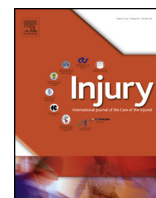




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Infective complications in tumour endoprostheses implanted after pathological fracture of the limbs



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ABSTRACT

Introduction: Pathological fractures represent an adverse prognostic factor in primary and metastatic bone tumours. The purpose of this study was to evaluate the results of tumour silver-coated prosthesis implanted after pathological fractures.

Materials and methods: A retrospective analysis was conducted on 30 patients with pathological limb fracture after primary or metastatic bone tumours treated by the same surgeon with wide margin resection and tumour prosthesis implant between 2005 and 2015. Silver-coated prostheses were implanted in 17 patients and uncoated prostheses were implanted in 13 patients. The primary outcome of the study was to evaluate the infective risk, the secondary outcomes were survival and functional level (visual analogue scale [VAS], 36-Item Short Form Health Survey [SF 36], and Musculoskeletal Tumour Society [MSTS] score) obtained at the longest follow-up available. A multivariate analysis was performed considering age, sex, tumour histology, grading and location, resection size, concomitant radiotherapy/chemotherapy, use of mesh for soft tissue reconstruction and local complications (dislocation, relapse, implant breakage). Scanning electron microscopy (SEM) analysis of explanted prosthesis was performed to study the residual silver-coating.

Results: The average age of patients in the study was 56.2 years (range 12–78 years). Silver-coated prostheses were implanted in 56.7% of patients, and uncoated tumour prostheses were used in the remaining 43.3%. The mean follow-up was 40.7 months. A total of 26.7% of patients died at a median time of 28.6 months after surgery. The overall rate of complications was 30%, with 16.7% due to infection. A total of 11.8% of the patients treated with silver-coated implants developed infection compared with 23.1% of the patients treated with uncoated tumour prostheses. There were no cases of early infection in the silver-coated prosthesis group, whereas early infection occurred in 66.7% of patients in the uncoated prosthesis group. All the functional outcomes were significantly improved after surgery. None of the other parameters analysed can be considered a significant negative prognostic factor for infection. The SEM analyses showed severe silver-coating degradation 2 years after first implant. No case of silver toxicity was demonstrated.

Discussion: There are few papers in the literature about infective complications in tumour prosthesis after pathological fracture. Silver-coated implants showed a protective action against early infection. Late infection rate was similar between the groups, thereby indicating a reduction of antimicrobial activity for the silver-coating over time.

Conclusions: Silver-coated prostheses are a protective factor against early infections in limb salvage surgery after pathological fractures, so may represent the first-choice of implants in this type of surgery.

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Introduction

Pathological fractures represent an adverse prognostic factor in primary and metastatic bone tumours. The number of pathological

fractures is increasing because of the rising life expectancy of oncology patients.

Improved surgical technique and implanted devices ensured good survival and level of function even in patients who need a wide resection after pathological fracture. Many complications associated with this kind of surgeries are described: deep infections, dislocations, implant failures, periprosthetic fractures, and tumour relapses represent common but severe complications [1,2]. The failure rate could depend on different parameters: the age of the patient, site of replacement, resection dimension and the primary malignant tumour involved. The patients treated for limb salvage technique after pathological fracture seem to have worse results than patients treated electively. Preventing this complication is of the utmost importance, because those may often lead to secondary amputation. Oncology patients are often debilitated by one or more of the following: the tumour itself, chemotherapy and concomitant illness involving other organs. Furthermore, the large surface area of the implants predisposes to bacterial colonisation; several systems have been proposed in order to prevent infections in this kind of surgery. Many intra- and perioperative antibiotic prophylaxes have been tested showing the important role of the systemic treatment [3,4]. Silver-coated surgical devices were introduced in medical practice long time ago. Silver has garnered much interest because of its excellent antimicrobial activity coupled with low toxicity [5]. Different medical devices exploiting the properties of silver are now available, not only in orthopaedic surgery. Silver-coated megaprotheses, initially used with the aim of treating local periprosthetic infection, have been recently proposed as the first choice implant in pathological fractures in patients with an acceptable life expectancy, for the demonstrated prophylactic effect on the infections onset. In A. Gemelli Hospital the use of silver-coated prosthesis as the first choice implant in oncology limb salvage surgery began almost 15 years ago in selected cases. Considering the safety of these implants, without severe signs of silver toxicity, an increasing number of patients in recent years have been treated with silver-coated prosthesis showing good functional and survival results. The supposed advantages of these implants could be applied also in case of pathological fracture who need a prosthetic replacement.

The purpose of this study was to evaluate the results of tumour silver-coated prosthesis implanted after pathologic fractures. The primary outcome was to analyze the infection rate, the secondary outcomes analyzed were survival and functional level.

Materials and methods

A retrospective analysis was conducted on 30 patients with pathological limb fractures after primary or metastatic bone tumours treated with wide margin resection and tumour prosthesis implant. All patients were treated by the same surgeon (GM), an expert in oncological orthopaedics, between 2005 and 2015 in A. Gemelli Hospital and received the same antibiotic prophylaxis, which consisted of Cephazolin 2 mg, administered 30 min before surgery, followed by Cephazolin 1 mg every 12 h until removal of wound drainage. Patients were excluded if they had previous surgeries on the fracture site, were affected by severe diabetes, were under corticosteroid treatment or had other known major infective risk factors. The patients were systematically monitored in follow-up 1 month after surgery, then at 3, 6, and 12 months and then once a year. All patients had undergone radiotherapy and/or chemotherapy and/or other surgeries when indicated, following the indication of the Oncologist of “A. Gemelli Hospital” (Catholic University of the Sacred Heart, Rome).

The overall population of 30 patients (14 male, 16 female) was divided into two groups according to the type of prosthesis implanted: the first group received silver-coated prostheses

(MUTARS[®] Implantcast Ltd, Buxtehude, Germany), and the second group received uncoated tumour prostheses (MUTARS[®] Implantcast Ltd, Buxtehude, Germany). To improve functional results and aid faster recovery, our surgical technique involves when necessary, the use of Trevira Tube[®] to guarantee soft tissue and capsular reconstruction and reduce the risk of dislocations as described by other authors [6].

Aim of our study was to evaluate the risk of developing a periprosthetic deep infection, defined by common clinical, radiological and haematological (C-reactive protein [CRP], erythrocyte sedimentation rate [ESR]) signs. The analysis differentiated between early infections (defined as an infection that required a second surgery within 6 months after the first surgery) and late infections. When necessary, patients received antibiotic treatment based on microbiological results and following the indication of an expert infectious disease doctor before revision surgeries. The infections that resolved with only conservative treatment were defined as superficial or transitory infections and were not included in the analysis.

A multivariate analysis was performed considering different parameters: age, sex, tumour histology and grading, tumour location, resection size, concomitant radiotherapy/chemotherapy, use of mesh for soft tissue reconstruction (Trevira tube[®]) and local complications, such as dislocations, relapses, implant breakages or mobilisations. Statistical analysis was performed and significance was set at $p < 0.05$.

Assuming a reduction of silver activity was assumed, so a macroscopic visual analysis (MVA) and a scanning electron microscopy (SEM) analysis were performed on explanted silver-coated prostheses to evaluate the level of degradation of the silver-coating. The MVA was performed by three different authors who classified the level of degradation into four groups (1, no degradation; 2, initial degradation; 3, advanced degradation; 4, coating absence) and measured the percentage of the prosthetic surface involved in degradation processes.

After MVA, selected sections were cut using an EXACT machine, following a standardized procedure designed to avoid surface damages during preparation. The sections were analysed by field emission gun scanning electron microscopy (FEG-SEM) (LEO 1520, Oberkochen, Germany) with backscatter Centaurus detector (KE Developments, Cambridge, UK). Grain size was measured by SEM-coupled image analysis using the linear intercept method.

The secondary outcomes analyzed, were survival and functional level assessed using visual analogue scale [VAS], 36-Item Short Form Health Survey [SF-36], and Musculoskeletal Tumour Society Score [MSTS], recorded before surgery and at last follow-up available [7].

Close clinical surveillance was observed at each follow-up to monitor the risk of local or general silver toxicity.

Results

A total of 30 patients with pathological limb fracture were treated with wide margin resection and tumour prosthetic reconstruction. The average age of the patients was 56.2 years (range 12–78 years). The origin of the lesion was metastatic in 66.7% of patients, and among them the most common primary tumours were breast, urogenital and thyroid. The distribution of primary bone tumours is shown in Table 1. Perioperative adjuvant treatment was administered to 40% of the patients.

The average size of resection was 14.6 cm (range 7–53 cm).

Silver-coated prostheses (MUTARS[®] Implantcast Ltd, Buxtehude, Germany) were implanted in 17 patients (56.7% of patients) and uncoated standard titan tumour prostheses (MUTARS[®] Implantcast Ltd, Buxtehude, Germany) were implanted in the remaining 13 patients (43.3%).

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