



E-ISSN: 2616-3470

P-ISSN: 2616-3462

© Surgery Science

www.surgeryscience.com

2021; 5(3): 90-93

Received: 15-05-2021

Accepted: 17-06-2021

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Clinical profile of patients on prophylactic parenteral antibiotics with combined parenteral and pre-operative intra-incisional antibiotic administration in reducing surgical site infection

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DOI: <https://doi.org/10.33545/surgery.2021.v5.i3b.743>

Abstract

A number of observations by nineteenth-century physicians and investigators were critical to our current understanding of the pathogenesis, prevention, and treatment of surgical infections. In 1846, Ignaz Semmelweis, a Magyar physician, took a post at the Allgemeines Krankenhaus in Vienna. He noticed that the mortality from puerperal ("childbed") fever was much higher in the teaching ward (1:11) than in the ward where patients were delivered by midwives (1:29). The patients were divided into two groups: Group A: Prophylaxis by systemic (intravenous) infiltration of the antibiotic. Group B: Prophylaxis by both systemic (intravenous) and intra-incisional infiltration of the antibiotic. The first patient was allocated to group A. The second patient to group B, the third one to group A and so on so forth till we achieved our desired number of subjects in both the groups. In Group 1, duration of surgery of >1hr were 3(5%), same as in group 2. The percentage duration of surgery >1 hr and <1 hr of in both the groups were Equal.(P=1.000). In Group 1, the mean preoperative TLC was 6838.00 ± 1700.00 and in Group 2 it was 7126.00 ± 1815.00 . The mean preoperative TLC was comparable between the two groups ($P>0.05$).

Keywords: Surgical site infection, clinical profile, antibiotic administration

Introduction

Surgical infection, particularly surgical site infection (SSI), has always been a major complication of surgery and trauma and has been documented for 4000–5000 years ^[1].

A number of observations by nineteenth-century physicians and investigators were critical to our current understanding of the pathogenesis, prevention, and treatment of surgical infections. In 1846, Ignaz Semmelweis, a Magyar physician, took a post at the Allgemeines Krankenhaus in Vienna. He noticed that the mortality from puerperal ("childbed") fever was much higher in the teaching ward (1:11) than in the ward where patients were delivered by midwives (1:29). He also made the interesting observation that woman who delivered before arrival on the teaching ward had a negligible mortality rate. He then hypothesized that puerperal fever was caused by putrid material transmitted from patients dying of this disease by carriage on the examining fingers of the medical students and physicians who frequently went from the autopsy room to the wards. The low mortality noted in the midwives ward, Semmelweis realized, was due to the fact that midwives did not participate in autopsies. Fired with the zeal of his revelation, he posted a notice on the door to the ward requiring all caregivers to rinse their hands thoroughly in chlorine water before entering the area ^[2]. This simple intervention reduced mortality from puerperal fever to 1.5%, surpassing the record of the midwives. In 1861, he published his classic work on childbed fever based on records from his practice ^[3].

Unfortunately, Semmelweis' ideas were not well accepted by the authorities of the time.

Louis Pasteur performed a body of work during the latter part of the nineteenth century that provided the underpinnings of modern microbiology, at the time known as *germ theory*. His work in humans followed experiments identifying infectious agents in silkworms. He was able to elucidate the principle that contagious diseases are caused by specific microbes and that these microbes are foreign to the infected organism. Using this principle, he developed techniques of sterilization critical to oenology and identified several bacteria responsible for human illnesses, including *Staphylococcus*, *Streptococcus*, and pneumococcus ^[4].

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Joseph Lister, the son of a wine merchant, was appointed professor of surgery at the Glasgow Royal Infirmary in 1859. In his early practice, he noted that more than 50% of his patients undergoing amputation died due to postoperative infection. After hearing of Pasteur's theory, Lister experimented with the use of a solution of carbolic acid, which he knew was being used to treat sewage. He first reported his findings to the British Medical Association in 1867 using dressings saturated with carbolic acid on 12 patients with compound fractures; 10 recovered without amputation, one survived with amputation, and one died of causes unrelated to the wound. In spite of initial resistance, his methods were quickly adopted throughout Europe [5, 6].

Methodology

Study design

The Present study was a prospective, descriptive, comparative, case series study

Study population

All patients admitted to department of general surgery.

Sample size and sampling technique

Dogra *et al.* in their study reported a proportional difference of surgical site infection between the two groups to be 15.5%. Based on this proportional difference we have calculated our sample size. Sample size calculation revealed that 57 patients per group will be required to detect a proportional difference of 15.5% between two groups, at an alpha of 0.05 with power of 80%.

P values < 0.05 were considered to indicate statistical significance. Hence, we took 60 patients per group.

Formula

This calculator uses the following formula for the sample size n: $n = (Z_{\alpha/2} + Z_{\beta})^2 * (p_1(1-p_1) + p_2(1-p_2)) / (p_1 - p_2)^2$, where $Z_{\alpha/2}$ is the critical value of the Normal distribution at $\alpha/2$ (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), Z_{β} is the critical value of the Normal distribution at β (e.g. for a power of 80%, β is 0.2 and the critical value is 0.84) and p_1 and p_2 are the expected sample proportions of the two groups.

Grouping

The patients were divided into two groups:

Group A: Prophylaxis by systemic (intravenous) infiltration of the antibiotic.

Group B: Prophylaxis by both systemic (intravenous) and intra-incisional infiltration of the antibiotic.

The first patient was allocated to group A. The second patient to group B, the third one to group A and so on so forth till we achieved our desired number of subjects in both the groups.

Inclusion criteria

1. Patients in age group of 25–65 years
2. Patients of either gender
3. Procedures that lasted for less than 2 hours clean and clean contaminated surgical procedures
4. Patient and/or his/her legally acceptable representative willing to provide their voluntary written informed consent for participation in the study.

Exclusion criteria

1. Patients with Diabetes mellitus, immunocompromised and

those on steroid therapy.

2. Patient and/or his/her legally acceptable representative not willing to provide their voluntary written informed consent for participation in the study.
3. Pregnant women.
4. Patients with bleeding disorders and on anticoagulant treatment.
5. Antibiotics related complications (known hypersensitivity)

Results

Table 1: Distribution according to age

Age	Group 1 (n=60)		Group 2 (n=60)	
	No.	%	No.	%
31-40 years	6	10.0	6	10.0
41-50 years	31	51.7	23	38.3
51-60 years	23	38.3	28	46.7
61-70 years	0	0.0	3	5.0
Total	60	100.0	60	100.0
Mean ± SD (years)	48.75 ± 6.11		50.43 ± 6.68	
‘t’ Value	-1.44, df=118			
P Value	0.155, NS			

Unpaired 't' test applied. P = 0.155, Not significant

The above table shows the distribution of patients of both the groups according to age.

In Group 1, majority of the patients 31 (51.7%) were in the age group 41-50 years, while 23 (38.3%) patients were in the age group 51-60 years.

In Group 2, majority of the patients 28 (46.7%) were in the age group 51-60 years, while 23 (38.3%) patients were in the age group 41-50 years.

The mean age in Group 1 was 48.75 \pm 6.11 years, while in Group 2 it was 50.43 \pm 6.68 years. The difference was found to be statistically not significant ($P > 0.05$), showing that the two groups were comparable with respect to age.

Table 2: Comparison of ASA score

ASA score	Group 1 (n=60)		Group 2 (n=60)	
	No.	%	No.	%
1	20	33.33	26	43.33
2	40	66.67	34	56.67
Total	60	100.0	60	100.0

Pearson Chi-Square = 1.269, DF = 1, P-Value = 0.260

Fisher's exact test: P-Value = 0.347916

The above table shows the comparison of % ASA score difference in both the groups.

Total %ASA score 1 in Group 1 was 33.33, in Group 2 was 43.33. Total %ASA score 2 in Group 1 was 66.67, in Group 2 was 56.67. The %ASA score 1 and 2 in both the groups were comparable ($P > 0.05$).

Table 3: Distribution according to gender

Gender	Group 1 (n=60)		Group 2 (n=60)	
	No.	%	No.	%
Female	13	21.7	16	26.7
Male	47	78.3	44	73.3
Total	60	100.0	60	100.0

$\chi^2 = 0.409$, df=1, P value = 0.522, Not significant

The above table shows the distribution of patients of both the groups according to gender.

In Group 1, 13 (21.7%) patients were females and 47 (78.3%)

patients were males.

In Group 2, 16 (26.7%) patients were females and 44 (73.3%) patients were males.

In both the groups, there was a male preponderance in relation to the females.

There was a proportional similarity in both the genders between the two groups ($P>0.05$).

Male SSI was higher in Group 1 in comparison to Female, but we could not find the statistical significance as there was only 1 patient in Group 2.

Table 4: Comparison of duration

Time taken	Group 1 (n=60)		Group 2 (n=60)	
	No.	%	No.	%
<1 hr	57	95	57	95
>1 hr	3	5	3	5
Total	60	100.0	60	100.0

Pearson Chi-Square = 0.000, DF = 1, P-Value = 1.000

The above table shows the comparison of duration of surgery in both the groups.

In Group 1, duration of surgery of >1hr were 3(5%), same as in group 2. The percentage duration of surgery >1 hr and <1 hr of in both the groups were Equal.($P=1.000$)

Table 5: Comparison of mean preoperative TLC

TLC	Group 1 (n=60) [Mean±SD]	Group 2 (n=60) [Mean±SD]
Mean ± SD (per cumm)	6838.00 ± 1700.00	7126.00 ± 1815.00
't' Value	-0.90, df=118	
P Value	0.372, NS	

Unpaired 't' test applied. $P = 0.372$, Not significant

The above table shows the comparison of mean preoperative TLC in both the groups.

In Group 1, the mean preoperative TLC was 6838.00 ± 1700.00 and in Group 2 it was 7126.00 ± 1815.00 .

The mean preoperative TLC was comparable between the two groups ($P>0.05$).

Table 6: Comparison of mean cost of treatment

Cost of Treatment (Rs.)	Group 1 (n=60) [Mean±SD]	Group 2 (n=60) [Mean±SD]
Mean ± SD (Rs.)	22950.00 ± 2500.00	22017.00 ± 1621.00
't' Value	2.43, df=118	
P Value	0.017*	

Unpaired 't' test applied. $P = 0.017$, Significant

The above table shows the comparison of mean cost of treatment in both the groups.

In Group 1, the mean cost of treatment was Rs. 22950.00 ± 2500.00 , while in Group 2 it was 22017.00 ± 1621.00 .

There was a significantly higher expense in Group 1 in comparison to Group 2 ($P<0.05$).

Discussion

In our study in Group 1, majority of the patients 31 (51.7%) were in the age group 41-50 years, while 23 (38.3%) patients were in the age group 51-60 years. In Group 2, majority of the patients 28 (46.7%) were in the age group 51-60 years, while 23 (38.3%) patients were in the age group 41-50 years. The mean age in Group 1 was 48.75 ± 6.11 years, while in Group 2 it was 50.43 ± 6.68 years. The difference was found to be statistically not significant ($P>0.05$), showing that the two groups were

comparable with respect to age. As Kaye *et al.* [7] revealed a significant relationship between age and risk of SSI ($P=0.006$). Risk of SSI increased by 1.1%/year between ages 17 and 65 years ($P=0.002$). At age ≥ 65 years, risk of SSI decreased by 1.2% for each additional year ($P=0.008$). Sangrasi *et al.* [8] considered increasing age as a significant risk factor for increased surgical site infection ($P<0.05$). Neumayer *et al.* [9] found that Patients aged over 40 had a statistically significantly increased risk of developing SSI compared with those under 40 years (OR 1.24, 95% CI 1.07 to 1.44)

In our study total %ASA score 1 in Group 1 was 33.33, in Group 2 was 66.67. Total %ASA score 2 in Group 2 was 43.33, in Group 2 was 56.67. The %ASA score 1 and 2 in both the groups were comparable ($P>0.05$). As Chattopadhyay *et al.* [10] found that there were significantly higher SSI and nosocomial infection rates among patients with combined American Society of Anesthesiologists (ASA) scores II and III than those with ASA score I in contaminated or dirty wounds ($\chi^2 = 5.06$ and $\chi^2 = 6.34$ respectively). Khan *et al.* [11] found that there were significantly higher surgical site infection rates among patients with combined ASA score II and III than those with ASA score I in clean contaminated ($p=0.0007$), and dirty cases ($p=0.0212$). Ridgeway *et al.* [12] conducted a study in which they found, In the single variable analysis of THRs, American Society of Anesthesiologists (ASA) score was significantly associated with the risk of SSI ($P<0.05$). similar results were found with hemiarthroplasty and revision THRs. Also the multivariate analysis identified ASA score as significant, independent risk factors for SSI.

In our study in Group 1, the mean BMI level was 21.38 ± 1.68 kg/m², while in Group 2 it was 21.18 ± 1.64 kg/m². The mean BMI in both the groups were comparable ($P>0.05$). As Waisbren *et al.* [13] found that in univariate analyses, one of the significant predictors of SSI was percent body fat (%BF) $p = 0.005$ and in multivariable analysis, obese patients by %BF had a 5-fold higher risk for SSI than nonobese patients (odds ratio = 5.3; 95% CI, 1.2-23.1; $p = 0.03$). Linear regression was used to show that there is a positive, nonlinear relationship between %BF and BMI. Tserenpuntsag *et al.* [14] found in a multivariable analysis that SSI following colon procedure was associated with body mass index greater than 30 (odds ratio [OR], 1.48 [95% confidence interval (CI), 1.21-1.80]) Lynch *et al.* [15] studied that multivariate analysis revealed BMI >30 to be independent risk factors for SSI following renal transplantation.

In our study we found that in Group 1, 13 (21.7%) patients were females and 47 (78.3%) patients were males. In Group 2, 16 (26.7%) patients were females and 44 (73.3%) patients were males. In both the groups, there was a male preponderance in relation to the females. There was a proportional similarity in both the genders between the two groups ($P>0.05$). Male SSI was higher in Group 1 in comparison Females, but we could not find the statistical significance as there was only 1 patient in Group 2. Similar result was found by Razavi *et al.* [16] in which majority were females and SSI is not correlated with sex ($p = 0.093$). In our study we found that in Group 1, duration of surgery of >1hr were 3(5%), same as in group 2. The percentage duration of surgery >1 hr and <1 hr of in both the groups were Equal. ($P=1.000$). As Dogra *et al.* found that Five out of 45 cases developed SSI, when the duration of surgery was between 1 and 2 hours whereas seven out of 75 cases developed SSI, when the duration of surgery was less than 1 hour. In a multivariate analysis by Cheng *et al.* identified duration as independent parameter correlating with the occurrence of SSI with operative duration more than 120 minutes (OR 4.289; CI

1.773-10.378; $P=0.001$). Also the results of multivariate analyses by Jeong *et al.* indicated that prolonged operation time ($P = 0.002$) is an independent risk factors for SSI after gastric surgery.

Conclusion

Total %ASA score 1 in Group 1 was 33.33, in Group 2 was 66.67. Total %ASA score 2 in Group 2 was 43.33, in Group 2 was 56.67. The %ASA score 1 and 2 in both the groups were comparable ($P>0.05$).

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