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Protocol for Antibiotic Prophylaxis in General Surgery: Influence on Prescribing Patterns

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ABSTRACT

Objective: *The main aim of this prospective study was to identify the influence of introduction of a new protocol for antibiotic prophylaxis in general surgery on prescribing patterns.*

Methods: *A pre-intervention versus post-intervention study was conducted during March-October 2010 and April-June 2011 in the General Surgery Department of Khartoum Teaching Hospital, Sudan. All patients, ages >18 years, admitted for elective surgery were recruited consecutively. Pre-intervention prescriptions were assessed against a set of predetermined international criteria and against a locally developed protocol post- intervention.*

Results: *A total of 681 and 384 patients were recruited in pre- and post- intervention phases respectively. Administration of antibiotics in the operating rooms to patients for whom prophylaxis was recommended declined from 99.3% in the pre-intervention period to 95.3% in the post-intervention one, (P=0.014). The percentage of patients for whom prophylaxis was not recommended and given preoperative antibiotic doses decreased from 95.3% to 31.1%, (P=0.000) before and after the intervention respectively. Significant improvements in adequacy of antibiotic choice, dose accuracy, and percentage of patients who were given prophylaxis as single dose were documented after introduction of the new protocol compared to baseline results; {74.2% to 92.6% ; P=0.000), (68.5% to 91.7% (P=0.000), and (13.3 % to 31.4% ; P= 0.000) respectively}. No significant change was found in the percentage of patients who were given the first preoperative doses in the proper time window in the post-intervention phase 3.3%; compared to 1.9% in the pre-intervention period; (P=0.716). Overall adherence to all aspects of the new protocol was 46.6%, significantly higher than adherence to the predetermined criteria during the pre- intervention phases ;(P<0.001).*

Conclusion: *Significant improvement in several performance measures related to the use of antibiotic prophylaxis was observed following introduction of clinical guidelines in a tertiary care teaching hospital.*

Key wards: *Antibiotic Prophylaxis, Clinical practice guidelines, General surgery, Prescribing patterns.*

INTRODUCTION

The use of antibiotic for prophylaxis is the standard of care for many surgical procedures [1]. Approximately 30-50 % of antibiotics use in hospital practice is for surgical prophylaxis; however between 30-90% of this prophylaxis is inappropriate [2].

Antibiotic prophylaxis in surgery is indicated for clean-contaminated and clean operations that involve insertion of implants [3]. Important performance measures that increase the success of prophylaxis are proper selection of antibiotic, proper timing of administration of the right dose and intra-operative re-dosing of antibiotic when appropriate [4]. Clinical evidence showed that a single dose of antimicrobial with a long enough half-life to achieve activity throughout the operation is adequate for the majority of commonly performed surgical procedures [5-7].

Introduction of clinical practice guidelines for the use of antibiotic in surgical prophylaxis alone or combined with other interventions as documented in many studies improved performance measures related to prescribing patterns [8-11]. On the other hand; measurement of adherence to clinical practice guidelines for the use of antibiotics as prophylactic agents in surgery in many studies conducted in different parts of the world revealed discrepancies [12-14].

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The major objective of this study was to identify the influence of introduction of clinical practice guidelines for antibiotic prophylaxis used for surgical prophylaxis in elective surgery on prescribing patterns.

METHODS

Study design: A pre-intervention versus post-intervention study.

Setting: The study was conducted in the General Surgery Department, Khartoum Teaching Hospital in Sudan. The hospital is currently a thousand bed tertiary referral one. Services cover all the major specialties, including medicine, surgery, obstetrics and gynecology, urology, psychiatry, pediatric surgery, and orthopedics.

Patients:

All adult patients (ages ≥ 18 years) admitted for elective clean and clean- contaminated surgery during March 1st to 31th October 2010 and 1st April to 30th June2011 were recruited. Patients were excluded in the presence of one or more of the following criteria: contaminated or dirty procedure, use of antibiotics for non prophylactic purposes before surgery, and patients who died inside the hospital were deleted after inclusion.

A total of 681 and 384 patients were recruited on a consecutive base during the pre and post-intervention phases respectively.

Data collection:

Data was collected by trained nurses using a pre-coded questionnaire, which was developed by the research team and tested among 25 patients for applicability. Demographic data was obtained directly from the patients, intra-operative data was collected on observational-base, and data on postoperatively prescribed antibiotics was extracted from the patients' hospital files.

The recorded variables included: gender; age in year; dates of admission, surgery and discharge; body mass index; and presence of co-morbidities. The American Society of Anesthesiologists score [15], category and name of operation, surgical technique (conventional or laparoscopic), and wound class were also documented. For patients receiving prophylactic antibiotics in the operating room the following core indicators were registered: antibiotics' generic names, strength of first preoperative doses, and timing of administration of first preoperative doses. Antibiotics' generic names, doses, in addition to duration of prophylaxis were registered for patients who were given antibiotics postoperatively.

Guidelines development and implementation processes:

Guidelines were developed by a multidisciplinary committee consisting of three surgeons, two pharmacists and an infection control physician. The development process involved adoption of the clinical evidences published by Scottish Intercollegiate Network (SIN)/Guidelines for Surgical Prophylaxis - July 2008 [16].

The guidelines were approved by the department in a grand meeting. The summary of the guidelines was distributed in posters in the operating rooms and surgeons' offices (Appendex-1). The dissemination process was accompanied by academic detailing conducted by the principal author. The objective of the detailing process was to provide healthcare providers with evidence –based information on the use and administration of antibiotics in surgical prophylaxis.

Criteria for evaluation of prophylactic antibiotics:

In the pre-intervention phase prescriptions were audited against the predetermined international criteria to evaluate:

- Indications for prophylaxis were considered to be 'recommended' if the indication was 'highly recommended', 'recommended', or 'should be considered' using the SIGN guidelines, and 'not recommended' if it was not.
- Choice of antibiotic with respect to the spectrum of coverage and the bacteria most likely to be encountered at the specific surgical site: 'narrow' - did not cover the anticipated range of bacteria; 'adequate' - covered the anticipated bacteria; 'broad' or 'unnecessary combination' - covered more bacteria than anticipated [3].
- Time of administration of the first preoperative dose/s: 'too early' - if given > 1 hour before incision was made; 'proper' - if given within 30–60 minutes before incision [17]; 'late' - if given between 0–29 min before the incision; and 'too late'- if given after the incision was made).
- Accuracy of first preoperative doses was based on concentration used for surgical prophylaxis purposes in clinical trials for each antibiotic.
- Duration of prophylaxis: 'appropriate' - if given as one preoperative dose, and 'inappropriate' - if extended postoperatively [5, 7].

In the post-intervention phase the above mentioned parameters were assessed against the new protocol. If more than one drug was prescribed for a single operation, all the parameters for each drug were evaluated separately. If an antibiotic was given when it was not indicated, the parameters were not evaluated. Finally, the prescription was considered 'concordant' if it satisfied the above mentioned criteria for every drug prescribed. If there was any divergence from the criteria for any of the antibiotics, the prescription was considered 'discordant'. If data on a certain parameter on the antibiotic prescription were lacking, they were classified as missing data for only that parameter. For patients who developed a wound infection during admission, only antibiotics prescribed prior to the onset of infection were registered; this was done to differentiate between prophylactic and treatment courses.

Statistical analysis:

Frequencies and proportions/ percentages were used to describe all variables. Differences in proportions between the evaluated parameters of prophylactic antibiotics and overall adherence before and after the intervention were assessed by using chi-square tests or Fisher exact tests. All statistical tests were conducted at an a priori significance level of P<0.05 using Stata version 12 [18].

RESULTS

Patients and procedures characteristics:

A total of 681 and 384 patients were recruited in the pre and the post-intervention phases respectively. Females were the majority in the pre-intervention and post-intervention phases 513(75.3%) and 273(71.1%) respectively. Healthy patients were 491(72.1%) in the pre-intervention and 289(75.3%) in the post-intervention phase. Demographic characteristics of the patients recruited in both phases of the study are presented in **Table 1**.

The total number of the performed surgical operations was 688 and 385 in the pre and post-intervention phases respectively. Before the intervention clean procedures were done for 477(70%) patients and the clean –contaminated for 204(30%). After intervention clean procedures were done for 283(73.7%) patients, while clean contaminated cases were 101 (26.3%). The majority of the performed procedures were done conventionally for 656(96.2%) in the pre-intervention phase and 377(98.2%) post-intervention p. **Table 2** shows the categories of the performed surgical procedures in both phases of the study.

Prophylactic Antibiotics:

In the pre-intervention phase 661(96.9%) of the patients were given preoperative antibiotic in the operating rooms. Cefuroxime was the prophylactic agent of choice; it was administered intravenously to 625 (94.5%). Patients operated on after implementation of the new protocol and given preoperative antibiotic in the operating rooms were 201(52.3 %); of these 137 (68.2%) were given co-amoxiclav intravenously.

Evaluation of prescriptions against the stated criteria and the new protocol showed that; administration of antibiotic/s in the operating rooms for patients for whom prophylaxis was recommended declined from 99.3% in the pre-intervention period to 95.3% in the post-intervention phase, (Fischer's Exact Test; *P*= 0.014). The percentage of patients for whom prophylaxis was not recommended and given preoperative dose/s was decreased from 95.3% in the pre-intervention phase to 31.1% after implementation of the new protocol, (*P*=0.000).

The percentage of patients given antibiotics with adequate spectrum of activity increased from 74.2% in the pre-intervention period to 92.6% in the post-intervention period; (*P*=0.000). The percentage of patients who were given proper first preoperative dose/s in the pre-intervention was 68.5%. This percentage increased to 91.7% in the post-intervention phase, (P=0.000). No significant change was observed in the percentage of patients regarding the timing of administration of preoperative dose/s in the proper time window. It was 1.9% in the pre-intervention phase and 3.3. % in the post-intervention phase; (*P*= 0.716). The percentage of patients who were given prophylaxis as single dose in the post-intervention phase was 31.4% compared to 13.3 % in the pre-intervention phase; (*P*= 0.000). **Table 3** shows an evaluation of the antibiotic prescription parameters in the pre and post-interventions periods.

The percentages of postoperatively prescribed cefuroxime, amoxicillin +clavulanic acid, and cefriaxone decreased in the post-intervention phase compared to the percentages in the pre-intervention as follow: (54.6%-33%; *P*= 0.000), (41.4%-14.3%; *P*= 0.000), and (19.7-3.1%; *P*= 0.000) respectively. Table (4) shows antibiotics prescribed postoperatively before and after the intervention.

Assessment of prescriptions in the pre-intervention phase showed that only 19(2.8%) of the audited prescriptions were found to be complying with the stated criteria. In contrast; 178(46.4%) of the audited prescriptions post-intervention were found to be conformed to the new protocol; (*P*= 0.000). In the post-intervention phase; healthcare providers completely adhered to the new protocol in 172(60.8%) of the prescriptions issued for clean cases; compared to only 6(5.9%) of the prescriptions prescribed for clean-contaminated procedures.

Table No. 1: Patients' demographic characteristics in pre-intervention and post-intervention phases

Background variable	Pre-intervention 'n' (%)	Post-intervention 'n' (%)	*P* value
Gender			0.142
Male	168 (24.7)	111 (28.9)	
Female	513 (75.3)	273 (71.1)	

Age /years			0.508
<50	466 (68.4)	271 (70.6)	
≥50	215 (31.6)	113 (29.4)	
Body mass index/ kg/m²			0.000
	92 (13.5)	88 (22.9)	
<20	317 (46.5)	127 (33.1)	
20-<25	202 (29.7)	122 (31.8)	
25-<30	70 (10.3)	47 (12.2)	
≥30			
Co morbidity			0.043
Yes	107 (15.7)	43 (11.2)	
No	574 (84.3)	341 (88.8)	
Diabetic			0.223
Yes	40 (5.9)	16 (4.2)	
No	641 (94.1)	368 (95.8)	
ASA score			0.422
1	491 (72.1)	289 (75.3)	
2	110 (16.1)	58 (15.1)	
3	77 (11.3)	37 (9.6)	
4	3 (0.5)	0 (0.0)	
Total	681 (100)	384(100)	

Table No. 2: Surgical procedures performed in pre- intervention and post-intervention phases

Category of surgical procedure	*Pre-intervention* 'n' *(%)*	*Post-intervention* 'n' *(%)*
Neck surgery	203 (29.5)	106 (27.5)
Cholecystectomy	143 (20.8)	70 (18.2)
Mastectomy	128 (18.6)	71 (18.7)
Hernia repair	91 (13.2)	68 (17.4)
Laprotomy	25 (3.6)	5 (1.3)
Thoracic surgery	11 (1.6)	8 (2.1)
Vascular surgery	10 (1.5)	7 (1.8)
Appendectomy	10 (1.5)	8(2.1)
Gastric surgery	10 (1.5)	-
Splenectomy	9 (1.3)	7 (1.8)
Colon surgery	5 (0.7)	-
Small bowel surgery	4 (0.6)	1 (0.3)
Oesophageal surgery	3 (0.4)	3(0.8)
Liver surgery	1 (0.1)	-
Others	35 (5.1)	24 (6.2)
Total	688	385

Table No. 3: Evaluation of prescriptions parameters in pre-intervention and post-intervention phases

Parameter	Pre-intervention 'n' (%)	Post- intervention 'n' %	*P value*
Choice of antibiotic/s:			
Narrow	38 (14.0)	5 (4.1)	0.000
Adequate	201 (74.2)	112 (92.6)	
Broad	32 (11.8)	4 (3.3)	
Accuracy of first preoperative dose/s:*			
Accurate			
Sub-dose	185 (68.3)	111 (91.7)	0.000
Missing	85 (31.4)	10 (8.3)	
	1(0.3)		
Timing of first preoperative dose:			
Early	1 (0.3)	- -	0.716
Proper	5 (1.9)	4 (3.3)	
Late	230 (84.9)	100 (82.7)	
Too late	35 (12.9)	17 (14.0)	
Duration of prophylaxis:			
Single dose	36 (13.3)	38 (31.4)	0.000
Extended duration	235 (86.7)	83 (68.6)	
Total	271(100)	121(100)	

Table No. 4: Antibiotics prescribed postoperatively in pre- intervention and post-intervention phases

Antibiotic	Pre-intervention 'n' (%)	Post-intervention 'n' (%)	*P value*
Cefuroxime	373 (54.6)	127 (33.0)	0.000
Co-amoxiclav	282 (41.4)	55 (14.3)	0.000
Ceftriaxone	134 (19.7)	12 (3.1)	0.000
Mertonidazole	167 (24.5)	63 (16.4)	-
Cefpodoxime	59 (8.7)	2(0.5)	-
Ceftizoxime 1g	6 (0.9)	-	-
Ciprofloxacin oral	4(0.6)	-	-
Benzyl penicillin	4(0.6)	-	-

Others	6(0.9)	3(0.8)	-

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Table No. 5: Policy for antimicrobial prophylaxis for elective clean and clean contaminated surgery

Procedure	Antibiotic(s)
Clean, benign neck surgery	None required
Clean , malignant neck surgery	Co- amoxiclav1.2g
Breast cancer surgery	Co- amoxiclav1.2g
Gastric-esophageal Surgery	Co- amoxiclav1.2g **or** Cefuroxime 1.5g**+** metronidazole 500mg
Small bowel resection	Co- amoxiclav1.2g **or** Cefuroxime 1.5g
Colorectal surgery	Co- amoxiclav1.2g **or** Cefuroxime 1.5g+ metronidazole 500mg
Biliary tract surgery	Co- amoxiclav1.2g **or** Cefuroxime 1.5g
Appendicectomy	Co- amoxiclav1.2g **or** Cefuroxime 1.5g**+** metronidazole 500mg
Hernia repair with mesh	Co- amoxiclav1.2g
Hernia repair without mesh	None required
Vascular surgery	Co- amoxiclav1.2g **or** Cefuroxime 1.5g
Urological procedures	Cefuroxime 1.5g
Clean scrotal /genital surgery	None required

- First dose/s should be administered in a time window **30-60 min** before skin incision.
- For prophylaxis **one** preoperative dose is sufficient in most cases. **No need for continuing oral antibiotics postoperatively**.
- Give a second **intra-operative** dose for operations lasting longer than **3 hours** (This does not include gentamicin) or in case of major blood loss more than **1.5** liters.
- **1-3 doses** may be given in gastric-esophageal and colorectal surgery depending on the degree of contamination.
- The finding of **pus or a perforated** viscus at surgery implies that infection was present before surgery and warrants **a course of treatment**, not prophylaxis.
- If first line antibiotics is contraindicated give gentamicin (+ metronidazole 500mg) when indicated.
- Gentamicin dose = **1.5mg /kg** body weight; given over 3-5 minutes.

DISCUSSION

The ultimate purpose of clinical practice guidelines is to improve the quality of patient care by implementation of evidence – based care in daily practice [19]. The main aim of this study was to identify the influence of clinical guidelines on prescribing patterns of antibiotics used for surgical prophylaxis in general surgery.

The results of this study showed a significant reduction in administration of preoperative prophylaxis in the operating rooms to patients for whom it was not recommended. In this respect; for a large number of procedures like benign neck surgeries, hernia repairs, and benign breast operations prescribers adhered fully to the guidelines. The observed adherence may be attributed to the fact that most of the prescribers knew that bacterial contamination is less likely to happen in such surgical sites.

In present study; introduction of guidelines improved the appropriate choice of preoperative antibiotics administered in the operating room from 74.2 to 92.6%. Improvement of performance in this parameter may be highly attributed to the extensive detailing provided to healthcare providers in the operating complex. In contrast Disseldorp *et al.* [20] had observed that antibiotic choice was not concordant with the guidelines in 69% of the prescriptions analyzed.

The results of the current study showed a decrease in the percentage of the prescribed third generation cephalosporin. In contrast Zhang and Harvey [21] after introducing treatment guidelines and educational intervention observed no improvement in the inappropriate choice of unnecessary broad- spectrum and expensive drugs.

Introduction of the new protocol did not produce significant improvement in administration of first preoperative doses in the proper time window. This was expected because; no change was made in the organizational processes in the operating complex. In contrast to our result; Forbes *et al.* [22] reported improvement in timing of preoperative antibiotic dose from 5.9% to 97%.

In the post-intervention phase of this study and for two third of patients for whom prophylaxis was recommended; the duration was extended beyond single dose. In contrast to our findings; Tourmosusoglou *et al* [23] observed optimal duration of prophylaxis for 36.3% of the studied cases. Prolonged use of prophylactic antimicrobials has been associated with the emergence of resistant bacterial strains [24] and excess use of antimicrobial can contribute to secondary infections such as those caused by *Clostridium difficile* [25].

Generally the improvements observed in some performance indicators related to antibiotic use after implementation of the new protocol may be attributed to many factors. The recommendations were adapted from international guidelines; this increased healthcare providers commitment. The participation of the surgeons in the development of the guidelines created a sense of ownership. The guidelines were simple so it improved the selection and proper dosing of prophylactic agents. In addition; the strong desire of some surgeons to change the practice encouraged other healthcare providers to adhere to the protocol.

Non adherence to the protocol in some performance measures may be attributed to many reasons. Despite the fact that the protocol was approved in a grand meeting full agreement with the protocol was not reached. Another important factor was registrars' rotation between hospitals. Each rotation was accompanied by deviations from the protocol norms until the new member was informed about the new policy.

The principal finding of this study was that 46.4% of the analyzed prescriptions were found to conforming to the new protocol. In contrast this percentage was lower than what was observed by Alerany *et al.* [26] (94.9%) and higher than the reported by Van Kasteren *et al*. [13] (28%) and Tourmosusoglou *et al.* [23] (36.3%).

This study had some limitations; absence of a control group may decrease the strength of the study. In addition; patients who might be at high risk of developing postoperative infection were not considered specifically. The parameters of antibiotic prophylaxis in these cases were evaluated strictly according to what was stated in the guidelines without clinical feedback. Another deficit is that in some cases the postoperatively prescribed antibiotics were not documented in either patients' hospital files or discharge cards so this data may not be available for registration.

CONCLUSIONS

Significant improvements in several performance measures related to the use of antibiotic for surgical prophylaxis were observed following introduction of clinical practice guidelines in a tertiary care teaching hospital. These included a marked reduction in both administrations of antibiotics in the operating rooms and in postoperative period. In addition; significant improvements in adequacy of antibiotic choice, accuracy of first preoperative dose/s, duration of prophylaxis, together with overall adherence to the protocol were documented.

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