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

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No. of Tables: 4.

Summary:

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.

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. Preoperative administration of antibiotics for the aim of preventing possible post-surgical infections represent a cornerstone of modern medicine as a general rule; prophylactic antibiotics are indicated when the risk of infection exceeds 10%.

Prophylaxis for other clean surgical operations is controversial. 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.

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.

Study period: 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

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, it is considered optional for most
clean procedures, although it may be indicated
for certain patients and clean operation that
fulfills risk criteria. 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)

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) 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.

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

Age has an important effect on wounds healing with an increasing risk of wound infection at extreme of ages\(^1\), 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\(^2\).

**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

<table>
<thead>
<tr>
<th>Impact on the wound</th>
<th>Treatment group (patients were not given antibiotics postoperatively) n=40</th>
<th>Control group (patients were given antibiotics postoperatively) n=40</th>
<th>Total (N=80)</th>
<th>(P) value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clean</strong></td>
<td>40</td>
<td>37</td>
<td>77</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td><strong>Infected</strong></td>
<td>0</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Independent variables</th>
<th>Impact on the surgical wound</th>
<th>Treatment group (patients were not given antibiotics postoperatively)</th>
<th>Control group (patients were given antibiotics postoperatively)</th>
<th>Total</th>
<th>(P) value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Infected wound</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0.52</td>
</tr>
<tr>
<td></td>
<td>Clean wound</td>
<td>23</td>
<td>20</td>
<td>43</td>
<td></td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Infected wound</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0.19</td>
</tr>
<tr>
<td></td>
<td>Clean wound</td>
<td>14</td>
<td>20</td>
<td>34</td>
<td></td>
</tr>
<tr>
<td><strong>Age Group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>20-40 years</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Infected wound</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>Clean wound</td>
<td>26</td>
<td>27</td>
<td>53</td>
<td></td>
</tr>
<tr>
<td><strong>40-60 years</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Infected wound</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0.48</td>
</tr>
<tr>
<td></td>
<td>Clean wound</td>
<td>11</td>
<td>13</td>
<td>24</td>
<td></td>
</tr>
</tbody>
</table>
Table No. 3: Distribution of patients by type of clean operations and status of postoperative wounds

<table>
<thead>
<tr>
<th>Types of operations</th>
<th>Clean wound</th>
<th>Infected wound</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>%</td>
<td>No. of patients</td>
</tr>
<tr>
<td>Hemorrhoidectomy</td>
<td>11</td>
<td>29.7</td>
</tr>
<tr>
<td>Hernia operations</td>
<td>8</td>
<td>21.6</td>
</tr>
<tr>
<td>Thyroidectomy</td>
<td>3</td>
<td>8.1</td>
</tr>
<tr>
<td>Cervical lymph node biopsy</td>
<td>3</td>
<td>8.1</td>
</tr>
<tr>
<td>Fistula in ano</td>
<td>4</td>
<td>10.8</td>
</tr>
<tr>
<td>Excisional biopsy</td>
<td>2</td>
<td>5.4</td>
</tr>
<tr>
<td>Others*</td>
<td>6</td>
<td>16.3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>37</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Impact on the wound</th>
<th>Treatment group (patients were not given antibiotics postoperatively) n=22</th>
<th>Control group (patients were given antibiotics postoperatively) n=8</th>
<th>Total N=30</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infected Clean</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>27</td>
</tr>
</tbody>
</table>

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

References: