



ORIGINAL RESEARCH PAPER

General Surgery

A RANDOMIZED CONTROL TRIAL TO ASSESS THE EFFICACY OF POVIDONE IODINE IRRIGATION IN REDUCING SURGICAL SITE INFECTION AFTER ELECTIVE ABDOMINAL SURGERIES

KEY WORDS: Surgical Site Infection, Povidone Iodine

Dr. Kartthick Subburaj*

Post Graduate Resident, Department Of General Surgery, Meenakshi Medical College Hospital & Research Institute, Enathur, Kanchipuram -631552, Tamilnadu, India. *Corresponding Author

Dr. P. S. Saravanan

Professor And Head, Department Of General Surgery, Meenakshi Medical College Hospital & Research Institute, Enathur, Kanchipuram -631552, Tamilnadu, India.

ABSTRACT

Surgical site infection (SSI) is a common cause of morbidity and prolonged hospital stay among patients undergoing surgical operations. Povidone-iodine is a chemical complex of (poly-vinyl-pyro-lidone) and elemental iodine. Free iodine is gradually released from this complex and is chemically toxic to microorganisms. This anti-septic provides broad-spectrum bactericidal activity at a low cost and with minimal toxicity. This Study is a randomised controlled trial that involved 100 patients who have undergone elective abdominal surgeries in Department of Surgical gastroenterology in Meenakshi Medical College Hospital. It was done to assess the efficacy of Povidone iodine irrigation in reducing the surgical site infection after elective abdominal surgeries (Irrigating the subcutaneous layer before Skin closure). The statistical evidence suggested the effectiveness of topical povidone-iodine in decreasing the (SSI) surgical site infections over normal saline irrigation. The CDC, WHO, and International Consensus Meeting Clinical Practice Guidelines for the use of a diluted povidone-iodine wash for wound irrigation during surgical procedures. An intraoperative soak of 0.3% povidone-iodine solution for up to 3 minutes is an efficacious and cost-effective tool for reduction of SSI.

INTRODUCTION

Surgical site infection is quite infrequent but a serious complication of surgery. Surgical site infection (SSI) is a common cause of morbidity and prolonged hospital stay among patients undergoing surgical operations. It decreases the health associated quality of life and increases the risk of mortality. It's a leading risk factor for re-admission during the first 30 days after hospital discharge. It increases in the overall hospital expenses significantly. Despite the increased usage of prophylactic antibiotics however, surgical site infection still happens and is quite detrimental to patients ¹. Many different wound irrigation solutions, including soaps, antibiotics and antiseptics, are utilised to lower the chance of surgical site infection.

Povidone-iodine, a complex made of poly-vinyl-pyro-lidone and elemental iodine. Free iodine is gradually released from this complex and is chemically toxic to microorganisms. This anti-septic shows broad-spectrum bactericidal effect at a lower cost and with reduced toxicity. In antimicrobial testing, ipovidone-iodine killed methicillin-resistant Staphylococcus aureus (MRSA) and other antibiotic-resistant ones in 20-30s of exposure. ² Studies have also proved in vitro polymicrobial efficacy of povidone-iodine against Staphylococcus epidermidis, Haemophilus influenzae, Pseudomonas aeruginosa, Burkholderia cepacia, and Escherichia coli.

MATERIALS AND METHODS

- **Study Design:** Randomised controlled trial
- **Study Setting:** The study was conducted in Department of General Surgery with the support of Department of Surgical Gastroenterology, Meenakshi Medical College Hospital and Research Centre (MMCHRI), Enathur, Kanchipuram after obtaining IEC Approval.
- **Study Period:** 18 months
- **Sample Size:** 100

After obtaining informed consent, Patients were randomised in to two groups

Study population:

- Group 1: Povidone iodine group (n=50)
- Group 2: Normal saline irrigation (n=50)

Inclusion Criteria

- All open abdominal elective Abdominal surgeries

Exclusion Criteria

- Patients who are known to harbour atypical mycobacteria
- Patients who are terminally ill.
- Patients previously diagnosed with Diabetes, Systemic Hypertension, Ischemic Heart Diseases, Chronic Kidney Disease, Tuberculosis, AIDS, Hepatitis and other immunocompromised conditions.

Procedure

Povidone Iodine Irrigation Steps

- Mix 30 mL of sterile 10% povidone-iodine (from sterile pack) with 1 L of 0.9% saline in a sterile splash basin
- Prior to fascial closure, pour in the diluted 0.3% povidone-iodine solution described above into the wound
- Leave to soak for up to 3 min
- Suction away any remaining povidone-iodine solution.

Normal Saline Irrigation Steps

- Freshly opened 1 L of 0.9% normal saline bag was opened and used to irrigate the wound just before closure.
- Patients who had a previous History of Surgery (Open/Lap or Elective / Emergency)

RESULTS

Mean age in group 1 is 39.68 and the mean age in group 2 is 41.48 and the two values do not differ statistically with respect to age and the association is not statistically significant (P=0.32). In our study there were equal number of males and females in both the groups. 25 males and females were present in each group. Among 100 patients, 27% had incisional hernia, 23% had umbilical hernia. Least diagnosed cases were Left direct inguinal hernia (2%). In our study group 19% had infection and 81% did not have infection. In our study povidone irrigation group had less infection rate compared to normal saline group and the association is statistically significant (P<0.0001). In our study 1% infection occurred in the age group of less than 30 years. 13% of infection occurred in age group in 31-40 years.

Table 1: Age wise distribution of study participants

Age in years	Frequency	Percentage	Range	Mean \pm S.D
≤ 30	18	18	22-55years	40.58 \pm 9.02
31-40	32	32		
41-50	39	39		
51-60	11	11		
Total	100	100		

Table 2: Infection status among two groups

Group	Infection		Chi square	P value	
	Yes	No		227.49	0.0001
1	2	48	50		
2	17	33			
Total	19	81			

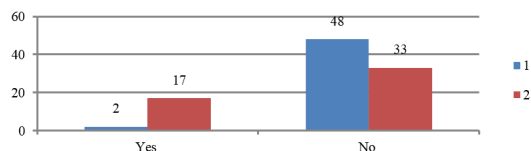


Figure 1: Infection status among two groups

Table 3: Association between age and infection

Duration	Yes	No	Total	CHI square	P value
30 min	7	0	8	213.60	0.0001
40 min	11	38	49		
45 min	1	4	5		
50 min	5	27	32		
55 min	0	2	2		
60 min	1	3	4		
Total	19	81	100		

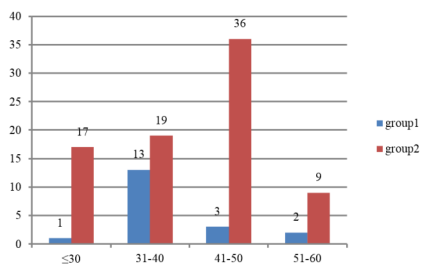


Figure 2: Association between age and infection

Table 4: Association between sex and infection

Sex	Yes	No	X2	P
Female	8	42	212.6	0.0001
Male	11	39		
Total	19	81		

Table 5: Association between duration of surgery and infection

Age in years	Yes	No	Total	Chi square	P value
≤ 30	1	17	18	15.08	0.02
31-40	13	19	32		
41-50	3	36	39		
51-60	2	9	11		
Total	19	81	100		

The association between duration of surgery and infection is statistically significant.

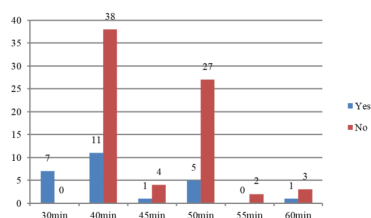


Figure 3: Association between duration of surgery and infection

DISCUSSION

This Study is a randomised controlled trial that involved 100 patients who have undergone elective abdominal surgeries in Department of Surgical gastroenterology in Meenakshi Medical College Hospital. After getting informed consent from the patients they were randomised in to two groups each group contained 50 participants after following the steps of allocation concealment.

Group 1 received Povidone iodine irrigation
Group 2 received normal saline irrigation

Diagnosis

Among 100 patients, 27% had incisional hernia, 23% had umbilical hernia. Least diagnosed cases were Left direct inguinal hernia (2%).

Procedures

In our study 55% have undergone meshplasty, 18% have undergone right meshplasty, 12% have undergone open appendicectomy and 8% have undergone bilateral meshplasty.

Status of infection among study groups

In our study group 19% had infection and 81% did not have infection. In our study povidone irrigation group had less infection rate compared to normal saline group and the association is statistically significant (P<0.0001). In our study 1% infection occurred in the age group of less than 30 years. 13% of infection occurred in age group in 31-40 years.

Association between demographic factors and infection

The age and infection is statistically associated. (p<0.02) The association between sex and infection is statistically significant. (<0.0001). 8% of infection occurred in females and 11% of infection occurred in males. About 100% of infection occurred in obese individuals. The association between duration of surgery and infection is statistically significant.

Demographic factors compared with present study and other studies

Studies	Mean age
Present study	39.68- intervention group
	41.48- control group
Johnson et al ³	68.3-intervention group
	67.2-control group
Sinderlar et al ⁴	51.5 intervention group
	51.7-control group
Parker et al ⁵	69-intervention group
	68-control group
Angelini et al ⁶	61-intervention group
	58-control group
Cheng et al ⁷	64-intervention group
	61-control group

Comparison of infection rates

Studies	Infection rate	P value
Present study	2% in povidone group	0.0001
	17% in control group	
Cheng et.al ⁸	0% in povidone group	0.01
	3.4% in control group	
Chang et.al ⁹	0% in povidone group	0.03
	4.83% in control group	

CONCLUSION

There was limited evidence for the intra-operative use of topical antiseptics before closure of wound. This evidence suggested the effectiveness of topical povidone-iodine in decreasing the (SSI) surgical site infections over Normal saline irrigation. The CDC, WHO, and International Consensus Meeting Clinical Practice Guideline's for the use of a diluted povidone-iodine wash for wound irrigation

during surgical procedures. An intraoperative soak of 0.3% povidone-iodine solution for up to 3 minutes is an efficacious and cost-effective tool for reduction of SSI.

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