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Original Research Article

The outcome of antibiotics as surgical prophylaxis in gynecological procedures - a retrospective study in a south Indian hospital

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ABSTRACT

Background: The aim of the study was to evaluate the outcome of antibiotics as surgical prophylactic measure for gynecological procedures in a south Indian Hospital.
Methods: A retrospective study was conducted in 150 women who underwent caesarean, hysterectomies, Dilation and Curettage, myomectomy, operative vaginal delivery and were prescribed antibiotics. The data regarding demographic details, presenting complaints, parity, obstetrics history, diagnosis and need for surgery was evaluated.
Results: A total of 206 women admitted with surgical procedures performed were taken into consideration of which 150 were prescribed antibiotics alone but 26 patients did not respond to treatment and were given other antibiotics, 30 patients were shifted to other specialist departments or other hospital for better treatment due to economic status, hence 150 patients formed the study population. The mean age was years. Patients above years were mostly seen.
Conclusions: In our study, cefuroxime appeared to be effective in prophylaxis against infections. Metronidazole appeared to be ineffective compared to Cefuroxime. Combination of Cefuroxime and metronidazole was less effective compared to Amoxicillin and potassium clavunate. Cefazolin was commonly prescribed for gynecological procedures.

Keywords: Antibiotic, Gynaecological procedures, Infections, Surgical prophylaxis

INTRODUCTION

Postoperative wound infections have an enormous impact on patients' quality of life and contribute substantially to the financial cost of patient care. The potential consequences for patients range from increased pain and care of an open wound to sepsis and even death. Approximately 1 million patients have such wound infections each year in the United States, extending the average hospital stay by one week and increasing the cost of hospitalization by 20 percent.[1] This translates to an additional $1.5 billion in health care costs annually.[2]

The occurrence of wound infection requires a local inoculum sufficient to overcome host defences and establish growth. The process is complex and depends on the interaction of various host, local tissue and microbial virulence factors. Measures intended to prevent wound infection typically attempt to modify the host and local tissue factors and include, for example, preoperative optimization of comorbid illness, control of the operative environment, proper cleansing of the skin and use of aseptic surgical technique. Antibiotic prophylaxis is only one relatively minor effort among numerous preventive measures, but the efficacy and impact of antimicrobial prophylaxis has clearly been demonstrated to be significant.[3,4]

Table 1: Classification of operative wounds and risk of infection.[9]

Classification	Criteria	Risk (%)
Clean	Elective, not emergency, non-traumatic, primarily closed, no acute inflammation, no break in technique, respiratory, gastrointestinal, biliary and genitourinary tracts not entered.	< 2
Clean contaminated	Urgent or emergency case that is otherwise clean, elective opening of respiratory, gastrointestinal, biliary, genitourinary tract with minimum spillage (eg appendectomy) not encountering infected urine or bile, minor technique break.	< 10
Contaminated	Non-purulent inflammation, gross spillage from gastrointestinal tract, entry into biliary or genitourinary tract in the presence of infected bile or urine, major break in technique, penetrating trauma < 4 hours old, chronic open wounds to be grafted or covered.	~ 20
Dirty	Purulent inflammation (eg abscess), pre-operative perforation of respiratory, gastrointestinal, biliary or genitourinary tract, penetrating trauma > 4 hours old.	~ 40

Following the introduction of antibiotics, early clinical trials in the 1950s reported either no benefit or a higher infection rate with antibiotic prophylaxis.[5–7] Moreover, the emergence of resistant strains was attributed, in part, to such use of antibiotics. Although a small number of authors supported the use of prophylactic antibiotics for "dirty" or contaminated cases, most did not recommend their use in cleaner cases. Criteria are based on clinical information defined by the National Academy of Sciences, National Research Council (NRC), Division of Medicine, Ad Hoc Committee on Trauma.[8] The classification is provided in Table 1.[9] The incidence of infection ranges widely across classes less than 2 percent for clean procedures (e.g., breast biopsy) to over 40 percent for dirty procedures (colon perforation with diffuse fecal contamination). It is generally agreed that antibiotic prophylaxis is warranted in all procedures in the categories of clean-contaminated, contaminated or dirty.

The adult obstetrics and gynaecology antibiotic prophylaxis guidelines as shown in Fig 1states:

1. The antibiotics should be administered intravenously ≤30 minutes prior to surgical incision / procedure (oral and rectal antibiotics must be given one hour prior to the procedure)
2. Intra- operative doses are required if :
   a. Blood loss is ≥1500 mls
   b. Surgery lasts longer than 4 hours (excluding gentamicin and teicoplanin)
3. Additional post-operative prophylactic doses, up to 24 hours total, may be given if there is :
   c. gross spillage from viscus
   d. Devitalised viscus
   e. Major break in sterile technique
4. If an infection is discovered e.g pus or peritonitis, an appropriate course of antibiotic treatment should be prescribed.
5. Check MRSA status before prescribing prophylaxis
   f. Treat unscreened patients, and patients with a history of MRSA as positive unless cleared by infection control.
6. Check allergy status
   g. Severe penicillin allergy e.g. angioedema, anaphylaxis or Stevens Johnsons Syndrome.
   h. Patients with non-urticarial rash allergy to penicillin may receive cephalosporins in a controlled environment.
7. All antibiotic doses are for adults with normal renal function. Gentamicin doses should be rounded nearly up to 80mg.

The argument against prophylaxis for clean procedures, based on the intrinsically low rate of infection without antibiotic treatment, is overly simplistic for several reasons. For specific clean procedures, infection may be unlikely, but the morbidity and cost of even infrequent infection can justify the use of prophylaxis. An example is the insertion of prosthetic devices, such as heart valves or joints. Also, clean procedures constitute approximately 60 percent of all surgical procedures and account for approximately 40 percent of all wound infections.[10] It is estimated that prophylaxis for clean procedures would reduce the overall incidence of wound infection by 17 percent.[11]

An appropriate prophylactic antibiotic should (1) be effective against microorganisms anticipated to cause infection; (2) achieve adequate local tissue levels; (3) cause minimal side effects; (4) be relatively inexpensive, and (5) not be likely to select virulent organisms. The

microbial context of the wound and the hospital environment may influence the choice of antibiotic, but coverage should primarily target those organisms known to cause postoperative infection. Species of Staphylococcus may cause infection in the majority of procedures that do not violate mucosa or a hollow viscus. In general, a first-generation cephalosporin fulfills these criteria and is regarded as sufficient prophylaxis for the majority of procedures.

Table 2: Adult obstetrics and gynaecology antibiotic prophylaxis guidelines.

Procedure	Choice 1	Choice 2 (In case of mild penicillin allergy)	Choice 2 (In case of severe penicillin allergy)	MRSA Positive (for increased risk)
Caesarean Section	Co-amoxiclav 1.2g IV	Cefuroxime 1.5g IV	Gentamicin 3mg/kg IV+ Clindamycin 600mg IV	Add Teicoplanin 400mg IV
Manual removal of placenta Perineal tear involving anus/ rectum	Co-amoxiclav 1.2g IV	Cefuroxime 1.5g IV + Metronidazole 500mg IV	Gentamicin 3mg/kg IV+ Clindamycin 600mg IV	Add Teicoplanin 400mg IV
Hysterectomy (Vaginal, abdominal and laparoscopic) Laparotomy Vaginal repair	Co-amoxiclav 1.2g IV	Cefuroxime 1.5g IV + Metronidazole 500mg IV	Gentamicin 3mg/kg IV+ Clindamycin 600mg IV	Add Teicoplanin 400mg IV
Diagnostic and operative laparoscopy (where vaginal vault not opened) Laparoscopic/ hysteroscopic sterilization Diagnostic/operative hysteroscopy Endometrial ablation Endometrial biopsy	Antibiotic Prophylaxis not routinely recommended			
Surgical termination of pregnancy Evacuation of retain products of conception (1 trimester) Hysterosalpingogram Laparoscopy with dye hydrotubation	Metronidazole 400mg PO or 1 g PR + Azithromycin 1g PO (to overcome Chlamydia) one hour pre operatively.			
Methicillin-resistant Staphylococcus aureus (MRSA) Infection				

Table 3: Recommendation of Cefazolin in gynaecological and obstetric surgeries.

Procedure	Infection causing agent	Drug of choice	Dose preferred
Gynecology and obstetric	Enteric gram-negative bacilli, group B streptococcus, anaerobes	Cefazolin**	1 to 2 g intravenously

The most commonly administered drug is cefazolin (Ancef, Kefzol). For procedures of the alimentary tract, genitourinary tract and hepatobiliary system, coverage should be additionally influenced by site-specific flora, such as gram-negative and anaerobic microorganisms. In such cases, cefotetan (Cefotan) or cefoxitin (Mefoxin) is a suitable agent. For patients with documented allergy to cephalosporins, vancomycin (Vancocin) is a reasonable alternative for coverage of Staphylococcus, and metronidazole (Flagyl) or clindamycin (Cleocin) and an aminoglycoside may be used for coverage of anaerobic and gram-negative organisms, respectively. Aztreonam (Azactam) can be combined with clindamycin but not with metronidazole in the same setting.[12] A quinolone, such as ciprofloxacin (Cipro), may also be effective for coverage of gram-negative organisms, although data for the context of prophylaxis are not available.

Timing of administration is critical. The drug should be administered ideally within 30 minutes and certainly within two hours of the time of incision.[13] The first dose should always be given before the skin incision is

performed. For longer procedures, readministration of the drug is indicated at intervals of one or two times the half-life of the drug (using the same dose).[4,14] This ensures adequate tissue levels throughout the duration of the procedure. The duration of an adequate tissue level of the antibiotic need not exceed the operative period. The duration of administration is extended only in special circumstances, such as gross contamination secondary to a ruptured viscus or severe trauma; the data usually provide no evidence for the efficacy of extending coverage to 24 to 48 hours in such contexts.[15]

Prophylaxis is indicated for cesarean section and abdominal and vaginal hysterectomy. Numerous clinical trials have demonstrated a reduction in risk of wound infection or endometritis by as much as 70 percent in patients undergoing cesarean section.[16] For cesarean section, the antibiotic is administered immediately after the cord is clamped to avoid exposing the new-born to antibiotics. Despite the theoretic need to cover gram-negative and anaerobic organisms, studies have not demonstrated a superior result with broad-spectrum antibiotics compared with cefazolin. Therefore, cefazolin is the recommended agent.

METHODS

The study was conducted over a period of 3 months from March 2016 to June 2016.

Pharmacoepidemological studies can help in minimizing the inherent risk of drug use in Pregnancy by establishing a profile of drug consumption, by evaluating the existing health services and by investigating the interventional measures.[17] The present retrospective study was conducted in Antenatal in Patient Department of Obstetrics and Gynecology of Owaisi Hospital and Research Centre to evaluate the outcome of antibiotics when used as for surgical prophylaxis.

Gynaecological procedures

The Institutional ethics committee permission was not required as retrospective study was conducted with no direct contact with the study population.

The demographic profile along with parity, present and past history of associated medical, surgical, gynaecological and obstetrical illness, presenting complaints of the patient pertaining to main indications leading to gynaecological procedures were recorded from the case sheets of the patients admitted in Female ward for gynaecological procedure.

Inclusion criteria

All hospitalized women in Obstetrics and gynaecology department who underwent gynaecological and obstetric surgeries were enrolled via convenience sampling greater than or equal to 20yrs of age, with or without co-morbidities after screening and monitoring.

Exclusion criteria

Patients diagnosed with acute and chronic medical conditions other than requirement for surgical procedure, patients given other antibiotics or combination of other antibiotics were excluded from the study.

Statistical analysis

Statistical analysis was done by using descriptive statistics. Data was collected, tabulated and graphs were designed in Excel-2007.Continuous variables were presented as mean values ± Standard Deviation (SD) and categorical variables were presented as percentages. Chi square calculator for a single raw value was used to obtain chi square value and P value was calculated at significance level $p<0.05$.

RESULTS

A total of 206 women admitted with surgical procedures performed were taken into consideration of which 150 were prescribed antibiotics alone but 26 patients did not respond to treatment and were given other antibiotics, 30 patients were shifted to other specialty departments or the hospital for better treatment due to economic status, hence 150 patients formed the study population.

As the study was retrospective, the data was recorded from the case sheets of the patients admitted in Female ward for gynecological procedure. Table 1 shows the classification of wound infections, Table 2 shows the antibiotic prophylaxis for adults undergoing gynaecological procedures Table 3 shows the prescribing pattern of commonly used antibiotic for gynaecological procedures and Table 4 shows the Socio demographic characteristics of the patients studied.

The socio demographic characteristics are shown in Table 2.The mean age was 37.5±10 years. The majority of the patients belonged to 20-30 years (37.3%) followed by 54 (36%), 26 (17.33%) and 14 (9.33%) patients in the age group 31-40 and 41-50 and above 51 respectively as shown in Table 5.

The gynaecological procedures contributing to use of Surgical antibiotic prophylaxis are cesarean in 66 (44%) Hysterectomy 48 (32%), Myomectomy 4 (2.66%), Dilation and curettage 7 (4.66%) Operational vaginal delivery 19 (12.66%) and oophorectomy 6 (4%) patients respectively as depicted in Table 6.

Table 4: Socio demographic characters of the patients in number (%).

Characteristics	No. of patients (%)
AGE	
20-30	56 (37.3)
31-40	54 (36)
41-50	26 (17.33)
51 ABOVE	14 (9.33)
Gynaecological procedures	
Cesarean	66 (44)
Hysterectomy	58 (32)
LAVH	10
LSH	12
TAH	14
TLH	8
TVH	14
Myomectomy	4 (2.66)
Dilation and Curettage	7 (4.66)
Operational Vaginal Delivery	19 (12.66)
Oophorectomy	6 (4)
Factors associated with risk of Infection	
Use of Corticosteroids	10 (6.66)
Obesity	6 (4)
Extremes of age	12 (8)
Malnutrition	8 (5.33)
Past operative history	14 (9.33)
Massive transfusion	41 (27.33)
Pre-operative co morbid conditions	
Hypertension	40 (26.66)
Diabetes	32 (21.33)
Hypothyroidism	10 (6.66)
Anemia	68 (45.33)
Epilepsy	04 (2.66)
Eclampsia /Pre eclampsia	17 (11.33)
Renal Calculi	09 (6)
HbsAg+	06 (4)
Infection complications	
Febrile episodes	86 (57.33)
Wound infection	32 (21.33)
Pelvic infection	74 (49.33)
Wound dehiscence	13 (8.66)
Urinary tract infection	45 (30)
Antibiotic Use	
Cefazolin	22 (14.66)
Cefuroxime + Metronidazole	33 (22)
Vancomycin	16 (10.66)
Amoxicillin + potassium clavunate	37 (24.66)
Clindamycin	18 (12)
Ciprofloxacin	14 (9.33)

The factors associated with risk of infection were use of corticosteroids in 10 (6.66%), Obesity in 6 (4%) extremes of age 12 (8%), past operative history 8 (5.33%), massive transfusion 41 (27.33%) patients respectively. Hypertension 40 (26.6%), Diabetes 32 (21.33%), Hypothyroidism 10 (6.66%), Anemia 68 (45.33%), Epilepsy 4 (2.66%), Eclampsia/pre-eclampsia 17 (11.33%), Renal calculi 9 (6%), HbsAg+ 6 (4%) were observed as Pre-operative co morbid conditions in patients respectively. The infection complications noted were febrile episodes 86 (57.33%), wound infection 32 (21.33%), pelvic infection 74 (49.33%), wound dehiscence 13 (8.66%), and UTI 45 (30%) patients respectively as illustrated in Table 7.

Table 5: Age and number of patients.

Age	No. of patients
20-30	56
31-40	54
41-50	26
51 above	14

Table 6: Gynaecologic procedure and number of patients.

Procedures	No. of patients
Cesarean	66
Hysterectomies	48
Myomectomy	4
D and C	7
OVD	19
Oophorectomy	6

Table 7: Complications and number of patients.

Infections	No. of patients
Febrile Episodes	86
Wound Infection	32
Pelvic Infection	74
Wound Dehiscence	13
UTI	45

Table 8: Use of antibiotics and number of patients.

Antibiotics	No. of patients
Cefazolin	22
Cefuroxime + Metronidazole	33
Vancomycin	16
Amoxicillin + potassium clavunate	37
Clindamycin	18
Ciprofloxacin	14

In our study we recorded patients treated with Cefazolin 22 (14.66%), Cefuroxime + metronidazole 33 (22%), vancomycin 16 (10.66%), Amoxicillin + potassium clavunate 37 (24.66%), clindamycin 18 (12%), ciprofloxacin 14 (9.33%) respectively as shown in Table 8. Cefuroxime + metronidazole were most commonly prescribed in our hospital depending upon the socio economic status of the patients but most of our

prescriptions were with amoxicillin + potassium clavunate which was found to be effective in treating surgical wound infections followed by less commonly prescribed Cefazolin 22 (14.66%), vancomycin 16 (10.66%), clindamycin 18 (12%), ciprofloxacin 14 (9.33%). Cefazolin was used mostly in cesarean patients, ciprofloxacin in patients affected with UTI, Cefuroxime+ metronidazole was preferably found in patients with hysterectomies, vancomycin was found mostly in patients with contaminated wounds.

The statistical data reveals that the continuous variables were presented as mean values ± Standard Deviation (SD) were obtained in a sample of 150 patients. Mean age was found to be 37.5, with a range of 10 and Standard deviation calculated from mean was 15.33 and categorical variables were presented as percentages. Chi square calculator for a single raw value was used to obtain chi square value as 7.33855, P value was calculated at significance level $p<0.05$ and was found to be $P=<0.00001$ significant at $p<0.05$ as shown as below:

Chi square calculator for a single raw value:

Raw score (X) = 150

Population mean = 37.5

Standard Deviation = 15.33

Z = (Raw square (X)- Mean(μ)/ S.D)

Z= 150-37.5/15.33

Z = 7.33855

P= <0.00001 (significant at P<0.05)

DISCUSSION

Infections are responsible for a significant proportion of postoperative morbidity. Hysterectomy is a clean-contaminated operation, and postoperative infections are polymicrobial, as vaginal bacteria inoculate the surgical site. The majority of postoperative pelvic infections involve anaerobic bacteria.[18] The UK guidelines provide no recommendations separately for VH, and for AH they state. There is insufficient evidence that prophylactic administration of antibiotics results in fewer surgical site infections.[19]

A limitation of our evaluation is the lack of randomization. We were unable to affect the power or the sample sizes realized. Therefore, unintentional bias may have occurred: a single-drug regime may have been chosen for the less challenging cases, for example patients with no co-morbidities, such as diabetes.

The efficacy of modifying prophylactic regimens for patients without full immune competence (for example, patients with advanced malignancy or those infected with human immunodeficiency virus [HIV] has not been adequately evaluated.

CONCLUSION

The growing concern about long-term consequences of early life exposures to antibiotics requires the contemplation of new strategies for risk stratification after surgeries and the deployment of new approaches. Long-term studies of current prescribing practices of antibiotics need to be implemented so that the magnitude of the problem can be documented. In our study, Cefuroxime appeared to be effective in prophylaxis against infections. Metronidazole appeared to be ineffective compared to Cefuroxime. Combination of Cefuroxime and Metronidazole was less effective compared to Amoxicillin and Potassium Clavunate. Cefazolin was commonly prescribed for gynecological procedures.

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