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**ROLE OF CONTRAST ENHANCED CRANIAL CT SCAN ON THE
MANAGEMENT OF PATIENTS WITH CLINICAL DIAGNOSIS
OF STROKE**



Miss. Sukalaya Lerdlum

**สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย**

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By : Sukalaya Lerdlum
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Thesis Advisor : Professor Pirom Kamol-ratanakul, M.D., M.Sc.
Thesis Co-advisor : Associated Professor Somjai Wangsuphachart, M.D., M.Sc.

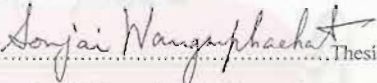
Accepted by the Faculty of Medicine, Chulalongkorn University in partial fulfillment of requirement for Master's Degree


.....Dean of Faculty of Medicine
(Professor Pirom Kamol-ratanakul, M.D., M.Sc.)

Thesis Committee:


.....Chairman
(Professor Kamimant Phanthumchinda, M.D., M.Sc.)


.....Thesis Advisor
(Professor Pirom Kamol-ratanakul, M.D., M.Sc.)


.....Thesis Co-advisor
(Associate Professor Somjai Wangsuphachart, M.D., M.Sc.)


.....Member
(Assistant Professor Somrat Lertmaharit, M.Med.Stat)

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

ศุภกิตยา เลิศล้ำ : บทบาทของการตรวจเอกซเรย์คอมพิวเตอร์สมองร่วมกับการฉีดสารทึบรังสีเข้าหลอดเลือดดำ ในการวางแผนการรักษาผู้ป่วยในกลุ่มที่มีอาการผิดปกติเฉียบพลันของระบบประสาท เนื่องจากสถานะผิดปกติของหลอดเลือด (Role of contrast enhanced cranial CT scan on the management of patients with clinical diagnosis of stroke) อาจารย์ที่ปรึกษา : ศาสตราจารย์นายแพทย์ภิรมย์ กมลรัตนกุล, อาจารย์ที่ปรึกษาร่วม : รองศาสตราจารย์แพทย์หญิงสมใจ หวังสุกชาติ, 80 หน้า ISBN 974-17-1521-8

วัตถุประสงค์ : เพื่อศึกษาผลของการตรวจเอกซเรย์คอมพิวเตอร์ (CT) ที่มีการฉีดสารทึบรังสีเข้าหลอดเลือดดำร่วมด้วยต่อการวางแผนการรักษาผู้ป่วยที่มีอาการผิดปกติของระบบประสาทอย่างเฉียบพลัน ที่ได้รับการวินิจฉัยเบื้องต้นว่ามีสาเหตุเนื่องจากสถานะที่สมองขาดเลือด

รูปแบบการวิจัย : การวิจัยโดยการสังเกตเชิงพรรณนา

สถานที่ทำการวิจัย : โรงพยาบาลจุฬาลงกรณ์ สภากาชาดไทย

ประชากรที่ศึกษา : ผู้ป่วยอายุมากกว่า 45 ปี จำนวน 257 ราย ที่มีอาการผิดปกติทางระบบประสาทอย่างเฉียบพลัน ที่แพทย์ให้การวินิจฉัยเบื้องต้นว่ามีสาเหตุมาจากสมองขาดเลือด ไปเลี้ยงและแพทย์ส่งตรวจเอกซเรย์คอมพิวเตอร์ของสมองเพื่อวางแผนการรักษา

วิธีการศึกษา : ผู้ป่วยได้รับการตรวจ CT โดยเห็นใบยินยอมรับการตรวจวินิจฉัย แพทย์ประจำบ้านสาขารังสีวิทยาเป็นผู้ประเมินผล CT แพทย์ผู้ส่งตรวจจะวางแผนการรักษาผู้ป่วยเมื่อทราบผล CT โดยจะมีการตรวจ CT เพิ่มเติมหลังจากฉีดสารทึบรังสีเข้าหลอดเลือดดำ ในกรณีที่แพทย์คิดว่าจำเป็นต้องการวางแผนการรักษา

การวัดผล : สัดส่วนของผู้ป่วยที่ผลการตรวจ CT ซึ่งมีการฉีดสารทึบรังสีเข้าหลอดเลือดดำร่วมด้วยที่ มีผลในการเปลี่ยนแปลงแผนการรักษาจากภาวะสมองขาดเลือดไปเลี้ยง รวมทั้งการวิเคราะห์ต้นทุน-ประสิทธิผลของการตรวจวินิจฉัยที่มีผลต่อการวางแผนการรักษา

ผลการวิจัย : จากจำนวนผู้ป่วยทั้งหมดที่แพทย์ส่งตรวจ CT 257 ราย มีการฉีดสารทึบรังสีร่วมด้วย 52 ราย (20.2%) มีเพียง 5 ราย ที่ผลการตรวจดังกล่าวมีผลเปลี่ยนแปลงการวางแผนการรักษาจากภาวะที่มีการอุดตันของหลอดเลือด หรือภาวะเลือดออกจากความดันโลหิตสูงเป็นการรักษาแบบอื่น จากการวิเคราะห์ต้นทุน-ประสิทธิผลพบว่า ต้องมีการใช้เงิน 29,000 บาท ต่อ 1 รายที่มีการเปลี่ยนแปลงการรักษานอกจากนี้ในกรณีที่มีการใช้สารทึบรังสีชนิด nonionic แทนสารทึบรังสีชนิด ionic จะมีค่าต้นทุน-ประสิทธิผลเป็น 31,500 บาท

สรุป : ในการวางแผนการรักษาผู้ป่วยในกลุ่มอายุเกิน 45 ปี ที่ได้รับการวินิจฉัยเบื้องต้นว่ามีอาการผิดปกติเฉียบพลันของระบบประสาทจากภาวะเลือดไปเลี้ยงสมองไม่เพียงพอ เนื่องจากภาวะหลอดเลือดอุดตันหรือมีเลือดออกในสมองจากผลของความดันโลหิตสูง ส่วนใหญ่ของผู้ป่วยสามารถใช้เพียงผลการตรวจเอกซเรย์คอมพิวเตอร์ที่ไม่จำเป็นต้องฉีดสารทึบรังสีเข้าหลอดเลือดดำ ที่แสดงลักษณะความผิดปกติของสมองที่เกิดจากการอุดตันของหลอดเลือดในตำแหน่งที่เฉพาะเจาะจง, การอุดตันของหลอดเลือดขนาดเล็ก, การมีเลือดออกในสมองในตำแหน่งเฉพาะเจาะจงจากภาวะความดันโลหิตสูง หรือไม่พบความผิดปกติจากการตรวจ CT ช่วยวางแผนในการรักษาได้ถ้าแพทย์ผู้ทำการตรวจรักษาผู้ป่วย และรังสีแพทย์มีหลักเกณฑ์การวินิจฉัยที่แม่นยำและมีประสิทธิภาพเพียงพอ

หลักสูตร การพัฒนาสุขภาพ
สาขาวิชา การพัฒนาสุขภาพ
ปีการศึกษา 2545

ลายมือชื่อนิสิต.....
ลายชื่ออาจารย์ที่ปรึกษา.....
ลายมือชื่ออาจารย์ที่ปรึกษาร่วม.....

##4275394030: MAJOR HEALTH DEVELOPMENT

KEYWORD: STROKE, CONTRAST ENHANCED COMPUTED TOMOGRAPHY, CECT

SUKALAYA LERDLUM, M.D. : ROLE OF CONTRAST ENHANCED CRANIAL CT SCAN ON THE MANAGEMENT OF PATIENTS WITH CLINICAL DIAGNOSIS OF STROKE) THESIS ADVISOR PROF. PIROM KAMOL-RATANAKUL M.D., M.Sc. THESIS CO-ADVISOR ASSOC. PROF. SOMJAI WANGSUPHACHART, M.D., M.Sc.

Objectives : To identify the therapeutic impact of contrast enhanced computed tomography (CECT) that the treatment plan made by clinicians are altered as a result of application of CECT in patient with clinical diagnosis of stroke.

Design : Observational prospective descriptive study

Setting : King Chulalongkorn Memorial Hospital

Participants : Two hundreds and fifty seven adult patients, age more than 45 years old with clinical diagnosis of stroke who need CT scan for treatment plan were enrolled in this study.

Methods : CT scans were performed with informed consent and interpreted by radiology residents. The treatments were planned by clinicians after CT result. Additional CECT were performed only in cases that clinicians request with various reasons.

Outcome measures : Main outcome was proportion of cases which required CECT that change treatment plan from stroke to others and cost effectiveness analysis was evaluated.

Results : In 257 cases of the patients with clinical diagnosis of stroke who need CT for treatment planning additional CECT were requested in 52 cases (20.2%). Only 5 cases that treatment plan were changed from ischemic stroke and hypertensive bleeding. By using cost effectiveness analysis the cost effectiveness ratio is about 29,000 Baht. By using sensitivity analysis, the cost effectiveness ratio of CECT will increase up to 31,500 Baht if nonionic contrast media is used instead of ionic contrast media.

Conclusion : Only nonenhanced CT scan should be enough for treatment plan in neurologic condition of stroke in aging (more than 45 years old) if normal CT scan, typical patterns of ischemic stroke or hypertensive bleeding are demonstrated. However, experience in using criteria of clinical diagnosis and experience in CT interpretation are needed.

Department Health Development

Field of study Health Development

Academic year 2002

Student's signature.....

Advisor's signature.....

Co-advisor's signature.....

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CHAPTER I

BACKGROUND AND RATIONALE

Many of the advances in diagnostic radiology over the past decade have significantly improved the work up of patients undergoing evaluation in emergency departments. Patients with acute traumatic and acute nontraumatic emergencies now benefit from faster and more accurate diagnosis that use newer helical CT, MR imaging and ultrasound protocols as well as advances in image processing, PACS and teleradiology.

At King Chulalongkorn Memorial Hospital, 24-hour CT scanning facilities have been available. A retrospective study of emergency CT scans at this institute in 1988 revealed 665 cases during 6 months. Major indications were stroke (49%) and head injury (19%); positive CT findings were found in 60% of cases.⁽¹⁾ During October 1, 1998 to September 30, 1999 emergency CT scans is increased up to 2,821 cases and 2,350 cases (83.3%) are cranial CT scans. A significant number of emergency cranial CT scans were performed both without and with intravenous contrast enhancement (about 55.2 % of cranial CT scan). The purpose of the administration of any contrast material is that of producing density changes within the lesions, thereby facilitating its recognition and separating it from the surrounding normal structures. These studies were requested by the resident or fellow or attending staff from each specialty. These emergency CT scans were preliminary interpreted by radiology residents.

At present, contrast agents used for both CT and MRI of the brain depend on the status of the blood - brain barrier. In the presence of an intact blood - brain barrier, only a few normal structures enhance. The iodinated contrast medium is commonly used in neuroradiologic applications including CT scan. Contrast agents have certain inherent properties. These properties are density, viscosity and osmolality. In spite of allergic

reaction to contrast agent caused by iodine allergy, adverse reactions to contrast media are also initiated by chemotoxic reactions related both to the hyperosmolality of the contrast media and to toxic effects of cation in ionic group. Type of adverse reactions are varies from mild degree to severe reaction. Speculation by several researchers that marked hyperosmolality of contrast media was a major source of adverse reactions led to the development of low osmolar agent.⁽²⁾ However, this new agent is expensive.

Concerning clinical economics, cost identification of contrast enhanced CT is more than nonenhanced CT because process of performing images must be repeated with additional intravenous injection of contrast media and more increase if low osmolar contrast media is used. If adverse reaction to contrast media happens, there will be additional cost for treatment of this reaction. Intangible cost of double radiation exposure is also to be taken into account. Retrospective study by Wood, et al.,⁽³⁾ 1990 concluded that in the acute nontraumatic neurological disorder, if a nonenhanced CT is normal, a contrast study is usually unnecessary. The patients receiving contrast administration after cerebral infarction may have a worse prognosis.⁽⁴⁾ In economic crisis as this period of time, judgement of using contrast enhanced CT scan in appropriate condition is essential. Use of diagnostic test appears to be of little value in situations in which no change in management result from the use of the test. However, no study concerning clinical economics that reveal cost effectiveness of contrast enhanced CT on the management of the patients with clinical diagnosis of stroke was previously performed. Treatment plan in patient with clinical diagnosis of stroke guided by contrast enhanced CT result will be the primary outcome of this study because stroke is a major indication of nontraumatic emergency cranial CT scan. This outcome will be used for cost effectiveness analysis of contrast enhanced CT (CECT) and nonenhanced CT (NECT).

CHAPTER II

REVIEW OF RELATED LITERATURES

Stroke and cerebrovascular accident are terms that relate to a broad category of conditions characterized by the sudden onset of a neurological deficit caused by abnormality of blood supply to central nervous system. Clinical strokes can occur in various settings, including hypertensive hemorrhage and parenchymal hemorrhage from other causes, such as arteriovenous malformation, ruptured amyloid angiopathy, drug abuse and tumors and also subarachnoid hemorrhage due to ruptured aneurysm. However, 80% are caused by infarction, that is, the cessation of blood flow to a specific area for a period of time sufficient to lead to cell death.^(5,6)

Infarction may be caused by atherosclerotic disease in the vasculature directly supplying the central nervous system (CNS), cardiac emboli or artery to artery emboli within the carotid or vertebral vasculature, lacunar infarction, or other etiologies such as vasculitis and also undetermined etiology.^(5,6)

In recent years, great strides have been made in understanding the pathophysiological mechanisms of cerebral ischemia and infarction. As more aggressive therapeutic options are explored, including systemic and selective intra-arterial thrombolytic therapies and various brain salvage medications,^(7,8) early diagnosis undoubtedly will continue to play a critical role. Computed tomography (CT) and magnetic resonance imaging (MRI) can provide significant information to clinicians when such anatomic images are integrated into an understanding of pathophysiology.^(9,10,11,12,13,14)

Normal mean cerebral blood flow is approximately 50 ml/100 gm. of brain tissue per minute. When cerebral blood flow decreases to below 10 to 15 ml/100 gm./minute, failure of the oxygen - dependent cellular membrane ion pump occurs, resulting in intracellular accumulation of sodium and potassium. Water then diffuses into cell body

along these new gradients and results in swelling of the cell bodies, cytotoxic edema. Reperfusion, if it occurs within 3 to 6 hours or before perfusion decreases below 10 ml/100 gm./ minute, reverse the changes. This process indicates that reversible ischemia, such as in transient ischemic attacks (TIA), can lead to morphological changes identifiable on imaging studies.^(5,6)

Approximately 4 to 6 hours after the onset of ischemia, there is break down of the blood - brain barrier (BBB), allowing a marked efflux of water and proteins from the intracellular space, vasogenic edema. Vasogenic edema occurs in several pathological process other than ischemia and infarctions such as cerebritis, abscess or tumor. However, in these conditions cytotoxic edema involving the gray matter generally is not observed. It is the combination of cytotoxic and vasogenic edema that gives the typical appearance of the large vessel infarction, that is, parenchymal lucency involving gray and white matter extending to the periphery in a wedge - shaped pattern.

Classically, the diagnosis of stroke has been and remains, primarily a clinical one, ie, the acute onset of a neurological deficit. The role of CT in the hyperacute setting is to rule out mimicking conditions, such as hypertensive hemorrhage and bleeding related to conditions such as amyloid angiopathy, vascular malformation and tumors. Negative CT scan in a patient with an acute neurological deficit is highly suggestive of acute infarction. There are studies showing early CT signs of ischemia, even during the first few hours of ischemic stroke and early CT signs may allow the prediction of further infarct locations and also indicate the degree of severity of ischemia.

Positive findings on initial CT studies are related to gyral changes and those related to the affected vascular itself. As cytotoxic edema develop and the gray matter swells, there is resultant sulcal effacement. The CT attenuation value of the gray matter decreases so the distinction between gray and white matter becomes obscured. Changes involving the affected vasculature relate to slow or absent flow so CT may show hyperdensity from thrombus or embolus in the arteries.^(15,16,17,18)

In addition to conventional CT imagings, assessment of cerebral perfusion and arterial anatomy in hyperacute stroke with three dimensional functional CT and also CT angiography are new diagnostic procedures that require spiral computed tomography and special software.⁽⁹⁾ This machine and technique for the study are different from conventional CT scan.

In our current cost - conscious medical economic environment, there is increasing emphasis upon justifying the value of high technology, extensive tests, and procedures. Many studies^(19,20,21) have evaluated the usefulness of emergency cranial computed tomography (CT) for a variety of clinical problems, including trauma, headaches, ischemia, and seizure. A large proportion of the scans that are obtained to evaluate these problems show no acute abnormality. In many institutions, a significant number of emergency CT scans are performed both without and with contrast administration. Many physicians feel that IV contrast significantly improves the diagnostic yield. The underlying assumption is that nonenhanced CT has a significant false negative rate and that the additional information contributed by contrast administration may alter the patient final status. The exclusion of obstructive hydrocephalus, significant mass effect or intracranial hemorrhage is easily demonstrated by nonenhanced CT, supplying adequate information for immediate patient management. False negative nonenhanced CT studies are well documented in case of meningitis, vasculitis, vascular malformation, acute infarction, subarachnoid hemorrhage, sagittal sinus thrombosis and also metastasis. However, CT studies in acute meningitis and encephalitis, even performed with contrast, may well be unremarkable and lumbar puncture is needed for definitive diagnosis as well as condition of subarachnoid hemorrhage. When subarachnoid hemorrhage is evident, further angiography is needed. Magnetic resonance imaging (MRI) is now the test of choice in diagnosis of metastasis and superior sagittal sinus thrombosis. However if MRI is not available, contrast enhanced CT scan may demonstrate evidence of thrombosis. Normal CT findings are common in case of acute infarction. The use of CT in this setting is primarily to exclude hemorrhage if anticoagulation

or intravascular thrombolytic therapy is being considered or to exclude a mass which may simulate an infarct.

Retrospective study by Wood, et al., 1990⁽³⁾ concluded that in the acute non-traumatic neurological disorder, if a nonenhanced CT is normal, a contrast study is usually unnecessary. A retrospective study suggested that patients receiving contrast administration after cerebral infarction may have a worse prognosis.⁽⁴⁾ However, in real practice, contrast administration either from clinician or radiologist is mostly requested to avoid false negative including stroke condition.

This study partly aims to confirm Wood's conclusion about 10 years ago in the subgroup of clinically stroke criteria using more promissible prospective methodology including clinical economic evaluation that no study is now available about topic of clinical economics.



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CHAPTER III

CONCEPTUAL FRAMEWORK, RESEARCH QUESTION AND RESEARCH OBJECTIVES

3.1 Conceptual Framework

A framework for clinical evaluation of CECT as a diagnostic test for patient with clinical diagnosis of stroke includes the following steps.

1. Computed tomography (CT) of the brain is generally accepted to be a diagnostic test to detect abnormality in this group of patients.
2. Nonenhanced computed tomography (NECT) can demonstrate abnormality that is necessary for therapeutic decision by abnormal density, location of the lesion and mass effect specific for ischemic stroke and also hemorrhagic stroke in specific location for specific disease such as hypertensive bleeding.
3. Contrast enhanced computed tomography (CECT) can demonstrate abnormality other than ischemia or hemorrhage in group of patients with clinical presentation same as infarction such as tumor, infection and subdural hematoma due to pattern of abnormal enhancement and abnormal vessels that can be demonstrated in case of vascular malformation or aneurysm.
4. Confidences of diagnosis and treatment plan made by clinicians depend on history taking, physical and neurological examination, diagnostic test and also experience of clinicians.
5. The change in management from the result of CT scan is expected to improve the ultimate outcome which is decreased mortality or morbidity or improved the quality of life.

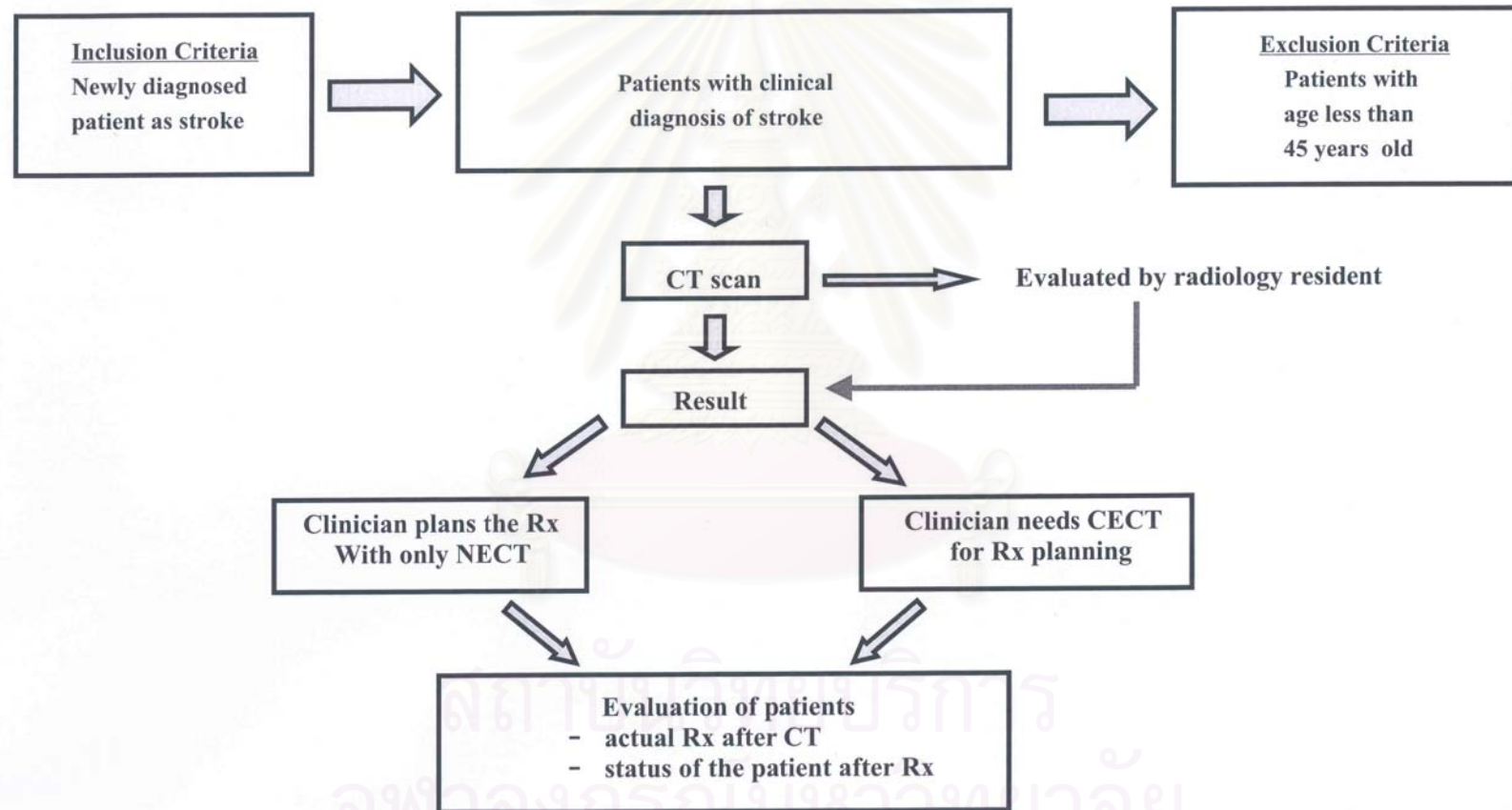


Figure 3.1 : Flow chart diagram of the study

The proportion of cases which required CECT that change treatment plan from stroke to others will be the outcome of this study and it will be used to identify cost effectiveness of CECT.

3.1.1 Operational Definition

1. Stroke - Any sudden or acute neurological deficit due to damage to the brain or central nervous system caused by abnormality of blood supply. Clinical diagnoses are seldom absolute certainties. Although focal neurological deficits may be most evident, some important symptoms such as severe headache, nausea, vomiting and alteration of consciousness are associated ancillary symptoms. These symptoms also weight the probabilities of different stroke mechanism.

There are two major categories of brain damage in stroke patients :

1. Ischemic stroke - a lack of blood flow, can be further subdivided into three different mechanism : thrombosis, embolism and decreased systemic perfusion.

2. Hemorrhagic stroke - the release of blood into the extra vascular space within the cranium, can be further subdivided into two subtypes : subarachnoid and intracerebral hemorrhage. (with and without intraventricular hemorrhage)

2. Computed Tomography - X-ray computed tomography that can demonstrate cross-sectional image of the organ.

Nonenhanced CT (NECT) - A diagnostic imaging using computed tomography without intravenous injection of contrast media during examination.

Contrast enhanced CT (CECT) - A diagnostic imaging using computed tomography with intravenous injection of contrast media during examination.

Normal findings of nonenhanced and contrast enhanced CT scan of the brain

- Normal density of gray matter and white matter of brain parenchyma.
- Normal physiologic calcification in specific anatomical location related to patient age.

- Normal size of the ventricular system and subarachnoid space related to patient age.
- No evidence of displacement of midline structures.
- Normal enhancement of specific areas of the brain. (enhanced CT)

Abnormal findings demonstrated by nonenhanced CT scan.

- Hydrocephalus and level of obstruction.
- Diffuse or focal brain edema.
- Intraparenchymal and extraparenchymal mass lesions (solid or cystic).
- Abnormal calcification.
- Hemorrhage (intraparenchyma, intraventricular, subarachnoid, sudural or epidural areas).
- Mass effect (effaced sulci, compressed ventricle, displacement of midline structure, herniation).
- Brain atrophy (diffuse or focal)

Additional abnormal findings demonstrated by contrast enhanced CT :

(areas of impaired blood - brain barrier, vascular structure).

- parenchymal enhancement.
- ependymal enhancement.
- leptomeningeal enhancement.
- abnormal thick dural enhancement.
- abnormal vessels.

The abnormal CT findings in ischemic stroke^(22, 23) will be described in terms of abnormal density of brain parenchyma, brain swelling, location and size of the lesion related to vascular anatomy and abnormality of the vessel, itself.

● Pattern of abnormal CT findings will be categorized into acute brain infarction, subacute brain infarction, chronic infarction and specific ischemic pattern using the following criterias :

Acute infarction - normal finding.

- blurring of the clarity of the internal capsule.
- loss of distinction between the insular ribbon cortex and the adjacent white matter.
- swelling of cortical gray matter resulting in mild effacement of interposed sulci.
- “dense MCA sign “ secondary to lodged embolus or thrombus in the middle cerebral artery.
- “hemorrhagic infarct “ due to hemorrhage into an infarct presented as small hyperdense bands within the confines of a hypodense infarct, found most often in the brain cortex and at the infarcted margins.

Subacute infarct - increasingly prominent subtle CT change that characterize acute period and correspond to a known vascular distribution.

- increased mass effect.
- evidence of abnormal contrast enhancement, usually peripheral and ring - like or gyriform pattern.

Chronic infarct - resolved brain edema.

- encephalomalacia.
- shrunken gyri, enlarged sulci and adjacent ventricular dilatation.

Specific ischemic pattern

- Watershed infarction.
- Lacunar infarction.
- Venous infarction.

3. Contrast media (CM) (water soluble iodinated contrast media)

Iodinated contrast media is directly imaged by its attenuation of an x-ray beam. High osmolar CM is ionic compound with osmolality about 5 times of the blood.

Low osmolar CM is ionic or nonionic compound with osmolality about 2 times more than or equal to blood.

Side effects that may happen when intravenous contrast media is used; classify into

1. Mild reaction - side effects considered physiologic, no treatment.
2. Moderate reaction - transient, non-life threatening, occasionally treated.
3. Severe reaction - life threatening, treatment and hospitalization required.

Incidence of adverse reaction caused by low osmolar CM is less than high osmolar CM about 4 times.⁽²⁴⁾

4. Treatment Planning - Treatment planning for acute stroke syndrome in King Chulalongkorn Memorial Hospital will depend on findings demonstrated by emergency CT scan.

4.1 Hyperdensity (hemorrhage) with mass effect - consult neurosurgery.

4.2 Nonstroke - appropriate consultation and treatment.

4.3 Normal or hypodensity (ischemic stroke) will be divided into 5 subgroups.

- Definite time of onset less than 3 hours with normal CT scan - consider thrombolytics.

- Large infarct with midline shift or herniation - consider surgical decompression.

- Large infarct without midline shift or herniation - close observation for brain edema, hemorrhagic transformation, brain herniation and avoid anticoagulant in the first 4 days.

- Medium sized infarct - consider anticoagulant.

- Lacunar infarct - consider antiplatelet.

5. Cost effectiveness of CECT : Cost of the test per case which treatment plan is guided by the result of CECT.

3.2 Research Questions

Primary : Considering all cranial computed tomography required for patients with clinical diagnosis of stroke, what is the proportion that contrast enhanced computed tomography (CECT) is essential for treatment planning ?

Secondary : 1. What is the reason that CECT is requested by clinicians ?
2. How much does it cost per treatment plan that change from stroke to the other for patients with clinical diagnosis of stroke guided by CECT (cost effectiveness of CECT) ?

3.3 Research Objectives

1. To identify the therapeutic impact of CECT that the treatment plan made by clinicians are altered as a result of application of CECT in patient with clinical diagnosis of stroke.

2. To identify the reasons why CECT allows clinicians to be more confident of their treatment plan in patient with clinical diagnosis of stroke.

3. To determine the cost effectiveness of CECT as a diagnostic test for treatment plan with good outcome in patient with clinical diagnosis of stroke.

CHAPTER IV

RESEARCH METHODOLOGY

The design of the study will be “observational prospective descriptive study” to identify the proportion of the adult patients with clinical diagnosis of stroke who require CECT that change treatment plan from stroke to others. The reason that CECT is requested by clinicians and also cost effectiveness of CECT will be evaluated.

4.1 Research Design

Observational prospective descriptive study

4.2 Population

4.2.1 Target population

Adult patients with clinical diagnosis of stroke.

4.2.2 Sampled population

Patients with clinical diagnosis of stroke who meet the following eligible criteria.

4.2.3 Inclusion criteria

Newly diagnosed patients with clinical diagnosis of stroke evaluated by computed tomography at Department of Radiology, King Chulalongkorn Memorial Hospital., (less than two week)

4.2.4 Exclusion criteria

The patients with age less than 45 years old because the relative incidence of the various causes of stroke is different from the older and different treatments are needed in young adult.

4.2.5 Sampling Technique : Data from every case will be collected

Sample size: Because objective of this study is to estimate the proportion of necessary CECT as the diagnostic test for treatment plan in patient with

clinical diagnosis of stroke so formula for estimated proportion is used as follows (with 95% confidence interval)

$$\begin{aligned}
 n &= Z^2 \alpha p (1 - p) / d^2 \\
 p &= \text{proportion of treatment plan guided by CECT} = 0.2^{(3,4)} \\
 1 - p &= 1 - 0.2 = 0.8 \\
 d &= \text{acceptable error} = 0.05 \\
 Z_{0.05} &= 1.96 \quad (\text{two tails}) \\
 n &= 1.96^2 (0.2) (0.8) / (0.05)^2 = 246 \text{ cases}
 \end{aligned}$$

For incomplete questionnaire dropouts, we should add 10 percent of sample size. There for total of 271 patients are required.

4.3 Method

- Prospective study of CT examination of the brain in patient presenting with clinical diagnosis of stroke from April 1, 2000 to November 30, 2000.
- CT scan of the brain was performed with informed consent.
- CT result was evaluated and reported by radiology resident in charge.
- Clinicians planned the treatment after CT result.
- Patient's condition was evaluated 2 weeks after CT examination to evaluate the validity of the treatment plan and before the patient is discharged from the hospital to evaluate patient outcome.
- Interobserver reliability of CT interpretation between radiology resident and neuroradiologist was randomly performed to assess the resident's capacity (every 5 cases).

4.4 Observation and Measurement

1. Independent variables

1.1 Patient

1.1.1 Clinical evaluation - patients with acute nontraumatic neurological deficit were clinically diagnosed as stroke by history taking, physical and neurological examination and also necessary laboratory tests.

1.1.2 Recording chart - the following informations were collected.

- Age, sex, hospital number, chief complaint, underlying disease, time from onset of symptom to CT examination, vital sign, neurological sign
- Preliminary diagnosis by clinician
- Reason that additional CECT was required for CT examination

1.2 CT machine and process of performing the images :

To make this step valid and reliable, we listed the step and procedure for performing CT scan as the followings

- We used new model 4th generation CT machine (General Electric Sytec 4000).
- The CT machine was calibrated every month.
- The images were performed using standard protocol for brain imaging as the followings.
 - axial plane parallel to an orbitomeatal line
 - 5 mm. interval through the posterior cranial fossa and 10 mm. interval through supratentorial compartment.
 - repeated study after intravenous injection of contrast media (300 mg. Iodine/ml) 50 ml., about 1 ml/kg body weight in case that CECT was requested.
 - CECT was not performed in case of impaired renal function and case of high risk to develop adverse reaction to contrast media.
 - for the CECT cases, gray scale quality of image was controlled by the same window and level.

1.3 Image interpretation

CT findings were evaluated by radiology resident. For criterion validity, we used standard criteria for diagnosis abnormality proved by many experts.^(4,9,22,23)

For reliability of image interpretation between radiology resident and neuroradiologist, Kappa - statistics was used to test inter - observer reliability (one every 5 cases) because the study will be preliminary interpreted by radiology residents.

2. Dependent variables

2.1 CT findings

2.2 Treatment plan of each individual guided by information from CT.

2.3 Patient outcome

4.5 Data Collection

All the results were recorded in the questionnaire (appendix I and II)

1. Administrative data - name, hospital number
2. Zero state variables - age, sex, time from the onset of symptom to CT examination
3. Outcome variables
 - Numbers of cases which CECT were requested and reasons that clinicians require CECT.
 - Patterns of CT findings in cases which CECT were requested.
 - Patterns of CT findings in cases which CECT were not requested.
 - Number of cases which treatment plan were guided by the result of CECT.
 - The patient's condition 2 weeks after CT examination.
 - The treatment plan after CT examination versus the actual treatment as validity check.
 - Status of the patients when the patient was discharged from the hospital, checking for outcome improvement due to the treatment guided by the CT result.

4.6 Data Analysis

1. Zero state variables were analyzed by descriptive statistics
 - age - mean and range
 - sex - proportion
 - time - mean and range

2. Outcome variables were analyzed by descriptive statistics as proportion of cases with treatment plan guided by result of CECT to total cases that CECT were requested by clinician in patient with clinical diagnosis of stroke.

4.7 Economic Evaluation

Cost identification:

Calculation of cost involved in the disease or medical care service including the followings:

1. Direct cost
 - direct medical cost
 - direct nonmedical cost
2. Indirect cost
3. Intangible cost

Only direct medical cost (cost of NECT and CECT) was analyzed for cost identification of these diagnostic tests. However, there were also intangible cost in this study that could not be analyzed. These were anxiety for risk of developing adverse reaction caused by contrast media and also uncomfortable feeling of the patient when adverse reaction happened.

The direct cost included labor cost, material cost, capital depreciation cost of CT study as the followings :

- | | |
|---------------------------|--|
| Labor cost | - radiologist, technician, clerk, worker |
| Material cost | - film & development solution (developer and fixer) envelope, contrast media, syringe & needles. |
| Capital depreciation cost | - CT machine, film processing machine, x-ray tube |

However, if adverse reaction to contrast media happened, cost of adverse reaction treatment was also included.

Cost effectiveness of CECT :

Cost effectiveness of CECT was calculated from cost effectiveness ratio as the following :

Total cost of CECT samples in this study divided by proportion of cases with treatment plan guided by result of CECT.

4.8 Ethical Consideration

Although this was an observational, descriptive study, the CT scans were performed with informed consent.

4.9 Limitation

No definite gold standard in diagnosis of the CT findings, only criterion validity and clinical course of the patient as well as follow – up outcome were used in this study.

Contrast enhanced CT scan was not performed in case of impaired renal function and in case of high risk for adverse reaction development.

4.10 Expected Benefit & Application

Decreased number of contrast enhanced CT scan as investigation for patient with clinical diagnosis of stroke will decrease the expenditure and also decrease risk of adverse reaction to contrast media.

4.11 Obstacles

Optimum time to evaluate patient outcome should be 3 months after treatment. However, evidence from previous stroke records showed that only a few cases can be followed up 3 months after treatment. To solve this problem, the patient outcome was evaluated by status of the patients when they were discharged from the hospital.

CHAPTER V

RESULTS

5.1 Characteristics of Patients

A total of 257 patients with clinical diagnosis of stroke that CT scans were requested for treatment plan in King Chulalongkorn Memorial Hospital during June 2000 to September 2001 were included in this study. Of these 257 patients, 132 were male and 125 were female with mean age about 64 years old (range from 46 to 91 year old) as shown on *Table 5.1*

The patients presented with acute neurological deficits with various symptom and sign as demonstrated on *Table 5.2* and duration of symptom before CT examination as demonstrated on *Table 5.3*

Stroke risks including diabetes mellitus, hypertension, cardiovascular disease, smoking, hyperlipidemia and previous CVA were detected in 239 cases (93%) as demonstrated on *Table 5.4*

5.2 Primary Outcome Analysis

Considering all cranial computed tomography required for patients with clinical diagnosis of stroke, what is the proportion that contrast enhanced computed tomography (CECT) essential for treatment planning ?

5.2.1 The preliminary clinical diagnosis.

All CT examinations were requested in emergency time by neurology resident in 164 cases (63.8 %), internal medicine resident who rotating to neurology in 89 cases (34.6 %) and neurosurgery resident in 4 cases (1.6 %)

The preliminary clinical diagnosis are demonstrated on *Table 5.5*

The confidence in clinical diagnosis were also evaluated in 243 cases as demonstrated on *Table 5.6* with mean about 87.5% (range from 20% to 100%).

5.2.2 Number of cases with CECT are requested.

The clinicians required only NECT scan for treatment in 79.8% of the cases (205/257). Only 52 cases (20.2%) that CECT were requested and in only 5 cases (9.6%) that treatment plan was changed. The 95% confident that CECT will be requested for patient with clinical diagnosis of stroke in this study falls between 15.2% and 24.9% (80% of stroke caused by infarction)^(5,6)

5.2.3 Patterns of CT findings

The results of CT scans were evaluated by radiology resident including 230 cases (89.5 %) by the first year residents, 24 cases (9.3 %) by the second year residents and 3 cases (1.2%) by the third year resident. The scans were reviewed by neuroradiologist in one every 5 cases. The interobserver reliability is about 0.89 using Kappa statistics.

The CT interpretations are demonstrated on **Table 5.7**. Pattern of contrast enhancement in cases with additional CECT were requested are demonstrated on **Table 5.8**

Samples of CT findings in group that only NECT were requested are demonstrated on **Figure 5.1- 5.6** and in group with additional CECT are demonstrated on **Figure 5.7-5.16**

5.2.4 Treatment planning and outcome of the patients.

The treatment planning and the actual treatment of two groups of these patients are demonstrated with the patient's condition at least 2 weeks after treatment on **Table 5.9, 5.10 and 5.11**.

In conclusion only 5 cases in 52 cases that CECT is essential for treatment planning. Details of these cases are demonstrated on **Table 5.12**.

Table 5.1 Age distribution of the patients

Age rang (years)	NO. of patients (%)
> 45 – 50	33 (12.8%)
51 – 60	72 (28%)
61 – 70	81 (31.5%)
71 – 80	48 (18.7%)
81 – 90	20 (7.8%)
> 90	3 (1.2%)
Total	257 (100%)

(mean 64 years old, SD 11.04 minimum 46 years old, maximum 91 years old)

Table 5.2 Characteristic of neurological deficits

Symptom & Sign	NO. of patients (%)	
	NECT	CECT
Focal neurological deficit	159 (77.6%)	39 (75%)
Severe headache	6 (2.9%)	2 (4%)
Nausea, vomiting	2 (1%)	1 (2%)
Alteration of conscious	30 (14.6%)	5 (9.5%)
Others (seizure, dysarthria, aphasia, vertigo, visual hallucination, stiffneck)	8 (3.9%)	5 (9.5%)
Total	205 (100%)	52 (100%)

Table 5.3 Duration of symptom before CT examination

Duration of symptom	NO. of patients (%)	
	NECT	CECT
Less than 1 day	137 (66.8%)	26 (50%)
Between 1 day – 3 days	44 (21.4%)	13 (25%)
Between 3 days – 7 days	18 (8.9%)	11 (21%)
Between 1 – 2 weeks	6 (2.9%)	2 (4%)
Total	205 (100%)	52 (100%)

Table 5.4 Detail of stroke risks

Risks	NO. of patients (%) *
Diabetes mellitus	66 (25.7%)
Hypertension	144 (56%)
Cardiovascular disease	28 (10.9%)
Smoking	17 (6.6%)
Hyperlipidemia	15 (5.8%)
Previous CVA	15 (5.8%)

* more than one risk are detected in some patients

Table 5.5 Preliminary clinical diagnosis

Diagnosis	NO. of patients (%)	
	NECT	CECT
Ischemic stroke	165 (80.5%)	37 (71%)
Hemorrhagic stroke	34 (16.6%)	9 (17%)
Indetermine	6 (2.9%)	6 (12%)
Total	205 (100%)	52 (100%)

Table 5.6 Confidence in diagnosis of clinicians

(no answer in 14 cases)

Percent of confidence in diagnosis	NO. of patients (%)
< 30	3 (1.2%)
31 – 40	0 (0%)
41 – 50	15 (6.2%)
51 – 60	7 (2.9%)
61 – 70	22 (9.1%)
71 – 80	42 (17.3%)
81 – 90	25 (10.3%)
91 – 100	129 (53%)
Total	243 (100%)

Table 5.7 CT imaging interpretation

CT Diagnosis	NO. of patients (%)	
	NECT	CECT
Normal	33 (16.1%)	9 (17.3%)
Ischemic infarct	129 (62.9%)	29 (55.8%)
Intracerebral hemorrhage	37 (18%)	10 (19.2%)
Intraventricular hemorrhage	*8	**3
Extracerebral hemorrhage	4 (2%)	2 (3.8%)
Others (NECT – post op. Rt. frontal lobe hematoma, CECT – AVM, mass)	1 (0.5%)	2 (3.8%)
Total	205 (100%)	52 (100%)

*** Associate with intracerebral hemorrhage in 7 cases**

**** Associate with intracerebral hemorrhage in 3 cases**

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Table 5.8 Pattern of contrast enhancement in cases with additional CECT were requested

Pattern of enhancement	NO. of patients (%)
No enhancement	45 (86.7%)
Ring or nodular enhancement	2 (3.8%)
Gyral enhancement	2 (3.8%)
Abnormal enhanced vessel	1 (1.9%)
Others (enhanced membrane)	2 (3.8%)
Total	52 (100%)

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5.3 Secondary Outcome Analysis

Reason that CECT is requested by clinicians ?

A total of 52 cases in 257 cases that additional CECT were requested due to the following reasons

- confirmed diagnosis of stroke	9 cases	(17.3%)
- to assess size, location and abnormal vessel	5 cases	(9.6%)
- to reassure patient or family	- cases	
- to exclude other disease	16 cases	(30.8%)
- to satisfy myself for legal purpose	- cases	

No answer for reason of the request in 22 cases (42.3%) including 16 cases of ischemic infarcts, 2 cases of intraparenchymal hemorrhage and normal CT in 4 cases.

5.4 Cost – effectiveness Analysis

Only direct cost of imaging procedure and effectiveness of the investigation were analyzed. The main outcome measurement in this analysis was cost per treatment plan that change from stroke to the other for patients with clinical diagnosis of stroke guided by CECT.

5.4.1 Cost – effectiveness ratio (Baht/one patient that treatment plan was changed by CECT) was analyzed by using.

$$\text{Cost – effectiveness ratio} = \frac{\text{cost of CECT}}{\text{Effectiveness of CECT}}$$

Cost of CT scan

- Nonenhanced CT scan including

Capital cost = 1,656 Baht

(CT machine, Automatic Film Processor, x-ray tube / case)

Labor cost = 408 Baht

(radiologist, technician, clerk, worker /case)

Material cost = 38 Baht

(film, developer, envelope/case)

$$\begin{aligned} \text{total cost} &= 1,656 + 408 + 38 \\ &= 2,102 \text{ Baht} \end{aligned}$$

- Contrast enhanced CT scan including

$$\text{Capital cost} = 2,106 \text{ Baht}$$

(CT machine, Automatic Film Processor, x-ray tube / case)

$$\text{Labor cost} = 408 \text{ Baht}$$

(radiologist, technician, clerk, worker /case)

$$\text{Material cost} = 270 \text{ Baht}$$

(film, developer, contrast media, syringe and needle, envelope / case)

$$\begin{aligned} \text{Total cost} &= 2,106 + 408 + 270 \\ &= 2,784 \text{ Baht / case} \end{aligned}$$

Effectiveness

Stroke patients who need CECT for treatment plan = 5 cases from 52 cases

$$\begin{aligned} \text{CEA of enhanced CT} &= \frac{2,784 \times 52}{5} = 29,000 \text{ Baht} \end{aligned}$$

5.4.2 Sensitivity analysis (varying the cost of contrast media)

In this study, there is moderate adverse reaction to contrast media happened in one case (angioedema with urticaria)

Adverse reaction to contrast media will be decreased if nonionic contrast media (low osmolarity contrast media) is used instead of ionic contrast media (high osmolarity contrast media). However the price of contrast media will increase up to 417 Baht/case. If the nonionic contrast media is used, cost /case will be 3,024 Baht

$$\begin{aligned} \text{CE of CECT} &= \frac{3,024 \times 52}{5} \\ &= 31,500 \text{ Baht} \end{aligned}$$

5.4.3 Opportunity Cost

If CECT is requested, more time will be need for the examination and other acutely illd patients that also need CT scan will loss opportunity for rapid life saving management. For example, time for CT brain in case of head injury.



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**Table 5.9 Treatment plan and actual treatment after
CT examination in group of NECT**

Actual treatment Treatment plan	Surgery because of hemorrhage	Treatment as non-stroke	Treatment as ischemic stroke					Total
			Thrombolysis	Surgical decompression	Close observation	Anticoagulant or antiplatelet	No information	
Surgery because of hemorrhage	9	-	-	-	15	-	6	30
Treatment as non-stroke	-	2	-	-	2	4	1	9
Treatment as ischemic stroke								
- Thrombolysis	-	-	-	-	-	-	-	-
- Surgical decompression	-	-	-	-	-	-	-	-
- Close observation	-	2	-	-	18	11	1	32
- Anticoagulant or antiplatelet	-	3	-	-	18	92	8	121
- No information	1	1	-	-	4	2	5	13
Total	10	8	-	-	57	109	21	205

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**Table 5.10 Treatment plan and actual treatment after
CT examination in group of CECT**

Treatment plan \ Actual treatment	Surgery because of hemorrhage	Treatment as non-stroke	Treatment as ischemic stroke					Total
			Thrombolysis	Surgical decompression	Close observation	Anticoagulant or antiplatelet	No information	
Surgery because of hemorrhage	4	-	-	-	3	-	3	10
Treatment as non-stroke	-	5	-	-	-	-	-	5
Treatment as ischemic stroke								
- Thrombolysis	-	-	-	-	-	-	-	-
- Surgical decompression	-	-	-	-	-	-	-	-
- Close observation	-	1	-	1	1	3	-	6
- Anticoagulant or antiplatelet	-	-	-	-	2	17	1	20
- No information	-	1	-	-	-	6	4	11
Total	4	7	-	1	6	26	8	52

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Table 5.11 Outcome of the patients after treatment

Status of the patients after treatment	NO. of patients (%)	
	NECT	CECT
Improvement	114 (55.6%)	27 (51.9%)
Stable	25 (12.2%)	7 (13.5%)
Death	22 (10.7%)	7 (13.5%)
Refer to other hospital	11 (5.4%)	3 (5.7%)
Loss follow up	33 (16%)	8 (15.4%)
Total	205 (100%)	52 (100%)

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Table 5.12 Details of cases that treatment plans were guided by CECT

No.	Sex	Age (year)	Symptom	NECT findings	CECT findings	Treatment	Outcome
1	male	63	Visual hallucination for 5 days	Abnormal mixed low and high density at left occipitoparietal lobe	Serpiginous enhancement of abnormal vessels with dilated left posterior cerebral artery	Surgery	Improve
2	female	48	Headache with focal neurological deficit for 1 week	Low density areas in left frontal lobe and pons with obstructive hydrocephalus	Ring enhancement around the lesions (about 2 cm in diameter) with surrounding brain edema	Surgery (Pathology – Squamous cell CA)	Refer
3	female	74	Underlying CA colon with focal neurological deficit and alteration of conscious for 4 day	Bilateral crescent shaped subdural collection at frontoparietal areas	No enhancement	Medical treatment for hepatic encephalopathy	Improve
4	female	72	Alteration of conscious with focal neurological deficit for 1 day (underlying CA lung)	Diffuse low density area at region of pons	No enhancement	Conservative treatment	Death
5	female	53	Severe headache, nausea vomiting and alteration of consciousness for 1 day (underlying mitral stenosis on coumadin)	Mixed iso and hyperdensity crescent shaped lesion at peripheral aspect of left frontotemporal area	Thin enhanced membrane of subdural collection	Surgery (burr hole) - remove subdural hematoma	Improve

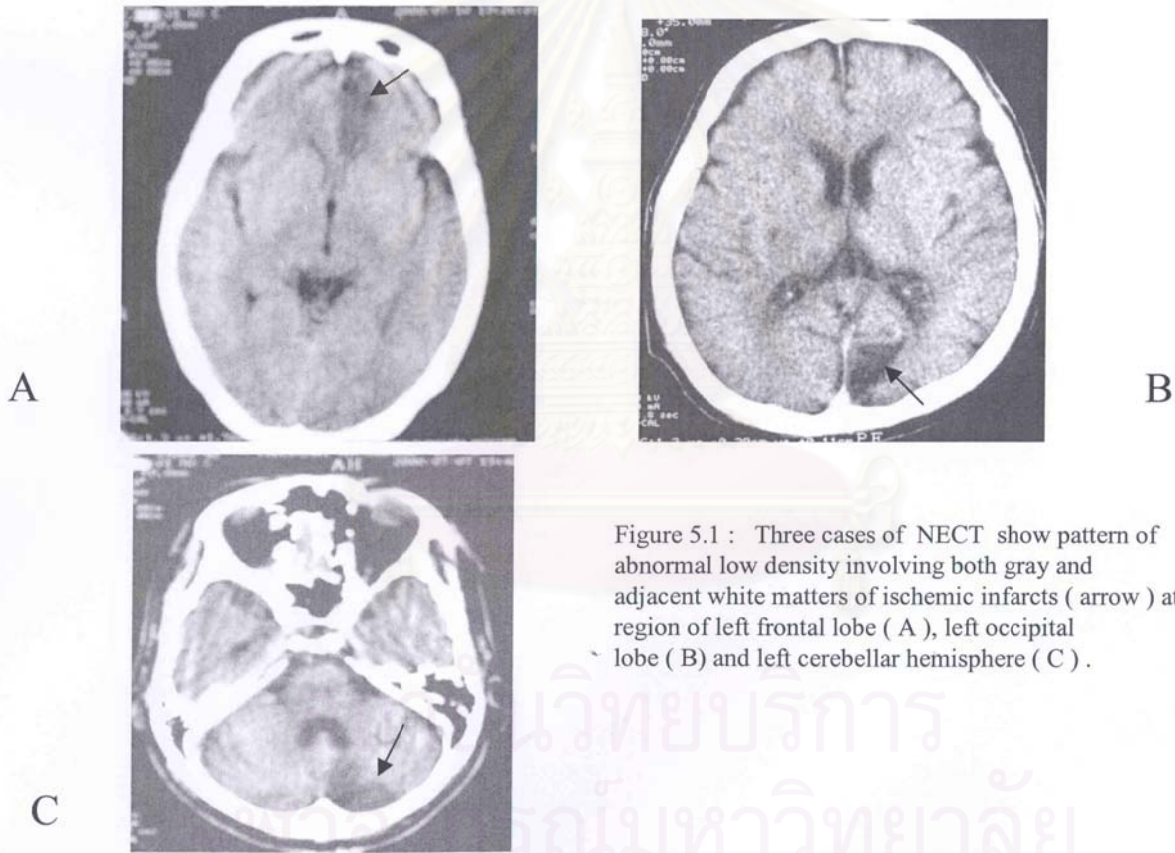
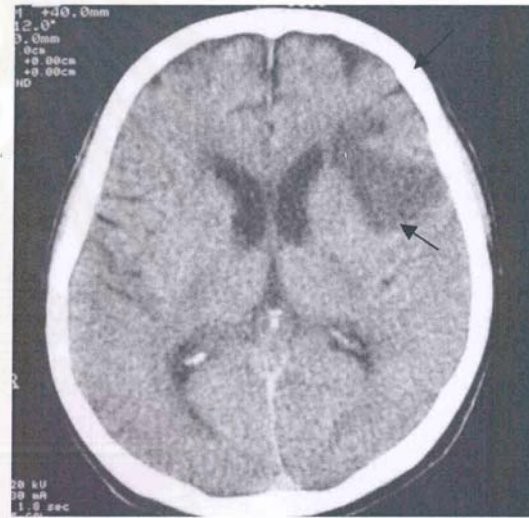


Figure 5.1 : Three cases of NECT show pattern of abnormal low density involving both gray and adjacent white matters of ischemic infarcts (arrow) at region of left frontal lobe (A), left occipital lobe (B) and left cerebellar hemisphere (C) .



A



B

Figure 5.2 : NECT scans in two cases reveal large areas of low density involving gray and white matters of right frontotemporal lobes, right insular lobe and also right basal ganglia with effacement of adjacent sulci and right sylvian fissure (A) and lesion involving left frontal lobe and left insular lobe (B) representing areas of ischemic infarcts caused by deminished blood flow in middle cerebral artery.

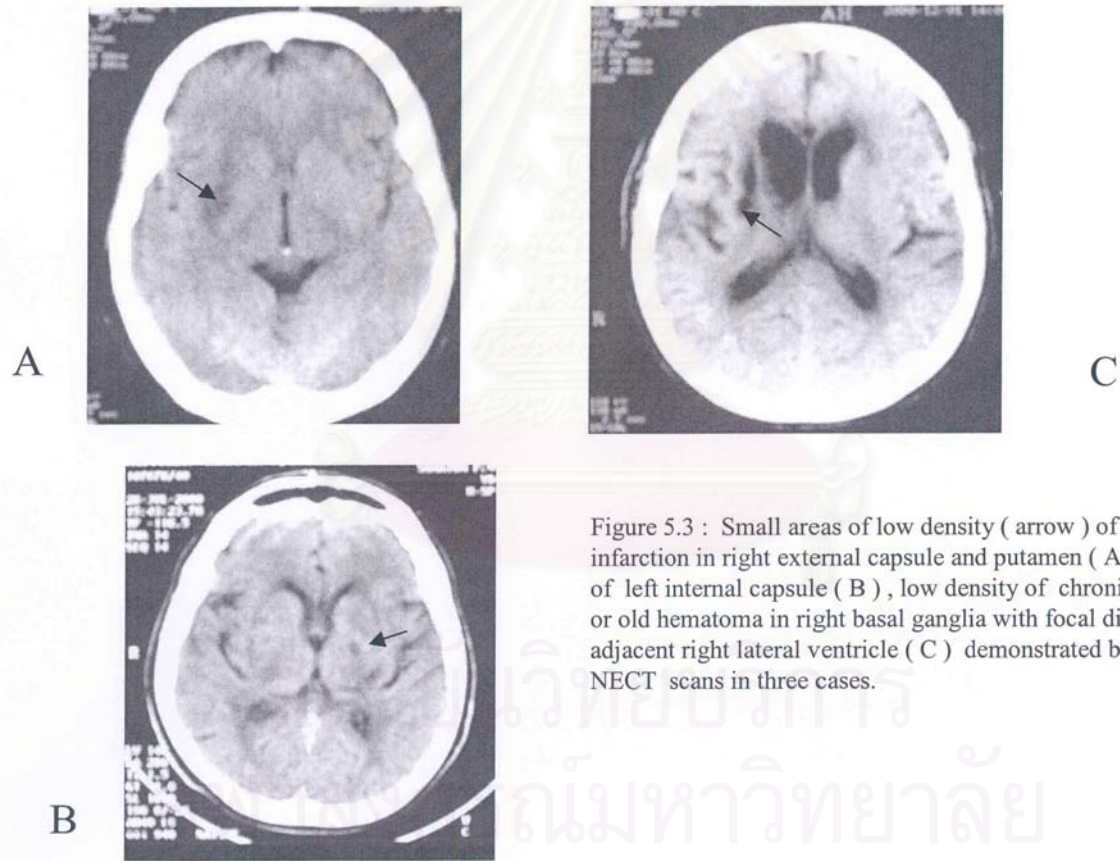


Figure 5.3 : Small areas of low density (arrow) of acute infarction in right external capsule and putamen (A), genu of left internal capsule (B), low density of chronic infarct or old hematoma in right basal ganglia with focal dilated adjacent right lateral ventricle (C) demonstrated by NECT scans in three cases.

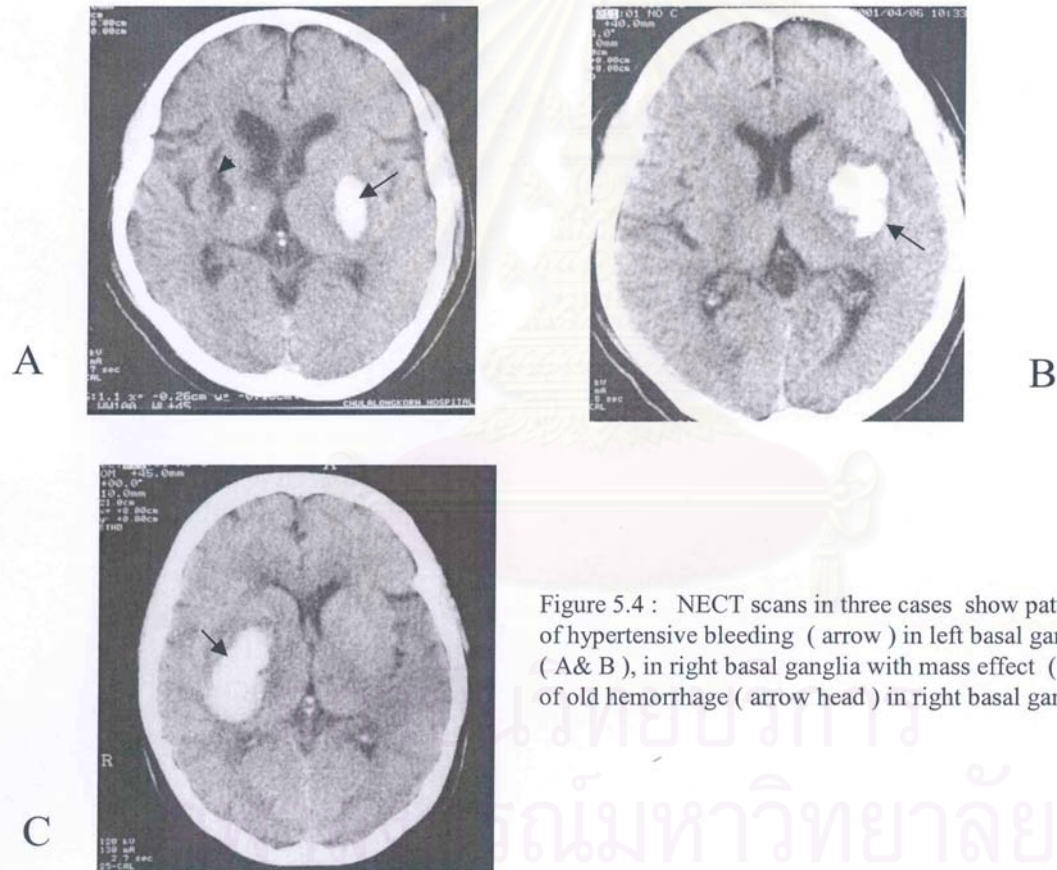


Figure 5.4 : NECT scans in three cases show pattern of hyperdensity of hypertensive bleeding (arrow) in left basal ganglia with mass effect (A& B), in right basal ganglia with mass effect (C) and low density of old hemorrhage (arrow head) in right basal ganglia (A).

A



B

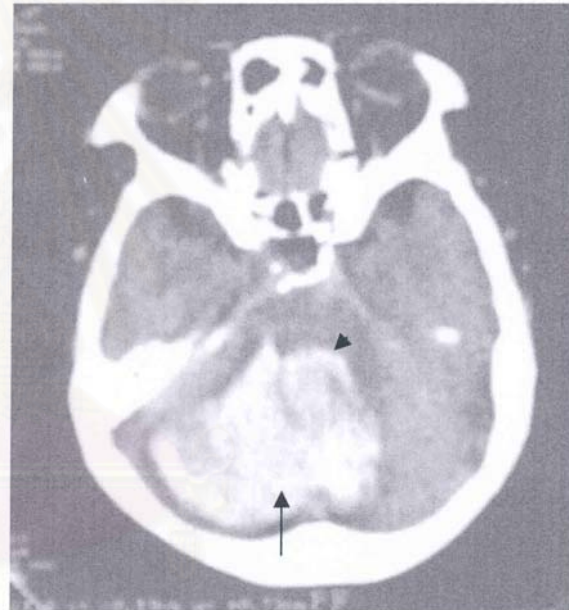


Figure 5.5 : NECT scans show small high density area of acute hemorrhage (arrow) in posterior aspect of pons on the right side (A) and massive bleeding in right cerebellar hemisphere with extension of bleeding (arrow head) into fourth ventricle (B) in cases of hypertensive bleeding.

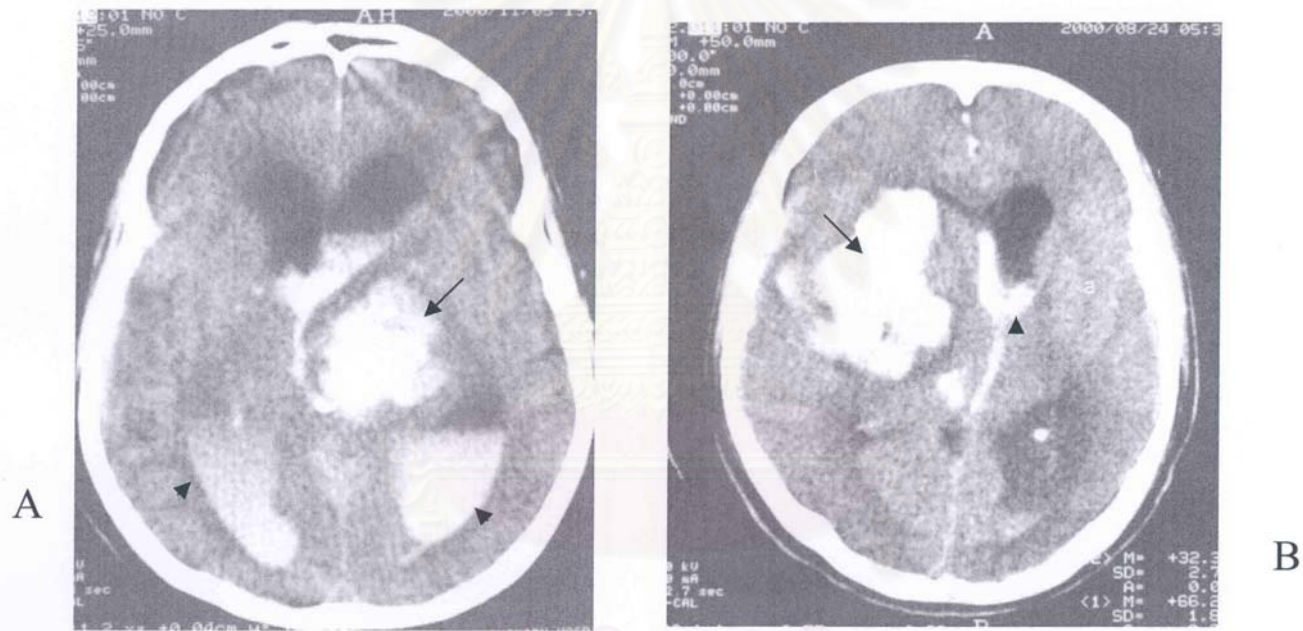
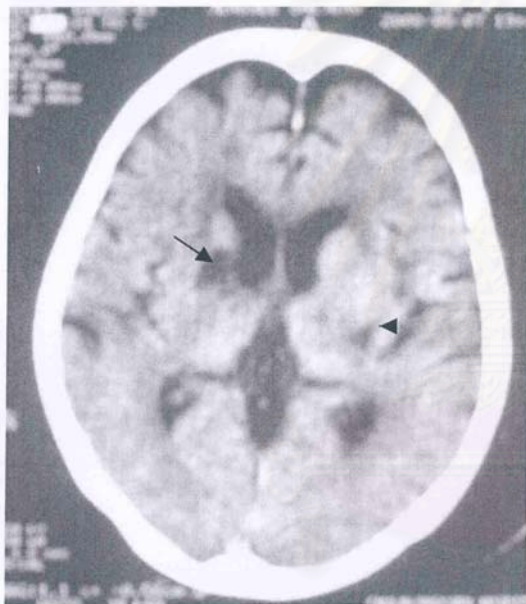


Figure 5.6 : NECT scans in two cases reveal large areas of acute hemorrhage (arrow) in left thalamus (A) and right basal ganglia (B) with extension of bleeding into dilated ventricular system (arrow head).

A



B



Figure 5.7 : NECT scan (A) shows low density areas of lacunar infarcts in anterior limb of right internal capsule (arrow) and posterior aspect of left external capsule (arrow head) without evidence of enhancement on CECT (B).

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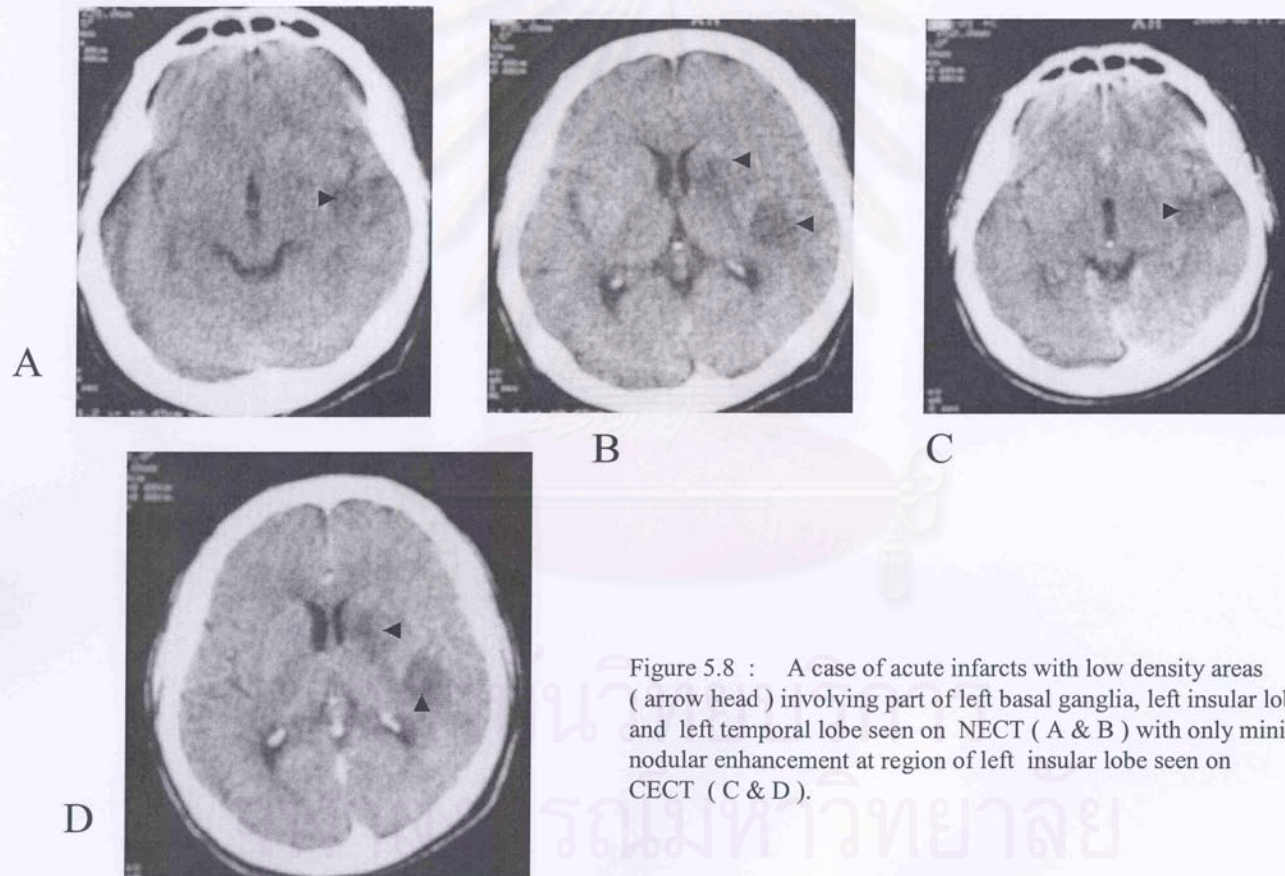


Figure 5.8 : A case of acute infarcts with low density areas (arrow head) involving part of left basal ganglia, left insular lobe and left temporal lobe seen on NECT (A & B) with only minimal nodular enhancement at region of left insular lobe seen on CECT (C & D).

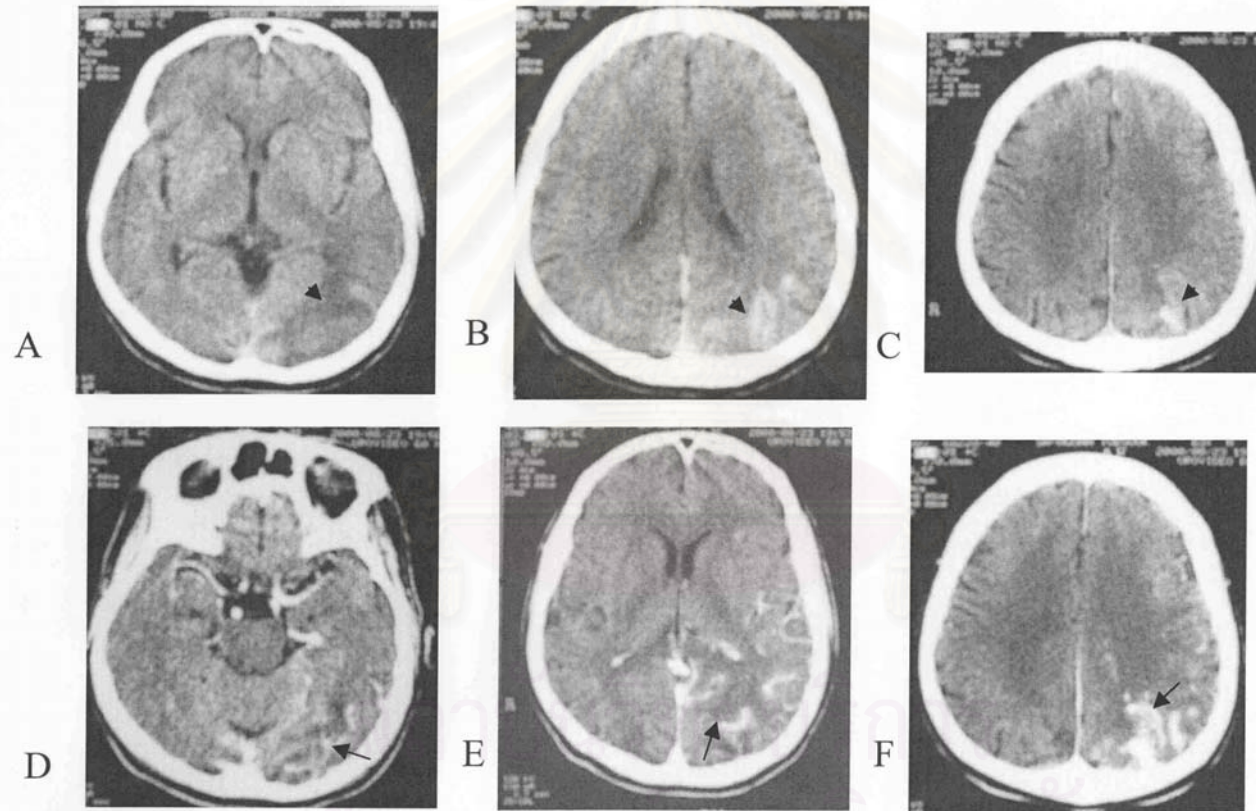


Figure 5.9 : A case of left occipital lobe arteriovenous malformation (AVM) with inhomogeneous low density in left occipital lobe and tubular area of high density in adjacent left parietal lobe (arrow head) seen on NECT (A,B, C). Serpiginous enhancement of abnormal vessels with dilated left posterior cerebral artery are demonstrated (arrow) on CECT (D, E, F) .

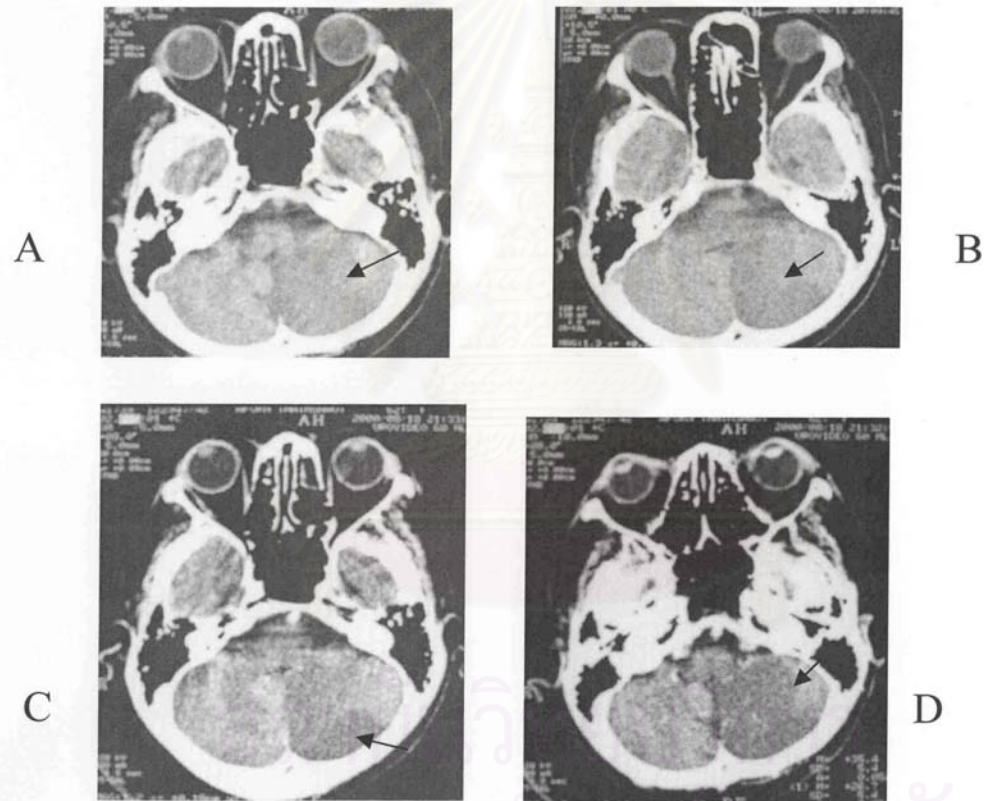


Figure 5.10 : Low density area of acute infarct (arrow) in posteromedial aspect of left cerebellar hemisphere is demonstrated on NECT (A & B) without abnormal enhancement of this lesion on CECT (C & D).

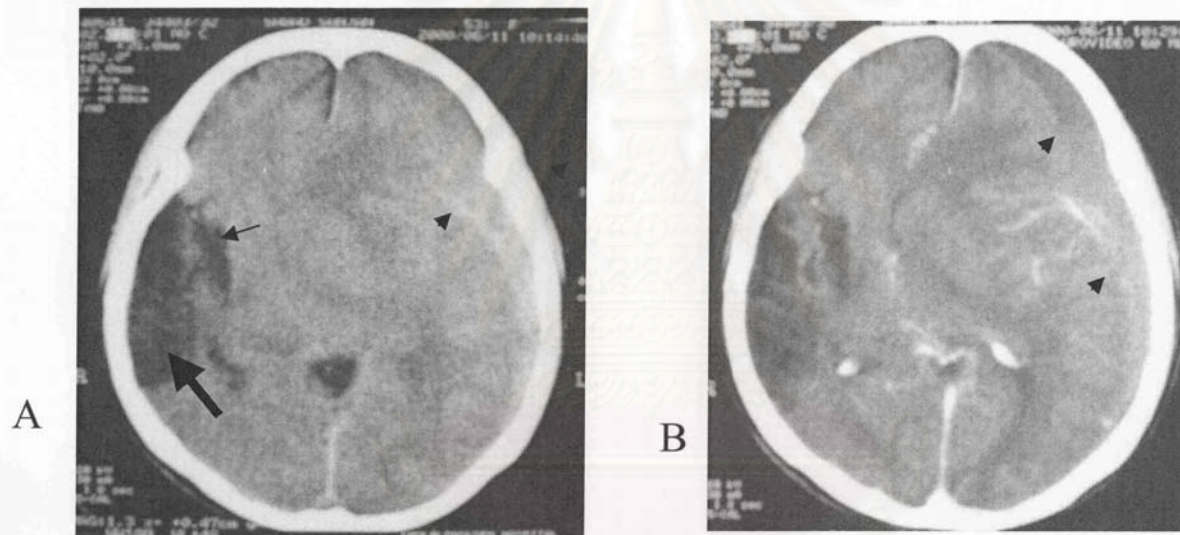


Figure 5.11 : NECT shows subdural hematoma over left frontotemporal area (arrow head) causing marked displacement of midline structures to the right (A). The hematoma is well separated from adjacent brain by thin enhanced membrane (arrow head) on CECT (B). Low density area of old infarct is also noted in right temporal lobe (large arrow) and also possibly low density area of old hemorrhage (small arrow) in right external capsule .

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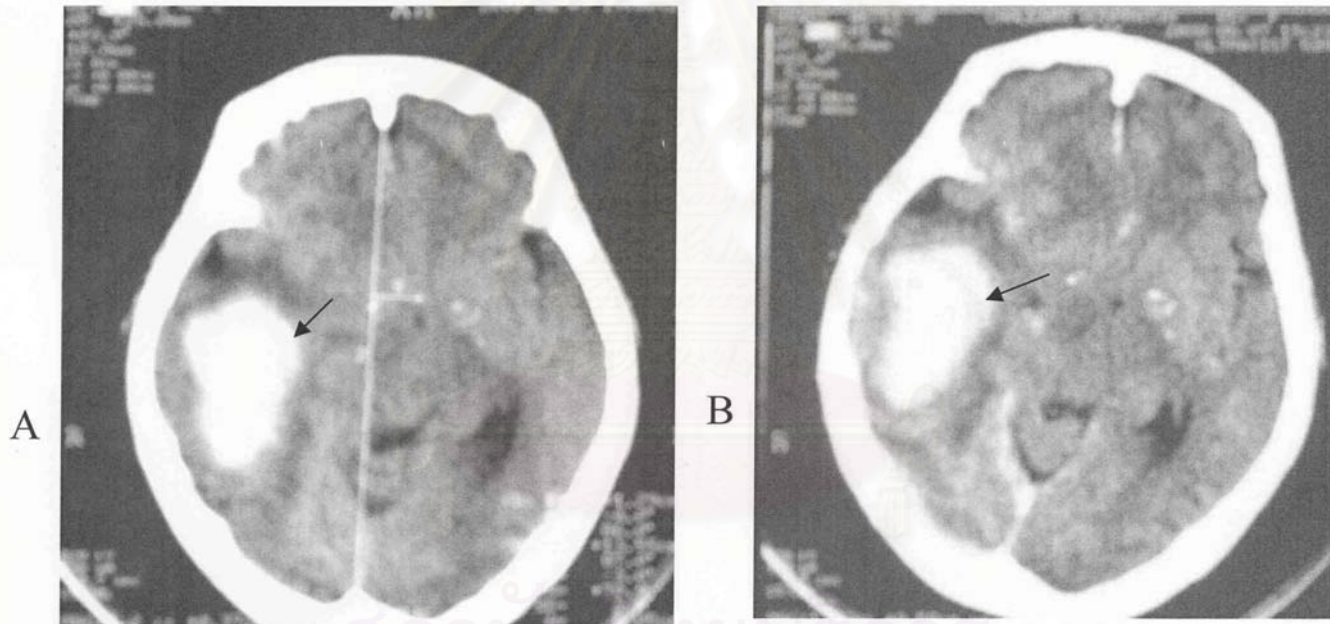
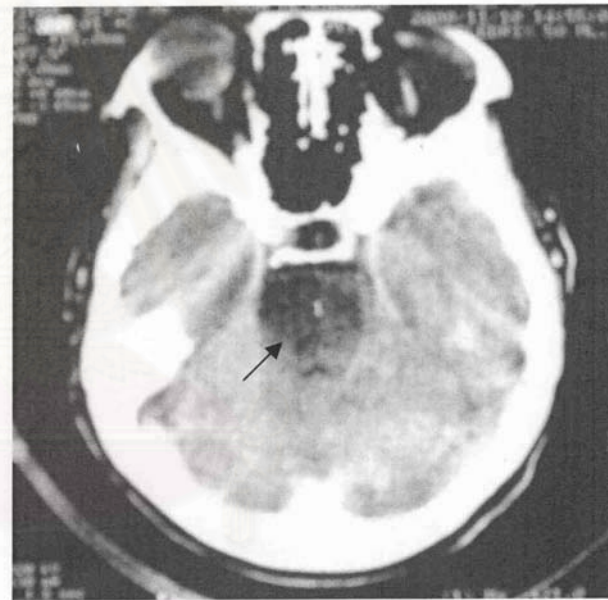


Figure 5.12 : NECT shows area of acute hemorrhage (arrow) in the right temporal lobe (A) without abnormal enhancement on CECT (B)

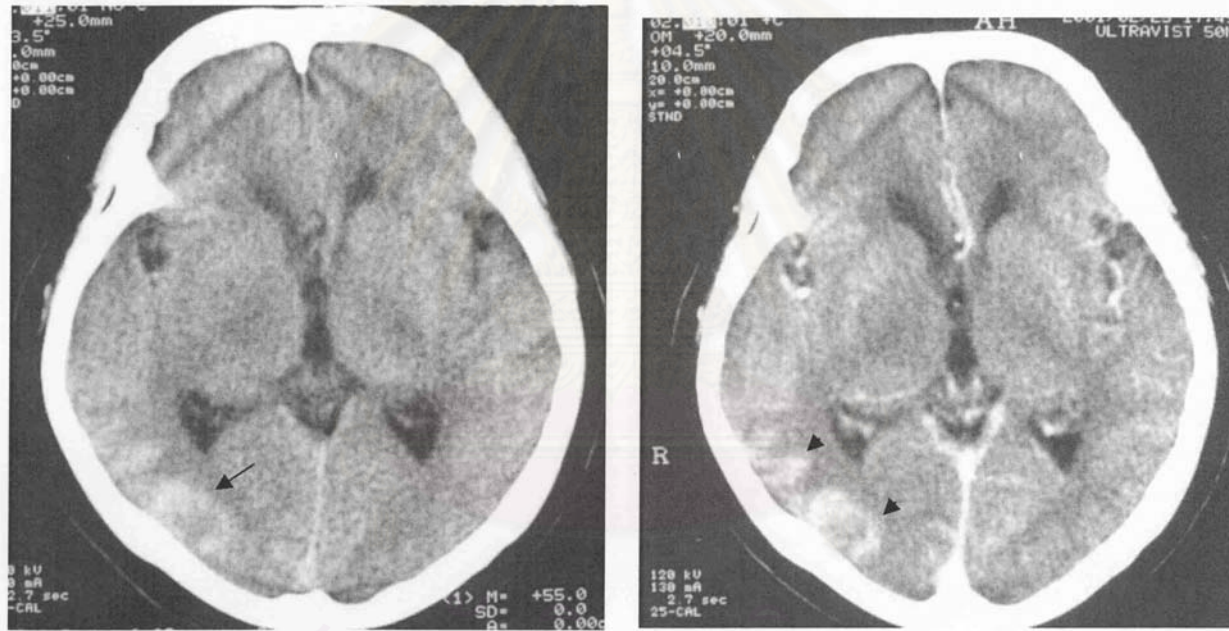


A



B

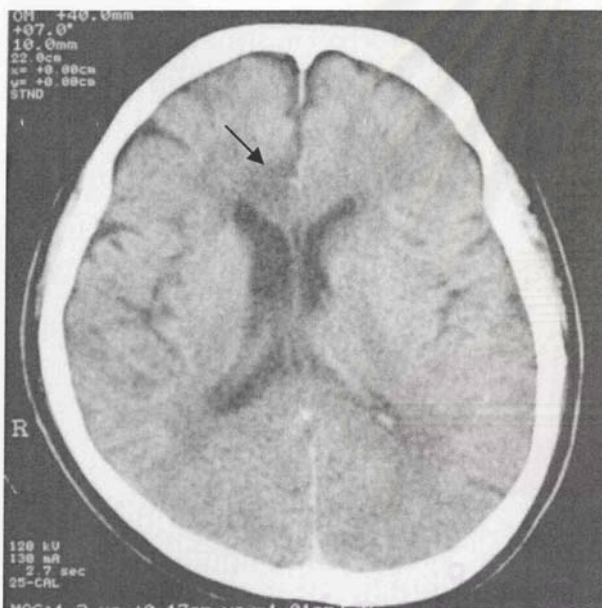
Figure 5.13 : Diffuse low density in the pons due to ischemic infarct (arrow) is seen on NECT (A) without enhancement of this lesion on CECT (B).



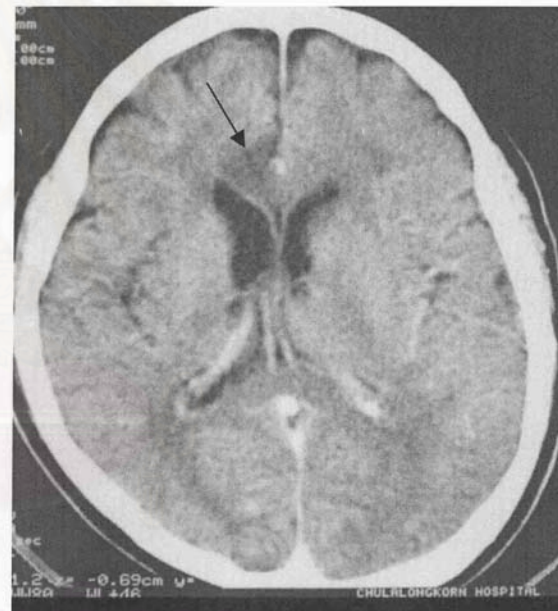
A

B

Figure 5.14 : Area of hemorrhagic infarct in right temporo-occipital lobe (arrow) is noted on NECT (A) with gyral enhancement (arrow head) demonstrated on CECT (B).

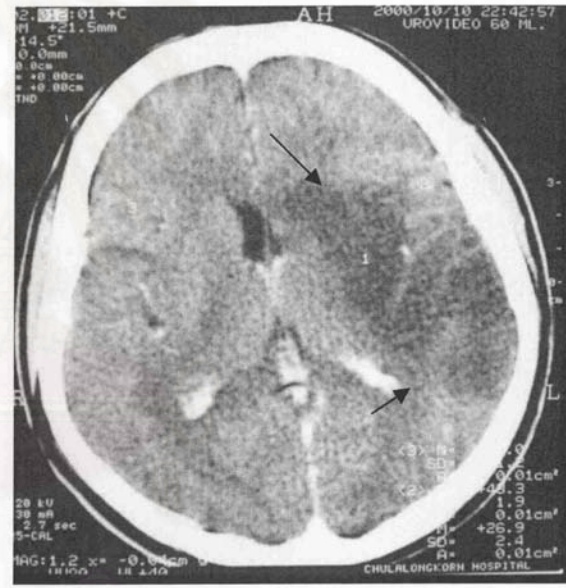
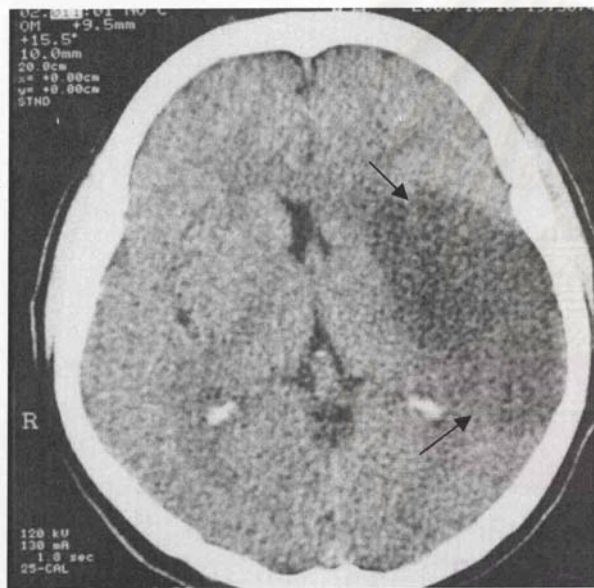


A



B

Figure 5.15 : NECT reveals a small area of ischemic infarct (arrow) at medial aspect of right frontal lobe (A) without abnormal enhancement of this area on CECT (B).



A

B

Figure 5.16: Large area of low density involving both gray and white matters due to ischemic infarct in basal ganglia, external capsule, insular lobe and temporal lobe on the left side (arrow) is demonstrated on NECT (A) without abnormal enhancement on CECT (B) .

CHAPTER VI

DISCUSSION AND CONCLUSION

6.1 Discussion and Conclusion

Technology assessment includes the evaluation of the safety, effectiveness, efficiency and appropriateness of devices, medical and surgical procedures and pharmaceuticals promoted as improving a patient's condition or quality of life.

As physicians, our primary commitment is to provide excellent care to our individual patients. However, as responsible members of our societies, we want to spend the available funds in the most effective fashion. It is in decision making by individual physicians about individual patients that the biomedical and economic considerations of clinical practice come together.

Since the resource has been used, the opportunity to use it for another purpose is lost. Therefore, its value in another use, which is no longer possible, is called its "opportunity cost"

Even if a type of medical care can work in an idealized setting, it may not be effective in a real-life setting, perhaps because of side effects of the drug, its cost, or other problems leading to poor compliance.

Stroke is one of the most resource – demanding disease in health care. The cost of illness may be divided into direct and indirect costs. The direct costs for stroke are those generated by diagnosis, treatment and rehabilitation, while the indirect costs are those caused by production loss due to sick leave, early retirement and premature death.

Classically, the diagnosis of stroke has been and remains, primary a clinical one, such as the acute onset of a neurological deficit. For an experienced clinician the patient history and clinical examination soon leads to a probable diagnosis which, in more than 90 percent of cases, is eventually confirmed by the course of the disease.

The primary goals of stroke treatment are to minimize the extent of cell damage in the brain and to improved blood flow, if obstructed.

Recent advances in a number of imaging techniques have allowed more sensitive and specific means for documenting cerebral ischemia. The development of therapies for limiting or reversing cerebral ischemia has provided the impetus for a change in the role of imaging cerebral ischemia.

The purpose of imaging in patient suspected of having a stroke has evolved from primarily documenting the presence of infarction (and distinguishing it from nonischemic causes of a neurologic deficit) to making the distinction between tissue that is irreversibly injured (infarcted) and tissue that is reversibly impaired (purely ischemia)

The major techniques in use for the evaluation of hyperacute stroke are computed tomography (CT) and magnetic resonance (MR) imaging. Generally speaking, conventional CT is substantially less sensitive than MR imaging for the detection of hyperacute stroke. In many instances, findings indicating infarction will not be seen clearly until late in the first 24 hours after the onset of ischemia.

CT scan is more available than MRI in emergency department in Thailand. CT scanning is motivated in patients with suspected stroke who, because of advanced age, are not candidates for more active treatment if the onset is unclear.

Access to CT scanning is also necessary for optimal treatment planning. This is particularly important in anticoagulant treatment when intracerebral hemorrhage needs to be ruled out.

Remembering that clinical strokes can be caused by many disease processes, only one of which is infarction. The role of conventional CT in such condition is to rule out mimicking condition such as hypertensive hemorrhage and bleeding related to conditions such as amyloid angiopathy, vascular malformations and tumors. Thus the role of CT in the hyperacute (eg. emergency department) setting is limited. Infact most CT scans in the hyperacute phase of infarction are negative. Thus, the finding of a negative CT in a patient with an acute neurological deficit is highly suggestive of acute infarction. However, a number

of findings on nonenhanced CT images can be used to facilitate earlier diagnosis. These findings include decreased attenuation of gray matter structures, tissue swelling and increased attenuation of the thrombosed arteries.

Among the forms of hypoattenuation of gray matter structures that can be seen are blurring of the basal ganglia, decreased attenuation of the insular cortex and blurring of the gray white matter junction caused by cortical cytotoxic edema. Hypoattenuation and blurring of these structures primarily results from ischemia within the territory of middle cerebral artery.

Infarct, it is the combination of cytotoxic and vasogenic edema that gives the typical appearance of the large vessel infarction, that is parenchymal hypoattenuation involving gray and white matter extending to the periphery in a wedge – shaped pattern.

Classic gyral enhancement is seen in 100% of cortical infarcts that are 1 to 2 weeks old, however it can be seen as early as several days post ictus. Other enhancement patterns, including homogeneous and ring enhancement also can be observed.

CT has two disadvantages with regard to diagnosing stroke. It does not provide evidence about the extent of a cerebral infarction until several days following the acute onset. The other disadvantage is that CT cannot clearly image infarction in brain stem because of its proximity to bone tissue. The most important positive feature is that CT can quickly identify hemorrhage.

In addition to dismissing the presence of other conditions, CT provides further essential information. In case of hemorrhage, CT can determine size, position, influence of surrounding tissue, and flow into ventricles. In cases of cerebral infarction, CT may provide clues on the underlying mechanism. Multiple infarctions suggest cardiac embolism while central localization may suggest lacunar infarct.

Contrast agents using for CT imaging include iodinated compounds for intravenous administration. All currently used water soluble contrast media are derivatives of triiodobenzoic acid.

Contrast agent toxicity can be divided into three general categories : 1. idiosyncratic (or anaphylactic), 2. dose dependent or chemotoxic and 3. organ specific. There are various risk factors that have been shown to increase the likelihood that a patient will have idiosyncratic reaction. These include a history of a prior reaction, cardiovascular disease, age greater than sixty years or less than one year, anxiety and a significant allergic or asthmatic history.⁽²⁴⁾

Concerning chemotoxicity, there is a direct relationship between the osmolality of the contrast agent and its toxicity. For this reason, nonionic contrast agents are significantly less neurotoxic than ionic agents, whether given intrathecally or intravenously.

The contrast agents have a chemotoxic action in addition to the osmotic damage. The enhancement of brain in the pathologic state depends upon the abnormal permeability of the blood – brain barrier. However, this leakage of a chemotoxic agent into areas of neuronal tissue that may be tenuously surviving can have a potentially deleterious effect on the tissue and thus on the clinical outcome. A retrospective study suggested that patients receiving contrast administration after cerebral infarction may have a worse prognosis.⁽⁴⁾

Contrast media are also known to have direct effect on the renal tubules. In patients with a preinfusion serum creatinine of greater than 4.5 or in diabetic patients with abnormal serum creatinine, the risk of nephrotoxicity is ranging from 31% to 87% for 43 gram of iodine.⁽²⁵⁾

Additional risk factors for kidney damage include multiple myeloma (due to precipitation of proteins in the renal tubules), sepsis, congestive heart failure, small infants, dehydration and concomitant administration of other chemotoxic drugs such as aminoglycoside antibiotics and certain chemotherapeutic agents. In randomized controlled human trials, there have been no substantial differences in nephrotoxicity between low and high osmolar contrast media.⁽²⁶⁾

The nonionic contrast agents have been shown to have a significant lower overall incidence of severe reaction.⁽²⁴⁾ However, using a nonionic agent does not guarantee that a severe reaction will not occur.

In fact, with the advent of widespread low-osmolar contrast media, there has not been a dramatic fall in the reported incidence of contrast media related death.⁽²⁴⁾

Perhaps the most important management of contrast agent reactions involves their prevention. This involves judicious decision making on the physician's part to ensure that contrast administration will provide additional information necessary for the patient's management and treatment.

Results from this study show that CECT were requested in 20.2% (52/257 cases). Only 9.6 % (5/52 cases) of this group of patients that treatment was guided by result of CECT and cost of CT scan per case that treatment was guided by CECT (cost effectiveness) is about 29,000 Baht. If adverse reaction to contrast media happens, there is additional cost for treatment of allergic reaction to contrast media. In this study, moderate adverse reaction to contrast media developed in one case which was treated by intravenous antihistamine and dexamethasone. The incidence of moderate adverse reaction is about 0.5% - 1% for high osmolarity contrast media and probably one fourth of this incidence for low osmolarity contrast media.⁽²⁴⁾ By using cost of the contrast agents in the sensitivity analysis, the cost of CT scan per case that treatment was guided by CECT (cost effectiveness) will increase up to 31,500 Baht if nonionic contrast media is used instead of ionic contrast media due to awareness of adverse reaction to contrast media. At present time and also in the future, the cost per clinically stroke case whose treatment plan is guided by CECT will increase if we consider about capital cost of CT machine. Nowadays the price of CT machine increases (about 5 times more than the old one) due to more advance in technology and facility of the machine. The cost per clinically stroke case whose treatment plan is guided by CECT even more increases if both new CT machine and nonionic CM are used. In busy emergency department such as in King Chulalongkorn Memorial Hospital, not only stroke patients that require CT study, other emergency condition such as trauma also needs CT study. The time for scanning will increase if additional enhanced scan is required. This is the additional cost that we need to concern. Two common reasons for requirement of CECT are to exclude other diseases such as tumor, infection, extracerebral collect and to assess size, location of the lesion including visualization of abnormal vessel. In this study, there is no evidence of

enhancement in up to 86.5 % of the cases. Only three cases show patterns of enhancement typical for arteriovenous malformation, parenchymal mass and membrane of subdural hematoma.

Requirement of knowledge to diagnose stroke patient is essential in judgment of treatment plan. In this study nearly whole clinicians are 2nd year residents and most of them are neurology resident (63.8 %). The others are internal medicine residents (34.6%) and neurosurgery residents (1.6%). Only NECT were required by neurology resident in 64.8% (133/205 cases). Overall confidence in clinical diagnosis of the residents is rather high (mean 87.5 %)

Abnormal CT findings in ischemic infarction and hypertensive bleedings are different and rather typical for radiologist in diagnosis of these diseases and interobserver reliability in this study is about 0.89 using Kappa statistics. The pattern of disagree interpretation is small area of infarction. The common CT patterns in this study demonstrated by NECT are areas of low density that specific for diminished blood flow in specific vessel or small areas of lacunar infarct in 61.5%, intracerebral hemorrhage in the typical location for hypertensive hemorrhage in 18.3% and no focal lesion in 16.3%.

6.2 Conclusion

In conclusion, only 20.2% of patient with clinical diagnosis of stroke (age more than 45 years old) required CECT for treatment planning by clinicians. In this group of patients (52 cases) only 9.6% that treatment plan was changed.

6.3 Recommendations

When reviewing the CT scan of potential stroke patients in aging (more than 45 years old), the radiologist should systematically answer several questions that determine the patient's medical management. Can the cause of the neurological problem be identified on the scan? Are the findings on NECT consistent with an acute infarct as correlate with clinical information? The results from this study reveal that if the imaging findings demonstrated by NECT are area of low density that specific for diminished blood flow in the specific vessels or small areas of lacunar infarct or intracerebral hemorrhage in the typical location for

hypertensive hemorrhage or negative finding, only NECT is necessary for treatment planning. Many neurological disorders can mimic an acute infarct, including tumors, subdural hematomas, hemorrhage from underlying masses or vascular malformations. These diagnoses can often be excluded on NECT that require experience in clinical diagnosis and experience in CT interpretation. However confirmation of these diagnoses need CECT.



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APPENDICES

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APPENDIX I

CT ordering form for patient presenting with stroke

Part I Pre CT questionnaire form

Patient Name.....Sex ₁ M ₂ F Age yrs HN ward.....

Onset of symptom DD / HH / MM

- Chief complaint
- 1 focal neurological deficit
 - 2 severe headache
 - 3 nausea, vomiting
 - 4 alteration of conscious
 - 5 other (specify.....)

Stroke risk factor ₁ yes ₀ No (specify.....)

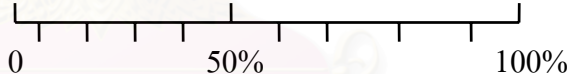
Vital sign : BP..... mm. Hg, PR...../ min., RR...../ min.

Localizing sign : ₁ yes ₀ No

What is your preliminary diagnosis ?

- 1 Ischemic stroke
- 2 Hemorrhagic stroke
- 3 Other (specify)

Confidence of your diagnosis



Part II post NECT result treatment plan

Please review your treatment plan with additional CT result, how would your plan be now ?

- 1 consult neurosurgery because of hemorrhage
- 2 appropriate consultation and treatment because CT finding shows disease which is non-stroke.
- 3 treatment as ischemic stroke

If you choose number 3, which treatment are you going to give the patient

- 3.1 thrombolytics
- 3.2 surgical decompression
- 3.3 close observation
- 3.4 anticoagulant
- 3.5 anti platelet

Part III : If CECT is requested

Is a primary purpose for requesting CECT :

- 1 to confirm diagnosis of stroke ?
- 2 to assess size, location, abnormal vessel, etc ?
- 3 to reassure patient or family ?
- 4 to exclude other disease such as tumor, infection, extracerebral collection, etc ?
- 5 to satisfy myself for legal purpose ?

Please review your treatment plan with additional CECT result, how would your plan be now ?

- 1 consult neurosurgery because of hemorrhage
- 2 appropriate consultation and treatment because of non - stroke by CT finding
- 3 treatment as ischemic stroke
 - 3.1 thrombolytics
 - 3.2 surgical decompression
 - 3.3 close observation
 - 3.4 anticoagulant
 - 3.5 antiplatelet

Your name.....Experience after M.D. graduate yrs.

- 1 Staff 2 Resident I II III

Specialty 1 Neurosurgery 2 Neurology 3 other (specify.....)

Date YY / MM / DD Time AM. PM.

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APPENDIX II

CT report of patients with clinical diagnosis as stroke

Patient Name.....Sex ₁ M ₂ F Age yrs HN ward.....

CT findings 1. Normal 2. Probably normal 3 Probably abnormal 4 abnormal

If 3 or 4 is checked, go further

Characteristic of lesion

Density : 1 Hypodense 2 Isodense 3 Hyperdense
 4 mixed with calcification
 5 mixed without calcification
 6 calcification alone

Mass effect :

1 nonvisualized
 2 ventricular distortion
 3 ventricular displacement
 4 effaced sulci
 5 effaced cistern

Brain swelling 1 absent 2 Probably present 3 Present

Hydrocephalus 1 absent 2 Probably present 3 Present

Localization of lesion (s) if CT finding suggest ischemic infarct

1 area fed by anterior cerebral artery
 2 area fed by middle cerebral artery
 3 area fed by posterior cerebral artery
 4 area fed by posterior circulation
 5 area specific for lacunar infarct
 6 area specific for watershed infarct
 7 area specific for venous infarct

Localization of lesion (s) if CT finding suggest hemorrhage

1 intraparenchyma
 2 intraventricular
 3 subarachnoid
 4 other.....

Localization of lesion (s) if CT finding suggest others.

1 Frontal 1 Lt 2 Rt
 2 Parietal 1 Lt 2 Rt
 3 Temporal 1 Lt 2 Rt

- 4 Occipital 1 Lt 2 Rt
 5 Basal ganglia 1 Lt 2 Rt
 6 Thalamus 1 Lt 2 Rt
 7 Brain stem 1 Lt 2 Rt
 8 Cerebellum 1 Lt 2 Rt
 9 Other (Specify.....)

Number of lesion (s) 1 single 2 multiple

Enhancement 1 Yes 0 No

If "yes" what type of enhancement it is ?

- 1 Homogeneous
 1 nodular 2 Diffuse
 2 Heterogenous
 1 Mutiple nodular 2 Ring shaped
 3 Tubular serpiginous 4 mixed

Information from abnormal enhancement confirmed diagnosis of infarction
 changed diagnosis to others.

Radiological Diagnosis

- 1 normal
 2 ischemic infarct
 3 lacunar infarct
 4 watershed infarct
 5 venous infarct
 6 intracerebral hemorrhage
 7 intraventricular hemorrhage
 8 extracerebral hemorrhage (specify.....)
 9 other (specify.....)

Radiologist Name

- 1 Staff 2 Resident I II III

Date YY / MM / DD Time AM. PM.

APPENDIX III

Informed Consent



โรงพยาบาลจุฬาลงกรณ์ สภากาชาดไทย
หนังสือยินยอมทำการตรวจพิเศษหรือรักษาทางรังสีวิทยา

นาย/นาง/น.ส./ด.ช./ค.ญ.....อายุ.....ปี HN.....
ประจำเดือนครั้งสุดท้าย (G.M.P.).....

หนังสือฉบับนี้เป็นหลักฐานแสดงว่าข้าพเจ้า.....

ได้ยินยอมด้วยความเต็มใจที่จะรับการตรวจหรือรักษา :

- เอกซเรย์พิเศษด้วยการฉีดสารทึบรังสี
- เอกซเรย์คอมพิวเตอร์รวมทั้งการใช้สารทึบรังสี
- การตรวจและรักษาทางเวชศาสตร์นิวเคลียร์ โดยการใช้สารกัมมันตรังสี
- คลื่นสะท้อนในสนามแม่เหล็ก (MRI) รวมทั้งการฉีดสารเพื่อแยกความต่างของความเข้มในภาพ (Contrast medium)
- การตรวจและรักษาทาง Interventional Radiology
- การรักษาด้วยรังสี และ/หรือ เคมีบำบัด

ข้าพเจ้าขอรับรองว่าไม่ได้อยู่ระหว่างการตั้งครรภ์

ข้าพเจ้าขอสัญญาว่า ข้าพเจ้าก็ดีหรือผู้แทนของข้าพเจ้าก็ดี ได้รับทราบข้อมูลของการตรวจหรือรักษา รวมทั้งผลแทรกซ้อนอันอาจเกิดขึ้น ไม่ว่าจะด้วยเหตุผลประการใด จะไม่ฟ้องร้องในผล อันพึงเกิดเป็นผลตรงข้าม อันเป็นเหตุสุดวิสัย ซึ่งอาจจะเกิดขึ้นจากการตรวจหรือการรักษานี้

ลงชื่อ.....ผู้ป่วย.....ลงชื่อ.....ผู้ปกครอง.....
(.....) (.....)

หรือ

ลงชื่อ.....พยาน.....ลงชื่อ.....พยาน.....
(.....) (.....)

วัน.....เดือน.....พ.ศ.....

(แบบพิมพ์หมายเลข SR42)

APPENDIX IV

Detail of Unit Cost of Nonenhanced CT (NECT)

1. Capital cost including

1.1 CT machine including maintenance / case

= 1,158 Baht

1.2 Automatic Film Processor including maintenance / case

= 48 Baht

1.3 X-ray tube / case = 450 Baht

Total capital cost = 1,656 Baht

2. Labor cost including

2.1 Radiologist / case = 63 Baht

2.2 Technician / case = 109 Baht

2.3 Clerk / case = 63 Baht

2.4 Worker / case = 47 Baht

Total labor cost = 282 Baht

3. Material cost including

3.1 Film / case = 25 Baht

3.2 Developer / case = 8 Baht

3.3 Envelope / case = 5 Baht

Total material cost = 38 Baht*

* Electricity and water supplying x-ray tube are not included

APPENDIX V

Detail of Unit Cost of Contrast Enhanced CT (CECT)

1. Capital cost including

1.1 CT machine including maintenance / case

= 1,158 Baht

1.2 Automatic Film Processor including maintenance / case

= 48 Baht

1.3 X-ray tube / case = 900 Baht

Total capital cost = 2,106 Baht

2. Labor cost including

2.1 Radiologist / case = 186 Baht

2.2 Technician / case = 110 Baht

2.3 Clerk / case = 64 Baht

2.4 Worker / case = 48 Baht

Total labor cost = 408 Baht

3. Material cost including

3.1 Film / case = 50 Baht

3.2 Developer / case = 16 Baht

3.3 Envelope / case = 5 Baht

3.4 Syringe & needle / case = 22 Baht

* 3.5 Contrast Media (ionic compound) = 177 Baht

Total material cost = 270 Baht**

* Contrast Media (nonionic compound) = 417 Baht

Total material cost = 510 Baht**

** Electricity and water supplying x-ray tube are not included

APPENDIX VI

**Detail of interobserver reliability evaluation for CT interpretation
using Kappa Statistics**

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
CTDX * CONFIRM	51	100.0%	0	.0%	51	100.0%

CTDX * CONFIRM Crosstabulation

Count

		CONFIRM				Total
		1	2	3	6	
CTDX	1	8	1	1		10
	2	1	20			21
	3	1		11		12
	6				8	8
Total		10	21	12	8	51

Symmetric Measures

		Value	Asymp. Std. Error ^a	Approx. T ^b	Approx. Sig.
Measure of Agreement	Kappa	.890	.053	10.594	.000
N of Valid Cases		51			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

VITAE

Miss Sukalaya Lerdlum was born on 17 March 1956 in Bangkok, Thailand. She graduated from Faculty of Medicine, Chulalongkorn University and earned the degree of Bachelor of Science (B.Sc) in 1977, Doctor of Medicine in 1979. She completed her residency training program in General Radiology from King Chulalongkorn Memorial Hospital and obtained the Thai Board of General Radiology from Thai Medical Council in 1985.

She has been admitted in the Master Degree Program of Health Development in Faculty of Medicine, Chulalongkorn University since June 1999, granted by Faculty of Medicine, Chulalongkorn University. Currently, she is Assistant Professor in Department of Radiology, Faculty of Medicine, Chulalongkorn University and also Head of Diagnostic Division in Department of Radiology, King Chulalongkorn Memorial Hospital.

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย