Efficacy and safety of pure hypochlorous acid solution for neonatal skin bacterial decolonization

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Background

Neonates colonized with Staphylococcus aureus (SA)are at increased risk for developing invasive infections, prolonged hospitalization, worse neurodevelopmental outcomes and increased mortality. Pediatric and adult studies report efficacy of skin decolonization with chlorhexidine gluconate (CHG) bathing. Multiple concerns exist about CHG systemic absorption, multi-cellular toxicity and local skin injury when applied to full term and preterm neonates. There is an urgent need to identify safe topical antiseptic for neonates, to prevent/reduce both methicillin resistant and methicillin sensitive SA (MRSA & MSSA) colonization.

Current Challenges and Needs

Challenges with topical antiseptic products and neonates:

- CHG concerns: cutaneous local burns, dermatitis. Systemic absorption with Toxicity to multiple cell lines as well as cytotoxicity to healing wounds and delay in granulation tissue growth. Skin of 22-25 weeks neonates can be compared to a wounded area in a pediatric/ adult patient; therefore, concerns exist on applying CHG on both preterm and term neonatal skin.
- Povidone-iodine (PI) concerns: systemic absorption, poor regulation of iodine uptake into thyroid and potential for transient hypothyroidism. Concerns are especially high with preterm infants.
- Alcohol-based solutions pose concerns due to rapid evaporation and thus Heat loss/fire hazard, short-lasting efficacy, significant cutaneous absorption and reports of skin burns and necrosis in neonatal population.

Needs are:

- Need for gentle, non-toxic yet effective topical antisepsis as skin is often colonized
- Need for anti-inflammatory topicals as neonates have minimal anti-oxidant activity
- Need for product that will not delay epidermal growth and injure new cell layers
- Need for topical antisepsis with either no systemic absorption or no toxicity to cells from systemic absorption

Aim

- Primary aim was to evaluate the efficacy of pure hypochlorous acid (pHA)* cleansing solution in reducing SA colonization.
- Secondary aims: assess both cutaneous and systemic safety and tolerability with 3 times/ week topical pHA solution full body wipe in neonates.

Why pure Hypochlorous Acid solution?

- Pure hypochlorous acid (pHA) cleansing solution where the hypochlorous acid(HOCl) acts as an antimicrobial preservative, is produced via a patented, proprietary electrochemical process. It contains 300 ppm HOCl, some stabilizing ingredients such as sodium chloride that are natural to the body, and water. HOCl is endogenous to all mammals and is effective against a broad range of microorganisms. Between pHs of 3.5 and 5.5, the solution contains only the desired antimicrobial preservative, HOCl and within this range, there in minimal contamination with hypochlorite anion, which forms significantly only at a pH over 6.5. The acidic pH range of pHA is similar to the acid mantle of healthy skin and improves skin integrity.
- Hypochlorous acid is used widely in multiple industries. It is safe in animals if ingested, safe in eye care and non-toxic to various cell lines. Some researchers believe that hypochlorous acid at pH 5 is a safe alternative to sterile water. Its use in adults has exploded, with wound society's recommendation as number one safe antiseptic. Pediatric and neonatal case studies support its easy application, seemingly safe outcomes and efficacy in wound cleansing.

Methods

Full body surface was wiped 3 times/week(Su/Tue/Th), using sterile separate pHA saturated gauze pieces. Standard-of-care hygiene practices for colonization prevention were continued. Weekly SA nasal colonization surveillance PCR was sent. Incidence of colonization 6 months pre and post intervention was compared. Neonatal skin condition score(NSCS) was assessed twice a week. Weekly complete metabolic panel(CMP) was recorded.3 cohorts were used over time, each with decreasing gestation age(GA) and day-of-life(DOL) eligibility for solution application.(Table1)

Table 1

Cohort description	Months	Qualified Patients	Total Applications
C1: <26 weeks GA and >28 days of life 26-30 weeks GA and>14 days of life 31-32 weeks GA and> 7 days of life >33 weeks GA and >3 days of life	June	46	138
	July	35	105
C2: ≤24 weeks GA and >28 days of life 25-26 weeks GA and>14 days of life 27-31 weeks GA and> 7 days of life ≥32 weeks GA and >3 days of life	August	48	144
	September	33	99
C3: ≤24 weeks GA and >14 days of life 25-26 weeks GA and>7 days of life 27-31 weeks GA and> 4 days of life ≥32 weeks Ga and >2 days of life	October	42	126
	November	41	123
	December	49	147

Conclusion

To our knowledge this is the first neonatal study describing decreased MRSA and MSSA colonization with topical pHA solution application, while highlighting systemic and topical safety manifested by normal CMP and NSCS. We recommend considering topical pHA wipe for neonatal units concerned with MSSA/MRSA colonization as part of the comprehensive colonization prevention bundle.

*Vashe, Urgo Medical, TX

Results

- Between 6/25- 12/25 242 neonates between 23- 40 weeks GA (average GA at birth 33 wks.) and between 3-28 DOL received 882 pHA applications.
- **There were 17 MRSA colonization pre intervention and 7 after (58% decrease). There was 1 CLABSI pre-intervention and none after. There were 87 MSSA colonization events pre and 57 post intervention (35 % decrease).**
- Average composed NSCS was 4. Mild increase in skin dryness(scores of 2) was improved with lotion application. Breakdown and erythema scores of 2 or 3 were attributed to diaper dermatitis, not pHA application. In our unit application of pHA to diaper area is actually a part of moderate/severe diaper dermatitis management bundle. No increase in erythema or breakdown in any another body part was noted(besides diaper area-unrelated to pHA application)(Table2)
- Comprehensive Metabolic Panel(Table3)components were within normal values. When compared to pre-application values no significant difference was appreciated. Individual patients' abnormalities in electrolytes values were clinically explained by ongoing diagnoses/ interventions, felt not to be related to pHA application.
- Initially 2% of neonates in open cribs experienced post application mild hypothermia(decreased in T by 0.2-0.3C, none less than 36.3C). This was mitigated by warming the solution prior to application. No hypothermia was documented in heated incubators.

Table 2

NSCS Parameters	Average Score/Range
Dryness	1.3 (1-3)
Erythema	1.4 (1-3)
Breakdown	1.3 (1-3)

Table 3

Complete Metabolic Panel	Average value / (range)
Sodium	140 (135-149)
Chloride	101 (95-109)
Potassium	5.3 (3.4-7.8*) *-hemolyzed
Bicarbonate	19 (14-25)
BUN	12 (6-40)
Creatinine	0.3 (0.15-1.1)
Glucose	77 (38-172)
Calcium	10 (7.7-11.3)
Phosphorus	5.7(4.8-9)
AST	28 (11-42)
ALT	14(12-50)