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ANTIBIOTIC PROPHYLAXIS IN CLEAN AND CLEAN-CONTAMINATED SURGERY AND SURGICAL SITE INFECTION IN GENERAL SURGICAL WARDS IN IBRAHIM MALIK HOSPITAL AT KHARTOUM STATE

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ABSTRACT

Background: The use of antimicrobial prophylaxis for surgical procedures is one of the measures employed to prevent the development of surgical site infections. **Objectives:** To study evaluate the impact of develop antibiotic prophylaxes protocol in clean and clean-contaminated surgery and surgical site infection in general surgical wards in Ibrahim Malik Hospital at Khartoum State. **Methods:** This is interventional, prospective case-control hospital based study assessed 226 clean or clean contaminated surgical procedures at Ibrahim Malik Hospital for adult patients. A protocol was established by the team consist of clinical pharmacist and two general surgeons. Study populations were divided into two major groups; 113 patients; (case group) underwent surgical procedures and supervised by surgeons who received guidelines for prevention of SSI and (control group) whose surgeons didn't receive guidelines. Clean Surgical procedures included hernia repair and thyroidectomy, and two clean contaminated procedures (cholecystectomy and appendectomy). Patients' data was obtained preoperatively and up to 14 days post-operatively through pre-designed questionnaire. Data was analyzed using (SPSS, vers. 23); both frequencies and chi squares were calculated**. Results:** The SSI was reported with rate of 35.4%; it was significantly less among case group when compared to control group (26.5% vs. 44.2% respectively, P = 0.003). The overall adherence was found significantly higher in case group when compared to control group (56.7% vs. 43.3% respectively, P < 0.0001). Adherence to duration of post-operative antibiotic was reported in 62.8% and 44.2% respectively, (P < 0.0001). **Conclusion:** The study concluded that, setting protocol for prevention of surgical site infection is significantly effective in reducing the risk of infection.

KEYWORD: Surgical prophylaxis, surgical site infection, prophylactic antibiotics, wound infection, antibiotics, Sudan.

INTRODUCTION

The use of antimicrobial prophylaxis for surgical procedures is one of the measures employed to prevent the development of surgical site infections. SSI is the second leading cause of hospital-acquired infections and rates are increasing globally.[1] The Centers for Disease Control and Prevention (CDC) estimates that approximately 500,000 surgical site infections occur annually in the United States Surgical wound infections are the second most common nosocomial infection.[2] Accounting for nearly 40 percent of nosocomial infections in surgical patients, and account for 3.7 million excess hospital days and more than $1.6 billion in excess costs annually, and also these infections reduce

patients' quality of life and declines in mental health, functional status, productivity, and increased morbidity and death.[3] Errors in antimicrobial prophylaxis for surgical patients remain one of the most frequent types of medication errors in hospitals.[4] Surgical antibiotic prophylaxis (SAP) is not indicated just for contaminated or dirty surgical procedures, It is also recommended for clean-contaminated and some of the clean procedures.[5] The Surgical Care Improvement Project (SCIP) contains standards that are nationally reported with the aim of improving patient outcomes after surgery.[6] The 4 elements of appropriate antimicrobial prophylaxis are timing, antibiotic selection, dosing, and intraoperative re-dosing. Effective use of antimicrobial prophylaxis also requires monitoring of and feedback on patterns of use programs to improve antimicrobial prophylaxis should be multidisciplinary and should aim to improve use of medications, not simply to change physician practice patterns[7], should be primary care physicians participate in the pre and postoperative care of patients; they should be familiar with the Surgical Care Improvement Project recommendations.[8] The aim of study To evaluate the impact of develop antibiotic prophylaxes protocol in clean and clean-contaminated surgery and surgical site infection in general surgical wards in Ibrahim Malik Hospital at Khartoum State.

METHODOLOGY

This is interventional, prospective case-control hospital based study, included 226 patients who underwent both clean and clean contaminated general surgeries operations, namely: hernia repair, thyroidectomy, appendectomy and cholecystectomy from the 4 surgical units in general surgical wards in Ibrahim Malik Hospital at Khartoum State. From August 2017 to April 2018. All patients of both sexes above 18 years and less than 65 years undergoing elective surgery were suitable for inclusion into the research. The following patients were excluded, Diabetics, those with malignant disease, patients undergoing long term antibiotic therapy, pregnant and lactating women, immune-suppressed patients. Random sampling technique was followed for selection of participants. The sample size was calculated according to the following formula: $\mathbf{n=}\frac{N}{1+N.e^2}$ [9,10] The above formula gave a total sample size of 226 participants. Educational intervention by way of directed lecturers and seminars were done by the clinical pharmacist to surgical teams involved in the management of patients in the study group. There were no established local guidelines in the study area, so as a result of these lectures and in collaboration with surgeons local guidelines (protocol) were established by the team consist of clinical pharmacist and two general surgeons, then effective dissemination of guidelines was ensured to reach the targeted surgeons in the study group.[11,12,13,14,15] Patients were divided into two major groups; case group, which involved 113 patients, underwent surgical procedures and supervised by surgeons who received guidelines for prevention of surgical site infection and control group which involved 113 patients whose surgeons didn't receive guidelines, then the two groups was compare regarding proper antibiotic usage and SSI. The study was conducted on a real-time basis, data were collected for every patients and using a pre-formed questionnaires. The questionnaire included personal data, medical history, the type of operation and details about antimicrobial surgical prophylaxis. The following aspects of surgical prophylaxis were examined: the antibiotic agent, the route of administration, the dosage, the timing of administration, the timing of operative re-dosing and the duration of prophylaxis and prevalence of SSI. Patients were followed by interviewed preoperatively and Post-operatively, the wounds were examined on day 3, day 7 and day 14 in outpatient department (OPD).

RESULT

We followed 226 patients, operated on during the study period from August 2017 to April 2018, in Ibrahim Malik Hospital. The commonest age in control groups and case group was 30-60 years 45.1% and 49.6% respectively. There is slight difference regarding gender distribution; females were 54% in control group versus 49.6% in case group. Also, the two groups reported predomination of normal weight (BMI: 18.5-25 kg/m2) 86.7% and 89.4% respectively. Distribution of patients in case and control groups according to surgery class showed that, 51(45.1%) had clean surgery (hernia, thyroidectomy), versus 62(54.9%) who had clean-contaminated surgery (appendectomy, cholecystectomy) in case group and the same frequency was reported regarding control group. The distribution of patients in case and control groups according to type surgery showed that, 80 (35.4%) hernia, 64 (28.3%) Cholecystectomy, 60(26.5%), Apendectomy and 22(9.7%) thyroidectomy, from surgical operations.

The overall adherence was found in case group compared to control group with rates of 56.7% vs. 43.6% respectively, $P < 0.0001$.Adherence to the recommended antibiotic selection was reported by 78(69%) in case group versus 59(52.2%) of control group. adherence to dosing time was reported in 87(77.0%) of case group versus 75(66.4%) in case and control group respectively, adherence to the recommended duration of antibiotic usage was reported in 71(62.8%) of case group versus 46(44.2%) in the control group. There is a statistically significant difference between case and control group ($P < 0.05$). (Table 1).

Wound infection was assessed 14 days post-operatively, and it was reported in 50(44.2%) of patients in control group versus 30(26.5%) of patients in case group, the total rate of Surgical site infection was observed 80(35.4%)cases (Table 2), the distributed cases of infection according to type of surgery revealed that, Cholecystectomy reported infection in (26.6%) in control group versus (17.2%) cases in case group, Apendectomy reported infection in (21.7%) in control group versus (10%) cases in case group, Hernia reported infection in

(20%) in control group versus (12.5%) cases in case group, thyroidectomy reported infection in four cases of control group (18.2%) versus three cases in case group (13.6%).(Table 3).

Regarding dose regimen of prophylactic antibiotics, single pre-operative dose was administered to 25(22.1%) of patients in the control group versus 40(35.4%) of patients in the case group, multiple post-operative doses less than 24 hours was administered by 21(18.5%) of control group versus 31(27.4%) of case group. Outside the recommended dosage, 24(21.2%) in control group and 21(18.6%) in the case group administered multiple post-operative doses more than 24 hours while 43(38%) and 21(18.6%) in the two groups respectively administered an extended post-operative dose + oral antibiotics. (Table 4). Distribution of dose regimen of prophylactic antibiotics according to event of infection showed that, single pre-operative dose was administered by 37(56.9%) patients without post-operative infection and 28(43.1%) of those who developed post-operative infection, multiple post-operative doses less than 24 hours was administered by 39(75.70%) patients without post-operative infection and 13(25.0%) of those who developed post-operative infection, Outside the recommended dosage, 28(62.2%) patients without post-operative infection and 17(37.8%) of those who developed post-operative infection during administered multiple post-operative doses more than 24 hours, while 42(65.6%) patients without post-operative infection and 22(34.4%) patients developed post-operative infection during administered an extended post-operative dose + oral antibiotics.

History of infection and use antibiotics medication before surgical operation in case and control groups revealed in 25(22.1%) and 34(37.5%) respectively. For infection among whom 9(36%) and 11(32.4%) respectively had Common cold, 6(24%) and 10(29.4%) respectively had tonsillitis, and for use antibiotics medication among whom 9(36%) and 11(32.4%) were receiving beta B- lactam, while 5(20%) and 7(20.6%) were taking Cephalosporine, 4(16%) and 7(20.6%) were taking Macrolides respectively. Ten patients (40%) in case group and 12 patients (35.3%) in control group were using previous medication for 1-2 weeks before surgical operation, while 9(36%) and 17(50%) using previous medication more than two weeks before surgical operation respectively.

Regarding duration of hospital stay before surgery in case and control group, 93(82.3%) and 92(81.4%) stayed for one day respectively while 18(15.9%) and 20(17.9%) stayed for two days.

Post-operative hospital stay for one day to two days was reported in 79(69.9%) of patients in control group versus 89(78/8%) patients in case group, staying for 2-4 days was reported in 30(26.5%) of control group versus 22(19.5%) in case group, staying for more than 4 days was reported in 4(3.5%) of patients in control group versus two patients (1.7%) in case group.

DISCUSSION

Surgical site infection is a major contributor to serious post-operative complications which might lead to increase the risk of mortality; this risk can be reduced by appropriate antibiotic prophylactic use. Adherence of general surgeons to SAP guidelines in major aspects of surgical prophylaxis in the current study was assessed by evaluating three major criteria; (type of antibiotic selected, dose and duration of its usage); The overall adherence was found significantly higher among surgeons who were reminded about protocol of prophylactic antibiotics before surgery (case group) when compared to surgeon who didn't received the protocol (control group) with rates of (56.7% vs. 43.6% respectively, $P < 0.0001$). Yet, among case group still number of doctors didn't adhere to the recommended guidelines. Such findings suggest that, sustainable educational sessions to educate or remind health providers about the recommended protocol will significantly improve surgeons' performance. The study of Al-Momany NH, et al reported that, adherence to international guidelines for antimicrobial prophylaxis is far from optimal in QAHI [16]. Other studies were conducted in Iran and Nicaragua, where rates of complete adherence to practice guidelines were 0.3%24 and 7%, 28 respectively[17,18]. Also, Gorecki et al. (1999, United States), van Kasteren et al. (2003, the Netherlands), Lallemand et al. (2002, France), and Voit et al. (2005, United States) found in their studies that overall adherence was achieved in 26%, 28%, 41.1%, and approximately 50% of surgical patients, respectively.[19-20- 21]

Adherence and non-adherence to antibiotic selection, duration and dosing time showed significantly higher regarding occurrence of SSI in the case group (29.5% vs. 20%, 25.3% vs. 30.8% and 26.8% vs. 26.2% respectively), ($P = 0.000$). The study in Palastine reported similar findings showing poor adherence to the three assessed criteria of using prophylactic antibiotics in, their study has illustrated low adherence to appropriate surgical antibiotic prophylaxis in Palestine, with high rate of broad spectrum antibiotic use; long duration and inappropriate time of first dose.[22]

Surgical site infection was found very common among patients in the current study; it was reported with rate of 35.4% among the different procedures conducted. Protocol of prophylactic antibiotics in general surgery procedures revealed a positively significant effect in reducing wound infection when compared to control group (25.7% vs. 44.2% respectively, $P = 0.003$). This significant difference is most probably impacted by adherence to guidelines; This is higher than rates of SSI reported in two Sudanese studies conducted by Ahmed SO, et al and Galal S, et al (12.7% and 8% respectively)[11,12]. Other interventional study conducted

by van Kasteren, et al in Netherland which reported much less rate of SSI, they showed that, the overall SSI rates before and after intervention were 5.4%(95%CI: 4.3–6.5) and 4.6% (95% CI: 3.6–5.4), respectively.[23]

Risk of infection according to type of surgery 14 days postoperatively didn't reveal significant difference, but showed decrease among case group when compared to control group in thyroidectomy, appendectomy, cholecystectomy and hernia (13.6% vs. 18.2%, 10% vs. 21.7%, 17.2% vs. 26.6% and 12.5 vs. 20.0 respectively). The study by Ahmed SO, et al in Sudan reported that, surgical infections among listed operation revealed that thyroidectomy had lowest rate at 3.7% while hernia repair had the highest rates, 15% [12].

Distribution of SSI according to type of surgery revealed more frequent infection among patients of cholecystectomy, hernia and appendectomy (35%, 32.5% and 23.8% respectively). (Table 5). On the other hand, patients who received multiple post-operative doses for more than 24 hours plus extended oral antibiotic reported high rate of infection (56.3%), when compared to those who received multiple post-operative dose less than 24 hours and single pre-operative dose (18.8% and 25.0% respectively). Our findings found - to some extent - in consistent with the study of Galal, Mahadi and Ahmed in Sudan who reported that regardless of type of surgery, patients who received multiple doses of antibiotics for more than 24 hours reported higher risk of SSI (14%), while those who adhered to the recommended regimen reported less rate of SSI (single dose pre-operatively SSI= 1.6%, multiple doses < 2 hours postoperatively SSI = 9.6%) [12].

Non-adherence to the recommended duration of antibiotic use was found very common in the two groups. However, surgeons in control group reported significantly more frequent prescription of multiple post-operative doses after 24 hour (21.2% vs. 18.6% respectively) or extended postoperative dose (38% vs. 18.6%). Expecting nosocomial infection seem to impact doctors and acts as an obstacle against their adherence to the guidelines, and this most probably influenced by the general status of hospitals in Sudan and the high risk of non-sterile environment. The study in Palastine shown by Musmar SMJ and colleagues who observed adherence to duration antibiotics in 3 hospitals and reported rates of (36.6%, 27.4% and 31.5%)[22]. The Turkish study [7] also found that prolonged antibiotics prophylaxis was used in 56.9%, however the US study where protocols are usually followed showed excellent compliance (92.6%) in antibiotic selection.[16,24,25]

Using multiple post-operative doses within less than 24 hours reported that is Statistically significantly (P = 0.000), and better outcome regarding management of SSI (SSI in 25.0%) when compared to other options such as single pre-operative dose, Multiple post-operative doses more than 24 hrs and Extended post-operative dose + oral antibiotic (43.1%, 37.8% and 34.4% respectively). from what is mention before we can observe that, case group tend to prescribe single pre-operative dose or multiple post-operative doses less than 24 hrs (35.4% and 27.4% respectively), which gained less risk of surgical site infection when compared to control group who preferred prescribing an extended post-operative dose + oral antibiotic (38%).

This agrees with the published guidelines of the American Society for Hospital Pharmacist (ASHP), which reported that, antibiotic administration should be discontinued within 24 hours after the end of surgery, to prevent emergence of resistance.[14]

Some patients in the control and case groups have infection before the procedure operation before the procedure mostly more than two weeks, which were reported in (37.5% and 22.1% respectively). In rational antibiotics used led to increase SSI and increased antibiotics resistant.

Long hospital stay is considered in studies as one of the main risks of developing of nosocomial infections.[26,27] Studies agree that, hospital-acquired infections (HAIs) are associated with length of stay in the hospital [28,29]. Also study by Choudhuri AH, et al reported nosocomial infection in 58.86% of cases admitted to ICU, and the risk of infection found significantly associated with prolonged stays.[30]

Table (1): Frequency distributions of respondents according to adherence and non-adherence with Antibiotic selection & Dosing time &duration of antibiotic use.

	Group		Total	P value
	Case Group	Control Group		
Antibiotic selection				
Adhered	78(69.0%)	59(52.2%)	137(100%)	< 0.0001
Not adhered	35(31.0%)	54(47.8%)	89(100%)	
Dosing time				
Adhered	87 (77.0%)	75(66.4%)	162(100%)	< 0.0001
Not adhered	26(23.0%)	38(33.6%)	64(100%)	
duration of antibiotic use				
Adhered	71(62.8%)	46(44.2%)	117 (100%)	< 0.0001
Not adhered	42(37.2%)	67 (55.8%)	109 (100%)	

Table (2): Frequency distributions of respondents according to Wound follow up 14 day.

Wound follow up D14	Control group Frequency	Case group Frequency	P value
Clean	63(55.8%)	83(73.5%)	0.003
Infected	50(44.2%)	30(26.5%)	
Total	113(100.0%)	113(100.0%)	

Table (3): Correlation between type of surgery and risk of SSI in case and control groups.

Type of surgery	Infection		Total Infection	P value
	Control group	Case Group		
Hernia (N=80)	16(20%)	10(12.5%)	26(32.5%)	
Thyroidectomy (N = 22)	4(18.2%)	3(13.6%)	7(31.8%)	0.434
Apendectomy (N = 60)	13 (21.7%)	6(10%)	19(31.7%)	
Cholecystectomy (64)	17(26.6%)	11 (17.2%)	28(43.8%)	

Table (4): Frequency distribution of respondents according to SAP duration of antibiotic regimen used.

SAP regimen used	Control group	Case group
	Frequency	Frequency
Single pre-operative dose	25(22.1%)	40(35.4%)
Multiple post-operative doses less than 24 hrs	21(18.5%)	31(27.4%)
Multiple post-operative doses more than 24 hrs	24(21.2%)	21(18.6%)
Extended post-operative dose + oral antibiotic	43(38.1%)	21(18.6%)
Total	113(100.0%)	113(2100.0%)

Table (5): Distribution of surgical site infection according to type of surgery and regimen of prophylactic antibiotics.

Type of surgery		Single pre-operative dose	Multiple post-operative < 24 hrs	Multiple post-operative doses > 24 hrs + Extended oral antibiotic	Total	P value
Hernia	**N**	27(33.8%)	18(22.5)	35 (43.8 %)	**80(35.4%)**	0.000
	SSI	5 (19.2%)	8 (30.8 %)	13 (50.0%)	**26(32.5%)**	
Thyroidectomy	**N**	10(45.5%)	5(22.7%)	7 (31.8%)	**22 (9.7%)**	0.049
	SSI	3 (42.9 %)	0 (00.0)	4 (57.15%)	**7 (8.8%)**	
Appendectomy	**N**	14(23.3 %)	20(33.3 %)	26 (43.3%)	**60(26.5%)**	0.047
	SSI	6 (31.6 %)	2 (10.5 %)	11(57.9%)	**19(23.8%)**	
Cholecystectomy	**N**	13(20.3%)	14(21.9%)	37 (57.8 %)	**64(28.3%)**	0.000
	SSI	6(21.4%)	5 (17.9 %)	17(60.7%)	**28(35.0%)**	
Total	**N**	64(28.3 %)	57(25.2%)	105(46.5%)	**226(100%)**	0.062
	SSI	20 (25.0%)	15(18.8%)	45(56.3%)	**80(100%)**	

CONCLUSION

Rate of wound infection of all population in the current study was found very common. However, protocol of prophylactic antibiotics in general surgery procedures revealed a positively significant effect in reducing wound infection when compared to control group. Assessing adherence of general surgeons to surgical antibiotic prophylaxis (SAP) through type of antibiotic selected, dose and duration of its usage was found significantly higher among case group when compared to control group, which suggests the positive effect of protocol.

Recommendations

- There is urgent need for establishing local protocol to prevent surgical site infection so as to be applied in Ibrahim Malik and other Sudanese Governmental Hospitals by participation of relevant professions (e.g. surgeons, clinical pharmacists, anesthetists).
- High competence of health providers in theatre and adherence to basic theatre discipline and measures expected to reduce rate of surgical site infection.
- Correcting the major misconception among surgeons regarding long duration of using antibiotic, its timing and type of prescribed drug.

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