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## ROLE OF QUINOLONES AS ANTIMICROBIAL PROPHYLAXIS IN ORTHOPAEDIC SURGERY.

### A CLINICAL TRIAL

by

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#### ABSTRACT.

This study was carried out to see the role, efficacy of a given dosage of Quinolones (broad spectrum antibiotics) as antimicrobial prophylaxis in Orthopaedic surgery especially that involving the use of implants. For this purpose patients without any obvious focus of infection were given Enoxabid (a Quinolone) orally. The dose was as follows: 2 Tabs (i.e. 400 mg) before surgery and 2 tablets on the day of surgery at night. Then for next three days one tablet was given in B.D. dosage.

In total 30 patients were studied and out of these 26 showed satisfactory healing. However four patients developed complications (infection). In three out of these patients, risk of infection was more than normal population and satisfactory healing was seen by continued use of Enoxabid. However one case failed to respond to Enoxabid and got infected (resulting in removal of implant finally).

Thus excluding these three cases which were high risk patients and were cured by continued use of drug only, one out of thirty got infected.

Thus Enoxabid showed 96.67 % efficacy and played a satisfactory role as prophylactic antibiotic in Orthopaedic surgery

#### INTRODUCTION.

Osteomyelitis continues to haunt the orthopaedic surgeon even today because once it is established it is very difficult to eradicate in spite of the availability of a lot of antibiotics and if the infection occurs in a case where implants have been used to fix a fracture or replace a

joint, this frequently results in an implant failure, loss of bone, fusion of joint or even amputation of a limb. However pyaemia and even death as a complication of osteomyelitis is rarely seen now a days but still it is a frustrating experience for the surgeon as well as the patient.

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It is therefore imperative to prevent development of such disastrous situation by taking appropriate measures such as maintenance of aseptic environment of operating room, standard sterilization of instruments and implants and scrubbing of surgical team, preparation of patient's body part for surgery, and less traumatic surgical approach and gentle tissue handling. For maintaining aseptic environment laminar flow both from wall and ceiling are extensively used in the western world. In developing countries use of ultraviolet light is now becoming popular. Niaz A Khan et al (1992) at University of Agriculture, Faisalabad has shown that for *Pseudomonas* the exposure time to ultraviolet light for elimination of this bacteria is 12 minutes. To reduce further the risk of infection, successful use of different antibiotics in different institution in various parts of the world have been reported. Saleem and Parviz (1989) has shown in Agha Khan Hospital, Karachi that antibiotics are often misused clinically. As a result bacterial

resistance is increasing in frequency, especially with strains of *Salmonella*, *Pseudomonas*, *Escherichia coli*, *Klebsiella*, *Enterobacter*, *Staphylococcus* and *Shigella*. This is largely because laboratory microbiological diagnosis is not readily available for 80% of total population of Pakistan (120 million people). Awais et al in April 1991 carried out a study of operation theaters of Department of Orthopaedic Surgery, Mayo Hospital and cultured 12 air samples and 75 swabs from instruments, sucker tubes, anesthesia machine pipes, ventilator ducts, boiler, scrub basin, tap water, O.T. toilet floor, Stienman pins in the legs, Shanz screws in the legs, nose of doctors and nurses and throat of doctors and nurses. Out of 87 samples subjected to culture no bacteria could be cultured in 52. In rest 35 samples different bacteria cultured were Gram positive 49%, Gram Negative 46% Mixed 5%, (Table I.) shows occurrence of different microorganisms in Orthopaedic Operation theater. (Awais et al, 1991).

**TABLE-I:**

**RELATIVE OCCURENCE OF DIFFERENT BACTERIA DETECTED IN A SURVEY.**

**Gram Positive**

Staph aureus.....	28.2%
Staph Albus .....	05.13%
Staph Saprophytes.....	02.5%
Streptocci .....	07.7%
Strep B Hemolytic.....	05.13%
Strep Pyogenes .....	02.56%
Diphtheria .....	02.56%
Total	48.71%

**Gram Negative**

Proteus.....	17.95%
Pseudomonas.....	15.38%
Klebsella.....	05.13%
Total	46.15%

Mixed ..... 5.13%

Grand Total ..... 100%

The study of sensitivity to various drugs showed the bacteria most resistant to new broad spectrum antibiotics included

few strains of staphylococcus. In present study on Enoxabid (a new quinolone with broad spectrum bactericidal activity) has been used as antimicrobial prophylaxis for surgical wounds.

**Material and Methods.**

Enoxabid in the form of 200 mg tablets were provided by the Abbott Pharmaceutical. 30 patients were included in this study. The protocol consisted of oral administration of Enoxabid 400 mg before surgery with a sip of water, 400 mg on evening of the day of surgery, followed by 200 mg twice daily for the next three days. Thirty patients included in the trial were from both sexes and received implants into their body during surgery. During surgery the nature of procedure, duration of surgery, type of implant used, wound wash if carried out, suction drain if used were recorded. After surgery wound was examined at one week, and three weeks for signs of infection. Exclusion criteria strictly excluded those patients who had active focus of infection in the body before surgery.

**Results.**

30 cases were included in the study, mean age was 42 years (minimum 11 years and max. 90 years) 17 were male and 13 were female. Summary of case No, age, sex diagnosis and implants used is given in table II.

**TABLE-II**

Case No	Age/Sex	Diagnosis	Procedur	Implants used
1.	11 F	Malunited Fr. Humerus	Osteotomy & fixation.	K-wirs.
2.	90 M	Fv. neck of femur	Hemiarthoplasty	A.M. Prosthesis.
3.	50 F	-do-	-do-	-do-
4.	32 M	Trochanteric Fr. of famur	O.R.I.F.	Dynamic hip screw (D.H.S.)
5.	35 M	-do-	-do-	-do-
6.	55 M	-do-	-do-	-do-
7.	65 F	Fv. neck of femur	Hemiarthoplasty	A.M. Prosthesis.
8.*	45 M	Fv. tibia (type I open	O.R.I.F.	D.C.P.
9.	45 F	Fv. radius	-do-	D.C.P.
10.	20 M	Fv. shaft femur	-do-	K-Nail.
11.	25 M	Fx. radius	-do-	D.C.P.
12.	21 M	shaft femur	-do-	K-Nail.
13.*	20 F	Fv. shaft radius & ulna (Gunshot injury)	-do-	Rush Nail & Ext. fixation.
14.	45 M	Fx. shaft radius & ulna	-do-	D.C.P.s
15.	50 M	Fr. neck of femur	T.H.R	Muller T.H.
16.	44 M	Pertorch Fr. femur	O.R.I.F.	D.H.S.
17.	30 M	Fr. shaft femur	-do-	K. Nail
18.	30 M	Comm. Fr. tibia	-do-	Buttress plate
19.	32 F	Fv. Hmerus	-do-	D.C.P.
20.	45 F	Fv. radius & ulna	-do-	D.C.P.s
21.	67 M	Fv. Humerus	-do-	D.C.P.
22.	60 M	Fv. neck of femur	Hemiarthoplasty	A.M. prosthesis.
23.	75 F	Petroch. Fr. femur	O.R.I.F.	D.H.S.
24.	20 F	Old Fr. acetabulum	Arthrodesis	Cobra-head plate.
25.	11 F	Genu Valgus	Valgifying osteotomy	D.C.P.
26.	90.F	Fr. neck of femur	Hemiarthoplasty	A.M. Prosthesis.
27.	25 M	Patella	O.R.I.F.	K. Wries.
28.*	23 M	Malunited Fr. radius & ulna	Osteotomy & ORIF	D.C.P.
29.*	60 F	Fr. neck of femur	Hemiarthoplasty	A.M Prosthesis.
30.	23 M	Fx. tibia & fibula	Close I.M. nailing	K. Nail + Scrw

\* Cases which developed infection

Information regarding the duration of surgery, drains used and wound washed with normal saline is given in Table III, IV and V.

Table III. Duration of Surgery in Minutes.

Minimum	Maximum	Mean
20	150	83

Table IV. Drains used in the wounds.

Suction drain	Over flow drain	Not Used
26	2*	2**

\* Cases No 1 and 7

\*\* Case No 2 and 13 (case 13 got infected).

Table V. Wound Toilet with Normal saline before closure of wound.

With One Liter	With More Than One Liter	Toilet Not Performed
24	5	1*

\* Case 13

After surgery patient was shifted to the ward and wound was examined for redness, swelling/edema & discharge on day 7 and at 3 weeks. Results are given in table VI.

Table VI. Examination of Wound and State of Healing.

Wound Exam.	Normal Healing	Swelling/Edema	Discharge
At 7 Days	26	2*	2**
At 3 Weeks	28		2***

\* Case 28.

\*\* Case 8 and 13.

\*\*\* Case 28 and 29.

### Discussion.

Practice of using prophylactic antibiotics is not new. Usually injectable antibiotics are preferred for this purpose. In present study Enoxabid has been used orally. Kumadant and Neu (4) has shown that new quinolones are orally effective against a wide range of both gram negative and gram positive pathogens. Ross Ers (5) showed that bacteria like Pseudomonas which have received many courses of a variety of antibiotics are usually sensitive to quinolone agents.

Efficacy of an antibacterial agent in the treatment of osteomyelitis cannot be predicted by in vitro study alone, penetration into the affected area must also be evident.

Numerous clinical trials regarding use of various drugs in vivo and vitro to kill the bacteria have been published in the literature. To present review of these papers is beyond the scope of this paper. In present study 4 cases out of 30 (14%) got infected. In 26 cases (87%) wounds healed satisfactorily. These were cases No 8, 13, 28 and 29 which got infected.

Case 8 was a 45 year old male who sustained type 1 open fracture of tibia and fibula. Wound was less than one cm. In size. Surgery was performed and fracture was fixed with plate and screws. Wound was found infected within first week after surgery. Patient was treated by prolonging treatment with Enoxabid 200 mg twice a day. At three weeks wound was found completely healed without any sign of infection.

Case 13, was 20 years female got fracture of radius and ulna with gun shots. Her soft tissue injury was treated with debridements and skin grafting. Surgery was repeated and fracture was fixed. Examination of wound at day 7 showed redness and discharge from the wound. Treatment with

Enoxabid was continued for 2 weeks. At three weeks examination of wound showed complete healing.

Case 28, was a 23 years old male who had malunited fracture of upper 1/3 of radius and ulna with a lot of scar tissue formation. He presented with a swelling on the third post operative day so Enoxabid was continued for another week. He presented with discharge at three weeks. Enoxabid was restarted and the infection finally settled.

Case 29, a 60 years old female had a closed fracture neck of femur. Her hemiorthoplasty was done with a A.M. Prosthesis but the pt. presented to us after 2 weeks with a discharging sinus. Culture sensitivity showed the presence of E. Coli and sensitivity to Enoxabid. So Enoxabid was continued but there was no relief from infection so ultimately the removal of implant was carried out.

Although evaluation of prophylactic use of enoxabid in open injury (case 8) and in previously treated contaminated wounds was not included in the objectives of present study. However the experience has



shown that use of Enoxabid for longer duration in these patients treated the infection. Evaluating the success rate at the end of three weeks showed infection treated. Thus it can be shown that

Enoxabid given orally in dose mentioned above proved a good prophylactic antibiotic in Orthopaedic Surgery.

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