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## Abstract

**Background:** Surgical prophylactic antibiotics (SPA) were proven to reduce surgical site infections, however; non-adherence to SPA guidelines or protocols carries serious risks. Many interventions aiming to improve utilization of SPA were implemented worldwide; some met their goals while others failed.

**Objectives:** To assess the effect of an educational intervention program on the adherence to the hospital SPA protocol at surgical gastrointestinal tract unit, Soba University Hospital, Sudan.

**Method:** Data were collected from the patients' records using well-constructed data collection sheet for 8 weeks. The form contains patient's related data, operation related data and antibiotic related. Then an interventional program was conducted which was composed of a presentation, follow up with doctors and printed documents provided to all unit's doctors. Then, re-collection of data was done for another 8 weeks. The before and after data were compared to the hospital SPA protocol and then the differences between the two results were analyzed using t-test/Wilcoxon test for the numerical data and McNemar/Marginal Homogeneity test for the categorical data.

**Results:** Thirty patients underwent operations before and after the intervention. 23 of them appropriately received pre-operative prophylactic antibiotic/s. The frequency of proper SPA administration time significantly increased from 2 to 21 after the intervention (p < 0.001). The combination of Ciprofloxacin and Metronidazole was the pre-operative choice in 17 operations. After the intervention Cefuroxime alone or in combination with Metronidazole were given to 20 patients (p < 0.001). The median duration of improper post-operative antibiotic prophylaxis significantly decreased from 6 to 2 days after the intervention (p = 0.046). Moreover, four operations that the protocol doesn't provide recommendations for were performed before and after the intervention. The combination of Ciprofloxacin and Metronidazole to 3 and 2 patients before and after the intervention, respectively. The median duration for the post-operative prophylaxis was 5 and 7 days before and after the intervention, respectively.

**Conclusion:** The intervention improved proper administration time of the first SPA dose, changed the type of antibiotic/s used and decreased the improper prophylaxis.

Keywords: Intervention Program; Surgery; Prophylactic Antibiotics; Adherence

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## Introduction

Surgical site infections (SSI's) are considered to be the most frequent type of nosocomial infections in low and middle income countries, affecting one third of patients undergoing surgical procedures [1]. They are associated with a high morbidity and can double hospitalization days, thereby increasing medical cost [2]. Administration of surgical prophylactic antibiotics (SPA) which are given to patients before, during and/or occasionally for a short time after the operation was proven to reduce the risk of SSI's in many operations [3].

Numerous clinical practice guidelines and protocols were developed to regulate the administration of surgical prophylactic antibiotics worldwide [4-6]. Generally, the spectrum of the recommended prophylactic antibiotic covers the most likely encountered pathogen at the operation site while having minimal effect on patients' microbiota [3]. The prophylactic dose is the same one used for therapeutic purposes and it should be given at a time that ensures that the antibiotic's concentration is above the minimum inhibitory concentration when starting the operation [6] and for the whole duration of the surgery and hence a second dose should be given if the surgery lasted for more than two halves of the used antibiotic or if the patient has lost more than 1.5L of blood [6]. For most operations, no further post-operative antibiotic prophylaxis is required and antibiotic administration should be discontinued by the end of the surgery [4,6].

Despite the presence of guidelines and protocols, many studies in Sudan and worldwide have shown that the adherence rate is low [7-10]. This malpractice carries serious risks, such as unnecessary expenses, manipulation of patients' microbiota and emergence of bacterial resistant strains [11]. Thus, many interventions have been conducted around the globe to enhance proper utilization of antibiotics for surgical prophylaxis; some of which did succeed to improve adherence to all aspects of antibiotic prophylaxis, others improved some aspects, namely: drug choice, administration time, dosage or duration of prophylaxis, while others failed to enhance adherence rate [12,13]. This study aimed to conduct an interventional program for doctors to improve their practice toward surgical prophylactic antibiotics.

# **Materials and Methods**

## Design

A pre, post intervention study conducted from January to October 2018. It was conducted through three phases:

- Phase one was situation analysis where the records of all patients admitted in the period of March 27<sup>th</sup> to May 22<sup>nd</sup> were compared to the hospital SPA protocol.
- Phase two was the interventional phase, it took place from July 11<sup>th</sup> to August 8<sup>th</sup>.
- Phase three was re-comparing the data to the hospital protocol, conducted from August 14<sup>th</sup> to October 9<sup>th</sup>.

#### Intervention

The intervention was composed of a meeting with doctors working in the unit in which the results of phase one was presented and then a presentation on SPA was conducted by the clinical pharmacists. The presentation discussed the importance, benefit and risk and the principles of administration of SPA and reviewed the hospital protocol. Minutes of the meeting and the SPA guidelines were distributed to the doctors and then the clinical pharmacists were following up the doctors for 4 weeks.

#### Setting

The study was conducted with the surgical gastrointestinal tract (GIT) unit at Soba University Hospital which is one of the health teaching facilities of the University of Khartoum.

#### **Study population**

All doctors and patients' records that met the following inclusion criteria were included in the study.

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## Inclusion criteria:

- Consultants, registrars and house-officers working at the surgical GIT unit at Soba University Hospital and they were 22 doctors.
- Records of adult patients who underwent elective clean, clean contaminated or contaminated surgeries. Thirty operations were performed in both phases.

#### **Exclusion criteria:**

Patients who underwent surgeries performed by doctors other than those working in the surgical GIT unit at Soba University.

#### **Data collection tool**

The data were collected from the patient's records using a self-constructed data collection sheet that contains patients, operations and antibiotics related data.

#### Statistical analysis

Statistical Package for Social Sciences (SPSS) version 23 was used for data analysis. The distribution of all numerical data was determined using sample Kolmogorov-Smirnov test, and then the difference between the two phases was determined using paired t-test when the data were normally distributed and Wilcoxon test when they weren't normally distributed. The difference of the categorical data was determined by McNemar test when the data were dichotomous and by Marginal Homogeneity test for the rest of the data with more than two variables.

#### **Ethical clearance**

An ethical clearance (FPEC-06-2018) was obtained from the Ethical Committee of the Faculty of Pharmacy, University of Khartoum. Additional approval for checking the medical records was obtained from Soba Teaching Hospital.

#### **Results**

## Characteristics of doctors, patients and operations

The surgical GIT unit at the hospital was composed of 9 consultants, 10 registrars and 3 house-officers.

After excluding three patients from phase three; thirty patients were included in both phases, with 16:14 male/female ratio in phase one and 13:17 male/female ratio in phase three. The mean age of patients in phase one was  $47 \pm 11$  years and  $50 \pm 14$  in phase three. The characters of the performed operations before and after the interventional program are presented in table 1.

Character	Before the intervention	After the intervention		
Site of surgery				
Upper GI	23.3 %	3.3%		
Lower GI	30 %	50%		
Hepatobiliary	33.3 %	26%		
Breast	6.7 %	6.7%		
Others	6.7 %	13.3%		
Wound type				
Clean	16.7 %	20 %		
Clean-contaminated	53.3 %	33.3 %		
Contaminated	30 %	46.7 %		
Median of operations duration	1.75 hour	2 hours		

Table 1: Characteristics of operations before and after the intervention.

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# Antibiotics administration Pre-operative prophylactic antibiotics

Appropriateness of indication of pre-operative SPA for the 30 operations before and after the intervention is presented in table 2.

Indication	Phase one	Phase three
Not recommended and not given	1 patient	0
Not recommended but given	2 patients	3 patients
Recommended and given	23 patients	23 patients
Not specified in the protocol	4 patients	4 patients

For the 23 patients who received SPA where indicated; only two patients received the antibiotic at proper time in phase one compared to 22 patients in phase three, this difference was found to statistically significant with a p < 0.001. One patient received the indicated antibiotic in phase one compared to seven patients in phase three. The pattern of antibiotic prescribing has changed after the intervention as shown in table 3.

Antibiotic/s	Phase one	Phase three
Ciprofloxacin	3	0
Ciprofloxacin and Metronidazole	17	2
Ciprofloxacin, Metronidazole and Ceftriaxone	1	0
Cefuroxime	1	8
Cefuroxime and Metronidazole	1	12
Ceftriaxone and Metronidazole	0	1

**Table 3:** Prescribed antibiotic/s in phase one and three.

## Post-operative prophylactic antibiotics

Appropriateness of indication of post-operative SPA in the 30 operations before and after the intervention is presented in table 4.

Indication	Phase one	Phase three
Not recommended and not given	8 patients	4 patients
Not recommended but given	13 patients	11 patients
Recommended and given	5 patients	11 patients
Not specified in the protocol	4 patients	4 patients

 Table 4: Appropriateness of post-operative SPA indications in phase one and three.

The post-operative antibiotic prophylaxis was prolonged in 4 out of the 5 patients who needed it in phase one, compared to 7 out of the 11 patients in phase three. This change was found to be statistically insignificant. The improper post-operative prophylaxis had decreased after the intervention. The median of phase one was 6 days and that of phase three was 2 days.

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#### Discussion

The benefit of SPA in some clean, clean-contaminated and contaminated surgeries has been established long ago and many guidelines and institutional protocols are available [4-6]; however compliance with these guidelines or protocols is an issue. Many interventions worldwide have been conducted to enhance the proper utilization of SPA [13-17]. The interventions' results are varied. In this study, the appropriateness of indication hasn't significantly changed after the interventional program (Table 2), this is probably because most operations in both phases needed prophylactic antibiotics and patients received the antibiotics.

The timing of the pre-operative antibiotic has significantly changed after the intervention. 21 patients after the intervention received the antibiotic at the correct time, compared to 2 patients only before the intervention. This resulted from the change in prescribing patterns after the intervention (Table 3). The practice of giving the antibiotic with the induction of anesthesia hasn't changed after the intervention, but because Ciprofloxacin that needs to be administered 60 - 120 minutes prior to skin incision was the most commonly used medication for prophylaxis in phase one has been replaced by Cefuroxime which is injected over 3 - 5 minutes.

Although the intervention failed to significantly increase the use of proper choice of pre-operative antibiotic, it changed the prophylactic antibiotic chosen for prophylaxis, Ciprofloxacin and thus reduces the negative consequence of using antibiotics with collateral damage in routine practice [18]. This poor results could be because lower GIT surgeries were the most performed operations in phase three (Table 1), and according to the protocol: patients should receive the combination of Gentamicin and Metronidazole [5], but most of the patients in phase three received the combination of Cefuroxime and Metronidazole, doctors declared their concern about using Gentamicin for prophylaxis in the day of the presentation, but evidently the assurance of the Clinical Pharmacists and the hospital's Microbiology Department that a single dose of Gentamicin wouldn't do any harm to the auditory and nephrology systems of patients didn't convince them and they felt more comfortable replacing it with Cefuroxime. Antibacterial agent therapy is associated with increased bacterial lipopolysaccharides (LPS) and amyloid peptide release from bacteria, thus measuring of plasma levels of LPS and amyloid peptide may evaluate the antimicrobial activity [19,20].

Studies have shown that the false belief that a single pre-operative dose of the antibiotic or a short prophylaxis period wouldn't be enough for preventing SSI in most surgeries exists worldwide, and it results in unnecessary prolongation of antibiotic administration after the end of surgeries [9,21,22]. This malpractice carries serious risks, like unnecessary waste of money, manipulation of the patient's microbiota and emergence of bacterial resistant strains [22,23]. This intervention failed to significantly stop the administration of prophylactic antibiotic after the end of surgeries since 11 patients in phase three received unneeded post-operative antibiotics compared to 13 patients before the intervention. Moreover, for most of the lower GIT surgeries, the protocol recommends administration of two doses of Metronidazole after the end of the surgery [5]. This interventional program failed to stop the unnecessary prolongation of antibiotic administration because some doctors in the unit insisted on giving therapeutic regimens to patients undergoing colorectal surgeries.

The positive side in this study with regard to the post-operative prophylaxis duration is that it reduced the median of improper duration to 2 days compared to 6 days before. The improper duration was calculated by adding the extra prophylaxis days of operations that required post-operative antibiotics to the days where antibiotics were given to patients post-operatively when there was no need for them. On other hand, the protocol doesn't provide recommendations for anal surgeries like hemorrhoidectomy and fissurectomy, but they are performed in the hospital and 4 operations were performed during both phases [5].

## Conclusion

The clinical pharmacist's intervention program lead to improve the adherence of doctors to guidelines, through improvement of proper administration time of the first SPA dose, changing the type of antibiotic/s used and decreasing the improper prophylaxis duration.

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## **Disclosure of Interest**

The authors report no conflicts of interest.

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