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A Prospective Study Of Management Of Orthopaedic Device Related Infection – A Regional Hospital Study

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Abstract

Background: Orthopaedic device related infections are one of the most frequent post operative complications and require an individualized combined surgical and antibiotic management. The treatment modality depends on duration of infection, stability of the implant, antimicrobial susceptibility of the pathogen and condition of the surrounding soft tissue.

Material and methods: We prospectively studied 30 patients with clinically diagnosed orthopaedic device related infections. Patients with closed and open fractures treated with internally fixed implants were included and patients with open fractures treated with external fixators and patients with closed fractures treated with K-wires were excluded.

Results: Out of 30 cases, 15 were consolidated fractures. In all 15 cases, first stage treatment of debridement and implant removal was done, out of which 2 cases needed second stage treatment of debridement. 15 cases were non-consolidated fractures. In 8 cases, first stage treatment of irrigation and debridement with retention of implant and insertion of 1gm vancomycin antibiotic cement beads done. 7 cases needed se cond stage of treatment. Most commonly isolated microorganism was Staphylococcus aureus accounting for 43.3 % followed by Pseudomonas accounting for 23.3%.

Conclusion: This study demonstrates an acceptable success rate in a clinical challenging problem of orthopaedic device related infection by a standardized treatment regime using aggressive surgical debridement and immediate broad combination antibiotic therapy and choice of other surgical procedure depending on the status of fracture consolidation.

Keywords: Antibiotic cement beads,Fracture consolidation,Internal fixation,Orthopaedic device related infection

Introduction:

Orthopaedic device related infections in orthopaedic surgery are a dreaded complication, leading to non-union, loss of function, and even amputation. It is not only a source of morbidity and mortality,[1] but it also brings an important socio-economic burden.[2] The success rate in the treatment of orthopaedic device related infections is between 70% and 90%.[3] Some studies report an incidence of orthopaedic device related infections for closed fractures of 1% to 2% with an incidence even reaching up to 30% in open fractures.[4] However, the real incidence of orthopaedic device related infections is probably underestimated due to a lack of precise definition. When looking at the current literature, many studies have concentrated on prosthetic infections. Most of the applied concepts in the treatment of orthopaedic device related infections are adaptations of algorithms found in prosthetic infections management. It is important to notice that those two identities must be distinguished. While the ultimate goal in the treatment of infected total joint is the

eradication of the infection and a sterile implant, the goal of the treatment of an orthopaedic device related infections is the healing of the fracture and the avoiding of chronic osteomyelitis. Furthermore, after consolidation of the bone, the implant can be extricated, contrary to the prosthesis. This allows for a more permissive attitude, with use of suppressive antibiotics until retrieval of the implant. Diagnostics in implant related infections can be complicated because identification of the germ is often only possible after intraoperative sampling, in contrast to prosthetic infections where joint aspiration can help preoperatively with diagnostics and establishment of a treatment plan.

Compared to patients presenting for elective surgery, traumatic patients have generally more soft tissue damage, with even direct contamination in case of open fractures. Those delicate cases often need multiple surgeries going from delayed definitive fixation to cutaneous coverage by plastic surgeons. The infection rate between a patient scheduled for elective surgery and the fracture patient is thus not equivalent. On the other hand, mechanic stability is required in order to prevent infection and gain definitive bone healing. [5,6]

Materials And Methods:

A prospective study was conducted on 30 patients with clinically diagnosed orthopaedic device related infection in the Department of Orthopaedics, Basaveshwara Teaching and General Hospital, Kalaburagi. The study was conducted between June 2019 to March 2021.

Data Collection:

Patients' baseline characteristics, such as age, gender, clinical history were collected on admission. White blood cell counts, ESR levels and C-reactive protein levels were collected at clinical presentation and post operatively . Type of orthopaedic device, the presence of fever, intraoperative presence of pus, the causative pathogen were assessed.

Inclusion Criteria

1. Patients of all age groups of either gender with closed fractures treated with internally fixed implants
2. Patients of all age groups of either gender with open fracture treated with internally fixed implants

Exclusion Criteria

1.Patient with open fractures treated with external fixators.

2.Patient with closed fractures treated with K-wires.

3.Patient with closed fractures treated conservatively.

4.Patient treated with orthopedic prosthesis

Results:

In our study of 30 patients, majority of the patients were males with mean age of 50.50 ± 12.43. Out of 30 patients, majority of cases i.e 13 plates were infected, 10 intramedullary nails were infected and 7 CC screws were infected. Out of 30 sample cases, 9 (30.0%) cases of bone involvement of infection were femur, followed by 8 (26.6%) cases involvement of bone was tibia. In our study treatment strategies were mainly dependent on fracture consolidation. Fracture consolidation is determined by looking at callus size, cortical continuity in plain radiographs and by clinical assessment in which absence or presence of pain at fracture site, ability to bear weight in lower limbs and ability to lift weight in upper limbs were considered. Stable and painless bone on angulation on examination was considered. After fracture consolidation patients were treated with debridement and implant removal and intravenous antibiotic therapy according to sensitivity. Out of 30 cases, 15 (50.0%) were consolidated fractures. In all 15 cases, first stage treatment of debridement and implant removal was done, out of which 2 (6.7%) cases needed second stage treatment of debridement. In consolidated cases; 12 (40.0%) cases wound closed by primary suturing, 1 (3.3%) case wound closed by secondary suturing and 2 (6.7%) cases vacuum assisted closure was used for wound healing. For non-consolidated fractures, decision of retention of implant was taken considering the duration of infection, stability of implant, status of fracture union (delayed/non-union) and most importantly surgeons' decision. If decided to retain the implant, through debridement and 1gm Vancomycin antibiotic cement beads are inserted for 6 weeks. If needed, second

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stage surgery is planned as needed. If decided not to retain the implant, through debridement and implant removal is done and appropriate fracture fixation techniques like limb reconstruction system, redo implant fixation with bone grafting etc were done.15 cases were non-consolidated fractures. In 8 cases, first stage treatment of irrigation and debridement with retention of implant and insertion of 1gm vancomycin antibiotic cement beads was done. In 5 of these cases, antibiotic cement beads removal at 6 weeks was sufficient for treatment. In 2 cases, old implants and antibiotic cement beads were removed and redo bone fixation and bone grafting done. For one case, exchange intramedullary nailing (PFN) was done. 5 cases were presented as infected implant with non-united fracture,3 of them treated with debridement, implant removal and limb reconstruction system. 2 of them treated with debridement, implant removal and redo internal fixation of fracture with bone grafting. For 2 cases, with retention of implants, multiple stages of debridement are done. In non-consolidated fracture cases 8 cases wound closed by primary suturing, 5 cases wound closed by secondary suturing and 2 cases wound closed by vacuum assisted closure (Table 1).

Microbiology:

In our study, most commonly isolated microorganism was Staphylococcus aureus accounting for 43.3 % followed by Pseudomonas accounting for 23.3%. Other isolated organisms were Klebsiella pneumonia, Staphylococcus hominis, Burkholderia cebacea, Enterococcus faecium (Graph 1).

Lab Investigations:

Comparison of WBC, ESR and CRP in pre- and post-op in consolidated fracture cases (Table 2).

There was statistically very highly significant difference of mean WBC, ESR and CRP between pre- and post-op in consolidated fracture cases ($P<0.001$). In the post-op mean WBC counts, ESR levels and CRP levels significantly reduced as compare to pre-op (Table 3).

Comparison of WBC, ESR and CRP in pre- and post-op in not consolidated fracture cases (Table 3).

There was statistically very highly significant difference of mean WBC, ESR and CRP between pre- and post-op in non-consolidated fracture cases ($P<0.001$). In the post-op mean WBC counts, ESR levels and CRP levels significantly reduced as compare to pre-op.

There was no statistically significant difference of mean WBC, ESR and PCV between consolidated and not-consolidated fracture cases in pre-op ($P>0.05$). There was no statistically significant difference of mean WBC between consolidated and not-consolidated fracture cases in post-op ($P>0.05$). Whereas there was statistically significant difference of mean ESR and PCV between consolidated and not-consolidated fracture cases in post-op ($P<0.05$).

Comparison of duration of healing with consolidated and not-consolidated fracture cases (Table 4)

In our study, in fracture consolidated cases, 10 cases were healed within 15 days, 5 cases healed within 15 days to 6 months. In non-consolidated fracture cases, 1 case healed within 15 days, 9 cases healed within 15 days to 6 months and 5 cases took more than 6 months to heal. There was statistically significant difference of duration of healing between consolidated and not-consolidated fracture cases ($P<0.05$)

Illustrative case 1:

27 years old male with distal femur non-union with infected implant in-situ.

Discussion:

The aim of the study was to evaluate outcome of irrigation, debridement and retention of the implant combined with antibiotic therapy for orthopaedic device related infection in consolidated fracture cases and to evaluate outcome of debridement, implant removal or exchange (one or multiple stages) with accompanied antibiotic therapy for orthopaedic device related infection in non-consolidated fractures. Results demonstrate a high success rate in fracture consolidated cases with debridement and implant removal, wound closure achieved with primary closure in almost all cases. In non-consolidated fractures, most of the implants were retained with thorough debridement and 1 gm antibiotic cement beads in-situ. In cases where implants could not be retained, appropriate treatment strategy like limb reconstruction system, redo fixation with bone grafting etc. is done and high success rate with

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fracture consolidation is achieved and infections are resolved. Richard Kuehl et al included 229 in observational prospective study and concluded overall success rate was 87-90% independent of time of revision. The infection after fracture fixation affected 185 long bone 147 fixations (80.8%) and 44 fixations of other locations (19.2%, such as foot, pelvis or patella). Failure rate was 10.3% (19/185) in long bone implants, and 18.2% (8/44) in implants from other locations (p=0.19). Staphylococcus aureus was the most common pathogen in total (in 42%, 96/227) as well as 150 in each time interval. Enterobacteriaceae accounted for the second most common 151 pathogens in early infections whereas coagulase-negative staphylococci increased to the rate of S. 152 aureus in late infections (each 39.1%, 36/92) [7]. Zimmerli et al. as well as Barberan et al. and Drancourt et al. studied infection following osteosynthesis and the effect of antibiotic combination therapy with rifampicin [8-10]. They analyzed both PJI and osteosynthesis treated with initial implant retention and combination antibiotic therapy and found a success rate of 48% after an average follow-up of 23.5 months. The study of Barberan et al. solely included patients with osteosynthesis and found a success rate of 72%[9]. Notably, they only performed surgical debridement in 72% of the cases. In contrast, Zimmerli et al. studied rifampicin combination therapy for infection associated with orthopedic implants, combining prosthetic surgery, and osteosynthesis and showed a 100% success rate in the rifampicin combination group[8]. Additionally, a recent study showed high success rates (90%) with the use of rifampicin in staphylococci-positive infections. In contrast with our study, they handled strict selection criteria for patients to be treated according to their algorithm, whereas we included all patients in spite of the condition of the soft tissue or found pathogens.

Microbiology:

In our study, most commonly isolated microorganism was Staphylococcus aureus accounting for 43.3 % followed by Pseudomonas accounting for 23.3%. The microbiology of post-operative wound infection in implants has changed very little over time except for the emergence of resistant organisms. It was similarly most common in various other reports worldwide. The relative rates however vary from centre to centre. At the National Orthopaedic Hospital Lagos, Onche[11] found it accounted for 71.4% of his isolates while in Zaria, North Central Nigeria, Mbamali[12] isolated *staphylococcus aureus* in 60% of patients while Classen et al[13] in USA noted that it occurred in 16.3% of their cases. The picture was however different at Jos where Oguachuba[14] found *Proteus spp* to be the most common isolate with a rate of 41.9% followed by *Staphylococcus aureus* with 25.6%.

Antibiotic Prophylaxis: In our study, intravenous antibiotics were given according to susceptibility for 2 weeks post operatively and oral antibiotics for 6 weeks. Most commonly used antibiotics were Inj. Cefeperazone with Sulbactum 1.5 gm, Inj. Amikacin 500mg, Inj. Linezolid 600mg, tab. Clindamycin 300mg.Micheal Warnock et al 26849 trauma procedures were included with an overall SSI rate of 1.34% (95% Confidence interval [CI] 1.21 to 1.49). Single dose flucloxacillin (2 grams) with single dose gentamicin (3mg/kg) was the most commonly used protocol used in 3 different hospitals for a combined 13.5 years covering 11445 procedures. The SSI rate was 0.72% (95% CI 0.58-0.89). Triple dose cefuroxime (1.5 grams) was used in 2 different hospitals for a combined 10 years covering 8864 procedures. The SSI rate for this regime was 2.46% (95% CI 2.16-2.80). Single dose cefuroxime (1.5 grams) was used in 2 different hospitals for a combined 8 years covering 6540 procedures. The SSI rate was 0.92% (95% CI 0.71-1.18) [15].

Additionally, we included all acute infections after osteosynthesis, creating a heterogeneous group, affected all body parts, and choice of all internal fixation implants adding up to the difficulty to assign results to specific elements. However, considering the low overall incidence of 1–2% for infection following osteosynthesis, it is not feasible to form a cohort with a homogeneous population, concerning fracture and implant type. Another drawback is the fact that there was a fair amount of variation within the treatment regime. However, we wanted to show the real-time results of a standardized treatment, and in that way present current practice. Due to the fact that we analyzed a single cohort from one, level 1 trauma center, one may argue that the results found in this study could not be generalized. Yet, since we are a specialized center, also patients from level 2 and 3 centers were referred and included. In addition, open

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fractures, seen more in multi-trauma patients, are known to be at higher risk to develop infection.

Moreover, lacking a control group, no comparison could be drawn with results in patients treated according to a different protocol. However, this is the one of the few series to describe outcome of standardized aggressive treatment for infection after osteosynthesis, consisting of implant retention, thorough surgical debridement, and intensive antibiotic combination therapy in non-consolidated fractures and debridement and implant removal and intensive antibiotic combination therapy in consolidated fractures.

Conclusion:

This study demonstrates an acceptable success rate in a clinical challenging problem of orthopaedic device related infection by a standardized treatment regime using aggressive surgical debridement and immediate broad combination antibiotic therapy and choice of other surgical procedure depending on the status of fracture consolidation. Surgical management as well as microbiology changed according to the time of infection. Debridement and implant removal have high success rate in fracture consolidated cases. Further comparison studies and randomized trials are needed to evaluate this concept.

Tables And Figures:

Table 1: Treatment strategies

Fracture consolidation	1st stage		2nd stage	
	Treatment	No	Treatment	No
Consolidated fractures (15)	Implant removal& Debridement	15	Debridement	2
Not consolidated fractures (15)	Implant removal& Debridement	3	Limb reconstruction system	2
			Bone grafting & fixation	1
	Debridement & Antibiotic cement bead in-situ	8	Antibiotic cement bead removal	5
			Bone grafting & fixation	2
			Exchange PFN nailing	1
	Debridement & distal screw removed	1	Debridement	1
	Debridement & Limb reconstruction system	1	Debridement	1
	Debridement & Retention of implants	2	Debridement	2

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Total	---	30 (100.0%	---	17 (56.7%)

Table 2: Comparison of WBC, ESR and CRP in pre- and post-op in consolidated fracture cases.

Lab. Results	Consolidated		Paired t-test value P-value & significance
	Pre-op	Post-op	
	Mean ± SD	Mean ± SD	
WBC	20267.0 ± 3781.8	8567.2 ± 2122.5	t = 9.905, P = 0.000 VHS
ESR	52.67 ± 11.23	28.80 ± 7.61	t = 7.657, P = 0.000 VHS
CRP	44.30 ± 22.40	22.40 ± 4.70	t = 7.869, P = 0.000 VHS

Table 3: Comparison of WBC, ESR and CRP in pre- and post-op in not consolidated fracture cases

Lab. Results	**Not consolidated**		**Paired t-test value P-value & significance**
	Pre-op	**Post-op**	
	Mean ± SD	**Mean ± SD**	
WBC	20351.3 ± 5377.9	9900.0 ± 3361.1	**t = 7.627, P = 0.000 VHS**
ESR	56.26 ± 12.60	31.93 ± 12.05	**t = 7.134, P = 0.000 VHS**
CRP	51.58 ± 17.84	26.86 ± 8.84	**t = 6.380, P = 0.000 VHS**

Table 4: Comparison of duration of healing with consolidated and not-consolidated fracture cases

Duration of healing	**Consolidated fractures**		**Non-consolidated fractures**	
	Frequency	**Percentage**	**Frequency**	**Percentage**
< 15 days	10	66.6	1	6.7
15 days -6 months	5	33.3	9	60.0
>6 months	0	0.0	5	33.3
Total	15	100.0	15	100.0

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Fisher exact probability test	**P = 0.018 S**

NS= not significant, S=significant, HS=highly significant, VHS=very highly significant

Image 1: Sinus at infected implant site

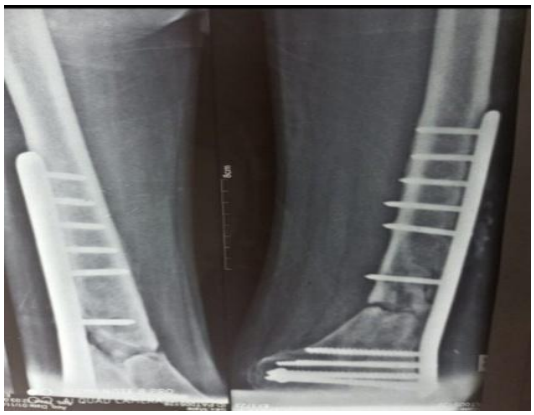

Image 2: Preoperative X-ray showing non united distal femur infected plate in-situ

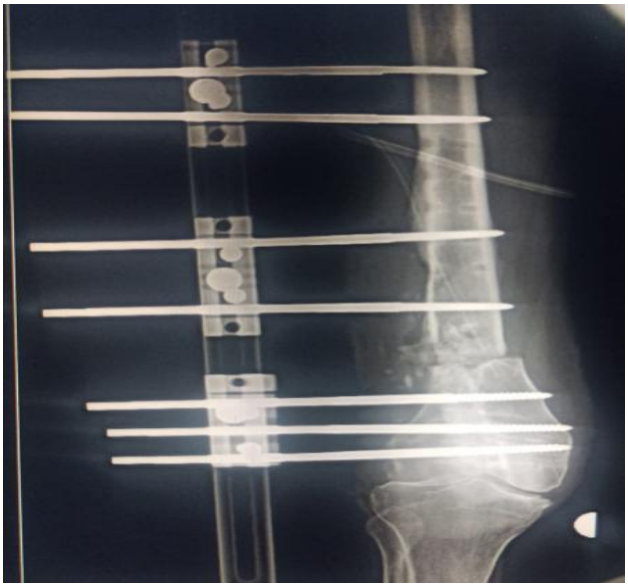

Image 3: X ray radiograph of immediate

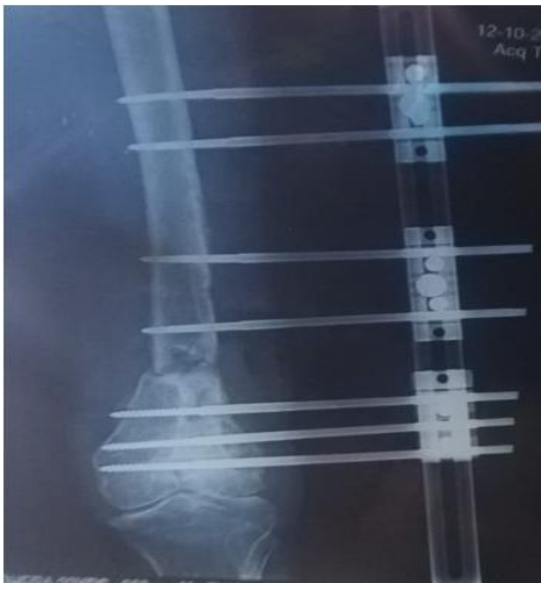

Image 4: X ray radiograph of post OP

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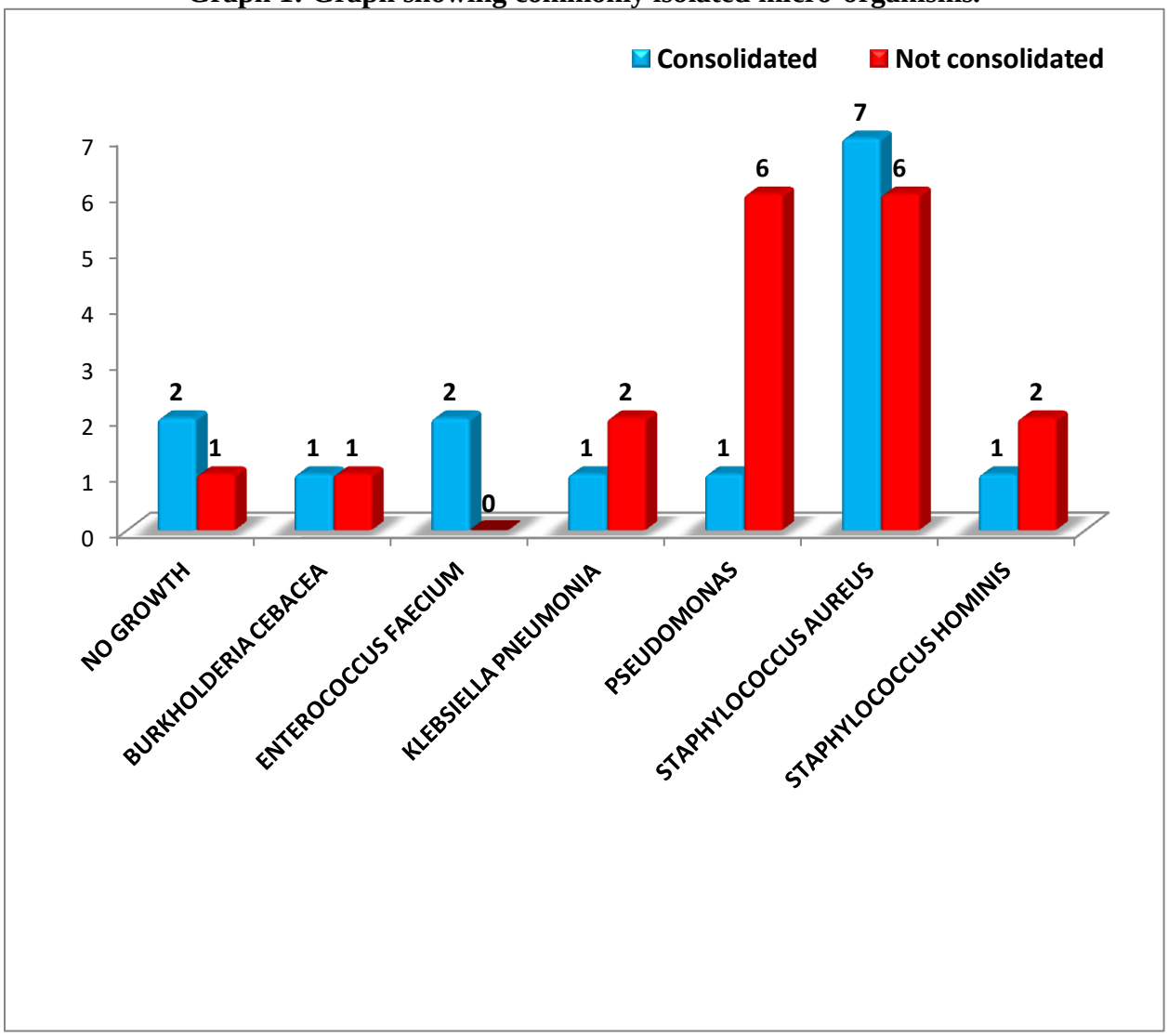
Graph 1: Graph showing commonly isolated micro-organisms.



References:

1.Hak DJ, Fitzpatrick D, Bishop JA, et al. Delayed union and non-unions: epidemiology, clinical issues, and financial aspects. 2014;45: S3–7.

2.Thakore RV, Greenberg SE, Shi H, et al. Surgical site infection in orthopedic trauma: a case-control study evaluating risk factors and cost. J Clin Orthop Trauma 2015; 6:220–26.

3. Tschudin-Sutter S, Frei R, Dangel M, et al. Validation of a treatment algorithm for orthopaedic implant-related infections with device-retention-results from a prospective observational cohort study. Clin Microbiol Infect 2016; 22:457. e1-9.

4.Trampuz A, Zimmerli W. Diagnosis and treatment of infections associated with fracture-fixation devices. 2006;37: S59–66.

5.Metsemakers WJ, Kuehl R, Moriarty TF, et al. Infection after fracture fixation: current surgical and microbiological concepts. 2018; 49:511–522.

6.Worlock P, Slack R, Harvey L, Mawhinney R. The prevention of infection in open fractures: an experimental study of the effect of fracture stability. 1994; 25:31–8.

7. Kuehl R, Tschudin-Sutter S, Morgenstern M, Dangel M, Egli A, Nowakowski A, Suhm N, Theilacker C, Widmer AF. Time-dependent differences in management and microbiology of orthopaedic internal fixation-associated infections: an

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observational prospective study with 229 patients. Clin Microbiol Infect. 2019 ;25(1):76-81

8. Zimmerli W, Widmer AF, Blatter M, Frei R, Ochsner PE, Foreign body infection study group. Role of rifampin for treatment of orthopedic implant-related Staphylococcal infections; A randomized controlled trial. JAMA. 1998; 279:1537–41.

9. Barberan J, Aguilar L, Gimenez MJ, Carroquino G, Granizo JJ, Prieto J. Levofloxacin plus rifampicin conservative treatment of 25 early staphylococcal infections of osteosynthetic devices for rigid internal fixation. Int J Antimicrob Agents. 2008;32(1):154–7.

10. Drancourt M, Stein A, Argenson JN, Roiron R, Groulier P, Raoult D. Oral treatment of Staphylococcus spp. Infected orthopaedic implants with fusidic acid or ofloxacin in combination with rifampicin. J Antimicrob Chemother. 1997;39(2):235–40.

11. Onche II: Post-operative wound infection in implant surgery. Dissertation submitted to the National Post graduate Medical College of Nigeria, Lagos. 2000.

12. Mbamali EI. Internal fixation of femoral shaft fractures at the Ahmadu Bello University Teaching Hospital Zaria. Nigerian Medical Practitioner 1981; 2: 81 – 5.

13. Classen DC, Scott Evans R, Pestotnik SL et al.The timing of prophylactic administration of antibiotics and the risk of surgical wound infection. N Engl J Med .1992; 326: 281 – 5.

14. Oguachuba HN. Wound infection in the orthopaedic –traumatology department of Jos University Teaching Hospital, Jos, Nigeria. Nigerian Medical Journal. 1987; 17: 147 – 151.

15. Warnock M, Ogonda L, Yew P, McIlvenny G. Antibiotic Prophylaxis Protocols and Surgical Site Infection Rates in Trauma Surgery: A Prospective Regional Study of 26,849 Procedures. Ulster Med J. 2019 ;88(2):111-4.

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