Remote Head CT Evaluation for Acute Stroke Diagnosis Using a Smartphone: Reliability and Diagnostic Equivalence with a Primary Medical Interpretation Workstation

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Abstract— **The aim of this study was to evaluate the equivalence of head computed tomography (CT) interpretations performed with either a diagnostic workstation or a smartphone in an emergency telestroke service. After institutional review board approval, a factorial design with 1504 interpretations was used (188 patients, 4 radiologists, and 2 reading systems). The variables evaluated included the following image findings: presence of hemorrhagic lesion, imaging contraindications for the administration of intravenous tissue plasminogen activator (tPA), ischemic lesion in the anterior cerebral artery (ACA), middle cerebral artery (MCA), and/or posterior circulation (PC) territory, hyperdense MCA, and a dichotomized score of the well-known Alberta Stroke Program Early CT Score (ASPECTS). The statistical equivalence between each variable was studied for all reading systems, and the reliability was analyzed using the Fleiss' kappa coefficient. The statistical equivalence ($P < 0.05$) was achieved at a 5% difference for all variables. To claim equivalence, the differences between the two reading systems were obtained and ranged from 0.5% to 4% - the minimum for hemorrhagic lesions and maximum for hyperdense MCA. Intraobserver agreements were classified as moderate, good or very good, with kappa values ranging from 0.52 to 0.94. In addition, we obtained a maximum agreement on the hemorrhagic lesions and a minimum agreement on the presence of ischemic lesions in ACA; this outcome deserves a particular analysis. Finally, we conclude that after providing radiologists with real clinical scenarios, the diagnostic performance for detecting acute stroke is likely equivalent regardless of the use of a smartphone or a diagnostic workstation. Mobile solutions are feasible alternatives for the interpretation of head CT images in patients with acute stroke and can be used as a handy tool in the development of more efficient telestroke services.**

Keywords-stroke; telestroke; teleradiology; smartphone; reliability; equivalence.

I. INTRODUCTION

Stroke is an acute neurologic dysfunction of vascular origin involving focal areas in the brain. It is considered a major cause of death and disability in developed and developing countries [1][2].

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Patients with acute stroke symptoms who arrive at the emergency room require a comprehensive initial evaluation including the time of symptom onset, baseline risk factors, severity of their neurologic condition [3]-[5] and their potential for recuperation based on several clinical predictors, most importantly, an ischemic versus hemorrhagic etiology [6]-[9]. This task requires high levels of clinical and radiological expertise. For patients with ischemic stroke, determining whether to perform an endovascular thrombectomy and/or treat the patient with the administration of intravenous tissue plasminogen activator (tPA) is always a challenging task [10]. However, few eligible patients receive these treatment modalities due to their geographic distances from primary stroke centers or the limited availability of vascular neurologists and neuroradiologists to define the eligibility to receive this treatment.

In most hospitals in Colombia, there are no neuroradiologists at all. Similarly, in our location, which is a Joint Commission International (JCI)-certified primary stroke center with endovascular thrombectomy capabilities, there are not enough neuroradiologists *in situ* to support a telestroke network. To increase the availability of neuroradiologists, mobile solutions using smartphones should be evaluated.

Noncontrast head CT is the most widely used first imaging technique in patients with acute stroke symptoms [11]. This examination allows us to establish whether the stroke is hemorrhagic or ischemic and for ischemic strokes, determine whether it is acute or chronic; in addition, it allows professionals to rule out any contraindications to tPA administration from the imaging point of view. These contraindications may be the presence of the following: intra-axial neoplasm, intracranial neoplasm, arteriovenous malformation, aneurysm, hemorrhagic transformation of an ischemic infarct, and infarction > 1/3 of middle cerebral artery territory, which may be estimated using the ASPECTS [12].

The aim of this study was to evaluate the reliability and diagnostic equivalence of head CT interpretations when using a smartphone compared to a primary diagnostic interpretation workstation in an emergency telestroke service.

Next, we describe how the variables were determined, the characteristics of the remote equipment used, the methodology for data collection and the statistical tools for the analysis of the results; in Section 2, we describe the results according to the intraobserver agreement with respect to the diagnostic performance of stroke. Finally, we describe our experience with the reliability of the remote smartphone device and the projections of teleradiology in a society that seeks to efficient attention in the cases of stroke.

II. MATERIALS AND METHODS

The Institutional Review Board (IRB) of our institution approved this retrospective study and waived the requirement of informed consent. We employed a factorial design with repeated measures.

A. Sample

Patients with symptoms of acute stroke who presented to the emergency room for urgent evaluation between 2013 and 2018 were included in the study. The patients were randomly selected without repetition. Cases with image artifacts were excluded. The cases consisted of head CT examinations stored in our hospital Picture Archiving and Communication System (PACS), which were acquired using a General Electric LightSpeed 64 slice CT scanner (General Electric Healthcare, GE Medical Systems, Milwaukee, WI, USA), with 100 kV, 10 mAs, axial: 5 mm, sagittal: 3 mm, FOV: 26 cm, pixel spacing: 0.469, and matrix: 512 x 512.

B. Observers and interpretation variables

Four neuroradiologists were selected as observers (three with over ten years of experience and one with four years of experience in neuroradiology). They were asked to evaluate the presence of hemorrhagic lesions, the confidence in the presence of any ischemic lesion in the ACA territory, MCA territory, PCA territory, and the confidence in the presence of a hyperdense MCA. The confidence in the presence of these conditions was ranked using the following scores: 0, definitely absent; 1, most likely absent; 2, cannot decide; 3, most likely present; and 4, definitely present. For all cases in which an ischemic lesion was detected in the MCA territory (scores 3 or 4), time evolution was also inquired (i.e., acute, subacute, chronic). For acute lesions, the ASPECTS score was reported by selecting regions with infarcts in the MCA territory, obtaining a score that ranged from 0–10. Finally, the presence of one or more imaging contraindications for tPA administration, such as an intra-axial neoplasm, intracranial neoplasm, arteriovenous malformation, aneurysm or hemorrhagic transformation of an ischemic infarct, was also evaluated.

C. Display monitors and viewer software

The routine reading system for CT interpretations in our hospital is a PACS workstation with a Digital Imaging and Communication in Medicine (DICOM)-compliant viewer software Agfa IMPAX 6.5 (AGFA HealthCare, Mortsel, Belgium). Images were displayed using an E-2620 BARCO monitor (BARCO N.V, Kortrijk, Belgium), which is a 2-megapixel (MPx) LCD medical grayscale display, DICOM-compliant, dot pitch of 0.249 mm, with a spatial resolution of 1600 x 1200 pixels, a maximum luminance of 700 cd/m2, and an 8-bit grayscale. This reading system, hereafter referred to as Medical-IMPAX, was used as the reference reading system in this study.

As a mobile alternative, a Samsung Galaxy S8 Plus (Samsung Electronics, South Korea) smartphone, with a display of 146.5 mm (5.8"), 570 pixels per inch, a spatial resolution of 1440 x 2960 pixels, and a maximum luminance of 1000 cd/m2 was selected. The viewer software used on this smartphone was the Agfa XERO

Viewer 3.0 (Agfa HealthCare, Mortsel, Belgium) software. This reading system is hereafter referred to as Smartphone-XERO.

D. Procedure

Each radiologist read all cases using both the Medical-IMPAX and the Smartphone-XERO systems. At each reading, the radiologist determined the variables mentioned in the section "Observers and interpretation variables". The two reading software packages provided image manipulation tools to adjust the window/level, zoom and multiplanar reformation presentation. These tools were available for all images and could be used at the observer's discretion to improve the image interpretations.

The radiologists were blinded to the patient name, any individualizing items and the original image report. Data collection was performed using a web-based platform, and image readings were stored in a secured database. This software randomizes cases and guides the radiologist throughout the complete report, thus ensuring the integrity and completeness of the data. Relevant clinical data such as sex, age, main neurological symptoms and relevant past medical history (e.g., diabetes, hypertension, headache, Parkinson's disease, Alzheimer's disease, sleep apnea/hypopnea syndrome, or cardiac arrhythmia) were also available. Readings were performed over the course of one year in two or four-hour sessions per reader, with no time limitations for each case. This was a counterbalanced study for the reading systems used by each radiologist in each session.

E. Data analysis

The confidence scores were dichotomized to evaluate both reliability and equivalence. Scores from 0–2 were classified as negative, and scores from 3–4 were classified as positive. Patients with an ASPECTS score ≤ 5 are not eligible to receive tPA treatment. Thus, we dichotomized the ASPECTS score into two categories: 0 if the score ranged from 0–5 (a contraindication for tPA administration) and 1 if the score ranged from 6–10 (indicating eligibility for the administration of the tPA treatment). This variable was named "dichotomized-ASPECTS".

The variables presence of hemorrhagic lesions and presence of any imaging contraindications to tPA administration were not dichotomized as they were already binary (i.e., 0: negative, 1: positive).

Reliability was evaluated in terms of intraobserver agreements of interpretation (cases rated by the same observer using different reading systems), with the Fleiss' kappa coefficient [13]. The kappa coefficients were ranked as defined by Altman [14]: "very good", ($\kappa = 1$ to 0.81); "good", ($\kappa = 0.8$ to 0.61); "moderate", ($\kappa = 0.6$ to 0.41); "fair", ($\kappa = 0.4$ to 0.21); and "poor", ($\kappa < 0.2$). For these calculations, STATA 13.0 software (Stata Corp, College Station, TX, USA) was used.

The dichotomized variables were evaluated to determine their statistical equivalence by means of generalized estimated equations (GEE) [15] using IBM SPSS Statistics 19 software (IBM Corp., Armonk, NY, USA). To evaluate equivalence, mean differences and standard errors were obtained from the GEE analysis. The hypothesis test for equivalence was as follows: the null hypothesis H_0 was |Mean Difference (I-J)| - $\delta = 0$, and the alternative hypothesis H_a was |Mean Difference (I-J)| - $\delta < 0$, where I and J are the two reading systems compared and δ (delta) is the maximum allowable difference permitted to claim equivalence, as suggested by several authors in recent years [16]-[19]. We calculated a $(1\text{-}2\alpha)$% confidence interval for all comparisons, which is also a method to evaluate equivalence [18][19]. The significance level was set to 5% (i.e., $\alpha = 0.05$), and δ was set to 0.05 (5%). Finally, we calculated the required value of δ to claim equivalence for each variable (named δ_{eq} in our result tables).

The reading time was also recorded by the software to evaluate the equivalence between the two reading systems. As this variable is continuous, the mean differences and their standard errors were obtained from an ANOVA with the IBM SPSS Statistics 19 software.

III. RESULTS

There were 90 (47.87%) males and 98 (52.13%) females in the sample. The ages of the patients ranged from 30–97 years, with a mean age of 71.3 years (standard deviation of 15) overall, with a mean age of 69.1 years for males and 73.3 years for females.

To carry out the reliability and equivalence evaluation, each variable must be set by all four observers. The detection of any hemorrhagic lesion was set by all observers; hence, there were 188 patients for this variable and 1504 readings (188 patients by 4 observers by 2 systems). Of these 188 patients, 28 were classified as hemorrhagic lesions by all observers, and 160 were evaluated for other findings (e.g., contraindications to the tPA administration, infarct in the anterior, middle or posterior cerebral artery territories, and hyperdense middle cerebral artery). For these variables, 1280 readings were included in the reliability and equivalence evaluations. Finally, for patients with acute infarct in the middle cerebral artery territory, the ASPECTS score was calculated, ending up with 118 patients with ASPECTS score set by all radiologists; therefore, 944 readings were included in the evaluations.

A. Intraobserver agreement

The intraobserver agreements between the Medical-IMPAX and Smartphone-XERO reading systems, i.e., when each case was interpreted the same way using both the Medical-IMPAX and the Smartphone-XERO reading systems, by the same observer, are presented in Table I. There was very good intraobserver agreement on the hemorrhagic lesion detection, ($\kappa = 0.94$, $P < 0.001$).

There was a moderate intraobserver agreement on the detection of contraindications to tPA administration (presence of intra-axial neoplasm, intracranial neoplasm, arteriovenous malformation, aneurysm, or hemorrhagic transformation of an ischemic infarct), ($\kappa = 0.55$,

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P < 0.001). There was a good intraobserver agreement on the dichotomized-ASPECTS (0-5; 6-10) in the MCA territory (κ = 0.66, P < 0.001).

TABLE I. INTRAOBSERVER AGREEMENT BETWEEN THE MEDICAL-IMPAX AND SMARTPHONE-XERO READING SYSTEMS

Imaging findings	**Fleiss' Kappa**[a]	**Standard Error**	**Agreement**[b]
Hemorrhagic lesion	0.94	0.037	Very Good
Contraindications to tPA administration	0.55	0.039	Moderate
Anterior cerebral artery territory infarction	0.52	0.040	Moderate
Middle cerebral artery territory infarction	0.68	0.040	Good
Posterior cerebral artery territory infarction	0.63	0.040	Good
Hyperdense middle cerebral artery	0.62	0.040	Good
Dichotomized-ASPECTS	0.66	0.046	Good

[a] Readings were performed on the two systems by four observers. All values were significant (P < 0.001) [b] as defined by Altman [14]. Intraobserver agreement between both reading systems showed a very good agreement for the diagnosis of hemorrhagic lesions and an appropriate agreement for those variables that are the most important for stroke in which administration of tPA determines the survival of the patients.

TABLE II. EQUIVALENCE TESTS FOR THE IMAGING FINDINGS BETWEEN THE MEDICAL-IMPAX AND SMARTPHONE -XERO READING SYSTEMS

Imaging findings	**Mean difference**[a]	**SE**	**(1-2α)% Confidence Interval for equivalence testing**		**δ_{eq} (%)**
			Lower	**Upper**	
Hemorrhagic lesion	-0.001	0.002	-0.005	0.002	0.51
Contraindications to tPA administration	-0.003	0.007	-0.015	0.009	1.52
Anterior cerebral artery territory infarction	0.005	0.011	-0.013	0.022	2.23
Middle cerebral artery territory infarction	0.003	0.016	-0.023	0.029	2.91
Posterior cerebral artery territory infarction	0.005	0.014	-0.018	0.028	2.78
Hyperdense Middle Cerebral Artery	0.011	0.018	-0.018	0.040	4.01
Dichotomized-ASPECTS	0.017	0.009	0.002	0.032	3.23

[a] Equivalence tests for all variables were statistically significant, all P < 0.05, at a difference of 5% (δ = 0.05). SE = Standard error of the mean difference, α = significance of the test (0.05), δ = difference of the means set to test equivalence, δ_{eq} = minimum δ required to achieve equivalence. The null and alternative hypotheses were |difference| - δ = 0 and |difference| - δ < 0, respectively.

A moderate intraobserver agreement on the presence of an ACA territory infarction was also observed (κ = 0.52, P < 0.001). In contrast, good intraobserver agreements on the presence of an MCA territory infarction and the presence of a PCA territory infarction were observed, with κ = 0.68 and 0.63, respectively (both P < 0.001). In the presence of a hyperdense middle cerebral artery, a good intraobserver agreement was observed (κ = 0.62, P < 0.001).

B. Equivalence tests for the imaging findings

The mean differences between the variables using both reading systems, the standard error of the differences, and the (1-2α)% confidence interval for equivalence testing, at a delta (δ) difference of 5%, are presented in Table II. In addition, the minimum δ required to claim equivalence (δ_{eq}) was calculated and presented in the last column.

Equivalence tests for all variables were statistically significant, all P < 0.05, showing equivalence at a difference of 5%. The largest (1-2α)% confidence interval was for the presence of a hyperdense middle cerebral artery and the smallest was for the detection of a hemorrhagic lesion. The minimum δ required to claim equivalence (δ_{eq}) for each variable ranged from 0.0051 (0.51%) for the detection of hemorrhagic lesions to 0.0401 (4.01%) for the detection of hyperdense middle cerebral artery.

Both a low mean difference and a low minimum δ required to claim equivalence were observed for the presence of contraindications to tPA administration and for dichotomized-ASPECTS (δ_{eq} = 1.52% and 3.23%, respectively).

C. Reading time

The mean reading time was 114.31 s for the Medical-IMPAX system and 143.39 s for the Smartphone-XERO. The mean difference between the two reading systems was -29.08 s (standard error = 5.4). The equivalence tests for this variable produced a significant (P < 0.001) result at a reading time delta of 60 s. The minimum δ required to claim equivalence (δ_{eq}) for reading time was 38 s.

IV. CONCLUSION

High intraobserver agreements between the Medical-IMPAX and Smartphone-XERO reading systems were observed, with kappa values ranging from 0.52 to 0.94. This suggests that every time that a radiologist reads the same patient image using any of the two reading systems, either the Medical-IMPAX or the Smartphone-XERO, there are no differences in the initial patient outcome. A very good intraobserver agreement was observed for hemorrhagic lesions (κ = 0.94). These findings are consistent with other studies that used a tablet computer as a mobile solution [20]-[24].

Previous studies have reported nonsignificant differences in the detection of ischemic lesions between tablet computers and primary workstations [20][22][25][26]. However, the variables and evaluation methods used in these studies were different from those used in our analysis, and it is important to note that other similar studies did not include a smartphone as a diagnostic device.

To the best of our knowledge, this is the first study that used reliability and equivalence statistical methods to identify potential diagnostic differences between a smartphone and a primary diagnostic workstation in reading head CT examinations in a telestroke context prior to intravenous thrombolysis. Furthermore, when the gold standard is available, a diagnostic accuracy evaluation, using Receiver Operating Characteristics (ROC) curves, will be conducted.

The results of our study indicate that the patients who were not eligible for tPA administration based on imaging criteria, e.g., those having ASPECTS ≤ 5, or the presence of an intra-axial neoplasm, intracranial neoplasm, arteriovenous malformation, aneurysm, or hemorrhagic transformation of an ischemic infarct, were well detected when performed by experienced radiologists using both reading systems.

One limitation of this study centers on the illumination conditions. Readings using the Medical-IMPAX system were performed in diagnostic rooms with controlled ambient light levels. In contrast, readings using the Smartphone-XERO system were performed without controlling ambient light levels. Nevertheless, this situation is more realistic for a telestroke system in which a radiologist is asked to interpret a head CT as soon as possible wherever he or she is located.

The smartphone used in this study was an average-sized mobile phone compared to the ones used today, in which the XERO viewer software allows adjustments of window/level and changes over reconstruction planes (sagittal, coronal or axial), similar to a PACS workstation. Radiologists indicated the absence of ergonomic problems because the use of the smartphone was comparable with the daily use of personal devices. Finally, they reported better performance when making adjustments using a mobile pen than when they did it tactilely. Interpretation using the smartphone spent an average of 29 seconds more than a PACS workstation, which is a reading time that does not affect the goals stipulated in our protocol for stroke code and is negligible compared with the transport time of a neuroradiologist to the hospital in our city.

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In conclusion, there was no superiority of any specific reading system on the evaluated clinical variables. In addition, a high intraobserver agreement was documented for the same variables, providing evidence that the Medical-IMPAX and Smartphone-XERO reading systems may be interchangeable without any reliability loss.

This study provides evidence that the Smartphone-XERO reading system can be used for acute stroke diagnosis based on head CT examinations, ruling out possible imaging contraindications to tPA administration and ASPECTS quantification.

In the statistical design of this study, the radiologist and the reading systems were fixed factors because they were not selected at random; therefore, our results only apply to them. Nevertheless, as neuroradiologists are highly specialized readers of neurological images, we expect that our results may be extrapolated to other groups of neuroradiologists. Similarly, the reading systems in radiology must be DICOM-compliant, which allows us to generalize our results to other reading software or medical displays. In contrast, the smartphone display used in this study may be significantly different when compared to other smartphone displays; hence, our results only apply to smartphones with "retina" display or similar displays.

As future work, the web platform for reading the Head CT of patients with suspicion of acute stroke will be used to train radiologists for these cases, for example, to train them in evaluating the infarct size using the ASPECTS and finding contraindications for tPA administration. In addition, the data stored will be used with machine learning and data mining techniques to understand and improve the reading process of neuroradiologists and the subsequent search of diagnostic aids using image processing.

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