

16:00-16:20

유방초음파 품질관리

한양대학교병원

박 정 선

초음파 장비 1만5천대 중 75% 의원 보유 공단, 장비 적정관리 방안 마련 시급 주장 전국의 초음파 장비 수가 1만5005대이며, 이 중 75.2%를 의원급 의료기관이 보유하고 있는 것으로 나타났다. 그러나 초음파 장비는 특수의료장비에서 제외돼 있어 별도의 관리 기준이 필요하다는 지적이다. 국민건강보험공단은 "초음파 장비 관리의 문제점과 개선방안" 보고서에서 보건 의료기술 평가제도 및 정착되기 이전부터 의원급 의료기관이 다른 장비에 비해 가격이 낮은 초음파 장비를 이미 운영하고 있어 별도의 장비 관리를 받지 않겠다고 밝혔다. 또 장비 관리 기준을 마련해야 할데도 불구하고 의료기관이 얼마나 많은 초음파 장비를 보유하고 있는지 현황을 제대로 파악하는 것이 어렵다. 초음파 장비에 대한 적정 관리 방안을 시급히 마련해야 한다고 제안했다. 보고서에 따르면 2005년 3월 현재 공단에 등록된 초음파 장비수는 1만5005대이고, 의원급 의료기관이 전체 장비의 75.2%를 보유하고 있는 것으로 집계되고 있지만 과소 추계된 것으로 분석했다. 특히 초음파 장비의 중고시장 규모가 10~20%로 추정되고 있어 초음파 장비의 품질이 부적절하게 관리되고 있을 개연성이 높으며 초음파 장비의 적정 관리 필요성이 있다고 강조했다. 보고서는 초음파 검사와 품질은 일차적으로 검사자의 질적 수준 보장에 크게 좌우된다고 평가하며, 검사자와 유사한 초음파 검사 신입프로그램을 개발해 운영하는 것이 바람직하다고 제안했다. 또 질적적으로 기존의 초음파 장비 품질 관리제도와 검사자의 질적 수준 보장을 위한 신입프로그램을 하나의 프로그램으로 통합하는 것이 효율적이라고 언급했다. 이밖에도 근거 기반의 제정 또는 제정을 통해 초음파 장비를 품질 관리 대상 의료장비로 포함시켜야 한다고 덧붙였다.
--

초음파 검진 영상 질량 불량 고령화 위험, 영안 질환 등 발생 가능성 높아져 보고서 분석 추진수 : 0 목록 초음파 영상 가 가 건강보험 가입자를 대상으로 실시하는 건강검진 초음파 검진 영상의 질량이 불량한 것으로 드러났다. 국회 보건복지위원회 고령화 의원(한나라당)은 건강보험공단으로부터 받은 '2006년도 건강보험공단 검진기관의 방사선 장비의 영상 화질평가' 보고서를 분석한 결과 이상이 확인됐다고 23일 밝혔다. 분석 결과에 따르면 건강보험 검진기관에서 검사를 받은 환자 293명에 대해 촬영한 2545건의 초음파 영상의 품질을 분석한 결과 45.4%인 133명에 대한 영상이 불합격 판정을 받았다. 또 단순 초음파 소진 검사기(촬영자) 985개에서 촬영한 2358장의 영상을 분석한 결과 100명 미만 촬영기에서 60명 미만을 받은 불합격 기기는 20.7%인 183개에 달해 검사의 질 관리에 심각한 문제를 드러냈다. 불합격 비율은 의원이 26.9%로 가장 높았으며 방사선과 의원 21.4%, 병원 13.4%, 종합병원 4.4%, 공공기관 3.1% 순이었다. 고령화 위험은 "영상 품질 불량"이 절반에 이르는 등 국민을 대상으로 실시하는 건강보험 검진의 질 관리 문제가 심각할 수 있다"라며 "기계의 정도관리와 함께 촬영자 교육이 이뤄질 수 있는 실효성 있는 방안을 마련해야 한다"고 강조했다. 백성수기자 (paek3@dailymedi.com) 기사등록 : 2007-10-23 17:26 출처 : Dailymedi - 데일리메디 (www.dailymedi.com)

초음파 품질 관리 필요한가?

- 양질의 의료 서비스를 받아야 하는 환자의 권리 보호
- 급증한 초음파 검사 장비 및 초음파 진료 인력
→ 품질?
- 국가 보건 사업의 효율성 / 품질 관리 필요성
 - ✓ 국가암검진 사업 등을 통한 막대한 예산
 - ✓ 초음파 검사의 국민건강보험 실시 가능성
- 저급 의료를 퇴출하고자 하는 의료계 내부에서의 자정 운동

유방 초음파 품질 관리의 특수성

- 타장기에 비해 유방 조직 특성상 위양성 (false positive) 병변이 많음
- 유방 검진의 기본이 되는 유방촬영술 (mammography) 과의 상호 관계를 진단하는 것이 필수임
- 유방촬영술/ 초음파 이외에 악성/양성 감별 진단에 대처할 수 있는 영상 검사가 거의 없음
- 유방암 조기 발견, 진단, 및 조직 검사를 위해서는 전문가 교육 과정이 상당 기간 필요함

미국 유방 초음파 품질 관리 ACR (American College of Radiology)

1. 인력
2. 장비
3. 임상 검사 기준
4. 비용
5. QC Phantom

Interpreting Physician Qualifications

- licensed medical practitioners
- Have a thorough understanding of the indications for breast US
- Be familiar with the basic physical principles and limitations of the technology of ultrasound imaging
- Be familiar with alternative and complementary imaging and diagnostic procedures
- Be capable of correlating the results of mammographic and other procedures with US findings
- Have a thorough understanding of ultrasound technology and instrumentation, ultrasound power output, equipment calibration, and safety
- Be able to demonstrate familiarity with breast anatomy, physiology, and pathology

Interpreting Physician Qualifications Breast US

Qualifications	Interpreting Physician - Breast Ultrasound
Initial	Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada or Le College des Medecins du Quebec, and Involvement with the supervision and/or performance, interpretation, and reporting of 300 breast ultrasound examinations within the last 36 months¹ OR Completion of an Accreditation Council for Graduate Medical Education (ACGME) approved diagnostic radiology residency program and Involvement with the supervision and/or performance, interpretation, and reporting of 300 breast ultrasound examinations in the past 36 months OR Completion of an ACGME approved residency program in specialty practice plus 200 hours of Category I CME in breast ultrasound, and Supervision and/or performance, interpretation, and reporting of 500 breast ultrasound examinations during the past 36 months in a supervised situation
Continuing Experience	100 breast ultrasound examinations per year (recommended) OR Monitoring and evaluation that indicates acceptable technical success, accuracy of interpretation and appropriateness of evaluation
Continuing Education	Should be in accordance with the <i>ACR Practice Guideline for Continuing Medical Education</i> (CME) and should include CME in ultrasonography, as appropriate to the physician's practice needs (recommended)

Interpreting Physician Qualifications Breast US

항목	현재 자격증 유무	기간	필수 검사 건수
초기	Radiology 전문의	최근 3년	> 300 US
	타과 전문의	최근 3년	> 200 시간 Category I CME > 500 US
유지	> 100 US/year		

Interpreting Physician Qualifications US-guided Breast Biopsy

Qualifications	Interpreting Physician - Ultrasound-Guided Breast Biopsy
Initial	Be qualified to interpret mammograms under MQSA, or Review the mammographic findings with a MQSA-qualified physician AND Perform 3 ultrasound-guided breast biopsy procedures under the supervision of a qualified physician, or Complete a residency or fellowship that includes instruction in ultrasound-guided breast needle procedures AND Have 3 hours of Category 1 CME didactic instruction in ultrasound-guided breast biopsy
Continuing Experience	12 ultrasound-guided breast biopsies per year
Continuing Education	3 hours of Category 1 CME in ultrasound-guided breast biopsy every 3 years

Outcome Data US-Guided Breast Biopsy

- Total number of procedures
- Total number of cancers found
- Total number of benign lesions
- Total number of repeat biopsy, categorized by reason and type of biopsy (i.e., CNB, FNAC)
- Complications categorized by type of biopsy (i.e., CNB, FNAC)
 1. Total number
 2. Number with hematoma (requiring intervention)
 3. Number with infection
 4. Number with pneumothorax (CNB only)

Outcome Data US-Guided Breast Biopsy

Reason for Repeat Biopsy	Data
Insufficient sample	- total # cases # with repeat biopsy performed by core # with repeat biopsy performed by excision
Discordance with imaging	- total # cases # with repeat biopsy performed by core # with repeat biopsy performed by excision
Cellular atypia, radial scar	- total # cellular atypia cases - total # radial scar cases (CNB only) # with repeat biopsy performed by core # with repeat biopsy performed by excision
Other	- total # cases # with repeat biopsy performed by core # with repeat biopsy performed by excision

Physician Peer-Review Requirements

- CT, MR, Nuclear Medicine, PET, Ultrasound and Breast Ultrasound
- Breast US Accreditation 에 필수조건
- Includes a double reading (2 MDs interpreting the same study) assessment.
- Allows for random selection of studies to be reviewed on a regularly scheduled basis.
- Reviewer assessment of the agreement of the original report with subsequent review (or with surgical or pathological findings).
- A classification of peer-review findings with regard to level of quality concerns (one example is a 4-point scoring scale).
- Policies and procedures for action to be taken on significant discrepant peer-review findings for the purpose of achieving quality outcomes improvement

Physician Peer-Review Requirements Scoring

- 1 = Concur with Interpretation
- 2 = Difficult diagnosis, not ordinarily expected to be made
- 3 = Diagnosis should be made most of time
- 4 = Diagnosis should be made almost every time –misinterpretation of findings

Equipment

- High-resolution, real-time, linear arrays
- Operating at a center frequency of at least 10 MHz and preferably higher
- Capable of electronic focal zone(s) adjustment

Examination Identification

- Patient's first and last names (*required*)
- Identification number and/or date of birth (*required*)
- Examination date (*required*)
- Facility name and location
- Designation of right or left breast (*required*)
- Anatomic location using clock face notation or labeled diagram of the breast (*required*)
- Transducer orientation and distance from the nipple to the abnormality or the area being scanned. (*required*)
- Sonographer's identification number, initials, or other symbol

QC of Breast US

Recommended Quality Control for Breast Ultrasound		
Test	Frequency	Performed By
Maximum depth of visualization and hardcopy recording with a tissue-mimicking phantom	Semiannually	Service engineer/medical physicist
Vertical and horizontal distance accuracy	Semiannually	Service engineer/medical physicist
Uniformity	Semiannually	Service engineer/medical physicist
Electrical-mechanical cleanliness condition	Semiannually	Service engineer/medical physicist
Anechoic void perception	Semiannually	Service engineer/medical physicist
Ring down	Semiannually	Service engineer/medical physicist
Lateral resolution	Semiannually	Service engineer/medical physicist
Quality control checklist	Semiannually	Service engineer/medical physicist
Adherence to universal infection control procedures	After each biopsy	Technologist
Clean transducers	After each patient	Technologist
Vertical and horizontal distance accuracy	Quarterly	Technologist
Grey-scale photography	Quarterly	Technologist

Accreditation Testing

- Image quality and procedure performance assessments are the cornerstones of ACR accreditation programs. Facilities must apply for accreditation for all services provided. For example, if no biopsies are conducted, the facility should only apply for accreditation in breast ultrasound.
- If both core-needle biopsies (CNB) and fine needle aspiration cytology (FNAC) are performed, the facility must also apply for the Ultrasound-Guided Breast Biopsy Module and submit both types of cases.
- (For accreditation purposes, FNAC is the sampling for cytology of a *solid mass*. Do not submit needle aspirations of cysts for FNAC.)

Required Examinations

Breast Ultrasound Module	Ultrasound-Guided Biopsy Module
- Simple cyst, <i>and</i> - Solid mass	- Core needle biopsy, <i>and/or</i> - Fine needle aspiration cytology

Clinical Images

Breast Ultrasound Accreditation

Breast Ultrasound Accreditation (both cases required)

Simple Cyst	Solid Mass
1. 2-view mammogram with a single cyst (marked and visible on both views)	1. 2-view mammogram with a single mass (marked and visible on both views)
2. 2 orthogonal views (e.g., 1 transverse, 1 sagittal) with no calipers visible on the cyst	2. 2 orthogonal views (e.g., 1 transverse, 1 sagittal) with no calipers visible on the mass
3. 1 image with appropriate caliper measurements	3. 1 image with appropriate caliper measurements

- marking 을 안 했거나 여러 개 있으면 fail
- Evaluation of the quality of the mammogram is not part of the assessment

Clinical Images

US-Guided Breast Biopsy Accreditation Module

Core Needle Biopsy (either case)

Non-Vacuum Device	Vacuum Suction Device
1. 2-view mammogram with a single solid mass (marked and visible on both views)	1. 2-view mammogram with a single solid mass (marked and visible on both views)
2. Pre-biopsy sonogram showing solid mass in 2 orthogonal views (e.g., 1 transverse, 1 sagittal)	2. Pre-biopsy sonogram showing solid mass in 2 orthogonal views (e.g., 1 transverse, 1 sagittal)
3. Pre-fire sonogram showing needle in the long axis	3. Sonogram showing the needle adjacent to the solid mass in the long axis
4. Post-fire sonogram showing needle in the long axis	

And/Or

Fine Needle Aspiration Cytology (do not submit needle aspirations of cysts)

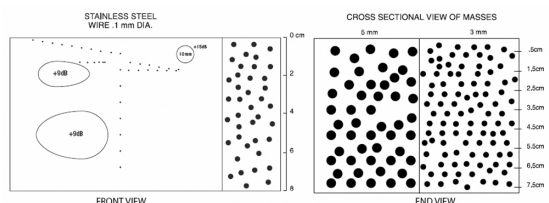
1. 2-view mammogram with a single solid mass (marked and visible on both views)
2. Pre-biopsy sonogram showing solid mass in 2 orthogonal views (e.g., 1 transverse, 1 sagittal)
3. Sonogram showing the needle clearly within the solid mass in the long axis

Accreditation Fees

Cycle	Fees*
Accreditation (Initial cycle and renewal)	\$1000 for breast ultrasound \$1200 for breast ultrasound with biopsy
Repeat	\$500 for one or both modules
Reinstate/Corrective Action Plan	\$1000 for breast ultrasound \$1200 for breast ultrasound with biopsy
Replacement Certificate	\$65 per certificate

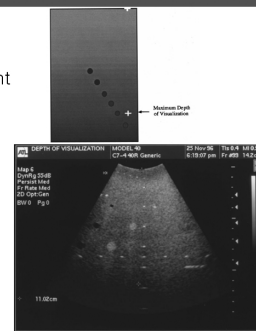
* Fees subject to change without notice.

Sample of US phantom



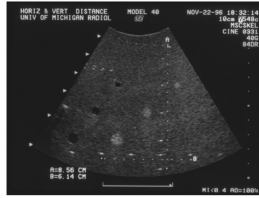
Maximum depth of visualization

- the point at which usable tissue echoes disappear from the image or the point at which cylindrical or spherical objects can no longer be perceived
- should remain constant over time
- variations indicate performance degradation



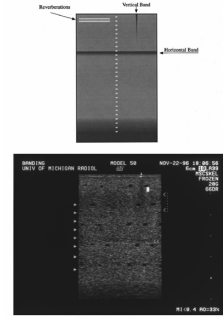
Vertical and horizontal distance accuracy

- The vertical distance test determines the accuracy of measured distances along the beam's axis. Vertical distance errors can be caused by drift or failure in the system's internal timing circuits, and are far less likely to occur than horizontal caliper inaccuracies.
- The horizontal test assesses the accuracy of measurements perpendicular to the beam axis. Horizontal distance errors can be the result of flaws in the transducer scan mechanism, and thus are particularly important for mechanical real-time transducers, including annular arrays, where motor wear can distort accuracy.



Uniformity

- Image uniformity is assessed by scanning a uniform region of a tissue-mimicking phantom and identifying any deviations from the expected smooth tissue texture.



Anechoic object

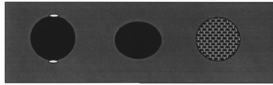


FIG. 5. (Left) The normal appearance of an anechoic object. Notice the sharp edges, clear black appearance, and round shape. Bright artifacts at the top and bottom are normal specular reflections. (Center) Flattened anechoic object indicates geometric distortion. (Right) Echoes inside the anechoic object may be the result of system noise or side lobe contamination.

Ring down/Dead zone
(Near field resolution)

- the distance from the front face of the transducer to the first identifiable echo

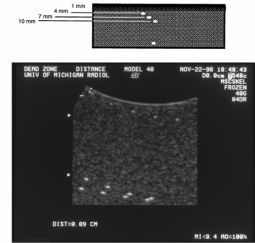


FIG. 8. The depth of an instrument's dead zone is determined by identifying the shallowest filament target that can be clearly visualized. In the pictorial representation (top) the dead zone is 4 mm deep. In the image of an ultrasound phantom (bottom), the dead zone is 0.09 cm or 0.9 mm.

TABLE III. Dead zone requirements.

Transducer central frequency (f_c) (MHz)	Dead Zone (mm)
≤ 3	< 7
$3 < f_c < 7$	< 5
≥ 7	< 3

Lateral Resolution

- assessed by measuring the width of filament targets at depths corresponding to the transducer's near, mid, and far field zones

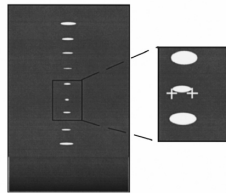


FIG. 9. The lateral resolution at a particular depth is determined by measuring the width of the filament target at that depth.

TABLE II. Recommended lateral resolution requirements.

Depth (cm)	Transducer frequency (f_c) (MHz)	Lateral resolution		
		Response width or spacing between targets (mm)	FWHM (mm)	FWTM (mm)
> 10	< 3.5	≤ 4	≤ 2	≤ 4
< 10	$3.5 \leq f_c < 5$	< 3	< 1.5	< 3
< 10	≥ 5	< 1.5	< 0.8	< 1.5

References

- www.acr.org
- 정수영, 김홍대. 유방초음파진단의 품질관리. 대한초음파의학회지 2006;25:55-60
- 김학희. Breast US Quality Assurance. 대한유방검진학회지 2005;2:85-88
- 고경희, 김은경, 김영아 외. 미국방사선의학회 기준에 따른 유방 초음파 영상의 질적 수준에 관한 평가. 대한초음파의학회지 2003;22:67-72
- Goodsitt MM, Carson PL, Will S, et al. Real-time B-mode ultrasound quality control test procedures Report of AAPM Ultrasound Task Group No. 1. Med Phys 1998;25(8):1385-1406
- Baker JA, Soo MS. Breast US: Assessment of Technical Quality and Image Interpretation. Radiology 2002; 223:229-238