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Selected Topics: Wound Care

PILOT STUDY TO EVALUATE THE ADJUNCT USE OF A POVIDONE-IODINE TOPICAL ANTISEPTIC IN PATIENTS WITH SOFT TISSUE ABSCESSES

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□ **Abstract—Background: Povidone-iodine (PVP-I) antiseptic solutions have been shown to be effective against methicillin-resistant *Staphylococcal aureus*, a common cause of superficial skin abscesses. Objectives: Our objective was to study the feasibility of using PVP-I as a treatment adjunct in patients with superficial skin abscesses and determine if it confers any benefit over incision and drainage (I&D) alone. Methods: This was a randomized controlled pilot study of adult patients with an uncomplicated skin abscess. Patients were randomized to PVP-I or standard treatment. All patients had I&D and abscess packing. Patients randomized to PVP-I were instructed on daily application of the agent to hands, wound, and surrounding skin with dressing changes. Subjects returned at 48–72 h and 7–10 days and followed-up by phone at 30 days. The primary outcome was clinical cure 7–10 days after I&D. The secondary outcomes were rate of development of new skin lesions and spread in household contacts within 30 days. Results: Clinical cure occurred in 91.3% of patients in the standard group vs. 88.2% of patients in the PVP-I group (difference, 3.1%; 95% confidence interval [CI] −10.7 to 16.8; $p = 0.53$). There was a significantly higher adverse event rate in the group who received PVP-I (59.6%) vs. standard care (26.5%) (difference 33.1%, 95% CI 13.2–50.2; $p < 0.001$). Conclusions: There was no difference in clinical cure rates among patients using PVP-I (88.2%) vs. standard care (91.3%) after I&D. There were no major adverse events, but the addition of PVP-I was commonly associated with local skin irritation. Published by Elsevier Inc.**

□ **Keywords—abscess; wound care; povidone; iodine; antiseptic**

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INTRODUCTION

Background

Community-acquired methicillin resistant *Staphylococcus aureus* (CA-MRSA) is the most common cause of skin abscesses (1). Skin and soft tissue infections (SSTI) have been on the rise with nearly a threefold increase in SSTI cases diagnosed in the emergency department (ED) from 1993 to 2005 (1–3).

Importance

Standard treatment for abscesses is incision and drainage (I&D) (4). A number of studies have previously investigated healing rates of abscesses with antibiotics, packing,

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and irrigation with saline after I&D (5–9). With the concern for increasing antibiotic resistance, use of nonantibiotic agents for SSTIs may be promising. The potential benefit of povidone-iodine topical antiseptic (PVP-I) is that it has bactericidal properties but may have fewer drug interactions or induced antibiotic resistance.

Provodine® (Microdermis; Princeton, NJ) is a PVP-I with demonstrated ability to kill a multitude of microscopic pathogens, including CA-MRSA. To our knowledge, no previous study has evaluated the efficacy of PVP-I in the treatment of skin abscesses. It is unclear if the addition of a topical antiseptic solution like PVP-I may improve healing rates in patients with superficial abscesses in the ED.

Objectives

The purpose of this study was to determine if the daily application of PVP-I in the wound cavity and as an antiseptic handwash would confer any benefit over I&D alone in superficial skin abscesses. This pilot study was performed to determine feasibility and guide sample size calculations to power future studies. The primary outcome was clinical cure 7–10 days after I&D. The secondary outcomes were rate of development of new skin lesions and spread of infection in household contacts within 30 days.

METHODS

Study Design and Setting

This study was a prospective randomized controlled trial of adult patients presenting with uncomplicated skin abscesses requiring I&D (registered under identifier NCT02600871 at http://www.clinicaltrials.gov). The study was approved by the institutional review board at the participating institution.

A convenience sample of patients was identified and enrolled by the available research personnel. A sample size calculation was not performed as the treatment effect and healing rates using PVP-I were not known. This study was designed to determine feasibility for a future study and define baseline rates of clinical cure using a PVP-I. This study was conducted at a county-based academic ED with 70,000 visits/year and two affiliated urgent care facilities (40,000 visits/year and 50,000 visits/year).

Selection of Participants

Patients aged 18 years and older presenting to the ED or urgent care center with an uncomplicated skin abscess requiring I&D between December 2015 and April 2017 were enrolled into the study. Patients were excluded if they were unable to provide informed consent, were homeless or incarcerated, had active intravenous drug use or iodine allergy, had an abscess on the breast or face, or required inpatient admission to the hospital or surgical drainage. Patients were randomized to PVP-I or standard care.

Methods of Measurement

Research personnel enrolled patients 7 days a week, 24 h a day as available. Standard data collection was completed on all enrolled patients, including contact information, age, gender, ethnicity, location of abscess(es), length and width of palpable fluctuance and induration, length and width of cellulitis, presence or absence of fever, and previous medical history. Measurements of the abscess and surrounding cellulitis were measured using a ruler provided in each enrollment packet.

A block randomization method was used, with allocation to each study group achieved by opening sequentially numbered, sealed envelopes. Patients assigned to the treatment group received instructions on how to use and apply PVP-I as part of wound care, and patients assigned to the standard-of-care group were advised about wound care and handwashing with soap and water.

Interventions

All abscesses were incised, drained, and irrigated according to standard practice. Abscess cavity wound cultures were obtained and sent for bacterial cultures and antibiotic susceptibility testing.

Patients randomized to PVP-I had the abscess cavity and surrounding skin gently painted with the PVP-I solution. The contents of one foil packet of PVP-I were applied with a cotton-tipped applicator to the walls and floor of the abscess cavity. The contents of a second foil packet were applied to the surrounding skin within 5 cm around the incision using a second cotton-tipped applicator. The abscess cavity was gently packed with $^{1}/_{4}$ -inch plain gauze strips and the wound was covered with 4” × 4” gauze and secured with tape.

Patients randomized to standard care did not apply PVP-I. They had the abscess cavity packed with $^{1}/_{4}$ -inch plain gauze strips and the wound was covered with 4” × 4” gauze and secured with tape.

Patients in both groups were instructed to leave the wound packing in place and change the outer dressing once a day until they returned at 48–72 h for their first wound recheck. Providers were discouraged from prescribing routine antibiotics unless the clinician felt it was clinically indicated.

Wound Rechecks and Follow-Up Visits

Subjects returned within 48–72 h for a wound recheck and data collection. The follow-up visit was based on convenience for the patient's schedule within that designated time period. Patients randomized to the intervention arm had the internal packing removed, PVP-I reapplied to the walls of the abscess cavity and surrounding skin, and instructed on wound care and hand hygiene. Patients were taught to first apply one foil packet of PVP-I to their hands and fingers as a protective barrier. They were then instructed to apply the contents of a second foil packet to the walls and floor of the abscess cavity using a cotton-tipped applicator. Patients were then instructed to apply a third foil packet to the skin surrounding the abscess within a 5-cm diameter of the wound using a separate cotton-tipped applicator. Patients were instructed to gently wash their hands and cover the wound with a 4" × 4" gauze dressing.

Patients randomized to standard care had the internal packing removed and the wound covered with a 4" × 4" gauze dressing. They were instructed on daily wound care with dry dressing changes and handwashing with soap and water after each dressing change.

Patients in both arms were instructed not to pack the wound cavity at home after it was removed in the ED. All patients were instructed to irrigate the abscess cavity at home by removing the outer dressing and soaking in water once a day for at least 2–3 min. They were instructed to gently massage the skin around the abscess in the bath or shower to allow further drainage of the wound.

Patients randomized to PVP-I were instructed to apply the topical agent with the three foil packets once daily until they were seen for their second wound recheck (7–10 days) or until wound cavity had closed. Patients also were instructed to keep a resealable storage bag of used PVP-I packets to assess compliance at the follow-up visits.

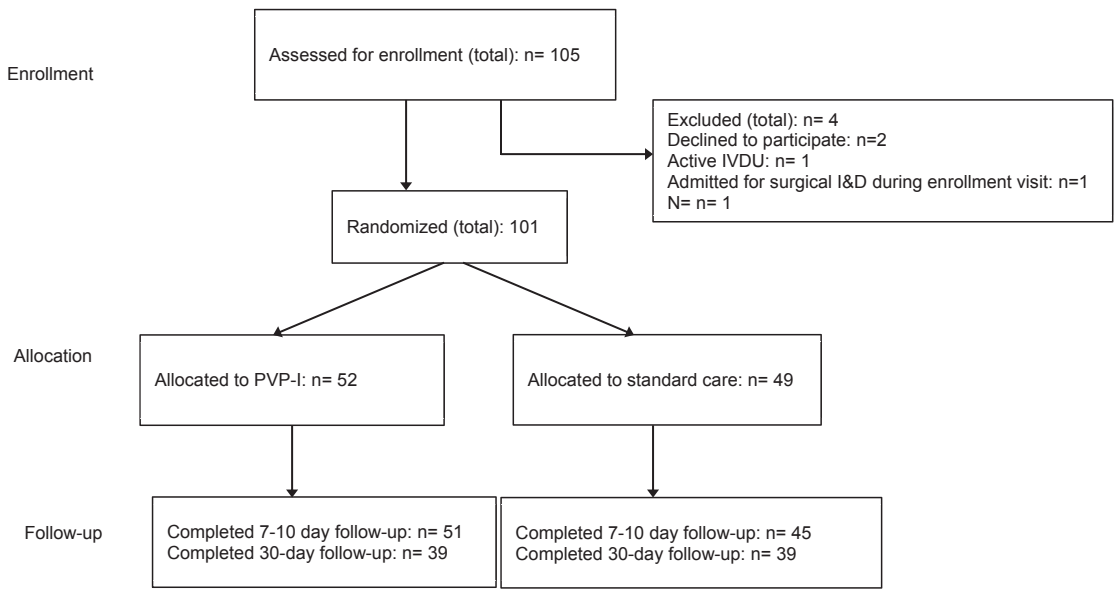
All patients were instructed to cover the abscess cavity with a 4" × 4" dry dressing after wound cleaning and to change the dressing as often as needed if soiled. Study subjects were asked to return at 7–10 days after enrollment for a second wound check. Research personnel contacted patients by telephone for data collection at 30 days after enrollment.

Data Collection

Study investigators recorded presence or absence of clinical cure, need for additional intervention, compliance with the PVP-I, and side effects at both return visits. Compliance with wound care was assessed by measuring the number of opened foil packets and by patient report. Patients were considered compliant with PVP-I if they used and returned all of the packets given to them. Data were collected regarding the presence of new lesions and spread in household contacts during each follow-up visit and at the 30-day follow-up phone call.

Outcome Measures

Our primary outcome was clinical cure 7–10 days after I&D. Clinical cure was defined as improvement in the



IVDU, intravenous drug use.

Figure 1. Study enrollment distribution. IVDU = intravenous drug use; PVP-I = povidone-iodine; I&D = incision and drainage.

Table 1. Baseline Characteristics of the Participants

Characteristics	Standard Care (%), n = 49	PVP-I (%), n = 52	*p* Value
Gender			
Female	19 (38.8)	19 (36.5)	0.98
Male	30 (61.2)	33 (63.5)	
Age (mean ± SD)	41.76 ± 13.57	41.33 ± 14.82	0.88
Race			
African American	3 (6.5)	9 (18.4)	0.25
Other	8 (17.4)	7 (14.3)	
Caucasian	35 (76.1)	33 (67.3)	
Ethnicity			
Hispanic	36 (75.0)	38 (73.1)	1.00
Non-Hispanic	12 (25.0)	14 (26.9)	
Culture results			
MRSA	17 (34.7)	17 (32.7)	
MSSA	10 (20.4)	6 (11.5)	0.34
Coag neg steph	13 (26.5)	9 (17.3)	0.38
Streptococcus	6 (12.2)	5 (9.6)	0.92
No growth	3 (6.1)	4 (7.7)	1.00
other	14 (28.6)	11 (21.2)	0.53
Abscess location			
Trunk	12 (24.5)	14 (26.9)	0.96
Extremity	14 (28.6)	16 (30.8)	0.83
Groin buttock	11 (22.4)	13 (25.0)	0.95
Axilla	6 (12.2)	5 (9.6)	0.76
Head and neck	5 (10.2)	5 (9.6)	1.00
Cellulitis, cm			
Median (IQR)	5 (0–9)	6 (1.25–12.5)	0.22
Range	0–28	0–25	
Abscess size, cm^2			
Median (IQR)	12 (5–33)	18 (8–27)	0.33
Range	2–126.5	1–180	

PVP-I = povidone-iodine; SD = standard deviation; MRSA = methicillin-resistant *Staphylococcus aureus*; MSSA = methicillin-sensitive *Staphylococcus aureus*; IQR = interquartile range.

initial wound with respect to a decrease in measured size, erythema, and purulent discharge without need for further clinical intervention. Wound management at the follow-up visits was left up to the discretion of the treating provider, but additional interventions for patients not clinically improving or worsening were considered a lack of clinical cure. The secondary outcomes were rate of development of new skin lesions and spread of infection in household contacts within 30 days after I&D. A new lesion was defined as a new abscess, pustule, carbuncle, or furuncle at least 5 cm away from the initial wound. Lesions within 5 cm of the initial wound were considered failures of the initial abscess treatment and were considered a lack of clinical cure.

Study data were collected and managed using REDCap electronic data capture tools hosted by the participating institution.

Statistical Analysis

Categorical outcomes were summarized with frequencies and percentages, and continuously distributed outcomes were summarized with the sample size, mean, and standard deviation. The significance of variation in proportions with treatment (PVP-I, Control) was assessed with the exact distribution of the binomial Fisher's exact test and variation in the mean with treatment was assessed with *t*-tests. All statistical testing was two-sided with a significance level of 5%. SAS Version 9.4 (SAS Institute Inc., Cary, NC) and StatXact Version 11 for Windows (Cytel, Cambridge, MA) were used throughout.

RESULTS

We assessed 105 patients for enrollment in the study (Figure 1). Baseline characteristics and antibiotic use at enrollment were similar among the 52 subjects randomized to PVP-I and the 49 randomized to standard care (Tables 1 and 2). All patients were treated as originally allocated.

For the 7–10-day follow-up, 97 of 101 (96%) subjects were available for follow-up. There was no difference in clinical cure rate between patients receiving PVP-I (45/51; 88.2%) and standard treatment (42/46; 91.3%). The addition of PVP-I had little effect on clinical cure rates in either the subgroup who received antibiotics or those

Table 2. Antibiotic Use at Time of Enrollment

Characteristics	Standard Care, n = 49	PVP-I, n = 52	*p*-Value
On oral antibiotics at enrollment	6 (12.2)	4 (7.7)	0.53
i.v. antibiotics only in the ED	1 (2)	0 (0)	0.36
i.v. antibiotics in the ED and prescribed oral antibiotics	0 (0)	3 (5.8)	0.10
Prescribed oral antibiotics only	24 (49)	21 (40.4)	0.39
On oral antibiotics at enrollment and prescribed new antibiotics	5 (10.2)	6 (11.5)	0.84
On oral antibiotics at enrollment, i.v. antibiotics in ED, and prescribed new antibiotics	0 (0)	2 (3.8)	0.22
No antibiotics	13 (26.5)	16 (30.8)	0.64

PVP-I = povidone-iodine; i.v. = intravenous; ED = emergency department.

Table 3. Clinical Cure at 7–10 Days After I&D

Clinical Cure at 7–10 Days	Standard Care (%)	PVP-I (%)	Difference (95% CI)	*p* Value
All subjects	(n = 46)*	(n = 51)		
Clinical cure	42 (91.3%)	45 (88.2%)	3.1 (−10.7 to 16.8)	0.53
No antibiotic use	(n = 12)	(n = 16)		
Clinical cure	11 (91.7%)	14 (87.5%)	4.2 (−29.0 to 31.0)	0.78
Antibiotic use†	(n = 34)‡	(n = 35)		
Clinical cure	31 (91.2%)	31 (88.6%)	2.6 (−14.2 to 20.0)	0.53
Additional intervention for treatment failures				
Admitted to hospital	1	1		
Discharged				
i.v. antibiotics in ED	1	0		
Re-I&D initial lesion	0	2		
I&D new lesion	1	1		
Add/change oral antibiotic	2	2		

I&D = incision and drainage; PVP-I = povidone-iodine; Difference = standard of care minus PVP-I; CI = confidence interval; i.v. = intravenous; ED = emergency department.
* n = 46, 45 patients followed up at 7–10 days, but 1 patient had lack of clinical cure at 48–72 h.
† Antibiotic use includes patients who were on antibiotics at time of enrollment, received i.v. antibiotics or were prescribed antibiotics at time of discharge.
‡ n = 34, 33 patients followed up at 7–10 days, but 1 patient had lack of clinical cure at 48–72 h.

who did not have antibiotics (Table 3). The rates of new lesion development and spread in household contacts were similar (Table 4).

There was a higher incidence of adverse events in the patients who received PVP-I (59.6%) than those who received standard treatment (26.5%). None of these adverse events were considered severe (Table 5). The most common reported adverse events of patients treated with PVP-I was burning upon application and local pruritis. Most people who reported burning stated it lasted 30–60 s, but several reported significant burning pain that lasted hours.

At 7–10 days, 91/96 (91%) patients self-reported compliance with wound care with 41/45 (91.1%) in the standard care group and 50/51 (98%) in the PVP-I group reporting compliance. However, measured compliance was significantly less. In the PVP-I group, at 7–10 days, 32/51 (62.7%) returned their used foil packets as instructed.

DISCUSSION

To our knowledge, we report the first study of PVP-I as an adjunct for skin abscesses in adults treated with I&D in an ED and urgent care setting. Our clinical cure rate is comparable with prior abscess studies (5–10).

The limited existing evidence for PVP-I as an antiseptic handwash and topical irrigation in wound care has largely been focused on prevention of surgical site infections. PVP-I solutions have been shown to be effective against MRSA, methicillin-sensitive *Staphylococcus aureus*, and vancomycin-resistant enterococcus (11,12). Previous surgical studies have demonstrated efficacy of PVP-I solutions for pocket irrigation to reduce bacterial contamination (13–17). Additionally, there is evidence that irrigation with PVP-I is effective in decreasing infections in spinal and intra-abdominal surgeries without negatively influencing wound healing or clinical outcome (18,19).

Despite some studies demonstrating a clinical benefit to PVP-I, a Cochrane review found the evidence base for intracavitary lavage with antiseptic solution was generally of low certainty and downgraded for risk of bias and possible publication bias (20). Additionally, almost all of the evidence to guide decisions about hand antiseptic technique explored were of low- or very low-quality evidence (21). Given the previous concern for publication bias in the literature, negative studies are important contributions to the body of data evaluating PVP-I in wound management.

The results of this preliminary study may help guide future studies. First, given the growing body of evidence

Table 4. Development of New Lesions and Infection in Household Contacts within 30 Days

	Standard Care (%) (n = 41)	PVP-I (%) (n = 39)	Difference (95% CI)	*p* Value
Development of new lesions	8 (19.5%)*	8 (20.5%)	−1.0 (−19.4 to 18.0)	0.96
Infection of household contacts	4 (9.7%)	2 (5.1%)	4.6 (−9.1 to 19.1)	0.53

PVP-I = povidone-iodine; Difference = standard of care minus PVP-I; CI = confidence interval.
* n = 41, 39 patients were available at 30-day follow-up and 2 patients lost to follow-up at 30 days developed a new lesion within 7–10 days.

Table 5. Adverse Events (AE)

Characteristics	Standard Care, n = 49	PVP-I, n = 52	Difference (95% CI)	*p*-Value
Total reporting AE	13 (26.5%)	31 (59.6%)	33.1 (13.2, 50.2)	<0.001
Burning/pain	1 (2%)	18 (34.6%)	32.6 (19 to 47.3)	<0.001
Pruritis	2 (4.1%)	7 (13.5%)	9.4 (2.4 to 22.5)	0.11
Tape irritation	7 (14.3%)	7 (13.5%)	−0.82 (−15.9 to 13.8)	0.95
Skin irritation around wound	0	4 (7.7%)	7.7 (0.03 to 19.2)	0.05
Skin discoloration	0	1 (1.9%)	1.9 (−5.8 to 10.6)	0.51
Diarrhea	0	1 (1.9%)	1.9 (−5.8 to 10.6)	0.51
Cough	0	1 (1.9%)	1.9 (−5.8 to 10.6)	0.51
Chills	0	1 (1.9%)	1.9 (-5.8 to 10.6)	0.51
Dizziness	1 (2%)	0	−2.0 (−11.2 to 5.3)	0.36
Decreased appetite	1 (2%)	0	−2.0 (−11.2 to 5.3)	0.36
Rash	2 (4.1%)	0	−4.1 (−14.3 to 3.1)	0.16

PVP-I = povidone-iodine; CI = confidence interval; Difference = PVP-I minus standard of care.

that trimethoprim-sulfamethoxazole improves clinical cure rates in skin abscesses after I&D, future studies should consider standardizing antibiotic use and anticipate even higher cure rates in both treatment arms. Second, a post hoc analysis can be performed to estimate sample size calculations for a definitive study based on our preliminary findings. Given the small differences found between groups, we estimate a sample size of over 2000 patients would be needed for future studies to determine if PVP-I confers a statistically significant difference in cure rates compared with I&D alone. Finally, although further studies could attempt to validate our findings, larger trials may be inadvisable given the significantly increased rate of adverse events.

We found no serious adverse events in either group; however, many patients did complain of a temporary burning sensation, local irritation, and itching when PVP-I was applied to the wound cavity. Future studies would need to weigh the risks of frequent skin irritation and adverse events against a potential small incremental benefit over the high clinical cure rate observed after I&D alone.

Limitations

This was a preliminary study to determine baseline clinical cure rates using PVP-I and assess potential for a future larger study. The sample size was not powered or designed to detect small differences between the two groups.

The study did not control for antibiotic use. It is important to note that providers in this study were discouraged from prescribing antibiotics for patients with uncomplicated cutaneous abscesses unless there was significant cellulitis, recurrence, or other clinical factors that warranted it. This practice was supported by prior evidence when the study was designed (5,6). However, a study published in March 2016, in the middle of our trial, showed a small but clinically significant improvement in outcomes in patients with cutaneous abscesses who received antibiotics (9). We acknowledged this and allowed providers to use their clinical judgment in light of this new evidence. However, antibiotic use was evenly distributed between the PVP-I and standard care groups. PVP-I did not improve clinical cure rates in either the subgroup who was prescribed antibiotics or the subgroup who was not prescribed antibiotics.

Although patients in the PVP-I group were instructed to bring back their empty packets of PVP-I, patient compliance with other aspects of wound care, including daily dressing changes and handwashing, was self-reported. The measured compliance rate with PVP-I was significantly less than the reported compliance rate. Although some patients forgot to save the used foil packets and accidentally threw them out prior to the wound recheck, other patients stopped using the agent secondary to skin irritation. Decreased compliance with PVP-I may have limited its measured impact on clinical cure.

Finally, as it was required that the patients and researchers apply the topical agent in the group who received the intervention, the study was not blinded.

CONCLUSION

In summary, there was no improvement in clinical cure rates in patients using PVP-I after I&D. There were no major adverse events, but the addition of PVP-I was commonly associated with local skin irritation. Further powered studies would be needed to determine if a treatment benefit exists, but need to be weighed against the increased adverse event rate with PVP-I and high clinical cure rate with I&D alone.

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ARTICLE SUMMARY

1. Why is this topic important?

Povidone-iodine (PVP-I) solutions have bactericidal activity and have been used as an antiseptic handwash and irrigation in surgical wounds to decrease infections. To our knowledge, this is the first study to evaluate the use of topical PVP-I in skin abscesses to determine if a clinical benefit exists.

2. What does this study attempt to show?

This study evaluated the feasibility of using PVP-I as an adjunct for treatment in patients with superficial skin abscesses. This preliminary study provides findings that would help future researchers anticipate sample size, estimated treatment effects, and adverse reactions that may guide future wound care studies.

3. What are the key findings?

The use of PVP-I did not improve clinical cure rates in patients with superficial skin abscesses. There were significantly more adverse events in the group who used PVP-I.

4. How is patient care impacted?

Although topical PVP-I has bactericidal properties that may affect wound healing, these preliminary findings suggest that any potential treatment effect is small and it may actually cause harm. Further powered studies would be needed to determine if a treatment benefit exists, but this needs to be weighed against the increased adverse event rate with PVP-I and high clinical cure rate with incision and drainage alone.