

PHYSICAL AND TECHNICAL ASPECTS OF QUALITY ASSURANCE IN MAMMOGRAPHY IN THE REPUBLIC OF SRPSKA

by

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Breast cancer is the most frequent malignant neoplasm affecting the female population. In order to reduce its morbidity and mortality rate, a mammography screening campaign has been established in both entities of Bosnia and Herzegovina. In this paper, a brief survey is given on the mammography screening practice in the Republic of Srpska. As an illustration, results of measurements of technical parameters, including mean glandular dose, for 31 mammography units are presented. Large fluctuations in dose among different measuring sites were found, unacceptable not only from the standpoint of mammography screening, but in clinical mammography as a whole. Subsequently, a series of quality control tests and corrective measures throughout the mammography imaging chain are proposed, in line with international guidelines and newly promulgated national legislation. Dose optimisation and image quality improvement are the first and foremost goals to be achieved in order to setup a successful mammography screening program.

Key words: mammography screening, quality control, mean glandular dose

INTRODUCTION

Breast cancer is the most frequent malignant solid tumour affecting the female population and one of the most frequent causes of cancer-induced deaths in women.

Mammography is the only method of detecting small lesions – masses and microcalcifications – which are neither palpable nor detectable by any other diagnostic method [1]. According to the methodology and patient target group, the classification is turned in early clinical detection and mammography screening. Clinical mammography is used in the diagnostics of ambiguous clinical findings in symptomatic patients, while early detection represents a diagnostic strategy for identifying clinically occult breast cancer at an early stage. Unlike the first two methods, mammography screening is used in asymptomatic women [2].

Mammography screening may be defined as mammographic imaging of a country's overall female population within a certain defined age group, with the

goal of early-stage breast cancer detection. Plain 2D mammography is the principal screening method of choice because of its high spatial resolution (~0.1 mm) and, thus, the detectability of the cancer at an early stage [2]. The mammogram is acquired in two views per breast – craniocaudal (CC) and mediolateral oblique (MLO). The whole of the breast tissue, as well as some of the surrounding tissues, have to be imaged. Image acquisition is preceded by breast compression which contributes to better image quality as it produces contrast enhancement and reduces blurring artefacts due to patient motion. Tissue structures get extended, reducing the distance between the tissue and image receptor, and prevent the anatomic structures from overlapping on a 2D-image. A further important effect of breast compression is the reduction of the dose to the breast because a smaller volume is exposed to X-rays. Compressed breast thickness is between 2 and 8 cm, whereas the area of the breast that is being imaged may vary between 35-250 cm² for each view [3].

Mammography also involves ionising radiation. Thus, there is a certain risk for inducing cancer, since the breast is a highly vulnerable radiosensitive organ,

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particularly in its developing phase, *i. e.* from adolescence to the beginning of the lactation period. According to some UK risk estimates, mammography contributes with a 1:100000 cancer risk per each view, with 1:21 being the overall risk of getting breast cancer in the course of a lifetime [4].

MAMMOGRAPHY SCREENING IN THE REPUBLIC OF SRPSKA

Despite the fact that Bosnia and Herzegovina now has a unified legislation on ionising radiation protection, as well as some healthcare strategies common to both entities, screening mammography is performed separately in the Republic of Srpska and the Federation of Bosnia and Herzegovina. Ministry of Healthcare of the Republic of Srpska has recently launched a mammography screening campaign, sponsored by the Republic of Srpska Health Insurance Fund. Screening practices took place at the Banja Luka Clinical Centre, as well as several other public and private healthcare institutions equipped for the task. Meanwhile, some multidisciplinary counselling bodies were founded with the aim of providing a means for more efficient breast cancer assessment and treatment, but their activity is not to be attributed to mammography screening in any way.

This was also the first mammography screening campaign originating from and carried out on the soil of Bosnia and Herzegovina itself. Nonetheless, the goals set and the way they were implemented, made this a rather untypical mammography screening attempt for numerous reasons, including the following ones:

- lack of census over the past 15 years, due to which exact data on the number of women aged >40 (or >50) are unavailable,
- lowering of the initial age limits of the target group down to 40 years of age; this step is justified by the absence of other types of systematic breast examinations and lack of medical insurance among a large portion of women belonging to the targeted age group,
- omission of the double-reading procedure for negative mammographic findings due to a serious lack of adequately qualified radiological staff, trained in compliance with mammography screening criteria, as well as the shortage of equipment (such as high-resolution mammography workstations, computer aided detection (CAD) software or a centralised softcopy/hardcopy archive of mammographic images),
- non-systematic, indiscriminate public information campaign relevant to the mammography screening program among the targeted population. Women were not called upon to take an examination from a single database, but by means of

public calls and advertisements, or through family physicians, and

- absence of quality assurance (QA) and quality control (QC) protocols for mammography; only recently have the new regulations on quality tests and dosimetry in mammography been released, leaving some undefined areas in the development of screening-specific QA protocols.

A periodic QC of all the X-ray units in the Republic of Srpska has been re-established in the post-war period, more precisely, between 2001 and 2004 [5].

With the goal of providing an insight in the present technical aspects of the Republic of Srpska mammography screening program, this paper reviews the main types of mammography equipment currently in use on its territory. Also, some results based on dose measurements (such as half-value layer, mean glandular dose and scattered radiation dose rates in proximity of mammographic units) for standard breast examination, are reported here.

MATERIALS AND METHODS

X-ray units. In the framework of the Republic of Srpska's healthcare system, 31 mammography units (2 of them being mobile) of different models and manufacturers are currently in use, deployed both in public and private clinical institutes, namely: Philips Fmax (1 unit), Philips Mammo Diagnost (3), Planmed Sophie (1), Metalronica Lilyum (2), Siemens Mammomat 1000 (7), Siemens Mammomat 3000 (4), Siemens Mammomat C3 (1), Hologic Lorad M-IV (1), GE Performa (2), GE Alpha RT (2), GE Alpha ST (2), GE Alpha III (2), GE Senographe 500T (2), and GE Medical Systems 800T (1).

Image receptors. Mammography systems use standard 18 cm × 24 cm, and 24 cm × 30 cm cassettes, depending on the size of the imaged breast. Various film-screen combinations are used as image receptors in 30 out of 31 mammography units. Films are processed in non-dedicated processing units which, it has to be added, are not routinely tested. The only case of indirect digitalization of mammography is found at the Department of Radiology of the Banja Luka Clinical Centre where an analogous mammo unit is coupled with KODAK 975 computed radiography reader, supporting both plain and mammography cassettes. After being read and post-processed, the digital image is viewed on high resolution BARCO monitors and filmed if necessary. Filming is performed on a KODAK DW6800 dry printer with an installed mammography upgrade.

Quality assurance and quality control. Mammography is one of the most technically demanding imaging procedures, requiring particular attention at each step. Regulatory bodies and institutions certified

for quality audits are important elements in the successful implementation of the mammographic diagnostic chain. In the Republic of Srpska, the authorized institution for dosimetry measurements of X-ray equipment is the Republic of Srpska Public Health Institute. X-ray equipment is checked in form of an acceptance test when the new piece of equipment is installed. For the units already in use, QC tests are performed on an annual basis, as well as after each major maintenance service.

The standard dosimetry protocol includes the control of licensed X-ray equipment, equipment premises, as well as of surrounding spaces such as cloak-rooms, waiting rooms, etc. The following parameters are measured:

- functionality of power supply (resistance, voltage fluctuations) [6],
- electrical safety (leakage currents, grounding, etc.),
- X-ray tube and generator parameters (such as accuracy of X-ray tube voltage, reproducibility of X-ray tube voltage, linearity of tube current for different values of tube voltage; reproducibility and linearity of radiation output, half-value layer – *HVL*) [7, 8],
- incident air kerma or ESAK for standard breast, functioning of automatic exposure control (AEC) system in terms of dose indication [9, 10], and
- scattered radiation dose rate for the purpose of workplace monitoring.

However, the functionality of AEC concerning the resulting image quality, film processor and viewing environment are still not subject to testing and measurements. Mammography examinations may yield excessive radiation dose values unless appropriate steps for dose optimisation are undertaken. While adjusting dose values to the lowest reasonably achievable, attention must be paid not to compromise the diagnostic quality of the image [4, 10-15].

An important mammography dose index is given by the so called mean glandular dose (also referred to as *MGD* or *DG*) [9, 10, 15]. Direct measurement of *MGD* is not possible; instead, an estimate for the real patient or standard poly-methyl metacrilate (PMMA) phantom is made, based on the measured value of incident air kerma on breast skin surface, corrected by appropriately chosen conversion factors. As a substitute to the real breast, a 45 mm PMMA dosimetry phantom is used as the standard in dose measurements [9, 15]. Assuming that the values of conversion factors for the given mammography unit, as well as the characteristics of the imaged breast (such as breast size and composition) are known, the mean glandular dose may be computed as follows [10, 11, 15]

$$MGD = K_{gs} c$$

where *K* is the air kerma at entrance surface, *g* – represents a factor accounting for 50% breast glandularity, varying with different *HVL* values, *c* – the correction

for the deviation of the breast tissue examined from 50% glandularity, whereas *s* is an indication of different target-filter combinations. According to the European guidelines for quality assurance in breast cancer Screening and Diagnosis [10], the reference value for *MGD* is 2.5 mGy.

For each mammography unit, 2 sets of measurements were performed. The first was a workplace monitoring or dose rate measurement by means of a portable instrument. The second set of measurements consisted in a series of QC tests of the mammograph itself, including X-ray tube parameters and dose-related quantities (such as air kerma), using appropriate phantoms.

Radiation measurement instruments used for these checks were the Scintillator Probe 6150AD-b (by Automess, Germany) and Barracuda (by RTI Electronics, Sweden). A 45 mm PMMA block was applied as dosimetry phantom.

MGD is computed for typical clinical values of the tube voltage (kVp), product of current and time (*It*) and target-filter combination. Among the 31 units tested, X-ray tube voltage was found to have a constant value for each single unit ranging between 24 kV and 34 kV. The current-time product varied between 20 mA and 160 mA, whereas exposure time took the values up to a maximum of 1.8 s. In X-ray tubes, a Mo/Mo target-filter combination was employed (see tab. 1). The focus-film distance during image acquisition was the same (65 cm) for all the units.

RESULTS

Half value layer. HVL values for the 31 units measured are given in tab. 1. They vary between 0.33-0.65 mm Al, whereas only the values comprised within the 0.36 – 0.02 mm Al range may be considered satisfactory, according to [10].

Mean glandular dose to the standard breast. The MGD for all 31 units was computed based on the measured values of incident air kerma on the surface of a 45 mm PMMA phantom. Mean glandular dose values lie within the 0.28-7.74 mGy range. In 21 cases (68%), MGD inferior to 2 mGy was found; the remaining 6 units (19%) had their MGD values comprised between 2 and 2.5 mGy (i. e. between the achievable and the acceptable value, as prescribed by [10]), whereas in 4

Table 1. Values obtained for the standard breast simulated with a 45 mm PMMA dosimetry phantom; *c*, *g*, and *s* values have been taken from [10]

| | min | max | mean | SD | median |
|-------------------|------|------|------|------|--------|
| <i>Uo</i> [kV] | 24 | 34 | 29 | 2 | 28 |
| <i>It</i> [mAs] | 20 | 160 | 77 | 30 | 80 |
| <i>K</i> [mGy] | 1.4 | 24 | 7.8 | 5.1 | 6.6 |
| <i>HVL</i> [mmAl] | 0.32 | 0.65 | 0.38 | 0.08 | 0.36 |
| <i>MGD</i> [mGy] | 0.27 | 7.7 | 1.7 | 1.6 | 1.3 |

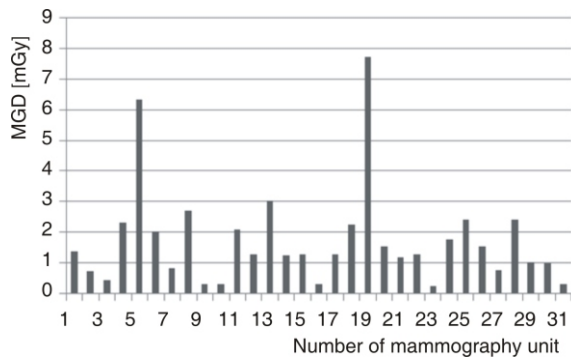


Figure 1. Results of MGD assessment in 31 mammography units

units (13%), the *MGD* measured more than 2.5 mGy (fig. 1).

Ambiental dose rate. Dose rate measurements show that for 24 out of 31 mammography units, dose rates do not exceed 0.10 Sv/h. In 3 cases, on the door of the technician's room, dose rates within 0.20-0.30 Sv/h were measured. Moreover, dose rates ranging between 0.13-0.60 Sv/h were measured behind mobile shields in 3 cases. In one of the two mobile units, the dose rate on the front side of the door reached 0.62 Sv/h.

DISCUSSION AND CONCLUSIONS

In the Republic of Srpska, a mammography screening practice has, at least declaratively, been applied in the past several years. Nevertheless, a strong belief that a whole series of steps along the existing mammography screening chain need to be undertaken in order to improve the screening procedure and bring it to the level of compliance with European quality standards and newly promulgated national regulative is all present.

Quality control protocols apply to all of the components of the screening process – not only the staff involved, but the equipment used, as well as practices and legal requirements implemented. It is, therefore, necessary to maintain the screening equipment in good technical condition, as well as to perform the prescribed periodic quality checks of – *i. e.* image acquisition, processing, viewing, archiving, and interpretation – such as light boxes, displays, computed radiography cassettes and readers, film developing systems, laser printers, as well as stereotactic biopsy units, *etc.*

According to the latest radiation protection regulations, establishing internal QA and QC protocols for each single mammography unit involved in screening is a mandatory step in the screening process. These protocols should include comprehensive equipment checks performed by a medical physicist once every

six months, as well as a series of much more frequent measurements to be performed routinely by radiographers/radiology engineers (A level measurements) and, occasionally, by a medical physicist (B level measurements) [10]:

- determination of the air-absorbed-dose at focus-breast skin distance,
- HVL measurement,
- high voltage [kVp] accuracy and reproducibility test,
- accuracy and reproducibility test for exposure time [s],
- linearity and reproducibility of tube current [mA],
- automatic exposure control (AEC) check,
- focus-film distance (FFD) indicator check,
- X-ray focal spot check,
- compression mechanism control,
- film processing elements: darkroom conditions, processor, film emulsion (for film-screen only),
- image quality check (optical density, threshold contrast visibility, resolution, homogeneity/artifacts; sensitometry (speed, contrast, fog), and
- viewing conditions (light boxes for hardcopy or digital displays of softcopy images; impact of ambient light on viewing of both of the image types).

QA for digital mammography systems. Current trends in radiological practice impose the acquisition of full field mammography units (FFDM) in the nearest future. Subsequently, QC protocols for DR mammography need to be introduced. National legislation prescribes the following FFDM specific tests, in addition to the above mentioned quality checks:

- digital image receptor (response function, X-ray field alignment with the image receptor's edge at chest wall side, detector element homogeneity, defective delts, *etc.*),
- monitors (geometrical distortion, contrast visibility, display artefacts, luminance range, distance-angle calibration, contrast resolution, DICOM greyscale standard display function, uniformity, *etc.*),
- digital image quality, and
- dry printers.

QA protocols for computed radiography systems are even more challenging to establish and implement, as the computed radiography imaging chain consists of following components: a mammography unit, computed radiography cassettes and reader, monitors and dry printer, usually provided by different manufacturers. Aside from the inherent properties of digital systems (quantum noise, detector sensitivity, different image processing algorithms, problems with system configuration in case of power loss, *etc.*), there are many other parameters that require fine tuning, both from image quality and dose optimisation point of view (kVp compensation, *etc.*).

Based on the statistical data presented in the form of tables and plots, it can be concluded that there are large fluctuations in *MGD*. Although for the majority of units tested, the *MGD* was found to comply with reference values, in several cases, the legally prescribed levels were significantly exceeded. This situation calls for a series of corrective measures, both on the maintenance and image acquisition level.

Even among the mammographs whose parameters comply with legal requirements, there are significant fluctuations in measured values of the parameters considered in this paper, which is unacceptable according to mammography screening quality criteria. It is, therefore, necessary to harmonize all parameters relevant to mammo imaging in all healthcare institutions appointed for the implementation of mammography screening.

Establishing a fully integrated QA and QC system is a joint task of all the participants in the mammography screening chain [10].

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**ФИЗИЧКО-ТЕХНИЧКИ АСПЕКТИ КОНТРОЛЕ КВАЛИТЕТА У
МАМОГРАФИЈИ У РЕПУБЛИЦИ СРПСКОЈ**

Рак дојке је најчешће малигна неоплазма у женској популацији. Са циљем да се смањи морбидитет и морталитет од рака дојке, у оба ентитета Босне и Херцеговине организоване су кампање скрининг мамографије. У овом раду дат је кратак приказ скрининг мамографије у Републици Српској. Као илустрација тренутног стања техничких параметара, наводе се средње вредности дебљине полуслабљења и врши се прорачун средње glandуларне дозе за 31 мамограф, на основу резултата мерења које је извршила за то сертификована институција. Уочљиве су велике флукуације у вредностима дозе између појединачних апарата обухваћених мерењем, што је недопустиво не само у светлу скрининг мамографије него и у клиничкој мамографији. Због тога се предлаже низ тестова квалитета и корективних мера које би требало да обухвате читав дијагностички процес, у складу са европским смерницама и недавно усвојеним националним правилницима. Оптимизација доза и побољшање квалитета дијагностичке слике представљају први и најважнији услов успостављања успешног програма скрининг мамографије.

Кључне речи: скрининг мамографија, контрола квалитета, средња glandуларна доза
