Development and clinical implementation of locking systems in the treatment of metastatic lesions of the long bones

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Summary. The paper presents the experience of treatment of oncological patients with pathological fractures of the bones of the limbs on the background of metastatic lesions of the skeleton. Has developed and introduced special model blocked stand-offs. The technology of the operation, the clinical examples. Assessment of the quality of life of cancer patients.

Key words: metal implants, malignant tumors and metastases of long bones, pathological fractures, surgery, quality of life

The bones of the skeleton is the fourth in the frequency of metastatic cancer area, behind only the metastatic lymph nodes, lungs, liver. The degree of involvement of the skeleton depends on the stage of neoprotsessa and can reach 80% with common forms of malignant tumors of different localization [6]. It should be noted, and the fact that the frequency of metastatic involvement of the musculoskeletal system of the person is 2-4 times higher than the rate of primary bone lesions [1,3,9].

According to different authors, the localization of bone metastases dominates the spine (70%), pelvis (40%) and the hip (25%) [1,2,11,12]. In the structure of metastatic long bones femur is the most common "target", involvement occurs in 45-60% of patients [2].

Often for metastatic bone complicated pathological fractures, the risk of which is correlated with the degree of destruction of the cortex [14]. FidlerM. (1989) indicates that the fracture is inevitable in the destruction of the cortex by more than 50% [13]. Pathologic fractures are terrible and often fatal complication of tumor lesions, leading to the death of up to 90% of patients in the first year after its occurrence. The main cause of death - is hypostatic complications (pressure ulcers, venous thromboembolism, pneumonia, urosepsis), developing on the background adynamii patients, expressed pain, progression of the disease [6,7].

Therapeutic Management of metastatic lesions of long bones should be based on an integrated approach and include both systemic anti-tumor therapy, radiation therapy,

bisphosphonates appointment and surgical treatment, which has no small, and sometimes paramount.

There is a question about using the appropriate operations with the ability to preserve anatomical and functional ability of the limb. Traditional methods of fixation (intramedullary, of plate, extrafocal) do not solve the problem completely. Violation of regeneration in pathological fractures, significant lengthening terms fusion and restructuring callus often exceeds life expectancy of patients with Stage IV-cancer process. A high percentage of metal instability, septic complications, anatomical shortening the amount of bone resection, the need for orthopedic products - all this brings more suffering and negative impact on the course of the underlying disease and the psychological state of patients [1,4,10,12].

The above demonstrates the relevance of medical and technical developments to create new models and new types of metal osteosynthesis, which would ensure greater stability of bone fragments in pathological fractures, facilitate recovery of the support function of a limb, early activation of patients and preserve their quality of life. [8]

The purpose of this report is the development and clinical testing of special lockable device for the surgical treatment of pathological fractures in cancer patients.

Materials and methods

This report is based on an analysis of clinical data and study the results of surgical treatment of 32 patients with pathological fractures of the limbs that were examined and treated in the trauma and orthopedic department GKB N_{0} 6 SMP Simferopol. Study group consisted of 12 men, 20 women with pathological fractures of the long bones. A retrospective analysis of medical records revealed the following primary tumor: breast cancer - 12 (37.5%), prostate cancer - 4 (12.5%), lung cancer - 3 (9.4%), cancer of the thyroid gland - 1 (3.1%), renal cell carcinoma - 5 (15.6%), cancer of the cervix - 2 (6.3%). In 5 (15.6%) cases, the primary focus was not diagnosed.

Metastasis of long bones of the skeleton are represented mainly by the involvement of the femur and humerus (Table 1).

As shown in table 1, the most common site of metastasis is the area metadiaphysis proximal femur (31.3%), which corresponds to the data of other authors [1,2,6].

Diagnosis is made according to uniform standards for diagnostic and treatment process of inpatient care of adult population in medical institutions of Ukraine, approved by the order of Ministry of Health of Ukraine № 226 from 27.07.1998g. List of mandatory diagnostic procedures included: physical examination abnormality, radiography of the affected segment in standard projections, computed tomography, scintigraphy, morphological verification. For diagnostic purposes also held radiography light, ultrasound of the abdomen and pelvis. According to bone scan determines the degree of tumor dissemination in the bones of the skeleton, specified number of metastatic sites (scale MS Soloway): solitary (one seat), single (2-6 lesions) and multiple (more than 6 outbreaks). [3] In the study, we noted: solitary metastases in 6 (18.8%) patients, single - in 19 (59.3%), multiple - in 7 (21.6%) patients. The final diagnosis is established by morphological verification of material abnormality obtained by open biopsy or trephine biopsy.

The study of quality of life was part of the International Protocol of the European association of research and treatment of cancer through questionnaires EORTC QLQ-C30 and EORTC QLQ-BM22, specific to patients with metastases to the skeletal system. [15] The survey is a questionnaire consisting of nine major scales: 5 functional scales, reflecting the physical, role, cognitive, emotional and social functioning, 3 symptom scales, including fatigue, pain, nausea and vomiting, the scale of overall health. Questionnaires to do before and after the treatment. For mathematical processing of the data used countable guide Scoringmanual EORTC.

Results and Discussion

Medical tactic was determined by the survey results. When solitary and isolated metastases in the bone system, complicated by pathological fracture, performed radical surgery, which include the removal of tumors in one piece in the range of visible healthy tissue with subsequent fixation of the bone fragments of metal structures. In cases of multiple lesions of the skeleton, palliative operation was aimed at stabilizing the fracture and symptom management. This approach to the treatment of cancer patients is justified and consistent with the opinion of many authors [1, 3, 12].

Surgical treatment was performed on the 10-14th day from the date of pathologic fracture. These dates recommended Zatsepin ST, explained the need for education of clear boundaries between hematoma and metastasis [5]. Depending on the location of metastatic tumor was performed segmental resection of bone, bone fragments approached and implemented blocking intraosseous fixation titanium clamp system Bliskunova. The latter is a solid round rod with decompression groove throughout. In the proximal and distal locking holes are through-blocking elements, allowing for stable fixation and to eliminate all possible bias and the use of high-strength titanium alloy VT16 provides improved mechanical and fatigue strength of the structure. [8]

An example is the following clinical observation. Patient S., 53 years old, (source bol. $N \ge 1002$), admitted to the orthopedic department with complaints of severe pain, the violation of the support function of the left lower limb. Following an examination in a hospital ambulance was diagnosed as a pathological fracture of the upper third of the left femur. From the history and medical records revealed that the patient is registered with an oncologist for cancer of the left breast (T2NIMx). In 2008. underwent radical mastectomy. Radionuclide study conducted bones showed increased accumulation of the radiopharmaceutical is not only in the field of pathological fracture left femur (280%), but also in the posterior segment of the left rib 8 (260%). When verification is defined pathological tumor growth of metastatic origin of the breast tissue. In order to relieve pain, restore limb function reference held segmental resection of the left femur in the visible range of healthy tissue, intraosseous fixation pin. The postoperative period was uneventful. The patient became active on the 7th day after surgery, walk, care for themselves, have not experienced pre-operative pain. Reduction of lower extremity was 10 cm for further specialized treatment transferred to the oncology clinic (Fig. 1).

In the future, the patient returned to their daily activities, move freely with a cane, used the orthopedic shoes, could independently make purchases, take the course of a comprehensive anti-tumor therapy, has ceased to be dependent on others. Death was due to progression of the underlying disease in 10 months.

This type of fixation allows early postoperative patients increase, preserve limb function for a long time, eliminates the use of additional funds medical immobilization and external structures. However, the disadvantage of this type of fixation is anatomic shortening the amount of bone resection, the need for orthopedic shoes, which brings additional inconvenience and negative impact on the psychological state of patients.

In order to avoid these drawbacks, we have developed new models of special steel made from high-strength titanium alloy (VT16), representing the rods (1), in which the proximal end of a cylindrical hole under compression screws (5), which turns into a through slot (4). The middle part of the rod is threaded length of 120 mm (2) and support-adjustable nut (3) with the possibility of moving to the threaded part of the lock by the amount of bone resection. In the distal locking screw located through-holes formed in perpendicular planes (6, 7), and blocking elements (8) (Fig. 2). Special lockable latches are designed for the femur, tibia and humerus (Fig. 3 B). In cases where the tumor is located in the distal femur applied the lock via an implantable knee joint, the type of femoral-tibial fusion (Fig. 3 A). The presented design enables preserve leg length, provide increased stability of the bone fragments, eliminate all possible displacements, reduce the load on the blocking elements.

Resection of bone with pathological centers conducted by common rules. The tumor is removed within the musculo-fascial sheath in which it is contained, departing from the visible border of the tumor not less than 5 cm and 3-5 cm proximal to distal. Sawdust processed electrocoagulator bones. Implantation of a special lockable cable lock antegrade through the proximal bone fragment. To the threads of the rod, before the introduction of the distal fragment of bone, are wound two supporting-adjustable nuts and bred by the amount of bone resection to the dense bone contact with sawdust, and then the nuts are locked. With the help of the guide (jig) sighting devices, from individual accesses (up to 2 cm) in the bone transverse channels formed by blocking elements and is proximal and distal locking. Superimposed layered stitches to the wound with a mandatory leaving active drainage. Postoperative wound infection be prevented, thromboprophylaxis, symptomatic therapy and physician. At discharge, all patients are sent to the Cancer Center for further specialist treatment.

As an example, we give the following clinical observation. Patient N., 53 years old (source bol. № 1330), admitted to hospital on an emergency basis with a diagnosis of pathological fractures of the distal left femur metadiaphysis. Osteostsintigraficheskoe conducted research confirmed high accumulation of radiotracer (650%) only in the lower third of the diaphysis of the left femur. The primary focus was not identified. Given the nature of the solitary metastatic lesion, as well as to enhance patient recovery support function of the limbs and the possibility of further examination and treatment performed segmental resection of the left femur in the visible range of healthy tissue fixation special locking pin. Metadiafizarnaya tumor location, a short distal bone fragment, overweight patients (122kg), the need for early activation and further testing provided the basis to perform the type of osteosynthesis of femoral-tibial arthrodesis. The postoperative period was uneventful. The patient is activated for 6 days after surgery, to serve themselves, to walk with a crutch to the load on the operated limb (Figure 4). When histopathological verification of material obtained by operating a biopsy revealed the growth in the bone of the alveolar clear cell structure. For further treatment of the patient is directed to the oncology clinic. In the course of the following diagnostic search revealed a cancer of the left kidney (T3NxM1).

Follow-up was 14 months. The patient is alive and returned to their daily activities, travels with a cane, does not feel the pre-operative pain and does not require constant care. Continues to adjuvant chemotherapy in the oncology clinic.

Surgical intervention in patients with stage IV cancer process are mostly palliative in nature and aimed at reducing pain, stabilization of the affected segment, facilitating patient care, providing opportunities for specific anticancer therapy.

Following the surgery good and satisfactory results were achieved in all patients. General surgical complications, and local recurrence of the tumor, both in the early postoperative period and in the period of 12 months. were observed. Complications in the form of metal instability identified. All patients underwent surgery enabled us to 6-8 day from the date of the operation, allowing the possibility of movement on crutches (walker) to the load on the operated limb. Following the surgery, and stabilization, all patients were sent to the Cancer Center for further investigation and take courses of adjuvant chemoradiotherapy.

In assessing the quality of life questionnaire EORTC QLQ-C30 and EORTC QLQmodule BM2 was an improvement of the functional value of the scale, symptomatic and general health status of the operated patients (Fig. 5).

According to the results of the survey index of "physical condition" of patients increased to 65.3 points (baseline values at 22.7 points), the index of "emotional development" increased from 43.3 to 66.7 points, "cognitive function" from 66.7 up to 80 points. Increased measures of "social activity" of patients from 20 to 56.7 points. Data has changed "common state" defined by the patients, from 23.3 to 40.7 points. Decreased values of indicators such as "pain", "fatigue", "sleep disorders".

Conclusion

The first clinical experience with special lockable metal in the system the treatment of metastatic lesions of long bones showed that they provide greater stability of the bone fragments to serve as a bone prosthesis shaft, you can save in the postoperative period and the length of limb function, improve quality of life.

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