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ORIGINAL ARTICLE

FUNCTIONAL OUTCOME FOLLOWING PROXIMAL TIBIAL TUMOR RESECTION AND RECONSTRUCTION BY MODULAR PROSTHESIS

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ABSTRACT

Background : The proximal tibia is a common site for bone tumors. Proximal tibial endoprosthetic reconstruction is one of the popular treatment options. However, proximal tibial reconstruction have been associated with many complications. The aim of our study was to evaluate the functional outcome and complications of patients with proximal tibial endoprosthesis.

Methods: A retrospective study of prospective database was done during the period between January (2000) and July (2017). Eighty one patients with proximal tibial tumor underwent resection and endoprosthetic reconstruction of the proximal tibia. The functional outcome was evaluated using Musculoskeletal tumor society (MSTS) scoring system and the range of knee motion. Postoperative complications were classified according to Henderson classification; Type 1(soft tissue failure), Type 2 (aseptic loosening), Type 3 (structural failure), Type 4 (infection) and Type 5 (local tumor progression).

Results: The mean follow up period was 73.08 ± 51.17 months (range 24 – 204 months). The mean MSTS score was 26.14 ± 2.62 (range 16-30), the mean ROM was 71.54 ± 25.55 (range 10 –120), the mean extension lag was 14.44 ± 14.66 (range 0-60). Overall complications occurred in 69.1% of our patients, Type 1 (soft tissue failure) occurred in 8.6%, Type 2 (Aseptic loosening) occurred 13.6%, Type 3 (structural failure) occurred in 19.8%, Type 4 (infection) occurred in 32.1%, Type 5 (tumor recurrence) occurred in 6.2%.

Conclusion Endoprosthetic replacement of the proximal tibia offers a reliable technique for preserving the limb with an acceptable limb function. Although complications are considerable, they are mostly manageable.

INTRODUCTION

The proximal tibia is considered the second most common location for primary malignant bone tumors. [(1)] Limb salvage has become the treatment of choice for proximal tibial tumors. Therefore, it has replaced amputation as the standard of surgical management. [(2)] The techniques for limb salvage in the proximal tibia include the endoprosthesis either custom-made or modular prosthesis, osteoarticular allograft, allograft-prosthesis composite or resection followed by arthrodesis. [(3)]

The advantages of proximal tibial endoprosthetic replacement include immediate stability, early weight-bearing, psychological acceptance and rapid functional recovery. [(4)]

Endoprosthetic proximal tibial replacement was fraught with high incidence of surgical complications and failure. These complications are wound-related complications, patellar tendon attachment problems, aseptic loosening, mechanical failure, infection and local recurrence, mainly as a result of the complex anatomy and lack of the soft-tissue coverage around knee joint.[(5,6)] The medial gastrocnemius rotation flap has been used to cover the proximal tibial prosthesis, to provide prosthetic coverage and an anchorage point for the patellar tendon and the joint capsule attachments. This reduced the incidence of septic complication significantly. [(7)]

METHODS

A retrospective analysis of prospective database was performed at the Center for Preservation and Transplantation of Musculoskeletal tissues at Cairo University and at Zagazig University Hospital. This study was done during the period between January 2000 and July 2017. This study was authorized by the local Ethical Committee and a written consent for participation in the study (after

explaining benefits and risks) was obtained from the patients or their parents.

Modular endoprosthetic replacement was used for reconstruction following resection of proximal tibial tumors in 81 patients. Tumor staging was done for all patients including plain radiographs, magnetic resonance (MR) imaging of the knee and whole tibia, chest CT and bone scan, followed by bone biopsy (Fig.1,2).

All patients underwent wide resection of the tumor and reconstruction by modular prosthesis. An anteromedial incision was done. [8] Neurovascular bundle exposure was done by splitting the soleal arch. Knee arthrotomy was done by cutting the capsule. The patellar tendon was incised 1 to 2 cm proximal to its tibial tubercle insertion. The cruciate ligaments were transected close to their attachment to the femur. Osteotomy of the distal tibial was done 3 to 5 cm distal to most distal marrow involvement.

The mean length of proximal tibial resection was 14.87± 2.85 cm (range, 10–23 cm). The modular endoprosthesis was assembled to have the same length of the current bone defect. We used the cemented technique in 57 patients (70.4%) and none cemented technique in 24 patients (29.6%). The remaining stump of the patellar tendon was distally advanced and secured to the endoprosthesis with Ethibond, which provided mechanical anchorage. An autologous bone graft was added to the tendon insertion in 13 patients (16%). The medial gastrocnemius flap was then sewn to the remaining fascia of anterior compartment to cover the whole the endoprosthesis. The limb was kept fully extended using posterior splint to prevent tension on patellar tendon reconstruction (Fig.3).

STATISTICAL ANALYSIS

All data were analyzed using SPSS 22.0 for windows (IBM Inc., Chicago, IL, USA), MedCalc 13 for windows (MedCalc Software bvba, Ostend, Belgium). Continuous Quantitative variables were expressed as the mean ± SD & median (range), and categorical qualitative variables were expressed as absolute frequencies (number) & relative frequencies (percentage). Continuous variables were checked for normality by using Shapiro-Wilk test. Independent samples Student's t-test was used to compare between two groups of normally distributed variables while Mann Whitney U test was used for non-normally distributed variables. ANOVA test was used to compare between more than two groups of normally distributed variables while Kruskal Wallis H test was used for non-normally distributed variables. Categorical data were compared using Chi-square test or Fisher's exact test when appropriate. Free survival rates and overall survival were estimated by Kaplan-Meier (KM) survival analysis using time (in months) to the measured event. All tests were two sided. p-value < 0.05 was considered statistically significant (S), p-value < 0.001 was considered highly statistically significant (HS), and p-value ≥ 0.05 was considered statistically insignificant (NS).

RESULTS

The mean follow up period was 73.08 ± 51.17 months (range 24 – 204 months). There were 43 males (53.1%) and 38 females (46.9%) with an average age of 24±11 years (range, 10 to 58 years) at the time of surgery. The pathological diagnosis were as follow; osteosarcoma in 55 patients (67.9%), chondrosarcoma in seven patients (8.6%), Ewing sarcoma in three patient (3.7%), malignant fibrous histocytoma in five patients (6.2%), metastatic carcinoma in two patients (2.5%), adamantinoma in one patient (1.2%), giant cell tumor in seven patients (8.6%) and benign fibrous histocytoma in one patient (1.2%). Neo-adjuvant chemotherapy was received by 58 cases; 50 ostesarcoma, 3 Ewing sarcoma and 5 malignant fibrous histocytoma.

A- Functional outcome: The mean MSTS score was 26.14 ± 2.62 (range 16-30), the mean ROM was 71.54 ± 25.55 (range 10 –120) and the mean extension lag was 14.44 ± 14.66 (range 0-60).

B- Oncological outcome: 1- Local recurrence: developed in five patients (6.2%). One patient died. Wide resection of the recurrence was done in one patient and now free of disease. Above knee amputation was done for remaining three patients (two patients were lost to follow up after amputation and one patient developed stump recurrence. Wide resection was done and the patient is now free of disease).

2- Chest metastasis: Chest metastasis developed in 17 patients (21%). One patient died and six patients did not resume treatment and were lost to follow up and probably died of disease. Metastatectomy was done for ten patients; only two patients survived and were free of disease at the last follow up. The remaining eight patients succumed to the disease.

3-Overall patient survivorship: The estimated 5-year and 10-year survival rates for the treated patients were 80% and 74.5% respectively (fig.4).

C- Complications:

Type 1: Soft tissue failure:Wound gapping developed in one patient (1.2%), wound sloughing developed in four patients (4.9%), inflamed wound in two patients (2.5%) and no wound problems in 74 patients (91.4%). Three patients were treated by skin graft. Four patients were treated by dressing and antibiotics and all patients improved.

Type 2: Aseptic loosening : Aseptic loosening developed in 11 patients (13.6%). Local recurrence developed in one of them so above knee

amputation was done and four patients underwent revision surgery and their prosthesis were in good condition until the last follow up. Six patients refused revision and were lost to follow up.

Type 3: Component breakage and periprosthetic fracture

Five implants failed 6.2% (broken prosthesis; one broken stem, two broken bushing, one broken yock and polyethylene and one broken bumper and axis screw). They were treated surgically and the broken component was revised.

Periprosthetic fracture occured in ten patients. Open reduction and internal fixation by locked plate was done in six patients and their fractures united. Three patients were treated by above knee cast and their fractures united. Revision with a new prosthesis was done in one patient.

Type 4: Infection :In the early postoperative period superficial infection developed in seven patients (8.6%); three patients were treated by antibiotics and improved. Four patients were treated by debridement and lavage and their infection were cleared.

Deep infection developed late in 19 patients (23.5%); the prosthesis was removed in all 19 patients and a gentamicin-impregnated cement spacer was inserted. Two patients had two stages revision, six patients were reconstructed by free vascularized fibular graft, four patients had above knee amputation and seven patients were lost to follow up.

D-Limb and prosthesis survivorship: Limb survivorship: The estimated 5-year and 10-year limb survival rates for the treated patients were 90.5% and 87.1% respectively (fig.5).

Prosthesis survivorship: The estimated 5-year and 10-year prosthesis survival rates for the treated patients were 80.7 % and 65.5 % respectively (fig.6). E- Correlation of the results

I- Factors affecting overall survivorship: The overall survivorship was statistically significantly better for the patients with benign bone tumor (p= 0.028), shorter operative time (p= 0.004), no local recurrence (p = 0.042) and no lung metastasis (p <0.001).

II- Factors affecting limb survivorship: The limb survivorship was statistically significantly better for the patients with tumor necrosis factor more than 90% (P=0.021), smaller resection length less than 15 cm (P=0.005), lesser extension lag (P=0.002), no local recurrence (P=0.042) and no wound closure problems (p=0.005).

III- Factors affecting prosthesis survivorship: There was a statistical significant impact of type 3 complication (p=<0.001), 4 complication (p=0.029) and the overall complications (p=0.004) on the prosthesis survivorship. The prosthesis survivorship was statistically significantly better for the patients without these complications.

IV- Factors affecting oncological outcome: There was a statistical significant impact of operative time on lung metastasis (p= 0.004). The incidence of lung metastasis increased with longer operative time. **V- Factors affecting complications:**

(a) Type 1 complications: The incidence of type 1 complication (According to Henderson classification) increased in patients operated before 2010 (p=0.043).

(b) Type 4 complications: There was statistical significant impact of chemotherapy (p= 0.001), wound closure problems (p=0.015) and the period of operation (before and after 2010) (p = 0.049) on the incidence of type 4 complications (infection).

(c) Stiff knee: The incidence of stiff knee increased in female (p=0.044).

VI- Factors affecting functional outcome: The functional outcome was statistically significantly better for the younger patients (p=0.016) with less operative time (p=0.017) and overall complications (p=0.047).

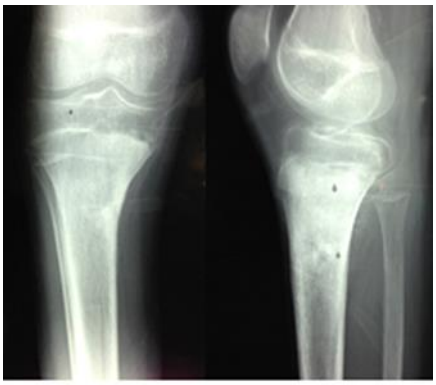

Fig (1): Plain radiograph anteroposterior and lateral view of the knee showing osteoblastic lesion of the proximal tibia.

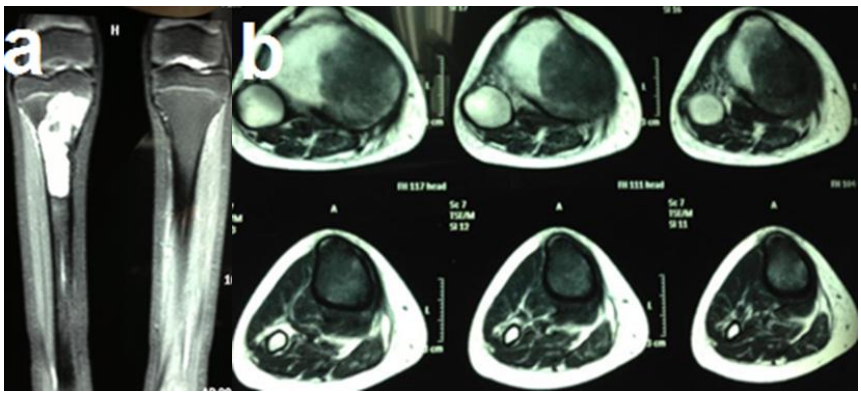

Fig (2): MRI cuts (a) coronal cut (b) axial cut showing medullary involvement and minimal soft tissue extension.

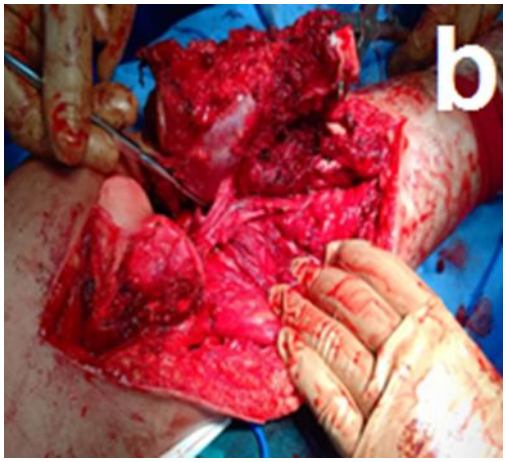

Fig (3): Intraoperative photos showing: (a) skin incision including biopsy scar (b) intact neurovascular bundle (c) development of the medial gastrocnemius flap (d) complete prosthetic coverage.

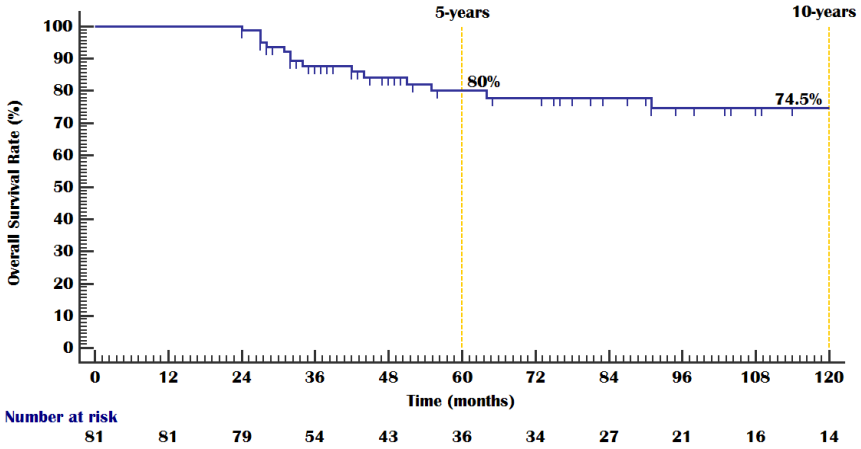

Fig (4): Kaplan Meier plot shows overall survival rate among the studied patients (N=81).

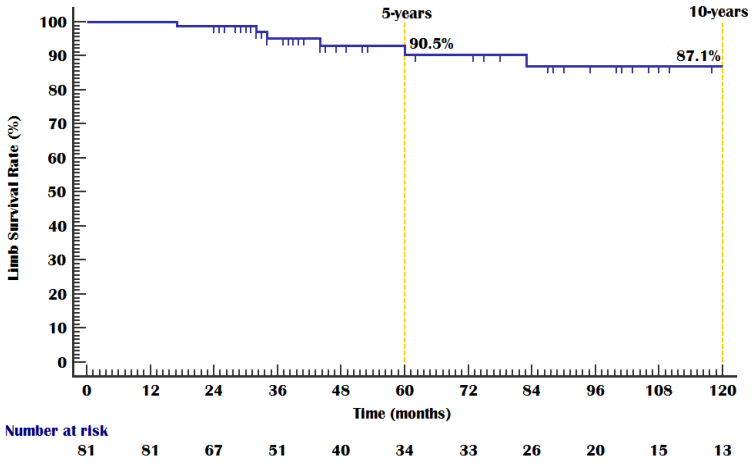

Fig (5): Kaplan Meier plot shows limb survival rate among the studied patients (N=81).

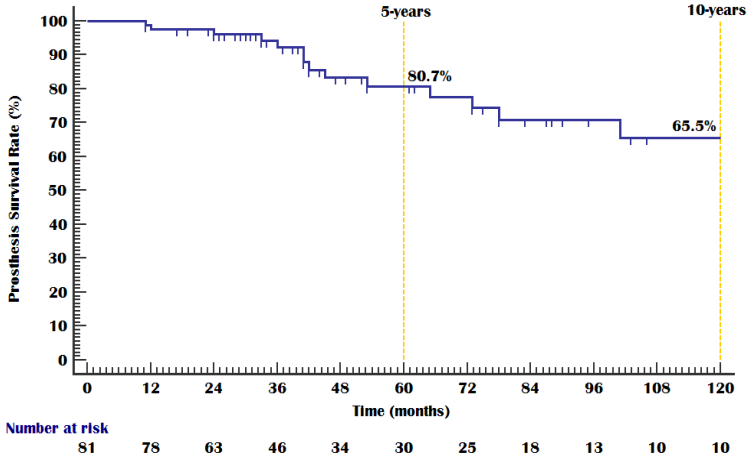

Fig (6): Kaplan Meier plot shows prosthesis survival rate among the studied patients (N=81).

DISCUSSION

The proximal part of the tibia is a difficult location for bone tumor resection and reconstructions and associated with high rate of surgical problems and failure. This is due to the complex anatomy, extensor mechanism reconstruction and the poor coverage of the soft tissues around the knee. [1,6]

Limb salvage surgery using modular endoprosthesis became the standard treatment. [9,10] because it achieves local control and overall survival equal to amputation as well as provide an acceptable function. [11] The current study included 81 patients with aggressive proximal tibial tumors treated using proximal tibial endoprosthesis and followed up for a minimum of two years. The functional and oncological out come as well as the factors affecting them were evaluated.

The incidence of local recurrence in the current study was (6.2%). This is comparable to that reported by many authors. [4,12,13] Their local recurrence rates ranged from 0% to 16 %.

The incidence of chest metastasis in the current study was (21%). This is in line with that reported by many authors. [9,14,15] Their chest metastasis rates ranged from 0% to 42 %. The variability in the incidence of local recurrence and chest metastasis is attributed to the heterogeneity in the pathological diagnosis.

In the current study the estimated 5-years and 10-years survival rates for primary treated patients were 80% and 74.5% respectively. Our 5years overall survival rates were comparable to that reported by many authors [9,16,17] their rates ranged from 64% to 93%. Our 10years overall survival rates were in line with that reported many authors [9,17,18] their rate ranged from 62% to 87%.

When we analysed the factors affecting the oncological outcome we only found a significant statistical correlation with the operative time. This could be attributed to the increased vascularity and size of the more aggressive tumors. Similar to the study of Puchner et al, [19] none of risk factors was a statistically significant predictor in univariate analyses. However, many authors showed that the resection margin, poor response to chemotherapy, pathological fracture and intravascular tumor extension were risk factors associated with increased recurrence. [20,21] As regard to the factors affecting the overall survivorship in the current study, there was a statistical significant correlation with operative time, pathological diagnosis, type 5 complications and the lung metastasis. The lung metastasis was highly significant. Lung metastasis was a poor prognostic factor for patient overall survival. In the current study only two of 17 patients survived.

Despite there was no correlation between chemotherapy and overall survivorship in our study, in the study of Zhang et al, [14] there was a statistical significant correlation.

Similar to that reported in the study of Bacci et al, [22] the overall patients survivorship was not related to the sex or age of the patient, resection length and the presence or absence of pathologic fracture. On the other hand, we found a statistical correlation between the overall survivorship and the pathological diagnosis (malignant tumors) opposite to that reported by Bacci et al. [22]

In the current study, the mean MSTS score was 26 (87%). The MSTS score was ≥22 (good-excellent) in 76 patients (93.8%) and <22 (fair-poor) in five patients (6.2%). Our results were comparable to the results of similar studies. [23,24,25] Their results ranged from 61% to 90%.

In the study of Pala et al, [26] the functional outcome was good or excellent in 97% of the patients with no difference between the distal femur and the proximal tibia. However, extensor mechanism reconstruction is an essential factor affecting the extensor lag and ROM. In the current study the mean ROM was 71.5 (range 10 –120) and the mean extension lag was 14.4 (range 0-60).

As regard the range of knee motion, our results were in line with the reported results in the literatures. [14,25,27] We attributed the decreased ROM in the current study to the older version of cemented Baumer prosthesis with maximum flexion of ninety degree. As regard to the extension lag of the knee, our results were in line with that reported by many authors [12,27,28] their mean extension lag ranged from 1º to 35º. However extension lag did not impact the functional outcome. When we analyzed the different factors which could affect the functional outcome we found the only factors which had a statistical significant impact were the age, the operative time and the overall complications .

We found better functional outcome in younger patients. Probably older patients had weaker muscles and need support which affects the walking ability. Moreover, in longer operation more muscles and bone were resected which probably had an impact on walking ability and functional score. The overall complications decrease the functional score because of repeated operation, medications, fractures and infection affecting muscle power, support and walking ability. In the study of Puchner et al, [19] there was no significant different in the MSTS functional score between patients with or without complications. Similar to Mavrogenis et al. and Puchner et al, [9,19] there was no correlation between the MSTS function and different extensor mechanism reconstructions. Nimi et al, [15] reported that patients with extension lag more than

thirty degree had worse MSTS functional score than those with extension lag lower than thirty degree. In the current study there was no significant correlation between the MSTS functional score and the extension lag. In the current study, Type 1 failure (soft tissue failure) rate was 8.6%. All of them were poor soft tissue coverage and treatable. Our results were comparable to that reported in the literatures. [30-32] Their rate ranged from 2% to 30%. When we analyzed the different factors which could affect type 1 complications we only found statistical significant relation between the incidence of type 1 complications among the patients who were operated before and after 2010. This was attributed to the improvement in the learning curve in resection tehniques and better soft tissue handling. In the study of Puchner et al, [19] they found that 44% of their patients with a soft tissues failure experienced also infections. Type one failure has been connected to higher infections rates and problems of wound healing. [29]

Several studies reported that aseptic loosening of proximal tibial endoprosthesis was one of the most common failures. [33] In the current study, only 11 (13.6%) of 81 patients developed aseptic loosening. Four patients underwent revision of the loose prosthesis, one of our revisions developed loosening and underwent 2nd revision. This incidence was comparable to that reported in the literatures. [4,16,27] Their results ranged from 0% to 56%. In the current study there were no factors that had a statistical significant impact on aseptic loosening incidence. However, the younger age of the patients, greater length of resection, smaller diameter of prosthetic stem was reported as the risk factors for developing aseptic loosening. [33,34] In the study of Unwin et al, [35] aseptic loosening developed with larger resections. Cementless endoprosthesis was expected to develop bone ingrowth as well as long-term prosthetic stability. [16,36] However, our results showed no significant difference between cemented and cementless endoprosthesis in the incidence of aseptic loosening. In the current study, prosthesis breakage occurred in five patients (6.2%). This was comparable to that reported in the literatures. [13,28,34] Their results ranged from 0% to 46%. In the current study two bushing failed and revision was required. Myers et al, [4] showed that more than one rebushings of the primary prosthesis were required in thirty six patients (18.5%) and the need for rebushing will be increased when the prosthesis remain in situ for long time. Despite there was no significant correlation between prosthesis breakage and resection length and stem size, Griffin et al, [36] reported that the stem breakage incidence increased when using smaller stem diameter and larger resection length. The rate of infection in the current study was high (32.1%), most of the studies in the literatures reported rates ranging from 1.8% to 37.5%. [19,23,35] The rate of proximal tibia prosthetic infection was reported to be much more than in the distal femur. [26] In the current study, the incidence was higher among the patients who were operated before 2010. This was statistically significant and was attributed to the improved technique and learning curve in resection and reconstruction procedures.

Moreover, we had a statistical significant impact of skin closure problems on the incidence of infection. However, there was no statistical significant impact of age, pathological diagnosis, chemotherapy and resection length on the incidence of infection. Although chemotherapy decreased the immunity, we didn't have a statistical significant impact of chemotherapy on the incidence of infection. Also the study of Grimer et al, [12] that found no association between infection and other factors such as age, resection length, the use of chemotherapy and previous operation. Our results don't coincide with that reported on the impact of the bone resection length on the incidence of infection. [12,37]

One of the main concerns regarding endoprosthesis in general is their longevity. Prosthesis don't last for life. They have an average survivorship which varies according to several factors. In the current series the 5 years and 10year survival were 80.7 % and 65.5 % respectively. The implant survival steadily decreased over time i.e almost one third of the prosthesis required removal by 10 years. However our results were in line with that reported in the literature that ranged from 40% to 93.8% at 5 years[30,35,38] and 30 to 86.4% at 10 years.[12,37,38]

In the current study, patients' characteristics, tumors' characteristics and operative data didn't have an impact on prosthesis survivorship. The only factors that had an impact were the complications, obviously type 3 (structural failure) and 4 complications (infection) which necessitated always exchange or removal of the prosthesis.

Similar to others studies, infection was the most common type of prosthetic failure. [16,26,39] Henderson et al, [40] reported that infection was ranked as the highest risk factor in prosthetic failure. The study of Zeegen et al, [39] showed there was a statistical significant impact of type 4 complications (infection) on the prosthesis survival but there was no a statistical significant impact of the length of resection on the prosthesis survival. Niimi et al, [15] found there were no statistical correlation between the prosthetic survival and the age, gender, peroneal nerve palsy and extension lag. Removal of the prosthesis doesn't always mean amputation. When we analayzed our series

we found that the limb survivorship were90.5% and 87.1% at 5-years and 10-years respectively. Our 5years limb survival rate was comparable to that reported in the literatures. [17,19,23] Their 5years limb survivor ranged from 78% to 95%. Our 10years limb survivor rate was comparable to that reported in the literatures. [5,17,32] Their 10years limb survivor ranged from 74.5% to 94.7%.

When we analyzed the factors that affected the limb survivorship we found that tumor necrosis factor, resection length, extension lag and type 5 complications had an impact on the limb survivorship. Patient with poor tumor necrosis obviously had local recurrence and eventually amputation. Larger resection denotes larger tumor size and more aggression and eventually local recurrence and amputation. Similar to Myers et al, [4] local recurrence and infection increase the risk of amputation. In the current study the incidence of amputation increased in larger resection, as there was statistical significant impact of the resection length on above knee amputation (P value .005). Other studies [65] reported that the length of resection was related to prosthetic failure.

Strengths of the study include; (1) Being prospective and retrospective study. (2) Considerable number of patients. (3) Long follow up period. (4) Extensive data on functional and oncological outcome.

Limitations of the study were: (a) Heterogeneous group of patients with different pathology that didn't give us real impact on the oncological outcome. (b) Patients were lost to follow up and had complications and refused to do any things.

CONCLUSIONS

Although limb salvage surgery using endoprosthetic replacement of the proximal tibia is frought with many surgical complications, it offers a reliable safe technique for preserving the limb with good limb function and good quality of life and so we recommend this procedure.

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