

Original Research Article

Limb salvage surgery with endoprosthesis reconstruction in management of locally advanced primary bone tumours: a functional outcome evaluation

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ABSTRACT

Background: Endoprosthetic reconstruction using a custom-made metallic mega-endoprosthesis is one of the common modalities for limb salvage operation. The new promising advance of material science, design and fabrication of the endoprosthesis enable an immediate rehabilitation program and provide a durable and functional limb. The aim of the study was to evaluate the efficacy and functional outcome in patients with primary bone tumours treated by limb salvage surgery using endoprosthetic replacement.

Methods: A total of 14 patients with primary bone tumour in major large joints of the body, selected between January 2019 to August 2020, were managed by limb salvage surgery via endoprosthetic replacement. This was a prospective study conducted at a Tertiary care Government Hospital in Kolkata, and all patients were followed up to a minimum of 1.5 years. The evaluation system used was proposed by Enneking, recommended by the musculoskeletal tumour society in addition to the radiologic evaluation.

Results: At final follow-up, the mean musculoskeletal tumour society score was 89.71 ± 3.58 . The mean Knee Society Score of 9 patients was 85.55 ± 3.64 and mean Harris hip score of 2 patients and Oxford shoulder score of 4 patients were 90.5 and 41.67 respectively by the end of 1.5 years. 12 (85.7%) patients did not have any complications. None of the cases had implant loosening or breakage, periprosthetic fracture, tumour recurrence or amputation.

Conclusions: Endoprosthesis are excellent choices for the treatment of bone tumours with limb preservation in relation to pain, strength, and patient's emotional acceptance as they reconstruct a limb with an acceptable oncologic, functional, and cosmetic result providing immediate weight-bearing capacity and generating a greater independence.

Keywords: Bone tumour, Limb salvage, Endoprosthetic reconstruction, Amputation, Joint prosthesis, Functional outcome

INTRODUCTION

Overall, bone sarcomas account for 0.2% of all malignancies, and the adjusted incidence rate for all bone and joint malignancies is 0.9 per 100,000 persons per year, while the 5-year overall survival rate is 67.9%.¹ Management of bone tumour needs a team of an orthopaedic surgeon, radiologist, pathologist, radiation oncologist and medical oncologist. An adequate history and physical examination are the first and most important

step in evaluating a patient of bone tumour. The term 'limb salvage surgery' comprises surgical techniques that are designed to resect a tumour and subsequently reconstruct a limb with an acceptable oncologic, functional, and cosmetic result.² Limb salvage surgery has replaced amputation as the treatment of choice for more than 90% of patients with a primary malignancy of bone, largely as a result of improvements in imaging, chemotherapy and the modern design of implants.³⁻⁷ A successfully salvaged limb in the well selected patients

can improve body balance, simplify the rehabilitation process and preserve intact body image.

Functional outcomes were of secondary importance in the early experience with limb salvage because patients with malignant disease had extremely poor survival rates.^{8,9} With improvements in medical therapies, long-term patient survival is often the expectation and, thus, the longevity and functional outcomes of reconstructions are becoming a more important consideration. Endoprosthetic reconstruction has the advantage of providing a simple and quick intra-operative reconstruction with immediate stability which allows early mobilisation, rehabilitation, weight bearing and functional recovery in comparison to biological reconstructions, a shorter operating time and hospital stay and it allows the early introduction of postoperative adjuvant therapy. As a result of these improvements, the overall survival from malignancies of bone ranges from 61% to 92%.⁴⁻⁹ Early endoprostheses were custom-made alloy of high strength and low weight, often replacing the entire involved bone and incorporating a simple hinge joint.¹⁰ Newer endoprostheses are modular and off-the-shelf, allowing reconstruction to be performed without delay, an advantage over other custom-designed implants. Although cadaver allografts and allograft-prosthetic composites are important biological reconstruction with potentially favourable long-term results, they are nevertheless associated with a high rate of early postsurgical complications including infection, fracture, and nonunion.¹¹

Custom-made prostheses allow early return of function but are liable to undergo loosening, wear and breakage. There is discussion as to whether skeletal reconstruction is best undertaken by endoprostheses or allografts. The decision as to which reconstructive technique should be used depends on the location and extent of the tumour spread and the preference of surgeon and patient. The objective of this study was to represent our experience comprising cases of bone tumors around major large joints of the body which were treated by limb salvaging surgeries using mega-endoprosthetic replacement to see whether the technique provides improved clinical and functional outcome. The aim is also to determine the prosthesis survival rates and investigate the rates of local recurrence. It will also give us an idea of the common complications of megaprosthesis during short-term follow-up along with amputation rates after endoprosthetic reconstruction and whether this treatment method achieves good quality of life with improved function and life expectancy.

METHODS

This study was performed in accordance with the ethical standards of the institutional review board. 14 patients with primary bone tumour in major large joints of the body who were treated by limb salvage surgery using endoprosthetic replacement in the Department of

Orthopaedics, IPGMER and SSKM Hospital, Kolkata from January 2019 to August 2020 and fulfilling the inclusion criteria were considered in this study.

Inclusion criteria

Inclusion criteria for current study were; patients having early stage of bone tumour upto Enneking stage IIB around shoulder, hip and knee joint and non metastatic tumour.

Exclusion criteria

Exclusion criteria for current study were; Enneking stage III bone tumour, neoplasm involving axial skeleton in which resection is not possible, very old age group in which expected survival is very less, tumour involving adjacent neurovascular structures, fungating tumour mass with poor skin condition, patients with comorbid conditions not fit for surgery.

Resection of tumour of distal femur with megaprosthetic limb reconstruction:

Patients were operated in supine position under spinal anaesthesia with affected limb placed in radiolucent operating table. Resection of distal femur was done through a lateral incision. Large anterior and posterior flaps were raised and dissection deep to rectus femoris, quadriceps tendon and patella was done. Knee joint capsule and ligaments were incised to allow better exposure for dissection around the distal femur. Femoral osteotomy was done with a wide margin proximal to the most proximal extent of marrow involvement as determined by pre-operative MRI. Joint line was preserved at the same level comparable to normal side. The length of resected tumour specimen was measured. Alignment guides were used to make the proximal tibial cut perpendicular to the tibial shaft and prepare the proximal tibia. Reaming of the femoral canal was done. Trial components were placed and the knee was moved through a full range of motion. The femoral and tibial components were cemented into place and in the proper orientation. Closure of the wound was done in layers over in situ suction drain. Aseptic dressing done and a knee immobilizer was applied.

Resection of tumour of proximal tibia with megaprosthetic limb reconstruction:

An anteromedial incision was made starting proximally at the distal third of the femur and extended distally to the lower third of the tibia. Medial and lateral flaps were developed beneath the investing fascia and the medial hamstring was divided proximal to its insertion. Medial head of the gastrocnemius muscle was mobilized and soleus muscle was split and the capsule of the knee was incised circumferentially 1 to 2 cm from its tibial insertion. Divide the cruciate ligaments at the femur. If the proximal fibula is not involved, the lateral collateral

ligament and its attachment to the fibular head was preserved. The tibia distal to the lesion was osteotomized at a level determined by pre-operative imaging. The extremity was reconstructed by prosthetic implantation. The extensor mechanism was advanced and the remaining patellar tendon was attached to the endoprosthesis. The medial head of gastrocnemius was transposed anteriorly and sutured to the remaining anterior muscles as well as the soft tissues of the extensor mechanism. Closure of the wound was done in layers over in situ suction drain. Aseptic dressing done and a knee immobilizer was applied.

Resection of tumour of proximal femur with megaprosthesis limb reconstruction:

Direct lateral approach (Hardinge) was used to gain access to the hip. The acetabulum was exposed, examined carefully and a new component was cemented in place with screw fixation. The type of acetabular liner was determined after completion of reconstruction of femur. The length of femoral component was determined through careful pre-operative planning and intraoperative

assessment. The length of the prosthesis usually equalled the length of the bone being resected. Tumour was dissected out from the surrounding tissue taking adequate care of surrounding neurovascular structures. A mark was made over the anterior aspect of distal fragment to check rotation of final implant. An osteotomy was made in the host bone at the most proximal area taking a margin of 3-4 cm depending on aggressiveness of the tumour. The maximum length of the native femur was maintained at all costs. The femur was prepared by broaching and preserving the cancellous bone. After completion of femoral preparation, trial components were inserted and the stability of the hip was examined. The femoral component was cemented into place, ensuring that the porous-coated portion of the stem is placed directly and firmly against diaphyseal bone with no interpositioning cement. The proximal portion of the femur, however poor in quality, was maintained and wrapped around the megaprosthesis at the conclusion of implantation. The muscle-tendon attachments were preserved whenever possible. The soft tissues, and in particular the abductors if present, were secured meticulously around the prosthesis. Closure of the wound was done in layers over in situ suction drain. Aseptic dressing was done.

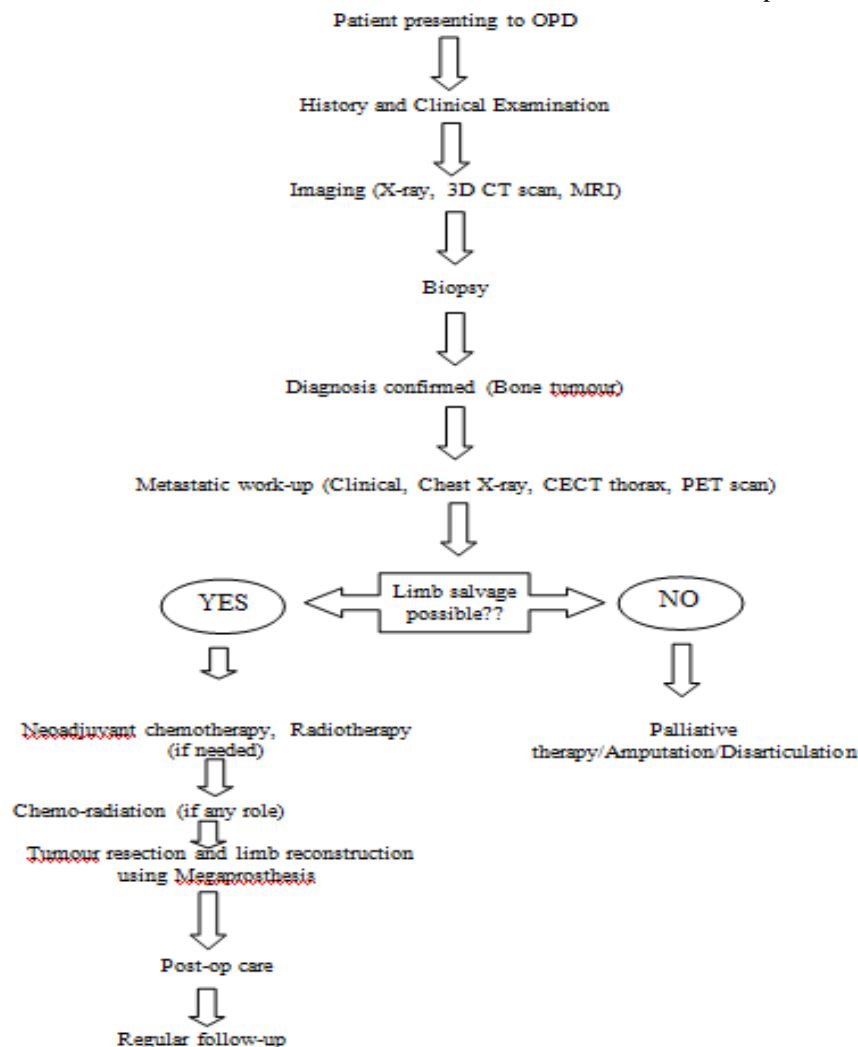


Figure 1: Approach to the patients.

Resection of tumour of proximal humerus with megaprosthesis limb reconstruction:

The patient was positioned supine on the operating table with a sandbag under the spine and medial border of the scapula and the head of the table elevated to 45°. The standard deltopectoral approach was used with the scope to extend the incision proximally or distally as needed. The plane of dissection was between deltoid and pectoralis major muscle. The shoulder joint capsule was opened with a vertical incision. The tip of coracoid process was excised to obtain further exposure. The entire tumour mass was dissected out from the neighbouring soft tissue taking care of neurovascular structures. The amount of bone to be resected was marked taking a margin of 2 to 4 cm depending upon grade of tumour. Anterior surface of distal fragment was marked to check rotation and version. Humerus osteotomy done using a saw trying to preserve as much of abductors as possible. Proximal humeral endoprosthesis was inserted taking care of version. Muscles were attached to the holes in the prosthesis. Soft tissue and skin closed in layers with a drain. A universal shoulder immobiliser was applied.

Rehabilitation

For neoplasm around knee, post-operative immobilization of the joint using a long knee brace was done allowing only static quadriceps, ankle pumps and active finger movements. By the end of 2 weeks, intermittent passive ROM upto 90° were started, increasing ROM to full till 4 weeks post-op and then knee brace was discontinued. Active knee ROM with quadriceps and hamstring strengthening exercises were started after 4 weeks. Partial weight bearing using bilateral axillary crutches were allowed at 2 weeks and full weight bearing at the end of 4 weeks. For neoplasm around hip, a de-rotation boot and an abduction pillow were given for a period of 2 weeks. Patients were allowed to sit at the side of bed with full ROM of knee. Static quadricepses were started as soon as patient could tolerate. Partial toe touch weight bearing was allowed from 3 weeks along with dynamic quadriceps and hamstring exercises gradually increasing weight bearing to full in 6 weeks.

Patients were advised to resume normal daily activities from 6 weeks. For neoplasm around shoulder, the affected limb was supported using an arm pouch for a period of 2 weeks. At the end of 2 weeks, passive ROM exercises were started which gradually increased to active movements from 4 weeks. Elbow and wrist ROM were started as soon as the pain subsided. Lifting heavy weight and putting pressure over limb were discouraged for 4 weeks. Patient were allowed to do daily household activities by the end of 1 month.

Follow-up

The patients were regularly followed up for 1.5 years at an interval of 2 weeks, 6 weeks, 3 months, 6 months, 9 months, 1 year and 1.5 years. Except for the first visit, in which only range of motion and local wound condition was addressed, subsequent visits included thorough clinical, functional and radiological assessment. Clinical examination included checking range of movement, status of ambulation and adequate muscle strength. The radiological examination was done at different intervals to look for status of prosthesis, bony abnormalities and any complications.

Functional assessment of the patients was done at the final follow-up as per the Knee Society Score, Harris hip score and Oxford shoulder score as per the joint involved.

Statistical analysis

The data was collected in Microsoft Excel (Windows 10; version 2016) and statistical software Statistica version 6 (Tulsa, Oklahoma: StatSoft Inc., 2001) was used for the analysis. Categorical variables were expressed as number of patients and percentage of patients and compared across the groups using Fisher's Exact Test. Continuous variables were expressed as mean, median and standard deviation and compared across the groups using Kruskal Wallis test. An alpha level of 5% was taken, i.e., if any p value is less than 0.05 it was considered as significant.

RESULTS

Age distribution

The youngest patient was 15 years old and the eldest patient was 48 years old. The mean age in this study was 35.8±10.15 years.

Table 1: Age distribution.

Age (years)	N	%
11-20	2	14.3
21-30	1	7.1
31-40	7	50
41-50	4	28.6
Total	14	100.0

Table 2: Tumour site distribution.

Tumour site	N	%
Distal femur	6	42.9
Proximal tibia	3	21.4
Proximal femur	2	14.3
Proximal humerus	3	21.4
Total	14	100.0

Table 3: Tumour type distribution.

Tumour type	N	%
Benign	1	42.9
Locally malignant	9	21.4
Malignant	4	14.3
Total	14	100.0

Table 4: Adjuvant therapy requirement.

Adjuvant therapy	N	%
None	10	71.5
Radiotherapy	3	21.4
Chemotherapy	1	7.1
Total	30	100.0

Sex distribution

10 patients were male and 4 patients were female in this study. Majority (71.4%) of patients were male.

Incidence of pathological fracture

Total 5 (35.7%) patients (3 male and 2 female) had a pathological fracture on presentation due to the tumour.

Surgery time

Operating time was defined as the duration from incision to the closure of skin. The average time for surgery was 2.92 ± 0.43 hrs (Range: 2-3.5 hrs).

Amount of blood loss

Blood loss was assessed by used mops and the amount of blood in the suction bottle. The average loss of blood was 416.42 ± 269.91 ml (Range: 180-800 ml).

Adjuvant therapy

Total 3 patients of chondrosarcoma required pre-operative radiotherapy and 1 patient of Ewing sarcoma needed pre-operative chemotherapy. This neo-adjuvant therapy helped to reduce tumour size which helps in resection and reduction of blood loss during surgery.

Musculoskeletal tumour society score

At final follow-up, the overall musculoskeletal tumour society score resulted in an average of 89.71 ± 3.58 with the lowest score being 82 and highest being 94. The mean knee society score of 9 patients with tumour around knee joint at the end of 1.5 years was 85.55 ± 3.64 with a range of 81-91. The mean Harris Hip Score of 2 patients with tumour around hip was 90.5 and the mean Oxford Shoulder Score of 4 patients with tumour around shoulder was 41.67 with a range of 40-43.

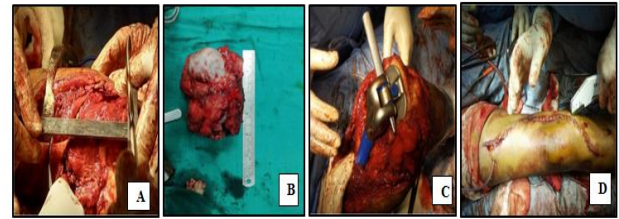


Figure 1: Intraoperative images; A) Tumour measurement before resection after taking appropriate margins; B) Resected tumour mass; C) Trial of endoprosthesis; D) Surgical wound closure with in situ suction drain.



Figure 2: Radiographs; A) distal femur tumour, B) distal femoral endoprosthesis, C) proximal tibia tumour, D) proximal tibial endoprosthesis, E) proximal femur tumour, F) proximal femoral endoprosthesis, G) proximal humerus tumour, H) proximal humeral endoprosthesis.

Complications

Out of 14, 12 (85.7%) patients did not have any complications. In 1 patient of proximal femur megaprosthesis there was a posterior hip dislocation on second post-operative day, which had to be revised by a repeat surgery. The reason discovered was inappropriate version of femoral stem. In 1 patient of proximal tibia Giant cell tumour superficial infection was seen at the end of 1 week which subsequently healed by regular dressing and intravenous antibiotics for 14 days. No major intra-operative complications such as excessive bleeding, iatrogenic fracture or neurovascular damage were encountered during the surgical procedure. Post-operative complications like thromboembolism, implant loosening or breakage, periprosthetic fracture, tumour recurrence, amputation or death were not seen any of the patients.



Figure 3: Postoperative clinical images; A) Healed surgical scar with 1 cm limb shortening, B) Knee flexion at final follow-up, C) Knee extension at final follow-up.

DISCUSSION

Limb-salvage surgery has replaced amputation as the preferred form of treatment for primary musculoskeletal tumours. Improvements in overall and disease-free survival, allowing greater rates of limb salvage are attributable to improvements in adjuvant and neo-adjuvant therapy, as well as advances in imaging and diagnostic modalities.^{8,12-14} Limb salvage offers considerable advantages in terms of function, appearance and psychological acceptance and is performed in 85% to 95% of patients without a reduction in oncological outcome.¹⁵⁻²⁰ An endoprosthetic replacement is now the most commonly used method of reconstruction for limb salvage.^{21,22} The principal aim of limb salvage is to preserve function without compromising survival. The reconstruction must allow optimal use with minimal risk of failure. Joint sparing surgery using biological reconstruction has many advantages; however, it also comes with many challenges. The main challenge is finding the appropriate reconstruction modality. The outcome of biological reconstruction is associated with a higher incidence of failure due to fracture, non-union and infection, in addition to the long operative time needed, especially when utilizing vascularized fibulas. There was also a frequent need for revision surgery as well as prolonged protected weight bearing after surgery and longer rehabilitation. The incidence of all major complications encountered in biological reconstruction ranges from 32 to 47%, with similar revision rates.²³⁻²⁵

Limb-salvage surgery itself is generally achieved through a wide excision, where the tumor is removed en-bloc with the surgical plane through a region of normal unaffected tissue. Despite the advantages of Limb-salvage surgery, unfortunately, this procedure is not always feasible for every kind of patients. Some considerations that should be taken in account are patient's general health condition, the size of the malignancy, the location, and the possible surgical margins. Furthermore, patient's response to chemotherapy and the extent of surgery also affects post-operative functional outcome. Therefore, strict follow-up is needed for patients receiving this procedure considering a higher recurrence rate compared to amputation, especially in close margin resection. Whenever this happens, amputation should still be

reserved as a back-up procedure.^{26,27} The development of musculoskeletal imaging makes it more possible to precisely define the borders of tumour infiltrating surrounding tissues, aiding surgeon's decision for resection margin, and furthermore resulting in better overall outcome. Whereas new surgical techniques in Limb-salvage surgery, such as compressive osseointegration, developments in endoprosthetic design, and bone graft reconstruction make Limb-salvage surgery a more preferred method of treatment in achieving promising outcome. A megaprosthesis is a large metallic device designed to replace the excised length of bone and the adjacent joint. Megaprotheses are available in a wide range of sizes and features to suit varying reconstructive needs. Often, fixation with cement gives the reconstruction immediate stability and allows rapid mobilization of the patient after surgery. Complications of endoprostheses include infection, implant dislocation and mechanical failure, aseptic loosening, instability, and tumour progression and recurrence.²⁸⁻³¹

Compared with the allograft and autograft reconstruction options, the endoprosthesis reconstruction of limb after wide resection of malignant tumour avoids the problems of disease transmission and limited source of supply that may be encountered in the autograft reconstruction and the paediatric patients. Custom-made oncologic endoprostheses can provide a wide available range of size and custom design to fit the needs of each patient. Many design principles and concepts have been evolved from clinical experience in the recent three decades to improve the function and decrease the complications. Thus, the endoprosthetic reconstruction becomes an alternative of allograft or autograft in the limb salvage procedures and becomes more and more common recently.

Megaprosthesis reconstruction has many advantages. The load-bearing characteristics of prosthetic reconstruction surgery offer immediate postoperative stability and facilitate rapid rehabilitation. Most endoprostheses are modular, thus allowing incremental prosthetic replacement in response to the length of resected bone. In addition, improvement in implant materials has greatly increased the durability of modern endoprostheses. They are able to achieve their primary aim of providing long-term function for some patients with relatively low physical demands.

Limitations

Limitations of current study included single institution bias, small group of patients, short follow-up period and a lack of Control group. The tumours were heterogeneous for type, stage and adjuvant treatment. Endoprosthesis of different companies from different countries were used, primarily to minimize the cost of treatment. Different procedures for soft tissue reconstructions were used, according to the case specific situation.

CONCLUSION

Limb preservation has become established for the treatment of bone cancer as it offers good oncological and functional outcome comparable with, if not better, than the other means of reconstruction particularly for large defects. Endoprosthetic reconstruction after excision of primary bone malignancies is an oncologically safe method of preserving the limb and optimising patient function and quality of life. The advantages of this procedure include early functional recovery, relatively low complication rate and a high level of emotional acceptance. However, the success of limb salvage procedure with endoprosthetic reconstruction depends on careful patient selection, meticulous surgical technique and good prosthetic design when performed at a specialist centre. A larger well-designed study is required to be conducted across the country to corroborate the findings of our study.

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Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee

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