Original Articles

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Comments to EULAR/EFORT recommendations for management of patients older than 50 years with a fragility fracture and prevention of subsequent fractures

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Osteoporosis is considered a serious public health and social concern that catches public attention worldwide. A set of recommendations for management of patients with fragility fractures were developed on an initiative of the European League Against Rheumatism (EULAR) and the European Federation of National Associations of Orthopedics and Traumatology (EFORT) in December 2016. Authors have reviewed the recommendations through provision of health care practices in the Russian Federation. A protocol of hip fracture surgery within 48 hours of admission to trauma services for fragility cases represent a needful tool for optimization of medical care system. Specific techniques and implant designs for fracture fixation in osteoporotic bone are described with the focus on subsequent fractures prevention and fracture risk assessment. Effective rehabilitation is shown to rely on patient's understanding of the pathogenesis of the pathological process. Specific drug therapies and non-pharmacological treatment can be administered for osteoporotic patients with low-energy fractures.

Keywords: osteoporosis, fragility fractures, fragility fractures fixation, subsequent fracture prevention

INTRODUCTION

Osteoporosis is a chronic systemic metabolic skeletal disorder characterized by low bone strength and deterioration of bone tissue which predisposes to low energy fracture. The major osteoporotic fractures are those of the proximal femur and humerus, vertebral body, and distal radius. Osteoporotic fracture is associated with significant morbidity, poor quality of life, lasting disability and higher mortality rate [1]. The incidence of fragility fractures increases with age among people over 50, and proximal femoral (PF) fractures are more common for individuals over 75 years of age. While there is an undeniable connection between menopause and osteoporosis in women, osteoporosis can be caused by a medical condition or a medicine and is called secondary osteoporosis. About 30 to 40 % of low energy fractures occur in men.

Osteoporosis is the most common bone disease in humans. Currently, one in three women aged 50 years and above will experience a fragility fracture due to osteoporosis, as will one in five men [2]. Seven vertebral fractures occur every minute and PF fracture every five minutes in the Russian Federation. For the year 2010, there were an estimated 112 thousand PF fractures in Russia, and by 2035, the incidence of PF fracture is projected to increase by 36 % in men and by 43 % in women due to longer life expectancy with total of 159 thousand cases per year [3].

Fragility fractures are a known comorbidity in patients with systemic diseases and can be prevented by proper medical therapy. Fragility fractures resulting from a low energy trauma reflect a two-fold greater increase in refracture risk [4]. There are a number of therapies and treatments available

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for the prevention of fragility fractures in people thought to be at risk, or to prevent further fractures in those who have already had one or more fragility fractures.

It is apparent from the above that organization of optimal care for fragility fractures would be dependent on the age, presence or absence of comorbidity based on a multidisciplinary approach with expertise from orthopaedic and trauma surgeons, general practitioners, geriatricians and rehabilitation specialists. The European League Against Rheumatism (EULAR) and the European Federation of National Associations of Orthopaedics and Traumatology (EFFORT) established for the first time collaborative recommendations of optimal acute care for the patients aged 50 years and over with a recent fragility fracture and the prevention of subsequent fractures in high-risk patients published in December 2016 [5].

A team of 10 orthopaedic surgeons, 7 rheumatologists, a geriatrician, a clinical epidemiologist formulated 10 research questions based on evidence from the literature and the systemic investigations. 10 recommendations were formulated after discussion and consensus building in the group of 23 specialists. Authors have reviewed the recommendations through provision of health care practices in the Russian Federation.

1. Preoperative and perioperative management. *Patients with fragility fractures should be managed in the context of multidisciplinary approach guaranteeing adequate preoperative assessment and preparation of patients including adequate pain relief, appropriate fluid management and surgery within 48 hours of injury (Level of evidence: IIA, Strength of recommendation: B, Level of agreement 9.8)*.

Early surgery is likely to improve morbidity and mortality in patients with fragility fractures who often have pre-existing chronic diseases which will influence on general management and functional recovery. The research conducted in the Russian Federation indicated to the need of multidisciplinary approach to the treatment of elderly with fragility fracture. A prospective two-year study showed that the mortality rate in patients with PF fracture was dependent on the patient's age, presence of diabetes mellitus, chronic renal insufficiency, ischemic heart disease, dyscirculatory encephalopathy and hemic diseases. Such acute medical conditions as shock, delirium, deep venous thrombosis of tibia, the ASA physical status score and length of preoperative bed/ days were found to be associated with mortality rate. Long-term mortality (at 3, 6, 12 and 24 months) was also dependent of presence of such chronic conditions as cardiac insufficiency, diabetes mellitus, dyscirculatory encephalopathy, etc. Cognitive function score on the MMSE was correlated with mortality at 1 and 2 years and was also included in prognostic model for predicting the risk of mortality at follow-up from 3 to 12 months [6].

It should be noted that safe and timely transfer from the emergency room to an orthogeriatric ward and definitive treatment including early surgery within 24–48 hours after admission significantly reduces short-term and mid-term mortality rates and reduces minor and major medical complications due to immobility and its accompanying effects: decubitus ulcer, pneumonia, increased length of hospital stay. Delay to the operation theatre to enable correction of acute medical problems has to be weighed up against the effects of potential impacts. Evaluation of preoperative length of hospital stay performed in the city of Yaroslavl showed mortality rate of 9.66 % and mean length of hospital stay of 22.02 days prior to the introduction of protocol of surgery to be produced within 48 hours of injury against 2.77 % and 8.57 days, respectively, after introduction of the protocol into clinical practice [6].

Venous thromboembolic (VTE) prophylaxis is administered to the patients with fractures who will undergo trauma and elective bone and joint surgeries and a procedure of longer than 2 hours in accordance with clinical guidelines of the Russian Federation. VTE of lower limbs is reported to occur in 11.2 % of the patients with PF fractures within three days of inpatient stay and in 39.1 % at a delayed period of time according to a Russian series. The above facts determine the need for optimization of medical care organization to ensure timely admission of patients with fragility fracture to the trauma hospital [7].

Recommendation 2. Orthogeriatric care. *To improve functional outcome, and to reduce length of hospital stay and mortality orthogeriatric comanagement should be provided, especially for elderly patients with hip fractures (Level of evidence: IA, Strength of recommendation: A, Level of agreement 9.2)*.

Orthogeriatric wards and services have been recently established in many countries to provide interdisciplinary care to elderly patients with fractures, PF injuries, in particular. Elderly fracture patients admitted to the hospital will benefit from multidisciplinary comanagement. The joint care model between geriatrician and orthopaedic surgeon on a dedicated orthogeriatric ward was shown to have the shortest time to surgery, the shortest length of inpatient stay and the lowest inpatient and one-year mortality rate. This as primarily achieved by prevention of complications related to increased mortality and morbidity: delirium, deep venous thrombosis, pressure sores and malnutrition.

Postoperative care should include appropriate pain management and antibiotic prophylaxis, correction of postoperative anaemia, routine systems examination, regular assessment of cognitive function, assessment of pressure sores, nutritional status and renal function, assessment and regulation of bowel and bladder function, wound assessment and care and early mobilization. Binding geriatric consultations will be helpful for the patients at all stages of treatment in absence of orthogeriatric wards at healthcare institutions of the Russian Federation.

Recommendation 3. Treatment of the fracture. *Appropriate treatment of the fractures in these often elderly and multimorbid patients with flail bones requires a balanced approach with regard to operative versus non-operative treatment and careful selection of fixation devices and techniques (Level of evidence: III, Strength of recommendation: C, Level of agreement 9.3)*.

The choice of treatment modalities and recommendations for surgical management are dependent on the fracture pattern and localization and on the individual patient. Indications to operative and non-operative treatment should be carefully considered although surgical management can provide comparatively better anatomical and functional outcomes but associated with a higher risk of complications. Some osteoporotic fractures, PF in particular, usually require surgical treatment for early mobilization and prevention of severe life-threatening complications and hypodynamic lifestyle [8, 9]. Arthroplastic procedure can be a method of choice in some cases. Total joint replacement is used for intracapsular fracture of the femoral neck and fragility multifragmental intra-articular fractures of the proximal and distal humerus and the bones forming the knee joint rather than osteosynthesis [10].

Patients with fragility fracture of upper limb can benefit from nonsurgical treatment to allow performance of basic activities of daily living like eating and showering. Apart from a method of treatment applied to repair a fracture immobilization with a plaster cast cannot be considered a good option. Skeletal traction can be used preoperatively at a short term to control pain but unacceptable for a long term [11].

Major approaches to surgical and non-surgical treatment of fragility fractures are well known to orthopaedic and trauma surgeons. However, specific details of surgical treatment with regards to low bone quality in osteoporotic patients are a matter of concern for dedicated specialists.

The quality of bone fixation is known to be dependent on bone mineral density. Implant stability relies on a contacting surface with the bone. Implants providing greater contacting area with the bone are more stable to cyclic loads and applicable for osteosynthesis of fragility fractures. Intramedullary nails of a larger diameter and interlocking spiral blades and a larger size of screws used to fix a plate are less likely to loosen and result in failure [11]. Bone cement based on polymethylmethacrylate constitutes a very important interface providing augmentation for most vulnerable metaphyseal fixation areas applying special implant design. The technologies were shown to be efficient for osteosynthesis of the proximal femur, proximal humerus and distal metaepiphysis of the radius [12–14].

Angular stable plate constructions allow adequate fixation of metaepihyseal fragility fractures preventing varus collapse and providing bridging plate osteosynthesis. Monocortical screw length corresponds to the cortex thickness and bicortical screw bridges over the diameter of the bone. Stress loads are better distributed throughout the implant with long bridging plates as compared to shorter screws to allow increase in the distance between next-to-the-fracture screws. Bicortical screws and longer plates should be used for fragility fractures. Adequate interfragmental compression of the fracture is another technical concern with osteoporotic bone due to its poor mechanical strength. Absolute stability with anatomical reduction and interfragmental compression is acceptable in osteoporotic patients with intra-articular fractures to provide adequate function of the involved joint with accurately recovered anatomy of the articular surface. Bone realignment, restoration of segment length and elimination of rotational displacement will be sufficient for relative stable fixation in the rest of the cases [11].

Slight bone shortening can be neglected in some cases to improve the contact of osteoporotic bone fragments with osteosynthesis of metaepiphyseal fractures [11]. Fragility fractures should be reduced with caution to avoid iatrogenic injury resulting from excessive manipulations. Several rules of osteosynthesis are to be followed in fragility fractures with poor bone quality in elderly patients:

1. The worse the bone quality, the longer the fixator.

2. The worse the bone quality, the less indications to anatomical bone reduction and the absolute stability of intra-articular fracture fixation.

3. Angular stable plates and screws are practical for fragility fractures.

4. Reaming of intramedullary canal is recommended for osteosynthesis using interlocking IM nail to allow a greater nail diameter.

Practical application of the above principles and rules can ensure a weighted and reasonable approach to the choice of appropriate treatment of the cohort of patients.

Recommendation 4. Organisation of postfracture care. *Each patient aged 50 years and over with a recent fracture should be evaluated systematically for the risk of subsequent fractures (Level of evidence: IA, Strength of recommendation: A, Level of agreement 9.5)*.

The Fracture Liaison Service (FLS) was shown to be the most effective organizational structure for risk evaluation and treatment initiation [6, 15, 16]. The central element of an FLS is a dedicated coordinator who takes care of all aspects of the process (identification, investigation and intervention with therapy). The coordinator is often a well-educated nurse, who works under supervision of an orthopaedic surgeon, an endocrinologist or a rheumatologist. The coordinator is responsible for the identification of all elderly patients with a recent fracture in the hospital, to organize the diagnostic investigations and to start interventions and providing adequate medical information to patients and primary care physicians. Foreign randomized controlled studies proved that a nominated coordinator significantly improves the implementation of osteoporosis treatment after a low energy fracture [16].

In 2012 the Russian Osteoporosis Association initiated Prometheus project on creation of the system on prevention of subsequent fractures in osteoporotic patients aimed at introduction of FLS in Russian institutions. The first Russian internationally recognized FLS was established in 2015 in Yaroslavl at the emergency hospital and there were 8 FLS mapped on International Osteoporosis Foundation (IOF) «Capture the Fracture» early in 2018 with two FLS rated and plotted on the Map of Best Practice as Silver and three as Bronze (http://www.capturethefracture.org/get-mapped, recent visit on 02.09.2018). FLS undertakes to identify patients with low energy fractures, evaluate a risk of subsequent fractures and administer antiosteoporotic therapy and follow-up in dynamics.

According to the findings of Russian researchers, a fracture liaison nurse could contribute to identification of a greater number of patients with fractures of the proximal femur who were referred to osteoporosis

specialist and administered an antiosteoporotic therapy. Osteoporosis consultations for the patients increased from 8.4 % to 94.3 % and prescriptions of calcium and/or vitamin D, pathogenetic antiosteoporotic medications increased from 8.4 to 92.9 % and from 8.4 to 70.6 % with introduction of FLS and nominated coordinator [6].

Recommendation 5. Evaluation of subsequent fracture risk. *Evaluation of the risk of subsequent fractures includes a review of clinical risk factors, Dual-energy X-rays absorptiometry (DXA) of spine and hip, imaging of the spine for vertebral fractures, evaluation of fall risks and the identification of secondary osteoporosis, which together predict subsequent fracture risk (Level of evidence: III, Strength of recommendation: C, Level of agreement 9.3)*.

Evaluation of the risk of subsequent fractures is essential for identification of osteoporosis treatment tactics and prophylaxis of subsequent fractures. Secondary fracture risk is high immediately after the fracture, persists within 12–24 months and gradually decreases over time. Patients with fractures 3–6 months old are supposed to receive diagnostic investigations, but investigations at a later stage might also be worthwhile.

Such clinical risk factors as advanced age, female gender, low body mass index, lifestyle, personal and family history of fracture and fall risk all play an important role in subsequent fracture risk. These (except falls) are included in Fracture Risk Assessment Tool FRAX. The FRAX tool is a freely accessible calculator which was developed to calculate the ten year probability of fracture with BMD and is available in many countries including the Russian Federation (https://www.sheffield.ac.uk/FRAX/tool.aspx?lang=rs). In Federal clinical guidelines on osteoporosis [17], treatment for osteoporosis is recommended in individuals with the probability of fracture exceeding intervention threshold to decrease the risk. The Frax tool is based on individual patient models that integrate the risks associated with clinical risk factors as well as BMD at the femoral neck.

DXA of the lumbar spine and hip is the standard method for measuring BMD, and independently contributes to the assessment of fracture risk. Imaging of the spine by radiography or with vertebral fracture assessment (VFA), a measurement based on additional software on a DXA device which involves lower irradiation than plain radiographs or CT, allows the detection of subclinical vertebral fractures, which are frequent (20 %) in patients with a recent non-vertebral fracture. The presence, number and severity of vertebral fractures are related to fracture risk and contribute to therapeutic decisions, independent of BMD and other risks.

Recommendation 6. Implementation of guidelines. *Implementation requires a local responsible lead, that is, a person/group that coordinates secondary fracture prevention based on guidelines liaising between surgeons, rheumatologists, endocrinologists, geriatricians in case of elderly with a hip or other major fracture and general practitioners (Level of evidence: IV, Strength of recommendation: D, Level of agreement 9.1)*.

The authors point out that implementation of clinical guidelines in routine daily practice is often difficult. However, the National Hip Fracture Database initiated in Great Britain and development of clinical standards for hip fracture care led to substantial improvements in care and survival of older people with hip fractures [18].

Recommendation 7. Rehabilitation. *An appropriate rehabilitation programme should consist of both the early postfracture introduction of physical training and muscle strengthening and the long-term continuation of balance training and multidimensional fall prevention (Level of evidence: IIA, Strength of recommendation: B, Level of agreement 9.5)*.

Comprehensive rehabilitation programme is recommended for patients with fragility fractures. Based on initial condition of the patient, appropriate physical therapy includes extremity strength exercises, long-term balance and functional training for fall prevention. Evaluation of fall risk suggests

analysis of falls during the last year, and special functional tests are conducted if indicated.

The most important aim for all patients sustaining a fragility fracture is to regain the level of morbidity and independence they enjoyed before the fracture occurred. A multidisciplinary and multifactorial comprehensive rehabilitation programme is advocated for elderly patients [19]. Early mobilization following surgery, preferably starting on the first postoperative day, is critical for a patient's functional independence and prevention of postoperative complications. In patients with fractures of the PF, this comprises immediate weight-bearing, early ambulation as tolerated by the patient and early verticalisation with transfer training in and out of bed. Individual multicomponent rehabilitation programme involves assessment of premorbidity level of activity and includes aerobic and stretching exercises combined with balance training. Positive effects on BMD and muscle strength are described in patients who exercise rigorously, as well as reduction in the frequency of falls, but the evidence for fracture prevention is limited [20, 21].

Recommendation 8. Education. *Patients should be educated about the burden of the disease, risk factors for fractures, follow-up and duration of therapy (Level of evidence: IV, Strength of recommendation: D, Level of agreement 9.2)*.

Education programmes are designed to increase public awareness of osteoporosis and targeted at lifestyle habits, appropriate medication use and non-medical treatments. An instance of a patient who suffered a distal forearm fracture showed an effective use of an individual osteoporosis consultation from a trauma surgeon who provided an educational material in print form and recommended DXA to motivate the patient for further evaluation and treatment [22]. Osteoporosis health promoting school is the most effective way of education regarding several aspects of osteoporosis including actual comprehension of the disease, risk factors, prevention and treatment through interactional education form that showed the efficacy in multicenter randomized study conducted in Russia [23].

Recommendation 9. Non-pharmacological treatment. *Non-pharmacological treatment is important in the prevention of fractures in high-risk patients; it includes at least an adequate intake of calcium and vitamin D, stopping smoking and limitation of alcohol consumption (Level of evidence: IV, Strength of recommendation: D, Level of agreement 9.3)*.

Non-pharmacological treatment plays an important role in the prevention of falls and fractures in high-risk patients. It includes at least adequate intake of calcium and vitamin D, smoking cessation and limited alcohol consumption.

Pharmacological treatment of osteoporosis must be accompanied by adequate calcium and vitamin D3 intake to be administered at the same time to ensure the efficacy. In addition to that, pathogenic medication intake can increase the need in calcium and result in hypocalcemia. Calcium intake of 1000–1200 mg can be recommended daily as a part of the diet or supplementation. Vitamin D supplementation is associated with reduction in falls acting to develop and maintain metabolism in muscular tissue. Vitamin D deficiency was shown to be associated with sarcopenia and an increased risk of falling in elderly patients aged over 65 years [24]. A daily intake of 800-2000 IU vitamin D is advocated daily for individuals with osteoporosis and then administered all year round following a fragility fracture.

Recommendation 10. Pharmacological treatment. *Pharmacological treatment should preferably use drugs that have been demonstrated to reduce the risk of vertebral, non-vertebral and hip fractures, and should be regularly monitored for tolerance and adherence (Level of evidence: IB, Strength of recommendation: A, Level of agreement 9.9)*.

Pharmacological treatment is indicated for patients who are at high risk for subsequent fractures using proven remedies. Bone fixation cannot be improved with anti-osteoporotic therapy immediately after fragility fracture due to its delayed effect on BMD of 6-to-12-month treatment. In Federal clinical guidelines on osteoporosis, antiresorptive drugs (orally or parenterally administered bisphosphonates,

denosumab, monoclonal antibody that neutralizes RANKL) or anabolic agent teriparatide are first-choice agents of pharmacological treatment [17]. Although there is no evidence of delayed consolidation of fractures due to antiresorptive therapy [25, 26], parenteral bisphosphonates are administered at least 2 weeks of vertebral fractures and 6-8 weeks following non-vertebral fractures or surgical interventions performed. By contrast, denosumab and teriparatide can be administered in the first days of injury [27, 28].

Alendronate, risedronate andibandronate are first-choice agents among oral bisphosphonates to prevent subsequent fractures because these drugs are well tolerated and effective. It is important that oral bisphosphonates should be taken alone on an empty stomach maintaining an upright posture not having food, medications or supplements for at least an hour. Intravenous bisphosphonates (ibandronate, zoledronic acids), denosumab and teriparatide avoid gastrointestinal intolerance and administered for severe cases of very low BMD, subsequent or multiple fractures.

Anti-osteoporotic treatment with oral bisphosphonates is usually prescribed for at least 5 years and parenteral administration for at least 3 years. The treatment can last longer in severe cases. Teriparatide is administered for not more than 24 months to be followed by antiresorptive drugs. Administration of Denosumab is not limited in treatment length but to be replaced by other drugs when cancelled. Effects of osteoporosis treatment in the cohort of patients can be evaluated with dynamics in BMD using DXA to be performed once a year and with absence of subsequent fractures. Patients should be treated under supervision of a general practitioner or an osteoporosis specialist (endocrinologist, rheumatologist or at the center of osteoporosis). Adherence to therapy is substantially higher in the FLS to be activated by secondary and tertiary referral centers at medical institutions for risk evaluation and treatment initiation.

CONCLUSION

Therefore, collaborative recommendations of optimal acute care for the patients aged 50 years and over with a recent fragility fracture and the prevention of subsequent fractures in high-risk patients were formulated on the initiative of the European League Against Rheumatism (EULAR) and the European Federation of National Associations of Orthopaedics and Traumatology (EFFORT) based on a multidisciplinary approach with expertise from orthopaedic and trauma surgeons and other specialists. The comorbidity profile varies across patients with osteoporosis which leads to an increased risk of fragility fractures. Recommendations rely on vast international experience that is supported by Russian specialists who reviewed the recommendations through health care practices in Russia. The recommendations can be successfully used in treatment of elderly patients with fragility fractures and conceived by national medical associations and incorporated into the national clinical guidelines of the Russian Federation.

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