Role of minimal antibiotic therapy and routine long term post-operative therapy in elective surgery: an evaluation

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ABSTRACT

Background: Antibacterial drugs are powerful agents to prevent infections but excess use of antibiotics led to increase of resistance towards the antibiotics used and thus has risen the expense in medical support. Methods: A total of 250 patients were included in the study. The patients were divided randomly into 2 groups, each containing 125 patients. Group I patients received. Three dosage of injectable ceftriaxone 1 gram intravenous perioperatively, first dose twelve hour before surgery and second dose half hour before surgical incision and third dose twelve hours after surgery. Group II patients were given injectable ceftriaxone 1 gram intravenous perioperatively, first dose twelve hour before surgery and second dose half hour before surgical incision and then followed by injection (conventional dose) ceftriaxone 1 gram/day I.V twice daily for the first 5-7 days post-operatively. Using Southampton wound grading system. The wound was inspected on the 3rd, 5th and 7th postoperative day days post operatively.

Results: In group I, 15 (12%) cases had grade 2 SSI and in group II, 11 (8.8%) cases had grade 2 SSI. There was no statistical significance: p value is 0.83 and c² 0.048.

Conclusions: A minimal dose antibiotic prophylaxis is equally efficient and has added advantage of reducing the duration of hospital stay and cost of medicines for the patients. Hence minimal dose antibiotic is better than a routine long term antibiotics therapy.

Keywords: Antibiotic prophylaxis, Surgical site infection, Southampton wound grading, Cost effective

INTRODUCTION

Antibacterial drugs are powerful agents to prevent infections but excess use of antibiotics led to increase of resistance towards the antibiotics used and thus has risen the expense in medical support. Resistance towards antibiotics is a world-wide dangerous phenomenon so, World Health Organization (WHO) in the year 2012 had raised a clarion call for the reduction of the usage of antibiotics and thereby raising measure to avoid the resistance towards antibiotics. The antibiotic prophylaxis is given to maintain adequate tissue concentration in body, right drug is given in the right time and for right duration, this will reduce the antibiotic resistance. It will also prevent the complications arising due to infections in therapies. The usage of antibiotics conventionally, is usually for fixed period of time after a procedure which is done therapeutically to prevent infections. Use of most effective, least toxic and least expensive antibiotic for precise duration of time need to cure or prevent infection. Pathogen specific guidance in hospital policy is encourage that is based on local antibiogram, availability, cost, toxicity, efficacy, action and pharmacokinetics. A coagulum of blood and fibrin is impenetrable to the bacteria and its formation time is 48-72 hours. Thus if the wound could be kept free from micro-organism till the coagulum formation, there would not be any infection subsequently. With respect to the usage of antibiotics, vital for infection control are careful surgical skill, handling tissues properly, a clean environment, good preparation done preoperatively, friendly theatre setting,
and good care of wounds; which are now being given less priority.6

The study done by Chambers in 2001 recommended that first generation cephalosporin be the drugs of choice for the prophylactic use for general surgical interventions.7 Post-operative wound infection is defined as surgical site infection from 0-30 days after surgery or infection to surgical site till one year in cases of implants like mesh, vascular grafts and prosthesis.8 Various analysis which have been done on the antibiotic choice and timing of antibiotics have agreed that first dose of the antibiotic has to be given half- one hour before surgery, and also that a long acting antibiotic is preferred.9 Many randomized clinical trials have been conducted to observe the role of antimicrobial therapies to decrease incidence of wound infections post-surgery.10,11 Currently, in “clean-contaminated” surgeries such prophylaxis is recommended and in some clean operations.12 However, it was observed that as the antibiotics were not administered at the proper time, the therapeutic concentration levels could not be attained in the operative period.13

In public hospitals where the patient load is more, in relevance to the emergence of surgical site infections, the antibiotics have been used for prolonged period of at least 7-10 days. This has led to the increased expenditure and in the rise of new strains of organisms which are being resistant to the traditional antibiotics administered and thus leading to the usage of higher antibiotics. Infections of surgical sites depend on the type and number of the organisms. Wound sepsis is unlikely when there is a count of less than 10 organisms/ml. Growth of bacteria is influenced by the organism’s virulence, the patient’s age, patient’s glycaemic status, obesity, patient’s immune status, and co-existing diseases.14 In hospitals despite the adherence of all sterile precautions, the contamination during the surgical procedure can lead to increase in the bacterial load in the blood, can lead to the use of antibiotics for long period to cover the postoperative infection. The conventional use of antibiotics for prolonged period often results in high cost to the patient.

With the above background, the present study was conducted to study the effect of three doses prophylactic antibiotic an hour before a surgical intervention with the chosen standard antibiotic with regard to the conventional use of same antibiotic for 5 to 7 days.

**METHODS**

The present prospective observational study was conducted on 250 Patients attending outpatient department of surgery, Government Medical College and Hospital, Ambikapur, Surguja, Chhattisgarh, India between November 2020 to April 2021.

Patients having age 18 years and above, both male and female with no co-morbid conditions undergoing elective surgeries and admitted a day before were included in the study. The patients who did not gave consent and with co-morbid condition like diabetes mellitus and malignancy, cephalosporin group hypersensitivity and history of treatment with steroids and those who are taking drug classified to cause immune deficiency. Patients having unclean wounds and females who were pregnant were excluded. Ethical consideration was made through institutional ethical committee and informed consent was taken from the subjects prior to study.

Patients were randomly assigned into group I and group II, where group I is defined as minimum antibiotic therapy group and group II is defined as the routine long term antibiotic therapy group. All surgical interventions were carried out in similar operative backgrounds, and with identical preoperative methods of safety, and care given post-operatively is followed for all patients.

The guidelines for antibiotic usage are decided as follows

Group I included three dosage of injectable ceftriaxone 1 gram intravenous peri-operatively, first dose twelve hour before surgery and second dose half hour before surgical incision and third dose twelve hours after surgery.

Group II included injectable ceftriaxone 1 gram intravenous peri-operatively, first dose twelve hour before surgery and second dose half hour before surgical incision and then followed by injection (conventional dose) ceftriaxone 1 gram/day IV twice daily for the first 5-7 days post-operatively.

Using Southampton wound grading system, surgical site infection in post-operative patients were recorded.15 Follow up was done on the 3rd, 5th, 10th and 15th days post operatively. Data was recorded in Microsoft excel and checked for its completeness and correctness then it was analysed by using suitable statistical software and p value<0.05 was considered as a statistically significant.

**RESULTS**

The age range of the patients in group I was 17–84 years with mean and standard deviation (SD) of 41.76±16.78 and the age range of the patients in group II was 18–74 years with mean and SD of 39.85±14.68. There is no significant variation between data of the two groups based on age. In group I, 82(65.6%) patients were male and 79 (34.5%) were female. In group II 79 (63.2%) patients were male and 46 (36.8%) patients were female.

Mean hemoglobin level in group I was 12.09 with SD of ±1.70 and in group II it was found to be 11.65 with SD of ±1.21. Mean serum protein levels found to be in group I and II was 6.74 with SD of ±0.71 (Table 1).

22 (17.6%) cases had diabetes in group-I and 20 (16%) cases in group II and addiction was present in 20 (16%) cases in group I and 12 (9.6%) cases in group II. There was...
no significant difference between both the groups based on diabetes and addiction (Table 2).

Out of 125 cases in group I, 22 cases were diabetic out of which 3 (13.6%) cases had post-operative infection on day 3 and 1 (4.5%) case had post-operative infection on day 5. 20 cases had history of addiction, out of which 2 (10%) cases had post-operative infection on day 3, no cases had post-operative infection on day 5. No significant results were found for post-operative infection on day 3 and day 5.

Similarly out of 125 cases in group II, 20 cases were diabetic out of which 1 (5%) case had post-operative infection on day 3 and 2 (10%) cases had post-operative infection on day 5, 12 cases had history of addiction, out of which no cases had post-operative infection on day 3 and 1 (6.25%) case had post-operative infection on day 5. No significant results were found for post-operative infection on day 3 and day 5 (Table 3).

Different surgical procedures performed in patients of Group I and II, the most common surgical procedure in both the groups was hernioplasty 46 (36.8%) in group I and 52 (41.6%) in group II followed by eversion of sac which 7 (46.67%) cases were infected in group I, 11 (8.8%) cases had grade 2 SSI (9 cases on POD 3rd and 6 cases on POD 5th). In group II, 11 (8.8%) cases had grade 2 SSI (7 cases on POD 3 and 4 cases on POD 5). The p value is 0.83 and is not significant. There was no statistical significant difference between both the groups based on Southampton grade (Table 6).

In group I, 15 cases were infected with grade II SSI, in which 7 (46.67%) cases were of hernioplasty followed by 5 (33.33%) cases of eversion of sac and in group II, 11 cases were infected with grade II SSI, in which maximum 7 (58.34%) cases were of hernioplasty, while 2 cases (16.68%) of eversion of sac and 1 cases (8.34%) each of enucleation, excision of lipoma (Table 4).

All cases of group I and II were observed on the basis of duration of surgery. The maximum numbers 44 (35.2%) and 50 (40%) of cases was of 50 min duration in both groups respectively. Second maximum cases were of 30 min and 80 min duration in both groups. There was no significant difference between both the groups based on duration of surgery. Group I had 15 post-operative infection and in group II, 11 had post-operative infection. Maximum cases 7(46.66%) which were infected in group I had an operative time of 50 mins each and in group II maximum cases 7 (63.63%) which were infected had an operative time 50 mins (Table 5).

Two groups of cases with 125 cases each were evaluated for post-operative SSI, it was found that in group I, 15 (12%) cases had grade 2 SSI (9 cases on POD 3rd and 6 cases on POD 5th). In group II, 11 (8.8%) cases had grade 2 SSI (7 cases on POD 3 and 4 cases on POD 5). The p value is 0.83 and is not significant. There was no statistical significant difference between both the groups based on type of surgery.

### Table 1: Patients demographic.

| Features      | Group I (N=125) | Group II (N=125) | T test, df, p value |
|---------------|-----------------|------------------|-------------------|
| Age           | 41.76±16.78     | 39.85±14.68      | 0.96, 248, 0.34, insignificant |
| Sex ratio (M/F) | 82/43           | 79/46            |                   |
| Hemoglobin    | 12.09±1.70      | 11.65±1.21       | 2.358, 248, 0.0192, significant |
| Serum protein | 6.79±0.74       | 6.74±0.71        | 0.545, 248, 0.58, insignificant |

### Table 2: Distribution of cases based on diabetes and addiction.

| History | Group I (N=125) % | Group II (N=125) % | Chi-square, df, p value |
|---------|-------------------|--------------------|-------------------------|
| Diabetic |                  |                    |                         |
| Yes     | 22 (17.6)         | 20 (16)            | 0.114, 1, 0.73, insignificant |
| No      | 103 (82.4)        | 105 (84)           |                         |
| Addiction |                 |                    |                         |
| Yes     | 20 (16)           | 12 (9.6)           | 2.294, 1, 0.1, insignificant |
| No      | 105 (84)          | 113 (90.4)         |                         |

### Table 3: Grade II SSI in group I and group II cases with history of diabetes and addiction.

| History | Group I | Group II | Chi-square, df, p value |
|---------|---------|----------|-------------------------|
| Diabetic |         |          |                         |
| Yes (N=22) |       | No (N=103) | 0.693, 1, 0.40, NS       |
| No (N=103) |       | 1 (5)    | 0.14, 1, 0.70, NS        |
| After 3rd day | 3 (13.64) | 6 (5.83) |                           |
| After 5th day | 1 (4.55)  | 5 (4.85) |                           |
| Addiction |         |          |                         |
| Yes (N=20) |     | No (N=105) | 0.238, 1, 0.62, NS       |
| No (N=105) |     | 2 (10)   | 1.42, 1, 0.23, NS        |
| After 3rd day | 2 (10)   | 4 (3.81) |                           |
| After 5th day | 0 (0)    | 6 (5.71) |                           |
Table 4: Type of surgery and percentage of infection in both group.

| Type of operation            | Group I (%) | Group II (%) | Infection in group I (N) (%) | Infection in group II (N) (%) |
|------------------------------|-------------|--------------|-----------------------------|------------------------------|
| Appendicectomy               | 10 (8)      | 8 (6.4)      | 0 (0.0)                     | 0 (0.0)                      |
| Eneucleation of fibroadenoma | 17 (13.6)   | 20 (16)      | 0 (0.0)                     | 1 (8.3)                      |
| Eversion of sac              | 21 (16.8)   | 16 (12.8)    | 5 (33.3)                    | 2 (16.7)                     |
| Excision of lipoma           | 3 (2.4)     | 7 (5.6)      | 1 (6.7)                     | 1 (8.3)                      |
| Hernioplasty                 | 46 (36.8)   | 52 (41.6)    | 7 (46.7)                    | 7 (58.3)                     |
| Lap cholecystectomy          | 20 (16)     | 21 (16.8)    | 1 (6.7)                     | 0 (0.0)                      |
| Lap hernioplasty             | 8 (6.4)     | 1 (0.8)      | 1 (6.7)                     | 0 (0.0)                      |
| Total                        | 125 (100)   | 125 (100)    | 15 (100)                    | 11 (100)                     |
| Chi-square, df, p value      | 8.57, 6, 0.20, insignificant | 0.54, 6, 0.99, insignificant |

Table 5: Duration of surgery and percentage of infection in both group.

| Duration (min) | Group I (%) | Group II (%) | Infection in group I, N (%) | Infection in group II, N (%) |
|----------------|-------------|--------------|-----------------------------|----------------------------|
| 30             | 24 (19.2)   | 21 (16.8)    | 6 (40.0)                    | 4 (36.4)                    |
| 40             | 14 (11.2)   | 12 (9.6)     | 0 (0.0)                     | 0 (0.0)                     |
| 50             | 44 (35.2)   | 50 (40)      | 7 (46.7)                    | 7 (63.6)                    |
| 60             | 5 (4)       | 7 (5.6)      | 0 (0.0)                     | 0 (0.0)                     |
| 80             | 24 (19.2)   | 21 (16.8)    | 1 (6.7)                     | 0 (0.0)                     |
| 90             | 10 (8)      | 9 (7.2)      | 1 (6.7)                     | 0 (0.0)                     |
| 120            | 4 (3.2)     | 5 (4)        | 0 (0.0)                     | 0 (0.0)                     |
| Total          | 125 (100)   | 125 (100)    | 15 (100)                    | 11 (100)                    |
| Chi-square, df, p value      | 1.43, 6, 0.96, insignificant | 0.176, 60.0.99, insignificant |

Table 6: Grading of SSI in group I and II.

| Southampton grade | Group I (%) | Group 2 (%) |
|-------------------|-------------|-------------|
|                   | POD3 | POD5 | POD10 | POD15 | POD3 | POD5 | POD10 | POD15 |
| Grade 1           |      |      |       |       |      |      |       |       |
| Grade 2           | 9 (7.2) | 6 (4.8) |       |       | 7 (5.6) | 4 (3.2) |       |       |
| Grade 3           |      |      |       |       |      |      |       |       |
| Grade 4           |      |      |       |       |      |      |       |       |
| Grade 5           |      |      |       |       |      |      |       |       |
| Chi-square, df, p value | 0.048, 1, 0.83, insignificant |       |

DISCUSSION

With advancement in the field of surgery, it is important to prevent the post-operative SSI. Antimicrobials play an important role in post-operative line of management. Over-enthusiastic use of anti-microbial drugs not only adds to the cost of treatment but also adds to resistance to antibiotic further increasing the global burden of antibiotic resistance. With evolving era from “anti-sepsis” to “a-sepsis”, the misuse and over use of antibiotic needs to be evaluated on risk-benefit ratio. In our study elective procedure was included that is not contaminated by flora of viscera. Hence, to cover skin commensals, injection ceftriaxone was used in 250 cases.

In our study, patients were distributed widely in both groups with age group 18 years and above. There was found no significant variation between data of the two groups based on age whereas a definite correlation was found between age and efficacy of antibiotics in a study done by Scott et al which involved around 2016 cases showing increasing age associated with a reduced efficacy of the antibiotic.16

In group I, mean hemoglobin was 12.09 and SD was ±1.70 and in group II mean hemoglobin was 11.65 and SD was ±1.21. One of the main factors for the development of SSIs is decreased oxygen supply. Londahl shown that in chronic infections, the decrease in tissue oxygen tension of the surrounding tissue seems to be a major driving cause for their persistence.17 In our study, we found that the levels of hemoglobin as found to be significant in the outcome of the surgery.

Serum protein levels were evaluated in both the group of cases mean of serum protein levels in group I is 6.79 with SD of ±0.74, the mean of serum protein levels in group II
is 6.74 with SD of \pm0.71. Study done by Sindigkar et al demonstrated that increased postoperative morbidity and mortality was associated with decreased serum protein levels whereas in our study, the level of serum protein did not have a convincing role in determining the outcome of surgery as the serum protein level in the cases taking part in the study were within the normal limits.\\textsuperscript{18}

Diabetes is known to decrease the immunity of the cases and increase the risk of infections post-operatively. Also diabetes decreases wound healing. hence diabetes increases SSI, but in our study no significant increase in rate of SSI was found and hence there is no added advantage of long term routine antibiotic post-operatively. So we conclude that there is no increase in post-operative infection in cases with history of addiction.

There have been multiple studies performed to show the relevance of the duration of surgery with regard to the SSI. A review of 57 observational studies by Korol et al was done which reported that the increased duration of surgery was found consistently to be associated with SSI.\\textsuperscript{19} It was found in study by Leuva et al that when the operative time was 15% or greater than the mean (i.e. >3 hours), the incidence of infections was found to be increased by two-fold.\\textsuperscript{20} But in our study, the duration of surgery and type of surgery were found to be an insignificant factor in association with post-operative SSI.

In our study, 2 groups with 125 cases each were evaluated for post-operative SSI, it was found that in group I, 15 cases had grade 2 SSI in group II total of 11 cases had grade 2 SSI.

In group I, 9 (7.2%) cases were having SSI in form of grade 2 on post-operative day 3 and 5. On post-operative day 5, grade 2 SSI were present in 6 (4.8%) cases. And in group II, 7 (5.6%) cases were having wound in form of grade 2 on 3\textsuperscript{rd} post-operative day and 4 (3.2%) cases were having grade 2 SSI on 5\textsuperscript{th} post-operative day. The p value was found to be 0.83 so there is no significant difference in post-operative infections in group I and group II. Hence there is no added advantage of long term routine antibiotic over three dose minimal antibiotic coverage. Following authors’ have demonstrated the efficacy of three dose antibiotics in prevention of infection.

Leuva et al conducted a study at Ahmedabad, in which they concluded three dose antibiotics are sufficient in preventing SSI. Prolonged administration of antibiotics is unnecessary and costlier. SSI is equal in both sex and not associated with sex predominance. Prolonged use of antibiotics is associated with emergence of resistant strains and superinfections, with can be prevented by cost-effective short term antibiotic prophylaxis.\\textsuperscript{6}

Khichy et al conducted a randomized comparative study in which it was found that incidence of SSI was 4% in group A and 24% in group B. It was concluded that short dose peri-operative antibiotic was sufficient in preventing SSI.\\textsuperscript{20}

Konidala et al in a prospective randomized study on comparison of short term three dose antibiotic prophylaxis with conventional prolonged post-operative antibiotic coverage in development of surgical site infection The overall incidence of SSI in the three dose antibiotic prophylaxis group 24%, which is high when compared with many other studies.\\textsuperscript{21} All the above studies support the results of our study that a three dose peri-operative antibiotic prophylaxis is almost as effective as multiple dose antibiotics in elective surgeries.

Table 7: Infection percentage reported by different authors.

| Sl. no. | Worker | Infection (%) | Year |
|---------|--------|---------------|------|
| 1       | Leuva  | 2             | 2014 |
| 2       | Khichy | 4             | 2017 |
| 3       | Konidala et al | 24          | 2018 |

CONCLUSION

There was no difference found in SSI either using single dose pre-operative antibiotic prophylaxis or using five days conventional post-operative antibiotic therapy. A minimal dose antibiotic prophylaxis is equally efficient and has added advantage of reducing the duration of hospital stay and cost of medicines for the patients. Hence minimal dose antibiotic is better than a routine long term antibiotics therapy.

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