Original Article

The study protocol for the China Health Big Data (China Biobank) project

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Background: Osteoporosis, obesity, and fatty liver are increasingly common chronic diseases that seriously threaten people's health. Low-dose chest computed tomography (LDCT) scan is frequently used for lung cancer screening in health screenings and checkups. Quantitative computed tomography (QCT) enables the accurate measurement of volumetric bone mineral density (vBMD), liver fat content, and abdominal fat area using the existing LDCT data without extra radiation. We initiated a new project, the China Health Big Data (China Biobank) , which combines the LDCT scan images from lung cancer screening of participants in health checkup with QCT to investigate the added value of QCT to LDCT, in order to establish the normative reference database and diagnosis criteria for the three aforementioned conditions.

Methods: The China Biobank project is a prospective nationwide multicenter cohort study that will combine QCT technology with LDCT scans to measure bone mineral density (BMD), intra-abdominal fat distribution, and liver fat content of the generally healthy checkup participants. Mindways QCT calibration phantom (Mindways Software Inc., Austin, TX, USA) and analysis software QCT PRO v6.0 will be used for all centers. Before data collection begins, the European Spine Phantom (ESP) will be used for quality control analysis at each collaborating center. The inclusion criteria are a healthy checkup participant aged 30–90 years, with LDCT as a part of his/her health checkup protocol. Exclusion criteria are pregnant women or participants with a metal implant in the CT scan area. The LDCT images will be transferred to the Mindways workstation for analysis, and vBMD in the L1 and L2 vertebrae, visceral adipose tissue (VAT), subcutaneous adipose tissue (SAT), and liver fat content will be measured. As part of the health checkup, the demographic, anthropometric parameters, blood pressure, and a routine blood laboratory test will be collected. The estimated sample size will be about 30,000.

Results: The combination of QCT with LDCT of the chest is validated in this project. The vBMD of spine, visceral fat and liver fat can be measured with a LDCT chest scan.

Conclusions: The China Biobank project will assess the added value of QCT to LDCT, and enable accurate evaluation of the prevalence of osteoporosis, obesity, and fatty liver disease in a very large Chinese cohort.

Keywords: Osteoporosis; quantitative computed tomography (QCT); bone mineral density (BMD); liver fat content; soft tissue composition; visceral adipose tissue (VAT); subcutaneous adipose tissue (SAT)

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Introduction

With the improvement in living standards across China, the aging population, a more sedentary lifestyle, and the increased consumption of sugar and fat, obesity is becoming more common. The consequent health problems involve issues with multiple human organs and tissues, and osteoporosis, obesity, and non-alcoholic fatty liver disease (NAFLD) are now major public health concerns in China (1-4). Obesity is the cause of several serious diseases, and its diagnosis should be based on accurate measurements of the actual fat content in the human body, especially the excessive accumulation of abdominal visceral adipose tissue (VAT), which can lead to problems with lipid metabolism, hypertension, and blood glucose while accelerating the development of diabetes along with cardiovascular and cerebrovascular diseases (5). Similarly, NAFLD is an important cause of chronic liver disease that presents a significant economic burden on society (6).

The elderly population is a group with a high incidence of osteoporosis and its associated fragility fractures. Measurements of bone mineral density (BMD) play an important role in the diagnosis and prevention of osteoporosis, and there is an increasing appreciation of the value of measuring BMD using a quantitative computed tomography (QCT) (7-10). In the study of obesity, there is an increasing number of reports about the relationship between abdominal obesity and BMD. VAT is significantly negatively correlated with BMD, while measurements of subcutaneous adipose tissue (SAT) content are uncorrelated (11-13). QCT scans can also be used to make accurate measurements of liver fat. Therefore, there is now a focus on how to accurately monitor osteoporosis, obesity, and NAFLD in the general population. As a non-invasive three-dimensional (3D) imaging method, QCT has an important role to play in accurately measuring BMD, VAT, and liver fat content.

QCT provides a precise and accurate method of measuring BMD based on conventional computed tomography (CT) scanning using a calibration phantom and relevant scan analysis software that is now widely used in clinic (7,8,10,12-15). The associated lateral CT scout scans can also be used to identify and grade vertebral fractures, and hence find individuals with a history of fragility fracture. With the improvements in CT technology, advanced image reconstruction algorithms have now made extremely low-dose clinical applications possible, and the combination of low-dose scanning with QCT technology is an area undergoing continuous development (16-19). The application of low-dose chest CT (LDCT) in screening for early lung cancer has been widely recognized and applied (20), and has increased the detection rate of pulmonary nodules with diameter <10 mm (21). Without any increase in radiation dose, LDCT scan images can be combined with QCT technology to measure BMD in the L1 and L2 vertebrae, and also to accurately measure VAT and liver fat content at the mid-plain of the L2 using recently developed scan analysis applications (17,21).

Recently, we initiated a large scale nationwide multicenter study, the China Health Big Data (China Biobank) project, to use health checkup LDCT images acquired for lung cancer screening to measure the BMD, visceral fat, and liver fat content (Supplement I). The aim of the project is to establish a normal reference database of spine BMD, visceral fat, and liver fat content for the Chinese population, in order to further establish the QCT criteria for diagnosing osteoporosis, obesity, and NAFLD.

Methods

Study design

The China Biobank project is a prospective nationwide multicenter cohort study. The study has been approved by the ethics committees of our respective institutions and written informed consent will be obtained by the study participants. Trial registration: this program has been registered with the US clinical trials database (clinicaltrials.gov) (trial identifier: NCT03699228).

Setting

Each center is qualified to conduct medical examinations and is a licensed institution for CT diagnosis and treatment, equipped with at least a 16-slice CT scanner along with software for performing QCT (Mindways Software Inc., Austin, TX, USA). The clinical center in each collaborating hospital is certified by the Ministry of Health and guarantees that a certain number of LDCT scans are performed daily. Each center also has a hospital information system (HIS) that enables data export and sharing. The recruitment of the participating center is open and ongoing; currently, there are 16 centers that have been recruited.

Participants

The participants will be subjects >30 years old who have a LDCT scanning for lung cancer screening as part of his/

her health checkup procedure. In China, the annual health checkup is benefit to each employee, and currently, the LDCT is only available for employees over 40 years old or senior employees. Usually, this selection depends on the age, without consideration for smoking or risk factors for lung cancer, and of course, the employee can choose not to undergo LDCT. The LDCT can also be selected with medical insurance coverage. For the younger subjects, radiation is more of a concern, extra caution is placed for a young person who wants to have a LDCT. Moreover, the rural residents and low-income population will be less represented in this project.

The current study will not intervene with a selection of LDCT of the subjects; this study only involves the added value of post-processing of existing LDCT raw data for BMD and fat measurement and for the screening of osteoporosis or obesity.

Inclusion/exclusion criteria

All existing LDCT raw data of the health check-up subjects will be included for further QCT analysis for BMD and fat measurement. The exclusion criteria for LCDT data are the following: (I) from subjects younger than 30 years old; (II) from subjects with metal implants within the upper abdominal scan area.

Sample size estimation

LDCT screening for lung cancer is a frequently performed examination in China. This project will continue for 2 years in the 16 collaborating centers (Supplement I), and the total sample size is anticipated to reach about 50,000 participants. The establishment of such a large data sample will aid future research and follow-up.

Conduct of the project

This project only involves the post-imaging process of existing LDCT image data for adding value for BMD and fat measurement, and thus, no extra radiation is involved. The primary goal is to investigate the normal BMD reference and the prevalence of osteoporosis across China with QCT. The secondary goal is to investigate the normal reference of visceral fat and liver fat in the Chinese population and its association with body mass index (BMI). Potential subjects meeting the above criteria who give written informed consent will receive a routine health check-up procedure and a brief introduction to the project. Healthy subjects who consent to participate and meet the required inclusion and exclusion criteria will be enrolled for anthropometric and clinical assessments, blood analysis, and QCT analysis of their LDCT images (*Table 1*). Smoking and alcohol use are collected in some, but not all centers. As explained earlier, in this health checkup procedure, the selection of an LDCT depends mostly on age, not on smoking status; even though the history of smoking is collected in some centers, therefore the smoker or alcohol user is not over sampled in this project.

Blood sampling and methods of analysis

The blood sampling and laboratory analysis are parts of the health checkup procedure, and this project will only retrieve these results for further analysis. Venous blood samples will be taken by a registered staff nurse between 7.30 and 9.30 am and will be sent for laboratory analysis within 30 minutes. Participants will be asked to fast for at least 8 hours overnight before venipuncture. All tests and analyses will be conducted in a certified clinical examination center at each of the collaborating medical centers.

Anthropometry and blood pressure measurement

Weight (kg) and height (m) will be measured using calibrated digital weighing scales and stadiometers. BMI will be calculated from the following formula: weight (kg)/height^2 (m^2). Abdominal circumference (an optional item) will be measured using a measurement tape at the level of the belly button.

Chest CT scanning and QCT quality control analysis

QCT measurements will be made from existing chest CT scan image data. Image reconstruction with a range from the diaphragm roof to the lower edge of the L2 is based on a standard Fourier back projection algorithm. The operators are all qualified technologists, with strict adherence to the relevant radiation protection requirements. Before commencement of any data collection, the European Spine Phantom (ESP No. 145) will be used for quality control analysis at each collaborating center based on 10 repeated scans acquired following a prescribed QCT scanning protocol. The collaborating centers will archive the reconstructed images in DICOM and QCT formats.

Table 1 The main parameters to be collected in this project

Parameters	Units
QCT	
vBMD of spine	mg/cm^3
Visceral fat area (VAT) at L2	cm^2
Subcutaneous fat area (SAT) at L2	cm^2
Total fat area (TAT) at L2	cm^2
Liver fat content	%
Demographic	
Age	year
Sex	M or F
Anthropometry	
Height	cm
Weight	kg
BMI	
Smoking (yes, no, or quit)	–
Alcohol use (yes, no, or quit)	–
Blood pressure	
Systolic pressure	mmHg
Diastolic pressure	mmHg
Blood lab	
Common	
Platelet count	10^9/L
Hemoglobin	g/L
Albumin	g/L
Triglycerides	mmol/L
Mean corpuscular hemoglobin	pg
Alkaline phosphatase	IU/L
High-density lipoprotein cholesterol	mmol/L
Low-density lipoprotein cholesterol	mmol/L
Glucose	mmol/L
Cholesterol	mmol/L
Optional	
Serum calcium	mmol/L
Phosphate	mmol/L
Parathyroid hormone	ng/L
Thyroid-stimulating hormone	mU/L
Free triiodothyronine	pmol/L
Free thyroxine	pmol/L

QCT, quantitative computed tomography; vBMD, volumetric bone mineral density

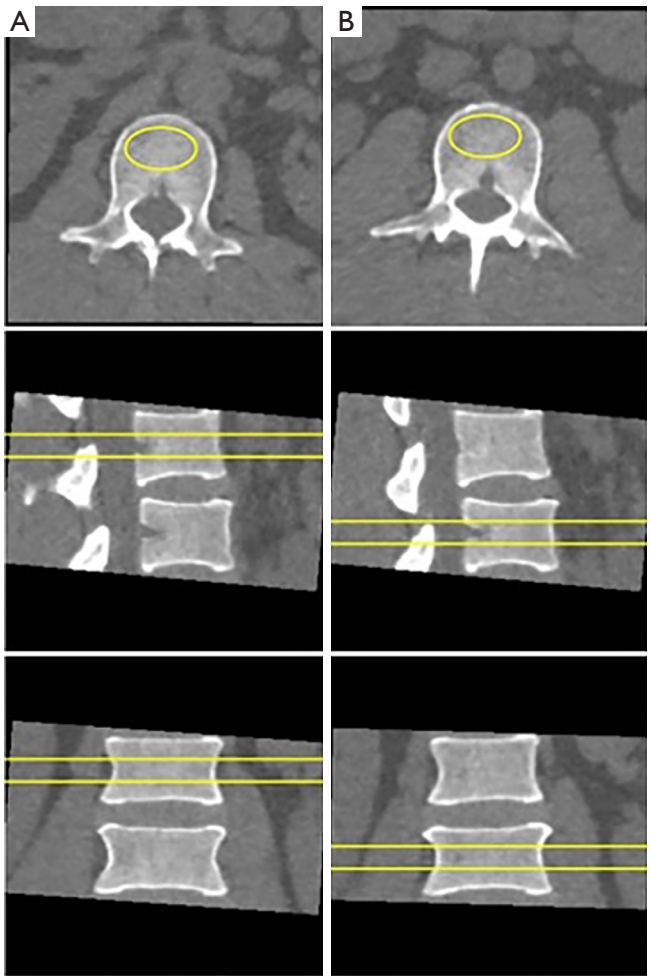

Figure 1 QCT measurement of L1 (A) and L2 (B) lumbar spine BMD. The dual-yellow lines indicate the location and upper and lower range of interest (region of interest, ROI), the yellow oval ROIs show the measurement range of vertebral, and the BMD unit is mg/cm3. QCT, quantitative computed tomography; BMD, bone mineral density.

Data analysis

QCT analysis will be performed by professionally trained medical personnel with the relevant qualifications.

BMD measurement procedure

(i) The reconstructed CT images will transferred to the QCT workstation and the subject's information will be verified; (ii) the L1 and L2 vertebrae will be identified (*Figure 1*), scan analysis will be performed according to the Mindways QCT-PRO operator's manual, and the results

will be transferred to the database; (iii) if the L1 or L2 vertebrae are found to be fractured or have other lesions on the CT images, the BMD measurements will be omitted and a note made in the database.

Measurement of abdominal fat

(i) Measurement of VAT will be conducted using the Supplementary Tissue Measurements application of the Mindways QCT-PRO v6.0 spine module software; (ii) the mid-slice of the L2 vertebra will be selected and measured according to the QCT-PRO operator's manual, and the total abdominal fat and the VAT measurements will be obtained; (iii) SAT at the same level will be obtained by subtracting VAT from the total abdominal fat (*Figure 2*), and the results will be transferred to the database; (iv) if it is found that CT images cannot be used to measure abdominal fat, this will be noted in the database.

The QCT-PRO scan analysis software uses the threshold segmentation method to mark the total abdominal fat in the scan plane in blue (*Figure 2*). By automatically outlining the outer edge of the abdominal wall muscle (the green closed curve in *Figure 2*), the total fat is divided into the visceral fat area (the fat area within the green closed curve) and the subcutaneous fat area (the fat area outside the green curve). Both measurements are in units of cm^2.

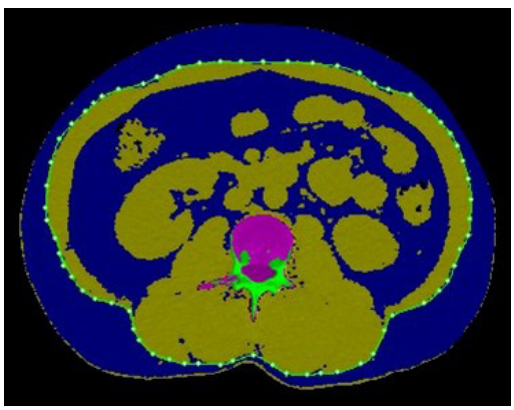

Figure 2 Measurement of abdominal fat by Mindways QCT software. The blue color represents the fat, and the yellow dashed line depicts the abdominal wall. The fat inside this wall is visceral fat (VAT), while the fat outside the wall is subcutaneous fat (SAT). Total fat area (TAT) = VAT + SAT. QCT, quantitative computed tomography.

Measurement of liver fat content

QCT quantification of liver fat content will be performed using the Supplementary Tissue Measurements application of the Mindways QCT-PRO v6.0 spine module scan analysis software as described by Cheng *et al.* (22). The slice where the right branch of the portal vein enters the liver will be chosen for the measurement. Three circular regions of interest (ROI) each with a cross-sectional area 300 mm^2 (deviation <10 mm^2) will be placed in the left lobe and the anterior and posterior segments of the right lobe respectively (*Figure 3*). The ROIs will be placed in the subcapsular region of the liver, avoiding the bile duct and blood vessels. If the left lobe of the liver is too small to be visible in this slice, the slice in which the left lobe had the largest area will be used for the measurement.

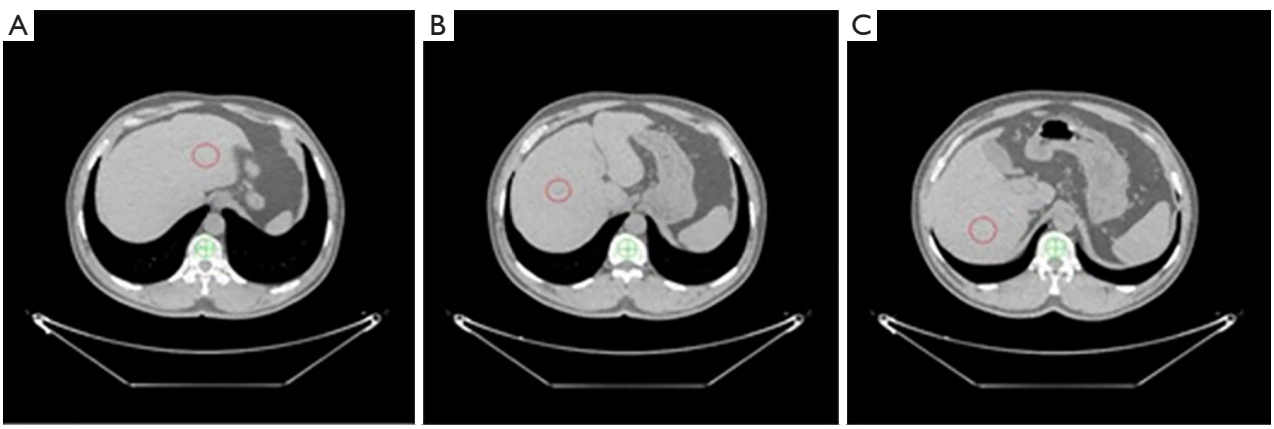

Figure 3 Measurement of liver fat content by QCT using Mindways liver fat module. The slice in the middle of the L2 is chosen, 3 region of interests (ROIs) (shown in red circle) are measured, with one in the left robe of the liver (A) and two in the right lobe (B,C). The liver fat content in % is shown and saved in the database. The average of 3 ROIs is the value for this subject. QCT, quantitative computed tomography.

(IV) Data collection of physical examination population

The basic health information of the physical examination population will be retrieved from the HIS system of each collaborating center, including the name, gender, age, height, weight, abdominal circumference, blood pressure, blood routine, and blood biochemical examination results.

Discussion

Bone density measurement is the internationally accepted basis for the diagnosis of osteoporosis. In the clinic, there are two widely adopted methods, dual-energy X-ray absorptiometry (DXA) and QCT. While DXA is a two-dimensional (2D) projection scan that measures areal BMD, QCT provides a true 3D BMD measurement, and, compared with DXA, is less affected by severe degeneration of the spine, vascular calcification, oral contrast agent, and body position. Therefore, QCT is receiving wider recognition as the more accurate method for the quantitative evaluation of osteoporosis.

The International Society for Clinical Densitometry (ISCD) and American College of Radiology (ACR) has the following recommendations for the diagnosis of osteoporosis using QCT: osteoporosis, BMD <80 mg/cm^3); osteopenia, BMD 80–120 mg/cm^3; and normal, BMD >120 mg/cm^3) (23,24). In the present protocol, we will measure the 1st and 2nd lumbar vertebrae, select the mid-plain of each vertebra, calculate the BMD, and take the average of the two vertebrae.

The excess visceral fat area can lead to disorders of lipid metabolism, hypertension, or blood glucose, and accelerate the development of cardiovascular and cerebrovascular diseases (6,25). Currently, the CT diagnostic criteria adopted in Japan for the diagnosis of intra-abdominal obesity is a visceral fat area at the level of the belly button >100 cm^2 (26,27), while at present there is a lack of a unified diagnostic standard in China. In previous studies, the level of the belly button or the level of the L4 and L5 vertebrae were measured, and several new studies have shown that measurements at the level of the L2 and L3 are better correlated with the total fat area (28). There is presently no unified standard for the measurement of VAT at the level of the L2 vertebra, and this project aims to establish a reference standard for the diagnosis of intra-abdominal obesity in China.

There are a few limitations for this project. First, this project only includes the health check-up population with LDCT available; this project thus does not represent the general population of China; the rural residents/farmers and low-income populations, for instance, will be under-represented. Secondly, LDCT with health checkups is common in most parts of China, but less common in north-west China, which will, therefore, be less sampled.

In summary, the aim of this project is to combine QCT technology with LDCT to measure the BMD, VAT, and liver fat content in a large Chinese checkup cohort for the purpose of investigating the added value of QCT to existing LDCT data for health management. This will provide the normative reference database of spinal BMD, visceral fat area, and liver fat content, establish diagnosis criteria and survey the prevalence of osteoporosis, obesity, and steatosis.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The study has been approved by the ethics committees of our respective institutions and written informed consent will be obtained by the study participants.

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Supplement I

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