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Delayed Onset Implant Associated Infections in United Closed Fractures - An Analysis of a Rare Phenomenon

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Abstract: ***Purpose: Implant related infections occurring for the first time in healed closed fractures are a poorly understood phenomenon. Very little is known about their exact incidence and the risk factors involved. We aim to address this issue by a retrospective analysis of a case series of delayed onset implant associated infections in healed closed fractures. Methods: Retrospective cohort study conducted in a tertiary care hospital. Patients with united fractures and implant in situ presenting with infection for the first time were included. Open fractures and routine implant removal surgeries were excluded. Diagnosis made by using Metsemakers et al diagnostic criteria for implant related infections. Patient factors fracture and treatment related factors were recorded. Results: A total of 14 cases fulfilled the inclusion criteria. Ten were males (70%) and four females (30%). Mean age was 46 years with time to diagnosis of infection ranging from one year to 10 years (mean=51 months).The most common presenting complaint was discharging sinus (n=10) and the most common implant affected was Tibia ILN (n=6). Diabetes Mellitus was seen in eight patients and one developed it subsequently after initial presentation with impaired glucose tolerance. Radiological evidence of infection was seen in all patients. All patients recovered completely after implant removal and antibiotic therapy. Conclusion: The possibility of an implant related infection occurring any time after fracture union should be acknowledged and studied in further detail so that appropriate measures can be taken to reduce patient morbidity and health care costs.***

Keywords: Delayed onset, Infections, Implants, United Closed Fractures

1. Introduction

Infection after fracture fixation (IAFF) is a well-known complication with incidence ranging from 30% in open fractures to about 1-2% in closed fractures[1]. Based on the time of onset of infection, Willeneger and Roth classified infections into three groups – early (less than 2 weeks), delayed (2-10 weeks) and late onset (more than 10 weeks) [2]. This classification helps in management of the infection and also prognosticate their outcome.

However, infections occurring for the first time in fractures which have united with implant in situ have not been reported as much and hence poorly understood. Unlike IAFF these new onset infections lead to entirely different problems for patients like fresh pain involving the affected limb, implant loosening and irritation of surrounding soft tissue structures, discharge from previously healed surgical scar and its attendant soft tissue complications like non-healing ulcers etc.

Well defined risk factors have been identified for infection after fracture fixation[3,4]. In fact a risk score has been developed to predict infection in open fractures [5]. But there is no mention about the chances for development of infection after fracture unites in a previously uninfected patient. This despite the fact that infection remains as one of the leading causes of implant removal after fracture union in both adults and children [6–8].Data is also lacking about the incidence and prevalence of infection in healed fractures with implant in situ.

We are presenting a retrospective analysis of a case series of delayed onset infections in united closed fractures with implant in situ in the hope of addressing this issue.

2. Materials and methods

We retrospectively analyzed implant removal cases done in our institute from January 2015 to March 2020. The study was conducted in a tertiary care hospital. We included healed fractures with implants in situ (which were closed to begin with) presenting with evidence of infection for the first time in all age groups.Routine implant removals, implant removals done for persistent IAFFs and open fractures (irrespective of the presence or absence of infection) were excluded. We also excluded infections that occurred within one year of index surgery regardless of bony union.

Patient data was collected from the operation theatre registry and from the medical records department. X-rays were collected from PACS. The following data was collected and entered in an excel master sheet – age, sex, fracture diagnosis, date of index surgery, type of surgery done (open vs. closed reduction), implant used, material of the implant, immediate post-operative course, the presenting complaints, presence of co-morbidities and the time to diagnosis of infection from the date of index surgery.

Follow-up data was also obtained from patient records and entered.

3. Results

A total of 295 implant removals were done in our institute in the aforementioned time period. Of which only 14 cases fulfilled our inclusion criteria (n=14). The diagnosis was made by applying the diagnostic criteria for implant related infections in fracture fixation by Metsemakers et al [9].

Ten patients were males (70%) and four were females (30%). Their ages ranged from 20 years to 73 years at the time of presentation with mean age being 46 years. The most common presenting complaint was discharge from healed surgical scar which was seen in 10 cases (70%) followed by implant loosening in 3 cases. One patient had swelling and cellulitis of the affected limb.

The time to diagnosis of infection from the date of index surgery ranged from one year (12 months) to 10 years (120 months) with mean duration being around 51 months as shown in Table 1.

Table 1: Patient details and diagnoses with presenting complaints and time to onset of infection

Patient ID	Age	Sex	Diagnosis	Presenting complaint	Time to onset of infection
Patient 1	42	Male	Left united both bone leg fracture with IM nail in situ	Distal bolt loosening	6 years (72 months)
Patient 2	49	Female	Left united both bone leg fracture with IM nail in situ	Proxima bolt loosening	8 years (96 months)
Patient 3	73	Male	Left united lateral femoral condyle fracture with DFLP in situ	Discharging sinus	2 years 6 months (30 months)
Patient 4	46	Female	Right united S/C with I/C Humerus fracture with distal Humerus locking plates and TBW for olecranon osteotomy	Discharging sinus	1 year 3 months (15 months)
Patient 5	57	Male	Right united Proximal tibia fracture with dual plates in situ	Swelling with cellulitis and impending surgical scar breakdown	6 years 7 months (79 months)
Patient 6	41	Male	Left united both bone leg fracture with IM nail in situ	Discharging sinus	7 years (84 months)
Patient 7	63	Female	Left united S/C with I/C Humerus fracture with distal Humerus locking plates and TBW for olecranon osteotomy	Discharging sinus	2 years (24 months)
Patient 8	21	Male	Right united both bone leg fracture with IM nail in situ	Proximal bolt loosening	1 year 6 months (18 months)
Patient 9	55	Male	Left united both bone leg fracture with IM nail in situ	Discharging sinus	4 years (48 months)
Patient 10	65	Female	Left united Proximal Humerus with PHILOS in situ	Discharging sinus	1 year (12 months)
Patient 11	45	Male	Left united both bone leg fracture with IM nail in situ	Discharging sinus	7 years (84 months)
Patient 12	20	Male	Left united Bimalleolar fracture with CC screw for medial and 1/3rd tubular plate for lateral malleolus	Discharging sinus	1 year (12 months)
Patient 13	48	Male	Left united shaft of Humerus fracture with LCP in situ	Discharging sinus	10 years (120 months)
Patient 14	24	Male	Right united femur fracture with IM nail in situ	Discharging sinus	2 years (24 months)

Legend:
IM nail – Intramedullary Nail
S/C – Supracondylar
I/C – Intercondylar
DFLP- Distal Femur Locking Plate
TBW – Tension Band Wiring
PHILOS – Proximal Humerus Internal Locking System
CC screw – Cannulated Cancellous screw
LCP – Locking Compression Plate

From Figure I it is evident that tibia interlocking has been the most common implant associated with new onset infection (42% of all cases). It is also interesting to note that all the nailing surgeries were performed by means of closed reduction.

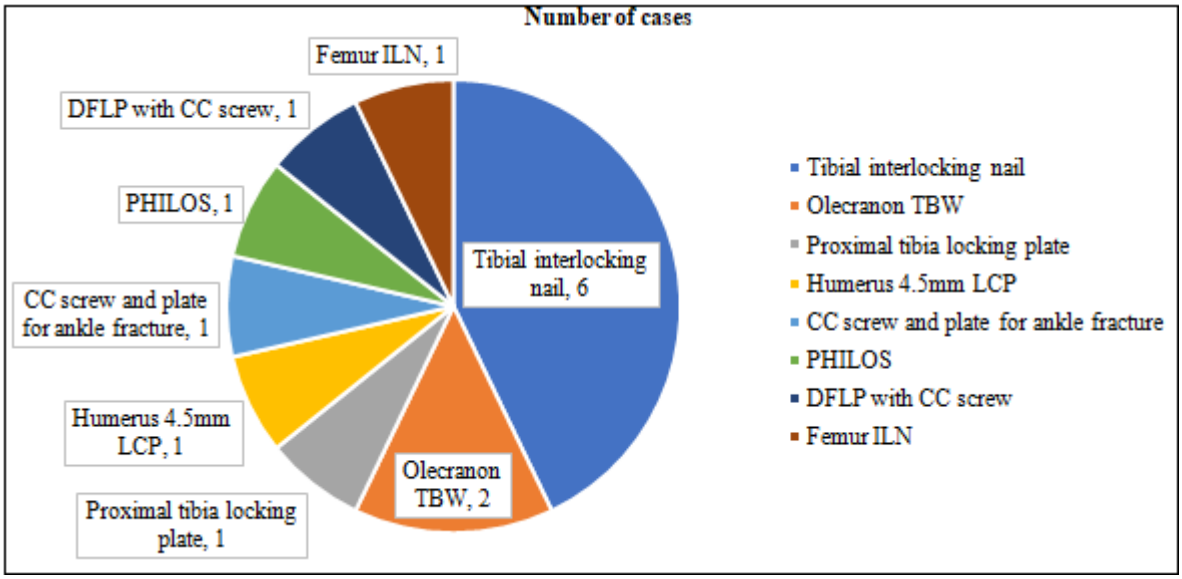

Figure I: Distribution of cases based on type of implant

Details about early post-operative period were also obtained from the medical records. None of them had any history suggestive of wound infection either in the early post-operative period or at any point of time prior to the current episode. All of the implants were made of stainless steel.

Eight out of the 14 patients were under treatment for Diabetes Mellitus for varying periods of time during their first presentation with signs of infection. One patient had impaired glucose tolerance (Patient 5) and went on to be diagnosed as Diabetes Mellitus during follow up.

However, all these patients with Diabetes Mellitus presented with poorly controlled blood sugar levels which needed parenteral insulin for control during their hospital stay. The average duration of hospital stay was 6 days.

Only the patient with cellulitis presented with systemic symptoms. Remaining patients had only local symptoms.

Radiological evidence of infection ranged from obvious implant loosening as shown in Figure IIto subtle peri-implant osteolysis as shown in Figure III.

Figure II: Patient 1 showing distal bolt loosening and peri-implant osteolysis

Figure III: Patient 3 showing subtle osteolysis around the cancellous locking screws

In some cases where the infection was more severe, periosteal changes and cavitation was obvious in addition to peri-implant osteolysis as seen in Figures IV and V.

Figure IV: Patient 14 showing extensive periosteal reaction almost involving whole femur.

Figure V: Patient 5 showing cavitation as well as peri-implant osteolysis. Periosteal reaction can also be appreciated

Out of 14 patients only six patients had a positive culture report with Staphylococcus aureus being the causative organism in four of them.

All 14 patients recovered and did not show any signs of infection in the subsequent follow-ups as per record. The follow-ups lasted for a period of 3 months to 2 years from implant removal surgery with mean duration of 9 months.

4. Discussion

Infections in closed fractures are rare. Unlike in open fractures where the source of contamination is the open wound, closed fractures are uncontaminated and have extremely low risk of infection. This also explains the low rate of IAFF (1-2%) in comparison to open fractures which is around 30% [1].

This low rate however describes only infections which occur during healing at variable time intervals after the primary surgery[10]. Hence scientific literature is heavily focused on the control and management of these infections [1,2,11]. This is to be expected as such infections are associated with

prolonged hospital stay, increased healthcare costs, delayed fracture healing and less than optimal functional outcome [12].

However, infections which occur after fracture healingas described in our case series, brings its own set of problems. Majority of the patients (70%) developed a discharging sinus from the previously healed surgical scar. Few of them had developed pain and irritation due to implant loosening.

The mean time to diagnosis of infection was approximately 51 months. It is yet unclear why these infections occur so late after index surgery. This phenomenon was even more unusual considering the fact that all the fractures in the case series were closed to begin with.

A study by Haseeb et al on hardware removal indications also had a similar phenomenon of infections in healed fractures which lead to implant removal [6]. The mean duration since first surgery to diagnosis of infection in their case series was around 47.57 months. However, their study included delayed and late onset infections as their time line ranged from 2 months to 156 months since index surgery. There is also no mention on whether the fracture was initially open or closed to begin with where in the former the most likely cause could be attributed to external contamination.

Tibia was the bone most commonly affected in our case series which is consistent with the existing literature on implant removal due to infections [3,6]. Diabetes Mellitus was also the most common predisposing risk factor seen in the majority of patients with new onset infections. This was also in line with the previous research findings with respect to implant related infections[3,13].

All the patients in our study had radiological signs ranging from implant loosening to peri-implant osteolysis which have been termed as universally accepted suggestive signs of infection in fracture internal fixation in a study by Govaert et al [14].

Despite more than 50% of patients having a negative culture report the diagnosis of implant associated infection in a healed fracture was made using the criteria laid out by Metsemakers et al [9]. As per the consensus from the international expert group the diagnosis can be confirmed by the presence of wound breakdown into a sinus or fistula along with purulent discharge. In addition, we had clinical and radiological signs which were termed as suggestive criteria in the study.

Implant associated infections usually occur due to one of the following mechanisms.

- Inoculation at the time of trauma or during surgery.
- Contiguous spread from an adjacent focus of infection.
- Spread via blood or lymph from a distant focus of infection.

Inoculation at the time of trauma has been ruled out by excluding open fractures from our study. Any possible contamination during surgery, though cannot be ruled out completely, seems unlikely as all the patients had an uneventful post-operative period and remained asymptomatic for a long time until their time of presentation.

Contiguous spread is a possibility in one patient (Patient 5) where patient presented with cellulitis of the lower limb in which patient had undergone dual plating for proximal tibia fracture. In the remaining patients there were no foci of infection adjacent to the affected limb which could suggest contiguous spread.

This leaves the only possibility of hematogenous or lymphatic spread from a distant focus. Such a mechanism of spread has been described as one of the causes of late onset prosthetic joint infections (PJIs)[15].

However, there is no such phenomenon described for the occurrence of implant infections in fractures which have united. Once the fracture unites an implant is considered to be an inert device. This is also the reason why implant removal is not routinely recommended [8]. Even in our case series we find a smaller number of patients presenting with such infections at such a late stage when compared to the total number of implant removal surgeries done in that time period.

Nevertheless, all of them required in-patient admission, surgical management in the form of debridement with implant removal and antibiotic therapy based on culture sensitivity pattern. This begs the question as to why it happened in the first place in these patients. More than 50% of these patients had Diabetes Mellitus with poor glycemic control. But not all diabetic patients with implant in situ develop infections at a later date. In fact, a few of these patients had no risk factors suggesting poor immunity and yet they developed infections. What additional factors played a role remains largely unknown.

Unfortunately, our sample size is quite low to arrive at a conclusion of statistical significance. And since all of the data is retrospective, we could not get more detailed information about the onset of infection and the exact circumstances which triggered it. These were our principal limitations.

Multi-center prospective studies with much larger study sample may yield more information about this largely under-reported phenomenon.

5. Conclusion

Infections associated with fracture fixations are a dreaded complication. Most of the scientific literature reports on how they affect fracture healing and compromise functional outcome. The efforts are thus concentrated towards prevention in the peri-operative period by a combination of aggressive early debridement for open fractures, strict aseptic precautions for closed fractures and a sound post-operative antibiotic policy. The aim here is to ensure successful fracture union. Once the fracture unites the implant ceases to play any role and is generally considered inert not requiring any further intervention.

New onset implant related infections in united fractures pose a challenge to this notion. The possibility of an infection at a later stage, however small, needs to be addressed and studied in more detail so that patients who are at risk of such infections can be identified before they develop it. We believe that an appropriate early intervention could be done in such high-risk patients to reduce morbidity and health care costs.

6. Ethical approval/ Justification

As the study was conducted with data from hospital records and no personal identifying patient data has been mentioned in the study no ethical issue was involved.

7. Level of Evidence

Level 4 evidence

8. Acknowledgements

None

9. Conflicts of Interest

No conflicts of interest involved.

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