Original Article

Use of Prophylactic Antibiotics in Clean Surgical Operations: A Clinical Trail in Ibn-Sina Teaching Hospital in Mukalla, Yemen

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Summary:

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This is a randomized controlled clinical trial carried out to assess the necessity of the use of prophylactic antibiotics for clean surgical operations in the surgical wards of Ibn-Sina teaching hospital during the period from December 2002 to April 2003. A total of 80 patients with clean surgical operations and eligible for the study were randomly allocated to either treatment or control group (40 patients in each group).

Only 7.5% of patients who were not given antibiotics postoperatively developed wound infection while none of the control group, without statistical significance (P>0.05). Neither age nor sex have statistical significant association (P>0.05). All the surgical wound infections were observed in patients were operated for inguinal hernia.

The study concluded that use of postoperative prophylactic antibiotic is not necessary for wound healing in case of clean surgical operations except for hernia operations.

Key Words: Antibiotic use, Surgerical operation, Hadhramout.

Introduction:

Nosocomial infection is any infection which is not present or incubating at the time of admission, or an infection which is acquired in the hospital and become evident after discharge from hospital. Surgical infections is the most frequent nosocomial infections with a global cumulative incidence of 7.7% ranging from 3.4% for clean surgery to 23.7% for dirty surgery[1].

Clean surgical operations are those in which only preoperative sterile tissues are handled after the skin is incised. Factors that contribute to the development of surgical site infection (SSI) include those arise from the patient's health status, those that related to the physical environment where surgical care is provided, and those that result from clinical interventions that increase the patient's inherent risk[2]. Preoperative administration of antibiotics for the aim of preventing possible post-surgical infections represent a corner stone of modern medicine[3]; as a general rule; prophylactic antibiotics are indicated when the risk of infection exceeds 10%.

Prophylaxis for other clean surgical operations is controversial [4,5,6]. Yousuf & Hussain (2002) reported in their study in Pakistan that a single dose of prophylactic antibiotic therapy is satisfactory to prevent the emergence of nosocomial infections in a developing country such as Pakistan with extremely limited health care resources[7].

In the case of Yemen with marked socioeconomic and health system challenges

as a developing country; the tradition was gone to use antibiotics as postoperative prophylaxis in Ibn-Sina teaching hospital in Mukalla in Yemen.

The aim of this study was to investigate the hypothesis of there is no significant benefits from the use of prophylactic antibiotics in clean surgical operations.

Subjects and methods:

The setting: The study was carried out in Ibn-Sina Teaching hospital; it is a general hospital and the referral hospital for the three eastern governorates of Yemen with a 240 beds; out of them 60 beds for surgical wards of male and female patients.

Studyperiod: from 15th December 2002 to 30 April 2003.

Subject: Sample size was calculated by using EPI-Info version 6; a total of 80 patients with clean surgical operation were included in the study after writing consents were obtained from them, ages of patients were 20 years or more. Patients were allocated in either treatment group (No prophylactic antibiotic were given); and control group (Classical antibiotic were given); each group include 40 patients.

Four general surgeons in the hospital were trained on the purpose and methodology of the study, criteria of inclusions, criteria of exclusion, case definition of clean surgical operations and postoperative clinical observation of the surgical wounds

Criteria for inclusions:

- Patients with clean surgical operations
- Age 20 years or more
- Patients have no systematic risk factors

Criteria of exclusions:

- Patients age less than 20 years
- Patients with systemic risk factors (DM, using corticosteroids, malnourished, cancer, or patient under chemotherapy)

Definition of the clean surgical operation (as adopted by the National Academy of Sciences, National Research Council of USA (NRC): Clean, elective not emergency, not traumatic, primarily closed, no acute inflammation, no break in technique, respiratory, gastrointestinal, biliary and genitourinary tracts not entered[8].

Statistical method: Data were entered and analyzed by using EPI-INFO version 6 computer program; Chi square was used with alpha level of 0.05 to test any significant association.

Results:

A total of 43 male patients and 36 female patients were enrolled in the study. Only three patients (two female and one male) whose not given antibiotics postoperatively (7.5%) developed wound infection while none of the control group developed postoperative wound infection without statistical significance (PN.05). Neither age nor sex have statistical significant association with surgical wound infection (P>0.05). All the surgical wound infections were observed in patients were operated for inguinal hernia. This study revealed that 27.3% of patients with hernia operations have developed wound infection post-operatively and there is a true significant difference between hernia operations carried out with prophylactic antibiotics and those without (p-value<0.03).The observed signs of wound infections were pus discharge in two patients and tenderness in only one patient.

Discussion:

Although the importance of antibiotic use in clean-contaminated and contaminated surgical operations has been proved there still argument about the necessity of it in clean operations[9], it is considered optional for most clean procedures, although it may be indicated for certain patients and clean operation that fulfills risk criteria[7]. The recent study show that 7.5% of patients not using antibiotics for wound infection postoperatively compared to no wound infection among those using antibiotics but not statistically significant difference; this is similar to results of Leaper & Mlling (200 I)[9].

This study revealed that 27.3% of patients with hernia operations have developed wound infection post-operatively and there is a true significant difference between hernia operations carried out with prophylactic antibiotics and those without; this was different with what reported by Platt et a1 (2002)[10] when they assessed the efficacy of antibiotic prophylaxis in 1218 patients undergoing hernioraphy where the difference of infection rate was not statistically significant. The administration of antibiotics prophylaxis for hernia repair operation is currently controversial issue (4). In our

opinion, based on this study and due to the local condition of Ibn-Sinna hospital, the use of antibiotics prophylaxis in hemia repair operation is indicated.

Age has an important effect on wounds healing with an increasing risk of wound infection at extreme of ages[11], in this study Age and sex have no significant association difference in those using antibiotics postoperatively versus those not using antibiotic because most the studied subjects were young adults or in the middle ages; no patients with extreme ages in this study. Pus discharge presented as a sign of surgical wound infection which is consistent with the criteria used by Centers of Diseases Control (CDC) to define a surgical wound infection[12].

Conclusion:

The study concluded that the use of postoperative prophylactic antibiotic is not necessary for wound healing in case of clean surgical operations except for hernia operations.

Table No. 1: Impact of using prophylactic antibiotics in clean surgical wounds

Impact on the wound	Treatment group (patients were not given antibiotics pos-operatively) n=40	Control group (patients were given antibiotics post-operatively) n=40	Total N=80	P value
Clean	40	37	77	>0.05
Infected	0	3	3	

Table No. 2: Impact of using post operative prophylactic antibiotic on surgical wound with stratification of age and sex

Independent variables	Impact on the surgical wound	Treatment group (patients were not given antibiotics postoperatively)	Control group (patients were given antibiotics postoperatively)	Total	P value
Sex					
Male	Infected wound	1	0	1	0.52
	Clean wound	23	20	43	
Female	Infected wound	2	0	2	0.19
	Clean wound	14	20	34	
Age Group					
20-40 years	Infected wound	2	0	2	0.25
	Clean wound	26	27	53	
40-60 years	Infected wound	1	0	1	0.48
	Clean wound	11	13	24	

Table No. 3: Distribution of patients by type of clean operations and status of postoperative wounds

Types of operations	Clean wound		Infected wound	
	No. of patients	%	No. of patients	%
Hemorrhoidectomy	11	29.7	0	0
Hernia operations	8	21.6	3	100
Thyroidectomy	3	8.1	0	0
Cervical lymph node biopsy	3	8.1	0	0
Fistula in ano	4	10.8	0	0
Excisional biopsy	2	5.4	0	0
Others*	6	16.3	0	0
Total	37	100%	3	100

Table No. 4: Impact of using prophylactic antibiotics in clean surgical wounds in patients with hernia

Impact on the wound	Treatment group (patients were not given antibiotics postoperatively) n=22	Control group (patients were given antibiotics postoperatively) n=8	Total N=30	P value
Infected	3	0	3	0.025*
Clean	19	8	27	

* Significant, chi square by using Fischer exact test = 5.75 DF=1

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