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Radiation hygiene in X-ray imaging to estimate body composition (in particular bone densitometry) by means of dual X-ray absorptiometry (DXA)

Statement by the German Commission on Radiological Protection

Adopted at the 274th meeting of the German Commission on Radiological Protection on 19/20 February 2015

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Strahlenhygienische Aspekte bei Röntgenuntersuchungen zur Bestimmung der Körperzusammensetzung (insbesondere Knochendichtemessungen) mittels Dual X-ray Absorptiometry (DXA)

Stellungnahme der Strahlenschutzkommission

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1 Introduction

Dual X-ray absorptiometry (DXA) is an X-ray method that uses radiation absorption to analyze tissue composition. It is primarily used to estimate bone density in presence of metabolic bone diseases such as osteoporosis and primary hyperparathyroidism. Apart from these medical indications, DXA is also increasingly used in lifestyle diagnostics, e. g. as a means of proving a reduction in abdominal body fat levels while cutting weight or for monitoring muscle gain achieved by sports or bodybuilding. Manufacturers and radiological practices both advertise this as a "motivational aid", which in Germany is often offered as an "individual health service" (*IGEL-Leistung*). Such individual health services are not covered by German statutory health insurance companies. Accordingly they are not budgeted for and the patient/customer is personally liable to pay the incurred fees.

DXA can possibly lead to exposures from unjustified X-ray imaging, which is why the advisory mandate issued by the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) on 31 July 2012 called upon the SSK to scrutinise the benefits of DXA from a radiation protection perspective and to issue a statement as to whether and under which circumstances an indication for the use of DXA can be considered justified.

2 Methodological aspects

2.1 Procedure

2.1.1 Dual X-ray absorptiometry (DXA)

Dual X-ray absorptiometry (DXA) involves two X-ray beams with different spectral energy levels that are used to measure the extent to which the beams pass through the human body. To simplify matters, it is assumed that the body consists of both bones and soft tissue. The two X-ray beams are generated either by means of K-edge filters or by changing the X-ray tube voltage. DXA uses mean mass attenuation coefficients of bone and soft tissue to measure the bone mineral density (BMD) or bone mineral content (BMC) projected onto a surface. DXA scans of the lumbar spine and femur in PA projection are standard clinical practice. A DXA scan generally results in a numerical value. Additionally, these scanners can also provide images albeit at a lower quality than conventional diagnostic X-ray scanners.

2.1.2 Vertebral fracture assessment (VFA)

Vertebral fracture analysis (VFA) is a technical add-on to DXA that generates X-ray images which can be used, e. g. to depict bone deformations. It complements DXA by providing additional diagnostic information, but there is no separate indication for it as a stand-alone procedure. The diagnostic quality of VFA is not comparable to conventional radiography, however, it does allow to screen for fractures which may have occurred in the meantime. Morphometric X-ray absorptiometry (MXA) can be used to additionally take measurements for quantifying the vertebral body shape.

2.1.3 Quantitative computed tomography (QCT)

Quantitative computed tomography (QCT) is an imaging procedure used to obtain local information about the three-dimensional structure of the cortical and trabecular bone, e. g. density, geometric distribution and mechanical parameters such as bone deflection stability. In contrast to conventional CT scans, QCT uses a phantom to calibrate the CT Hounsfield units

according to tissue-equivalent densities. QCT scans of a single lumbar vertebra are standard clinical practice.

Peripheral QCT (pQCT) is a special type of QCT where CT scans are performed on extremities (mainly the radius and tibia).

High-resolution QCT (HR-QCT) can provide information about the microarchitecture of the bone in addition to bone density.

2.2 Radiation exposure

The dose applied to patients when using X-rays to estimate body composition is low compared to other kinds of X-ray imaging, albeit highly dependent on the selected procedure (pQCT, DXA, VFA, QCT, HR-QCT). There is also a broad range in terms of the applied dose within a given procedure (cf. Table 1). The dose generally depends on the irradiated part of the body, the direction of projection, the scanner used, the acquisition parameters and the use of dose-saving techniques and image processing software.

Table 1: Magnitude and range of effective patient doses based on the procedure used

Procedure	Magnitude and range of applied effective dose [µSv]
DXA*	
Lumbar vertebrae 1-4 (adult)	0.2 - 2.5**
Hip	1.5 - 10*
Full body	1 - 10*
VFA	2 - 40***
QCT (including HR-QCT)	100 - 3,000
pQCT (including peripheral HR-QCT)	< 0.1 - approx. 10****
Conventional X-ray	10 - 2,500*****
e. g. thoracic spine (two levels)	200 - 800
e. g. lumbar spine (two levels)	600 - 1,400

* Doses as per Blake et al. 2006, 2013, Damilakis et al. 2010, CRCPD 2006, Njeh et al. 1999
** With older scanners, exposures of up to 70 µSv may occur.
*** Doses, e. g. from Lewiecki and Laster 2006
**** Doses as per Burrows et al. 2010; Engelke et al. 2008, 2009; Braun et al. 1998
***** Doses as per K. Engelke Lektion Strahlenschutz DVO Grundkurs II (Part II of the DVO's basic radiation protection course)

If the scanner parameters and field size are not adapted to the patient's stature (size and weight), this may cause a dose three times higher during paediatric imaging (Damilakis et al. 2013, Thomas et al. 2005, van Rijn et al. 2003). During QCT and pQCT scans, the dose will be in the upper range when HR-QCT settings are used. Depending on the procedure used, organ doses may be several times higher than the effective dose.

With DXA scans, exposure of medical staff depends on the scanner used, their distance from the scanner during imaging, the acquisition parameters and the radiation protection measures taken. The length of time medical staff spend in the examination room during use plays a major part in individual exposure. The primary beam is scattered by the patient, which makes them the main source of radiation for medical staff. At a distance of one metre from the patient, environmental dose equivalents of between 0.012 µSv/h and 5 µSv/h have been measured (Patel et al. 1996, Sheahan et al. 2005, Larkin et al. 2008, Guglielmi et al. 2014).

3 Areas of application and indications

3.1 Bone densitometry in osteology

The use of bone densitometry is indicated in clinical practice, both for the diagnosis of osteoporosis and follow-up. Indication is primarily based on the guidelines issued by the German Osteology Society (*Dachverband der Osteologie* – DVO). Bone densitometry can be used to diagnose osteoporosis and other bone metabolism disorders (primarily hyperparathyroidism, Paget's disease of bone, osteomalacia) with the aim of assessing the overall clinical picture and of setting up a treatment plan.

3.1.1 Indication for using bone densitometry to provide a diagnosis

Below is a summary of the main indications for using bone densitometry to support a diagnosis. Among others, the DVO's guidelines on diagnosing osteoporosis recommend using DXA to measure bone density of the lumbar spine (mean of lumbar vertebrae 1 to 4 of at least two assessable vertebrae) and the entire femur (individual measurement or mean of left and right femur) (cf. DVO Guideline 2009, 2014 for Prevention, Diagnosis and Therapy of Osteoporosis).

Subjecting asymptomatic persons to DXA assumes that according to risk estimates involving recognised models the fracture probability will be over 20% for the next ten years. DXA is permitted within the scope of statutory health care in Germany "...to optimise therapeutic decision-making if, due to a specific medical history and clinical findings such as a clinically manifest vertebral or hip fracture without adequate trauma, there is an intention to treat an osteoporosis using a specific form of medication" (BMG 2013, cf. SSK 2012).

Age is one of the main and non-modifiable risk factors, while living habits (diet, movement, stimulants) constitute modifiable risk factors. Comorbidities and concomitant medication may influence bone metabolism and increase the risk of fracture.

Table 2 summarises the main components of a medical history that influence the risk of fracture. The form in which these risk factors include indication for DXA can be found in the DVO's Guideline (cf. DVO Guideline 2009, 2014 for Prevention, Diagnosis and Therapy of Osteoporosis).

Table 2: Risk factors for bone fractures as a basis for indication for using DXA

Medical history with enhanced risk of fracture

- Age
  - Women ≥ 70 years
  - Men ≥ 80 years
- Previous fractures
  - Vertebral fractures without trauma
  - Non-vertebral fractures above the age of 50
- Familial disposition
  - Proximal femoral fracture in one of the parents
- Multiple falls
  - > 1 fall in the past year
- Immobility
  - No longer able to leave dwelling independently
  - Walking distance < 100 m
- Underweight
  - BMI < 20
- Noteworthy alcohol or nicotine consumption

Medication causing increased risk of fracture/osteoporosis

- Oral glucocorticoids ≥ 3 months
- Aromatase inhibitors
- Anti-androgen therapy in men
- Diabetes therapy with glitazones in women
- Fall-risk increasing drugs
  - Sedatives
  - Antidepressants
  - Medication for orthostatic hypotension

Illnesses associated with an increased risk of fracture/osteoporosis (secondary osteoporosis)

- Endocrine disorders
  - Primary hyperparathyroidism
  - Hyperthyroidism, subclinical hyperthyroidism (TSH < 0.3)
  - Cushing's syndrome
  - Diabetes mellitus type 1
  - Diabetes mellitus type 2
  - Hypogonadism
- Haematologic disorders
  - Multiple myeloma, monoclonal gammopathy of undetermined significance
  - Mastocytosis
- Gastrointestinal disorders
  - Billroth’s operation II or gastrectomy in the past
  - Inflammatory bowel disease
  - Lactose intolerance
  - Primary biliary cirrhosis
  - Bariatric surgery in the past
- Other illnesses
  - Organ transplantation in the past
  - Epilepsy
  - Chronic renal disease
  - Rheumatoid arthritis
  - Ankylosing spondylitis
  - Cardiac insufficiency
  - Chronic obstructive pulmonary disease

Together with the result of bone densitometry, clinical risk factors such as age, comorbidities, concomitant medication and the risk of falling are used for estimating the overall fracture risk and for deciding upon a possible bone-specific therapy.

According to guidelines, the DXA procedure is recommended for diagnosing osteoporosis. There is no recommendation for QCT since it lacks sufficient evidence to justify its use, and because its radiation dose is higher than that used in DXA (Blake et al. 2013). Studies are still being conducted to evaluate peripheral QCT (pQCT), which is why also here no sufficient evidence is available (Braun et al. 1998, Burrows et al. 2010, Engelke et al. 2008).

Whenever a vertebral fracture is suspected, VFA obtained together with a DXA scan is a useful instrument, since it can specifically prove vertebral deformities at their most common locations and, using a comparably low dose, support the decision whether or not to perform further imaging studies (Gowin et al. 1997). The device must be approved for such use according to the German Medical Devices Act, though (*Medizinproduktegesetz* - MPG).

3.1.2 Indication for using bone densitometry during follow-up

Follow-up for Osteoporosis:

Follow-up for risk of osteoporosis should be indicated depending on patients' individual risk profiles. For those who are not receiving medication, an interval of one to two years is considered sufficient to assess the risk of fracture and support possible decisions to change the course of treatment. With an initial T-Score >-1SD, measurement intervals of >5 years are generally deemed sufficient (DVO Guideline 2014). Within the scope of statutory health care in Germany, bone densitometry "may be repeated 5 years later at the earliest...to optimise therapeutic decision-making...unless bone densitometry is required sooner due to a specific medical history and clinical findings" (BMG 2013, cf. SSK 2012).

The coefficient of variation for the lumbar spine measurement and for the (entire) femur is around 1 to 1.5%. To adequately detect changes over the follow-up period, these must be at least as large as the least significant change (LSC), which is defined as being 2.8 times the coefficient of variation (Bonnick et al. 2001, Glüer 1999). This implies that a change in bone density during the follow-up period will have to be at least 3 to 4.5% to be clinically relevant. As a result, the monitoring interval has to be long enough, i.e., around two years. Shorter follow-up intervals only make sense in special risk situations when rapid bone mass changes are expected (e. g. high-dose glucocorticoid therapy). Whenever possible, the same DXA scanner should be used for follow-up.

For patients receiving bone-specific medication, the benefits of routine bone densitometry have not been proven . Only roughly do changes in bone density permit conclusions regarding the response to medication: If there is an increase in bone density during antiresorptive therapy this does not indicate that it will reduce the risk of fracturs. There should, however, be no significant loss in bone density (>4% per year), especially not over a follow-up period spanning several years. Along with other parameters, a change in bone density is in routine clinical practice nonetheless an important criterion for assessing the course of the illness throughout medication, and a two years interval is generally sufficient. The *clinical* course is always crucial in this regard. In any case of a progression of the illness, i.e. occurrence of new fractures, the condition should be entirely re-evaluated immediately including bone densitometry, even if two years have not elapsed. In case of a decrease in bone density and/or several new fractures despite bone-specific therapy, a change in the regime should be considered, depending on the overall risk of fracture. In this context, a DXA may be supplemented with a VFA to decide upon additional imaging studies.

Follow-up for other metabolic bone diseases or illnesses with risk secondary of osteoporosis:

Depending on the disease severity and the treatment (conservative vs. surgical), the follow-up interval for patients with primary hyperparathyroidism should be less than two years due to possible therapeutic consequences (operative therapy or additional medication recommendation) (Leidig-Bruckner et al. 2012).

3.2 Measuring body composition under medical aspects

In contrast to DXA used in osteology, several parts of the body (e. g. arms, legs, torso, head) are scanned in order to estimate a person's proportion of fat or muscle. These are calculated separately to obtain the percentage of body fat, based on the fact that mineral, fat, and muscle tissue will absorb differing quantities of the two X-ray beams with their different spectra. These scans can be performed for individual parts of or for the entire body using corresponding phantom measurements as a reference. For technical reasons, there is currently a body weight limit of 140 kg.

Body composition measurements have been used as surrogate parameters for clinical end points, e. g. for growth hormone studies or for determining body composition among paediatric or HIV patients during clinical studies (Scherzer et al. 2008, Bauer et al. 2012). It is currently unclear, however, whether and to what extent such scans have any impact on clinical decisions. The same is true for DXA scans accompanying bariatric surgery for morbid obesity (adipositas permagna) whenever they are not related to osteological questions. Extremely obese persons are notoriously at risk of osteoporosis after bariatric surgery owing to a reduction in nutrient intake .

DXA fat measurements are moderately to satisfactorily correlated with CT and MRT scans for the assessment of fat percentage and distribution (Salamone et al. 2000, Taylor et al. 2012, Micklesfield et al. 2012). Due to their methodical benefits, MRT scans appear to provide more objective results regarding body composition changes (Pourhassan et al. 2013).

The current overall situation is as follows:

1. There are no studies showing that fat measurements have an influence on relevant end points in obese or diabetic patients.
2. Relevant cardiovascular end points in obese or diabetic patients cannot be influenced by lifestyle changes.
3. Most obese patients weigh more than 140 kg, and can for technical reasons not be examined with DXA scanners (radiation scattering).

From a clinical perspective, a DXA scan for body composition will not result in therapeutic measures or lifestyle recommendations beyond what is already indicated based on medical history and clinical findings. Nevertheless, this does not preclude its use in clinical studies.

3.3 Sports medicine

DXA has been used in sports medicine studies to learn how certain types of sport would influence quantitative fat and muscle tissue changes in various parts of the body (Avlonitou et al. 1997). However, two aspects must be considered. Firstly, there are sources of error due to methodological limits when determining muscle mass. Differing levels of hydration, e. g., can influence scan results (Pourhassan et al. 2013). Furthermore, other procedures can provide more accurate results regarding specific aspects. Secondly, muscle mass is not equivalent to muscle

function. To this end, one now makes a distinction between the terms sarcopenia (lack of muscle mass) and dynapenia (lack of muscular strength, performance or functionality) (Mitchell et al. 2012, Clark und Manini 2012). This distinction is of particular importance when it comes to sports performance.

The above issues are currently under attention in research, including the use of DXA. Beyond research, DXA is not medically indicated for estimating sports performance in patients. The SSK notes that DXA should therefore not be used to assess the level of success achieved through sports training.

3.4 Paediatrics

There is an international consensus that a bone mineral density scan may be indicated for children with primary bone diseases (e. g. osteogenesis imperfecta) at increased risk of secondary bone disease (immobility, cerebral palsy, chronic inflammatory diseases, etc.) if interventions can influence an increased patient risk in a clinically relevant manner.

The child must be stabilised and correctly positioned (which may be difficult with contractures and uncompliance to lie still) in order to perform a DXA scan to measure bone mineral density.

The main focus of diagnostics are the bone mineral content (BMC) and areal bone mineral density (aBMD) of the spine and of the total body less head (TBLH). Therapeutic interventions are not performed on the basis of an isolated DXA scan, and appropriate paediatric reference values are needed to properly assess the bone density scan. If there is an additional growth retardation, DXA measurements must be corrected for body size according to standards. T-Scores are not applicable to children and adolescents. For following the course of rachitic disorders (vitamin D deficiency, calcium deficiency, loss of phosphate), bone density scans are not indicated.

Bone density scans on children and adolescents should only be performed due to osteological indication, by paediatric endocrinologists and diabetologists who have proven expertise in bone metabolism (Bianchi et al. 2013, Lewiecki et al. 2008).

4 Radiation protection requirements

Official notification is legally required to operate body composition scanners that use ionising radiation. Furthermore, operators must have aquired the required knowledge (cf. table 4.2.1 „Anforderungen zum Sachkundeerwerb für Ärzte“ in the revised guideline „Fachkunde und Kenntnisse im Strahlenschutz bei dem Betrieb von Röntgeneinrichtungen in der Medizin oder Zahnmedizin“ (BMU 2006)). Moreover, the general principles for radiation protection of patients shall apply like with all other imaging methods that use ionising radiation (in particular examinations on pregnant women and radiation-sensitive organs). In particular, the following general radiation protection measures should be noted when performing X-ray imaging to determine body composition:

- Operators should be trained and instructed in the operation of the scanner.
- Dose-saving scan modes should be used wherever deemed sensible for the intended purpose.
- The radiation field should be limited to the body region to be examined.
- Acquisition parameters should be adjusted to the patient’s stature.

- Imaging artefacts should be avoided wherever possible. Potential sources include contrast agent residues in the digestive tract, metallic objects on the body or in clothing, osteosynthesis material and intracorporeal objects.
- Adequate quality assurance measures must be taken (O'Connor et al. 2008).
- Dose measurements should be taken on a regular basis (dose area product (DAP) measurements should be given priority over other dose measurement types).

The following radiation protection measures for staff should in particular be taken:

- Staff should be offered training in the operation of the scanner.
- During operation, the staff should stay as far away from the patient, no less than one metre.
- Scans of the femoral neck should preferrably be performed on the side which is opposite of the operating staff member.

The following requirements are for the scanner manufacturer:

- Training and instruction should be offered on the operation of the scanner.
- A freely accessible emergency stop button must be present to immediately stop the scanner. Technical measures are required to prevent unintentionally high dose rates. The X-ray source must emit radiation only during the scan.
- Operators should be provided with a choice of adapted protocols, in particular for paediatric imaging.
- Scanners should be calibrated on the basis of internationally recognised phantoms, and corresponding quality assurance requirements should be provided.

5 Statement

The SSK notes the following:

- Despite the low doses with DXA measurements, an awareness for the use of radiation is needed, and the principles of radiation protection must be adhered to.
- For every DXA scan a justifying indication is mandatory that will be verified by the competent medical authority.
- DXA scans must be subject to quality control and quality assurance measures.
- In Germany there exist no quality standards with regards to technical requirements for VFA and DXA imaging quality and measurement values. For this reason, the ICRU Report 81 "Quantitative Aspects of Bone Densitometry" (ICRU 2009) should be consulted.
- The use of imaging for diagnosing osteoporosis and optimising treatment is indicated accorting to guidelines.
- Vertebral fracture analysis (VFA) is an imaging procedure to specifically prove bone deformities using a comparably low dose that can simplify indication for further imaging procedures.
- Special radiation protection skills and/or expertise are required for all DXA scans, including VFA.

In particular, the SSK notes the following:

- The use of DXA scans to establish bone density with the aim of detecting postmenopausal osteoporosis at an early stage is not justified in the absence of additional risk factors.

- DXA scans for monitoring obesity or diabetes, for preventing sarcopenia and in sports medicine are only permitted within the scope of approved studies and therefore not suited to examinations in a purely clinical context.
- DXA scans are inadmissible without medical indication, e. g. solely to improve patient compliance or accompanying lifestyle activities.
- DXA scans are not suitable for routine paediatric use other than the stated indications, and they should only be used by qualified and approved centres and practices in specific individual cases and for research purposes.
- Due to the current state of knowledge, scientific studies are required to clarify the role of DXA beyond the scope of osteoporosis diagnostics. Such studies are subject to official approval as set out in Section 28a of the German X-ray Ordinance (RöV 2003).

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