

Original Articles

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DOI 10.18019/1028-4427-2021-27-1-6-12

Treatment outcomes in patients with multiple and concomitant trauma managed with minimally invasive osteosynthesis technologies and electromagnetic waves of the terahertz range

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Purpose To assess the effectiveness of minimally invasive technologies of osteosynthesis and electromagnetic waves of the terahertz range in patients with multiple and concomitant trauma. **Materials and methods** The process of rehabilitation was studied in 513 patients with polytrauma of varying severity which was more than 26 points on the ISS scale. The patients were diagnosed with 545 injuries of different organs and systems. All patients with severe concomitant and multiple trauma were divided into 3 groups: Group I of controls, treated in 1995–2001, consisted of 269 patients whose treatment was conservative and aggressive (surgical, with the use of plating or intramedullary osteosynthesis); Group II was the experimental study group consisting of subgroup A of 202 patients treated in 2002–2009 in whom “damage control” concept was applied and subgroup B of 42 patients treated in 2010–2017 using the damage control tactics and new minimally invasive methods of treatment and devices (non-invasive lung ventilation in intensive care for fat embolism; rational osteosynthesis in closed chest trauma; minimally invasive guided method of transosseous osteosynthesis, including the use of fixators with hydroxyapatite coating; rational surgical approach to pelvic bones; universal guide for reaming the medullary canal) and exposure to electromagnetic waves of the terahertz range (EMWTHR) of the xiphoid process of the sternum to stimulate the immune system. **Results** It was revealed that the use of minimally invasive, low-traumatic methods of treating bone fractures in severe polytrauma and methods stimulating the immune system and tissue regeneration (subgroup II B) contributed to an improvement of anatomical and functional results of treatment by 1.3 times compared with the control group. The quality of life of patients in this group, in comparison with the control group, was 1.6 times higher for injuries of the upper limb and 1.9 times higher for injuries of the lower limb. An integral analysis of the effectiveness of the treatment revealed a reliable increase in the effectiveness to a satisfactory level. **Conclusion** The use of EMWTHR in the complex treatment of such patients is a promising method for stimulating hematological and immunological processes. The first results described in the literature are optimistic.

Keywords: multiple and concomitant trauma, bone fractures, electromagnetic waves, Ilizarov apparatus, transosseous osteosynthesis, complications, treatment results, quality of life

INTRODUCTION

Treatment of skeletal trauma in the patients with polytrauma is a particularly difficult problem due to traumatic shock, risks of fat embolism, thromboembolism, poor treatment outcomes associated with nonunion and post-traumatic bone deformities, pathological ossification of para-articular tissues, a high level of disability, and mortality, which, according to some authors, may reach 80 % [1, 2]. The analysis of literature sources revealed that human compensatory and adaptive reactions (metabolic, coagulation, immunological) have an impact on the timing and manifestation of reparative processes in patients with concomitant and multiple trauma [3]. Therefore, in severe concomitant and multiple trauma, measures should be taken to stop acidosis, enhance immunity, restore the coagulation balance of the body using minimally invasive and minimally traumatic osteosynthesis technologies [4].

Several literary sources [5–8] report that electromagnetic waves of the terahertz range (EMWTHR) provide correction of such pathophysiological disorders as hypoxia, hypercoagulation and decreased immunity. Their use in the complex treatment of such patients is a rather promising method of stimulating reparative processes. The effects of minimally invasive osteosynthesis technologies in combination with EMWTHR exposure in multiple and concomitant trauma are of great interest.

We used clinical, radiological, statistical research methods, as well as questionnaires to study the results of treatment in patients with severe multiple and concomitant trauma in a comparative aspect, between the classical treatment regimens and minimally invasive technologies of transosseous osteosynthesis along with electromagnetic effects on the xiphoid

✉ Lukin S.Yu., Soldatov Yu.P., Diachkov A.N. Treatment outcomes in patients with multiple and concomitant trauma managed with minimally invasive osteosynthesis technologies and electromagnetic waves of the terahertz range. *Genij Ortopedii*, 2021, vol. 27, no 1, pp. 6-12. DOI 10.18019/1028-4427-2021-27-1-6-12

process of the patient's sternum in order to correct pathophysiological disorders.

Sets for transosseous osteosynthesis produced by the Experimental Plant of the Ilizarov Center (registration certificate No. FSR 2007/00756 dated July 30, 2012); instruments and implants for osteosynthesis (manufacturer by Sintez GmbH, Switzerland, registration certificate No. RZN 2015/3342 dated July 20, 2017); sets of screws, pins and instruments for osteosynthesis of fractures of the femur, tibia, humerus and forearm bones, manufactured by OSTEOMED according to TU 9438-006-58261811-2008 (RF, registration certificate No. FSR008 / 02791 from 30.05.2008); and standard surgical instruments were used for performing the interventions.

To have an effect on microcirculation, the device for EHF-therapy Orbita was used (registration certificate No. FSR 2009/05497 dated August 14, 2009, the validity period of which is

not limited, manufactured by OOO Strela, DP OAO CNIIIA, Russia).

The research followed the ethical standards set out in the Declaration of Helsinki "Ethical principles for conducting scientific medical research with human participation", the Rules of Clinical Practice in the Russian Federation, approved by Order of the Ministry of Health of the Russian Federation of June 19, 2003, No. 266, and GOST R ISO 14155-1-2008 "Guidelines for clinical trials of medical devices. Part 1. General requirements". The study was approved by the Ethics Committee of the National Ilizarov Center of the Ministry of Health of Russia. The results of the study were processed statistically with the calculation of the arithmetic mean and standard deviation ($\bar{X}_i \pm SD$).

Purpose To assess the effectiveness of minimally invasive technologies of osteosynthesis and electromagnetic waves of the terahertz range in patients with multiple and concomitant trauma.

MATERIAL AND METHODS

The study was conducted at the clinical departments of the Traumatological City Hospital No. 36 in Yekaterinburg and the National Ilizarov center. The patients were treated between 1995 and 2017. The process of rehabilitation was studied in 513 patients with polytrauma of varying severity, more than 26 points on the ISS scale (moderate and severe). The severity of polytrauma was assessed using the ISS scale (17–25 points – mild, 26–40 – moderate, 41 and more – severe).

Also, the study was guided by the classification according to the periods of traumatic disease [9]: days 1–3 after the injury – an acute period of the traumatic disease; days 4–10 – an early period of the traumatic disease; more than 10 days after injury – a late period of the traumatic disease.

Inclusion criteria into the study: 1) two or more concomitant injuries, one of which or their combination led to a direct threat to life and was the direct cause of the traumatic disease; 2) bone injuries (bones of the upper, lower extremities, chest, pelvis); 3) ISS severity of polytrauma higher than 26 points; 4) age of 18–65 years. Exclusion criteria: 1) lack of signed voluntary informed consent to participate in this scientific study; 2) uncompensated conditions on the part of internal organs and systems, as well as a history of chronic disease exacerbation before the trauma.

All patients had a total of 1,598 injuries and an average number of diagnosed injuries was three or more injuries per patient. There were 28 individuals in a coma state in who a traumatic brain injury was combined with fractures of ribs and limb bones. Most of the admitted patients were with polytrauma class IV (52.8 % of all the admitted) and at a young age (59.3 %

of the total number of patients admitted for treatment).

All patients with severe concomitant and multiple trauma were divided into 3 groups: Group I was a control group treated in the period 1995–2001 and consisted of 269 subjects. Their treatment included a waiting phase (conservative treatment) and an aggressive (interventions with the use of plating and (or) intramedullary osteosynthesis) tactics; Group II was an experimental one with subgroup A consisting of 202 patients treated in 2002–2009 with the damage control concept and subgroup B of 42 subjects treated in 2010–2017 using the damage control tactics and improved new minimally invasive methods of treatment and devices (non-invasive lung ventilation in intensive care for fat embolism; rational osteosynthesis in closed chest trauma; minimally invasive guided method of transosseous osteosynthesis (according to the rational proposal No. 10/2009), including the use of fixators with hydroxyapatite coating; rational surgical approaches to the pelvic bones; universal guide for reaming the bone marrow canal (patent for a useful model No. 159297 dated 05.06. 2015), a developed method for predicting complications in patients in the acute period of polytrauma (patent for invention No. 2631026 dated 06.14.2016) and exposure of the xiphoid process of the sternum to electromagnetic waves of the terahertz range (EMWTHR) to stimulate the immune system).

Treatment of patients of the groups I and IIA corresponded to generally accepted standards. The treatment system for the patients of the experimental group B followed the implementation of the algorithm developed by us (Table 1), including an anti-shock therapy, diagnostic and therapeutic manipulations, emergency operations on damaged internal organs

in a life-threatening condition, interventions on the skeletal system, correction of pathophysiological disorders using EMWTHR, stimulation of tissue regeneration, prevention of early and late complications. The treatment was staged in time depending on the period of the traumatic disease.

Complex correction of pathophysiological disorders was performed in polytrauma patients at an inpatient stage of treatment using EMWTHR according to the methodological recommendations "Application of terahertz therapy in clinical practice" (V.F. Kirichuk, A.P. Krenitsky, 2011). The EMWTHR was applied to the xiphoid process of the sternum for 15–30 minutes. Earlier, the positive results of using EMWTHR for the correction of immune, metabolic and hemostatic changes in patients with polytrauma was presented by us in the co-works with M.V. Stogov [5, 10].

The effectiveness of treatment was determined using the table for the integral assessment of rehabilitation measures in patients with bone fractures in the conditions of polytrauma, developed by us (Table 2).

In each group of patients, the index of rehabilitation (group M) was determined. It was based on:

1) average value of the treatment outcome (Rav), calculated using the modified Mattis-Luboschitz-

Schwarzberg scale [11] (Table 3) (from 0 to 200 points): $Rav = A / n$, where A is the sum of points in all patients in the group, n is the number of cases;

2) average quality of life in points Kav (from 0 to 80 for the lower limb and up to 100 for the upper limb): $Kav = B / n$, where B is the sum of points in all patients (if the fractures were combined on both the upper and lower limbs, then the average value of the sum of points for the upper (K1) and lower (K2) limbs was calculated – $K = (K1 + K2) / 2$), n is the number of cases). To do this, we used the questionnaire of the American Academy of Orthopedic Surgery and the USA Institute for Labor and Health "Evaluation of outcomes in impaired function of the arm, shoulder, hand" and the questionnaire "Oberger: Assessment System of Lower-Extremity Dysfunction", developed U. Oberger et al in 1994 [12];

3) total percentage (grade) of disability (from 0 to 100) (I) in the group of patients.

The formula for calculating the rehabilitation index in each group of patients is as follows: $M = Rav + Kav + I$.

The minimum value of 0 points is a good result of rehabilitation measures, the maximum value of 400 points is a poor result of rehabilitation measures.

Table 1

Developed algorithm of inpatient treatment in patients with bone fractures in the conditions of polytrauma

| Period of treatment | Period of traumatic disease (duration) | Time of manipulations, interventions post-injury | Volume of medical and specialized orthopaedic care | Goal |
|--|---|--|---|---|
| Admission unit (before intensive care) | | First hours post-injury | Anti-shock medical measures and intensive care | Stabilization of hemodynamic parameters, tissue hypoxia therapy |
| | | | Urgent medical and surgical manipulations | |
| | | | Clinical, laboratory, instrumental and radiological diagnosis and examination | Diagnosis of injuries, blood loss estimation, severity of injuries, detection of risks |
| Intensive care | First period (acute shock) days 1–3 | Day 1 | Antishock measures and intensive care therapy | Stabilization of the work of internal organs and systems |
| | | | Urgent surgical interventions on internal organs, urgent neurosurgical operations | |
| | | | Low invasive fixation osteosynthesis of the limb bones and pelvis with external fixation (Ilizarov apparatus) (both preliminary and final osteosynthesis) | Antishock therapy Prevention of secondary complications Creation of conditions for fracture consolidation |
| Specific clinical | Second period (relative adaptation) (days 4–10) | Day 4 | Osteosynthesis of floating ribs | Restoration of organs’ anatomy and functions |
| | | | Repeated operations on the internal organs | |
| | | | Gradual reduction with the Ilizarov apparatus or final osteosynthesis (intramedullary nailing or plating according to indications) | |
| | Days 5–10 | Prophylaxis of complications according to the risks detected | | |
| | Late period (period of possible complications) (days 11–30) | Days 11–14 | Correction of pathophysiological disorders | |
| | | | Stimulation of reparative regeneration | |
| | | | Prophylaxis of pathological ossification of tissues | |
| | Day 5 and the following | Osseous plasty (reconstruction) operations | | |
| Rehabilitative | Period of complete stabilization of important functions of the body | After discharge from the hospital and up to one-year follow-up | Symptomatic therapy | Improvement in quality of life, prevention of disability |
| | | | Physiotherapy and exercise therapy | |
| | | | Measures of tissue regeneration stimulation | |

Table 2

Table for integral evaluation of rehabilitation measures results in patients with bone injuries in the conditions of polytrauma

| Parameters | Results of rehabilitative measures, points | | |
|---|--|--------|---------|
| | Good | Fair | Poor |
| Anatomic and functional treatment result (R av) | 0–50 | 51–140 | 141–200 |
| Average quality of life (K av) | 0–20 | 21–45 | 46–100 |
| Disability or invalidity (I) | 0–10 | 11–25 | 26–100 |
| Index of rehabilitative measures (M of the group) | 0–80 | 81–210 | 211–400 |

Table 3

Evaluation of long-term anatomic and functional results of treatment in patients with limb bone fractures (modified Mattis-Luboschitz-Schwarzberg scale adapted for cases of polytrauma)

| Parameter | Results (points) | | |
|---|--------------------|---------------------------------|--|
| | 0 | 100 | 200 |
| Pain | None | Only in heavy physical activity | May appear in light physical activity |
| Fracture consolidation (in radiographs) | Full | Delayed union | Nonunion or pseudarthrosis |
| Limb shortening | None | 2 cm | More than 2 cm |
| Bone deformity | None | 10° | More than 10° |
| Joint range of motion | Physiological norm | Reduction up to 50 % | Reduction to more than 50 %, ankylosis |
| Segment tissue atrophy a | None | 2 cm | More than 2 cm |
| Angiotrophic changes | None | Moderate swelling | Severe edema, bedsores, necrotic changes |
| Neurological deficit | None | Paresis | Paralysis |
| Infection | None | Soft tissues | Bone, joint |
| Self-service | Full | Partial | Sharply decreased |

RESULTS

Lethal outcomes at various stages of treatment were recorded in 100 patients (19.5 % of all patients admitted for treatment) including 60 patients in the intensive care period (11.7 % of patients admitted for treatment), 26 in the specific clinical period (5.7 % of survived patients), in 14 rehabilitation period (3.3 % of survived patients by this stage). We divided all the complications that were encountered in patients with multiple and concomitant trauma into the following groups: metabolic, immunological, hematological, neuroorthopedic, and mental.

A total of 580 cases of various complications were recorded. Thus, 72.2 % of complications happened in the first group of patients (of the number of all complications in patients admitted for treatment),

26.4 % in IIA group and 1.4 % in IIB subgroup (Table 4). Long-term results of treatment of 337 patients were analyzed. Positive results of treatment were achieved in 271 patients (80.4 %) (Table 5).

The effectiveness of treatment was better in patients of group IIB. Fractures healed within the average statistical time; severe late complications were absent; household, social and labor rehabilitation was satisfactory. The quality of life in patients with fractures of the lower and upper extremities was studied at the rehabilitation stage of treatment by the questionnaire method in 113 patients with fractures of the upper limb and polytrauma and in 209 patients with fractures of the lower extremity and polytrauma (Tables 6, 7).

Table 4

Number of complications at the stages of treatment in patients with multiple and concomitant injuries and fractures

| Complications | Number of complications in the groups | | | Total | |
|------------------|---------------------------------------|-----|-----|-----------------|------|
| | I | IIA | IIB | Absolute number | % |
| Metabolic | 156 | 51 | 2 | 209 | 36.0 |
| Immunological | 92 | 28 | 1 | 121 | 21.0 |
| hematological | 24 | 7 | - | 31 | 5.3 |
| neuroorthopaedic | 138 | 60 | 3 | 201 | 34.6 |
| Mental | 9 | 7 | 2 | 18 | 3.1 |
| Total | 419 | 153 | 8 | 580 | 100 |

Table 5

Treatment results in patients with polytrauma (n = 337)

| Groups | Treatment result | | | | | | Total | |
|-----------------|------------------|------|------|------|------|------|-------|------|
| | Good | | Fair | | Poor | | | |
| | N | % | N | % | N | % | N | % |
| Controls (I) | 19 | 9.2 | 144 | 69.6 | 44 | 21.2 | 207 | 61.4 |
| Main 2A | 7 | 7.8 | 62 | 68.9 | 21 | 23.3 | 90 | 26.7 |
| Experimental 2B | 27 | 67.5 | 12 | 30.0 | 1 | 2.5 | 40 | 11.9 |
| Total | 53 | 15.7 | 218 | 64.7 | 66 | 19.6 | 337 | 100 |

Table 6

Quality of live evaluation points in patients with upper extremity fractures (n = 113)

| Fracture site | Group | Follow-up after discharge (6–8 months) |
|---------------|---------------|--|
| Humerus | I (n = 29) | 76.19 ± 13.6 |
| | II A (n = 27) | 68.54 ± 3.5 |
| | II B (n = 4) | 47.14 ± 18.2 |
| Forearm | I (n = 33) | 73.04 ± 13.8 |
| | II A (n = 16) | 68.73 ± 9.1 |
| | II B (n = 4) | 60.32 ± 13.1 |

Table 7

Quality of live evaluation points in patients with lower extremity fractures (n = 209)

| Fracture site | Group | Follow-up after discharge (6–8 months) |
|---------------|---------------|--|
| Femur | I (n = 50) | 67.3 ± 11.8 |
| | II A (n = 45) | 54.25 ± 9.6 |
| | II B (n = 34) | 49.01 ± 10.9 |
| Tibia | I (n = 40) | 61.76 ± 16.4 |
| | II A (n = 30) | 32.23 ± 11.5 |
| | II B (n = 10) | 31.54 ± 10.6 |

It follows from the tables that the quality of life in patients was higher in group II, especially in subgroup IIB.

The results of the integral assessment of the results of rehabilitation measures in patients with bone fractures in the conditions of polytrauma are summarized in Table 8.

In accordance with the table for the integral

assessment of the results of rehabilitation measures in patients of group I, the overall result of treatment (209.1 points) corresponded to the border between fair and poor outcome. In group IIA, the score of 138.7 points corresponded to fair (middle of the scale of satisfactory results). In group IIB patients, the result of 90.1 points corresponded to fair outcome but was closer to the score of good results.

Table 8

Results of integral evaluation of rehabilitation measures results in patients with bone injuries in the conditions of polytrauma (points)

| Parameters | Number of points in the groups | | |
|--|--------------------------------|-------|------|
| | I | IIA | IIB |
| Anatomic and functional treatment result (R av) | 95.1 | 49.3 | 28.8 |
| Average quality of life (K av) | 68.5 | 53.5 | 46.1 |
| Disability or invalidity (I) | 45.5 | 35.9 | 15.2 |
| Index of rehabilitative measures (M of the group) | 209.1 | 138.7 | 90.1 |

DISCUSSION

The choice of the treatment method and techniques of bone fracture repair in multiple and concomitant injuries remains an open question [13–17]. A large number of authors show the need to use low-traumatic surgical operations and provide a sufficient patient's activity [14, 18]. At the same time, individual “surgical control” of trauma, “immune control” [19], a team approach [20], involvement of relatives in the rehabilitation process [21] are important factors in the management of polytrauma.

Unambiguously, as concluded by the literature [22–25] and from the data of this study, the use of transosseous osteosynthesis in multiple and concomitant trauma can improve the results of medical rehabilitation. The method is simple to perform, relatively safe while its invasiveness in regard to soft tissues is minimal [4, 26]. However, as noted

by A.V. Shteinle (2009) [15], execution of external fixation is not always fast. This is due to insufficient knowledge of minimally invasive techniques of transosseous osteosynthesis, insufficient theoretical and practical training of surgeons. Therefore, external fixation may not always be a low-traumatic method that does not aggravate the patient's condition. In postoperative care of patients, stiffness of the adjacent joints and inflammatory complications may occur [23]. In this regard, the development of a system for the application of external fixation techniques in patients with polytrauma, the creation of a system for training the surgeons in the techniques for various clinical situations is urgent. Early surgical stabilization of fractures is the prevention and treatment of fat embolism and improves treatment results [27].

Numerous experimental and clinical studies have shown that severe multiple and concomitant trauma leads to pathophysiological disorders, both local and systemic. The main factors determining the severity of multiple and concomitant trauma and consequently of the course of the post-traumatic period, are the severity of hypoxia, hypercoagulability and immune disorders [28–30].

Considering the fact that the effectiveness of the treatment of patients does not always satisfy the surgeons, measures have been developed that have become the basis for the system of treatment of patients with severe multiple and concomitant trauma. They are a consistent implementation of emergency, urgent and delayed surgical interventions in the acute period of the traumatic disease; better availability of minimally invasive diagnostic and treatment technologies; the use of methods for arrest of acidosis, for immunity

improvement and restoration of coagulation reactions with medication therapy and with the use of EMWTHR, which has been currently seen as a promising method of non-invasive influence on metabolic processes [6–8, 31]; development and implementation of treatment methods aimed at early patients' activation, increased immunity, as well as minimally invasive ways to optimize osteoreparation and prevent complications. All this provided an increase in the effectiveness of treatment and a decrease in the number of complications.

Thus, a staged system of therapeutic and prophylactic measures in polytrauma has been developed and introduced into clinical practice, aimed at reducing the number of complications, improving the quality of treatment through the use of complex correction of pathophysiological disorders in patients with severe multiple and concomitant trauma through exposure to EMWTHR.

CONCLUSION

Thus, the use of minimally invasive and less traumatic methods for bone fracture repair in severe polytrauma in combination with EMWTHR in group IIB patients resulted in improved anatomical and functional treatment results by 1.2–1.3 times compared with the control group. The quality of life in this group, in comparison with the control group, was 1.6 times higher in injuries of the upper limb

and 1.9 times higher in injuries of the lower limb. An integral analysis of the treatment effectiveness revealed a reliably clear increase in the efficacy to a satisfactory level. The use of EMWTHR in the complex treatment of such patients is a rather promising method for stimulating reparative processes. The first results described in the literature are optimistic.

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Received: 06.02.2020

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