

COMPARATIVE STUDY OF INTRAPERITONEAL INSTILLATION OF NORMAL 1.25% POVIDONE-IODINE AND SUPER-OXIDIZED SOLUTION IN PATIENTS WITH CONTAMINATED AND DIRTY ABDOMINAL SURGERIES

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Abstract

Background: Antimicrobial agents are sometimes used locally at the site of incision in major or minor surgical procedures in order to prevent SSI especially in contaminated and dirty surgeries. Present study was aimed to compare intraperitoneal instillation of normal 1.25% povidone-iodine and super-oxidized solution in patients with contaminated and dirty abdominal surgeries. **Material and Methods:** Present study was single-center, Prospective Randomized comparative study, conducted patients of age 18- 70 years, either gender, undergoing contaminated and dirty abdominal surgeries. 60 Patients were distributed as Group 1 – SO GROUPS (200 ml of Super-Oxidized Solution 99.97% w/v ‘OXUM’ was instilled) & group 2 – PI GROUPS (200 ml of 1.25% of Povidone-Iodine was instilled). **Results:** In present study, most common site of perforation was Prepyloric area of stomach (35%), followed by Ileal (18.34%) and caecal (8.34%) perforation. In PI group 16.67% patients had Surgical Site Infection (SSI) and in SO group 20% had Surgical Site Infection (SSI), difference was not statistically significant (p – 0.74). In PI group 6.67% patients had Fascial Dehiscence and in SO group 13.33% had Fascial Dehiscence, difference was not statistically significant (p – 0.39). Mean Post-operative stay in PI group was 16.3 ± 7.82 days & in SO group was 16.77 ± 8.37 days. Mean Days of Complete Wound Healing (SR) in PI group was 13.13 ± 3.60 days & in SO group was 14.13 ± 5.58 days. In PI group 10% patients had drain culture organism present and in SO group 6.67% had drain culture organism present, however this finding was not statistically significant. 20% of the patients in the PI group and 16.67% of patients in the SO group showed positive intraoperative cultures. **Conclusion:** Super oxidized solution is as effective 1.25% povidone-iodine solution for intra operative instillation after peritoneal lavage following laparotomy in contaminated and dirty abdominal surgeries.

INTRODUCTION

Surgical Site Infection (SSI) is defined as an infection occurred within 30 days of the operation without implant and involved only skin or subcutaneous tissue (superficial infection) or deep soft tissue e.g., Fascial or muscle layers (deep infection). SSI is the most common hospital acquired infection after surgery.^[1] Severe intra-abdominal sepsis arising from perforated peptic ulcer, typhoid ulcer, appendicitis

and other causes like abdominal trauma, stab abdominal injury, bites and burns, there is a high rate of surgical site infection (SSI) in spite of the use of potent antibiotics.^[2,3] Surgeons are able to reduce systemic infection, but SSI remains a challenge where incidence still may be as high as 60-70%.^[2]

Antimicrobial agents are sometimes used locally at the site of incision in major or minor surgical procedures in order to prevent SSI especially in contaminated and dirty surgeries. Peritoneal lavage

with Normal Saline is the mainstay of decreasing the contamination after class 3 and 4 surgeries. Although saline irrigation can succeed in removing debris, foreign material and blood clots, which often contain bacteria, from a surgical wound, it does not suffice to eliminate bacterial contamination.^[4] For this purpose, various antiseptic solutions like, Povidone iodine, Chlorhexidine gluconate, kanamycin, Super-oxidized solution have been instilled directly into wounds or used as irrigation solutions.^[5,6,7] Present study was aimed to compare intraperitoneal instillation of normal 1.25% povidone-iodine and super-oxidized solution in patients with contaminated and dirty abdominal surgeries.

MATERIAL AND METHODS

Present study was single-center, Prospective Randomized comparative study, conducted in department of General Surgery, Medical College Baroda and Sir Sayajirao General Hospital Vadodara, India. Study duration was of 18 months (June 2019 to November 2020). Prior approval for study was obtained from the Scientific and Ethical Review Committee of Medical College and Sir Sayajirao General Hospital, Baroda, between June 2019 and November 2020 with letter no IECHR-PGR /31-19 dated 12/06/2019.

Inclusion Criteria

- Patients of age 18- 70 years, either gender, undergoing contaminated and dirty abdominal surgeries, willing to participate in present study

Exclusion Criteria

- Renal disease (S. Creatinine more than 1.5 mg/dl), Hepatic disease (S. Bilirubin more than 2 mg/dl), Diabetic mellitus, HIV, Redo-surgery.

Study was explained to patients in local language & written consent was taken for participation & study. Details of patients were collected including history and clinical examination on case record proforma attached herewith. Routine preoperative investigations were carried out. During emergency laparotomy, after opening of abdominal cavity pus or fluid from peritoneal cavity was sent for culture. After definitive procedure in all patients peritoneal cavity was washed 2L normal saline than it was sucked out. One or two drain was placed as per individual choice at these drains were kept blocked for two hours further management during laparotomy was done as per allocated groups.

Methods of Randomization – 60 Patients were distributed in two groups by closed envelope technique,

- Group 1 – SO GROUPS (200 ml of Super-Oxidized Solution 99.97% w/v ‘OXUM’ was instilled)
- Group 2 – PI GROUPS (200 ml of 1.25% of Povidone-Iodine was instilled)

Wound was closed with sutures using nonabsorbable monofilament sutures (zero or one number). Post-operatively, the culture was taken on 3rd and 5th POD through the drain and was sent in a sterile container to the Microbiology Department.

In post-operative course the antibiotics were given in all the patients for 7 days (according to the weight) i.e., Inj. Ceftriaxone (50 mg/kg/dose), Inj. Gentamycin (2.5 mg/kg/dose), Inj. Metronidazole (7.5 mg/kg/dose). If SSI occurs antibiotics were changed according to its culture and sensitivity. The drain output was noted daily and also its character (serous/purulent). Drains were removed when output < 50 ml and serous.

Day of drain removal was noted. If two drains were present then day of removal of both drains was noted separately. TLC, DLC and serum electrolytes were done as routinely. Day of recovery of bowel sound was noted and observed by hearing 3 to 4 bowel sounds per minute by stethoscope just right to the umbilicus. In the post-operative period, fever if present and its duration were recorded.

Patients were followed for any complications such as superficial wound infection and burst abdomen. When bowel sound returns to normal, feeding was started, days of starting feeding and hospital stay was recorded. The day of wound healing was noted. The data was recorded as per the proforma. The results were then compiled, analyzed and statistically evaluated.

Statistical analysis was carried out using tabular and diagrammatic presentation. Chi-square test and t test was applied to find out association between various variables of PI group and SO group and to calculate p value, and a p value < 0.05 was considered significant.

RESULTS

In present study, 60 patients were divided as 30 patients in the Super-oxidized solutions (SO) group and 30 patients in Povidone-iodine (PI) group. Mean age in PI group is 36.53 years & in SO group is 42.37 years, difference was not statistically significant. Male: female ratio found to be 7:1 In PI group 90% were male patients while 10% were female patients. In SO group 83.33% were male patients while 16.67% were female patients.

Table 1: General characteristics

	PI groups (n=30)	SO groups (n=30)	P value
Age in years			0.60
≤ 40	19	17	
>40	11	13	
Mean age	36.53	42.37	

Gender			0.45
Male	27(90%)	25(83.33%)	
Female	03(10%)	05(16.67%)	

The most common site of perforation was Prepyloric area of stomach (35%), followed by Ileal (18.34%) and caecal (8.34%) perforation. The least common site of perforation was colon.

Table 2: Site of Perforation

Site of Perforation	PI group(n=30)	SO group(n=30)
Prepyloric Gastric Perforation	09(30%)	12(40%)
Duodenal Perforation	03(10%)	01(3.33%)
Jejunal Perforation	02(6.67%)	03(10%)
Ileal Perforation	07(23.33%)	04(13.33%)
Appendicular Perforation	01(3.33%)	01(3.33%)
Caecal Perforation	04(13.33%)	01(3.33%)
Sigmoid Perforation	00	01(3.33%)
Rectal Perforation	02(6.67%)	02(6.67%)
Intestinal Obstruction	01(3.33%)	04(13.33%)
Rupture Liver Abscess	01(3.33%)	01(3.33%)

In PI group 3.33% patients were of contaminated surgery (class-3) while 96.67% patients were of dirty(class-4) surgery. In SO group 16.67% patients were of contaminated surgery(class-3) while 83.33% patients were of dirty(class-4) surgery. In PI group 16.67% patients had Surgical Site Infection (SSI) and in SO group 20% had Surgical Site Infection (SSI), difference was not statistically significant (p – 0.74).

In PI group 6.67% patients had Fascial Dehiscence and in SO group 13.33% had Fascial Dehiscence, difference was not statistically significant (p – 0.39). Mean Post-operative stay in PI group was 16.3 ± 7.82 days & in SO group was 16.77 ± 8.37 days. Mean Days of Complete Wound Healing (SR) in PI group was 13.13 ± 3.60 days & in SO group was 14.13 ± 5.58 days. In PI group 40% patients had paralytic ileus and in SO group 43.33% had paralytic ileus for more than 3 days, difference was not statistically significant (p – 0.79).

Table 3: Operative & post-operative characteristics

	PI group (n=30)	SO group (n=30)	P value
Class of Surgery			
Class 3	01 (3.33%)	05 (16.67%)	0.09
Class 4	29(96.67%)	25 (83.33%)	
Surgical Site Infection			
Present	05(16.67%)	06(20%)	0.74
Fascial Dehiscence			
Present	02(6.67%)	04(13.33%)	0.39
Mean Hospital stays (Days)	16.3 ± 7.82	16.77 ± 8.37	0.41
Mean Complete Wound Healing (Days)	13.13 ± 3.60	14.13 ± 5.58	0.21
Prolonged Paralytic ileus			
Present	12(40%)	13(43.33%)	0.79

Drain culture was sent on Day 3 and Day 5 post-operative day. In PI group 10% patients had drain culture organism present and in SO group 6.67% had drain culture organism present, however this finding was not statistically significant.

Table 4 Drain culture

Drain culture	PI group	SO group
Positive	03 (10%)	02(6.67%)
Negative	27(90%)	28(93.33)

In present study, 20% of the patients in the PI group and 16.67% of patients in the SO group showed positive intraoperative cultures.

Table 5: Intra-operative culture

Intra-operative Culture	PI group	SO group	P value
Positive	06(20%)	05(16.67%)	0.74
Negative	24(90%)	28(83.33%)	

DISCUSSION

This prospective, randomized study was done in General Surgery Department, SSG hospital to compare effectiveness of intraoperative instillation of 1.25% of povidone-iodine and super oxidized solution after peritoneal lavage following exploratory laparotomy in contaminated and dirty abdominal surgery.

Super-oxidized solutions are natural pH, hypotonic solution with a controlled number of reactive species and low chlorine content. Its antiseptic properties are due to its reactive species of oxygen and chlorine. Super-oxidized solutions having used as an irrigating solution in humans for various indications including the treatment of infectious skin defects or ulcers, mediastinal irrigation after open heart surgery, and treatment of peritonitis and intraperitoneal abscesses.^[2,8]

Povidone-iodine is a combination of iodine and a water-soluble polymer known as polyvinylpyrrolidone. The antimicrobial action of povidone-iodine occurs after iodine disassociates from the complex. Once in the free form, iodine rapidly penetrates microbial cell membranes and interacts with proteins, nucleotides, and fatty acids in the cytoplasm and cytoplasmic membrane. This interaction ultimately results in rapid cell death. Povidone-iodine solution, specifically, was used to irrigate battle wounds and was instilled into the abdominal cavity after hemostasis.^[9]

In Present study the most common site of perforation was the Prepyloric area of stomach (35%), followed by Ileum (18.34%) and caecum (8.34%). The least common site was colon. While study done by Garg P.*et al.*^[2] and Singal R.*et al.*,^[13] showed ileum as most common site of perforation. Deference of incidence of peptic ulcer disease on different geographic area could be the reason behind this disparity of data. These both studies were conducted in North India while present study conducted in Western India. Secondly our hospital is also catering patients from Madhya Pradesh and Rajasthan where smoking is more prevalent. This may be the reason behind higher incidence of stomach perforation in present study.

In PI group 05 patients had Surgical Site Infection (SSI) and in SO group 06 had Surgical Site Infection (SSI), difference was statistically not significant. Results of SSI in SO group of present study are comparable with Garg P.*et al.*,^[2] Results of SSI in PI group of present study are comparable with Baig *et al.*,^[11]

Unlike present study, study done by Singal R.*et al.*^[10] showed significantly higher occurrence of SSI in SO groups. Diabetes was exclusion criteria for present study while diabetic patients were included in study done by Singal R *et al.* This may be reason of significantly higher occurrence of SSI in that study compare to present study.

In PI group 02 patients had Fascial Dehiscence and in SO group 04 had Fascial Dehiscence, P value is 0.39 which is statically insignificant. This means that incidence of facial dehiscence is equal in both groups. Fascial dehiscence rate were significantly higher in Garg P.*et al.*^[2] and Singal R.*et al.*^[10] studies than present study. Etiology of Fascial dehiscence is multifactorial which includes patients factors and suturing technique including suture material there was no standardization of suturing technique in present as well as other to compare studies. This may be reason of higher rate of fascial dehiscence in present study.

In our study, 10% of the patients in the PI group and 6.67% of patients in the SO group showed positive drain cultures. Garg P.*et al.*^[2] 90% of the patients in the study group and 94% of patients in the control group showed positive cultures. The most common organism in both groups was Escherichia coli and Klebsiella in our study. Garg P.*et al.*^[2] in found the most common organisms to be E. coli. Singal R.*et al.*^[10] 85% of the patients in the group I and 84% of patients in the group II showed positive cultures in their study.

In present study, 20% of the patients in the PI group and 16.67% of patients in the SO group showed positive intraoperative cultures. Unlike present study intraoperative fluid culture was positive in 90% of patients in study done by Garg P.*et al.*^[2] and 84% of patients in study done by Singal R.*et al.*^[10]

In present study peptic perforation rate in significantly high and these patients have generally sterile biliary/ gastric peritonitis. These may be the reason for low detection of organism in present study. The most common organism in both study groups was Escherichia Coli in our study. like studies done by Garg P.*et al.*^[2] and Singal R.*et al.*^[10] in present Escherichia Coli was positive organism.

Limitations of study was an open label study, small sample size. A multi centric study with larger population belonging to various socioeconomic classes should be assessed to decide its effectiveness. Strength of the study was prospective study and this study is probably one of the first of its kind from India.

CONCLUSION

The present study concluded that super oxidized solution is as effective 1.25% povidone-iodine solution for intra operative instillation after peritoneal lavage following laparotomy in contaminated and dirty abdominal surgeries. Both solutions have equal outcome in prevention of surgical site infection (SSI), Prevention of Fascial Dehiscence, Wound healing time and prolonged paralytic ileus. Even though we have not compared cost of both these solutions as a part of this study,

but in market super oxidized solution is almost three time costlier than povidone-iodine solution. So, povidone iodine solution is cost effective camper to super oxidized solution.

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