EVALUATION OF ANTIMICROBIAL PROPHYLAXIS USAGE IN THE SURGICAL PROCEDURES

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ABSTRACT

Surgical site infections (SSIs) are the most common postoperative complications and represent a significant burden in terms of patient morbidity, mortality, and health costs. Choice of regimen, time of administration, and duration of antibiotic prophylaxis were inappropriate in 25-50% of cases from previous studies. Therefore, the main aim is to evaluate the appropriateness of antimicrobial prophylaxis use in surgery at the Misurata Central Hospital (MCH). The study included 247 surgical inpatients of any age, who were admitted and discharged from surgical departments: gyneocology and obstetrics, orthopedics, and general surgery in the Misurata Central Hospital (MCH) over a period of six months from (1st January to 30th June 2016). The total of 247 patients underwent surgery and administered antimicrobial prophylaxis in the perioperative period. Appropriateness of antimicrobial prophylaxis was evaluated according to published guidelines of the American Society of Health-System Pharmacists (ASHP) for every aspect of antibiotic prophylaxis. All data were coded and analyzed using statistical software (Stat View version 5.1). The study showed 94.3% of prescribed and administered prophylactic antibiotics were in accordance with the American Society of Health-System Pharmacists (ASHP) guidelines regarding prophylaxis indication. The total compliance for the studied parameters was (3.2%), only (10.5%) had appropriate antibiotic selection, and (50.6%) of patients received antibiotic in appropriate duration. The general surgery department had higher total adherence to the ASHP guidelines (P=0.006). The gyneocology department had much compliance regarding duration of antibiotic use (P = 0.00001); however, general surgery had higher proper antibiotic selection (P = 0.0001). A lack of concordance between the use of antimicrobial prophylaxis and prescribing guidelines was identified in this study at the MCH.

KEY WORDS: Adherence, Antibiotic prophylaxis, Guidelines, Surgery.

INTRODUCTION

Surgical site infections (SSIs) are the most common nosocomial infections among surgical patients⁽¹⁻³⁾. They represent 14-16% of hospital-acquired infections⁽³⁾, up to 2% to 5% of patients undergoing clean extra abdominal operations and up to 20% of patients undergoing intra-abdominal operations^(4,5). They associated with increased healthcare cost, use of antimicrobial agents, prolonged hospitalization, permanent disability or mortality^{(1)(3,6)}. Mortality rates are 2-3 times higher in patients in whom SSIs develop compared with un-infected patients⁽⁷⁾.

The risk of SSIs depends on patient-related factors such as age, nutritional status and co-existing infection and surgical factors, such as duration of surgery and class of wound (clean, clean-contaminated, contaminated, and dirty-infected)⁽⁷⁾. Consequently, the basic principle of Surgical Antimicrobial Prophylaxis (SAP) use is to achieve adequate serum and tissue drug levels that exceed the total duration of operation, and prevent the occurrence of surgical site infections^(7,8). In addition, the efficacy of surgical antimicrobial prophylaxis depends on several factors, including selection of appropriate antibiotic, timing of administration, dosage, duration, and route of administration⁽¹⁾. Furthermore, adequate use of preoperative antibiotic prophylaxis can reduce the rate of SSI in up to $50\%^{(2)}$.

Because, there was a wide variation of overall compliance towards surgical antimicrobial prophylaxis

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(SAP) guidelines ranging from 0 to 71.9% from previous studies⁽¹⁾. The American Society of Health System Pharmacists (ASHP) has developed therapeutic guidelines on antimicrobial prophylaxis in surgery⁽⁹⁾. According to the ASHP guidelines, antibiotic should be administered within 1 hour before incision to achieve prophylactic level during surgery and optimize efficacy⁽⁹⁾. For vancomycin, the infusion should begin within two hours before incision, and doses should be repeated during operation if the operation is still in progress two half-lives after the first dose⁽⁹⁾. Antibiotic administration should be discontinued within 24 hours after the end of surgery to prevent emergence of resistance⁽⁹⁾. Finally, inexpensive, non-toxic, and narrow spectrum antibiotic should be used; therefore, intravenous (I.V) cefazolin is recommended for the most of surgical procedures at recommended dose 2gm for patients < 120 gm and 3gm for \geq 120kg (9). Cefoxitin is recommended for appendicectomy and colorectal procedures and vancomycin is reserved for patients with beta lactam allergy⁽⁹⁾.

Therefore, the main aim of this study was to determine retrospectively the appropriateness of antimicrobial prophylaxis use in surgery at the Misurata Central Hospital (MCH) through assessing adherence to the American Society of Health-System Pharmacists (ASHP) therapeutic guidelines.

MATERIALS AND METHODS

Study design and setting:

This was a clinical type, conducted as a descriptive, retrospective study in the largest referral and teaching hospital in Misurata, which is the Misurata Central Hospital (MCH) over a period of six months from 1st January through 30th June 2016. The study

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involved the surgical patients who were admitted to three surgical departments, gyneocology and obstetrics, general surgery and orthpaedic department.

Selection of patients:

The study was carried out on surgical inpatients of any age who discharged from the MCH over a period of study. The design of the study included 247 patients in total who were consecutively selected from the total surgical list. There was no restriction to type of surgery, or whether procedures were open or laparoscopic, elective or urgent, and clean or clean contaminated. The total 247 patients underwent surgery and received preoperative antibiotics were compared with the published therapeutic guidelines of the ASHP 2013⁽⁹⁾.

Inclusion and exclusion criteria:

Any patient underwent surgery and received surgical antimicrobial prophylaxis for clean surgery which is operative procedure does not enter into a normally colonized viscus or lumen of the body⁽¹⁰⁾ or clean contaminated surgery in which the operative procedure enters into colonized viscus or cavity of the body, but under elective and controlled circumstances⁽¹⁰⁾ in the study period was included in study. Patients who received antibiotics to treat infection prior to surgery were excluded, as were patients for whom it was not possible to determine whether antibiotic was given as treatment or prophylaxis. In addition, contaminated and dirty surgeries were excluded because antibiotics would be routinely administered as therapeutic intervention. Furthermore, complicated appendicitis such as perforated or gangrenous was also excluded.

Data collection:

Data were collected directly from medical files of patients and entered on data collection form. The data included patient demographics, Type of surgery, and antibiotic therapy received such as type of antibiotic, dose, and dose interval, route of administration, initiation time, and duration of prophylaxis. Compliance with recommendations of the ASHP therapeutic guidelines was assessed for every aspect of antibiotic prophylaxis.

Statistical analysis:

All variables were entered and analyzed by using statistical software (Stat View version 5.1). The results were presented as mean \pm standard deviation and percent (%) where applicable. Comparison of qualitative data was performed by Chi-square test. Assessment of surgeon adherence to the ASHP guidelines (compliance versus noncompliance) was performed. A significant difference was considered when the P value was less than 0.05.

RESULTS

A total of 247 (17 male & 230 female) patients were included in the study. Mean age of patients was 31.8 \pm 14.4 years. The great majority (60.7%) of patients had an elective procedure while (39.3%) were operated on an emergency basis. Most patients were admitted under General surgery department (45.3%).

Caesarean section was the most frequent surgical procedure performed (40.5%). (Table 1) shows the demographic data of patients and distribution of procedures according to surgical specialty.

prophylactic antibiotics	(Table 1) Characteristi	cs of the	surgical	patients	received
	prophylactic antibiotics				

Characteristics		Value (%)
Age (years)	Mean Range	31.8 ±14.4 3-89
Gender	Male Female	17 (7) 230 (93)
Length of hospital stay (Days)	Mean Range	2.9 0-23
Surgical wards	General surgery	(45.3)112
	Gyneocology and obstetric	(40.5)100
	Orthopaedic	(14.2)35
Operation types	Cesarean section	(40.5)100
	Cholecystectomy	(30.4)75
	Appendicectomy	(12.6)31
	Fracture reduction and fixation	(10.9)27
	Herniotomy (herni- orrhaphy)	(2.1)6
	Others	(3.1)8
Electivity of surgical	Elective	150 (60.7)
operation	Emergent	97 (39.3)
Wound class	Clean	14 (6)
	Clean contaminated	233 (94)
Surgery type	Open	173 (70)
	Laparoscopic	74 (30)

According to the ASHP guidelines, prophylactic antimicrobials were indicated and administered in (94.3%) of all cases; however, were administered inappropriately in (5.6%) patients such as herniorrhaphy and clean operations involved hand. A total number of 455 antibiotics were prescribed and administered in the current study. The most commonly prescribed and administered antibiotic was ceftriaxone (89.4%) followed by metronidazole (71.6%) and co-amoxiclav (Amoxicillin + clavulanic acid) (19%). Ceftriaxone was appropriate in 26 of 247 evaluated surgical procedures (10.5%) and the dose and dosing interval were appropriate.

In addition, metronidazole and co-amoxiclav were the most antibiotics frequently used inappropriately. Furthermore, 202 patients for whom a single antibiotic was indicated, 150 (74.2%) received two or three antibiotics.

(Table 2) shown surgical prophylactic antibiotics used in three wards. Regarding the duration of prophylaxis in current study, it was consistent with the ASHP recommendation for 125 (50.6%). In 94 (38%) procedures, duration was more than 24 hours, and mean duration of prophylaxis was $4.5 \pm \text{days}$. In

14 (6%) procedures, the duration of prophylaxis was less than 24 hours.

(Table	e 2)	Antimic	crobials	used	in	different	wards	for	sur-
gical p	rop	hylaxis ((n=247)						

Type of antibiotic		Surgical wards			Rate of compliance	
		Gyneocology and obstetric	General	Total	With ASHP guidelines (%)	
Single						
Ceftriaxone	30	0	29	59	10.5	
Co-amoxiclav	0	0	4	4	0	
Two drug combinations						
Ceftriaxone+Metronidazole	0	59	73	132	0	
Co-amoxiclav+ Metronidazole	0	18	2	20	0	
Ceftriaxone+Cloxacillin	5	0	0	5	0	
Cefotaxime+Metronidazole	0	2	0	2	0	
Ceftriaxone+Coamoxiclav	0	0	1	1	0	
Three drug combinations						
Ceftriaxone+Metronidazole + Co-amoxiclav	0	21	2	23	0	
Ceftriaxone+Metronidazole + Gentamicin	0	0	1	1	0	
Total	35	100	112	247	10.5	

The overall rate of compliance with the ASHP guidelines was (3.2%) and the remaining (96.7%) of cases did not comply as in (table 3).

(**Table 3**) The percentage of compliance with the ASHP therapeutic guidelines of antibiotic prophylaxis in surgery in study

Variable	No (%)
Appropriate indicatio	233 (94.3)
Appropriate antibiotic choice	26 (10.5)
Appropriate antibiotic dose and	43 (17.4)
dose interval	
Appropriate duration of	125 (50.6)
prophylaxis	
Overall compliance	8 (3.2)

The main reasons for noncompliance with the ASHP guidelines were inappropriate selection of antibiotics (89.4%), inappropriate dosing (83%), inappropriate duration of prophylaxis either prolonged duration (38%), or too short duration (6%) and improper indication (5.7%). Regarding surgeons adherence to the ASHP guidelines, there was statistical difference in the compliance rate between three different surgical specialties (P = 0.006). In addition, the gynaecology and obstetric department had higher compliance regarding duration of antibiotic use (P = 0.00001); however, the general surgery department had much proper antibiotic selection and dosing (P =0.00001). There was no statistical difference in the adherence to the ASHP guidelines between clean and clean contaminated surgeries (P = 0.48). Furthermore, the compliance rate was significantly higher for elective and laparoscopic procedures (P =0.02, 0.00001) respectively as in (table 4, 5).

(**Table 4**) Assessment of surgeon's adherence to antibiotic prophylaxis guidelines

	Compliance (%)	Noncompliance (%)	P value
Wound class			0.48
Clean	0	14 (6)	
Clean contaminated	8 (100)	225 (94)	
Surgical proce-			0.006*
dures			
General surgery	8 (100)	104 (43.5)	
Gynecology surgery	0	100 (41.8)	
Orthopaedic sur-	0	35 (14.6)	
gery			
Electivity of surgi			0.02*
cal procedure			
Elective	8 (100)	142 (59.4)	
Urgent	0	97 (40.5)	
Surgery type			0.00001*
Open	0	173 (72.4)	
Laparoscopic	8(100)	66 (27.6)	

P value* (P < 0.05): indicates the difference is statistically significant

(Table 5) Compliance with	th antibiotic	prophylaxis	accord-
ing to surgical department			

	Compliance	Noncompliance	P value
	(%)	(%)	1 value
Appropriate dura			0.00001*
tion of prophylaxis			
General surgery	41 (32.8)	71 (58.2)	
Gyneocology sur-	74 (59.2)	26 (21.3)	
gery			
Orthopaedic surgery	10 (8)	25 (20.4)	
Appropriate antibi			0.00001*
otic selection			
General surgery	26 (100)	86(38.9)	
Gyneocology sur-	0	100 (45.2)	
gery			
Orthopaedic surgery	0	35 (15.8)	
Appropriate dos-			0.00001*
ing			
General surgery	27 (62.7)	85(41.6)	
Gynecology surgery	0	100 (49)	
Orthopaedic surgery	16 (37.2)	19 (9.3)	

P value* (P < 0.05): indicates the difference is statistically significant.

DISCUSSION

This study reports adherence to ASHP surgical antibiotic prophylaxis guidelines at three surgical departments in the MCH. The results can provide evidence for recommendations that may help to improve health care. In current study, adherence to ASHP guidelines was very low (only eight cases). Low adherence was also shared by other studies; for example, The Iranian study found only three surgical procedures of the 1000 patients were adherent to all parameter of prophylaxis guidelines with varying degrees of compliance in different parameters⁽¹¹⁾. In addition, the commonest reasons for noncompliance were inappropriate antibiotic selection (89.4%). The third generation cephalosporins were reported as the first used regimen in this study and this finding was similar to study via Aljarari and Pella (2013)^(3,5). Broad spectrum antibiotics for surgical prophylaxis were recommended mainly for severe infection or in acute infection while waiting for the results of cultures⁽¹⁰⁾ and excessive use of broad spectrum antibiotics increase risk for resistance, adverse effects and healthcare $cost^{(12)}$. The main reason could being easy availability of drug in the hospital pharmacy according to Aljarari and Pella (2013)⁽³⁾.

The second reason for noncompliance was prolonged duration of prophylaxis in this study. Extended prophylaxis had been shown no benefit and is potentially harmful due to the development of drug toxicity, superinfection, and bacterial resistance⁽¹²⁾. The adherence rate was similar between clean and clean contaminated surgery (P = 0.48) in this study. This finding was different from previous studies; as compliance rate was significantly higher for clean surgery than clean contaminated surgeries^(10,12). The general surgery department had higher adherence to the ASHP therapeutic guidelines (P = 0.06). In addition, general surgery department showed a better adherence in selection of antibiotics (P = 0.00001), however; the gynaecology and obstetric department had higher compliance regarding duration of antibiotic use (P = 0.00001). This finding was similar to studies conducted in and Turkey and Palstine in 2003, 2014 respectively^(7,13).

The limitations of the current study include the involvement of small number of patients which did not give complete overview of the compliance rate among the different departments. Moreover, the current study did not analyze one important element of surgical antibiotic prophylaxis the timing of antibiotic administration before incision due to lack of data. However, this is not crucial in the results as being noncompliant with one element of the prophylaxis is considered as a guidelines deviation.

CONCLUSION

The study highlighted limitations in prescription of prophylactic antimicrobial agents in surgical procedures according to the published therapeutic guidelines, as defined by the ASHP guidelines. Surgical prophylaxis was inappropriate in terms choice of antimicrobial agent, prolonged duration of prophylaxis following surgery. Interventions are warranted to promote the development, dissemination and adoption of evidence-based guidelines for antimicrobial prophylaxis.

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