Genij Ortopedii. 2021. Vol. 27, no. 6. P. 800-807.

Original article

https://doi.org/10.18019/1028-4427-2021-27-6-800-807

Asynchronous quantitative computed tomography in outpatient settings

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Abstract

Introduction The prevalence of osteoporosis is predicted to increase among individuals over 50 years of age. Research was initiated to evaluate the effectiveness of the clinical use of asynchronous quantitative computed tomography (QCT) facilitating the diagnosis of the condition. **Objective** Review the results of asynchronous QCT introduced in an outpatient clinic in Moscow, with reference to the risk factors included in the FRAX tool. **Material and methods** Bone mineral density (BMD) was measured in patients referred for QCT by specialized clinicians employed at the same medical institution. The QCT scanning included two areas: the lumbar spine and the proximal femur and was produced with the Toshiba Aquilion 64 CT Scanner, and BMD measured using QCT PRO. A sampling analysis of the 10-year probability of a major osteoporotic fracture was produced using the FRAX tool with the exclusion criteria of anti-osteoporotic treatment, unreliable data in the questionnaire, artifacts in the images of the proximal femur. Based on the results, patients were assigned to groups by indications for initiating treatment in accordance with the FRAX strategies, FRAX corrected for BMD of the femoral neck, QCT, FRAX in conjunction with QCT. **Results** Within a year of the study, QCT scans were performed for 710 women with the mean age (MA) of 67.3 (9.3) years. Based on CT findings of three sites of interest patients were diagnosed with osteoporosis (n = 418, 59 %), osteopenia (n = 252, 35 %), and 40 (6 %) showed normal manifestations. The FRAX-based 10-year probability of major osteoporotic fractures was used selectively for 111 patients with a high risk detected in 15.2 %, and BMD of the femoral neck adjusted in 14.3 %. QCT findings revealed a high risk of fractures in 46.4 % of the surveyed patients who could receive treatment. The use of QCT in addition to FRAX allowed optimal identification of patients who had antiresorptive treatment indicated in 30.4 %. **Conclusion** QCT findings detected osteoporosis in 59 % of patients, while the FRAX-based estimates of 10-year fracture probabilities indicated to the need for initiation of treatment in 15.2 % only. Using the FRAX tool and QCT findings together allowed optimization in the proportion of patients who required anti-osteoporotic treatment up to 30.4 %. The results of the study can be used in the development of a clinical decision support system for management of patients with suspected osteoporosis.

Keywords: osteoporosis, treatment, risk factors, fracture risk assessment tool, quantitative computed tomography, bone mineral density, T-score, osteodensitometry

For citation: Petraikin A.V., Sergunova K.A., Nisovstova L.A., Soloviev A.V., Petryaykin F.A., Akhmad E.S., Semenov D.S., Abuladze L.R., Iassin L.R., Kiseleva A.N., Vladzymyrskyy A.V., Morozov S.P. Asynchronous quantitative computed tomography in outpatient settings. *Genij Ortopedii*, 2021, vol. 27, no 6, pp. 800-807. https://doi.org/10.18019/1028-4427-2021-27-6-800-807

INTRODUCTION

Quantitative computed tomography (QCT) is one of the current methods of osteodensitometry. This method of quantitative measurement of bone mineral density (BMD) was introduced in the 1970s, almost simultaneously with computed tomography technology. In the past, phantoms with preset values of potassium hydroorthophosphate concentrations placed under the patient during scanning were used for measurements. The approach was termed as synchronous CT densitometry. Asynchronous technology is also used with the procedure performed without a phantom that is scanned monthly in a separate way. The first Russian publication on the use of QCT was brought out in the 90s by S.K. Ternovoy and I.S. Vlasova.

QCT is used to measure the volumetric BMD of the vertebral bodies in mg/cm^3 and projection BMD of the femoral neck and the proximal femur as a whole ("the whole femur"). According to the International Society for Clinical Densitometry (ISCD), the T-criterion measured with QCT calculated from the projection BMD of the femoral neck and "whole femur" is equivalent to the corresponding T-score measured with by dual-energy X-ray absorptiometry (DEXA), and can be used to diagnose osteoporosis and initiate treatment according to the criteria of the World Health Organization (WHO). Although the T-score adopted by WHO cannot be used for the lumbar spine with QCT, the antiresoption treatment can be initiated for those at a higher risk of fracture according to ISCD. The American College of Radiologists (ACR) suggested using threshold measurements corresponding to osteoporosis (less than 80 mg/mL) and osteopenia (80-120 mg/mL) to determine volumetric BMD of the spine.

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A method for assessing the 10-year absolute risk of fractures is widely used to initiate treatment in addition to the diagnosis of osteoporosis based on measurement of BMD. This tool is called the "Fracture Risk Assessment Tool, FRAX" (Sheffield, UK). According to the Clinical Recommendations for osteoporosis and the ISCD statement treatment can be initiated initiation with a decrease in BMD measured with densitometry (the T-score being less than -2.5 SD in one of the three regions of central densitometry: spine, femoral neck, proximal femur) and a high risk of fractures seen from the FRAX questionnaire. Since 2013 the hip neck projection BMD index calculated from QCT has also been included in the FRAX fracture risk assessment tool. Diagnosis of osteoporosis is important with increased prevalence of the condition and the economic burden of the complications because of the lack of timely treatment using available methods including opportunistic screening technologies. GBUZ "NPCC DiT DZM" initiated in 2017 a pilot project to assess the effectiveness of the clinical use of asynchronous CT. Due to the presence of different recommended strategies for prescribing treatment, a comparison was made of the distribution of patients by categories: "treat" and "not treat". The Research and Practical Center of Medical Radiology, Department of Health Care of Moscow initiated a pilot project in 2017 to assess the effectiveness of the clinical use of asynchronous QCT. Patients were categorized as "treatment needed" and "no treatment needed" due to the availability of different recommended strategies for treatment prescription.

Objectives included presentation of the results of asynchronous QCT introduced in an outpatient clinic in Moscow as a pilot project, with reference to the risk factors included in the FRAX tool.

MATERIAL AND METHODS

Design

A one-stage, one-center analysis of BMD measured in patients referred for QCT by specialized clinicians employed at the same medical institution was produced. A sampling analysis of the 10-year probability of a major osteoporotic fracture was produced using the FRAX tool with the exclusion criteria of anti-osteoporotic treatment, unreliable data in the questionnaire, artifacts in the images of the proximal femur.

Patient routing

As part of the pilot project, patients were referred for QCT according to indications formulated by the following specialists: general practitioner, endocrinologist, gynecologist, surgeon, oncologist, trauma surgeon and approved by the medical board. Computed tomography was performed with the consent form signed by the patient. A randomly selected group of patients filled out an additional questionnaire compiled according to FRAX risk factors before scanning.

QCT scanning

The QCT scanning included two areas: the lumbar spine and the proximal femur (Fig. 1a) and was produced with the Toshiba Aquilion 64 CT Scanner. BMD was measured using QCT PRO (Mindways Software, Inc., USA): the 3D QCT for the spine and CTXA™ for the proximal femur. The scanning with asynchronous QCT can be produced without a calibration phantom and calibration was performed in a monthly manner as recommended in the manufacturer's operating instructions.

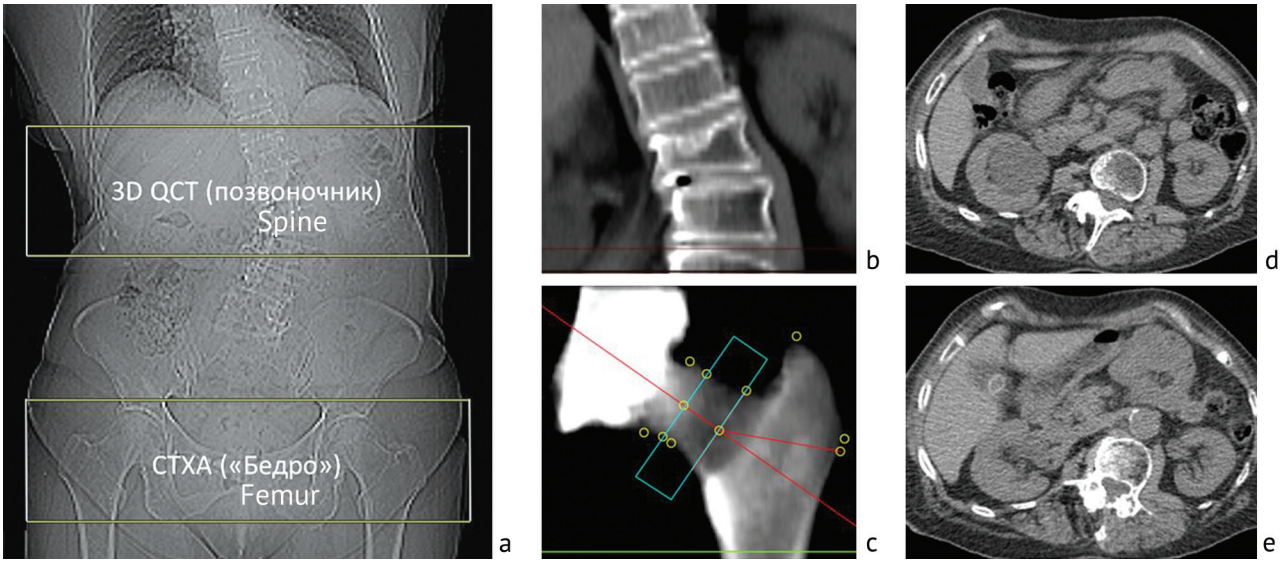

Fig. 1 CT images for QCT scan of a 80-year-old patient K. with concomitant pathologies showing (a) marking of the scanning area; (b) scan of the spine, coronal reconstruction demonstrating severe scoliosis, compression fracture of L1; (c) 3D reconstruction of the proximal femur with marks for measuring the BMD of the femoral neck and "the whole femur"; concomitant pathology of (d) cyst in the sinus of the right kidney and (e) concretions in the gall bladder

CT scanning protocols were used to reduce the radiation exposure for the patients differentiating the size of the scanning field and the current in the X-ray tube to match the patient's body mass index (BMI). The spine of patients with low and medium BMI was scanned with the following parameters: 120 kV; 50 mA; 0.5 s; an average dose of 1.25 mSv; for the hip the current on the tube increased to 70 mA; an average dose of 1.25 mSv. The average total dose per QCT was 2.5 mSv. The spine and hip of patients with increased BMI were scanned with the following parameters: 120 kV; 100 mA; 0.5 s; the mean dose per examination of one area was 2.09 mSv. The mean total dose per QCT ass 4.18 mSv. The size of the scanning field was D-FOV M, L, LL (300, 400, 500 mm). QCT measurements were sent to the URIS (Unified Radiological Information Service) for the audit (about 10 % of the total number, in random order). The audit indicated to The main shortcomings of the QCT seen with the audit included absence of a description of concomitant pathology (15 %), incorrect marking of the scanning area (10 %).

Questionnaire on risk factors for fracture

The questionnaire filled out by the patient included the following information:

– indications for CT;
– availability of the previous densitometric findings;
– the available clinical diagnosis;
– previous fractures in the history;
– hip fractures in parents;
– smoking;
– taking glucocorticoids;
– the presence of rheumatoid arthritis;
– alcohol consumption;
– receiving anti-osteoporotic treatment with medications administered.

The information obtained from the patient questionnaires was used for 10-year risks of major osteoporotic fractures calculated using the FRAX tool. The results did not contain personal data of patients being an addition to informed consent. The FRAX correction was carried out according to the projection BMD for the femoral neck, obtained from the CCT data.

Criteria for analyzing the results

According to the recommendations of WHO and ACR, treatment of osteoporosis can be initiated if at least one of the three areas examined with QCT shows a decrease in BMD below the critical value. The threshold value is 80 mg/cm^3 for volumetric BMD of the vertebra according to ACR recommendations. According to the ISCD the T-criterion can be used for the projection BMD measured in the femoral neck and the "whole femur" with QCT, and treatment can be initiated with the T-score measuring less than -2.5 SKO. According to the Russian FRAX version treatment can be initiated in patients with a high risk of major low-energy fractures. The authors would recommend the use of two options for FRAX intervention thresholds based on the 10-year absolute risk of major osteoporotic fractures: with the possibility of measuring the BMD in the femoral neck and the absence of such a possibility.

Statistical analysis

The McNemar criterion was used to compare patient distributions by groups of "osteoporosis" diagnosed and treatment initiated. The level of statistical significance was set at $p < 0.05$.

RESULTS

The pilot project lasted from August 2017 to August 2018. There were 710 QCT examinations performed for females with the mean age of 67.3 (9.3) years and for 47 males aged 62.7 (11.2) years. The majority of QCT examinations were performed for females and BMD measured in males were not included in the study.

As an example, we present the results of a QCT examination performed for a 80-year-old patient K. with BMI of – 22.5 (Fig. 2) showing severe osteoporosis with the mean volumetric BMD of 17.4 mg/cm^3 in the Th12 and L2 vertebrae and a compression fracture of the body of the L1 vertebra een on the CT scan of the spine.

The clinical instance demonstrates the advantage of CT densitometry as compared with conventional DEXA. Volumetric BMD of the spongy substance (Fig. 2b) can be measured with reference to severe scoliosis and compression fracture of the L1 vertebra that can be adjusted with “QCT PRO” software. Compacted vertebral fragments associated with spondylosis and spondyloarthrosis (Fig. 1b) and often calcified aortic fragments can be excluded from the zone of interest measuring volumetric BMD of the spine with the zone of interest being in the ventral portions of the preserved vertebral bodies. In addition to that, QCT allows visualization of the concomitant organic pathology within the scanning areas showing a large fluid formation in the sinus of the right kidney (Fig. 1d) and gallbladder concretions (Fig. 1e). The patient was referred for sonographic examination.

Risk assessment included in the protocol (Fig. 2a) can be employed to determine the probability of compression vertebral fracture. The case indicates a 100 % risk of osteoporotic fractures with the fracture seen at the L1 vertebra. When performing, The mean T-score measured minus 1.8 COE with DEXA of L1-L4 vertebrae performed after 1 week of QCT examination that indicated to osteopenia. So, osteoporosis was underestimated with DEXA due to severe degenerative vertebral changes (spondylosis, spondyloarthrosis) with increased BMD.

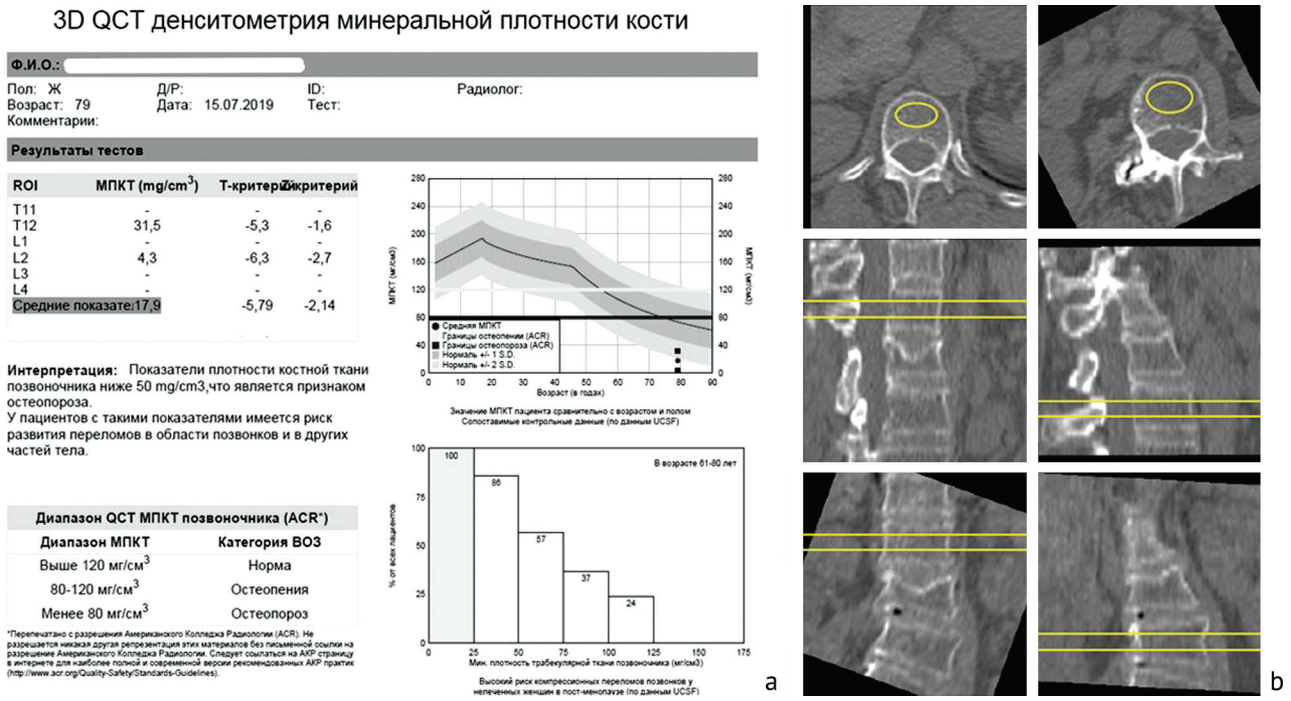

Fig. 2 An instance of a protocol based on the findings of QCT scan of the lumbar spine showing (a) assessment of BMD and comparison with threshold levels of ACR; (b) technical protocol indicating an area of interest

Female patients were distributed according to the results of the QCT study using the WHO criteria for the femoral neck, "whole hip" and ACR for the spine to diagnose "osteoporosis", "osteopenia" (Fig. 3). Osteoporosis was diagnosed in 418 patients (59 % of the total), osteopenia detected in 252 (35 %) and the normal measurements observed in 40 people (6 %) only. The proportion of patients diagnosed with osteoporosis using T-score for the femoral neck had a statistically significant difference with the corresponding distribution of patients with measurements in the spine ($p < 0.001$) and the "whole femur" ($p < 0.001$). BMD measurement analysis was not produced in males due to a paucity of examinations performed.

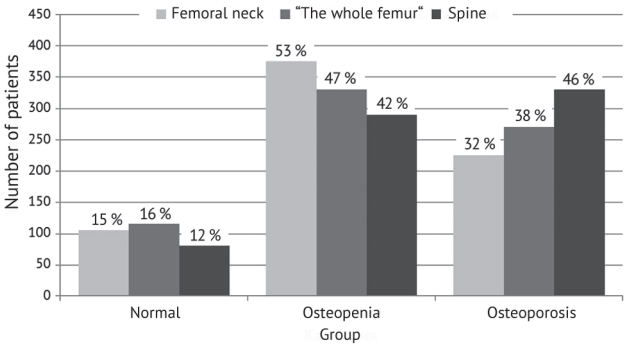

Fig. 3 Distribution of females by groups of osteoporosis/osteopenia/normal for three areas of central densitometry in QCT: femoral neck, proximal femur as the whole, spine

The results of the questionnaire on risk factors for fracture

Questionnaires on FRAX risk factors were completed by a random sample of patients referred for CT. The total of 167 individuals filled out the questionnaire. With questionnaires and QCT findings evaluated 55 people excluded from the study included those who underwent anti-osteoporotic treatment during the study period; who did not fill out the questionnaire; who had unreliable BMD data in the femoral neck. Overall, 112 women were included in the study with the data presented in Table 1.

Table 1

Characteristics of patients included in the study using the FRAX risk factors

Description	Measurement
Total number	167
Excluded (treatment unreliable data)	55
Included in the study	112
Age (mean ± MA)	65.8 ± 8.8
BMI (mean ± MA)	27.4 ± 5.7
Risk factors	**n (%)**
– previous fractures in the history;	16 (14 %)
– hip fractures in parents;	9 (8 %)
– smoking;	16 (14 %)
– taking glucocorticoids;	14 (13 %)
– rheumatoid arthritis;	18 (16 %)
– secondary osteoporosis	10 (9 %)
– alcohol consumption;	1 (1 %)
Additional	
No risk factors	58 (52 %)
More than one risk factor	20 (18 %)

The risks of major osteoporotic fractures were compared by FRAX factors for two cases: with BMD measured in the femoral neck (FRAX + BMD) and with no measurement performed (FRAX). The results of the risk assessment are shown in Figure 4. The upper dotted line indicates the boundary of the high-risk zone when treatment of osteoporosis is to be initiated. An intermediate solid line indicates the threshold for therapeutic intervention (TTI) when BMD cannot be measured. The dotted line at the bottom restricts the area from the above with no recommendations for treatment. The zone between the upper dotted and lower dotted lines determines an interval that necessiates the densitometry.

Comparison of measurements with FRAX and FRAX + MPC (Fig. 4a, b) showed greater fracture risk index in 55 patients that exceeded TTI in 7 patients. On the other hand, the risk of major osteoporotic fractures decreased in 47 patients with BMD introduced and moved below the threshold level in the other 7 patients. It can be concluded that BMD introducted in the FRAX calculator did not significantly change the calculation result and decision-making in 98 patients (88 %).

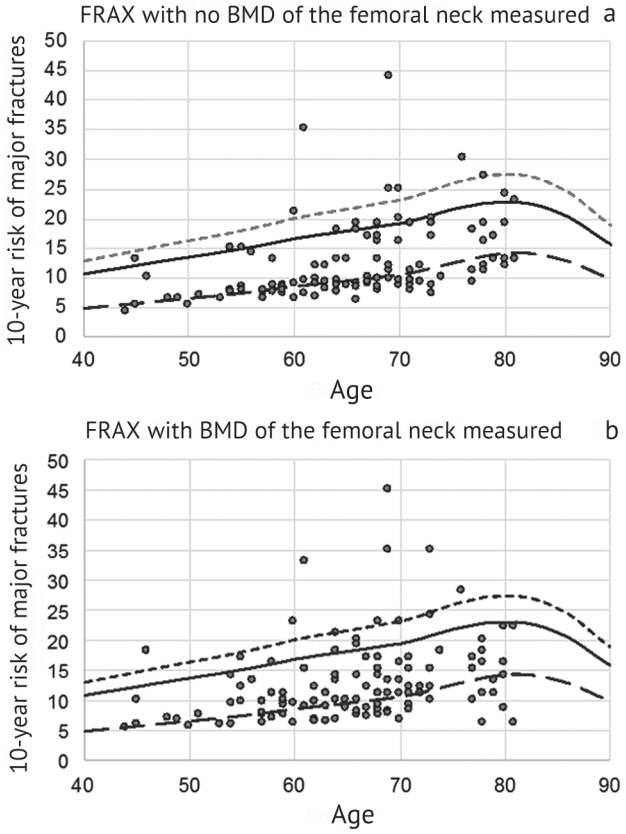

Fig. 4 The threshold of intervention based on the 10-year absolute risk of major osteoporotic fractures: (a) diagram of patient measurements with no BMD of the femoral neck measured; (b) diagram of patient measurements with BMD of the femoral neck measured

A fracture risk exceeding TTI in case of FRAX + BMD in 6 patients the T-score calculated with densitometry was less than -2.5 COE that corresponded to osteoporosis. Six patients with a reduced risk of fracture below TTI after the introduction of the MPC data, the T-score was at the level characteristic of osteopenia. If osteodensitometry cannot be performed a decision can be made with therapeutic intervention according to the diagram to be divided into two zones: treatment needed / no treatment needed (the border is a solid line in Figure 4). Diagram showing FRAX with no BMD of the femoral neck measured (Fig. 4a) demonstrates 15.2 % (n = 17) of patients who needed treatment and 14.3 % (n = 16) with BMD of the femoral neck measured (Fig. 4b), with no statistically significant difference between the groups of patients (p = 0.789).

Assessment of the threshold of intervention with the possibility for osteodensitometry showed 7 (6.3 %) cases who required therapy based on the results of FRAX, and 50 (45 %) to have BMD measured. Assessment of BMD in accordance with the T-score and ACR recommendations showed that treatment was indicated for 27 patients with the total proportion of 30.4 % considering the initial FRAX measurements. That was more than with the treatment indicated according to FRAX measurements only (statistically significant, p = 0.021), since treatment was also necessary for the patients diagnosed with osteoporosis with densitometry. The results with patient distribution depending on the treatment strategy are presented in Figure 5. QCT findings alone excluding FRAX showed the need for therapeutic intervention in 52 patients (46.4 %) which exceeds the data obtained on the DEXA (39.7 %). There was a statistically significant difference in the proportion of patients whose treatment was based on FRAX and those whose treatment was based on CT findings (p < 0.001).

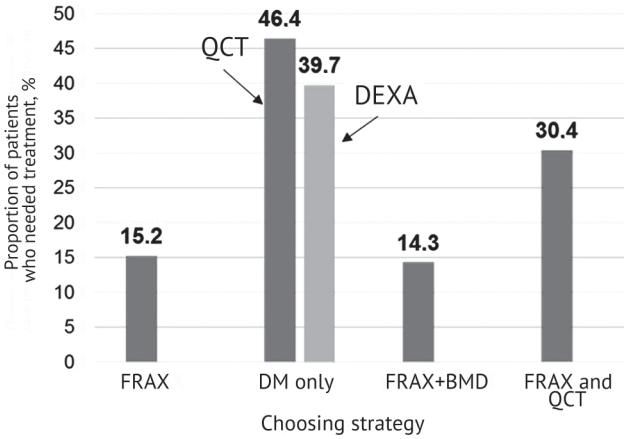

Fig. 5 Diagram showing distribution of patients whose antiresorptive treatment was indicated according to different strategies based on the results of a questionnaire using the FRAX tool

DISCUSSION

Figure 3 demonstrates the majority of patients with osteoporosis diagnosed with vertebral measurements of BMD that is comparable with DEXA measurements. Ivanov N.V. et al. reported osteoporosis can be diagnosed in 47.9 % of women aged 61 to 70 years using vertebral measurements of BMD and in 45.3 % with measurements of BMD in the proximal femur. Epidemiological investigations show the prevalence of osteoporosis and osteopenia diagnosed with DEXA of the lumbar spine and the femoral neck in females over the age of 50 years being 34 and 43 %, respectively. Review of the data in the city of Moscow shows osteoporosis developing in the lumbar spine in 29.8 % and osteopenia in 43.8 %.

Analysis of the distribution of the 10-year risk of major osteoporotic fractures depending on age shows the majority of values being grouped along the lower dotted curve (Fig. 4a). The curve represents the risk of fracture in absence of any risk factors [10]. The exact values of the curve correspond to the normal BMI. With increased BMI the risk of fractures decreases and increases with decreased BMI and the patient finds himself in the area that necessitates densitometry to be performed. The risk of osteoporotic fractures increases in presence of at least one risk factor being dependent on the "weight" of risk factors. The distribution becomes more uniform with BMD of the femoral neck measured with the FRAX tool (Fig. 4a). However, the number of patients who need treatment does not change significantly.

The results of the questionnaire and densitometry were analyzed and a comparison made on the distribution of patients who needed antiresorptive treatment in accordance with different strategies (Fig. 5). There was a significant difference in the proportion of patients who could have therapy based on the results of densitometry compared with FRAX. Previous studies compared the results of predicting the risk of major low-energy fractures using the FRAX together with BMD (FRAX + BMD) and FRAX alone. There were no significant differences in the number of patients whose treatment was based on FRAX + BMD and FRAX that corresponded to the results obtained in the work performed. In the Korean FRAX version, there was no significant difference in identification of the high risk of major osteoporotic fractures in both cases: FRAX (58 %) and FRAX + BMD (63 %). From patients who were diagnosed with osteoporosis according to DEXA using national standards, 74.6 % had a high risk of fractures according to FRAX + BMD and 62.4 % according to FRAX. A significant difference in the risk of fracture reported in the above study and our series can be ascribed to the fact that the authors included only patients with confirmed osteoporotic fractures in the study and the mean age of the subjects was 72.4 ± 6.9 years. The above foreign studies demonstrate comparable values for detecting a high risk of fractures in patients according to FRAX and FRAX + BMD, and the measurements reported are higher than those in our series. This may be due to different selection strategy with the pilot project when patients with different history were referred for QCT. There were more patients who initiated treatment based on QCT than on FRAX. The use of the FRAX questionnaire followed by densitometry has been shown to optimize the number of patients referred for treatment according to our data and clinical recommendations for osteoporosis. BMD measured in patients with an average risk of osteoporotic fractures according to FRAX helps to differentiate the decision on the treatment.

The most adequate decision-making is reported to rely on FRAX and densitometry. Densitometric examination is difficult to provide for all patients at risk in the city of Moscow due to the limited number of CT scanners and available QCT programs. However, the asynchronous QCT technique is practical for BMD measurements when CT is produced for other diagnostic purposes [7, 11, 20], i.e. through opportunistic screening and constitutes about 20 % of all CT scans performed. ERIS reported around 113 thousand examinations be performed for women over 60 years old in outpatient clinics of the Department of Health of the City of Moscow during 3 years. The figure is higher than that with DEXA examinations (93 thousand performed in 2018) that may contribute to a more thorough bone examination of the patients. BMD measured with QCT and included in the FRAX tool can be used for a concept Passport of bone health of patients at risk of osteoporotic fractures.

The main limitations of the study was the fact that the program for asynchronous CT densitometry was installed only on one model of CT scanner that is the common use in medical institutions of the city of Moscow. The survey of patients on risks of low-energy fractures was performed for a limited group of patients due to the lack of time for doctors to monitor the completion of the questionnaire by patients. The size of the sample was not enough to perform statistical analysis but a descriptive comparison made including previous publications. There was no comparison made with

dual-energy X-ray absorptiometry, the standard method of diagnosing osteoporosis. The study was scheduled and conducted, and the findings will be reviewed in a separate publication.

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The article was submitted 29.05.2020; approved after reviewing 25.09.2020; accepted for publication 25.09.2020.

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