shortreport

Regione Emilia-Romagna
SERVIZIO SANITARIO REGIONALE EMILIA-ROMAGNA
osservatorio regionale per l'innovazione

n. 4

Technology

Portable computed tomography (CT) for the study of diagnostic imaging in specialised areas or setting

Commercial technology name

CereTom NL 3000.

Outside Italy the following devices are also available:

» CereTom Otoscan for ENT (Neurologica, USA)

» xCAT® ENT (Xoran Technologies)

» ScanMate Mobile CT System (Schaerer Mayfield, USA)

» Tomoscan (Philips): no longer available.

Producer / supplier

Producer: NeuroLogica Corp. (USA)

Supplier: TEKMED (Italy)

Use

☐ therapeutic

■ diagnostic

☐ other .....

Category

Medical device

Therapeutic or diagnostic field of application

Diagnostics of head and neck regions.

Patients / clinical condition

- Patients hospitalised in an intensive or trauma unit, difficult to transport or critically ill, needing CT diagnostic evaluation of head or neck regions for maxillofacial, dental, ENT, neurosurgical, neurological or traumatological assessment.
- Patients requiring CT diagnostic evaluation of head or neck regions during maxillofacial, dental, ENT or neurosurgical intraoperatory sessions.

Technology description

CereTom is a portable device mounted on wheels (2 operators are required to push the manual version, only one for the electric tractor, joystick-driven version) enabling 8 slice, spiral CT scanning. Solid state detectors and a fixed-anode, X-ray tube are present on the equipment. Its weight equals to 360 kg, its size is of 153 cm (H) x 133 cm (L) x 73 cm (W). The minimum thickness during acquisition is 1.25 cm, acquisition time (NECT) is 25 cm in 6 seconds. The equipment is capable of performing 3D and flowmetric re-

The report

A brief presentation of a technology, providing sufficient information to decide whether to undertake a comprehensive assessment process.

The reported information derives from:

› the consultation of web materials supplied by the producer and of current national and/or regional registries

› the search of secondary studies on HTA databases and of primary studies, indexed on Medline.

! The report does not represent a definitive assessment of the technology.

Updated

January 2010

Issued by

ORI
Osservatorio regionale per l'innovazione

Agenzia sanitaria e sociale regionale

v.le Aldo Moro 21 - BOLOGNA
tel 051 527 7450 - 7451
fax 051 527 7053
asrdirgen@regione.emilia-romagna.it
http://asr.regione.emilia-romagna.it

constructions (Angio-, perfusion-, Xenon-CT).

Target patients

An estimate of the annual number of patients for whom the use of the device in the Emilia-Romagna Region could be hypothesised requires an ad hoc clinical audit. However, to determine a rough estimate, the number of patients (75) that have undergone neurosurgery in 2008 in Emilia-Romagna and remained in intensive care for more than 2 days (*a*), was added to the number of patients (273) with a trauma of medium/high severity and treated in intensive care units for more than 2 days (*b*). The estimate of potentially eligible subjects resulted to be around 350.

Standard treatment / method

Fixed CT scanning is the standard method, which requires transportation of the patient to the radiology department.

Main expected benefits

- Reduction of adverse clinical events associated with the transportation of critically ill patients from the ward to the radiology department.
- Promptness of diagnostic response in critically ill patients, where high resolution images are not required.

Available evidence and results

Literature Search

The literature search was performed on PubMed, using the combination of terms related to the device (*Tomography*, *X-Ray Computed*[Mesh], *computed tomography*) with terms related to its portability (*portable*, *mobile*, *transportable*, *bedside*).

N° and type of studies

The study search evaluated the literature available since the year 2000. A document of secondary literature (assessment of expected impact) (*1*) and 5 primary studies (3 publications) of low methodological quality were found:

- 1 study carried out on phantoms evaluating technical characteristics of the image (*2*)
- 2 studies of dosimetry also on phantoms (*2*; *3*)
- 1 case series on image quality (*2*)
- 1 controlled case series - historical control - aimed at an economic evaluation (*4*).

The study of image quality included 60 patients undergoing brain CT with both the traditional and the mobile device (*2*). The study aimed at the economic evaluation included 502 encephalic examinations performed with a portable CT device in patients admitted to an intensive care unit. They were compared with a historical series of 5 369 encephalic examinations performed with a traditional device at the radiology department (*4*).

Outcomes

- DIAGNOSTIC ACCURACY
  There is a lack of studies assessing the diagnostic accuracy; one study evaluated the image quality (*2*). The images obtained with a portable device, when compared with those obtained with the traditional method, showed an average lower level of contrast and a higher average number of artefacts. Images obtained with the conventional method were found to be qualitatively superior to those obtained with the mobile device in 93-98% of cases, depending on the anatomical region. All examinations obtained with the portable device were deemed adequate for the diagnostic purpose.

- EFFICACY
  Studies assessing outcomes on clinical efficacy were not found. The ECRI document (*1*) concludes that, for those patients candidate for the use of the device, the expected clinical improvement is probably negligible. The study aimed at the economic evaluation (*4*) estimated the reduction of the execution time of the examination from 50 minutes (traditional method) to 18 minutes (portable device). It also suggested a saving in transportation costs of the patient and a reduction in costs related to the use of radiology technicians' time. This study shows the limitations of a low quality design, not taking into account all sources of cost due to the new technology, and any clinical parameter (including the number of images obtained by a portable device not considered useful to the subsequent diagnosis).

- SAFETY

  Primary safety issues for every kind of CT equipment are related to patient exposure to ionizing radiation, significantly greater when compared to traditional X-ray imaging equipments. As the CereTom system acquires 8 slices and its gantry has contained dimensions, the total radiation dose to the patient is usually lower than that of traditional CT scanner (CereTom: 1.7 mSv per scan). A dosimetry study determined the Computed Tomography Dose Index on volume ($CTDI_{vol}$) per examination to be 41 mGy (120 kV/14 mAs) (*2*). Another study, based on dosimetric evaluations, concluded that the new methodology sets limitations to the total number of tests achievable per year, due to radioactive exposure of health personnel; the installation of additional shielding for radiation protection is thus required (*3*).

Costs

A typical configuration has a list price of € 480 000. A further sum of € 70 000 should be added if the neurosurgery headboard is also purchased. Variations on real costs are limited due to the dominance in the market niche. The cost of a fixed 16-layer CAT system is approximately € 300 000 - 400 000.

Presumed impact

Clinical issues

The major conceivable clinical impact would consist in the possibility, for critically ill patients, to receive a prompt diagnosis and thus have a faster access to specialist care. The clinical impact may be more relevant for those structures with a high number of patients whose transportation is risky and where a radiological department is located far away from the intensive ward.

Economic issues

The use of the technology could increase the costs of patients' management, probably because other radiology technicians would be required to operate the equipment; on the other hand it would lead to a more rapid diagnosis and, consequently, to a potentially more timely management of patients in surgery theatres and intensive care units. The purchase of a portable CT system could therefore be depreciated only by large structures, able to manage large number of acute patients, candidate to be transferred to radiology departments.

Organisational issues

When used in intensive care units, the technology can avoid the use of qualified personnel to transport the patients to the radiology department. However it can also require additional radiology technicians and/or support personnel, leading thus to a substantial re-organisation of a radiology department. The frequent use of the technology in the intensive care units and operating theatres might decrease set-up time, ensuring a certain continuity of care; however as eligible patients are low in numbers, workflow optimisation wouldn't be easily achieved. Finally, such a system, if placed in intensive care units, already crowded with specialised equipment (monitors, pulmonary ventilators, infusion systems, etc.), may increase the likelihood of adverse events, such as damage due to collisions with other equipment or contusions caused to patients and/or operators.

Ethical-social issues

Not evaluated.

Ongoing studies

Ongoing studies do not appear to be registered.

Authorisations

FDA Authorisation: July 2005.

CE mark: 2006.

Medical Devices Repertoire number (by Italian Department of Health): 4105/D.

Diffusion / diffusion prediction

More than 100 installations appear to have been carried out in the world (April 2009). In Italy 4 installations are present (Careggi Hospital-University Trust and Meyer Child Hospital, both in Florence; Hospital of L'Aquila; Maggiore Hospital at Milan Polyclinic). There are no equipments in the hospitals of the Emilia-Romagna Region.

Brief summary

The technology consists of a 8 slice CT scan, transportable on wheels. Its use is not to be considered

as an alternative to a standards fixed CT equipment. Its potential intended use involves a small number of patients in acute critical conditions, hospitalised in an intensive care setting, or selected patients subjected to highly specialised surgery, where high image quality is not required. Literature data on diagnostic accuracy and clinical efficacy are not yet available.

References

1. ECRI Institute. Portable computed tomography (CT) systems for bedside imaging of critically ill patients. Technology Forecast 06/08/2007.
2. Rumboldt Z, Huda W, All JW. Review of portable CT with assessment of a dedicated head CT scanner. AJNR Am J Neuroradiol 2009; 30:1630.
3. Stevens GC, Rowles NP, Foy RT, Loader R, Barua N, Williams A et al. The use of mobile computed tomography in intensive care: regulatory compliance and radiation protection. J Radiol Prot 2009; 29:483-90.
4. Masaryk T, Kolonick R, Painter T, Weinreb DB. The economic and clinical benefits of portable head/neck CT imaging in the intensive care unit. Radiol Manage. 2008; 30:50-4.

Footnotes

a. Database of Hospital Discharge Records of the Emilia-Romagna Region, year 2008. ICD9-CM selected codes: 01.0, 01.23, 01.24, 01.25, 01.26, 01.28, 01.3, 01.4, 01.5, 02.2, 02.3, 38.81, 39.51.

b. Regional Registry of severe trauma in Emilia-Romagna, year 2008. Selected patients: with Injury Severity Score >24 and cranial Abbreviated Injury Severity (AISc) >2 or AIS relative to external cranial surface >3.

Osservatorio regionale per l'innovazione
Agenzia sanitaria e sociale regionale

RESPONSIBLE
Luciana Ballini

CONTRIBUTORS
Maria Camerlingo
Tiziana Giovannini
Silvia Minozzi
Antonella Negro
Giampiero Pirini
Luca Vignatelli

Graphics
Giulia Guerzoni
ggguerzoni@gmail.com
Bologna

This document should be cited as:

L. Vignatelli, G. Pirini, A. Negro, T. Giovannini, L. Ballini *Portable equipments for computed tomography (CT) for the study of diagnostic imaging in specialised areas or setting - Short Report n.4* Agenzia sanitaria e sociale regionale - Regione Emilia-Romagna. Bologna, January 2010