

## Evaluation of the Efficacy of Sodium Fusidate and Ethanol Spray as Pre-Incision Skin Disinfectant for Abdominal Surgery

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### Abstract

**Background:** Surgical site infection is an overwhelming menace for the surgeon and it increases the morbidity and mortality of the patient, increases the hospital stay and cost of the treatment. One of the important factors among these is the preoperative preparation of the skin with antiseptic agent. For centuries there has been a search for an ideal agent for this purpose. **Aim:** This study was undertaken to evaluate the newly introduced Sodium fusidate and Ethanol spray as a preoperative skin preparation agent and compared it with other conventional methods. **Materials and Method:** This prospective study was conducted on 178 patients of general surgical wards during January 2020 to December 2020. It included all the clean and clean contaminated intra-abdominal surgical procedures conducted in planned surgery. **Result:** In the present study, we observed wound sepsis in 24 cases out of a total of 178 cases. Postoperative wound sepsis rates were higher in clean contaminated wounds (16.52%) as compared to clean wounds (7.9%). Maximum infection rate was present in Savlon and Spirit group (14.28%), while it was least in Fusidic acid spray group (5.88%). The most common organism isolated from infected wound was *Staphylococcus aureus* (41.67%), followed by *E. coli* (20.83%) and *Streptococci* (16.67%). **Conclusion:** Sodium fusidate and Ethanol spray is an effective skin preparation agent as concluded by our study in clean and clean contaminated elective abdominal procedures.

**Keywords:** Surgical Site Infections (SSIs), sodium Fusidate and ethanol spray, conventional methods, abdominal procedures.

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### Introduction

Surgical site infection (SSI) and post-operative wound sepsis is a serious problem and it continues to be a significant problem for surgeons in the modern era. Their spectrum of effect on individual's health ranges from slightest of inconvenience to major deleterious health effects and even death. The burden of high rates of surgical wound infection in terms of economics is also tremendous [1]. The financial drain that these infections place on the resource constrained hospitals in the form of prolonged hospitalization along with increased duration, dosage of medication, dressings and more intensive nursing care are like the proverb 'Last Straw Broke The Camel's Back'. For almost a century, there has been a continuing search for an antiseptic agent capable of sterilizing skin prior to surgical operation. But it is not possible to sterilize the skin; skin antiseptic aims to reduce the number of viable resident flora on or in the skin and to destroy pathogenic organism that may be on the skin as transients. By definition preoperative skin preparation is a safe, fast acting, broad spectrum, antimicrobial containing preparation that significantly reduces the number of microorganisms on intact skin. Several antiseptic agents are available for preoperative preparation of the skin at the incision site. These include Iodophores (e.g., Povidone iodine), alcohol containing products, mercurochrome, Cetrimide and chlorhexidine Gluconate [2]. It is beneficial to use the combination that contain two different antiseptics with two different mechanism of killing action to have an additive antiseptic effect and kill microorganism more effectively, that is critical [3-6]. Recently a newer Microbicidal agent Sodium Fusidate spray 2% with 60% ethanol has been introduced. This exerts antibacterial activity by

inhibition of protein synthesis by inhibiting the translocation enzyme by interfering with the binding of amino acyl transfer ribonucleic acid to ribosomes. This is produced by the fungus *Fusidium coccineum*. Fusidic acid possesses a steroid structure and is chemically related to cephalosporin P. It inhibits bacterial replication and does not kill bacteria and hence termed 'bacteriostatic'. Fusidic acid has spectrum of activity against *Staphylococci*, mainly *Staphylococcus aureus* and *Staphylococcus epidermidis* with remarkably high activity against both penicillin and methicillin resistant strains. Clostridium is also highly susceptible but less potent against *Streptococci*, *Enterococci* and *Corynebacterium*. It is active against *Neisseria*, *Bacteroides fragilis* and it has some activity against strains of *Mycobacterium leprae* [7-9]. The objective of the present is to evaluate the Sodium Fusidate and Ethanol spray as a pre-incision skin disinfectant in various clean and clean contaminated elective abdominal surgeries.

### Material and Methods

This prospective study was conducted at department of general surgery at government medical college, Bettiah. The study was approved by the institutional research and ethical committee. An informed and written consent was taken from all the subjects prior to commencement of the study. The study was conducted over a period of one year from January 2020 to December 2020. The study sample consisted of 178 patients from general surgical ward. It included all the clean and clean contaminated intra-abdominal surgical procedures conducted in planned surgery. The case recorded as per proforma were maintained for each patient from the time of admission to the time of discharge and updated on daily basis. All the patients included in this study undergoing surgical procedure were given broad spectrum antibiotics preoperatively and at least 3-6 days postoperatively or if sepsis occurs with eradication of infection. The study included intra-abdominal procedures with clean and clean contaminated wound in planned surgery. Patients were prepared by

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routine shaving of hair at operation site followed by soap and water scrub bath 1 day prior to surgery.

In operation theatre, the operation site was prepared by skin antiseptic and the following four groups are made:

Group I -- Fusidic acid + Ethanol spray

Group II --Povidine Iodine

Group III --Povidine Iodine + Metronidazole

Group IV -- Savlon + Spirit

Preoperative skin swabs were taken from the incision site before the application of the antiseptic agent and sent for the culture and

sensitivity testing. Then the skin disinfectant was applied and operative procedure carried out and dressings done with the same antiseptic. On the 2nd/3rd postoperative day the dressing were opened and wound assessed clinically for presence of any infection suggested by pain, erythema, tenderness, discharge etc., and dressings were done with same agent and wound followed up to 30 days. Again the swab was taken if any wound discharge or pus developed at the incision site and sent for the culture and sensitivity. The patient's Proforma was then used to evaluate the incidence of postoperative surgical site infection.

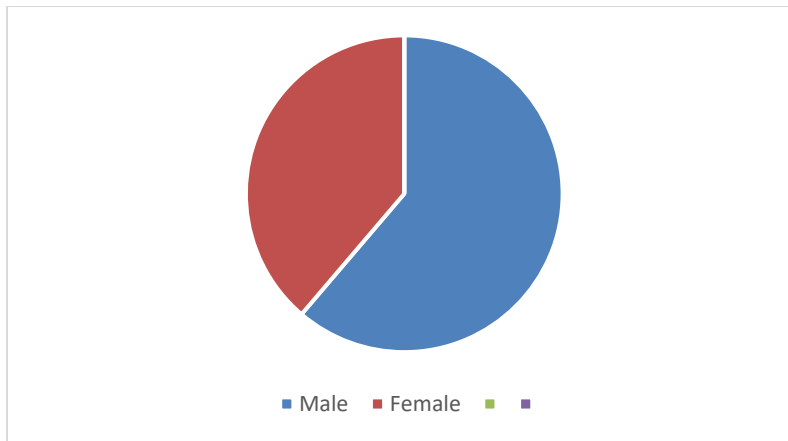
**Table 1: Surgical Wound Classification According to Degree of Contamination [10]**

| Wound Class        | Definiton   |
|--------------------|---|
| Clean              | An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital or infected urinary tract is not entered. Wounds are closed primarily and if necessary drained with closed drainage. Surgical wounds after blunt trauma should be included in this category if they meet the criteria. |
| Clean-contaminated | An operative wound in which the respiratory, alimentary, genital or urinary tract is entered under controlled conditions and without unusual contamination  |
| Contaminated       | Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique or gross spillage from the gastrointestinal tract and incisions in which acute, non-purulent inflammation is encountered are included in this category.  |
| Dirty              | Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation  |

**Results**

The present study covered a total of 178 patients who underwent surgical intervention for their disease processes on selective basis. In this study 109 patients (61.23%) of the total patients were male while females comprised 69 patients (38.76%). The median age of the

patient population was 45 years. Age group of 31 to 40 years comprised of maximum numbers of patients (23.59%) followed by the age group of 61 to 70 years comprising of 17.42%. Age group of >80 years comprised minimum number of patients (0.56%). (Graph - 1)



**Fig 1: Distribution of subjects according to gender**

The highest number of patients were operated for inguinal hernias 47(26.4%) and for urologic diseases 47(26.4%), renal, ureteric, vesicle calculus and cholecystectomies open 21(11.8%) and laparo-scopic 28(15.73%). In the present study, we observed wound sepsis in 24(13.48%) cases out of a total of 178 cases. The rate of postoperative wound sepsis observed in male and females was 12 (11.01%) and 12(17.39%) respectively. The highest rate of wound sepsis was noted in Urological procedures in 7 cases and Cholecyst-ectomies in

6 cases and appendectomies in 4 cases. Postoperative wound sepsis rates were higher in clean-contaminated (class II) wounds 19(16.52%) as compared to clean (Class I) wounds 5(7.9%). In this study majority of the preoperative cultures were sterile, in the positive cultures *Staphylococcus epidermis* was the most common isolate followed by *Staphylococcus aureus*. The most common organism isolated from infected wound was *Staphylococcus aureus* followed by *Escherichia coli* and *Streptococci* as shown in Table 2.

**Table 2: Organisms isolated from Preoperative incision site and Postoperative infected wound**

| S. No. | Preoperative incision site      |                  | Postoperative infected wound |                  |
|--------|---------------------------------|------------------|------------------------------|------------------|
|        | Organism                        | No. of cases (%) | Organism                     | No. of cases (%) |
| 1      | No growth                       | 124 (69.66%)     | No growth                    | 1 (4.16)         |
| 2      | <i>Staphylococcus epidermis</i> | 32 (17.97)       | -                            | -                |

|   |                              |           |                              |            |
|---|------------------------------|-----------|------------------------------|------------|
| 3 | <i>Staphylococcus aureus</i> | 17 (9.55) | <i>Staphylococcus aureus</i> | 10 (41.67) |
| 4 | <i>Bacillus species</i>      | 5 (2.81)  | -                            | -          |
| 5 | -                            | -         | <i>Escherichia coli</i>      | 5 (20.83)  |
| 6 | -                            | -         | <i>Streptococcus species</i> | 4 (16.67)  |
| 7 | -                            | -         | <i>Citrobacterfreundii</i>   | 2 (8.33)   |
| 8 | -                            | -         | <i>Klebsiellaoxytoca</i>     | 1 (4.16)   |
| 9 | -                            | -         | <i>Diphtheroids</i>          | 1 (4.16)   |

In this study overall rate of infection in clean abdominal surgeries was 7.9%. Maximum infection rate was present in savlon and spirit group (14.28%), while it was least in Fusidic acid spray group (5.88%). Overall wound sepsis rate in clean contaminated abdominal

surgeries was 16.52%. Maximum rate was present in savlon & spirit group (23.07%), minimum in P-I & metronidazole group (13.04%), while it was 16.28% in Fusidic acid spray group as shown in Table 3.

**Table 3: Wound sepsis rates with various agents in Clean and Clean contaminated surgeries**

| S. No. | Agent                             | Clean surgeries       |                        | Clean contaminated surgeries |                        |
|--------|-----------------------------------|-----------------------|------------------------|------------------------------|------------------------|
|        |                                   | No. of infected cases | Total no. of cases (%) | No. of infected cases        | Total no. of cases (%) |
| 1      | Sodium Fusidate and Ethanol Spray | 1                     | 17 (5.88)              | 7                            | 43 (16.28)             |
| 2      | Povidone-Iodine                   | 2                     | 24 (8.33)              | 6                            | 36 (16.66)             |
| 3      | P-I & Metronidazole               | 1                     | 15 (6.67)              | 3                            | 23 (13.04)             |
| 4      | Savlon & Spirit                   | 1                     | 7 (14.28)              | 3                            | 13 (23.07)             |
| 5      | Total                             | 5                     | 63 (7.9)               | 19                           | 115 (16.52)            |

In this study local reaction in the form of irritation, sneezing and coughing were present with the use of Fusidic acid spray in 3.33% of cases while one patient developed mild erythema in P-I & metronidazole group. None of the patient developed any systemic adverse effect.

#### Discussion

In this study male constituted 68.23% and females comprised the remaining 38.76% of the study population. This distribution of the patient population favouring males can probably be attributed to two reasons; sex ratio of the population favors males and attendants were more readily agreeable for surgical intervention for male patients in this mainly tribal belt. During the period of this study, a wide range of abdominal surgical procedures were performed on 178 patients who were included in this study. The most commonly performed surgery was inguinal hernioplasty (26.4%) and urologic procedures (26.4%). Postoperative follow up of the patients in this study showed that 13.48% developed postoperative surgical site infection. This overall sepsis rate of the present study is very high as compared to those reported by Byrne [11] (4.1%), Cruse and Ford [10] (4.8%), Mead [12] (2.8%) and Olson [13] (4.2%). The difference is statistically highly significant ( $P < 0.001$ ) and can be partially explained on the following reasons:

Poor nutritional status of the patient included in this study compared to the western studies.

Lack of facilities in the resource strapped government hospitals compared to western health care system.

Tendency of late discharge of patients from hospitals to provide adequate postoperative care and rest to patients who were mostly labourers and residents of rural interiors with minimal access to health care facilities.

Poor socio-economic status and the lack of health insurance coverage for the masses, limit the use of disposable and the latest technology, which carries a prohibitive price tag with it.

On studying the rate of postoperative wound sepsis across the age groups, our findings are essentially similar to the other international studies [12, 13]. On evaluating the distribution of postoperative wound sepsis across the wound class, clean- contaminated wounds were associated with a higher rate of wound sepsis (16.52%) as compared to clean wounds (7.9%). The rates were significantly higher as compared to other international studies [12-14]. In the clean abdominal surgeries minimal wound sepsis rate was present in the in whom surgical site was prepared with Fusidic acid spray (5.88%). This may be explained due to the fact that Fusidic acid has high activity against *Staph. Aureus* [7] which is the most common isolate in clean surgical wounds. Spray form of application also helps in

deeper and faster penetration of tissues and better efficacy. Maximum wound infection was seen when skin preparation was done only with Savlon and Spirit (14.28%). The infection rates in all groups when compared statistically was not significant ( $p=0.14$ ). In the clean contaminated abdominal surgical procedures least SSI rate (13.04%) was seen with Povidone-Iodine and metronidazole group. This can be explained by the fact that in clean contaminated surgeries the source of infection is mostly endogenous from the genito-urinary or alimentary tract as described by Hojer [15] and Cruse and Ford [16]. This combination covers the spectrum of activity against the causative pathogens. Maximum rate of infection was again seen with Savlon & Spirit group (23.07%) while the Fusidic acid spray group had the SSI rate of 16.28%. When analyzed statistically the difference was statistically non-significant among all groups ( $p=0.295$ ). In our study preoperative incision site culture swab showed sterile culture in 69.66% of cases, this may be explained due to soap and water scrub given to the patient and administration of preoperative antibiotics. In 17.97% of the cases *Staphylococcus epidermidis* was isolated while *Staphylococcus aureus* was isolated in 9.55% of cases. Postoperative culture from infected wound showed *Staphylococcus aureus* to be the most common pathogen isolated from 41.67% of cases followed by *E. coli* in 20.83% cases and Streptococci in 16.67% cases. Hojer [15] studied that in clean operations exogenous *Staph. aureus* is the usual cause of infection. Cruse and Ford [16] demonstrated that the most common isolate from class I wound was *Staph. aureus* followed by *Enterococci* and *Pseudomonas*. Class II wounds were most frequently infected by *Enterococci* then *Pseudomonas* and *Staph. aureus*. Haley *et al* [17] similarly showed that *Staphylococcus* was the most common pathogen, of these *CoNS* (*Coagulase negative Staphylococci*) accounted 18.9% of the isolates and *CoNS* were isolated in about 13.6%. Second most common offender was *Enterococcus* species at 13.6% of the isolates. Close on their heel were *E. coli* 8% and *Pseudomonas aeruginosa* 7.8%. Nichols [18], in his study showed that since 1984, *Staph. epidermidis* has been one of the three most frequently cultured wound infection pathogens, other two being *Staph. aureus* and *Pseudomonas*. Weiss *et al*. [19] described various pathogens isolated from postoperative SSI, *CoNS* were most common 25.6% followed by *Enterococcus* 11.5%, *Staph aureus* 8.7%, *E. coli* 6.3%, *Pseudomonas* 6%, *Klebsiella pneumoniae* 2.8%, *Citrobacter species* 2%. In this study adverse effect of the skin preparation agent for e.g. local reactions like itching, stinging, burning, erythema and systemic effects like absorption and toxicity to tissues and idiosyncrasies were also noted. None of the patient developed any systemic reactions, local reactions in the form of respiratory tract infection causing

sneezing and coughing due to spray were present in 3.33% of cases, while one patient developed mild erythema in the P-I & metronidazole group. No adverse reaction was observed in the Povidone Iodine group. Bogash [20] reported Betadine as an antiseptic on 5,900 patients over a 3 year period with only two idiosyncrasies. Ganeset *et al.* [21] used the Povidone-Iodine in the form of aerosol spray as an antiseptic for the preparation of skin & no evidence of local or systemic toxicity was observed. Jagadishan *et al.* [22] similarly showed that no skin reaction occurred in any patient.

#### Conclusion

Post-operative wound infection or surgical site infection is an overwhelming menace for the surgeon and it increases the morbidity and mortality of the patient, increases the cost of the treatment and a major burden to the economy of the developing countries like India. One of the important factors among these is the preoperative preparation of skin with antiseptic agent. For centuries there has been a search for an ideal agent for this purpose. We evaluated the newly introduced Sodium fusidate and Ethanol spray as a preoperative skin preparation agent and compared it with other conventional agents. Sodium Fusidate spray is effective against the common bacteria involved in postoperative wound sepsis like *Staphylococci*, *Streptococci*, *Enterococci* but it has no action against fungi, viruses and tubercle bacilli. The spray is non-toxic to tissues, hypoallergenic; no major adverse reaction has been noted. It is effective even in the presence of organic matter like blood, pus, serum etc., Combination of Fusidic acid with 60% ethanol provides better spectrum of activity.

Sodium Fusidate and Ethanol spray is an effective skin preparation agent as concluded by our study in clean and clean contaminated elective abdominal procedures, but it is also need to be further evaluated for class III and class IV i.e., contaminated and dirty surgical procedures and for surgeries done in emergency settings.

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