

Estimation and Imperative of Mammography Quality Control

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Abstract

Since 1987 American College of Radiology (ACR) published ACR Mammography Accreditation program. They know that mammography quality control is very important and very imperative due to inscrutable high sensitivity of mammogram characteristics. Taiwan governments have focused on mammography accreditation under the concerning of women health - a patient safety problem [8]. Through this estimation, we will know the situation and understand why they need to accessed these quality control tests combine with act in United States. Improvement of quality control, quality assurance, and quality procedure are major topics in hospital recently years. By establishing standard process and procedure we can reach the related criteria for FDA standard. The policy of screening mammogram has announced by Department of Health, Executive Yuan, Taiwan, and start on July, 2004. All mammogram facilities must be fit the standards by Bureau of Health Promotion mammography accreditation clinical trail. The mammography clinical trail project has been executed since 2002 in Taiwan [1]. In this project, 54 hospitals joined this project in 2002, 78 hospitals in 2003, and it will be approximately 108 hospitals joined this project in 2004 [1].

In this paper we compare the difference between the Mammography Quality Control of United States and Taiwan.

Keywords: Screening mammography clinical trail, mammography quality control, MQSA, MQSRA.

Preface

Mammography Quality Standard Act (MQSA) [9] was enacted in United States since 1992, and Mammography Quality Standard Reauthorized Act (MQSRA) [10] also has been enacted in 1998. All rules for final correction must be fit on Oct. 2002. The US governments spent 10 years to go through the quality control procedure and get together with law making. It's not only very powerful to execute this policy but also very necessary to do quality control essentiality. The following shows the key milestone of MQSA in United States:

- MQSA enacted – October 1992
- FDA delegated responsibility – June 1993
- Interim regulations issued – December 1993
- Interim regulations effective – February 1994
- First accreditation body approved – March 1994
- All mammography facilities certified – October 1994
- Annual inspections begun – January 1995
- Final regulations issued – October 1997
- MQSRA enacted – October 1998
- Final regulations effective – April 1999
- Screen/film facility certification can be extended to include
- Full Field Digital Mammography (FFDM) – March 2000

American College of Radiology (ACR) published Mammography Quality Control Manual in 1999 [7], this manual contains 4 sections: Radiologist's Section, Clinical Image Quality section, Radiological

Technologist's Section, and Medical Physicist's Section. The corresponding departments know the importance of these procedures and must be combined with acts imperatively.

Since 2002, Bureau of Health Promotion (BHP), Department of Health, Taiwan starts breast screening clinical trail in Taiwan [1]. There are not only governments joined this project but also relative organization participants such as Radiology Society Republic of China (RSROC) and Association of Radiology Technologist of ROC (ARTROC). Lots of conferences, symposiums, and lectures are focusing on mammography Quality Control (QC) topic these two years. There are 54 hospitals joined this project in 2002, 78 hospitals in 2003, and it will be approx. 108 hospitals joined this clinical trail in 2004 (see fig.1).

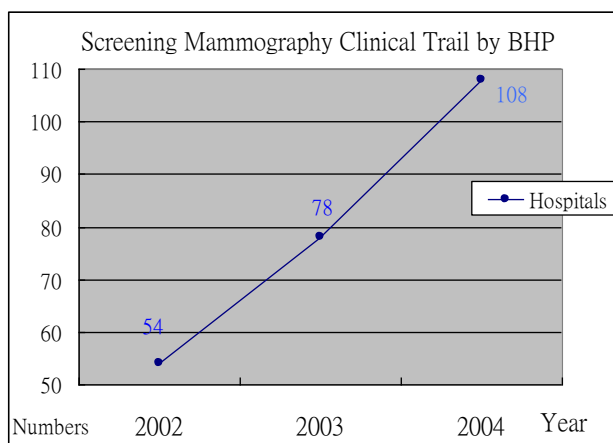


Figure 1 Screen Mammography Clinical Trail for Joined Hospital Numbers

Bureau of National Health Insurance, Taiwan also announced that screening mammography will be started on July, 2004. Female who older than 50 years old can free of charge to get mammogram every one to two years. Consequentially hospitals who want to meet this contract should be passed the criteria of mammography quality control by BHP established.

Due to more complicated QC checking procedure in United States (Total 22 checking procedures for medical physicist's sections and radiological technologist's sections) [7], the breast screening clinical trail established by BHP only includes four checking

procedures: processor daily control chart, beam quality assessment (i.e. Half Value Layer (HVL) measured), Average Glandular Dose (AGD) assessment, and phantom image evaluation. In this study, we estimated and evaluated the quality control procedures.

Method

1. ACR mammography quality control procedures.

Medical Physicist's Section (Annually) [7].

1. Unit Assembly Evaluation.
2. Collimation Assessment.
3. Focal Spot Performance.
4. Automatic Exposure Control (AEC) System Performance.
5. Uniformity of Screen Speed.
6. Artifact Evaluation.
7. Phantom Image Quality Evaluation.
8. KVp Accuracy and Reproducibility.
9. Beam Quality(HVL) Assessment.
10. Breast Entrance Exposure, Average Glandular Dose.
11. Viewbox Luminance/Room Illuminance.

Radiological Technologist's Section [7]

1. Darkroom Cleanliness(Daily)
2. Processor Quality Control(Daily)
3. Screen Cleanliness.(Weekly)
4. Phantom Images(Weekly)
5. Darkroom Fog Procedure(Semi-Annually)
6. Screen Film Contact Test(Semi-Annually)
7. Compression Test(Semi-Annually)
8. Film Retake Analysis(Quarterly)
9. View Box and Viewing Condition(Weekly)
10. Analysis of Fixer Retention in Film(Quarterly)
11. Analysis of Visual Check List(Monthly)

2. BHP mammography QC procedures.

RSROC was authorized to execute the breast screening clinical project for BHP. They are deliberating upon this important project, and finally making the four accredited programs.

1. Processor Quality Control (Daily): Inspect the

processor situation and check via standard check list form.

2. Beam Quality (HVL) Assessment (Annually): Use ion chamber dose meter, 99.9% pure aluminum filters to measure the HVL value of mammographic x-ray tube. Then evaluate the performance of x-ray beam quality.
3. Average Glandular Dose (Annually): Use ion chamber dose meter and standard phantom (RMI-156 or Nuclear Associated 18-220) to evaluate the AGD value [5][11].
4. Phantom Image Quality Evaluation (Annually): Use standard phantom to evaluate the phantom image quality.

RSROC evaluated upon programs by scoring the above items. Some volunteers flunked exams but still can join this project.

Result

Estimation results by BHP and RSROC

We have joined BHP and RSROC to estimate mammography quality control for two years [1], the results is summarize as follows(see figure 2, 3):

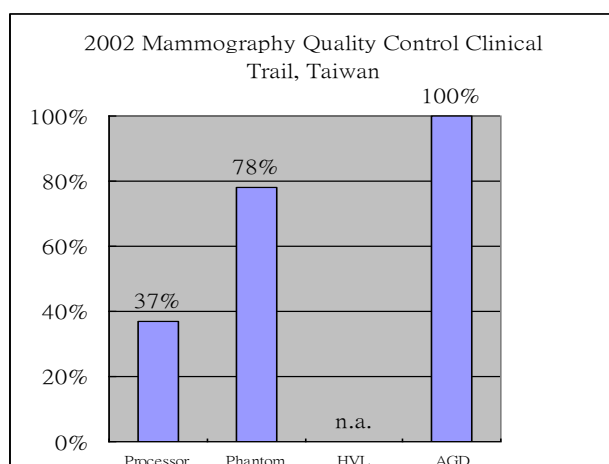


Figure 2 Histogram of mammography QC result (2002)

Through figure 2, we obtained that only 37% participants passed processor daily quality control check, 78% participants passed standard phantom evaluation, 100% participants passed average glandular dose evaluation, and due to wrong measuring procedures, HVL value was unexpected in first year.

Second year estimation (see figure 3), 79% participants

passed processor daily quality control check, 87.5% participants passed standard phantom evaluation, 96.7% participants passed HVL evaluation, and still 100% participants passed average glandular dose.

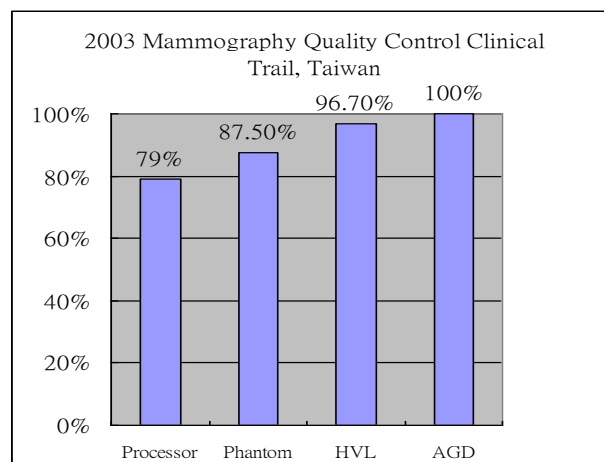


Figure 3 Histogram of mammography QC result (2003)

BHP, Taiwan has a draft act for accredited mammographic hospitals, and summarized as following:

1. Investigate documentation qualification.
2. Onsite estimate mammographic facilities after pass documentation in six months.
3. Radiologist and technologist accredited policy.
4. Clinical trail for positive cases.
5. Every one to two years must be under estimated by official checking procedure.

Advantages and disadvantages of the mammography quality control in Taiwan

Advantages:

1. Introducing this program has improved the mammography quality control.
2. The training courses for radiologists and radiological technologist are still in progress. Their related knowledge has been upgraded and improved.
3. Evaluating four procedures can save hospital cost and reduce starting barrier.

Disadvange:

The BHP mammography estimating procedures do not fully cover all mammography quality control procedures and may omit some important assessments. This is described in the following:

1. **Collimation Assessment:** Incorrect collimation assessment may cause the patient absorbing unnecessary X-ray radiation and missing diagnosis margin in chest wall side.
2. **AEC System Performance:** Incorrect or unstable AEC performance may cause under or over X-ray exposure. That influences to radiologist in mammogram reading. And needs to repeat mammogram again.
3. **Viewbox Luminance/Room Illuminance:** Highly performance of viewbox luminance(3000cd/m²) is recommended in mammogram reading [7]. We measured about 1500~2500cd/m² in some hospitals. Lower viewbox luminance will cause miss findings.
4. **Compression Test:** Compression of breast is a patient safety issue. Incorrect compressed force may cause injury of patient especially particular breast patient such as silicon or normal saline implant.
5. **Film Retake Analysis:** All films must be monitored due to patient safety. Double or more mammogram per study will cause unnecessary X-ray radiation absorbed by patients.

Conclusion

There are a few debates still progressing between radiologist and radiological technologist in Taiwan. A common consensus doesn't form due to different voices. Radiologists think that only estimating four sections rather than following ACR detail procedures will loose abnormal events. On the other hand, some hospitals think that doing such estimation things just waste time and refuse to do these checking procedure policies. That is why they need law to fit this QC procedure in United States.

Unfortunately, in Taiwan, the lack of physicists causes the major problems on executing check procedures. Technologist can take over assessment procedure; both of them need additional knowledge or certificate in concerning with QC issue such as film processor, HVL

and AGD.

Nevertheless improvement of quality control is growing up and forming common consensus in Taiwan. In addition to judging event by heuristic experience, we also need measuring tools to record correct digital result values. By establishing digital QC data, hospitals can maintain these results permanently and benefit for statistic or data mining analysis in the future.

Since FDA approved first Full Field Digital Mammography (FFDM) in 1999, the [Digital Mammographic Imaging Screening Trial \(DMIST\)](#), involving 49,500 women in the United States and Canada, compare digital mammography to standard film mammography to determine how this new technique compares to the traditional method of screening for breast cancer [12]. Unfortunately, because of difficult detection in micro-calcification and thin tumor on lower dose mode, digital mammographic unit still needs similar dose as conventional film mammographic unit used [4][6].

The benefit of digital mammography system bases on higher photon energy. That means they can use higher energy of exposure settings such as using Mo/Rh and higher kV (ex.27~29kV) instead of Mo/Mo and normal kV (ex. 25, 26kV) within contrast acceptable range [2]. On the other hand more algorithms for image recognition, analysis (CAD), and statistics term (BIRADS: Breast Imaging Report and Data System [3]) are still keep going and developing. We conjecture that digital mammography will save lots of cost in doing quality control checking, and increase improvement of quality control.

致謝

感謝台北醫學大學醫學資訊所徐建業副教授給予本論文之指導。三軍總醫院婦女保健中心許居誠主任、台北市立萬芳醫院放射線科魯承章技正與廖月美技術長對於該論文所提供之專業意見與建議，俾使本文順利完成，特此致謝。

Reference

1. 李三綱,許居誠,黃怡璇, 楊繼盛 (2004), 乳房 X 光攝影品質認證制度之臨床試辦計畫, 行政院衛生署。
2. Anne C., Per H. R., et al (1997), "Influence of Anode-Filter Combinations in Image Quality and Radiation Dose," Radiology vol. 203, No.2.
3. Carl J. D'Orsi, MD (2003), "BI-RADS (Breast Imaging Report and Data System) Fourth Edition," American College of Radiology.
4. Carl J. D'Orsi, MD, FACR (2002), "Digital Mammography. Current Women's Health Reports," 2, pp124–127.
5. Dance DR (1990), "Monte Carlo calculation of conversion factors for the estimation of mean glandular breast dose," Phy. Med .Biol. 35, pp1211-1219.
6. Etta D. Pisano,et al (2003), "Image Display:Softcopy and Printed Film Basics of Digital Mammography Display. Digital mammography," pp58-61.
7. Hendrick R. Edward, Bassett Lawrence, Botsco Margaret A., et al (1999), "Mammography Quality Control Manual. American College of Radiology, "
8. Kaveh G. Shojania(UCSF), Bradford W. Duncan, (Stanford),et al (2001), "Making Health Care Safer: A Critical Analysis of Patient Safety Practices," AHRQ Publication 01-E058.
9. Mammography Quality Standard Act (MQSA) (1992), FDA, Public Law 102-539.
10. Mammography Quality Standard Reauthorization Act (MQSRA) (1998), FDA, Public Law 105-248.
11. Wu X , Gingold E , Barnes G et al (1994), "Normalized Average Glandular Dose in Molybdenum Target – Rhodium Filter and Rhodium Target – Rhodium Filter Mammography," Radiology 193, pp83-89
12. Digital Mammographic Imaging Screening Trial (DMIST) (2001), The National Cancer Institute (NCI), the American College of Radiology Imaging Network(ACRIN)
<http://www.cancer.gov/search/viewclinicaltrials.aspx?cdrid=68399&version=healthprofessional>