Original Article

Outcome of Restricted Antibiotic Policy in a Tertiary-Level Paediatric Surgical Unit

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Abstract

Purpose: The purpose was to evaluate the effect of a more restrictive antibiotic policy on infective complications, mainly surgical-site infection (SSI) in clean and clean contaminated surgeries in children. **Materials and Methods:** The study included children who underwent clean or clean contaminated surgeries over a period of 18 months with a no-antibiotic or single dose of pre-operative antibiotic protocol, respectively. These were compared to historical controls in previous 18 months where the antibiotic policy was to continue the course for 3–5 days. The outcome looked for was presence of SSI or infection related to the operated organ. **Results:** A total of 933 (study group) patients were compared to 676 historic controls (control group). In the study group, 661 of 933 were clean surgeries and 272 were clean contaminated surgeries. In the study group, 490 of the 676 were clean surgeries and 186 were clean contaminated surgeries. Clean contaminated surgeries included urological surgeries, gastrointestinal tract surgeries and neurosurgeries, whereas clean surgeries were typically day-care surgeries. Comparing the infective outcomes in each type of surgery, there was no statistical difference between cases or controls in either subgroup. **Conclusion:** Antibiotic prophylaxis (AP) is not required for clean surgeries. For clean contaminated surgeries, just one dose of pre-operative AP is effective in preventing SSI.

Keywords: Clean contaminated wound, clean wound, restrictive antibiotic policy, surgical antibiotic prophylaxis surgical-site infection

Introduction

The WHO's first global report on antibiotic resistance, 2014, reveals serious, worldwide threat to public health and that without urgent action the world is headed for a post-antibiotic era, in which common infections can once again kill.[1] The 2014 WHO's South-East Asia Region data reveal that antibiotic resistance is a burgeoning problem in this region, which is home to a quarter of the world's population. The report's results show high levels of *Escherichia coli* and *Klebsiella pneumonia* resistance to third-generation cephalosporins. In some parts of the region, more than one-quarter of *Staphylococcus aureus* infections are reported to be methicillin-resistant *S. aureus*.[2]

Surgeons also have an important role in combating drug resistance. There are well-established guidelines by the Centers for Disease Control and Prevention (CDC),[3] Scottish Intercollegiate Guidelines Network, Joint Commission on Accreditation of Healthcare Organizations, National Health Service and others about the timing and dosing of antibiotic prophylaxis (AP) to prevent surgical-site infection (SSI). Despite this, there is considerable evidence that antibiotics are used excessively and inappropriately for the prevention of SSI.[4-9]

There are a number of studies in adults about the AP and SSI[10] but few in children.[11-15] Antibiotic protocols vary between institutes, and adherence to guidelines is variable. Development of antimicrobial resistance is directly proportional to the volume of antimicrobials consumed.[16] Therefore, regulation and restriction are essential to reduce the development of antimicrobial resistance.

Aim

The study aim was to evaluate the effect of a more restrictive antibiotic policy on infective complications,

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mainly SSI in clean and clean contaminated surgeries in children.

Materials and Methods

The study included 933 children aged between 0 and 18 years who had clean and clean contaminated surgeries over a period of 18 months with a no-antibiotic or single dose of pre-operative antibiotic protocol, respectively, as per CDC guidelines.[3] These were compared to historical controls in previous 18 months where there was no fixed protocol and the antibiotic policy was to continue the course for 3–5 days as per surgeon's choice. The outcome looked for was presence of SSI or infection related to the operated organ. These were compared to historical controls from the same unit in the preceding 18 months where antibiotics were given for an extensive period of time of 3–5 days. Contaminated and dirty wounds requiring therapeutic antibiotics were excluded. In addition, patients in whom antibiotics were continued for other reasons such as sepsis were excluded.

Control group – pre-protocol period

Clean surgeries received one dose of prophylactic antibiotic (cefotaxime) and clean contaminated surgeries received antibiotics (cefotaxime and metronidazole/amikacin) for variable periods of time (3–5 days) depending on surgeon preference and type of surgery.

Study group – protocol period

Clean surgeries did not receive any antibiotic and clean contaminated procedures received only prophylactic dose of antibiotic which were cefotaxime and amikacin for genitourinary surgeries, cefotaxime and metronidazole for gastrointestinal (GI) surgeries and ceftriaxone for central nervous system surgeries just before induction. One more dose of antibiotic was given if duration of surgery is >t ½ of the drug.

Data were obtained from inpatient case sheets, outpatient follow-up and department morbidity and mortality registers.

Parameters compared were SSI, other infections specific to organ operated and any other systemic infections. The follow-up period was defined as 30 days from initial operation and SSI was defined as per CDC criteria. Data were evaluated by Chi-square and Fisher's exact test. Routine microbiological investigation of causative organism was not included as part of the study.

Results

A total of 933 patients in the study group were compared to 676 historic controls where random antibiotic protocols had been used. Both were subdivided into clean and clean contaminated surgeries. A total of 490 of the 676 controls (72.5%) were clean surgeries and 186 (27.5%) were clean contaminated surgeries. In the study group, 661 of the 933 (70.8%) surgeries were clean and 272 (29.2%) were clean contaminated surgeries. Clean contaminated surgeries included elective opening of respiratory, GI, genitourinary and neurosurgical tracts with minimal spillage, whereas clean surgeries included circumcision, hernia, orchidopexy, pyloromyotomy and splenectomy where respiratory, alimentary and genitourinary tracts were not entered. Data are provided in Tables 1 and 2 and results are summarised in Table 3.

Our SSI in the control group for clean and clean contaminated cases was 0.82% and 3.23% and study group was 1.06% and 2.57%, respectively. There was definitely no advantage in giving prophylaxis to clean cases as per our results (0.82% vs. 1.06%, $P = 0.77$). In addition, for clean contaminated cases, one dose of prophylactic antibiotic was effective in preventing SSI compared to multidosing (3.23% vs. 2.57%, $P = 0.68$).

The difference in the proportion of SSI for clean cases in the control group as compared to the study group was between −0.0113 and 0.0146 (95% confidence). The difference in the proportion of SSI for clean contaminated cases in the study group as compared to the control group was between −0.0251 and 0.0452. The 95% confidence interval included 0. Fisher's exact test and Chi-square test were used to compare the SSI in the two groups. The difference in the proportion of SSI was not statistically different in both groups.

Discussion

SSI rates as per the traditional wound classification system by CDC are reported to be <2% for clean cases and 4%–10% for

Table 1: Clean cases: Comparing surgical-site infection in the control and study groups

Procedure	Control group		Study group		*P**
	Total number	Infections	Total number	Infections	
Circumcision	114	0	154	1	1
Hernia	233	1	294	1	1
Orchidopexy	42 open 28 lap	0	60 open 41 lap	0	1
Nephrectomy	4	0	5	0	1
Pyloromyotomy	10	1	20	1 SSI	1
Splenectomy	6	1 empyema	8	1 pneumonia	1
Miscellaneous (cysts, sinuses)	53	1	79	3	0.65
Total	490	4	661	7	0.77

*Fisher's exact test. SSI: Surgical-site infection

Table 2: Clean contaminated cases: Comparing surgical-site infection in gastrointestinal, central nervous system and urology surgeries in the control and study groups

Procedure	Control group		Study group		*P*
	Total number	Infections	Total number	Infections	
GI surgeries					
Colostomy	15	-	24	-	1*
Colostomy closure	20	1	33	2	1*
Lap appendicectomy	23	-	25	-	1*
Rectal biopsy	11	-	18	-	1*
Anoplasty	12	-	15	-	1*
PSARP	18	1 SSI, 1 UTI	28	-	1*
Lap cholecystectomy	2	-	4	-	1*
CNS surgeries					
VP shunt	4	-	10	-	1*
MMC repair	8	1 SSI	12	1 SSI	1*
Encephalocoele	2	-	3	-	1*
Urology surgeries					
Pyeloplasty	14	1 UTI	21	1 UTI, 1 SSI	1*
Hypospadias repair	57	1 UTI	79	2 UTI	1*
Total	186	6	272	7	0.68#

*Fisher's exact test, #Chi-square test. VP: Ventriculoperitoneal, MMC: Myelomeningocele, SSI: Surgical-site infection, PSARP: Posterior sagittal anorectoplasty, UTI: Urinary tract infection, GI: Gastrointestinal, CNS: Central nervous system

Table 3: Comparative summary of results of the study and control groups for clean and clean contaminated cases

Category	Control group		Study group		*P*
	Total	Infections (%)	Total	Infections (%)	
Clean cases	490	4 (0.82)	661	7 (1.06)	0.77*
Clean contaminated	186	6 (3.23)	272	7 (2.57)	0.68#
Total	676	10 (1.48)	933	12 (1.29)	0.91#

*Fisher's exact test, #Chi-square test

clean contaminated cases,[17] and the corresponding National Nosocomial Infections Surveillance System hospitals' reported data were 2.1% and 3.3%, respectively.[18]

We did not demonstrate a significant change in SSI rates in clean cases (1.48%) versus clean contaminated cases (1.29%) [Table 3].

Our results showed no advantage in giving any prophylaxis to clean cases with similar rates of SSI in those who received pre-operative antibiotics compared with those that did not (0.82% vs. 1.06%, $P = 0.77$). This was similar to a study by Horwitz *et al*.[11] who showed similar rates of SSI in clean cases that received pre operative antibiotics compared with those that did not (3.9% vs. 2.4%, $P = 0.34$). A prospective cohort study by Koshbin *et al*. on 5309 patients showed that 43.9% of the patient population who received AP, when not indicated by the guideline, had no reduction of SSIs.[19] This finding is important because giving antibiotics to all children would pose potential side effects and risks. Thus, the guideline obviated the need for antibiotics in approximately 45% of procedures. Our study also showed similar results, in that, clean cases did not require antibiotics and hence it was avoided in 70.9% (661/933) of our cases.

A study by Bracho-Blanchet *et al*.[13] of single- versus multi-dose prophylaxis in children showed significant decrease in SSI rates in single- or short-course prophylaxis compared to multi-dose (1.2% vs. 10.9%). Our study showed that there was no added benefit in giving multi-dose antibiotics to clean contaminated cases.

Early catarrhal appendicitis was treated as clean contaminated surgery and none had any SSI.

Newborns who underwent colostomy for anorectal malformation and children undergoing colostomy closure were considered as clean contaminated surgery because bowel was opened under controlled condition without spillage.

A prospective, randomised clinical study by Feza *et al*. compared the results of 1-day versus 7-day administration of the same prophylactic antibiotics to children undergoing colostomy closure and found no difference in the rate of infectious complications.[20] In our study, colostomy closure patients had bowel preparation but no oral AP. SSI in colostomy closure patients was 5% and 7% in the control and study groups, respectively, and not statistically significant [Table 2].

A study by Tofft *et al*. found that in patients with single-stage posterior sagittal anorectoplasty (PSARP), there was no difference in the risk of wound dehiscence irrespective of the duration of the antibiotic used (<1 day vs. >1 day).[21] In our study, 28 cases of PSARP for anorectal malformation also received only one dose of prophylactic antibiotics versus 18 cases receiving multidose, and there was no significant difference in SSI on comparison [Table 2].

Pyeloplasty and urethroplasty were included as clean contaminated surgeries. In the control group, antibiotics for both the above-mentioned surgeries were continued for 5 days and 7–10 days, respectively. None of the pyeloplasty or urethroplasty patients had SSI.

In the study group, only one pre-operative dose of antibiotic was administered, and none of the urethroplasty children developed SSI and 1/21 (4.7%) of the pyeloplasty children developed SSI. This was not statistically significant. In a review about the influence of perioperative factors on primary severe hypospadias repair by Castagnetti and El-Ghoneimi, post-operative AP did not have any impact on surgical complications.[22] A recent study by Baillargeon *et al*. does not support the routine use of prolonged antibiotics in hypospadias repair.[23]

There is insufficient evidence and bias regarding the role of empirical prophylactic antibiotics in all patients for as long as catheter is indwelling.[24] In our study, urethroplasties, pyeloplasties and PSARP cases had catheter *in situ* in the post-operative period ranging from 5 to 10 days. Symptomatic urinary tract infection was documented in 3.4% versus 2.3% cases in the control and study groups. We found that catheter was not an indication for continuing antibiotic.

Many studies, which used only perioperative antibiotics for neurosurgical procedures, have reported an incidence of SSI as low as 0.8% to as high as 5%–7%.[25] In our study, we included ventriculoperitoneal shunt and myelomeningocele (MMC) repairs as clean contaminated surgeries. Cases of ruptured MMC and those with post-operative cerebrospinal fluid leak were excluded. In the control group, antibiotics were given for 5 days and 7.1% (1/14) developed infection, whereas in the study group, only 4% (1/25) developed wound infection which again was not significant [Table 2].

Pyloromyotomy is considered a clean surgery and prophylaxis is not indicated in adults. However, a study by Ladd *et al*. suggested that it may benefit paediatric patients.[26] Our study did not show any statistically significant difference in SSI in the study and control groups [Table 1].

Research has shown that surgical techniques, skin preparation and method of wound closure are significant factors that can influence the incidence of subsequent infection. AP has also had a positive impact but mostly for contaminated wounds. Many other factors such as ASA classification, duration of surgery and contamination at the time of surgery have been identified as having an effect on the potential for infection. We should consider these factors before, during and after surgery. AP is an adjunct to, not a substitute for, good surgical technique.

Our results showed that restricting antibiotic use and adhering to guidelines does not increase the SSI rates.

Reviewing Indian literature also revealed that in a majority of cases, surgical prophylaxis was inappropriate in terms of choice of antimicrobial agent, timing of administration and duration of prescription.[27,28]

SSI risk classification systems such as those from Nosocomial Infection Control and the CDC are extrapolated from adult studies. In adults, SSI risk is influenced by the underlying comorbidities, whereas in children, that procedure-specific factors and markers of acute physiologic status strongly predict SSI risk.[11,12] Therefore, some paediatric surgeons may not consider adult AP guidelines to be relevant for their patients.

Therefore, meta-analyses and larger cohort studies are definitely required to establish antibiotic guidelines in paediatric surgical patients, especially infants and newborns. However, formulation of guidelines alone is incapable of changing the practice. Every institute must take strict measures to reinforce these guidelines in order to combat drug resistance.

Conclusion

AP is not required for clean surgeries. For clean contaminated surgeries, just one dose of pre-operative AP is effective in preventing SSI. Appropriate AP should be an integral component of an effective policy for the control of healthcare-associated infection.

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Conflicts of interest

There are no conflicts of interest.

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