

Indications and Complications of Orthopedic Hardware Removal in an Indonesian Tertiary Hospital: A Descriptive Study

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Abstract

Objective: To acquire clinical data regarding indications of implant removal and complications in orthopedic metal implant removal.

Methods: This was a cross-sectional observational descriptive study using patient medical records. The inclusion criterion was all patients who underwent orthopedic metal implant removal during 2018–2020 while the exclusion criterion was unintentional implant removal due to subsequent injury or loosening. Data regarding anatomic regions, indications, and complications were collected and presented in tables.

Results: In 112 patients participated in this study consisting of 75 (67%) men and 37 (33%) women, the implants were mainly located in thigh, lower leg, and ankle (53% combined). The most common indication for metal implant removal was conversion (31%), followed by infection (25%) and patient's request (20%). The only complication observed in orthopedic metal implant removal in this study was disturbed wound healing in a small percentage of the patients (16%). Most patients (84%) did not experience any complication due to metal implant removal.

Conclusions: Indications for metal implant removal may vary, with or without symptoms. Disturbed wound healing is a complication observed in metal implant removal. Despite the advantages of removal, further analysis and guidelines are needed to avoid unnecessary hardware removal considering the risk of complications.

Keywords: Complication, hardware, indication, removal

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Introduction

Internal fixation procedures using metallic hardware have been chosen as fracture management in several last decades due to its generally good results.^{1,2} After fractures had healed, typically the hardware will be removed from the body.^{3,4} Hardware removals are usually done in patients with or without any symptoms such as pain sensation,

infection, immobilization, or patient request.^{2,4} However, hardware removal procedures are still controversial among orthopedic surgeons because indications of metal implant removal have not been clearly documented.^{5,6} In addition, findings of complication from metal implant removal, such as neurovascular injury, refracture, infection, or problems in wound healing have caused indications of metal implant removal still controversial.^{7,8,9}

Hardware removal is usually done in lower or upper extremities, such as ankle and wrist, radius, and femur. Based on population based studies in 2009 and 2010 in Germany, metal implant removal procedures were mostly performed in ankle and wrist joints. Besides,

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Indication that was mainly found was due to doctors recommendation as much as 68%, followed by pain (31%) and impaired function (31%).⁴ In view of the surgeons, hardware removal is often needed after fractured has united, especially in a weight bearing long bones that risk an local osteoporosis due to prolonged load shielding to the bone structures, although this considerations is still disputable. From a biomaterial view, orthopedic implants is inert that will not result in reactions from the patients' body, but in some cases allergic reactions was reported, as well as implant related microorganism adherence. Based on a research conducted in the Netherlands in 2012, 89% of Dutch surgeons agreed to the metal implant removal procedures with implant infection as the main indication as much as >90%.¹⁰

Complications of metal implant removal varied based on each patient's condition. Based on a study in Japan from 2010 to 2015, perioperative complications were found after metal implant removal in 11 from 80 patients including arterial injury, blisters, nerve injury, skin necrosis, and infection.² In addition, 13 patients (22.4%) had infection with revision surgery based on a different study in Germany in 2014.¹¹

To the best of our knowledge, there was no prior study reporting orthopedic hardware removal in Indonesia yet. There is no clear guideline whether patients with metal implant

fixation should perform hardware removal or not. The objective of this study was to identify the indication and complication of metal implant removal to provide information for a clinical guideline for hardware removal in orthopedic practice.

Methods

This was a descriptive study with a cross sectional approach that has been approved by Padjadjaran University Ethics Committee (No.694/UN6.KEP/EC/2021) and from Dr. Hasan Sadikin Central General Hospital Bandung (No.7830/UN6.C1/TU.00/2021). Secondary data using patient medical records with history of orthopedic hardware removal from January 2018–December 2020 were collected. Anatomic region of the applied hardware, indications, and complications were gathered. Inclusion criteria was all patients that had orthopedic metal implant removal in Hasan Sadikin Hospital, and exclusion criteria was the patients with unintentionally removed implants due to subsequent injury or loosening.

All data obtained in this study were presented in a table and descriptive calculation was done using software IBM SPSS Statistics for Windows ver. 26.0 (Armonk, NY: IBM Corp.).

Result

As many as 112 patient's data were included to this study. As can be seen in Table 1, hardware removals were mostly performed in lower leg region (25%). Indication of the removal included conversion (31%), infection (25%), patient's request (20%), movement alteration (15%) and pain problems (9%) as shown in table 2.

Types of removed implants was described

Table 1 Distribution of Bone Injuries

| Bone Distribution | n=112 | % |
|-------------------|-------|----|
| Upper Extremity | | |
| Upper arm | 4 | 4 |
| Forearm | 7 | 6 |
| Wrist | 10 | 9 |
| Hand | 13 | 12 |
| Shoulder | 2 | 2 |
| Elbow | 2 | 2 |
| Lower Extremity | | |
| Thigh | 15 | 13 |
| Lower leg | 28 | 25 |
| Knee cap | 1 | 1 |
| Ankle | 17 | 15 |
| Foot | 8 | 7 |
| Pelvis | 4 | 4 |
| Spine | 1 | 1 |

Table 2 Indications/Reasons for Implants Removal

| Indication/Reason | n=112 | % |
|---------------------------|-------|----|
| Symptomatic | | |
| Pain Sensation | 10 | 9 |
| Motor Function Impairment | 17 | 15 |
| Infection | 28 | 25 |
| Asymptomatic | | |
| Patient's Request | 22 | 20 |
| Conversion | 35 | 31 |

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Table 3 Types of Removed Implants

| Types | n=112 | % |
|------------------------------|-------|----|
| Plate and screws | 45 | 40 |
| Screw(s) | 20 | 18 |
| Intramedullary nail | 19 | 17 |
| Kirschner wire | 16 | 14 |
| Schanz screw / Steinmann pin | 12 | 10 |

Table 4 Complication of Implants Removal

| Complication | n=112 | % |
|-------------------|-------|----|
| Wound Healing | 18 | 16 |
| No Complications* | 94 | 84 |

*Complications that were expected but not found in this study including refracture, neurovascular injury, blistering, skin necrosis, and prolonged numbness

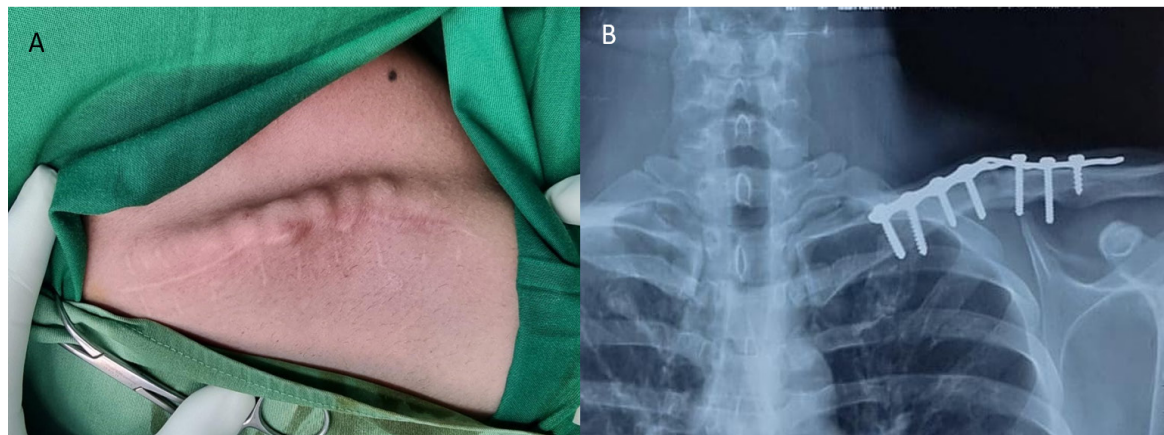


Fig. 1 (A) Preoperative clinical picture depicting a patient complaining pain due to irritation of the hardware to surrounding tissue; (B) Radiograph showing a united fracture with plate and screws applied

in table 3, depicting plate and screws as the most common implant construction to be removed. Table 4 showed the complications of hardware removal procedures. The complications were found in 18 patients (16%) comprised of disturbed wound healing.

Discussion

This was the first study in Indonesian hospitals concerning indications and complications of metal implant removal. It was revealed that the complications and indications were varied

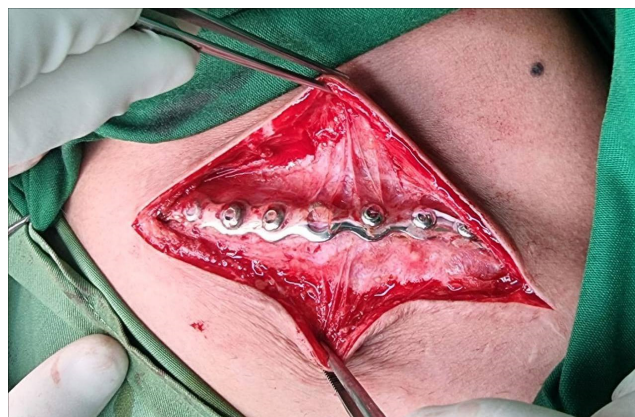


Fig. 2 Intraoperative Finding Showing Bone Formation and Inflamed Tissue



Fig. 3 Extracted Hardware Consisted of One Plate and Seven Screws

among the patients.

Indications of metal implant removal have not been clearly validated and secondly because complications of metal implant removal were found.^{5,6} In Indonesia, many patients wanted the hardware to be removed for some religious reasons, e.g. they did not want the foreign material still inside their body when they were deceased. Other irrelevant reason included some false information regarding the danger of the hardware, for example, the fear of the metallic hardware will attract lightning strike.

As shown in Table 1, fractures were mostly found in lower extremity, specifically in lower leg as much as 25%. This result is slightly different from previous research by Georg Reith *et al.* in Germany.⁴ Based on their research, fractures were mostly found in the ankle joint (21%) and wrist joint (15%). According to a study in German by Onche *et al.*, femoral fractures were the most common findings with 42,6%.⁵ The differences between this study and previous studies might be attributable to different injury pattern in different community, such as traffic regulations and people habit regarding daily transportation, housing, or sports activities.

In general, it is widely accepted that orthopedic hardware on lower leg should be removed after fracture healing, due to its weight bearing features. In a weight bearing bones, the internal fixation will induce local osteoporosis because of its load sharing characteristics. As shown in Table 3, most common removed implants are plate and screws construction. This was reasonable

due to the extramedullary feature of plate and screws implantation in which they cause attrition and inflammation to surrounding tissues. However, intramedullary nails were also considerably removed despite less risk of tissue attrition. In long bones, especially weight bearing bones, nail can be removed after union to restore the physiological mechanical loading to the bone, also to decrease the pain an insertion site.

There were several indications of metal implant removal found in this study. The main indication was presenting symptoms such as pain (Fig. 1-3), movement system impairment, infection, or surgeon's decision including hardware conversion. Other indications were patient's wishes without any symptoms. The hardware conversion is the changing of implanted metal implant to other type of hardware, due to inefficacy of prior hardware or fixation failures. This procedure was part of the metal implant reconstruction that must be done intentionally by the surgeon. Based on this study, symptomatic indication of metal implant removal that was mostly found in this study was infection as much as 25% cases. This data showed similar result with the study that have been done in Holland which the main indication of metal implant removal was infection with >90%.¹⁰ The infection indication can also be called as infection after fracture fixation (IAFF). IAFF that occurred in patients in this study mostly caused by bacterial growth on metal implant and spread to necrotic bone tissues. Based on time of onset, IAFF was classified into early infection (<2 weeks), delayed infection (2-10 weeks), and late

infection (>10 weeks).¹² As the complication of metal implant fixation, infection can be the most feared and challenging complication in treating patients with musculoskeletal trauma. This is because the complication can be progressive and lead to delay healing, permanent functional loss, or even amputation of the affected limb.¹² Focusing into infection after hardware removal, it is attributable to poor soft tissue due to repeated surgery, especially in regions that muscle pad is so thin that the underlying bone is directly beneath the skin, that will become a *port d'entrée* for subsequent infections.

The other indications were patient's demand (20%), motor function impairment (15%), and pain sensation (9%). There is a little difference between this findings and findings from previous research that mostly had pain as an indication for metal implant removal.^{1,4,5} This difference was caused by the variety of indications or reasons which depended on complaints or reactions from implant fixation in patients. A research that was conducted by R Shrestha *et al.* in Nepal showed that 45% of metal implant removal indications were pain.⁶ Based on different research by Georg Reith *et al.*, surgeons' recommendation (68%) was the most indication, followed by pain (31%) of metal implant removal. In this study, surgeons' recommendation were not included as measurement result because it can be interpreted as presenting symptoms in patients due to metal implant fixation.⁴ The pain sensation which felt by patients with implant metal fixation can be caused by varied factors: intrinsic factors and extrinsic factors. The usually occurring intrinsic factors were the malunion or nonunion of the metal implant fixation, thus led to longer period of rehabilitation and might resulted in disability. The external factors were due to poor postoperative pain control which had been explained in a study done in Marshall University of United States. In that study, the difficulty in pain controlling was caused by the high incidence of tolerance to narcotics as analgesics.^{13,14}

Based on literature, the findings of complication of metal implant removal vary and differ depending on the type of implant and the anatomic site of the removal. Most of the complications can be subjective depending on patient's complaints such as a larger scar or increased numbness at the anatomic site of removal.¹⁵ Out of 112 samples, 94

samples did not experience complications due to metal implant removal as much as 84% (Table 3). The other 18 samples only experienced wound healing complications by 16% in which inflammatory process did not go as expected. It is known that wound healing is a physiological process of the body that aims to maintain the integrity of the skin after trauma. There were 3 phases of wound healing, that were homeostasis/inflammation, proliferation and remodeling phase.^{16,17} This wound healing complication occurs due to trauma caused by open surgery from the metal implant removal. Other complications of metal implant removal such as arterial injury, nerve injury, blistering, skin necrosis, infection and increased numbness were not found in data from patients with metal implant removal.

The results obtained in this study were similar with previous studies, where in previous studies there were various types of complications from metal implant removal. Based on research in Japan from 2010 to 2015 by T Kasai *et al.*, perioperative complications were found after metal implant removal in 11 (14%) from 80 patients. Complications that were found such as 1 patient with arterial injury, 3 patient blistering, 3 patient nerve injury, 2 patient skin necrosis, and 2 patient infection.²

This study had four main limitations: (1) the specific bones was not described, instead we chose to mention only the region, because there are some region containing too many bones to described one by one; (2) the surgical features including follow-up period were not homogenous so that will complicate the analysis when clinical consideration was taken into account; (3) various first surgeons or hospitals, making it more difficult to investigate the causes and indications of implant removal; and (4) single-centered study origin that might result in lack of external validity and scientific flaw.

As a conclusion, indications for metal implant removal still be vary in different hospital referral level. Considering the risk of developing complications from hardware removal, it is recommended that further research be conducted on the indications and complications of metal implant removal in a larger scale, more understanding to unnecessary hardware removal urge from the patients, and to promote a guideline regarding this matter to be used in orthopaedic practice.

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