

TECHNICAL ASPECTS OF QUALITY ASSURANCE IN MAMMOGRAPHY: PRELIMINARY RESULTS FROM SERBIA

by

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Short paper

UDC: 621.386.83/.84:618.19-006

DOI: 10.2298/NTRP1001055Ž

Mammography is the method of choice for early detection of breast cancer. In Serbia, mammography is performed only clinically, although there is a plan to introduce mammography as a screening method. Currently, there are 60 mammographic units in practice, resulting in 70 000 mammographies annually. The survey was conducted in order to investigate mammographic practice in Serbia, identify weak points and suggest appropriate corrective measures. Basic technical parameters of the X-ray tube and generator, processing, image quality, and patient doses in 20 mammographic units were studied. The survey demonstrated considerable variations in technical parameters that affect image quality, and patients doses. Patient dose levels, in terms of the mean glandular dose, were fairly consistent with current European reference levels: 1.8 (0.40-4.3) mGy. However, due to inappropriate image receptors, image processing and viewing conditions and automatic exposure control adjustment, suboptimal image quality was a common finding. Simple improvements of the radiographic technique and maintenance procedure, along with the rigid implementation of the quality control procedure and training of the operating staff, would improve the performance levels of mammographic practice in Serbia, *i. e.* result in the production of high quality images with a reasonably low radiation risk to patients.

Key words: mammography, quality control, image quality, dose

INTRODUCTION

Mammography is the method of choice for early detection of breast cancer and a well accepted screening method for women of certain age groups [1-3]. Using mammography, it is possible to detect cancer in a phase when treatment is most effective, but only if a constant production of quality images in terms of contrast and resolution is assured. On the other hand, the use of ionizing radiation is an intrinsic part of mammography. Thus, the control of the dose and risk to the highly radiosensitive glandular breast tissue is equally important and all mammographic examinations have to be justified in terms of corresponding benefits and risks [4].

In Serbia, mammography is performed only clinically. However, a large number of women are referred to mammographic examinations asymptotically, without any clinical signs. There are more than 100

mammographic units in use, resulting in more than 70 000 mammographies annually. The number of mammographic units has, it has to be said, also dramatically increased in the last decade [2].

The Serbian Ministry of Health has decided to support a mammographic screening in which women in the age group of 45-69 years will be screened every two years with the main goal of reducing breast cancer mortality.

Technically speaking, mammography is one of the most demanding radiological examination techniques. Both image quality and dose depend on the characteristics of the equipment used and the skill of the operator. The goal of every mammographic examination, screening in particular, is the early diagnosis of breast cancer, *i. e.* efficient detection of very small lesions [5]. A positive net benefit relies on a constant production of quality images that enable the visualisation of the finest details.

A systematic implementation of the quality assurance (QA) programme is a way of providing high quality diagnostic information with a minimal risk to

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the patient [2]. It is also a part of the optimisation strategy enabling permanent production of sufficient diagnostic information accompanied by a minimal possible radiation risk. This is feasible only if all parts of the diagnostic chain are adequate, reliable and subject to regular quality control (QC) [6-11]. Periodic evaluations of mammographic practice worldwide have demonstrated the importance of systematic QC and standardisation in mammography as a tool for improving image quality and dose management [5, 7, 11, 12]. It has been proved that regular dose measurements and image quality assessment using suitable test objects can significantly improve the performance of a mammographic unit [12, 13].

This work presents the initial evaluation of mammographic practice in Serbia, with the aim of identifying the weak points and proposing appropriate corrective actions, having in mind the annual workload and its distribution, available diagnostic equipment and the fact that mammography is performed asymptotically on a large number of women.

MATERIALS AND METHODS

Selection of mammographic units

A total of 20 mammographic units of different manufacturers were included in the study, such as: Elscint Glory (1 mammographic unit), GE-CGR Senographe 800 T (1), Hologic Lorad M IV (4), Metaltronica Lilyum (2), Philips Mammo Diagnost 3000 (2), Philips Mammo Diagnost BC (1), Philips Mammo Diagnost UC (1), Philips Mammo Diagnost UM (1), Planmed Sophie (4), Siemens Mammomat 1000 (2), and Siemens Mammomat 3000 (1). All the units were based on the screen-film combination as the image receptor, routinely utilized in clinical mammography. The same protocol and equipment were used for all mammographic units.

Quality assurance and quality control

For the evaluation of the mammographic practice, a QC protocol specifically designed for the purpose has been developed and implemented in 20 representative mammographic units of different technological properties. QC of physical and technical aspects of the mammographic imaging chain is a way to achieve high and stable image quality in mammography, allowing early detection of small lesions in line with the ALARA dose to the breast [14]. The practical implementation of QA takes into account all relevant medical, organisational and technical aspects of mammography. Detailed recommendations for the implementation of the QA programme in mammography are given in the "European Guidelines for Quality Assur-

ance in Breast Cancer Screening and Diagnosis" [15]. Efficient mammography is based on the good quality of the final product, *i. e.* mammographic image. Therefore, parameters that impact image quality have to be tested and controlled. The list of these parameters and methods and frequency of testing applied, form a QC protocol. The following groups of parameters of the mammographic imaging chain were addressed by our protocol [15, 16]:

- visual inspection, mechanical stability and ambient conditions,
- image processing,
- automatic exposure control (AEC),
- parameters of X-ray tube and generator,
- beam collimation device,
- antiscattering grid,
- image receptor,
- image quality assessment,
- viewing conditions, and
- dose to the standard breast.

The X-ray tube and generator parameters were measured using a calibrated multimeter Barracuda with a solid state MPD detector and ionisation chamber Magna 1 cc (RTI Electronics, Molndal, Sweden). The focal spot size was measured using a star test pattern with 0.3° angular segments. Optical density (OD) in reference points was measured using the densitometer Lullus 1.21 D (Wellhofer, Scanditronix, Germany), while image processing stability was assessed by a stability test using sensitometer Lullus 1.21 S (Wellhofer, Scanditronix, Germany). Ambient light level and the luminance of viewing boxes were measured using a calibrated light detector L-100 (RTI Electronics, Molndal, Sweden).

The protocol is dedicated exclusively to analogue, screen-film mammographic systems, since digital mammographic units require testing of the specifics of parameters relevant for different digital technologies [15]. The number of digital mammographic units in Serbia has increased rapidly, from a single system to ten systems within a year. In line with the experiences gained from screen-film systems, the implementation of QC in digital mammography is a prerequisite for efficient screening in the future.

Image quality

Image quality in mammography is of utmost importance. The consequences of poor image quality are multiple: on one side, the content of diagnostic information is insufficient and on the other side, the radiation burden to patients increases, due to repeated examinations. Nevertheless, image quality is highly dependant on the subjective interpretation of visual data and it does not have an explicit analytical definition.

To achieve the primary goal of mammography, which is the early detection of the disease, optimal practice must be established. Image quality assessment is an important part of the optimisation process and its basis is a definition of what is considered sufficient diagnostic information for a particular diagnostic task. As the interpretation of a mammographic image depends on the composition and size of the breast, these factors also have an impact on the quality criteria for image quality assessment. In general, as far as visualisation goes, lesions of importance are calcifications, distortions of the breast architecture and masses [16]. Successful diagnostics is based on the presence of these lesions on the image, their number, size, shape and configuration and, therefore, on the capability of the imaging system to visualise these small differences in soft tissue contrast or small calcifications.

The quality of the image is a significant factor in imaging sciences and it depends on a number of components within the imaging chain. Basic physical parameters, such as the modulation transfer function (MTF), are measurable quantities. However, these measurements are highly impractical in day to day practice. Another possibility is the receiver operating characteristics (ROC) analysis, encompassing both the observer's individual perception and the imaging chain as a whole. Although very detailed, this method is difficult to implement routinely, as far as image quality assessment is concerned. In practice, one of the most valuable methods is based on the use of test objects (TO) [11, 17]. TO are constructed to mimic mammographic examinations in terms of the shape and composition of the compressed breast. Details embedded in the TO must be clinically relevant and sensitive enough to detect small changes in the characteristic of the mammographic systems, especially those that influence contrast and resolution. In other words, such TO render possible quality scoring, *i. e.* image quality evaluation in a quantitative manner.

Test object TOR MAS (Leeds Test Object Ltd., Leeds, UK), containing structures for the assessment of low and high contrast resolutions, as well as those for the visualisation of small details such as micro-calcifications and low contrast sensitivity, was used in this survey [17]. In this TO, relevant details are presented in the form of linear and circular structures of various dimensions and positions within the breast. For high contrast resolution assessment, a line pair test object was used in conditions of maximal geometrical sharpness and minimal noise level. Low contrast linear details gave us an assessment of fibre structure detection with respect to sharpness, contrast and the signal-to-noise ratio. Circular low contrast details of 5.6 mm in diameter are used for the evaluation of contrast sensitivity of the mammographic system and thus, tumour mass detectability. Two sets of circular details (of diameters of 0.5 mm and 0.25 mm) are also relevant for the visualisation of small details such as

micro calcifications in the breast. Wedge filters with 10 steps of different thicknesses are used for the formation of characteristic curves and the assessment of the contrast of the mammographic film. Optical density close to value 1.0 is the speed index (SI), while the difference in optical density between maximal density and SI represents the contrast index (CI). CI is a measure of the system's capability to present the difference between 100% fatty and 100% glandular tissue, and thus, an important quantitative parameter of image quality in mammography [12, 14].

As another aspect of image quality assessment, the TOR MAS test object was processing images in a routine clinical setting. The film was processed using a processor used in daily practice in the mammographic unit. The following parameters were assessed: reference OD, CI, threshold contrast resolution and low and high contrast detectability.

Dose to standard breast

The relevant dose index in mammography is the mean glandular dose (MGD). Direct measurement of the MGD is not possible; however, it can be assessed for a patient or a standard phantom using a set of conversion coefficients. The dosimetric properties of a mammographic system can be evaluated by assessing the dose to the standard breast, using a 45 mm polymethylmetacrylat (PMMA) dosimetric phantom as a breast substitute [15, 17]. This method is based on the similarity between the attenuation properties of the breast and the PMMA phantom, where 45 mm PMMA corresponds to the 53 mm thick compressed breast [14, 15, 18]. Using a PMMA and calibrated ionisation chamber Magna 1 cm³ with an electrometer module (RTI Electronics, Sweden), the incident air kerma (K) for a standard breast was measured. Based on the results of the measurements suitable conversion factors, the MGD for a standard breast was calculated [15, 18]

$$MGD = K g c s \quad (1)$$

where g is the factor related to 50% glandularity, factor c is the correction for the difference from the 50% glandularity and s allows for different target-filter combinations [16]. The MGD was calculated for typical clinical setting in terms of tube voltage (kVp), current-time product ($I \cdot t$) and target-filter combination.

RESULTS

The results of relevant technical parameters of the mammographic imaging chain with a significant impact on image quality and doses to patients are presented here.

Radiation output

The radiation output at 1 m from the focal spot of the X-ray tube was higher than 30 $\mu\text{Gy}/\text{mAs}$ in 85% of the mammographic units. The mean value and range of the radiation output for 20 mammographic units were 44 (26-73) $\mu\text{Gy}/\text{mAs}$. The attenuation of the compression plate was taken into account during output measurements.

X-ray beam filtration

The half-value layer, as a measure of X-ray beam filtration from all 20 mammographic units, ranged from 0.14-0.42 mm Al. In two cases, the filtration was below the minimally required 0.30 mm Al for the Mo/Mo target-filter combination.

X-ray tube voltage

The deviation of measured X-ray tube voltage from the nominal X-ray tube voltage value was less than the maximum acceptable 5% in 80% of the surveyed mammographic units. In 4 cases, this deviation was less than 7%.

Automatic exposure control

The performance of the AEC was tested in 16 mammographic units where this device was available (with an OD in reference point which is 60 mm from the chest wall and laterally centred). In order to simulate mammographic examinations for over the range breast thickness, the OD was measured in images of the PMMA phantom of thicknesses 2, 4, 4.5, 6, and 7 cm. The mean value of the coefficient of variation for the OD was 10%, ranging from 1 to 44%. A common trend related to older AEC systems is that film density decreases with the increasing thickness of the phantom.

Image receptors

A variety of screen-film combinations used was observed during this study. Only in 60% of the mammographic units examined, screens and films were spectrally matched.

Image processing and viewing conditions

Out of the 20 surveyed, QC of image processing was practiced in a single mammographic unit. For the purpose of assessing it, light sensitometry was imple-

mented in merely 14 mammographic units, due to limited technical capabilities. Significant variations in the mean gradient were observed, the said parameter being an important characteristic of the image reception system, as it directly reflects the contrast of the image [15]. Overall, the mean gradient was found to be 3.9 (0.94-6.9), speed index 0.97 (0.54-1.2), and base plus fog 0.27 (0.19-0.42).

Viewing environment

In 40% of the centres surveyed, a dedicated viewing box was used. Overall, the mean luminance was 3000 cd/m^2 , with a range of 1260-5800 cd/m^2 , while ambient light intensity, in terms of illuminance, was 14-363 lux. The viewing boxes' homogeneity was better than the required 30% in all mammographic units included into the study.

Image quality

An objective assessment of image quality was performed using a TOR MAS test object. The results of our image quality scoring are presented in figs. 1 and 2. The minimal detectable contrast for 5.6 mm circular details, simulating tumour masses of 0.5 mm and 0.25 mm details, simulating microcalcifications, is presented in figs. 3 and 4, respectively. Results obtained demonstrate a wide range of image quality indicators: high contrast resolution ranges from 5.6 to 14.3 lp/mm, while the low contrast resolution was in the range of 1.8-5.0 lp/mm. With respect to the minimal acceptable level of high contrast resolution, this parameter, related to image sharpness, was suboptimal in 90% of the surveyed facilities. Similar findings pertain to all cases of low contrast and low detectability of microcalcifications, as presented in figs. 3 and 4. In a significant number of centres (40-90%), threshold contrast detectability was lower than the minimal re-

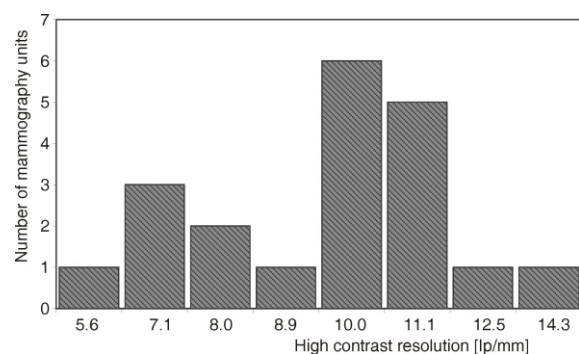


Figure 1. Results of high contrast resolution measurements in 20 mammographic units

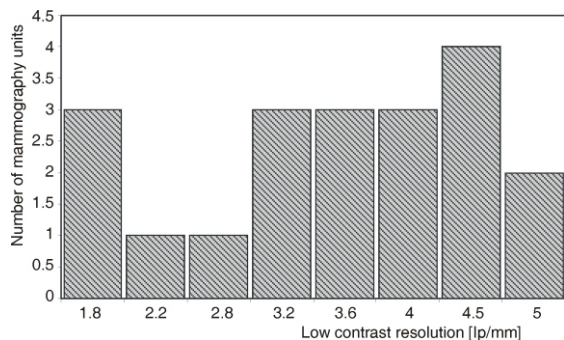


Figure 2. Results of low contrast resolution measurements in 20 mammographic units

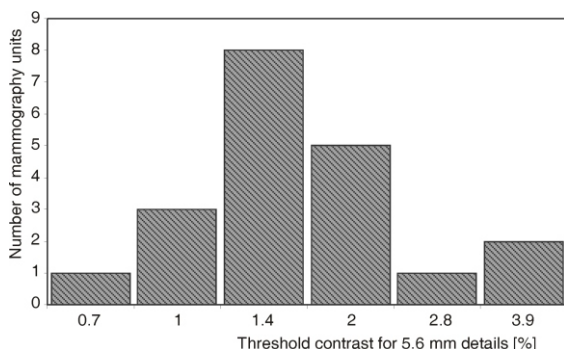


Figure 3. Distribution of measured values for minimal detectable contrast of 5.6 mm diameter details in 20 mammographic units

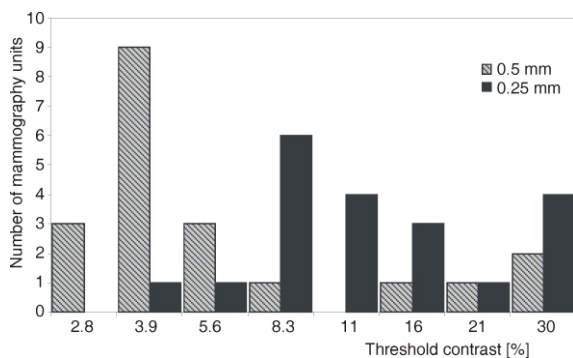


Figure 4. Distribution of measured values for the threshold detectable contrast of 0.5 mm and 0.25 mm diameter details in 20 mammographic units

quired (1.2, 5, and 8% for details of 6 mm, 0.5 mm, and 0.25 mm diameter, respectively).

Dose to standard breast

The MGD in the 20 mammographic units surveyed was calculated based on incident air kerma measurements, on top of the 45 mm PMMA phantom, representing a standard breast. Mean values and associated

ranges for MGD and incident air kerma for all 20 facilities were 10 (2.3-20) mGy and 1.8 (0.40-4.3) mGy, respectively. In 40% of the mammographic units, the MGD was higher than the achievable 2 mGy and, in one unit, even higher than that of the acceptable 3 mGy. The third quartile of the distribution of assessed MGD values was 2.3 mGy. This value should be considered as a preliminary diagnostic reference level (DRL) for the mammographic practice in Serbia [15, 19].

DISCUSSION

Out of 20, only one mammographic unit fully complied with the required performance characteristics, while other units needed the implementation of corrective measures. In some cases, significant intervention on the part of service engineers was required, due to the complex nature of irregularities or even the need to replace parts of the mammographic imaging chain. In some other, the proposed remedial actions were simple, related to daily practice and immediately implemented. Examples of such corrective actions were: modification of applied technical exposure parameters (kVp/mAs), adjusting of the temperature of the developer, storage conditions, or simply, the cleaning of intensifying screens and working surfaces.

Increased dose levels can be attributed to inadequate image reception systems used and inappropriate technical exposure factors. The former being particularly true for units in which the AEC was not adjusted properly or not functioning. It is necessary to underline that X-ray tube voltage, filtration, and geometrical properties were similar in all units, regardless of the manufacturer and mode. These findings reveal the impact that other factors of the mammographic imaging chain have on image quality and dose, as well as the need for regular calibration of AEC devices.

A significant correlation between image quality and dose was not observed. It has been demonstrated that extremely low doses are related to underexposed images and suboptimal optical density. However, high doses do not correlate with good image quality. The relationship between image quality indices, dose and technical parameters, although complex, allows a relative grading of parameters in terms of their impact on image quality and dose. Although the correlation between image quality and OD in the reference point was not significant, a clear consequence of an underexposed imaged ($OD < 1.2$) was limited detectability of clinically relevant details, such as tumour masses and microcalcifications. Furthermore, technical image-quality ensures the minimum of quality standards, while the overall success of mammography depends on the quality of the clinical image. It is, therefore, of utmost importance to include clinical image quality assessment into all quality assurance programmes [20].

We have demonstrated that the X-ray tube and generator are the most stabile elements of the mammographic diagnostic chain, as in most cases the requirements of the QC protocol were fulfilled. The basic elements of instability were related to image receptors, image processing, and viewing conditions. Out of 20 units, only in one case was a daily QC test a standard practice. In 40% of surveyed mammographic units, a dedicated viewing box (3000-6000 cd/m²) was available [15]. Furthermore, a lack of spectral matching of the films and intensifying screens was a common finding, accompanied by an insufficient number of cassettes required for the operation of the said mammographic unit. Screens were found not to be regularly cleaned and replaced, and due to the presence of scratches, scratch traces were present on developed films. Dust on working surfaces and intensifying screens turned out to be another source of the same problem/effect.

Most of the relevant physical parameters can be controlled and corrected through a regular implementation of the QC programme. However, it was observed that certain mammographic units did not meet the minimal requirements for either clinical or screening mammography, due to limited technical capabilities and obsolete technology, such as the lack of an AEC, manual compression or antiscattering grid.

CONCLUSIONS

For the pilot implementation of the QC protocol in mammography, hospitals with the highest workload have been selected, representing typical mammographic practice in Serbia. A developed QC protocol, based on European guidelines for quality assurance in breast cancer screening and diagnosis [15], actual practice and resources, includes equipment testing and maintenance, staff training and QC management, and allocation of responsibilities. Subsequently, the protocol should be implemented on a national scale. Our survey demonstrated considerable variations in technical parameters that affect image quality and patient doses. The main problems are to be associated with film processing, viewing conditions, and optical density control (AEC) with an impact on image quality. Therefore, a significant number of images had to be characterized as poor in terms of the detectability of clinically relevant details.

The preliminary survey of mammographic practice in Serbia highlighted the need for the optimization of radiation protection and training of the operating staff. The survey itself was also a valuable learning process for all involved. The presented results, demonstrating significant variations in image receptors, radiographic techniques, and equipment and processor performances, were used for the identification of existing problems and recommendations for necessary actions. The feedback from hospitals after the imple-

mentation of these corrective actions will be reported subsequently. Furthermore, systematic implementation of the QC protocol should provide a reliable performance of mammographic units, maintain satisfactory image quality and keep patient doses as low as reasonably possible.

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Received on January 20, 2010
Accepted on February 25, 2010

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**ТЕХНИЧКИ АСПЕКТИ ОСИГУРАЊА КВАЛИТЕТА У МАМОГРАФИЈИ:
ПРЕЛИМИНАРНИ РЕЗУЛТАТИ ИЗ СРБИЈЕ**

Мамографија је метода избора у раном откривању карцинома дојке. У Србији, ова дијагностичка метода се изводи клинички иако постоји план о успостављању мамографског скрининга. Тренутно се користи око 60 мамографских рендген-апарата помоћу којих се оствари око 70 000 прегледа годишње. У раду су приказани резултати анализе мамографске праксе у Србији, са циљем да се утврде елементи мамографског дијагностичког ланца са незадовољавајућим перформансама и предложи одговарајуће корективне мере. Анализирани су физичко-технички параметри експозиције, квалитет слике и доза за пацијенте у 20 репрезентативних мамографских јединица. Уочене су значајне промене у параметрима који одређују квалитет мамографске слике и дозу за пацијенте. Средња вредност дозе за glandularно ткиво била је у складу са европским референтним нивоима: 1.8 (0.40-4.3) mGy, док је субоптималан квалитет слике (у смислу детектабилности детаља ниског и високог контраста) уочен у већини мамографских јединица, углавном услед неадекватних пријемника слике, услова обраде и посматрања филма, али и неодговарајућег функционисања уређаја за аутоматску контролу експозиције. Предложене су једноставне корективне мере које воде ка побољшању карактеристика мамографске праксе а односе се на радиографску технику, сервисно одржавање мамографских рендген-апарата, обуку руковалаца и строгу примену програма контроле квалитета. Ове мере довеле би до побољшања карактеристика мамографске праксе у Србији, то јест, константне производње квалитетних мамографских слика уз разумно мали радијациони ризик за пацијенте.

Кључне речи: мамографија, контрола квалитета, квалитет слике, доза