Comparison between different hard-copy film digitizer's devices for plain X ray with CT correlation: multiple-reader receiver operating characteristic (ROC) study as an alternative to the developing world.

Poster No.: C-2260
Congress: ECR 2011
Type: Scientific Exhibit
Authors: J. Camacho¹, A. Salazar², G. Triana¹, D. Aguirre¹, ¹CO, ²Bogotá/CO
Keywords: Teleradiology, Technology assessment, Conventional radiography, Thorax, Computer applications
DOI: 10.1594/ecr2011/C-2260

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Purpose

Common teleradiology practice is film digitizing to perform remote diagnosis. Due to elevated costs, assessment of capable and less costly devices is needed.

We aim to compare three different film digitizers, maintaining adequate diagnostic quality.
Methods and Materials

Materials and Methods

This study used a treatment-by-reader-by-case factorial design in which each case (Chest X-ray) underwent each of the treatments (digitization by three devices). Resulting images were observed once by each reader (six radiologists).

Study population

Outpatients and emergency patients (male and female) who visited the Fundación Santa Fe de Bogotá (FSFB), Bogotá, Colombia, between November 2007 and June 2009, for evaluation by chest X-ray were included in the study. Chest X-rays cases were randomly selected, without repetitions and were included in the sample when a CT was available to establish the condition status of the case (CT was set as gold standard).

Observed variables

According to Grigsby selected conditions were included according to the following criteria: high incidence, difficulty to diagnose, subtle findings, significant adverse outcomes if delayed diagnosis or misdiagnosis and result in large burden of suffering.

Selected conditions for this study were interstitial opacities, pneumothorax and pulmonary nodules (according to Fleishner's society definitions).

Three main variables were defined to calculate AUC: the confidence level for the presence of interstitial opacities, pneumothorax and nodules. These variables could take the following scores: 0-definitely absent, 1-probably absent, 2-cannot decide, 3-probably present, 4-definitely present.

Secondary variables included interstitial opacities distribution, interstitial opacities patterns, nodule size and percentage pneumothorax size (quantified by the Collins' Method). Image quality was assessed through the variable "it was easy to select the score".

Sample size

According to the Obuchowsky accuracy table as follows: (a) the expected accuracy was greater than 0.8; thus, the high accuracy category of the table (AUC>0.9) was selected; (b) in accordance with our hypothesis, the expected difference between the AUC values
was moderate (0.1); (c) the ratio of pathological and normal cases in the test was 1:1; and (d) moderate interobserver variability (0.05) was expected. For six readers, sample size should be 39 cases; however, as stated by Kundel, the images used in these tests are usually highly selected and, in the absence of a representative sample, it is impossible to extrapolate the results to the clinical population. In order to have a large representative sample and guarantee that at least one case for each secondary variable was included, the sample size was increased from 39 to 136 cases (see sample size and distribution in Figure 1, 2 and 3).

Readers

The readers were six FSFB radiologists classified according to their total work experience as a radiology specialist: senior faculty (10 years), junior faculty (5 years) and fellows (1 year). Two radiologists from each category were selected as readers.

Capture devices

Each X-ray film was digitized using the following devices:

(a) an iCR-612SL (iCRcompany, Torrance, CA) film digitizer, hereafter referred to as ICR, with a maximum spatial resolution of 875 dpi (29 µm pixel spot size), 16-bit grayscale, an optical density (OD) of 3.6, Twain protocol, a light box and a cost of US $15,000;

(b) a PowerLook 2100XL (UMAX Technologies Inc., Dallas, TX) flatbed scanner, hereafter referred to as UMAX, with a maximum spatial resolution of 800 dpi (32 µm pixel spot size), 8-bit grayscale, an OD of 3.4, Twain protocol and a cost of US $1,600;

(c) a Lumix DMC-FZ28 (Panasonic Corporation of North America, Secaucus, NJ) digital camera, hereafter referred to as LUMIX, which is a 10-megapixel camera with an aspherical lens, a focal length of 4.8 to 86.4 mm, a minimum focal distance of 30 cm, a 1/2.33" CCD, 100-6400 ISO, manual settings (for aperture, exposure and ISO), black/white (BW) mode and a cost of US $450.

Capture and display software

The AndesPACS software, which was developed at the Universidad de Los Andes by one of the authors of this study, was used to digitize, store and display the cases according to the DICOM standard (Figure 4) and to force the radiologist to select a value for each study variable.

Display station
According to the American College of Radiology (ACR) standard for teleradiology, digitized films must be visualized on a monitor with a large matrix, minimum 10-bit grayscale, 50 ft-L luminance (171 cd/m²) and 2.5 lp/mm (lines pairs per millimeter). On the other hand, the DICOM standard recommends the use of monitors with a 500-cd/m² luminance. Thus, an NEC MD213MG monitor (dot pitch 0.21 mm, 3 megapixels and 1024 grayscale) was selected for this study.

**Procedure**

The cases were printed on 14x17” films. They were then digitized at 375 dpi using the two scanners: for ICR (6488x5248 matrix), the exposure option for "Normal" films (between light and dark) was selected, and for UMAX (6375x4500 matrix), the "Automatic" exposure option was selected, as manual adjustments are difficult with this device. Finally, the films were photographed with LUMIX at 10 megapixels (3648x2736 matrix), using the intelligent aperture mode (automatic aperture adjustment, exposure time and ISO, with priority given to the aperture adjustment), BW, auto white balance and auto focus, without flash, in a dark environment, at a distance of 50 cm. The camera was supported on a specially designed structure to guarantee alignment between the camera and light box (see figure 5).

For all of the devices, the entire film was digitized and stored in DICOM format and 8-bit grayscale, without compression.

The digital camera was used at the maximum resolution (equivalent to 197 dpi for the picture conditions) that was superior to the requirements of the ACR for teleradiology (i.e., 2.5 lp/mm). The other devices could also have been used at the same resolution, but in that case their accuracy would have been decreased, unnecessarily affecting the results of these devices. So appropriate resolutions for transmission in developing countries low networks were used.

The interpretation of the data was carried out over a 6-month period in 2-hour sessions for each radiologist. A 2-month interval between two cases for the same patient was established to avoid recall bias.

**Data analysis**

For the purpose of statistical analysis of main variables, the DBM-MRMC 2.2 software, which was developed by Dorfman-Berbaum-Metz based on multireader-multicase ROC analysis of variance, was used. Parametric binormal adjustment with binormal model was selected. The hypothesis of the equality of average AUC for all three devices was evaluated. In order to evaluate the quality variable, the proportion of treatment cases
labeled, as "It was easy to select the score" was determined. For the secondary variables, the proportion of correctly classified cases was analyzed. For all estimations, standard error (SE) and a two-sided 95% confidence interval (CI) were calculated.
Fig. 0: Figure 1: Sample size calculation

© Obuchowski NA. Sample size tables for receiver operating characteristic studies. AJR 2000;175:603-608.
**Fig. 0:** Figure 2: Normal and Pathologic Cases Used in this study Listed by Disease Category.

<table>
<thead>
<tr>
<th>Pathology</th>
<th>Qty.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interstitial opacities distribution</td>
<td>21</td>
<td>15.4%</td>
</tr>
<tr>
<td>Lobe - Unilateral</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Lobe - Bilateral</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Diffuse – Unilateral or bilateral</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Percentage pneumothorax size</td>
<td>19</td>
<td>14.0%</td>
</tr>
<tr>
<td>Less than 25 %</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Between 25-50 %</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>More than 50 %</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Nodules size</td>
<td>22</td>
<td>16.2%</td>
</tr>
<tr>
<td>Less than 7 mm</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Between 7-15 mm</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Greater than 15 mm</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Total Pathologic cases</td>
<td>62</td>
<td>45.6%</td>
</tr>
<tr>
<td>Total Normal subjects</td>
<td>74</td>
<td>54.4%</td>
</tr>
<tr>
<td>Total sample cases</td>
<td>136</td>
<td>100%</td>
</tr>
</tbody>
</table>

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**Fig. 0:** Figure 3: Interstitial opacities Cases by distribution / Interstitial patterns.

<table>
<thead>
<tr>
<th>Pathology</th>
<th>Qty.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lobe - Unilateral</td>
<td>8</td>
</tr>
<tr>
<td>Fine reticular pattern</td>
<td>2</td>
</tr>
<tr>
<td>Reticular pattern</td>
<td>2</td>
</tr>
<tr>
<td>Reticulonodular pattern</td>
<td>4</td>
</tr>
<tr>
<td>Lobe - Bilateral</td>
<td>4</td>
</tr>
<tr>
<td>Fine reticular pattern</td>
<td>1</td>
</tr>
<tr>
<td>Reticular pattern</td>
<td>1</td>
</tr>
<tr>
<td>Reticulonodular pattern</td>
<td>2</td>
</tr>
<tr>
<td>Diffuse – Unilateral or bilateral</td>
<td>9</td>
</tr>
<tr>
<td>Fine reticular pattern</td>
<td>2</td>
</tr>
<tr>
<td>Nodular pattern</td>
<td>2</td>
</tr>
<tr>
<td>Reticular pattern</td>
<td>2</td>
</tr>
<tr>
<td>Reticulonodular pattern</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total Interstitial opacities</strong></td>
<td><strong>21</strong></td>
</tr>
</tbody>
</table>

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Fig. 0: Figure 4: Visualization of data entry form directly from AndesPACS.

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**Fig. 0:** Figure 5: Different film digitizers used during the trial (left upper and bottom: LUMIX, right upper: iCR and right bottom: UMAX)

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Results

Main variables

The ROC curve forms for each device and pathology (and for mixed pathologies) were very similar (Figure 6 to Figure 9). Figure 10 shows the statistics provided by the DBMMRMC software that allowed us to analyze the equal accuracy hypothesis for each device classified by pathology: there was no significant difference in accuracy between the devices for any comparison (i.e., p>0.05 in all comparisons).

Figure 11 shows the overall ROC curves for each pathology of mixed devices. The three curves greatly differed in form and AUC. The greatest accuracy was achieved for the pneumothorax (AUC = 0.9139, SE = 0.0108), followed by interstitial opacities (AUC = 0.8443, SE = 0.0115) and finally nodules (AUC = 0.7468, SE = 0.0154), with significant differences between them.

The lowest reader variability for AUC was 0.06 for infiltrates with LUMIX and the highest was 0.27 for nodules with ICR.

Secondary variables

Figure 12 shows the proportion of correctly classified cases per device for each secondary variable (interstitial opacity distribution, interstitial patterns, nodule size and percentage pneumothorax size). For all of these variables, more than 84% of cases were correctly classified. Nodules that were less than 7 mm in length had the lowest percentage of correct detection with ICR (84.07%, 686/816), whereas nodules longer than 15 mm had the highest percentage of correct detection with UMAX (97.92%, 799/816).

Quality variable

The percentage of cases labeled as "It was easy to select the score" is shown in Figure 13. The percentages for ICR (91.4%, SE = 1.92%) and LUMIX (91.2%, SE = 1.95%) were high, whereas it was very low for UMAX (23.4%, SE = 2.91%). Figure 14 shows similar results, classified by pathology and device.
**Fig. 0:** Figure 6: Graph of ROC curves for interstitial opacities by device

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**Fig. 0:** Figure 7: Graph of ROC curves for pneumothorax by device

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Fig. 0: Figure 8: Graph of ROC curves for nodules by device

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**Fig. 0:** Figure 9: Graph of ROC curves for any pathology by device.

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Table 3. Comparison of Area Under ROC Curves (AUC) for each device classified by pathology.

<table>
<thead>
<tr>
<th>Pathologies</th>
<th>Device</th>
<th>N</th>
<th>AUC</th>
<th>SD</th>
<th>95% IC</th>
<th>p-value&lt;sup&gt;a&lt;/sup&gt;</th>
<th>DNS</th>
<th>Pairs of Devices</th>
<th>p-value&lt;sup&gt;b&lt;/sup&gt;</th>
<th>DNS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any pathology</td>
<td>ICR</td>
<td>816</td>
<td>0.8760</td>
<td>0.0371</td>
<td>0.8027</td>
<td>0.9493</td>
<td>0.5207</td>
<td>x</td>
<td>ICR-LUMIX</td>
<td>0.3642</td>
</tr>
<tr>
<td></td>
<td>LUMIX</td>
<td>816</td>
<td>0.9180</td>
<td>0.0309</td>
<td>0.8569</td>
<td>0.9790</td>
<td></td>
<td>x</td>
<td>ICR-LUMIX</td>
<td>0.8833</td>
</tr>
<tr>
<td></td>
<td>UMAX</td>
<td>816</td>
<td>0.8692</td>
<td>0.0613</td>
<td>0.7480</td>
<td>0.9904</td>
<td></td>
<td>x</td>
<td>LUMIX-UMAX</td>
<td>0.2906</td>
</tr>
<tr>
<td>Interstitial</td>
<td>ICR</td>
<td>816</td>
<td>0.9350</td>
<td>0.0213</td>
<td>0.8928</td>
<td>0.9771</td>
<td>0.1625</td>
<td>x</td>
<td>ICR-LUMIX</td>
<td>0.4054</td>
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<tr>
<td></td>
<td>LUMIX</td>
<td>816</td>
<td>0.9184</td>
<td>0.0253</td>
<td>0.8684</td>
<td>0.9685</td>
<td></td>
<td>x</td>
<td>ICR-LUMIX</td>
<td>0.2836</td>
</tr>
<tr>
<td></td>
<td>UMAX</td>
<td>816</td>
<td>0.9563</td>
<td>0.0145</td>
<td>0.9276</td>
<td>0.9850</td>
<td></td>
<td>x</td>
<td>LUMIX-UMAX</td>
<td>0.0575</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>ICR</td>
<td>816</td>
<td>0.7912</td>
<td>0.0342</td>
<td>0.7235</td>
<td>0.8588</td>
<td>0.1715</td>
<td>x</td>
<td>ICR-LUMIX</td>
<td>0.9312</td>
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<tr>
<td></td>
<td>LUMIX</td>
<td>816</td>
<td>0.7936</td>
<td>0.0455</td>
<td>0.7037</td>
<td>0.8835</td>
<td></td>
<td>x</td>
<td>ICR-LUMIX</td>
<td>0.1138</td>
</tr>
<tr>
<td></td>
<td>UMAX</td>
<td>816</td>
<td>0.7463</td>
<td>0.0522</td>
<td>0.6430</td>
<td>0.8496</td>
<td></td>
<td>x</td>
<td>LUMIX-UMAX</td>
<td>0.0955</td>
</tr>
</tbody>
</table>

<sup>a</sup> AUC from binormal model and fixed readers.
<sup>b</sup> The hypothesis Ho is mean AUC for each device are the same: AUC(ICR) = AUC(LUMIX) = AUC(UMAX).
<sup>c</sup> The hypothesis Ho is mean AUC for each pair of devices are the same.
DNS: Difference are not statistically significant (p > 0.05).
N: number of observations.
ROC = Receiver Operating Characteristic.

**Fig. 0:** Figure 10: Comparison of Area Under ROC Curves (AUC) for each device classified by pathology.

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**Fig. 0:** Figure 11: Graph of ROC curves for all cases by pathology.

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**Fig. 0:** Figure 12: Cases of correctly classified (by pathology) disease categories and devices. A comparison is shown of the ability to correctly identify the disease category. Results represent the percentage of correctly identified categories for 816 observations with each device. Standard deviations for a 95% confidence interval were calculated for each category.

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Fig. 0: Figure 13: Image quality assessment by device. Results represent the percentage of cases marked as appropriate for accurate diagnosis for 816 observations with each device. Standard deviations for a 95% confidence interval were calculated.

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**Fig. 0:** Figure 14: Image quality assessment by pathology and device. Results represent the percentage of cases marked as appropriate for accurate diagnosis for observations with each device by pathology (21 interstitial opacities, 19 pneumothorax, 21 nodules and 74 normal subjects). Standard deviations for a 95% confidence interval were calculated for each device.

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Conclusion

No statistically significant differences between devices were found. Given differences in costs of devices, LUMIX (U$ 500) is an alternative for institutions with limited resources. UMAX (U$ 1000) could also be a valid economic solution and special operator training is required. The iCR costs 30 times more than other devices with similar results. Productivity of iCR is five times faster than the UMAX. Digital camera acquires images quickly, but the transfer process is slow and no direct communication protocol between the digitized image and patient's clinical records is available. Selection criteria will be based on costs and productivity.
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Personal Information

Camacho J., Triana G. and Aguirre D.

Univertidad El Bosque. Hospital Universitario Fundación Santa Fe de Bogotá. Departamento de Radiología e Imágenes Diagnósticas, Bogotá, Colombia. juan.camacho@fsfb.edu.co or diego.aguirre@fsfb.org.co.

Salazar A.

University of los Andes, Bogotá, Colombia. Department of Electrical and Electronic Engineering, Biomedical Engineering Group (GIB), Laboratory of Telemedicine and Electrophysiology. ant-sala@uniandes.edu.co