Comparison of the efficacy and patients' satisfaction of povidone iodine and commercially prepared guava extract feminine wash as an external genital antiseptic among women who underwent vaginal delivery with episiorraphy in a tertiary hospital: A randomized clinical trial*

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ABSTRACT

Background: One of the most common complications of episiotomy is infection. Most infections will resolve with local perineal care. Hence, episiotomy wound care is important. In preventing wound infection cleansing the vulva and external genital area with an antiseptic solution prior to, and several days after the procedure until the wound is healed is potentially beneficial.

Objective: To compare the efficacy and patients' satisfaction of commercially prepared guava extract with povidone iodine as external genital antiseptic wash in women who underwent vaginal delivery and had episiorraphy in a Tertiary Hospital.

Results: There were 248 women who underwent episiotomy and randomized to the guava leaf extract (n=122) and povidone-iodine (n=126) feminine wash groups. Episiotomy wound infection rate between guava (0.81%) and povidone iodine (2.38%) feminine wash, was not significantly different (p=0.33). Occurrence of adverse event was lower in the guava leaf extract (1, 0.81%) as compared to povidone iodine (4, 3.17%) feminine wash group, but is not statistically significant (p=0.19). The mean patient satisfaction score for the guava feminine wash is 4.4 which was significantly higher than the mean score of those in the povidone iodine feminine wash which is 3.6 (p< 0.001).

Conclusion: The efficacy in preventing episiotomy wound infection and rate of adverse reaction with the use of commercially prepared guava leaf extract is comparable with povidone iodine as an external genital antiseptic. With regards to patients' satisfaction and cost this was found to favor the use of commercially prepared guava leaf extract external genital wash

Keywords: episiotomy, wound infection, guava leaf extract, povidone iodine feminine wash, antiseptic external genital wash

INTRODUCTION

Episiotomy is an incision of the pudendum or the external genital organs. It is the surgical enlargement of the vaginal orifice by an incision of the perineum during the last part of the second stage of labor or delivery. The incision may be made in the midline, creating a median or midline episiotomy. It is directed laterally and downward away from the rectum, termed a mediolateral episiotomy.[1]

The World Health Organization (WHO) recommends the use of episiotomy only for selected indications. The benefits of episiotomy include reduction in 3rd and 4th degree perineal tears, ease of repair and wound healing, preservation of the muscular and fascial tissue and reduction in neonatal trauma. The repair of a surgical incision is also more likely to be anatomically correct and thus less likely to result in long term complications from irregular perineal lacerations.[10] On the other hand, the most common complications of episiotomy are bleeding, infection, dehiscence, and rectal extension. Rarely necrotizing fasciitis or a fistula may occur from the episiotomy wound. Most infections will resolve with local perineal care. Hence, care of episiotomy wounds becomes an important aspect of postnatal care specifically on the healing of Episiotomy wounds (Steen, 2007).

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In many institutions, the common practice is to give a systemic antibiotic to avoid perineal infection post-partum. However, based on the WHO recommendation routine administration of antibiotic before or after episiotomy is not recommended. There was insufficient evidence to assess the clinical benefits and harms of routine antibiotic use for episiotomy repair after vaginal delivery according to Cochrane published in 2017.[20] This recommendation puts emphasize on avoidance of emerging antimicrobial resistance at the global level. Moreover, routine antibiotic prophylaxis is only recommended for women with third and fourth degree perineal tear.[19]

Another strategy in preventing infection of the episiotomy wound is to cleanse the vulva and external genital area with an antiseptic solution prior to, and several days after the procedure until the wound is healed. One of the most common antiseptic used is povidone iodine. An antiseptic product containing 7.5% Povidine-Iodine is used for the relief of external genital itching and irritation common during excessive secretions, menstruation and menopause. It is also used as a postpartum wash after perineal repair.

Another potential antiseptic agent is the Psidium guajava Linn (guava) plant which has known antibacterial properties based on folkloric belief. This potential is currently being explored by researchers from different parts of the world. Commonly leaves of the guava tree in decoction is used as a wash for vaginal and uterine problems especially where an astringent remedy is needed. Chemical content and properties of guava leaf consist of Tanin, essential oil, Flavonoids, ursolic, Oleanolic, Carotene, Avicularin, Guaijaverin, B1, B2, B3, B6 Vitamin and C vitamin. The benefits of Psidium guajava leaf are proven to accelerate the healing of skin infections commonly caused by Staphylococcus aureus, Streptococcus spp, Escherichia coli, Salmonella typhi, Proteus mirabilis, and Shigella dysenteria (Desiyana et al., 2016). Hence, in this study we would like to address the research question: "Is guava leaf extract comparable with povidone – iodine in preventing episiorhaphy wound infection when used as an external genitalia antiseptic wash by women who delivered via vaginal delivery?".

BACKGROUND OF THE STUDY OR REVIEW OF LITERATURE

Episiotomy or spontaneous vaginal tear of any kind increases the risk of infection due to the disruption of the protective epithelial layer of the mucosa and skin. In many instances of infection, the microorganisms that normally colonize the vaginal canal and the vulvar epithelium are the causative agents. However according to Saifuddin in 2014 over 50% the causative agent is streptococcus anaerobe, which is actually a non pathogenic bacteria normally found in the birth canal.

The use of systemic antibiotics as prophylaxis to prevent postoperative infection is a common practice. However, it has several disadvantages particularly the potential to cause adverse drug reactions, disrupt the normal vaginal flora resulting to superinfection with fungi, as well as, drug resistance. Thereby, antibiotic use for this purpose is not cost efficient. One way to prevent postoperative wound infection is proper wound care. This is done by cleansing the vulva and external genital area with an antiseptic solution prior to, and several days after the procedure until the wound is healed. This would avoid many of the problems associated with the use of systemic antibiotics at the same time prevent occurrence of wound infection. One of the more popular anti-septics are Povidone-iodine.

Povidone iodine (PVP-I) is a complex which contains elemental iodine and a neutral ampiphatic organic compound called polyvinyl pyrollidone. The active germicidal component is elemental iodine and its complex form serves as a reservoir of this active pharmaceutical ingredient.[5]

Povidone iodine has the same broad spectrum germicidal activity as pure tinctures from where it is derived. However, because the iodine is within a complex, povidone iodine is devoid of many of the undesirable features attributed to pure solutions of elemental iodine which include reduced incidence of toxicity and irritation (e.g. skin and mucosal membrane irritation). This is because tissues are not unduly exposed to extremely high amounts of iodine at a given time but to low effective concentrations over time. Severe complications are uncommon when this antiseptic is applied on intact skin. The active ingredient of povidone iodine is proven to have broad spectrum biocidal agent with in vitro activity against bacteria, yeast, molds, fungi, protozoa, actinomyces, and viruses.[5]

The mechanism of action which renders the biocidal effects of povidone iodine are two-fold. The first target of iodine action is the quarternary structures in the cellular membrane which are disrupted by activated iodine. This disruption within the membrane provides access into internal cellular structures, specifically cytoplasmic molecules essential for biological viability and DNA, both of which are likewise destroyed.

In 2007, Manalastas et. al. conducted a randomized controlled trial that compared the efficacy, acceptability and safety of chlorhexidine digluconate against povidone iodine and lactic acid as an external genital antiseptic among 270 women who have undergone vaginal surgery. The primary efficacy outcome in this study is the development of surgical site infection (SSI). Majority of patients (208 out of 216, 92.3%) in their study did not develop SSI. Surgical site infection was only noted in 1

out of 71 participants using chlorhexidine digluconate (1.4%, 95% CI: .04 – 7.6%); 2 out of 71 among those using povidine-iodine developed (2.8 %, 95% CI: 0.34 – 9.8%); and 5 out of the 74 participants using lactic acid (6.8%, 95% CI: 2.2 -15.1). One significant aspect of the findings in this study is the apparent efficacy of the use of an antiseptic alone, instead of systemic oral antibiotics, in preventing SSI among women undergoing episiotomy or episiorrhaphy. Among the 216 women who completed the trial, chlorhexidine digluconate, povidone- iodine and lactic acid were found to be comparable in terms of patient acceptability. These external genital antiseptic wash solutions were moderately-extremely acceptable, equally safe and well tolerated.

However prolonged use of povidone-iodine, such as repeated irrigation of open wounds and body cavities, may be associated with disruption of normal thyroid function that may lead to hyperthyroidism. This is due to the possible systemic absorption of the active ingredients which is elemental iodine. It has also been associated with other systemic adverse reactions such as hepatotoxicity, nephrotoxicity, metabolic acidosis, chemical peritonitis, seizures and neutropenia. Hence, the use of alternative solutions with similar antibacterial properties and void of such adverse effects should be further explored.

Aside from pharmaceutically prepared products, medicinal plants contribute significantly to primary health care in many countries. This serve as the starting point for several semi-synthetic analogs. Numerous plants and plant components have demonstrated anti-inflammatory and wound healing properties as well as cytotoxic activity. This illustrates the potential for novel agents to be identified from uncharacterized natural plant resources.[4] In cases of episiotomy wound care, their use has a potential benefit.

The guava tree, Psidium guajava Linnaeus (Myrtaceae), is a tropical hardwood plant that can reach a height of 10 meters. It is considered native of Mexico and extends throughout South America, Europe, Africa and Asia. Guava is used medicinally in many parts of the world due to its anti-inflammatory and antiseptic properties. The leaves are applied to wounds, ulcers and joints (for the relief of rheumatic pain) and are also chewed to relieve toothache.[4]

The wound healing properties of a methanolic leaf extract of Psidium guajava was studied by Chah et. al using the excision wound model. More than 90% wound healing was observed after 14 days post-surgery, compared to 72% healing in the group treated with distilled water. The wound healing process involves a variety of events such as inflammation, cell proliferation and contraction of the collagen lattice. This process may be hampered by the presence of oxygen free radicals or microbial infection.

In 2006 a study was conducted to evaluate the anti-inflammatory and analgesic effects of Psidium guajava Linnaeus (Myrtaceae) leaf aqueous extract in rats and mice. The anti-inflammatory property of the aqueous leaf extract was investigated in rats, using fresh egg albumin-induced pedal (paw) edema, while the analgesic effect of the plant extract was evaluated by the "hot-plate" and "acetic acid" test models of pain in mice. Diclofenac (100 mg/kg, i.p.), as an anti-inflammatory, and morphine (10 mg/kg, i.p.), as an analgesic, were used as standard reference for comparison. The Psidium guajava leaf aqueous extract (PGE, 50-800 mg/kg, i.p.) produced dose-dependent and significant ($p<0.05$-0.001) inhibition of fresh egg albumin-induced acute inflammation (edema) in rats as compared to Diclofenac. The plant extract (PGE, 50-800 mg/kg, i.p.) also produced dose- dependent and significant ($p < 0.05$-0.001) analgesic effects against thermally and chemically induced nociceptive pain in mice as compared to morphine. The numerous tannins, polyphenolic compounds, flavonoids, ellagic acid, triterpenoids, guiajaverin, quercetin, and other chemical compounds present in the plant are speculated to account for the observed anti-inflammatory and analgesic effects of the plant's leaf extract. The findings of this experimental animal study indicate that the leaf aqueous extract of Psidium guajava possesses analgesic and anti-inflammatory properties. Hence, the study suggested the ethnomedical, folkloric use of the plant in the management and/or control of painful, arthritic and other inflammatory conditions in some rural communities of Africa.

In 2014, Cruzada et. al conducted an antibacterial study comparing the relative efficiencies of guava leaf ethanolic extract and antibiotic standards against gram negative bacteria and Planktonic and Biofilm Lifestyles.[13] The susceptibility of planktonic and biofilm forms of Escherichia coli and Pseudomonas aeruginosa to Guava leaf ethanolic extract and the appropriate antibiotic standards were evaluated using a Kirby-Bauer disc diffusion assay and Biotimer assay. Based on the Kirby Bauer assay, guava leaf ethanolic extract exhibited comparable antibacterial strengths against both bacteria ($P > 0.05$), but was significantly less than the antibiotic standards ($P < .001$). However, in biotimer assay, there is no significant difference between the antibacterial properties of guava leaf ethanolic extract and the antibiotic standards ($P > .05$). The relative antibacterial properties of guava leaf ethanolic extract and standard antibiotics vary depending on bacterial biofilm lifestyle. Thus the need to use biotimer assay alongside Kirby Bauer when assessing the antibacterial properties of natural products has been suggested.

Ifeanyichukuwu et al, conducted a preliminary investigation of the antibacterial activity of guava extracts

in 2015 in Nigeria. The ethanolic and methanolic crude leaf and bark extracts of guava were evaluated against the pathogenic strains of Escherichia coli, Staphylococcus aureus, Klebsiella pneumonia, Pseudomonas aeroginosa and Streptoccocus pneumonia by agar well diffusion technique. The crude extracts of the plant at 100mg/ml were each tested on 6 mm punctured wells or holes on Mueller Hinton agar plates (Oxoid, UK) that were previously swabbed with the test bacteria. Zones of inhibition were recorded to the nearest millimeter (mm) after 24 hrs of overnight incubation at 37°C. Chloramphenicol was used as the positive control drug. The ethanolic and methanolic bark extracts of Psidium guajava had appreciable antibacterial effect against the test bacterial pathogens. Both Gram positive and Gram negative bacterial pathogens used in this study were considerably inhibited by the methanolic and ethanolic leave and bark extracts of Psidium guajava.

Another study in 2013 conducted by Fuentebella investigated the antimicrobial activities of oregano, garlic, ginger and guava extracts against microbial wound isolates from wound infections. This study demonstrated that the ethno-medicinal plants exhibited antimicrobial activities that can be as effective as the commercially prepared antiseptics. Hence, these plants have the potential to be used as an alternative natural treatment for infected wounds on the premise that the right method of extraction will be used.

According to the reported cases of episiotomy wound infection, the commonly identified isolates are Staphylococcus aureus, gram negative bacilli, enterococci, group B streptococci and anaerobes[21]. Based on the reported anti-microbial property of povidone iodine and guava, such organisms have been found to be susceptible to these antiseptic agents. In several studies, guava showed significant antibacterial activity against Staphylococcus, Shigella, Salmonella, Bacillus, E. coli, Clostridium and Pseudomonas. Hence these agents may be useful in preventing episiotomy wound infections. Thereby, the use of broad spectrum antibiotics may not be necessary.

To date there are few literatures found on Guava leaf extract used as an antiseptic wash. Through this randomized controlled trial we would like to investigate if guava leaf extract as an external genital antiseptic wash is comparable to Povidone iodine in preventing wound infection among women who underwent vaginal delivery and had an episiorrhapy.

SIGNIFICANCE OF THE STUDY

The risk of developing infection is found to be increased among women who underwent episiotomy. To minimize such risk proper wound care must be observed. One strategy is to cleanse the vulva and the external genital area with an antiseptic feminine wash as part of postpartum care. The available antiseptic feminine wash in the market is an iodine-based agent that may be efficacious but with potential adverse effects. This study was conducted to evaluate an alternative local option that has comparable efficacy with lesser adverse effect and cost. The alternative option we evaluated is the guava leaf extract feminine wash which has natural components hence with potentially less side effects and possibly less expensive than the marketed povidone-iodine anti-septic.

OBJECTIVES

General Objective:

To compare the efficacy and patients' satisfaction of commercially prepared guava extract with povidone iodine and as external genital antiseptic wash in women who underwent vaginal delivery and had episiorraphy in a Tertiary Hospital.

Specific Objectives:

1. To compare the following between povidone iodine and commercially prepared guava extract feminine wash
   a. wound infection rate
   b. patients' satisfaction
   c. adverse event rate

DEFINITION OF VARIABLES AND OPERATIONAL TERMS

Independent Variables

This refers to the intervention being evaluated in this study. This was encoded and entered as

1- Povidone iodione

2 – Commercially prepared guava extract feminine wash

Dependent Variables

This refers to the outcome of the trial

1. Wound infection

This is defined as the presence of one or more of the following signs and symptoms: swelling, redness, tenderness, abnormal discharge and wound dehiscence

This variable was entered and encoded as

1. absent
2. present

The rate was calculated as the number of participants with episiotomy site infection over the total number of participants per arm and will be reported in percent

2. Patient satisfaction

This variable was rated by the participant using 5 point scale adopted from the study by De la Cruz, C et. al; Efficacy of Povidone-Iodine Vaginal Suppository in the

Treatment of Bacterial Vaginosis: A Comparative Study with Standard Metronidazole Oral Regimen: A Preliminary Report. 2011 and was entered as:

1 – Very dissatisfied
2 – Dissatisfied
3 – Niether Dissatisfied or Satisfied
4 – Satisfied
5 – Very satisfied

3. Adverse events

This will be a secondary outcome and was recorded once any of the following occurs: Itchiness and Burning Sensation

1- absent
2 – present

The rate was calculated as the number of participants with adverse events over the total number of participants per arm and will be reported in percent
Further categorized as:

1- absent
2 – itchiness
3- burning sensation
4 – others

METHODOLOGY

Study Design

This is an open-labeled randomized clinical trial comparing the efficacy and patient's satisfaction on Povidone iodine and a commercially prepared guava extract as external genital antiseptic wash in women who underwent normal spontaneous delivery and episiorraphy in a Tertiary Hospital.

TARGET POPULATION and SETTING

The study was conducted among women with uncomplicated pregnancy who was admitted during the first stage of labor at a Tertiary Hospital

A. Inclusion Criteria- includes parturients who were admitted at the tertiary institution with the following characteristics:

a. 18 years to 35 years old
b. singleton pregnancy in cephalic presentation
c. cervical dilatation of 1 to 5 cm

B. Exclusion Criteria- excludes parturients who were admitted at the tertiary institution with the following characteristics:

a. known allergy to iodine based agents
b. dermatologic lesions that may be aggravated by povidone iodine
c. uncontrolled diabetes mellitus
d. Large for gestational age babies
e. Intake of antibiotics within 2 weeks from delivery
f. Known co-morbidities such as GDM, overt DM, SLE, psoriasis, atopic dermatitis and collagen disorders.
g. Cephalopelvic disproportion suspect
h. Premature rupture of membranes

C. Withdrawal Criteria- the participants withdrawn from the research study

a. Those patients whose pregnancy were terminated by emergency cesarean section
b. If the episiotomy wound had anal sphincter (3rd degree) and/or rectal (4th degree) extension

STUDY PROCEDURE

The participants eligible to participate in the study were asked to sign an informed consent at the Labor room during admission on the first stage of Labor. During the process of obtaining the informed consent a thorough explanation of the purpose of the study by the primary investigator was done. Once the informed consent was signed, randomization of the participants to their respective treatment groups was done using computer generated random numbers.

On admission those assigned to group A used 7.5 % povidone-iodine as feminine wash post-partum. For those assigned to group B they used a commercially prepared FDA approved guava extract feminine wash. All the participants, once they were brought back to the ward after delivery, were instructed to apply 2 to 3 drops of the feminine wash on to the palm of the hands and apply onto perineal area for 15 seconds twice a day for 6 weeks for perineal care.

With regards to the episiorrhapy, this was done by the second year resident on duty. This ensured that the technique for episiorrhapy were uniform among the participants. Episiorrhaphy was done by continuous closure of the vaginal mucosa and submucosa using absorbable chromic 2-0 or 3-0 suture. The vaginal mucosa was approximated in a continuous interlocking technique. A continuous technique of closure was used to close the fascia and muscles of the incised perineum. The continuous suture was carried upward as a subcuticular stitch to close the skin. The final knot was tied proximally to the hymenal ring.

The participants were asked to follow up at the OPD on weeks 1, 2, 4 and 6. During follow ups, assessment was done by another second year resident blinded to the treatment. The data included observation of the participants' perineum for the presence of swelling, redness, tenderness, abnormal discharge and integrity

of repair. The same resident assessed the patient's satisfaction to treatment using a 5-point scale on each follow up schedule. These data were collected using a standard data collection tool.

The participants were advised to observe for adverse events. These side effects include: occurrence of itchiness and burning sensation. If such adverse events occurred participants were instructed to follow up at once. They were then referred to the consultant in charge and appropriate intervention was given.

SAMPLE SIZE CALCULATION

The sample size computation used the formula of comparison of proportions from two independent variables. Sample size calculation was based on a proportion (P1) of 0.028 and a proportion (P2) of 0.068. These were the proportion based on the study of Manalastas et. al. where in surgical site infection rate was noted in 2.8 % of participants in the Povidone iodine wash group and 6.8% in the lactic acid group. The test of equality of proportions was carried out at the 0.05 level of significance. The sample size required based on the above data for this study is 248. This gives a probability of 80% of rejecting the null hypothesis of equal proportions if the alternative holds.

DATA ANALYSIS AND MANAGEMENT

The data was encoded and entered in Windows Excel. For data analysis Intercooled Stata version 9.1 was used. Univariate analysis such as mean and range was used to describe age, age of gestation, gravidity and parity of the subjects. Frequency distribution was used to describe the proportion of participants according to the degree of episiotomy extension, presence of wound infection, patients' satisfaction and presence of adverse events. For the comparison of povidone-iodine and commercially prepared guava extract femine wash with regards to wound infection rate, patient's satisfaction and adverse events rate, chi-square was used.

ETHICAL CONSIDERATION

An informed consent (please refer to appendix IA for details) was obtained from the eligible participants by the principal investigator upon admission at the delivery room suite during the first stage of labor. This provided them the information on the nature and purpose of the study, and the possible adverse complications that may arise from the study. The benefit gained by the participants in this trial was the provision of the guava feminine wash free of charge. However for the participants using poviode-iodine they were asked to purchase the feminine wash since it is part of our standard postpartum perineal care. Both of the commercially prepared feminine washed used in this study are FDA approved.

The participants were given assurance on the confidentiality of the results by protecting their identity through the use of number codes on the data collection tool. All information gathered in this study remained confidential. Only the principal investigator, the supervising investigator, and the Ethics Review Committee and the regulatory committees were granted direct access to the medical records of the subjects for purposes of verification with clinical trial procedures and data. The participants were given the prerogative to withdraw from the study without incurring penalty. All participants were informed regarding the outcome of the study.

The participants were given transportation allowance of 100 pesos to cover for their travel expenses during their follow up on 1st, 2nd, 4th and 6th week post partum. Expenses for commercially prepared feminine wash with guava extract and possible postpartum complication was shouldered by the primary investigator. If signs and symptoms of infection and adverse events as previously mentioned occurred, the participants were properly referred, thoroughly evaluated and managed accordingly. The participants were instructed to go the the Medical Center's Outpatient department or at the Emergency Room in case such events will occur. The participants were given the prerogative to withdraw from the study without incurring penalty. All participants were informed regarding the outcome of the study.

There were no pharmaceutical companies involved in the design, conduct of the study, analysis and interpretation of the data as well as in the review and writing process of the final manuscript.

RESULT

The study included 248 women with episiotomy. About 91.13% had a second degree extension while 8.57% had a first degree extension. The difference in the distribution of the participants according to the degree of episiotomy extension is not statistically significant between the guava and povidone iodine feminine wash group. (Table 1)

Table 1. Distribution of participants with episiotomy extension according to treatment group

Episiotomy extension	Commercially prepared with Guava extract n=122(%)	Povidone iodine n=126(%)	P-value
First degree	10 (45.45)	12 (54.55)	0.71
Second degree	112 (49.56)	114 (50.44)	

The mean age of the participant is 28 years old with a range of 17 to 39 years old. The mean age of gestation during admission was 38 weeks with the range of 37 to 41 weeks. The mean gravidity is two with range of one to six. For parity the mean was 1.9 with range of one to five. The difference in the baseline characteristic of the participants between two treatment arms were not statistically significant. (Table 2)

Table 2. Baseline characteristics of participants according to treatment

Baseline characteristics	Commercially prepared with Guava extract Mean (SD) N=122	Povidone iodine Mean (SD) n=126	P-value
Age (in years)	27.97 (5.14)	28.16 (5.32)	0.78
Age of gestation	38.27 (1.07)	38.14 (1.07)	0.35
Gravidity	1.94 (1.05)	2.09 (1.02)	0.29
Parity	1.81 (0.94)	2.02 (1.06)	0.10

The primary outcome of this study is the presence of episiotomy wound infection. Majority of the participants did not have any signs of wound infection. The overall rate of wound infection in this study is 1.61%. With regards to the comparison of episiotomy wound infection rate between guava and povidone iodine feminine wash, no statistically significant difference was noted. In terms of side effects this was only observed in one of the participant in the guava feminine wash group as compared to povidone iodine feminine wash group (Table 3). The adverse effect reported by the participant using guava extract feminine wash and povidone iodine is vulvar itchiness.

Table 3. Distribution of participants with outcome according to treatment group

Outcome	Commercially prepared with Guava extract N=122 n(%)	Povidone iodine N=126 n(%)	P-value
Wound infection	1 (0.81)	3(2.38)	0.33
Side effects	1(0.81)	4(3.17)	0.19

The patient satisfaction on the feminine wash used was also evaluated in this study. The mean patient satisfaction score for the guava feminine wash is 4.4 (SD 0.70) which was found to be higher than the mean score of those in the povidone iodine feminine wash which is 3.6 (SD 0.71). This difference is statistically significant (< 0.001). There was significantly greater proportion of participants who were very satisfied with the use of guava feminine wash (49.2%) as compared to povidone iodine wash (14.3%). For the details on the Patient's satisfaction score please refer to Table 4.

Table 4. Distribution of patient's satisfaction score according to treatment group

Patient's satisfaction	Commercially prepared with Guava extract N=122 n(%)	Povidone iodine N=126 n(%)	P-value
1- Very dissatisfied	0	1(2.38)	<0.001
2- Dissatisfied	2 (1.6)	4(3.17)	<0.001
3- Niether Dissatisfied or			<0.001
Satisfied	9 (7.4)	52 (41.3)	
4- Satisfied	51 (41.8)	51(40.5)	<0.001
5-Very satisfied	60 (49.2)	18 (14.3)	<0.001

DISCUSSION

Episiotomy is a surgical incision of the perineum performed to widen the vaginal opening to facilitate the delivery of an infant. It was recommended as a way of facilitating completion of the second stage of labor and reducing the maternal and neonatal trauma and morbidity associated with delivery. It was mentioned in the literature that one of the most common complication of episiotomy is wound infection which can be treated by administering systemic antibiotics. But to prevent infection routine use of antibiotics is not recommended. Hence, the use of an antiseptic solution days after the delivery until wound is completely healed can be advised as a preventive measure. Avoiding inappropriate use of antibiotics can lessen adverse drug reactions, disruption of normal flora and resistance to such antibiotics. This is the reason why we used local antiseptic wash from natural plant source to cleanse the perineum and compared it according to efficacy and acceptability in preventing episiotomy wound infection. At the same time such local antiseptic wash may provide cost benefit.

In our study the episiotomy wound infection rate with the use of external genital antiseptic wash among women who underwent episiotomy is 1.6 %. This is lower than the wound infection rate (7.7%) reported in the local study done by Manalastas et.al. wherein povidone iodine, chlorhexidine digluconate and lactic acid external genital wash were compared.

With regards to the comparison of the incidence of wound infection between commercially prepared guava

extract feminine wash and antiseptic povidone iodine external genital wash, among women who underwent of episiotomy in our study, these agents were found to be comparable. Povidone-iodine's ability to prevent infection is due to the antibacterial properties associated with the germicidal ingredient iodine. For Psidium guajava, an ethno-medicinal plant, it's exhibited antimicrobial activities can be due to the tannins and flavonoid. These two natural components of guava were suggested to have antibacterial and antifungal activities aside from their anti-inflammatory, and astringent properties. Hence, the guava leaf extract can be as effective as the commercially prepared antiseptics to combat pathogenic microorganisms and be a potential alternative natural agent to treat infected wounds. It was also stated that as part of primary health care and because of the increasing cost of drugs, the use of locally available medicinal plants has been advocated by the Department of Health (Cuevas, 2007).

Wound infection is a frequent occurrence in the postoperative period, which could delay the wound healing process and lead to complications culminating in chronic non- healing wounds.[18] Hence, to facilitate and enhance healing of postoperative incision wounds, agents with anti-bacterial and anti-inflammatory properties could be used. Psidium guajava has such properties. Another advantage that the quava leaf extract has it's anti-oxidant activity. All of the abovementioned properties will not only reduce the occurrence of infection but promote wound healing as well. This can be supported by the results of the study of Fernandes et.al., wherein guava leaf extract was found to heal the wound faster than the corticosteroid. Thereby demonstrating the effectiveness of guava leaf extract in hastening wound healing. However, in our study we did not evaluate the effect of guava on healing of the episiotomy wound.

Aside from efficacy in preventing wound infection, the commercially prepared guava leaf extract was shown to have an added benefit which is better patient acceptance. Although, both of the commercially prepared feminine wash used in this study were comparable in terms of safety and occurrence of adverse effects, our participants had greater satisfaction with guava extract external genital wash. This may be supported by the finding that only one participant experienced an adverse reaction in the form of vulvar itchiness in the guava anti-septic wash as compared to four of those in the povidone iodine feminine wash group. This can be due to the anti-allergenic property of Psidium guajava. Based on the report of Han et.al., the extract suppresses the IgE-mediated allergic response transduced by Fc RI- signaling in mast cells. Hence, due to this property guava leaf extract will have lesser chance to cause irritation over the area to which it is applied.

With regards to cost, the available 100ml 7.5% povidone iodine feminine wash has a retail price of 175 pesos, while the 150ml guava feminine wash only costs 80 pesos. Hence, the natural feminine wash product is commercially available at greater amount but with lesser cost. This will entail longer use of the product and possibly will be enough to cover for the time it is used from delivery until the episiotomy wound is healed. Therefore, the guava external genital wash is considered to be cost beneficial than the povidone iodine anti-septic wash.

However, this study was only conducted among uncomplicated cases of vaginal delivery. We excluded those at high risk for wound healing complications such as those with third and fourth degree episiotomy wound extension and medical complications like diabetes mellitus. Therefore, the results cannot be generalized to all women who had perineal trauma or lacerations associated with childbirth.

But the potential benefit of guava leaf feminine wash for those at low risk for infections such as uncomplicated pregnancies and deliveries has been established in this study. Aside from that the advantage of it's use is not only limited to it's antibacterial properties but to it's anti-inflammatory effect, low potential for irritation, and cost-wise it is affordable. Hence, it is worthwhile to recommend the use of guava leaf extract genital wash among these group of women.

CONCLUSION

This randomized clinical trial showed that the efficacy in preventing episiotomy wound infection as well as the rate of adverse reaction with the use of commercially prepared guava leaf extract is comparable with povidone iodine as an external genital antiseptic. Although, there is a tendency to have lower adverse reaction with the commercially prepared guava extract feminine wash. With regards to patients' satisfaction, this was found to favor the use of commercially prepared guava leaf extract external genital wash. Furthermore, it is less expensive than the povidone iodine feminine wash.

Hence, the commercially prepared guava leaf extract feminine wash may translate to better compliance due to better patient's acceptance as its use is associated with lesser adverse effects, low wound infection rate, as well as lower cost.

RECOMMENDATION

Further studies can be made on the evaluation of wound infection rate, patient's satisfaction and adverse events using aqueous crude extract of guava leaf on different degrees of episiotomy. We also recommend

inclusion of those with co-morbidities that are associated with poor wound healing such as gestational diabetes mellitus. This will establish incidence if those at high risk for wound infection would benefit from the potential effect of commercially prepared feminine wash with guava extract in preventing infection and adverse event. ■

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