
Antimicrobial prophylaxis to prevent surgical site infection in Adolescent Idiopathic scoliosis patients undergoing posterior spinal fusion– 2 doses Vs antibiotics till drain removal

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1

2 **ABSTRACT**

3 **Purpose:** There is much variation in the choice, timing and duration of antimicrobial
4 prophylaxis for preventing surgical site infections (SSI) but no guideline exists for scoliosis
5 surgery. The aim of study was to compare the efficacy of two antimicrobial prophylaxis
6 (AMP) protocols with cephazolin in preventing SSI in adolescent idiopathic scoliosis (AIS).

7 **Methods:** A retrospective comparative analysis of two post-operative AMP protocols (two
8 postoperative doses versus continued antibiotics till drain removal) was performed. Patient
9 characteristics, pre-operative, intra- and post-operative risk factors for infection, drain use,
10 generic drug name and number of doses administered were recorded from 226 patients with
11 AIS who had undergone posterior spinal fusion. Details of superficial or deep SSI and wound
12 healing aberrations, and serious adverse events were recorded. Analysis was performed to
13 evaluate differences in the pre-, intra- and post-operative variables between the two groups.

14 **Results:** 155 patients received 2 postoperative doses of AMP and 71 patients had antibiotics
15 till drain removal. The average follow-up was 43 months. The overall rate of SSI was 1.7%
16 for the spine wound and 1.3% for the iliac crest wound. 1.9% of patients with 2 doses of

1 AMP and 1.4% of patients with antibiotics till drain removal had SSI. No adverse reactions
2 attributable to cephazolin were observed.

3 **Conclusions:** This is the first study on the AMP protocol in scoliosis surgery for SSI
4 prevention. Results suggest that two doses of AMP are as effective as continued antimicrobial
5 use until drain removal. Cephazolin appears to be effective and safe for prophylaxis.

6

7 **Key Words:** Antimicrobial prophylaxis; adolescent idiopathic scoliosis; posterior spinal
8 fusion

9

1 **INTRODUCTION**

2 Surgical site infection (SSI) after spinal fusion results in increased patient morbidity,
3 prolonged hospital stay, long-term administration of antimicrobial drugs, multiple surgeries,
4 hardware removal, pseudarthrosis and added health-care cost.[1-5] The prevalence of post-
5 operative SSI increases with the complexity of the procedure and is reported to range from
6 <1% for discectomy[6,7] to as high as 10% for instrumentation surgery.[8,9] In adolescent
7 idiopathic scoliosis (AIS) surgery, the reported rate of infection is between 0.71% and
8 6.9%.[10-15]

9 Pre-operative antimicrobial prophylaxis (AMP) is one of the keys to reduce the rate of
10 SSI.[6,16-18] There is however, a great deal of variation regarding the choice of prophylactic
11 antibiotics, optimal timing and duration of treatment.[19,20] Surgical AMP refers to a very
12 brief course of antimicrobials initiated just before surgery.[21-24] It is a critically timed
13 adjunct used to reduce the microbial burden of the intra-operative wound to a level that
14 cannot overwhelm host defences, but not to sterilize tissues. The initial dose of antimicrobial
15 is timed so that bactericidal concentration is established in serum and tissues by the time of
16 skin incision with re-dosing to maintain therapeutic level of the drug in both serum and
17 tissues throughout the operation and until a few hours after wound closure.[25] AMP does
18 not pertain to prevention of SSI caused by post-operative contamination.[24] The fear of SSI
19 and its attendant complications prompts many surgeons to continue antibiotics in the post-
20 operative period ranging for 24-48 hours[20,23] and often until drain removal. There is
21 growing evidence in spine literature that this practice is unwarranted. AMP plays a vital role
22 for preventing infection but indiscriminate and prolonged use of these drugs may expose
23 patients to adverse drug reactions and encourage the emergence of resistant
24 bacteria.[22,26,27] Hence an antimicrobial prophylaxis protocol which is safe, efficacious,
25 requires the least number of doses to be administered and cost-effective is ideal.

1 The ‘Center for Disease Control (CDC) guideline for the prevention of SSI’[25] has
2 made recommendations regarding the possible choice of prophylaxis antibiotics, i.e. an
3 antimicrobial that is safe, inexpensive and bactericidal with an in-vivo spectrum that covers
4 the most probable intra-operative contaminants. It also recommends the timing of infusion of
5 the first dose and drug duration to establish and maintain therapeutic serum and tissue levels
6 throughout surgery. There is however a paucity of literature regarding the application of this
7 guideline in spine surgery[20,26,28] and none with regards to scoliosis surgery.

8 The main aim of study is to document the efficacy of our present AMP protocol in
9 preventing SSI and to compare it to our previous protocol of continued post-operative
10 antimicrobial drug administration until drain removal for AIS surgery. Additional aims
11 include evaluation of whether cephazolin (first-generation cephalosporin) is safe and
12 efficacious in preventing SSI and identifying its risk factors.

13

14 **METHODS**

15 This was a comparative analysis of two consecutive series of patients (1993-2004,
16 2005-2011) with AIS who had undergone posterior spinal fusion. Ethics approval was
17 obtained from a local institutional review board. Patient characteristics included age, sex, and
18 body mass index (BMI). Pre-operative risk factors for SSI including history of smoking, pre-
19 existing medical illness especially poor glycaemic control, recent infection or persisting focus
20 of infection and nutritional status in terms of total protein, albumin and globulin levels were
21 recorded. Intra-operative and post-operative risk factors including estimated intra-operative
22 blood loss, duration of surgery, number of vertebral levels fused and anchor points, post-
23 operative drain collection and its duration were recorded. The generic name and number of
24 doses of the antimicrobial administered was noted. For patients receiving AMP according to

1 the CDC criteria, two additional doses were received postoperatively. For patients who
2 received antimicrobials until drain removal, the number of days the drug was administered
3 was recorded. For these patients, three doses of cephazolin were given per postoperative day
4 (dosing every 8 hours). Serious adverse events including drug toxicity, allergic reaction or
5 anaphylactic shock and antimicrobial associated colitis were recorded.

6 A superficial infection was diagnosed with clinical signs of infection involving the
7 skin, subcutaneous tissue, or muscle located above the fascial layer and accompanied by
8 purulent drainage above the fascial layer and positive wound culture.[26] A deep infection
9 was diagnosed when infection was found to involve tissue below the fascia. For each patient
10 with SSI, the organism isolated, its antimicrobial sensitivity and subsequent management was
11 recorded. Wound healing aberrations including delay in wound healing, wound dehiscence,
12 hematoma or prolonged culture negative serous discharge, stitch abscess in the spine as well
13 as in the iliac crest wound were noted. The post-operative follow-up notes were scrutinized
14 for any late wound healing complications including infection after the skin healed and
15 imaging confirmed pseudarthrosis.

16 In our institution, patients were admitted the day prior to surgery and were screened
17 for any active infective focus. In the presence of an active infection, surgery was postponed
18 until the infection was eradicated. Necessary interventions were undertaken to optimize the
19 patient's preoperative general health status. All patients bathed the night prior to surgery, no
20 shaving was performed and skin preparation was standardized with providone-iodine scrub.
21 A standardized surgical procedure of autogenous bone grafting, implant insertion, deformity
22 correction and fusion was performed in a laminar airflow theatre. Three independent spine
23 specialists were involved in all the operations. All patients received autogenous blood
24 transfusion (stored 1 month prior to operation). No cell saver was used. Autogenous bone
25 graft used for fusion was harvested from the posterior iliac crest immediately prior to the

1 main spinal incision. No allograft bone or bone substitutes were used in any of the cases. The
2 surgical sites were irrigated with normal saline after completion of surgical dissection,
3 insertion of all anchors, after rod insertion and prior to wound closure. Standardized closure
4 was performed with watertight closure of fascia and subcutaneous with continuous vicryl
5 sutures, and buried subcuticular monocryl sutures. Single suction drain was routinely placed
6 in the spinal wound and removed when the collection was <50 ml over a 24-hour period. No
7 drains were placed in the iliac crest wound. No topical antibiotics were used. All preparation
8 and surgical protocols were standardized between the three surgeons.

9 Cephazolin, a first-generation cephalosporin, administered at a dose of 20-30mg/kg
10 body weight was used as AMP. It was administered 30 minutes before skin incision and an
11 additional dose administered intra-operatively every 4 hours to maintain therapeutic levels
12 throughout surgery. Prior to 2005, antimicrobials were continued in the post-operative period
13 until drain removal; however since then antimicrobials were only administered pre-incision
14 with re-dosing intra-operatively when the procedure duration exceeds 4 hours. This practice
15 was changed in 2005 following the advice of the infection control unit at our institution.

16 Statistical analysis was performed using SPSS version 19. Analysis of variance
17 (ANOVA) test was used to evaluate for differences in the pre-, intra- and post-operative
18 variables between the two groups. Pearson's chi-square test and Mann-Whitney tests were
19 used for outcome analysis. Fisher's Exact Test was employed when data points were less than
20 or equal to 5. A p-value of <0.05 was considered significant.

21

22 **RESULTS**

1 226 patients with average 43 months follow-up (range: 18-104 months) were included
2 in the study, of which 155 (68.6%) patients (group A) received 2 doses of postoperative AMP
3 and 71 (31.4%) patients (group B) received antimicrobials until drain removal (range: 3-5
4 days). No significant differences were observed between the two groups (**Table 1**) with
5 respect to mean age, sex, BMI, smoking, pre-operative hemoglobin, nutritional status (total
6 protein and albumin), scoliosis curve type, mean number of levels fused per patient, intra-
7 operative transfusion, post-operative transfusion and duration of drain left in-situ. A
8 significant difference was observed between the groups in terms of pre-operative globulin
9 levels, type of instrumentation system, mean number of anchor points per patient, intra-
10 operative and post-operative blood loss between the groups. Although there was
11 **approximately** 150ml more blood loss intra-operatively for group A, interestingly group B
12 had more intraoperative and postoperative transfusions. Patients in group A had lower pre-
13 operative globulin levels and more anchor points per patient as compared to group B. The
14 globulin levels however were in the normal range in both groups and hence this finding might
15 not be clinically significant. Group B had fewer patients with all pedicle screw constructs as
16 most of these patients were operated prior to popularization of all pedicle screw constructs
17 (**Table 2**). 14 of 71 patients in Group B had a deep spine wound drain whilst all group A
18 patients had a subcutaneous plane drain (due to a change in policy in drain usage) and this
19 accounted for the difference in total drain output. Too few patients in Group B had deep
20 spine wound drains to find any statistical significant differences in SSI. No statistical
21 differences in all patient parameters and outcomes were found between the 3 operating
22 surgeons.

23 For pre-existing medical problems, 14 patients had allergic rhinitis and or asthma, 2
24 had atopy, 3 had G6PD deficiency, 3 patients had thalassemia trait and 2 with thalassemia
25 minor, 5 patients had cardiac valve anomalies, 2 patients were obese and 1 had recovered

1 from leukemia. No patients had anemia or any active focus of infection. No patients had
2 diabetes or abnormal blood glucose prior to surgery.

3 The overall rate of SSI was 1.7% for the spine wound and 1.3% for the iliac crest
4 wound. For the spine wound, 3 of 155 (1.9%) patients in group A had SSI (1 superficial and 2
5 deep), while there was only 1 deep SSI (1.4%) in group B ($p=1.0$). For the iliac crest, two
6 (1.3%) patients in group A, and one (1.4%) patient in group B had a superficial SSI ($p=1.0$).
7 The organisms cultured and the management of the infected patients was detailed in **table 3**.
8 All the deep infections were managed with a single debridement and antibiotics given
9 according to culture sensitivity reports and none required implant removal. Duration of use
10 depended on clinical response and microbiologist consultation. The superficial infections
11 were managed with appropriate antibiotics only. There were no late infections seen. Nine of
12 155 (5.8%) patients in group A and seven of 71 (9.8%) patients in group B had spine wound
13 healing aberrations, but the difference was not significant ($p=0.489$). One of 155 (0.6%)
14 patients in group A and four of 71 (5.6%) patients in group B had iliac crest wound healing
15 aberrations, but the difference was also insignificant ($p=0.059$). None of these wound healing
16 aberrations required further treatment besides observation. No adverse drug reactions or side
17 effects attributable to cephazolin were observed.

18

19 **DISCUSSION**

20 This is the first study to compare the outcomes of two different AMP protocols. The
21 overall rate of SSI in this study is 1.7% which is within the range of 0.71% to 6.9% as
22 reported in literature.[10-15] In group A, the rate of spine wound SSI was 1.9%, while in
23 group B, the rate was 1.4%. Statistically speaking, there were no significant differences in the
24 prevalence of spine and iliac crest wound SSI. This implies that a short duration of AMP is

1 equally effective in reducing the rate of SSI as compared to post-operative continuation of
2 AMP until drain removal. This also implies that cephazolin is an effective prophylactic
3 antimicrobial agent. Furthermore, no adverse drug events are observed which demonstrates
4 its safety.

5 The particularly low infection rate in this study can be contributed to the type of
6 patients operated on. All the AIS patients in this study are healthy teenagers who generally do
7 not have high risk for infections to begin with. Poor glycemc control or diabetes mellitus has
8 been shown to increase the risk of SSI.[29] As expected, this is not a risk factor found in our
9 patients.

10 Late infection after the surgical treatment of AIS is a concern. Its incidence ranges
11 from 1.4% to 6.9% [13,30] and usually occurs at an average of 2 years after surgery. In our
12 series, 201 patients were followed up for a minimum period of 24 months and no cases of late
13 infection were found in either group. Our data suggests that a shorter duration of AMP does
14 not predispose to an increased rate of late infection.

15 A secondary outcome was to compare the prevalence of wound healing aberrations
16 even though they did not affect the overall clinical outcome. This was done to ensure that a
17 change in antibiotic schedule did not lead to any difference in wound healing. Interestingly,
18 despite a longer duration of antibiotic use in group B patients, a larger percentage of patients
19 had spine and iliac crest wound aberrations. Although this result was still statistically
20 insignificant, it suggested that a shorter antibiotic regimen did not negatively affect wound
21 healing. It should be noted that these wound healing complications did not result in delayed
22 suture removal or prolonged hospital stay.

23 The results of our study provide further evidence that short duration AMP is adequate
24 even in extensive surgical procedures such as scoliosis correction that involves massive soft

1 tissue dissection, bone decortication and a large amount of instrumentation. None of the
2 organisms isolated from group A patients were drug resistant, whereas 1 of 3 (33%)
3 organisms isolated from group B patients (prolonged antibiotics) was methicillin-resistant
4 *Staphylococcus Aureus* (MRSA). The prevalence of antibiotic resistant organism in our study
5 is too low to comment on whether prolonged antibiotic use may lead to development of
6 antibiotic resistance. However the evidence from our study and literature[17,22,26,31] leads
7 us to believe that short duration AMP is effective and that prolonged drug administration
8 post-operatively should be avoided to reduce the emergence of drug resistant organisms.
9 Kanayama et al.[26] reported in their study that 83.3% of organisms isolated from patients
10 with SSI in the multiple-dose group were resistant strains of bacteria, whereas none in the
11 single-dose group were resistant. Unlike these studies, we do not see an increase in culture of
12 resistant bacteria.

13 The choice of prophylactic antimicrobial drug is an important factor in preventing
14 SSI.[27,32] The ideal antibiotic should be safe, inexpensive, and bactericidal with an in-vivo
15 spectrum that covers the most probable intra-operative contaminants. For orthopedic surgery,
16 microorganisms classically recovered from wound infections in patients with no pre-existing
17 focus of infection include *Staphylococcus aureus*, *S. epidermidis*, *S. lugdunensis* and
18 *Propionibacterium acnes*.[15,22,27,33-36] Because of the frequency of isolation of these
19 organisms, β -lactams such as cephalosporins and penicillins are most often selected for AMP.
20 Cephalosporins have been shown in studies to be effective against many gram-positive and
21 gram-negative microorganisms.[37] They also share the features of demonstrated safety,
22 acceptable pharmacokinetics, and a reasonable cost per dose.[21] In particular, cephazolin is
23 widely used and generally viewed as the first choice antimicrobial drug for clean operations.
24 Authors of trials in which cephazolin was compared with second- and third-generation
25 cephalosporins have failed to show any difference in efficacy.[26,38,39] The results of our

1 study combined with Rubinstein et al.[17], Takahashi et al.[20] and Kanayama et al.[26]
2 provide evidence for the use of cephazolin as the first-line prophylactic antimicrobial agent
3 for spinal surgery.

4 The current study has the drawbacks of having a small sample size. An adequately
5 powered prospective randomized clinical trial would be ideal to verify our findings especially
6 considering this is a study on AMP. However considering the low rate of infection in
7 scoliosis surgeries (approximately 2-3%) as pointed out by Dimick et al.[32], for a baseline
8 infection rate of 2% it is necessary to enroll 2518 patients in each treatment group to detect a
9 difference in SSI rates. Clearly, the magnitude of this number indicates that a multi-center
10 clinical trial is required as we do not have over 5000 cases in our cohort to address this
11 issue.[40] This is not only necessary for scoliosis patients but for all spine disorders as the
12 current North American Spine Society guidelines provides only fair recommendations for
13 antibiotic prophylaxis in spine surgery.[41] It should be cautioned that the external validity of
14 the study may be limited for settings with increased resistance of *S. epidermidis* to β -lactam
15 antibiotics, or hyper-endemic occurrence of MRSA. Another limitation is that the two groups
16 include patients from two separate time periods and thus not as strong of a comparison as in a
17 prospectively matched cohort. There are inherent differences in instrumentation (modern
18 pedicle screw based and earlier hook based) and drain use (earlier deep placement beneath
19 the thoracolumbar fascia and modern superficial placement). This may have an effect on the
20 post-operative wound behaviour but interestingly there is no significant increase in operative
21 time or postoperative increase in drain output for hook instrumentation nor deep drains.
22 Although all three surgeons are experienced, the lack of differences in duration of surgery
23 may reflect the difficulties of engaging hook anchors to rods in earlier patients.

24 This is the first and largest study on AMP protocol in scoliosis surgery. Despite the
25 reported limitations, results suggest that short duration AMP with cephazolin is safe, effective

1 and cost-effective in scoliosis surgery. The rates of infection are comparable to that reported
2 in literature and there is no increased predisposition to late infection. Reduced number of
3 doses of antimicrobials may reduce health care cost. Reduced adverse effects, negating need
4 for intravenous access, reduced workload for the nursing staff and possibly prevention of
5 antibiotic resistance are other potential advantages. This study is a platform for future
6 prospective multicenter-randomized-controlled-trials to further establish this protocol for
7 scoliosis surgery.

8

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Table 1: Comparison of pre-operative, Intra-operative and post-operative variables between the two groups

Variable	Group A (n=155); Mean (SD; range)	Group B (n=71) Mean (SD; range)	P-value
Age (years)	15.03 (SD 2.642; 10-27)	15.11 (SD 2.72; 11-25)	0.833
Sex (Female/Male)	132/23	60/11	0.899
Body mass index (BMI)	18.3 (SD 2.5; 13.52-27.28)	18.73 (SD 3.52; 11.29-31.49)	0.297
Smoking (patients)	3	2	0.677
Pre-operative Haemoglobin (g/dL)	13.13 (SD 1.46; 9.8-12.9)	11.76 (SD 1.65; 9.3-16.4)	0.228
Pre-operative total protein (g/L)	75.15 (SD 6.54; 42-89)	75.52 (SD 6.70; 47-87)	0.699
Pre-operative albumin (g/L)	44.33 (SD 4.66; 17-52)	43.01 (SD 5.41; 22-55)	0.063
Pre-operative globulin (g/L)	30.80 (SD 3.78; 22-41)	32.55 (SD 3.17; 25-40)	<0.001
Scoliosis curve type (MT/DM/DT/TM/TL)	108/25/19/0/3	42/18/8/2/1	0.277
Mean number of levels fused per patient	9.26 (SD 2.06; 6-13)	9.8 (SD 2.23; 6-15)	0.770
Surgical duration (minutes)	283.91 (SD 64.85; 188-480)	277.94 (SD 70.7; 192-430)	0.533
Mean number of anchor points per patient	10.9 (SD 2.89; 6-21)	9.28 (SD 2.12; 7-17)	<0.001
Intra-operative blood loss (ml)	796.29 (SD 391.83; 250-2200)	638.56 (SD 406.33; 150-1850)	0.006
Intra-operative transfusion (ml)	Blood: 402.94 (SD 270.361; 0-1400) FFP: 248.01 (SD 210.30; 0-785)	Blood: 442.96 (SD 322.68; 0-1445) FFP: 402.07 (SD 301.15; 0-1000)	0.150

Post-operative transfusion (ml)	Blood: 191.25 (SD 198.80; 0-785) FFP: 23.32 (SD 76.88; 0-570)	Blood: 267.68 (SD 292.43; 0-1250) FFP: 12.48 (SD 75.47; 0-536)	0.241
Post-operative drain (spine) (ml)	Total drain: 228.01 (SD 231.78; 5-1510)	Total drain: 473.01 (SD 365.98; 5-1740)	0.01
Post-operative duration of drain in-situ (days)	3.1 (SD 0.65; 2-6)	3.2 (SD 0.72 ; 2-7)	0.356

Group A: Two doses of postoperative antimicrobials; Group B: Antimicrobials till drain removal

*MT- Main thoracic, DM-double major, DT- double thoracic, TM- triple major, TL- thoracolumbar, SD-standard deviation, FFP- fresh frozen plasma