A study on the microbial profile of orthopedic implant infections and its risk factors in a tertiary care hospital

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Abstract

Aims: To identify the etiological agents of orthopedic implant infections in patients admitted in postoperative and septic ward. To identify the risk factors for orthopedic implant infection. To study the Antimicrobial susceptibility pattern of the isolates with a view to formulate an empiric antibiotic regimen. To detect emerging pattern of resistance in these organisms by standard methods (CLSI). To know the prevalence of multidrug resistant pathogens among the isolates.

Materials and Methods: The study period was one year. One hundred and sixty patients were investigated for early or late postoperative infections of orthopedic bone implants using conventional microbiological procedures. Antimicrobial susceptibility testing was then performed for the isolated bacteria according to the standard guideline.

Results: Out of 160 Orthopedic implant infections, the most common procedure that is complicated by infection is Open interlocking nail (Tibia/Femur) (47.5%) followed by closed interlocking nail Tibia/Femur (13.75%). Tibia is the most commonly infected bone (53.75%) after implant surgery followed by Femur (26.87%). Diabetes mellitus and longer duration of surgery were the important risk factors noted in our study. A total of 169 isolates were recovered (166 aerobes and 3 anaerobes). *Staphylococcus aureus* is the most common organism isolated followed by *Staphylococcus epidermidis* and *Proteus mirabilis.* 51.21% of *Staphylococcus aureus* and 73.52% of *Staphylococcus epidermidis* were found to be methicillin resistant. The majority of isolated gram positive cocci were sensitive to Rifampin and Vancomycin. 75% of *Klebsiella pneumonia* and *Proteus vulgaris*, 70% of *Proteus mirabilis* and 58.82% of *Escherichia coli* were found to be ESBL producers.

Conclusion: There is needed to develop a good treatment protocol for orthopedic implant infections and also to create a good protocol for prevention of orthopedic implant infections.

Keywords: Orthopedic implant, Antimicrobial susceptibility, Multidrug resistant, Staphylococcus aureus.

Introduction

Orthopedic implants have become an essential component of modern medicine. More than 2,00,000 total hip replacements are performed annually in the United States and >50,000 in the United Kingdom[23]. The safety and biocompatibility of these devices are excellent, and <10% of the patients at risk experience complication during their lifetime[1]. In the United States, >4.4 million people have at least 1 internal fixation device and >1.3 million have an artificial joint[2].

Total joint replacement and fracture fixation do help by alleviating the suffering of many patients but post-operative infection is a devastating complication[3]. Although incidence of orthopedic implant infection is now low – internationally <1%-2% in institution with highly trained surgeons[4] – even a very low risk of infection can result in a number of patients with orthopedic implant infections. Orthopedic implant infections are significant because of their morbidity and a tendency to serious relapses[5]. Studies in Ayub Medical College, Abbottabad showed incidence rate of 5.76%[49]. It can also be an economic disaster for hospitals that treat large numbers of these patients. The most important factor in both clinical and economic area is to prevent the infection from occurring at all. However, once deep infection is established, rapid, aggressive and definitive treatment must be rendered to the patient. In addition to protracted hospitalization, patients risk complications associated with additional surgery and antimicrobial treatment, as well the possibility of renewed disability[6].

A major risk factor for local infection is the extent of the soft tissue and periosteal damage associated with the fracture. Devascularised bone or other necrotic tissue is an ideal matrix for bacterial growth. Damage to the periosteal blood supply and lack of perfusion of the soft tissues will not only interfere with the fracture healing but also prevent the humoral and immunological host defense mechanisms from reaching the traumatized area and fighting the spread and multiplication of inoculated microorganisms at the bone-implant interface.

With regard to patient factors, several conditions have been recognized to significantly increase the risk of postoperative infection as: rheumatoid arthritis, diabetes mellitus, sickle-cell anemia, psoriasis, renal failure with hemodialysis, immunosuppression due to prior renal or liver transplant, malnourishment, obesity, concurrent urinary tract infection, malignancy and postoperative surgical infection[7].

Staphylococcus epidermidis and *Staphylococcus aureus* are the most common offending organisms, whereas *Streptococcus viridans*, *Escherichia coli*, *Enterococcus faecalis* and *group B streptococci* are less

frequently encountered. About one-third of these infections develop within 3 months, another third develop within 1 year and the remainders develop more than 1 year after surgery[3].

Removal and replacement of the prosthesis are usually required to eradicate the infection with attendant patient trauma and increased cost. Antibiotic treatment to reduce the risk of recurrent infection includes the use of antibiotic-impregnated bone cement for prosthesis fixation at revision surgery and the intravenous administration of antibiotics during revision surgery[8].

This study is conducted prospectively to evaluate the clinical and etiological profile of orthopedic implant infections. It may provide the necessary information to formulate a local antibiotic policy by coming to know about the various pathogens causing orthopedic implant infection and its sensitivity and/or resistance to various antibiotics.

Materials and Methods

This cross sectional study was conducted in the institute of microbiology, Madras Medical College in association with the institute of orthopedics. The study period was for one year from September 2010 to October 2011.

Inclusion Criteria: Diagnosis of orthopedic implant infection is based on clinical data (pain, swelling and warmth of the joint, discharge and fever), together with one or more of the parameters mentioned below: elevated ESR, elevated C-reactive protein and leukocytosis over 12,000 or WBC less than 4000 cells.

Exclusion Criteria: Patients admitted with open fracture and undergone more than one surgery for the same implant were excluded from the study.

Data collection included name, age, address, date of admission, diagnosis at admission, physical examination finding. Duration of hospital stay, nutritional status, underlying illness (diabetes mellitus, uremia, chronic arthritis and concurrent urinary tract infection), type of implant, duration of procedures, smoking and alcoholism were also recorded.

Sample collection: Under strict aseptic precautions samples (Pus or Fragments of excised tissue removed at wound toilet or curetting from infected sinuses or three swabs) were collected and transported to the laboratory immediately.

Sample processing and interpretations are done by standard conventional microbiological techniques as recommended by CLSI. Media and discs were tested for quality control using standard strains. The standard strains were used Staphylococcus aureus -ATCC 25923, Escherichia coli -ATCC 25922 and Pseudomonas aeruginosa -ATCC 27853. Minimum inhibitory concentration (MIC) technique was performed to detect vancomycin resistance.

Results

This study was conducted in the Institute of Microbiology and Institute of Orthopedics, Rajiv Gandhi Government General Hospital, Chennai. Of the 3114 patients who underwent Orthopedic implant surgeries for closed fractures during study period, 160 consecutive patients who developed infection pertaining to the implant were included in the study.

In the 160 infected patients, 138 patients (85.96%) were male and 22(14.03%) were females.

Table 1: Infection rate in different type of implants and time of onset

Type of implant	No: of cases n=160	Percentage
Open interlocking nail: Tibia/Femur	(54+22)76	47.50%
Closed interlocking nail: Tibia/Femur	(12+10)22	13.75%
LCP in distal: Tibia/Femur	(10+7)17	10.62%
Dynamic compression plate Tibia Femur Humerus Radius and ulna	18 11 4 2 1	11.25%
Dynamic hip screw	7	4.37%
Dynamic condylar screw	4	2.5%
Pedicle screw fixation in spinal fracture	4	2.5%
Custom made endoprosthesis	4	2.5%
Hemiarthroplasty for hip	3	1.87%
Reconplates in acetabulam fracture	2	1.25%
Total hip replacement	2	1.25%
Total knee replacement	1	0.62%
Time of onset		
Early postoperative infection	109	68.12%
Late chronic infection	45	28.12%
Haematogenous infection	6	3.75%

Out of 160 OIIs, the most common procedure that is complicated by infection is Open interlocking nail (Tibia/Femur) (47.5%) followed by closed interlocking nail Tibia/Femur (13.75%). Tibia is the most commonly infected bone (53.75%) after implant surgery followed by Femur (26.87%).

In this study, more number of early postoperative infections (68.12%) are found, rather than late chronic (28.12%) and Haematogenous infections (3.75%).

Table 2: Correlation between type of specimen collected and type of pathogens isolated

Type of pathogen	Swab n=77	Aspiration/ Peroperative samples* n=83	Total n=160
Insignificant growth	10 (12.98%)	6(7.22%)	16 (10%)
Monomicrobial	45 (58.44%)	74(89.15%)	119 (74.37%)
Polymicrobial	22 (28.57%)	3(3.61%)	25 (15.62%)

This strengthens the already known fact that aspirates are better samples than swabs, whenever possible[72]. ($p<0.001$)

Table 3: Correlation between orthopedic implant infection and risk factors

Risk factor	No. of cases n=160	Percentage
Alcoholism	83	51.87%
Concurrent urinary tract infection	14	8.75%
Duration of procedures >3hrs	42	26.25%
Diabetes mellitus	79	63.4%
Malignancy	4	2.5%
Nutritional status Albumin level of less than 3.4g/dL. or a total lymphocyte count of less than 1500cells/mm^3	28	17.5%
Steroids	14	8.75%
Smoking	114	71.25%
Type of implant Open interlocking nail Closed interlocking nail LCP in distal Tibia	 76 22 10	 47.5% 13.75% 6.25%
Uremia	7	4.37%

In this study, 63.4% of infected cases had Diabetes mellitus, 26.25% underwent surgery more than 3 hours, 17.5% of them were malnourished patients and 2.5% of them had malignancy. Apart from these proven risk factors smoking and alcoholism were also noted in 71.25% and 51.87%, respectively.

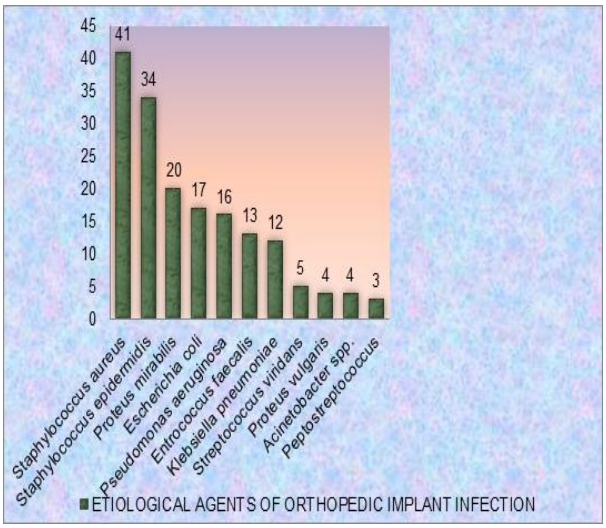


Fig. 1: Etiological agents of orthopedic implant infections

In the present study, aerobic Gram positive cocci were isolated in 55.01%, aerobic gram negative bacilli in 43.22% and anaerobic gram positive cocci in 1.77% of the positive cultures. *Staphylococcus aureus* is the most common individual organism [41(24.26%)] isolated in this study, followed by *Staphylococcus epidermidis* [34(20.11%)]. Among the Gram negative bacilli *Proteus mirabilis* is the most common isolate [20(11.83%)], followed by *E. coli*[17(10.05%)] and *Pseudomonas aeruginosa*[16(9.46%)].

Out of 169 pathogens isolated from infected cases, 113(66.86%) were from early postoperative infections. In early postoperative infections GNB(53.93%) > GPC (46%). Among late chronic cases GPC (72%) > GNB (22%). $p< 0.001$

Table 4: Antimicrobial sensitivity patterns of gram positive cocci (GPC)

Antibiotics	Staphylococcus aureus n=41		Staphylococcus epidermidis n=34		Entrococcus faecalis n=13		Streptococcus viridans n=5	
Amikacin	34	82.92%	19	55.88%	6	46.15%	5	100%
Ciprofloxacin	24	58.53%	21	61.76%	7	53.84%	5	100%
Chloramphenicol	20	48.78%	12	35.29%	8	61.53%	4	80%
Cotrimoxazole	4	9.75%	16	47.05%	-	-	4	80%
Clindamycin	25	60.97%	20	58.82%	12	92.3%	5	100%
Erythromycin	23	56.09%	17	50%	2	15.38%	5	100%
Penicillin	9	21.95%	7	20.58%	2	15.38%	4	80%
Rifampin	41	100%	34	100%	13	100%	5	100%
Vancomycin (MIC)	41	100%	34	100%	11	84.61%	5	100%

All gpc showed 100% sensitivity for Ritampin. Except enterococci faecalis all other GPC showed 100% sensitivity for Vancomycin.

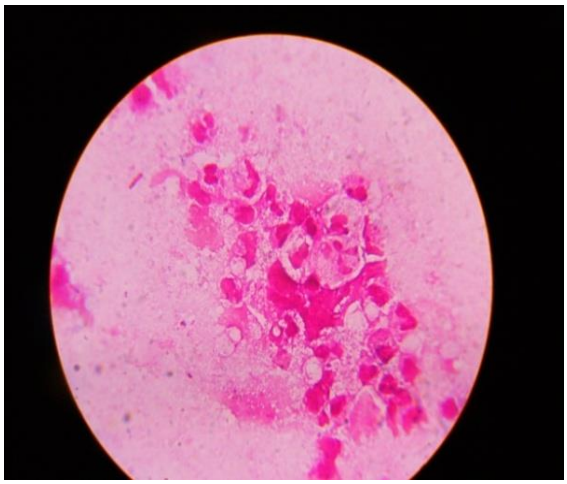
51.21% of Staphylococcus aureus and 73.52% of Staphylococcus epidermidis were found to be methicillin resistant by oxacillin salt agar technique.

Table 5: Antimicrobial sensitivity patterns of gram negative bacilli (GNB)

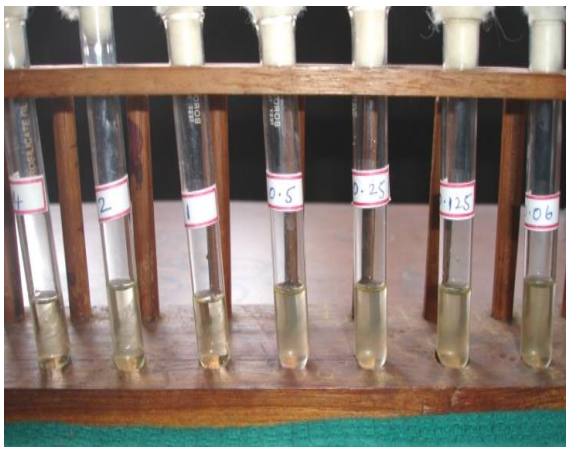
Antibiotics	Proteus mirabilis n=20		Escherichia coli n=17		Pseudomonas aeruginosa n=16		Klebsiella pneumoniae n=12		Proteus vulgaris n=4		Acinetob acter spp. n=4	
Ampicillin	2	10%	2	11.76%	-	-	0	0.0		-	0	0.0
Cefazolin	2	10%	4	23.52%	-	-	2	16.66%	-	-	0	0.0
Gentamicin	11	55%	14	82.35%	8	50%	6	50%	2	50%	1	25%
Amikacin	10	50%	14	82.35%	10	62.5%	10	83.33%	2	50%	1	25%
Cefotaxime	3	15%	5	29.41%	-	-	2	16.66%	1	25%	0	0.0
Ceftazidime	3	15%	5	29.41%	7	43.75%	3	25%	1	25%	0	0.0
Ciprofloxacin	10	50%	10	61.5%	11	68.75%	8	66.66%	2	50%	1	25%
Ofloxacin	6	30%	8	45.4%	10	62.5%	5	41.66%	1	25%	1	25%
Piperacillin	13	65%	10	58.82%	12	75%	7	58.33%	-	-	2	50%
Imipenem	20	100 %	17	100%	13	81.25%	12	100 %	4	100 %	4	100 %
Cefoperazone /sulbactam	19	95%	11	64.7%	3	18.75%	5	41.6%	2	50%	2	50%

All GNB showed high level resistance to third generation cephalosporin. All GNB except *Pseudomonas aeruginosa* showed 100% sensitivity for Imipenem.

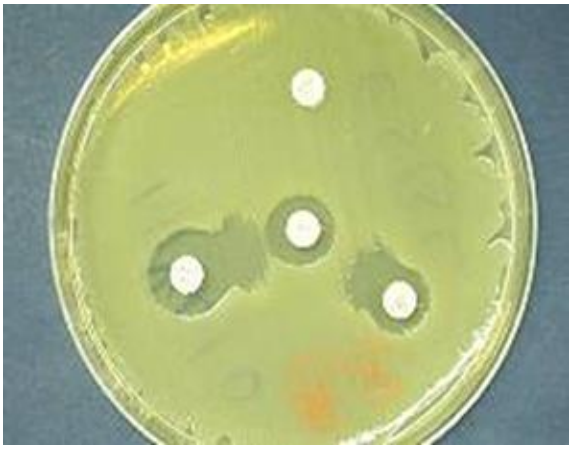
75% of *Klebsiella pneumonia* and *Proteus vulgaris*, 70% of *Proteus mirabilis* and 58.82% of *Escherichia coli* were found to be ESBL producers (Phenotypic confirmation disk diffusion test and double disk diffusion synergy test).



a) Direct gram stain showing plenty of neutrophils gram negative bacilli (proteus mirabilis)



b) Vancomycin MIC for Staphylococcus aureus (MIC = 1)



c) Distortion of zone of inhibition produced by an ESBL isolate on DDST

d) Biochemical reactions of Staphylococcus epidermidis

Fig. 2: Pictures related to study

Discussion

This study was conducted at the septic and postoperative wards of Institute of Orthopedics, Rajiv Gandhi Government General Hospital, Chennai. Of the 3114 patients who underwent Orthopedic implant surgeries for closed fractures during the study period, 160 consecutive patients who developed infection pertaining to the implant were included in the study.

The rate of Orthopedic implant infection in the present study is 5.13% which is much higher than accepted standard for post-operative wound infection (<1%)[3,4]. But, this high incidence has been noted by M.S.Khan et al., 2008[9], Iqbal MZ et al., 2001[10] and Tago I.A, et al, 2007[11] who have recorded 5.76%, 5% and 7.8% respectively. Among these 160 cases, 109 (68.12%) were included under early onset postoperative wound infections (<1 month after surgery); 45 (28.12%) under late chronic infection and 6 (3.75%) under haematogenous infection**(Table 1)**. Similar incidence has been quoted by A.D. Koshravi et al, 2009[12] (72.9%, 22.6% and 4.5% respectively.) Controversially, Gomez et al, 2003[13] and Giulieri et al, 2004[14] have reported early infection as 33.33% and 29% respectively. This high prevalence of early infections in the study may be related to inadequate disinfection procedures to eliminate micro organisms from the environment, contamination of surgical instruments and /or contaminated implants. More importantly, the low incidence of late and haematogenous infection may be due to short period of study and inability to follow up all the 3114 patients who underwent surgery. Zimmerili et al, 1998[15], has observed that studies lack appropriate statistical power because of patients being lost to follow up, change of residence or dying of underlying disease. He has further observed that for a publication of a statistically significant study for OIIs and for a formulation of good treatment protocol with a 2 year follow up would require a minimum of 6 years from the study design until results. These observations implies that the incidence of orthopedic implant infections in our study population would be still higher.

In this study, out of the 160 infected patients, 93 (57.89%) and 42(26.31%) were in the age group of 21-40 and 41-60 years respectively. Only 7.01% and 8.77% were in the age group of <20 and > 60 years respectively. This high percentage of implant infections in actively working population [21-60 years (84%)] may be explained by the similar high incidence of road traffic accidents in the actively working population. Road traffic accidents constitute about 78.7% of the causes of fractures in our study.

In the 160 infected patients, 138 patients (85.96%) were male and 22(14.03%) were females**.** This high male predominance can be attributed to the high incidence of male population who travel for work, and increased risk behavior for RTA (drunken driving, rash driving.). 5.3% of males operated and 4.2% of the females operated developed infection during the study (p=0.333). This shows that there is no significant gender difference in acquiring the infection as per our study.

In the study, 63.4% of the patients who were infected had a significant proven risk factor, i.e., uncontrolled diabetes. Prolonged surgery time (mean surgery time 3.45 hrs)[16], was another risk factor noted in 26.25%. Alcoholism and smoking were noted in 51.87% and 71.25% of the infected cases respectively**(Table 3)**.

In this study, it has been noted that infected implants were more common in surgeries done in tibia and femur [tibia (53.75%)> femur (26.87%)] **(Table 1)**. Infection has been noted in less numbers in surgeries in other areas.(Radius, Ulna, Humerus etc.). More commonly fractured bone and more commonly taken for implant surgery, periosteal stripping done in open nailing reduces the blood supply, old cases taken for surgery and distal one third of bone is subcutaneous explains the increased percentage of infections in tibia implant surgery. A.D. Khosravi et al.[12] and Lars Lidgreen et al[17] have observed that infection is more common in femur.(27.9%).

In this study, etiological agents of orthopedic implant infections were identified in 144 patients (89.99%). Out of the 144 culture positive patients, 119 (82.63%) showed monomicrobial growth. Poly microbial infection was seen in 25 (17.36%) patients. So, in this study, monomicrobial infection outnumbered poly microbial infection. Of the samples collected, 83(51.87%) were aspirates /per operative samples and 77 (48.13%) were swabs. Of the 83 per operative samples/aspirates, 74(89.15%) was monomicrobial and 3(3.61%) were polymicrobial. In contrast, an increased number (22) of polymicrobial infection was noted in swabs (28.5%), though monomicrobial infection was the commonest type even in swabs(58.4%)(p<0.001) **(Table 2)**. This strengthens the already known fact that

aspirates are better samples than swabs, whenever possible[18].

According to the present study, cultures were positive in majority of the studied patients (89.9%) **(Table 2).** This finding is similar to the observations of A.D. Khosravi et al. (93.9%)[12] and Zimmeli et al, 2004(89%)[19]. However, Gomez et al[5]. has reported culture positivity in only 60 % of the cases.

In the present study, aerobic Gram positive cocci were isolated in 55.01%, aerobic gram negative bacilli in 43.22% and anaerobic gram positive cocci in 1.77% of the positive cultures **(Fig. 1)**. This is in accordance with the data given by Barry D Brause[20] and A.F. Widmer[6] (gram positive cocci 70% and 69% respectively). The isolation of anaerobes in the study was comparatively lesser than that recorded by Barry D Brause[20] and A.F. Widmer[6] (10%each). Tunney et al 1999[21], in a controversial report, isolated anaerobes (propionibacterium spp.) in 60% of OIIs by using strict anaerobic bacteriological practices during the processing of samples. This emphasizes the need for better sample collection, avoidance of swabs, inoculation of multiple plates, and longer incubation period for better isolation of anaerobes from OIIs.

Of the 144 culture positive cases, *Staphylococcus aureus* was the most common pathogen isolated, 41, (21.26%) followed closely by *Staphylococcus epidermidis*, 34, (20.11%) **(Fig. 1)**. *Proteus mirabilis* was isolated in 11.83%, *E.coli* in 10.05% of cases, *Pseudomonas aeruginosa* in 9.46%, *Enterococcus faecalis* in 7.69 % and *Klebsiella pneumoniae* in 7.10%. These findings are supported by I. Onche et al[22]. And Lars Lidgreen et al[17], MS khan et al[9]. *Staphylococcus epidermidis* was isolated only in 9.05% and has been reported as fifth common cause of OIIs by A.D. Khosravi. In contrast, *Staphylococcus epidermidids* was the second most common isolate contributing to 20.11% in our present study. Interestingly, all anaerobes were isolated from patients with late onset of the implant infection reflecting that anaerobic microorganisms appear to play a significant role in the pathogenesis of late-onset postoperative infection in this study, especially where there is an extra medullary internal fixation device. These findings are similar to A.D. Khosravi et al. 2009, and Gomez, J. et al 2003.

Gram positive bacteria showed 100% sensitivity to Vancomycin and Rifampin. All Enterobacteriaceae showed 100% sensitivity to Imipenem **(Table 4).**

The commonest bacteria isolated in this study, *Staphylococcus aureus* showed 100% sensitivity to Vancomycin and Rifampin, 82.92% to Amikacin, 60.97% to Clindamycin, 58.53% to Ciprofloxacin, and 56.09% to Erythromycin. The second commonest isolate *Staphylococcus epidermidis* showed 100% sensitivity to Vancomycin and Rifampin, 61.76% to ciprofloxacin, 58.82% to Clindamycin, and 55.88% to Amikacin.

51.21% of *Staphylococcus aureus* and 73.52% of *Staphylococcus epidermidis* were found to be Methicillin resistant **(Table 4)**. These MRSA and Methicillin Resistant *Staphylococcus epidermidis* were more commonly isolated from early onset postoperative infection than late chronic infection and hematogenous infections. This indicates that use of inadequate antibiotics during empirical therapy and longer duration of hospitalization may selectively enhance the growth of drug resistant pathogens.

Vancomycin sensitivity was detected by macro broth dilution method. All isolates showed MIC within sensitivity range (< 2µg/ml). In spite of this sensitivity pattern, the patients not responded well clinically. This may be explained by need of biofilm elimination concentration which is much higher than MIC and poor penetration of Vancomycin into the biofilm. Rifampin is not used routinely in our hospital in the treatment protocol for OIIs. Based on our reports, 6 patients who did not respond to Vancomycin were started on Rifampin & Ciprofloxacin and 4 were lost to follow up and 2 had complete cure of symptoms and infection after 6 months of follow up. This clinical use of Rifampin could not be further validated because of the short period of study and inadequate follow up of patients. Further clinical trials are needed at our hospital to include Rifampin in the treatment protocol for gram positive infections in OIIs.

Enterococcus faecalis showed 100% sensitivity to Rifampin, 84.61% to Vancomycin, 61.53% to Chloramphenicol, 53.84% to Ciprofloxacin, and 46.16% to Amikacin. Two isolates identified as Vancomycin Resistant Enterococci (VRE) showed MIC > 32µg/ml by macro broth dilution technique. But these two strains were sensitive to Rifampin and Linezolid. *Streptococcus viridans* showed 100% sensitivity to most of the antibiotics tested.

Among gram-negative isolates, *Proteus mirabilis* was the most common isolate which showed 100% sensitivity to Imipenem, 95% to Cefoperazone/ Sulbactem, 50% to Amikacin and Gentamicin, 15% to Cefotaxime and Ceftazidime. *Escherichia coli* showed 100% sensitivity to Imipenem, 82.35% to Amikacin and Gentamicin, 61.5% to Ciprofloxacin, 58.5% to Piperacillin. *Klebsiella pneumoniae* showed 100% sensitivity to Imipenem, 83.33% to Amikacin, 66.66% to Ciprofloxacin **(Table 5).**

Among the mechanisms of resistance to third generation Cephalosporins, production of ESBL is the most common. 18.75% of the *Pseudomonas aeruginosa* were found to be MBL producers. However no isolate was found to be Amp C producer.

Out of 20 isolates of *Proteus mirabilis* screened for ESBL production 17(85%) were found to be positive. By phenotypic confirmative disc diffusion method, 14(70%) were confirmed as ESBL producers. Among 17 isolates of *E. coli* 12(70.58%) found to be ESBL

producer by screening test. By PCDDT 10(58.82%) were confirmed as ESBL producers.

Out of 16 isolates of *Pseudomonas aeruginosa* screened for ESBL and MBL production 6(37.5%) were found to be ESBL positive and 3(18.75%) were found to be MBL positive respectively both by screening and confirmatory test**.**

Hence, the choice of empiric antibiotics should be based both on local pathogen prevalence and antimicrobial susceptibility and on the identification of patients with selected clinical parameters at high risk of developing infections caused by multidrug resistant organism.

Conclusion

The infection rate in our study was quite high and there is need for proper measures of infection control as it has great financial burden on patient and on hospital resources and could lead to increased morbidity and mortality in patients. Diabetes mellitus and prolonged duration of surgery were the two important risk factors associated with infected cases in our study. Aspiration/Peroperative specimen are better samples than swabs, whenever possible. The choice of empiric antibiotics should be based both on local pathogen prevalence and antimicrobial susceptibility pattern. In future a more comprehensive study with a long follow up period is needed to develop a good treatment protocol for orthopedic implant infection and also to create a good protocol for prevention of orthopedic implant infections.

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