at 37° C. These specimens were evaluated at 24 and 48 hours.

Microorganism Identification: Pure cultures were obtained of all colonial types appearing on any plate. Standard laboratory procedures were used to identify each unique colony.

IP Samples

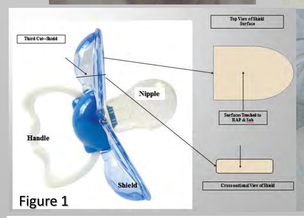

Figure 1


Figure 2

Discussion

Microbes cause diseases through 4 processes:

- **Infection:** Species such as *Staph aureus* (group 1) are known infectious pathogens; many other (groups 1- 8 & Y) can be infectious under proper conditions.
- **Toxicants:** *Bacillus cereus* (group 3) are capable of producing disease producing exotoxins.
- **Allergy/Asthma induction:** Fungi, especially molds, (data not shown) can be powerful inducers of allergy/asthma reaction.
- **Inappropriate modulation of the human immune system**: Sterile non-viable components of bacteria know as Pathogen Associated Molecular Patterns (PAMPs) are known to stimulate or suppress the human immune response.

Future Research

Analysis of the present study would be enhanced with additional pacifiers. The first order of additional work will be to have 30 pacifiers and swabs with 10 being from healthy children; 10 being from children with symptoms of AOM; and 10 being from children with symptoms of colic. In addition, information regarding length of pacifier use and pacifier hygiene will be collected and analyzed. Finally, the identified microorganisms from the pacifiers will be evaluated for correlations with the diseases (AOM and colic). From this data, recommendations can be made on a scientific basis for pacifier cleaning and discarding.

Results

The results of this study are summarized in Tables 1 and 2 and Figures 3,4,5, and 6. The protocol above was followed without exception. It is apparent that all IP were contaminated with a wide range of microorganisms. The actual numbers varied by sites, with a consistently high number of gram positive, catalase positive cocci (*Staphylococcus* type). A comparison of the gram positive cocci isolates, *Staphylococcus* vs S*treptococcus*, from swabs and nipples revealed a significant difference between the two populations. Statistical analysis showed significance of this data with a P value = 0.0061. A comparison of the gram positive bacilli isolates, *Bacillus* vs *Corynebacter*, from swabs and nipples revealed a significant difference between the two populations (P=0.0008). There were no significant differences between the populations of the nipples and shields.

Table 1. Distribution of bacteria and yeast from used IP and oral swabs. Interesting results are highlighted.

Group	Gram Positive Cocci		Gram Negative Cocci	Gram Positive Bacilli		Gram Negative bacilli			Yeast
	Catalase + Staph Type	*Catalase – Strep Type*		*Endospore + Bacilli Type*	*Endospore – Coryne Type*	*Non-glucose user*	*Glucose fermenter*	*Glucose oxidizer*	
GPS #2 Total (N=11)	1.27	0.09	0.00	0.64	0.73	0.18	0.09	0.27	0.92
GPS #2 Shield (N=11)	1.45	0.00	0.00	0.27	0.45	0.00	0.00	0.00	0.45
GPS #2 Nipple (N=11)	1.27	0.09	0.09	0.64	0.73	0.18	0.09	0.27	0.45
GPS #2 Swab (N=11)	1.18	1.18	0.09	0.00	1.91	0.09	0.00	0.09	0.09
GPS #2 Swab (N=11)	1.18	1.18	0.09	0.00	1.91	0.09	0.00	0.09	0.09
MS 1 Swabs (N=30)	0.57	0.27	0.00	0.03	1.03	0.00	0.03	0.00	0.16

Samples of colony growth

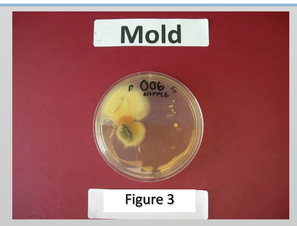

Figure 3


Figure 4

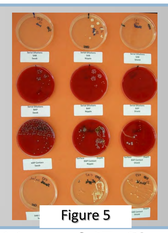
Figure 5

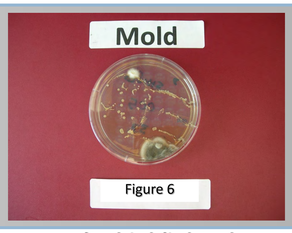

Figure 6

Table 2. Distribution of bacteria from 11 used IP. Significant results highlighted.

Group	Gram Positive Cocci		Gram Positive Bacilli		Totals
	Catalase + (Staph)	*Catalase – (Strep)*	*Spore + (Bacilli)*	*Non-Spore (Coryne)*	
Swabs	13	13	0	21	47
Nipple	14	1	7	8	30
Shield	16	0	3	5	24
Totals	43	14	10	34	101

Conclusions and Observations

The present study demonstrates that used IP are contaminated with a wide variety of microorganisms, including bacteria and yeasts. The study also found different numbers and types of microorganisms dependent upon the site on the IP. This result was particularly significant with regards to *Staphylococcus* verses *Streptococcus* and *Bacillus* verses *Corynebacter*. Similarly, comparison of the results from the buccal swab reveals that there are major differences between the microorganisms in the buccal mucosa and any of the sites on the IP. Finally, there are major differences between the findings on the buccal swabs from the study subjects as compared with medical students. This latter finding would suggest that buccal mucosa of infants are inhabited by different types of organisms than those found on the buccal mucosa of adults. These results may have important clinical application in the treatment of infants and the use of IP. The findings from this study support the previous recommendation of replacing IP on a weekly basis; at the beginning of an illness; when the child first feels better; and when the child is considered well[1-4].

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Implications of Tornado Impacts on Schools: An Historic Approach

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Introduction: Over 800 tornadoes develop on average in the United States annually. These storms can generate substantial numbers of casualties seen by the Emergency Health Care System. The nature of the casualties seen largely depends on the population demographics of the structures impacted. Community schools can represent areas where pediatric populations are concentrated during tornadoes. Little is known regarding the effect of tornado school impact in altering the overall proportion of pediatric casualties during tornados.

Study Purpose: This study is an initial attempt to determine fatality and injury characteristics when schools are occupied and receive tornado damage.

Study Setting: Public Access Data Base of tornado strikes on schools in the United States from 1865 to 2013.

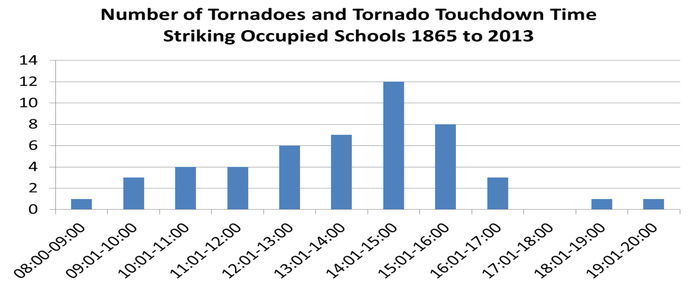
Methods: This is a retrospective historic study of public domain data from the National Weather Service Archives, as well as other public domain documents regarding tornadic storms involving schools. All tornadoes involving school impacts in the archives are included in the study. Descriptive analysis is performed. When available death and injury data are stratified into pediatric and adult cases. These data are compared with control storms of similar intensity during similar time-frames not involving school strikes.

Wallingford, CT Elementary School: August 9th 1878, Storm Struck unoccupied school at 5:00 PM. No children died. Total Storm deaths 34 with 70 Injuries (1, 2)

Longfellow School, Murphysboro, IL. Occupied School Struck with 17 Pediatric Deaths. "Tristate Tornado" March 18, 1925 (1,2)

Before and After Impact, **Plaza Towers Elementary School, Moore Ok**, May 20th 2013. A total of 7 pediatric deaths occurred at this location alone (2, 4,)

Results: There are 51 storms with reported school strikes with 50 meeting criteria for inclusion. In the school strike storms there were; School deaths 285 (mean 5.7), Total Storm Deaths 1373 (mean 27.4) and 5773 Storm Injuries (mean 115.4). Comparison of School Strike Storms with Control Storms found no difference in the Total Storm Fatalities or Injuries (P=0.61 Mean Diff -2.9 95%CI-15.5 to 9.8) and (p=0.88 Mean Diff -2.9 95%CI -49.0 to 43.2) respectively. The mean touchdown time for tornadoes striking occupied schools is 13:45 hrs (mode: 14:07:30 hrs; median 15:00:00 hrs). When pediatric fatalities are compared significantly more pediatric deaths are seen when schools are directly hit (p=0.01 mean diff 5.8 95%CI 1.7 to 9.8). Analysis of pediatric injuries verses adult injuries in case and control storms is not possible with this data set due to low resolution of early historic data (3).



Conclusions: Schools concentrate pediatric populations into a single location within a community. Tornado strikes impacting occupied schools significantly increase the number of pediatric fatalities (and by induction may increase pediatric injuries). This has clear implications for community planning in high risk tornado regions. Methods such as active warning systems, designated shelter areas and tornado sheltering protocols must be a routine part of every schools plan. In some cases, reinforced shelter locations should be considered. Schools in high risk tornado zones should develop protocols to consult with agencies such as the National Weather Service or state disaster management offices during periods of tornado watch. If excessively high risk predictions exist for a particular area, consideration should be given to school cancellation or early release from school.

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