EVALUATION OF ANTIBIOTIC PROPHYLAXIS AND OTHER FACTORS AFFECTING THE INCIDENCE OF SURGICAL SITE INFECTION IN APPENDECTOMY AT A TERTIARY MEDICAL CENTER IN LEBANON

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The Degree of Doctor of Pharmacy

By

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GRADUATE STUDIES

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ABSTRACT

By

RASHA HAMRA

Background: Appropriate antibiotic prophylaxis can reduce the incidence of surgical site infections (SSI) in many procedures. Its role in acutely inflamed appendicitis remains controversial. Complicated appendicitis is frequently associated with superlative complications.

Objectives: The objective is to evaluate the appropriateness of antibiotic prophylaxis in patients undergoing appendectomy at a tertiary care medical center; to assess the antibiotic choice, timing, and duration of administration; and to determine the impact and the value of intraoperative cultures on the selection of antibiotics.

Material and Methods: The medical charts of patients with a positive pathology for acute, gangrenous or perforated appendicitis who underwent appendectomy between January 1, 1999 and April 30, 2001 at American University of Beirut Medical Center (AUBMC), were retrospectively reviewed.
Results: 99% of patients received antibiotic prophylaxis. 37% of cases received their preoperative prophylactic dose at 30-60 minutes before incision. 73% of patients who had acute appendicitis received prophylactic antibiotics for more than 24 hours. The most common regimen used preoperatively was amoxicillin/clavulanic acid while the triple regimen was the most frequently used postoperatively. 7%, of the study population, developed surgical site infection (SSI); all had emergency appendectomy, and 71% received inappropriate preoperative prophylaxis. Other contributing factors to the development of SSI were found to be the pathological state of the appendix, open surgical procedure, and pediatric age group. The mean added hospital stay for patients with SSI was 5 days per patient. 47% received oral antibiotics upon discharge. The most common organism isolated intraoperatively was *Escherichia coli* in 70% of cases followed by *Enterococci* in 19% and *Pseudomonas aeruginosa* in 7.5%; no anaerobes were isolated. There was a 5% change in antibiotic regimen following the results of intraoperative cultures.

Conclusion: Antibiotic prophylaxis is widely used in appendectomy with tendency towards long courses. It is an effective modality of reducing SSI if applied appropriately. Inappropriate prophylaxis, emergency surgery, open procedures, complicated appendicitis, and pediatric patients are major contributing factors to development of SSI. Intraoperative culture results did not significantly influence antibiotic therapy.
To my family
ACKNOWLEDGMENTS

Those will be my last words as a student at this great university:

Six years of my life elapsed at LAU and reached an end now, as everything does in real life. But not in my heart, soul and mind where every bit of it will stay forever. It started and ended happily, thank GOD, and I owe a lot of what I know, what I learned and what I am to every single person I met in this university, especially my friends and all my teachers and on top of them Dr. Dib and Dr. Moukhachen whose guidance will play a major role in my future career. Thank you LAU, thank you teachers, Doctors, for all that you offered me. I promise I will always make you proud of me. I will always remember you and pay you a visit whenever possible, I hope as a colleague one day. So, thank you all and may the best thing that has ever happened to you all be the worst that shall be.
Contents

Title Page.......................................................................................... i
Abstract.............................................................................................. ii
Acknowledgements.............................................................................. v
Table of content.................................................................................. vi
List of Figures and Tables ..................................................................... vii

Article

Introduction.......................................................................................... 1
Purpose................................................................................................. 2
Methodology, Material and Methods..................................................... 3
Results.................................................................................................. 4
Discussion.............................................................................................. 7
Conclusion............................................................................................. 12
References............................................................................................. 14
Appendices............................................................................................ 18
List of Figures and Tables

Figures

1. Age Distribution of Appendectomy Patients ........................................... 18
2. Timing of Administration of Initial Dose of Antibiotic Prophylaxis
   in Relation to Incision Time (IT) ...................................................... 19

Tables

1. Duration of Postoperative Antibiotics in Complicated Appendicitis ............ 20
2. Pre- & Post-Operative Antibiotics Regimens Used .................................. 21
3. Characteristics of Patients with SSI and Duration
   of IV Antibiotic Treatment .................................................................. 22
4. Risk Factors Associated with Development of SSI ................................ 23
5. Intraoperative Culture Results ............................................................... 24
Introduction:

Appendicitis is the most common cause of acute surgical abdomen, and appendectomy is the most frequently performed emergency operation accounting for 1% of all surgical procedures \(^1\). Surgically removed appendixes are classified into four categories: normal (10-30%), acute or inflammatory (30-50%), gangrenous, and perforated, which constitute 15 to 20% \(^2\). Despite the dramatic reduction in mortality rate following appendectomy, septic complications remain a major problem, occurring in a large percentage of patients, and resulting in prolonged hospital stay or readmission. The incidence of wound or intraperitoneal infection after appendectomy depends on the pathological state of the appendix. The postoperative infection rate is 3% - 8% after removal of normal or inflamed appendix \(^2\). Appropriate preoperative administration of prophylactic antibiotics has proven to be safe and effective in reducing the incidence of SSI following clean-contaminated and contaminated surgeries. However, the role of such prophylaxis in patients with acute appendicitis has not yet been fully established \(^3\-8\). Since the SSI rate after appendectomy for gangrenous appendicitis varies from 10% - 30% and the incidence of wound related sepsis in perforated cases is as high as 70% - 85% the need for an effective prophylactic regimen is obvious \(^9\). The aim of prophylactic antibiotic administration is to decrease postoperative morbidity, shorten hospitalization and reduce overall cost \(^10\, 11\). Conversely, inappropriate use of prophylactic antibiotics may result in increased costs through unnecessary drug utilization and laboratory monitoring, drug toxicity and the selection for resistant organisms \(^12\).
Purpose:

The purpose of the current study is to evaluate the appropriateness of antibiotic prophylaxis in patients with proven pathologic appendix in a tertiary care medical center. It also aims at determining the risk factors associated with development of SSI and evaluating the yield and impact of intraoperative cultures.
Methodology, Material and Methods:

Retrospective evaluation of the medical charts of patients who underwent appendectomy between January 1, 1999 and April 30, 2001 at The American University of Beirut Medical Center (AUBMC). Further relevant data gathered from the departments of Pathology, Clinical Microbiology, and Surgery. Patients included where those who underwent appendectomy during the study period with final pathological diagnosis of acute (inflamed), gangrenous or perforated appendicitis. Patients, who had normal pathological appendix, had another concomitant surgical procedure, were immunocompromized, and were admitted with another diagnosis for which they received prior antibiotic treatment or had insufficient data in their medical records; were excluded.

Data collected, on specially designed flow sheets, included information such as: age; gender; drug history (chronic intake of medications and drug allergies); presence of co-morbid conditions; date, time, duration (incision time and closure time) and type of surgical procedure (open versus laparoscopic); final pathologic classification of the removed appendix; and length of hospital stay. Moreover, information about preoperative and postoperative antibiotics given (choice, route of administration, timing, dosage, number of doses, and duration); intraoperative doses given and timing of administration; antibiotics prescribed upon discharge; results of intraoperative cultures (microorganisms isolated, sensitivity and resistance patterns); and post-surgical infections and their management, were recorded.
Results:

During the study period, 206 patients with positive pathology for acute, gangrenous or perforated appendicitis underwent appendectomy; however, only 195 were included in the final analysis. Due to insufficient data in their charts or the presence of other admitting diagnoses, 11 patients were excluded. The age of the study population ranged between 3 and 75 years with a mean of 27.54 years. The majority of patients (56.4%) were between 10 and 30 years of age (Figure 1) and males constituted 57.9% of patients.

The pathological diagnoses of the removed appendices were as follows: 145 (74.4%) acute, 10 (5.1%) gangrenous and 40 (20.5%) perforated. Laparoscopic appendectomy was performed in 139 (71.3%) of whom 90% were adults; the remaining 56 (28.7%) had open appendectomy, and 76% of them were pediatrics.

All patients except for two received antibiotic prophylaxis. However, 159 (81.5%) received their first dose preoperatively and in only 30% of them the first dose was administered 30 - 60 minutes before incision time (IT). The timing of the initial dose in relation to IT is stated in Figure 2. In those who received preoperative prophylaxis, the first dose was delivered in 44% at emergency room, 36% on the surgical ward, and 20% in the operating room. More than one preoperative antibiotic dose was administered in 28 (17.6%) patients.

Sixty patients received intraoperative antibiotics; for half of them it was the first prophylactic dose. The operative procedure lasted more than 2 hours in 24 patients and only 12 (50%) received intraoperative antibiotics (as second dose).
In those with acute appendicitis only 2 (1.5%) did not receive prophylaxis while 103 (73%) received more than four doses (range between 5 - 20 doses). Patients with gangrenous and perforated appendices received intravenous antibiotics for more than 3 and 5 days respectively (Table I).

Preoperatively a single agent mainly amoxicillin/clavulanic acid, was the most commonly used regimen, followed by the triple regimen which was the most frequently utilized postoperatively (Table II). Changing antibiotics following surgery occurred in 32 (17%) cases. In seven patients with acutely inflamed appendix, the antibiotics were changed postoperatively from a double or triple regimen to a single agent. Meanwhile, 21 patients with perforation were upgraded to triple or double regimen after initially receiving no antibiotics or a single agent.

The number of patients who developed SSI was 14 (7%), 10 of whom had complicated appendicitis (8 perforated and 2 gangrenous). Furthermore, 9 belonged to the pediatric age group, and 12 had their appendix removed through an open surgical procedure. All had their operation done on emergency basis outside the routine working hours. 108 surgeries were performed outside the routine schedule, i.e. on emergency basis. Table III summarizes the characteristics of patients who developed SSI. The incidence of SSI was 16.4 % in the pediatrics versus 3.6% in adults, and 20% in complicated cases as compared to 2.8% in the acutely inflamed. In open appendectomy, 21% developed wound infections as compared to 1.1% in laparoscopy. For those who received their first preoperative dose more than one hour prior to surgery, 16% developed SSI compared to none of those who received it 30-60 minutes before surgery.
In operations lasting for more than two hours, 33% of patients who did not receive any intraoperative dose developed a wound infection. The risk factors associated with development of SSI are listed in Table IV.

The mean duration of intravenous antibiotic treatment in patients who developed SSI was 10 days, (range: 7-15 days). The mean hospital stay in days was 3.3 for acute appendicitis, 4.5 for gangrenous, and 5.5 for perforated cases. Meanwhile those who developed SSI had a mean hospital stay of 9.9 days.

Intraoperative cultures were obtained in 133 (68%) patients. In this group, 109 patients (82%) had growth. *E. coli* was the most commonly isolated bacteria followed by *Enterococci* and *Pseudomonas aeruginosa*. The microbiology results of intraoperative cultures are stated in Table 5. Perforation was present in 60% of those whose cultures grew *Pseudomonas aeruginosa*, and none of them had prior history of recent hospitalization or antibiotic intake. No anaerobes were isolated despite searching for them. Antibiotic therapy was changed in 7 (5.3%) patients following the results of intraoperative cultures. Meanwhile, wound cultures from SSI sites were positive in 12 out of 14. *E. coli* was isolated from 11 patients followed by *Enterococci* from 3 cases (Table V).

Upon discharge, 117 (60%) patients were switched to oral agents; only 11% of them had SSI. Amoxicillin/clavulanic acid was the most frequently used oral antibiotic followed by cefuroxime axetil.
Discussion:

The age distribution with the highest incidence between 10 to 30 years of age as well as the male to female ratio is comparable to published data (13). Acute inflammatory appendix accounted for 75% of the cases this is also in accordance with the international literature since the cases evaluated included only those with diseased appendix (2). Worth noting, was the high frequency of open appendectomy in the pediatric age group as compared to adults. This may be due to lack of solid evidence in the literature that favors laparoscopic removal of appendix in pediatrics (14) or lack of expertise on the behalf of our pediatric surgeons.

Despite the high percentage of acute inflammatory appendix, 98% of the patients received prophylactic antibiotics irrespective of the timing of the initial dose. Most authorities recommend prophylaxis even for suspected acute cases (3, 4, 5). However, some argue against this practice emphasizing that aseptic techniques and low postoperative infection rate negate the need for prophylaxis (6, 7, 8, 13).

It is well known that the effective use of prophylactic antibiotics largely depends on the appropriate timing of their administration (6, 15, 16, 17). Current recommendations call for starting prophylaxis within 30 to 45 minutes prior to incision.

The incidence of wound infection may increase if antibiotics were given more than one hour before incision (9). Only 30% of patients evaluated received their preoperative dose 30 to 60 minutes before IT, while the rest received their first dose either intraoperatively or more than one hour prior to incision.
The Antimicrobial Agents Committee of the Surgical Infection Society recommends against “on call” antimicrobial administration prior to operation; which often means that it is given 3 to 4 hours before surgery (18). In the current study, 80% of the patients who received preoperative prophylaxis received their first dose either in emergency room or on the surgical ward (i.e. on call to operating room).

It is generally recommended that a second antibiotic dose should be administered during long surgical procedures (≥ 2 hours, or twice the half-life of the antibiotic used). This serves to maintain serum concentrations well above the minimal inhibitory concentration of common pathogens (9). However, only 50% of patients evaluated and had surgeries longer than two hours received an intraoperative dose.

The shortest effective course of prophylactic antibiotics should be used according to King et al. Prolonged administration may lead to major changes in the patient’s normal flora and select for bacterial resistance (11). It is recommend that in acute cases a preoperative antibiotic dose followed by 2 – 4 postoperative doses (up to 24 hours) (19, 20) should be adequate. In the study group, there was an obvious overuse of long courses of antibiotics since 73% of patients with acute appendicitis received more than 4 doses (range 5 - 20), with a mean of 9.5 doses.

The use of antimicrobial agents in gangrenous and perforated appendicitis is considered therapeutic and not prophylactic (9). According to published literature, if the diagnosis of complicated appendicitis is made during surgery, it is recommended to continue antibiotic therapy for at least 3 days for gangrenous and 5 days for perforated cases (21-23).
In the study group, the subset of patients with gangrenous and perforated appendices received an average of 4.5 days of intravenous antibiotic treatment.

In patients who received preoperative prophylaxis with a single agent, 21% were switched to triple therapy when they were found to have complicated appendicitis. This was in accordance with previously published reports \(^ {21, 24}\). Meanwhile 9 % of those started on triple regimen preoperatively were shifted to a single agent mainly amoxicillin/clavulanic acid postoperatively. The most important determinant was the pathological status of the removed appendix, where in complicated cases, double or triple therapy was more frequently used as compared to mainly a single agent in acutely inflamed cases.

The microbiology of appendicitis is well studied in adults and children. \textit{E. coli} and \textit{B. fragilis} are the most common bacterial isolates from peritoneal cultures obtained intraoperatively while \textit{Enterococci} and \textit{Pseudomonas species} are occasionally isolated \(^ {25, 26}\). In the early stages, aerobic flora predominates while in later gangrenous and perforated phases mixed aerobic and anaerobic bacteria are mainly responsible \(^ {27, 28}\).

In the study group, \textit{E. coli} was the most frequently isolated either alone or in combination followed by \textit{Enterococci} and \textit{Pseudomonas aeruginosa}. Perforation was present in 60% of those whose cultures grew \textit{Pseudomonas aeruginosa}. This finding was also noted by Berne et al, who reported that \textit{P. aeruginosa} is a major pathogen in perforated appendicitis and was isolated in 26% of patients \(^ {29}\).
It is worth stating that no anaerobes were isolated despite searching for them. This could either be due to poor quality of anaerobic processing in our institution or delay in sending the specimens from the operating theater to the microbiology lab without appropriate transport media.

Although intraperitoneal cultures during appendectomy used to be routine \(^{26, 27, 30}\), many believe that they have no real value in the management of patients. This is mainly due to difficulties in growing anaerobic bacteria, and late reporting of results within 48-72 hrs after surgery when the clinical course is already predictable \(^{26, 27, 30}\). Rarely such cultures resulted in modifications of empirical antibiotic regimens, and in most of the cases, there is no correlation between intraoperative abdominal cultures and subsequent postoperative infections. Some suggested that abandoning routine cultures would result in significant reduction in cost and laboratory work without increasing the morbidity associated with appendicitis \(^{26, 27, 30}\). In the current study, the bacterial etiology of SSI correlated well with intraoperative cultures but antibiotics were only changed in 5.3% of patients with positive intraoperative cultures.

Controversy exists as to what antibiotic to use in prophylaxis and whether it is always necessary to cover for *Enterococci*. A good regimen should include coverage for *E. coli* and *B. fragilis*, the most likely organisms encountered especially when there is suspicion of perforation. Some authorities recommend that antibiotic prophylaxis should be restricted to a single broad-spectrum agent active against both aerobic and anaerobic organisms in acute cases and to continue with a triple regimen if complicated appendicitis was diagnosed intraoperatively \(^{22, 30, 31, 32}\).
In the current study, amoxicillin/clavulanic acid, as a single agent, was the most frequently used preoperatively, while the triple regimen was the most frequently utilized postoperatively.

Krukowski et al indicated that emergency appendectomy is associated with increased rate of infections since most operations when performed late after regular working hours lack adequate assistance and concentration on the surgeon’s part (21). All the patients who developed SSI in this study had their operations done on emergency basis outside the routine working hours. Several authors found reduced rates of SSI with the laparoscopic approach, since inflamed appendix does not contact the wound edges when removed from the toscar site (33).

In the study group, 85% of the patients who developed SSI had their appendix removed by an open surgical procedure. Haley et al concluded that a surgical wound infection prolongs hospitalization for approximately 1 week and adds 10% - 20% extra cost to the total hospital bill (3). The mean hospital stay was 9.9 days for patients who developed SSI, as compared to 3.3, 4.5 and 5.5 days for patients with acute, gangrenous and perforated appendicitis who did not develop SSI.
Conclusion

Appendectomy continues to be associated with SSI particularly when complicated by perforation or gangrene. Even though conflicting reports about efficacy of antibiotic prophylaxis exist; this practice remains popular among surgeons even in acutely inflamed cases. Despite advances in antibiotics and the availability of new broad-spectrum agents, the triple regimen continues to be widely used. If utilized appropriately, the triple regimen proved to be effective, relatively safe, and economic. A single agent with good aerobic and anaerobic coverage like amoxicillin/clavulanic acid is an effective acceptable and convenient alternative.

There was a tendency towards overuse of long courses of prophylactic antibiotics even in acutely inflamed cases not complicated by SSI. There was a direct relationship between the incidence of SSI the timing of the initial prophylactic dose, the need for intraoperative second dose, and the pathological stage of the appendix. There was also evident correlation between open procedures mainly in pediatrics and the occurrence of SSI. Pediatric surgeons need to gain more expertise and training in laparoscopic removal of appendix in order to decrease their high rate of suppurative complications. Performing appendectomy on emergency bases was significantly associated with SSI and risks versus benefits needs reassessment.

Intraoperative cultures did not contribute considerably to patients’ management in relation to the antimicrobial agents used. There is an evident need for improving anaerobic bacteria isolation and identification if intraoperative cultures are to be taken routinely. In perforated cases, empirical coverage with at least one anti-pseudomonal agent is advisable due to the high incidence of *P. aeruginosa* in such situations.
This was a retrospective evaluation of all patients with a positive pathology for diseased appendix. Patients who underwent similar procedure and had normal appendix were not included. SSI rates reported represent patients who developed their infection during their hospital stay or re-admitted for the management of this complication. Individuals who developed delayed onset SSI and treated on ambulatory basis could not included. The study was conducted in a tertiary care teaching medical center and the results do not necessarily represent those of the country in general. There is an evident need for larger multi-center prospective studies on preoperative antimicrobial prophylaxis in appendectomy and other surgeries to assess the impact of this practice on the incidence of SSI and the factors that influence their rates.
References:


APPENDIX I

FIGURES

Figure 1. Age Distribution of Appendectomy Patients
Table II. Pre- & Post-Operative Antibiotics Regimens Used

<table>
<thead>
<tr>
<th>Operative Regimens Percentages</th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triple***</td>
<td>38.5</td>
<td>46.7</td>
</tr>
<tr>
<td>Double**</td>
<td>17.4</td>
<td>22.5</td>
</tr>
<tr>
<td>Single*</td>
<td>39.5</td>
<td>29.7</td>
</tr>
<tr>
<td>None</td>
<td>6.4</td>
<td>1.1</td>
</tr>
</tbody>
</table>

*** Ampicillin, Gentamicin and Metronidazole (most common): 76%: 58.2% preop vs. postop

** Cefuroxime and Metronidazole (most common): 32.4%: 34% preop v. postop.

*Amoxicillin/Clavulanic acid (most common): 45.5%: 60% preop vs. postop.
Table IV. Risk Factors Associated with Development of SSI

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N*</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>9/55</td>
</tr>
<tr>
<td>Complicated appendicitis</td>
<td>10/50</td>
</tr>
<tr>
<td>Open appendectomy</td>
<td>12/56</td>
</tr>
<tr>
<td>Pre-operative dose &gt; 1hr</td>
<td>9/57</td>
</tr>
<tr>
<td>No pre-operative dose</td>
<td>1/9</td>
</tr>
<tr>
<td>Pre-operative dose &lt; 30min</td>
<td>1/12</td>
</tr>
<tr>
<td>Pre-operative dose at IT</td>
<td>1/31</td>
</tr>
<tr>
<td>No intra-operative dose in surgery &gt; 2hr</td>
<td>4/12</td>
</tr>
<tr>
<td>Afternoon emergency surgery</td>
<td>14</td>
</tr>
<tr>
<td>Obesity</td>
<td>2</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1</td>
</tr>
</tbody>
</table>

* n: number of patients with SSI
N: total number of patients

Afternoon surgeries (48 surgeries between 3-7 pm; 60 between 7pm-7am)
<table>
<thead>
<tr>
<th>Bacterial Isolates</th>
<th>N Total</th>
<th>N in combination</th>
<th>% Isolates</th>
<th>% Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>E. coli</em></td>
<td>94</td>
<td>46</td>
<td>61.0</td>
<td>70.7</td>
</tr>
<tr>
<td><em>Enterococcus</em></td>
<td>25</td>
<td>0</td>
<td>16.2</td>
<td>18.8</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td>10</td>
<td>8</td>
<td>6.5</td>
<td>7.5</td>
</tr>
<tr>
<td><em>Klebsiella pneumonia</em></td>
<td>8</td>
<td>0</td>
<td>5.2</td>
<td>6.0</td>
</tr>
<tr>
<td><em>Streptococcus viridians</em></td>
<td>6</td>
<td>5</td>
<td>3.9</td>
<td>4.5</td>
</tr>
<tr>
<td><em>Streptococcus Group D</em></td>
<td>5</td>
<td>0</td>
<td>3.2</td>
<td>3.8</td>
</tr>
<tr>
<td><em>Proteus vulgaris</em></td>
<td>2</td>
<td>1</td>
<td>1.3</td>
<td>1.5</td>
</tr>
<tr>
<td><em>Staphylococcus epidermidis</em></td>
<td>2</td>
<td>1</td>
<td>1.3</td>
<td>1.5</td>
</tr>
<tr>
<td><em>Proteus mirabilis</em></td>
<td>2</td>
<td>1</td>
<td>1.3</td>
<td>1.5</td>
</tr>
</tbody>
</table>