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DOES THE TERM OF DEFINITIVE OSTEOSYNTHESIS OF MULTIPLE LONG BONE FRACTURES OF LOWER EXTREMITIES IMPACT ON TREATMENT OUTCOMES IN POLYTRAUMA PATIENTS

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Abstract

The aim: to determine the timing impact of definitive multiple long bone fracture osteosynthesis of lower extremities on complications development, duration of Mechanical Ventilation (MV), Length of Stay in Intensive Care Unit (LOS-ICU), Hospital length of Stay (H-LOS) in patients with polytrauma treated according to Damage Control Orthopedics (DCO).

Materials and methods: a prospective controlled non-randomized trial in parallel groups conducted in polytrauma department of Kyiv City Clinical Hospital No. 17 from February 2016 to January 2020, which included 107 adult patients with polytrauma, multiple long bone fractures of lower extremities, one of which femur treated according to DCO.

The patients were divided into two groups: Group I included 51 patients who underwent definitive osteosynthesis of long bone fractures of lower extremities after patient condition stabilization ≥ 24 hours ≤ 5 days; Group II included 56 patients who underwent definitive osteosynthesis of long bone fractures of lower extremities during the period >5 days after injury.

Results: there were no statistically significant differences between Group I and Group II patients in demographics, injury mechanism, trauma severity and general patient condition. Group I patients who underwent osteosynthesis from 2nd to 5th days after injury had lower pneumonia incidence, compared to Group II patients (17.6 % vs. 26.8 %, $p=0.047$), shorter MV duration (9.3 ± 6.9 vs. 14.9 ± 9.1 , $p=0.048$), ICU-LOS (13.5 ± 8.3 vs. 19.1 ± 11.0 , $p=0.037$), and H-LOS (30.3 ± 13.9 vs. 38.9 ± 15.5 , $p=0.046$).

Conclusion: performing definitive multiple fracture osteosynthesis of lower extremity long bones after polytrauma patient stabilization from 2nd to 5th days after injury allowed to reduce the frequency of pneumonia, shorten the duration of MV, LOS-ICU and H-LOS, compared with its implementation after 5th days.

Keywords: polytrauma, long bone fractures, definitive osteosynthesis, complication, outcomes.

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1. Introduction

Lower extremities injuries are common in patients with polytrauma [1, 2]. Long bone fractures, especially of femur, are associated with development of numerous complications, including Acute Respiratory Distress Syndrome (ARDS), fat embolism, pneumonia, sepsis, Multiple Organ Failure (MOF) and death [3, 4].

Patients with injuries of two or more segments, presented with bilateral, ipsilateral and contralateral fractures of femur and tibia, have increased risk of complications, compared with a fracture of one long bone and these patients need special care management [5, 6].

The choice of timing and method of lower extremity bone fracture fixation in patients with polytrauma is a controversial question [7, 8]. The literature presents many studies confirming the benefits of early definitive osteosynthesis within ≤ 24 hours in patients with polytrauma according to Early Total Care (ETC), but these patients are in stable clinical condition and have a fracture of one long bone of lower extremity [9, 10].

The use of ETC tactics is possible in patients with multiple long bone fractures of lower extremities, but most researchers prefer using Damage Control Orthopedics (DCO) [11, 12].

Taking into consideration that DCO involves temporary external fracture fixation, such a question arises – when does it necessary to converse the temporary fixation method on definitive osteosynthesis [13, 14]?

According to some researchers, the performance of definitive osteosynthesis from 2nd to 5th days after injury causes numerous complications and patient death. First of all, it is explained by a period of persistent immunological changes caused by trauma and performance of definitive osteosynthesis is the cause of development “Second-Hit” effect. Therefore, it is recommended to perform the definitive osteosynthesis during the “Window of Opportunity” from 5th to 10th days [15, 16].

Other scientists confirm that performing of osteosynthesis during the period from 2nd to 5th days is safe for the patient and it does not affect or even reduce the frequency of complications, especially pulmonary, and it does not shorten duration of Mechanical Ventilation (MV), Length of Stay in Intensive Care Unit (LOS-ICU) and Hospital Length of Stay (H-LOS) [17, 18].

Therefore, the choice of conversion timing of temporary fixation on definitive osteosynthesis of long bone fractures of lower extremities remains a relevant and controversial issue in patients with polytrauma, it requires further scientific research.

The aim of the research – to determine the timing impact of definitive multiple long bone fracture osteosynthesis of lower extremities on the complication development, duration of MV, LOS-ICU, H-LOS in patients with polytrauma treated according to DCO.

2. Materials and methods

Study design: a prospective controlled not randomized trial in parallel groups conducted in polytrauma department of Kyiv City Clinical Hospital No. 17 from February 2016 to January 2020.

Inclusion criteria: patient agreement or his/her legal representatives (in case of patient consciousness disorder) to participate in the study; age ≥ 18 years; polytrauma (associated injury of two or more anatomical regions, the severity of each one ≥ 3 points according to the Abbreviated Injury Scale (AIS); presence of at least one of the following parameters: hypotension (systolic blood pressure ≤ 90 mmHg), Glasgow Coma Scale (GCS) \leq points, acidosis (base excess ≤ -6.0), coagulopathy (activated partial thromboplastin time ≥ 40 s or international normalized ratio ≥ 1.4), or age ≥ 70 years) [19]; open/closed multiple (≥ 2 segments) long bone fractures of lower extremities, one of which is the femur fracture; Injury Severity Score (ISS) ≥ 18 points; patients who were treated according to DCO.

Exclusion criteria: the death of the patient within the first day before the definitive osteosynthesis; borderline patients who have stabilized within 24 hours of injury and treated according to the ETC; severe chronic comorbidity, which complicates patient's condition and impede stabilization needed for surgical treatment; III degree open fractures (Gustilo-Anderson); neoplasm; pregnancy.

The study design was approved by the Commission on Bioethical Expertise and Ethics of Scientific Research of Bogomolets National Medical University №120 from 23.03.2020. According to expert opinion on materials, the study did not contain an increased risk for subjects of the study and was performed taking into account bioethical norms and scientific standards in accordance with the "Ethical principles for medical research involving human subjects" of the Helsinki Declaration of the World Medical Association.

The study included 107 polytrauma patients with multiple long bone fractures of lower extremities who were treated according to DCO.

Depending on the timing of the definitive osteosynthesis all patients were divided into two groups:

- group I included 51 patients who underwent definitive osteosynthesis of long bone fractures of lower extremities after patient condition stabilization ≥ 24 hours ≤ 5 days;
- group II included 56 patients who underwent definitive osteosynthesis of long bone fractures of lower extremities during the period > 5 days after injury.

On admission to the hospital all patients, included in the study, were evaluated on ISS [20], AIS [21], GCS [22], monitoring of hemodynamic parameters, Focused Assessment Sonography for Trauma (FAST), Whole-body Computed Tomography (after emergency surgery).

All patients were monitored for general clinical and biochemical blood parameters, including coagulation tests, metabolic parameters, arterial blood gas.

According to the Clinical Grading System (CGS), patients were divided into "stable", "borderline", "unstable" and "in extremis" [23].

Bone fractures were classified according to the Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) classification [24]. Open fractures were classified by Gustilo-Anderson [25].

Primary osteosynthesis of the long bones of lower extremities was performed by external fixation. Conversion of the temporary fixation on definitive one was performed depending on the localization and type of fracture in accordance with the recommendations of AO/OTA.

Criteria for the patient's readiness for the definitive fixation of long bone fractures of lower extremities were: relative stabilization of vital functions and patient clinical condition, stabilization of hemodynamics, without need for vasopressor support, metabolic parameters (venous blood lactate < 4 , bases excess ≥ -5.5 and pH ≥ 7.25) according to the Early Appropriate Care (EAC) protocol [26] and the Horowitz Index (PaO₂/FiO₂) ≥ 200 .

The control of the patient's condition at the post-hospital stage was carried out using telemedicine technologies. Counseling mode: synchronous and asynchronous "doctor-patient" consultations. Main method of evaluating treatment outcomes was counseling and completing the SF-36 scale. However, the results of telemedicine technologies usage in the treatment of patients with multiple fractures of the lower extremities will be demonstrated in our subsequent publications.

Endpoints: frequency of: pneumonia, ARDS, sepsis, MOF; duration of MV; LOS-ICU; H-LOS; mortality.

Pneumonia was defined on the basis of Clinical Pulmonary Infection Score (CPIS) ≥ 6 points [27]. ARDS was defined according to the “Berlin Definition” 2012 [28]. Sepsis was diagnosed according to the “Sepsis-3” criteria 2016 [29]. MOF was defined on the basis of the Sepsis-related Organ Failure Assessment (SOFA) [30].

Statistics

The normality distribution was verified using the Shapiro-Wilk test. Under normal distribution, the data is presented as mean, standard deviation \pm (SD). Qualitative comparative analysis was performed using Fisher’s exact test. The Student’s t-test was used to test the null hypothesis of no difference between groups. Statistically significant differences were considered at $p < 0.05$. The analysis was performed using the statistical software IBM SPSS Statistics 23.

3. Results

There were no statistically significant differences between the patients in the two study groups in demographics, mechanism of injury, severity of injury and general condition of the patient, localization and type of fractures $p > 0.05$ (Table 1).

Table 1

Cause and severity of trauma, demographic and clinical characteristics of study patients, localization and type of long bone fractures of lower extremities and methods of osteosynthesis

Indicators	Group I (n=51)	Group II (n=56)	P
Age (year)	42.4 \pm 17.2	40.2 \pm 15.8	0.243
Male (n/%)	38/74.5	39/69.6	0.194
Cause of trauma			
Traffic accident (n/%)	35/68.6	41/73.2	0.322
Fall (n/%)	12/23.5	12/21.4	0.219
Other (n/%)	4/7.9	3/5.4	0.368
Severity of trauma			
GCS (points)	9.3 \pm 3.4	9.1 \pm 3.8	0.517
ISS (points)	30.4 \pm 9.7	31.1 \pm 10.3	0.723
Severity of patient clinical condition			
Stable (n/%)	0	0	-
Borderline (n/%)	18/35.3	21/37.5	0.699
Unstable (n/%)	24/47.1	23/41.1	0.527
In extremis (n/%)	9/17.6	12/21.4	0.375
Characteristic of long bone fracture and method of definitive osteosynthesis			
Long bone fractures (n)	113	131	-
Closed fractures (n/%)	82/72.6	89/67.9	0.532
Open fractures (n/%)	31/27.4	42/32.1	0.276
Femur (n/%)	64/56.6	62/47.3	0.198
Tibia (n/%)	49/43.4	69/52.7	0.542
Diaphyseal fractures (n/%)	97/85.8	104/79.4	0.384
IMN (n/%)	92/81.4	99/75.6	0.495
Plate (n/%)	21/18.6	32/24.4	0.297
Simultaneously conversion (n/%)	33/64.7	42/75.0	0.128
Conversion in two stages (n/%)	18/35.3	14/25.0	0.549

IMN – Intramedullary Nailing

Treatment outcomes including the incidence of pneumonia, ARDS, sepsis, MOF, death and treatment timing are shown in **Table 2**.

Table 2

Outcomes of patients treatment with multiple long bones fractures of the lower extremities

Outcomes	Group I (n=51)	Group II (n=56)	p
Pneumonia (n/%)	9/17.6	15/26.8	0.047*
ARDS (n/%)	8/15.7	12/21.4	0.069
Sepsis (n/%)	7/13.7	6/10.7	0.218
MOF (n/%)	6/11.8	10/17.9	0.489
Duration MV (days)	9.3±6.9	14.9±9.1	0.048*
LOS-ICU (days)	13.5±8.3	19.1±11.0	0.037*
H-LOS (days)	30.3±13.9	38.9±15.5	0.046*
Mortality (n/%)	5/9.8	7/12.5	0.089

Note: * – the difference between groups is significant, $p < 0.05$

4. Discussion

Polytrauma is an important medical and economic problem of modern health care system, as it is one of the leading causes of death of young person under 45 years of age [31, 32].

Males were dominated among patients included in the study in Group I and II (74.5 % vs 69.6 % respectively, $p=0.194$). The mean age of patients was 42.4 ± 17.2 in Group I vs. 40.2 ± 15.8 ($p=0.243$) in Group II. Traffic accident was the main cause for the injury in Group I and II (68.6 % vs 73.2 % respectively, $p=0.322$) (**Table 1**).

An early accurate assessment of injury severity and patient clinical condition is important for the choice of further management in polytrauma patients [31]. Nowadays more than 50 scales have been proposed to evaluate the severity of injury and patient's condition, assessing anatomical lesions, physiological parameters, and combinations thereof.

We used the ISS to assess the severity of trauma, which points were 30.4 ± 9.7 in Group I and 31.1 ± 10.3 in Group II ($p=0.723$) (**Table 1**).

In our study we used the CGS to determine the severity of patient's condition. Although this scale is difficult to apply because it includes a large number of instrumental, laboratory, and clinical indicators, characterized four parameters (shock, acidosis, coagulation and soft tissue injury), it allows accurate assessment of the patient's condition [23, 31].

At admission to hospital, most patients were in unstable and borderline conditions (**Table 1**). Further management was based on the Pape H. C. algorithm (2005) [23].

The conversion of fixation method from temporary to definitive was performed in 100 % of cases. IMN was performed in 81.4 % of these cases in Group I and in 75.6 % in Group II (**Table 1**). The priority direction was the definitive osteosynthesis of femur fracture. After the definitive stabilization of one segment, the decision to perform the definitive osteosynthesis of the other injured segment was made, providing low risk assessed by the EAC and $\text{PaO}_2/\text{FiO}_2 \geq 200$.

The conversion of temporary fixation on definitive one was performed simultaneously in 64.7 % of cases in Group I and in 75.0 % in Group II. In other cases the conversion was performed in two stages. The time from trauma to definitive osteosynthesis of lower extremity long bones was 3.8 ± 1.1 days in Group I and 9.5 ± 3.8 days in Group II.

One third of all fractures were open (27.4 % vs. 32.1 % $p=0.276$) (**Table 1**). However, these fractures did not affect the timing of definitive surgery, as patients with Gustilo-Anderson type III fractures had been excluded from the study; and type I and II fracture osteosynthesis was performed the same as closed fractures with adequate antibacterial therapy.

As noted above, patients with multiple long bone fractures of lower extremities are characterized by general complications, among which pulmonary ones occupy a leading position.

In the literature the incidence of pneumonia in this category of patients ranges from 18.1 % to 50.0 % [3–5].

According to the results of the study, the most common complication was pneumonia, its incidence was higher in Group II patients compared to Group I (26.8 %, vs. 17.6 %, respectively), and it had a statistically significant difference ($p=0.047$) (**Table 2**).

Another common pulmonary complication was ARDS with incidence of 15.7 % in Group I and 21.4 % in Group II. There was no statistically significant difference between the groups, but there was a trend towards a significant difference ($p=0.069$) (**Table 2**).

There was also no statistically significant difference in sepsis rate ($p=0.218$) and MOF ($p=0.489$) between patients in compared groups (**Table 2**).

According to the literature, in this category of patients sepsis is diagnosed from 14.6 % to 21.6 % of cases [3, 5, 11], MOF from 12,0 % to 40,2 % [3, 5, 11].

Polytrauma is an important social problem as it is characterized by high morbidity and mortality rates. According to the literature, mortality ranges from 16.9 % to 35.5 % among patients with polytrauma and multiple long bone fractures of lower extremities [3, 5, 8, 11].

In our study, mortality among Group I and Group II patients was 9.8 % vs 12.5 %, respectively ($p=0.089$) (**Table 2**), and it had no statistically significant difference. However, it should be noted that, according to the study, 13 patients who had died within the first 24 hours before the definitive surgery were excluded. Mortality rate with excluded patients from the study was 20.8 %.

Also it should be noted that the majority of studies have demonstrated the incidence of complications and mortality during patient's stay in a hospital. Few studies describe these characteristics after patient discharge at outpatient stage of treatment. Therefore, in order to register complications and death of a patient within 1 year after polytrauma, we use the telemedicine technologies in our practice, designed by us. This method allows to monitor and correct the patient's rehabilitation process, to diagnose the development of the disease in time and to prescribe treatment.

In addition to social problems, polytrauma is a major economic expense cause because patients require long-term MV, longer LOS-ICU and H-LOS, which increases direct and alternatives costs, as other patients' access to this medical institution is limited [26].

According to various scientific sources, MV lasts from 7.8 to 13.3 days [3, 5, 7, 11], LOS-ICU is 8.8–19.4 days [5, 7, 8, 11], H-LOS ranges from 32.2 to 44.3 days in patients with multiple long bone fractures of lower extremities [5, 8, 11].

The results of our study, presented in **Table 2**, indicated that Group I patients who underwent definitive osteosynthesis from 2 to 5 days after injury had a shorter duration of MV ($p=0.048$), shorter LOS-ICU ($p=0.037$) and H-LOS ($p=0.046$), with statistically significant difference.

Study limitations. In our study we did not evaluate patients treated according to ETC tactics and who were underwent definitive multiple fractures osteosynthesis of long bones of lower extremities during the first day. In addition, patients with open Gustilo-Anderson type III fractures were not included because of delaying definitive osteosynthesis.

Prospects for further research. Further studies should be randomized to include more patients with multiple closed and open fractures of long bones of lower extremities treated according to ETC and DCO tactics.

5. Conclusions

Polytrauma patients with multiple long bone fractures of lower extremities are characterized by severe combined injuries that lead to numerous general and local complications.

Performing definitive osteosynthesis in case of multiple long bone fractures of lower extremities from the 2nd to the 5th day after the injury can significantly reduce the frequency of pneumonia, reduce the duration of mechanical ventilation, the length of stay in the intensive care unit and the length of hospital stay.

This study was not random for a number of reasons, but the question of the timing of definitive osteosynthesis is relevant and requires further study.

Conflicts of interest

The authors declare that they have no conflicts of interest.

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