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ORIGINAL ARTICLE

Prevention of Bacterial Infection after Knee Arthroplasty: a Randomized Control Trial

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ABSTRACT

Aim: To assess the efficacy of an absorbable calcium-hydroxyapatite (HAC) coating applied to the articular surface of prosthetic implants, in combination with vancomycin, following non-cemented total knee replacement (TKA).

Study Design: Randomized control trial

Place and duration: This study was conducted at Muhammad Medical College and Hospital Mirpurkhas, Pakistan from June 2020 to June 2021

Methodology: The 126 patients were split into two groups and each received a total of 135 noncemented TKAs. Knees in Group 1 had non-cemented implants put in without any kind of anti-infection care. The local anti-infection treatment, a pasty combination of 2 g absorbable Hac and 1–2 g vancomycin, was applied to 62 knees in Group 2. On the articular surface of the implants, a thin coating of the paste was applied. Both groups of patients got systemic antibiotic treatment. **Results:** Although there was no case of loosening, three deep infections occurred in group 1 (which did not get a local anti-infection treatment), which was 4.1 percent, in the early or intermediate postoperative phase. Arthroscopic debridement and antibiotics were utilized to treat the infection. No infections or joint laxity were seen in group 2.

Conclusion: In non-cemented TKA patients, our research found that a local anti-infection therapy may be a useful addition to systemic antibiotic therapy in preventing deep infections.

Keywords: bacterial infection, prevention, knee replacement.

INTRODUCTION

Following total knee arthroplasty (TKA), there is a risk of deep infection, which has significant functional impact. The use of acrylic cement (polymethylmethacrylate) to adhere the articular implants to the bone has been the subject of several studies aimed at preventing deep infection.(1-3) The infection incidence varies between 1% and 23 percent.(3-5)

These trials looked at the effects of systemic perioperative antibiotic prophylaxis, which was given for one or two days following surgery, as well as antibiotic-impregnated cement. (6) Studies adopting this 2 fold prophylaxis under optimal conditions of operating room asepsis and surgical expertise reduced the prevalence of deep infection to 2%–7%.(7)

Although perioperative antibiotic therapy reduces deep infection rates, the incidence remains between 2% and 7% in most studies. (8) A recent research found that combined antibiotic therapy prophylaxis is preferable than systemic antibiotics alone. (9) According to research, the concentration of vancomycin in bones after surgery is up to 100 times the infection-inhibiting minimum inhibitory concentration (MIC), and up to 4 times the MIC six months later when cement containing vancomycin is used.(4) (10, 11) Infection in cemented TKA may cause loosening of the prosthesis and bone damage. Because the cement serves as a barrier to osseous diffusion of the antibiotic, adapted antibiotic therapy alone is ineffective, and revision surgery in one or two sessions is difficult for the patient. Infections in non-cemented TKA implants, which has been using since 1988, are simpler to cure and don't necessarily need prosthetic revision. There is still a high risk of infection following knee replacement surgery; therefore, this study evaluated the efficacy of novel local anti-infection system containing a mixture of absorbable calcium hydroxyapatite with vancomycin in preventing infection after surgery.

METHODOLOGY

This randomized clinical trial was approved by the ethical review committee of the institute. Total 157 primary non-cemented TKAs were given to 148 patients in a row (9 bilateral). These TKAs were all the same kind, with tibial stem & condyle plots, a microporous metallic articular coating, and an adjustable polyethylene platform without the preservation of the knee ligaments, which were all non-cemented TKAs. We followed a strict protocol for doing polyethylene implant kneecap replacements, regardless of whether they were cemented (123 cases) or not (also 123 cases). Using the medial Para patellar approach and midvastus, the surgeon used a standard operating room under ultraviolet light without laminar flow ventilation, deep Vicryl (Ethicon) sutures, and continuous subcutaneous sutures (Vicryl) with fast resorption to perform the surgery without using a tourniquet and electrocoagulation and blood loss recovery.

The 135 noncemented TKAs were divided into two groups: those who received no anti-infection local therapy (group 1) and those who received anti-infection local

treatment (group 2). The first 12 TKAs were allocated to one of two groups (7 to group 2) at random, while the remaining TKS were assigned to one of two groups (1 or 2). 2 g of an absorbable Hac was combined with 1–2 g vancomycin (powder) and a few drops of physiologic serum in a pasty solution. The mixture was quickly prepared (less than a minute). Before placing the implants, the paste was thinned down into a thin layer. At the commencement of the experiment, the solution was administered to the articular surfaces of the femur and tibia prosthetic devices. Than we put the paste on the tibia implant or the tibia bone layer. We tracked parameters like the duration of surgery, total hospital stay, long-term outcomes, and pre- and postoperative IKS ratings.

All patients received intravenous antibiotic medication (cefazolin 500 mg) before to surgery, and this was maintained for the first 48 hours (2 g/d) after surgery. Regional (spinal) or general anesthesia was used (51 patients in group 1, 42 patients in group 2). In group 1, total 68 knees received a crural block, whereas group 2 received 56 knees. We took samples of the drained fluid from four patients in group 2 on day 3 or 4 (the day the drain was removed) to determine the vancomycin content.

Functional control was assessed after surgery at three and six weeks, three and six months, and subsequently every two years. The sixth week following surgery, six months later, and at the last appointment, radiography was performed. Infections were defined as superficial or deep intra-articular if they occurred within two months after surgery, intermediate (two months to two years), or late (more than two years). Articular fluid culture revealed the presence of deep infections. To compare the findings between the groups, Student t test was utilized.

RESULTS

Twenty-two participants (157 knees) were omitted from the research out of a total of 148. (As shown in Fig. 1). Patients who were lost to follow-up were also omitted from the study. The research included 126 patients who got 135 noncemented TKAs in total. Patients showed no evidence of infection before or after surgery.

The noncemented TKA without the anti-infection medication was performed on 73 knees (68 patients) in Group 1. The patients in group 1 were 72 (51–87) years old on average. In this group, the majority of the patients were female (56 knees). In all, 67 knees were diagnosed with primary degenerative arthritis, four with posttraumatic arthritis, and two with aseptic necrosis.

Individuals in Group 2 got the anti-infection therapy for 62 non-cemented TKA knees (58 patients). Group 2 participants ranged in age from 55 to 89 years on average, with the majority of them being female (46 knees). 57 knees were found to have primary degenerative arthritis, three knees had post-traumatic arthritis, and two knees had aseptic necrosis. There was no statistically significant difference between the two groups in terms of characteristics such as age, gender, and pre-operative diagnosis ($p > 0.05$) When comparing groups 1 and 2, there were no statistically significant differences in terms of surgical time (mean 75 and 80 minutes, respectively), hospital stay (6–9 days), knee IKS score before (mean 39 and 41) and after (mean 95 and 96) surgery, or follow-up period (3–7 years). Postoperative follow-up was the same for all patients, including cane walking on the first day and full assistance on the second day, active knee mobility, and no immobilization device. (As shown in table 1)

In the early phases of recovery, both groups had superficial and localized infections caused by Staphylococcus epidermidis (2 infections in group 1 and 1 in group 2). Local and oral antibiotics were used to treat these infections with no adverse effects or notable differences.

There were no infections or implant loosening in either group at the final follow-up. The concentration of vancomycin in drained fluid from four instances in group 2 was roughly 12 times the MIC. During the early and intermediate phases, three deep infections caused by Staphylococcus aureus (4.1 percent) were found in group 1; the infections were treated with arthroscopic debridement and antibiotics. In terms of infection, there was a significant difference between the two groups ($p = 0.014$).

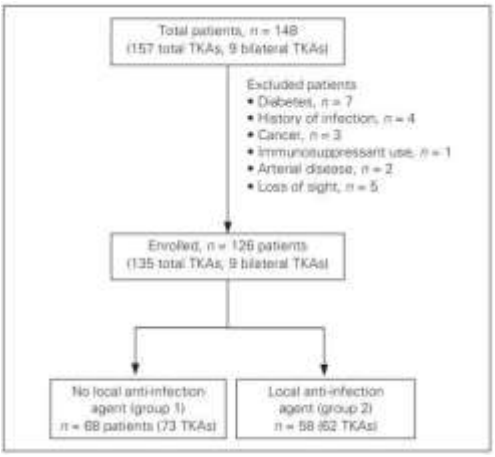

Figure 1: Flow diagram of study participants

Table 1: Demographic data and surgical features of the study participants

Characteristics	GroupI(no-anti-infection agents) n= 73	GroupII(anti-infection agents) n= 62
Age (Years)	51-87	55- 89
Preoperative diagnosis		
Primary arthritis	67	57
Post-traumatic arthritis	4	3
Aseptic necrosis	2	2
Duration of surgery	75	80
Length of hospital stay	7	7
Follow-up	5	5
IKS score		
Pre-operative	39	41
Post-operative	95	96

DISCUSSION

The incidence of deep infections remains between 2% and 7% in most studies despite the use of perioperative

antibiotic treatment. Double antibiotic prophylaxis (systemic and in cement) was shown to be superior than systemic antibiotic prophylaxis alone in a recent study.(6)

Infections in noncemented TKA are simpler to treat, and they may occasionally be treated without the need for a prosthetic device replacement.(12) (13) In 1988, noncemented TKA was started after seeing the long-term success of a noncemented total hip prosthesis covered with calcium hydroxyapatite. (14, 15) Total 439 noncemented TKAs were done between 1988 and 2001, with a worldwide infection incidence of 3.8 percent.

The major goal of this research was to see whether a novel anti-infection agent may help avoid deep infections after noncemented TKA. In the group that did not receive local antibiotic protection, three infections (4.1%) developed; these infections were treated with arthroscopic debridement and antibiotic therapy. In the group that got the anti-infection agent, there were no infections. In four instances, the articular concentration of antibiotics was higher than the MIC. There was a substantial difference in infection rates between the two groups.

As long as the implant and lower limb are perfectly aligned and the frontal ligaments are stable, noncemented TKA has a lifespan at least as long as cemented TKA. In the event of septic or aseptic loosening, noncemented implants may be treated more easily and with less bone loss than cemented implants since cement acts as a barrier to systemic antibiotic therapy. When an absorbable Hac paste that covers the implant's articular face contains an antibiotic, the bone concentration and gradual dilution of antibiotic in the articular fluids, as well as systemic antibacterial treatment, make it more resistant to infection throughout the postoperative period. This is a simple process with no mechanical repercussions, such as loosening, that boosts infection resistance. A larger research with a longer follow-up period (10–15 years) should be conducted, and the concentration of articular antibiotics in the first year after surgery should be assessed.

CONCLUSION

A novel anti-infection system has been shown to be beneficial as a supplement to systemic antibiotic treatment in the control of deep infection after TKA. Because it is so easy and inexpensive, we recommend it for all patients, especially those who are at greater risk of infection.

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