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Phase 2 Study Assessing the Bactericidal Effects of Electrolyzed Oxidized Water as an Antiseptic towards the Reduction of The Peristomal Germ Density Level in Child Colostomy in Dr. Soetomo Hospital, Surabaya

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ABSTRACT

Many risk factors cause infection in the surgical site. This study examined the bactericidal effect of oxidized electrolyte water (EOW) as an antiseptic against decreasing levels of peristomal germ density in children colostomy areas, selected experimental studies of phase 2 study. This study was conducted in pediatric patients with a colostomy who were going to undergo stoma lid surgery to prove the bactericidal effect of EOW on the density of pediatric stoma area. Frequency distribution of the number of pre-antiseptic bacteria of the research sample was 30 samples. There were 1 preparation (3.3%) with 0-1,000 bacteria, 4 preparations (13.3%) with 1,000-10,000 bacteria, and 25 preparations (83.3%) with bacteria >10,000. The results of the examination showed the number of post-antiseptic germs on 27 preparations (90%) with the number of germs of 0-1,000, 0 preparations (0%) with the number of germs of 1,000-10,000, and 3 preparations (10%) with the number of germs >10,000. This test obtained a significant difference between the 2 groups (p = 0.001), showing a significant difference between the pre-antiseptic EOW and post-antiseptic EOW groups. EOW can significantly reduce the level of skin germ density in children with colostomy peristomal.

Keywords: EOW, electrolyzed oxidized water, colostomy, germ density

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INTRODUCTION

Operating area infection in the pediatric surgery division of Dr. Soetomo Hospital, Surabaya, Indonesia reportedly amounted to 0.775% of all pediatric surgery operations in the past ten years. There were 20 cases of surgical wound infections out of a total of 2579 operations, with a comparison of types of surgery in cases of clean surgery of 0.116%, contaminated clean operations of 0.388%, contamination operations of 0.116%, and gross surgery/infection of 0.078%. However, the infection rate was more than 50% occurring in contaminated clean operations; in this case, it is the operation of the stoma cap in children (1).

One type of clean-contaminated operation is stoma closure surgery. Infection of the area of surgery that will occur can depend on the number of colonies and the density of germs found in the area around the stoma (peristomal) (2). Colostomy is a type of stoma often used in children (3). Colostomy has a huge impact on a patient's life, including physical, psychological, social, and spiritual aspects (4). According to previous studies, colostomy patients refrain from religious activities and experience problems, such as lack of adequate information (5).

Many risk factors cause infection in the operating area. These factors can be divided into three parts: microorganism factors in contact during surgery, local wound factors, and patient factors [1]. One effort to reduce the amount of germ density in the area around the stoma is by rinsing using an antiseptic before surgery (6). Many attempts were made to reduce infection of the surgical site in stoma closure in children. Preparation of surgery using an antiseptic around the stoma is one of the methods employed [2]. Many types of antiseptics are available in the market. Chlorhexidine and povidone-iodine are antiseptics which have an adequate function of reducing the peristomal germ density. They are expected to be useful in preventing infection of the operating area (7). The mechanism of chlorhexidine action is effective in inhibiting growth and killing gram-positive and gram-negative bacteria, depending on the concentration used (8).

Electrolyzed oxidized water (EOW) is more useful in preventing sepsis due to burns, compared to the use of povidone-iodine which sometimes causes side effects (9). The previous study has shown that exposure to *Pseudomonas aeruginosa* to EOW for 5 seconds causes a total inhibition of these bacteria's growth with a cytotoxicity effect of EOW on corneal epithelial cells, significantly less than 1% povidone-iodine [3]. Thus, the damage caused by EOW is more minimal compared to 1% povidone-iodine (10). The study found the results that the treatment of *P. aeruginosa* with EOW (15 seconds) significantly inhibits the onset of corneal infections and offers an effective and safe method for antiseptic on the surface of the eye (10).

Pseudomonas aeruginosa is a causative agent for infectious keratitis. The most common cause of this condition is related to the use of contact lenses, with the condition of the

infection causing a decrease in corneal transparency and damage to the structure of the cornea in relation to high inflammation. (11). *Pseudomonas aeruginosa* is known as one of the pathogenic bacteria important for medical purposes (12). In recent years, EOW has been used clinically to treat various types of infections, especially in wounds in diabetic patients, tooth root infections, and for cleaning and disinfection of hemodialysis devices (7,8). Electrolyzed oxidized water with a high positive oxidation-reduction potential has been used for decades as disinfection in the industrial sector, especially the food industry [4]. In research in Japan electrolyzed oxidized water has been shown to reduce the amount of *E. coli*, Salmonella, and *L. monocytogenes* in food products (15). *E. coli* also causes several infections, such as acute meningitis, pneumonia, intra-abdominal infection, and other organ infections (16). E. coli a gram negative bacteria, was more resistant to antimicrobials compared to gram positive bacteria (17).

EOW is an activated liquid obtained by passing aqueous saline solution (NaCl, KCl or MgCl2) through an electrolytic cell, causing production from the anode side in the form of electrolyte oxidizing water, which contains high dissolved oxygen, high chlorine and is characterized by a low pH (2.3-2.7) and high oxidation-reduction potential (ORP>1,000 mV). Unlike other chemical disinfectants, EOW has many advantages, including safety, it is a strong, different acid from hydrochloric acid or sulfuric acid because it is not corrosive to the skin, mucous membranes and organic matter, the price is relatively low. The usage costs are relatively low. The highest cost is the purchase of an electrolytic unit, but, after the initial investment, the costs are very low, requiring only water, salt, and electricity, the impact on the environment is low. When EOW is in contact with organic material or diluted with plain water, EOW is "normal" again, EOW can be directly produced on-site and can be used immediately, does not endanger the health of the caregiver, and has a bactericidal effect by inhibiting the growth of bacteria. The EOW production process requires an electrolyze that can electrolyze saline (NaCl) or mineral water containing sodium chloride whose levels have been determined.

This study examined the bactericidal effect of EOW as an antiseptic against decreasing the level of peristomal germ density in the area of children's colostomy, and experimental study of phase 2 study was selected

METHODS

This was a phase 2 study. The samples of the study were pediatric patients with colostomy who were going to undergo stoma lid surgery to prove the bactericidal effect of EOW on the density of pediatric stoma area. Sampling in this study was randomized simple random sampling. Sampling was carried out at the Surgical Polyclinic of Dr. Soetomo Hospital, Surabaya. The examination of germ culture was carried out before and after exposure to the EOW antiseptic in the sample group to determine the decrease in the level of germ density (effectiveness). Side effects of EOW antiseptic exposure were noted. Furthermore, a different test was carried out to reduce the level of germ density of the antiseptic. Research material criteria consisted of inclusion criteria and exclusion criteria.

EOW is produced through anode flow and water containing electrolyte salts through the diaphragm. EOW with a low pH (2.3-2.7), high positive oxidation reduction potential (ORP> 1,000 mV), and high concentrations of chloride and dissolved oxygen functions as bactericides. The pre-antiseptic and post-antiseptic levels of germ density were calculated on the Blood Agar culture media and MacConkey culture media after contact between the swab and the colostomy area, before being carried out with the antiseptic with EOW. The calculation of germ colonies was with the 65-001 1µ Disposable Inoculation Loops Biologix® tool, the maximum colony count could reach 105. The decreasing the level of germ density compared the results of the level of germ density in the pre-test and the level of germ density in the post-test. Data analysis was performed using the Paired Samples Test to compare the decrease in the level of germ density. Data processing was performed using SPSS for Windows version 18.

RESULTS

This research was conducted on 30 pediatric patients with colostomy. There were no subjects who resigned during the study. The research data included gender characteristics, patient age characteristics, diagnosis characteristics, and colostomy age characteristics. No subjects experienced side effects (itching, redness, swelling) after being given an EOW antiseptic exposure.

Table 1. Characteristics of Research Samples

Sample Characteristics	Sample Groups	Total
Sex		
Male	22	73.3 %
Female	8	26.7 %
Age		
0 – 2 years	19	63.3 %
2 – 4 years	4	13.3 %
> 4 years	7	23.3%
Disease Diagnosis		
Anterior Anus	1	3.3 %
Congenital Band	1	3.3 %
Anorectal Malformation	21	70.0 %
Hirschsprung's disease	5	16.7 %
Perineal Rupture	1	3.3 %
Anal Stenosis	1	3.3 %
Duration of Colostomy		
< 1 year	10	33.3 %
1 – 2 years	13	43.3 %
2 – 4 years	4	13.3 %
> 4 years	3	10.0 %

The sex distribution of the study sample included 22 boys (73.3%) and 8 girls (26.7%) (Table 1). The age distribution of the study sample was divided into 3 groups, i.e., the age group of <2 years, age group of 2-4 years, and age group of >4 years. The age group of <2 years were 19 children (63.3%), age group of 2-4 years were 4 children (13.3%), and age group of >4 years were 7 children (23.3%). This group included a time group of less than 1 year in 10 children (33.3%), a time group of 1-2 years in 13 children (43.3%), a time group of 2-4 years in 4 children (13.3%), and a time group of >4 years in 3 children (10.0%).

The distribution of diagnoses of primary diseases causing colostomies in this sample includes 1 type of anterior anus disease (3.3%), 1 type of congenital band disease (3.33%), 21 children with anorectal malformation (21.0%), 5 children with Hirschsprung's disease (16.7%), 1 child with perineum

rupture disease (3.33%), and 1 child with anal stenosis (3.33%) (Table 2).

Table 2. Distribution of Diagnosis of Research Samples

Diagnosis	Total	Percentage
Anterior Anus	1	3.3 %
Congenital Band	1	3.3 %
Anorectal Malformation	21	70.0 %
Hirschsprung's disease	5	16.7 %
Perineal Rupture	1	3.3 %
Anal Stenosis	1	3.3 %
Total	30	100 %

Distribution of colostomy area skin germ group included 17 gram-negative rod stem bacteria groups, 19-gram gram-positive coccus germic groups, and 0 sterile results. The distribution of types of skin bacteria colostomy area pre antiseptic included *Escherichia coli* bacteria in 12 samples, *Proteus mirabilis* bacteria in 2 samples, *Enterobacter aerogenosa* in 1 sample, *Klebsiella pneumonia* in 3 samples, *Acinobacter spp* in 2 samples, *Staphylococcus coagulase* negative bacteria in 1 sample, *Klebsiella pneumonia* in 3 samples, *Acinobacter spp* in 2 samples, *Staphylococcus coagulase* negative in 15 samples, and Streptococcus non haemolitycus in 4 samples (Table 3).

Table 3. Distribution of Skin Germ Types of Pre-Antiseptic Colostomy Areas

Types of Germ	Total
Escherichia coli	12
Proteus mirabilis	2
Enterobacter aerogenosa	1
Klebsiella pneumonia	3
Acinobacter spp	2
Staphylococcus coagulase negative	15
Streptococcus non haemolitycus	4

Distribution of types of skin bacteria post antiseptic colostomy area include *Escherichia coli* bacteria in 3 samples. Frequency distribution of the number of pre-antiseptic bacteria of the research sample was 30 samples. The test results showed the number of pre-antiseptic germs in 1 preparation (3.3%) with the number of germs from 0-1,000, 4 preparations (13.3%) with the number of bacteria 1,000-10,000, and 25 preparations (83.3%) with the number of germs >10,000. Frequency distribution of the number of post-antiseptic bacteria in the study sample was 30 samples. The results of the examination of the number of pre-antiseptic bacteria showed 27 preparations (90%) with the number of bacteria 0-1,000, 0 preparations (0%) with the number of bacteria 1,000-10,000, and 3 preparations (10%) with the number of germs >10,000 (Table 4).

Table 4. Frequency Distribution of the Number of Pre-Antiseptic and Post-Antiseptic Germ Colony of Research Samples

Number of Germs	Pre-Antiseptic		Post-Antiseptic	
	Frequency	Percentage	Frequency	Percentag
0-1,000	1	3.3%	27	90%
1,000-10,000	4	13.3%	0	0%
>10,000	25	83.3%	3	10%

Before analyzing the research data, a normality test for data distribution needs to be carried out. The results of the distribution normality test were examined using the Shapiro-Wilk test. From the normality test conducted, the data were not normally distributed (p = 0.000). Furthermore, for the purposes of analysis, non-parametric test was performed.

The effectiveness of electrolyzed oxidized water (EOW) is the antiseptic ability of electrolyzed oxidized water in reducing germ density. In this case, a different test was carried out on the level of density of germs before and after being given with antiseptic electrolyzed oxidized water using the Wilcoxon Signed rank test. From this test, a significant difference was obtained between the two groups (p = 0.001), showing significant differences between the pre-antiseptic EOW and post-antiseptic EOW groups (Table 5).

Table 5. Wilcoxon-Signet Rank Statistic Test

Number of Germs	Frequency	Frequency	P
0-1,000	1 (3.3%)	27 (90%)	0.001
1,000-10,000	4 (13.3%)	0 (0%)	
>10,000	25 (83.3%)	3 (10%)	

DISCUSSION

The results of this study showed that electrolyzed oxidized water can be used as an alternative choice for antiseptics in preparation for surgery, especially surgery to close a child's stoma. This study showed that the most diagnosis indicative of a colostomy in children is Anorectal Malformation, while the other diagnosis is in Hirschsprung's disease.

In the antiseptic group of electrolyzed oxidized water, the examination results obtained from 0-1,000 germs amounted to 3.3% to 90%; the number of germs 1,000-10,000 by 13.3% to 0%; and the number of germs >10,000 by 83.3% to 10.0%. There was a distribution of types of skin bacteria post antiseptic colostomy area, including *Escherichia coli* as many as three samples and sterile as many 27 samples. The presence of *Escherichia coli* in these three samples could be due to the antiseptic effect of EOW only on the surface of the peristomal skin, the presence of fecal exposure in the antiseptic area, and the time of antiseptic exposure for only one minute. From the results of the count of these colonies of germ density, the effectiveness of the electrolyzed oxidized water antiseptic as a whole can reduce the density of skin germs around the colostomy significantly. In this study, no subjects experienced side effects after being given antiseptic exposure to electrolyzed oxidized water.

In this study, the results of examining the number of pre-antiseptic germs showed one preparation (3.3%) with the number of bacteria 0-1,000, 4 preparations (13.3%) with the number of germs 1,000-10,000, and 25 preparations (83.3%) with the number of germs >10,000 There was a distribution of colostomy area skin germ groups including 17 gram-negative rods dominated by *Escherichia coli* with 12 samples, 19 gram-positive coccus groups dominated by *Staphylococcus coagulase* negative with 15 samples and with sterile results of 0 samples.

Children under five years were the age group with the highest number of colostomy statuses. This is due to the indication that colostomy has been made and is done at the time the child is born, as in the case of anorectal malformation or Hirschsprung's disease (3). Meanwhile,

stoma closure surgery is done after the problem in the distal stoma has been resolved and can function physiologically through definitive surgery to correct the congenital abnormalities.

Electrolyzed oxidized water has many advantages, including safety, containing strong acid different from hydrochloric acid or sulfuric acid because it is not corrosive to the skin, mucous membranes and organic matter, and the relatively low price. When electrolyzed oxidized water is in contact with organic material or diluted with normal water, the EOW becomes "normal" again. Electrolyzed oxidized water can be directly produced on-site and can be used immediately, does not endanger the health of the caregiver, and has a bactericidal effect by inhibiting the growth of bacteria (10).

The length of time a colostomy is also found in children not related to the type of colonization of germs. Compared to the theory of growth or colonization of germs, there is a change in the skin microbiota of skin from the type of Gram-Positive Coccus to Negative Gram Rods (18,19). In this study, microbiota changes were not affected by colostomy duration. This can occur due to local peristomal (20-24)

conditions in the form of fecal exposure variations and also the systemic conditions of the patient's body affecting the growth of germ microbiota. Meanwhile, in the sex of children, the type of colonization of these germs was spread evenly among boys and girls.

Collecting of peristomal skin swab culture is performed in room conditions, immediately after flushing the skin using an antiseptic solution. Delivery of transportation media canisters with Amies medium transport® also takes less than an hour. This prevents contamination of germs that do not originate from peristomal microbial germs. In addition to germination culture in Blood Agar, culture media, and MacConkey culture media using swab culture, germination in the same media is also carried out without being accompanied by swab culture. It aims to evaluate the sterility of the culture media used for research. In this culture media, all media with sterile culture results are obtained. Thus, the growth of germs can undoubtedly be derived from the culture of research swabs.

Skin microbiota around the stoma is influenced by the environment occurring around the stoma. The presence of a stoma will cause irritation and contamination of intestinal contents in the skin of the peristomal. Peristomal skin will contain microbiota with a composition that matches the skin microbiota and the microbiota of the intestine. Core microbiota is an increasingly popular mechanism for simplifying analysis and identifying critical microorganisms in the community (20). In peristomal skin, the density of germs that develops is very high. This is caused by exposure to feces that come out of the stoma itself, although the clinical condition of the patient also influences it (3). Microbiological examination results are highly dependent on the quality of the specimen.

CONCLUSION

Electrolyzed oxidized water can significantly reduce the level of skin germ density in children in colostomy peristoma. Electrolyzed oxidized water (EOW) can be used as an alternative choice for antiseptics in preparation for stoma closure surgery.

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