การเปรียบเทียบการใช้โฟร์สกอร์กับกลาสโกว์โคมาเสกล ในการประเมินผู้ป่วยใส่ท่อช่วยหายใจที่ห้องฉุกเฉิน

นายนิติ เมธีศิริวัฒน์

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
สาขาวิชาการพัฒนาสุขภาพ
คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
ปีการศึกษา 2554

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THE FOUR SCORE COMPARED GLASGOW COMA SCALE TO EVALUATE THE PATIENTS WITH INTUBATION AT EMERGENCY ROOM

Mr. Niti Matheesiriwat

A Thesis Submitted in Partial Fulfillment of the Requirements

for the Degree of Master of Science Program in Health Development

Faculty of Medicine

Chulalongkorn University

Academic Year 2011

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Thesis Title	THE FOUR SCORE COMPARED GLASGOW COMA SCALE TO EVALUATE THE PATIENTS WITH INTUBATION AT EMERGENCY ROOM
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Field of Study	Health Development
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นิติ เมธีศิริวัฒน์ : การเปรียบเทียบการใช้โฟร์สกอร์กับกลาสโกว์โคมาสเกลในการประเมินผู้ป่วยที่ได้รับการใส่ท่อช่วยหายใจที่ห้องฉุกเฉิน. (THE FOUR SCORE COMPARED GLASGOW COMA SCALE TO EVALUATE THE PATIENTS WITH INTUBATION AT EMERGENCY ROOM) อ.ที่ปรึกษาวิทยานิพนธ์หลัก: รศ.นพ.สมศักดิ์ คุปต์นิรัติศัยกุล, 40 หน้า

วัตถุประสงค์ : การประเมินระดับความรู้ตัวทางระบบประสาทเป็นสิ่งสำคัญของผู้ที่มารับการรักษาที่ห้องฉุกเฉินเพื่อที่จะวางแผนการรักษาได้อย่างทันท่วงทีและมีประสิทธิภาพ ได้พัฒนาวิธีการประเมินแบบต่างๆเพื่อช่วยในการประเมินโดยแก้ไขในข้อจำกัดของการประเมินระดับความรู้ตัวทางประสาทด้วยกลาสโกว์ โคมา สเกล(Glasgow Coma Scale) หนึ่งในนั้นคือโฟร์สกอร์ (FOUR Score)ประกอบไปด้วยการประเมินการตอบสนองของตา ระบบกล้ามเนื้อ ปฏิกิริยาของก้านสมอง และรูปแบบการหายใจ จึงได้ทำการศึกษานี้เพื่อเปรียบเทียบการนำโฟร์สกอร์กับกลาสโกว์โคมาสเกลไปใช้ในผู้ป่วยที่ใส่ท่อช่วยหายใจในห้องฉุกเฉิน

วิธีการศึกษา : ผู้ป่วย 80 รายได้รับการใส่ท่อช่วยหายใจที่ห้องฉุกเฉินจะได้รับการประเมินระดับความรู้ตัวทางระบบประสาทโดยใช้ทั้งโฟร์สกอร์และกลาสโกว์โคมาสเกล จากแพทย์ประจำบ้านเวชศาสตร์ฉุกเฉิน พยาบาลห้องฉุกเฉิน หรือนักเรียนแพทย์ปีสุดท้ายที่ประจำห้องฉุกเฉินโดยการสุ่มเป็นคู่ และติดตามเก็บข้อมูลจนผู้ป่วยออกจากโรงพยาบาล โดยใช้ วิลคอกสัน ซายด์ แรงค์ เทสท์ (Willcoxon's signed rank test)เพื่อหาความแตกต่างระหว่างกลุ่ม ใช้ความสัมพันธ์ สเปียร์แมน (Spearman's correlation) และ ความสัมพันธ์เคนเดล (Kendell's correlation) หาความสัมพันธ์ระหว่างการวัดระดับความรู้ตัวทั้ง2 ชนิด ใช้เวจเตดแคปปา(Weighted kappa)และความสัมพันธ์ในกลุ่ม (ICC: Intra-class correlation coefficient) เพื่อหาค่าความน่าเชื่อถือและค่าความสัมพันธ์ในกลุ่มแต่ละกลุ่มและใช้การวิเคราะห์การถดถอย(Logistic Regression)เพื่อหาอัตราการตายในโรงพยาบาล

ผลการศึกษา : คะแนนโดยรวมของผู้ประเมินมีทิศทางไปแนวเดียวกันดีถึงดีมากทั้ง 2 แบบประเมิน (FOUR: K_w=0.80, ICC= 0.96, 95%CI 0.93-0.97 ; GCS : K_w=0.83, ICC=0.92, 95%CI 0.96-0.98) และไม่พบความแตกต่างระหว่างผู้ประเมิน ความสัมพันธ์ของการประเมินทั้ง 2 แบบอยู่ในเกณฑ์ดี (r=0.82, T=0.74, p<0.01) อีกทั้งทุกๆ 1คะแนนรวมของทั้ง2 แบบที่เพิ่มขึ้นจะมีผลต่อการลดลงของอัตราต่อรองของการตายในโรงพยาบาล (FOUR: OR=0.87,95%CI 0.67-1.10 ; GCS : OR=0.91, 95% CI 0.57-1.45)

สรุปการศึกษา : แบบประเมินโฟร์สกอร์มีความน่าเชื่อถือในการใช้ประเมินผู้ป่วยที่ได้รับการใส่ท่อช่วยหายใจที่ห้องฉุกเฉินและยังสามารถนำไปใช้เพื่อทำนายโอกาสการเสียชีวิตของผู้ป่วยเมื่อเข้ารักษาในโรงพยาบาล

สาขาวิชา การพัฒนาสุขภาพ ลายมือชื่อนิสิต.....

ปีการศึกษา 2554 ลายมือชื่อ อ.ที่ปรึกษาวิทยานิพนธ์หลัก.....

537 49088 30 : MAJOR HEALTH DEVELOPMENT
KEYWORDS : FOUR SCORE / GCS SCORE / EMERGENCY ROOM / INTUBATION

NITI MATHEESIRIWAT : THE FOUR SCORE COMPARED GLASGOW COMA SCALE TO EVALUATE THE PATIENTS WITH INTUBATION AT EMERGENCY ROOM. ADVISOR : ASSOC. PROF. SOMSAK KUPTNIRATSAIKUL, M.D., 40 pp.

Background: The level of consciousness of patient is important at emergency room for a treatment plan quickly and efficiently. Many tools have been developed to evaluate various ways to help in assessing the limit of GCS score. One of them is the FOUR (Full Outline of UnResponsiveness) score, new coma scale, evaluates 4 components: eye and motor responses, brainstem reflexes and respiration pattern. Therefore this study was to compare FOUR score and GCS for use in patients with intubation in the emergency room.

Method: 80 patients with intubation at ER have evaluate by random pair of rater (ED Residents, ED Nurses, Extern on duty at ER) both FOUR and GCS score in each patient and tracking information until the patients are discharged from the hospital. The statistical of study used Willcoxon' s sign rank test to determine differences between group, Spearman's and Kendall's correlation to determine correlation between FOUR and GCS , weighted kappa and ICC to determine the degree of agreement and the logistic regression for in-hospital death.

Results: Inter-rater agreement were good to excellent for FOUR score (K_w =0.80, ICC= 0.96, 95%CI 0.93-0.97) and GCS score (K_w=0.83, ICC= 0.92, 95%CI 0.96-0.98) and there were no statistical significant differences between rater types. The score's correlation was good (r=0.82, T=0.74, p< 0.01). Every 1-point increase in total scores, there were reduction in odds of in-hospital mortality (FOUR: OR= 0.87, 95% CI 0.67- 1.10 ; GCS: OR= 0.91, 95% CI 0.57- 1.45).

Conclusion: The FOUR score is reliable for evaluate the patient with intubation at ER. The FOUR score can be used to predict in-hospital mortality.

Field of Study: Health Development Student's Signature .....

Academic Year: 2011 Advisor's Signature .....

ACKNOWLEDGEMENTS

The author would like to express his gratitude to the evaluator from Phramongkutklao Hospital i.e Emergency physician staff, Emergency resident, Emergency nurse and Extern from Department of Trauma and Emergency for their willingness to participate in this study. We also thanks the personnel from Thai Clinical Epidemiology and Research Trial Consorttium, Chulalongkorn University for their important contribution and the personnel from the Research Unit Phramonkutklao Hospital for assistance of data analysis. The collaborative research advice of the academic benefit from the Institutional review board/ independent ethic committee, Phramongkutklao Hospital and the Director of Phramongkutklao Hospital are greatly acknowledged.

This study was supported by a grant from Phramongkutklao Hospital and Research Unit and Chulalongkorn University.

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LIST OF ABBREVIATIONS

FOUR score	=	Full Outline UnResponsiveness Score
GCS	=	Glasgow Coma Scale
ER	=	Emergency Room
ED	=	Emergency Department
D	=	Emergency Resident
N	=	Emergency Nurse
E	=	Extern on duty at Emergency Room
SD	=	Standard deviation
Min	=	Minimum
Max	=	Maximum

CHAPTER I

INTRODUCTION

1.1 Background and rationale :

Glasgow Coma Scale is the worldwide tool used for evaluating the alteration of conscious in patients that are widely popular particularly pre-hospital care, emergency physician and neuroscience physician. But there are some limitations in such cases - patients with intubation, lock- in syndrome. [1] Because of affects of the limitations the overall decline can't be fully evaluated in patients.

Many score have been developed to assess the patient such as RAPS (The Rapid Acute Physiology Score), REMS (Rapid Emergency Medicine Score) [2], APACHE (Acute Physiology and Chronic Health Evaluation II) [3] and IHSS (In House Score System) [4], but no score has been used as the gold standard and some are difficult to use. Moreover, in many scores GCS is also part of the assessment.

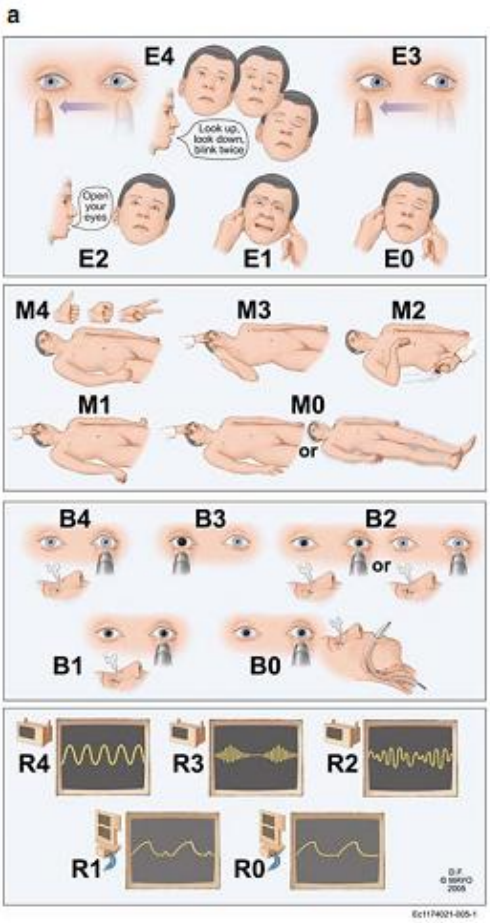
Later development The Full Outline of UnResponsiveness (FOUR) score to reduce the limitations of the GCS in an intensive care setting compared with the GCS in evaluating patients were the FOUR score can correlate well with the GCS to assess by evaluating several specific groups, such as nurses, neuroscience physicians. There has been widespread use of the FOUR score in evaluating patients more in the ICU MED [5], Neuro ICU [6], Pediatric population [7] and ER setting [8] by comparison with the GCS assessment in alteration of consciousness divided into groups such as alert, drowsiness, stuporous and coma. All study results were effective.

The FOUR score consists of four components –eyes, motor, brainstem and respiration pattern and evaluator assign a score of 0 to 4 in each of four functional categories. The maximal total score is 16 and minimal 0 point. (Figure 1)

In Thailand, the FOUR score are applied to evaluating patients in the neuro ICU that is comparable to the GCS, which the study did not differ from prior study. [9] But no study that compared the advantages of the FOUR score with GCS in patients with intubation at emergency room. Our aim was to study the inter-observer reliability, validity and functional outcome at hospital discharge.

FOUR score visual aid

Four score visual aid



b

EYE RESPONSE
4 = Eyelids open or opened, tracking or blinking to command
3 = Eyelids open but not to tracking
2 = Eyelids closed but opens to loud voice
1 = Eyelids closed but opens to pain
0 = Eyelids remain closed with pain stimuli

MOTOR RESPONSE
4 = Thumbs up, fist, or peace sign
3 = Localizing to pain
2 = Flexion response to pain
1 = Extension response
0 = No response to pain or generalized Myoclonus status

BRAINSTEM REFLEXES
4 = Pupil and corneal reflexes present
3 = One pupil wide and fixed
2 = Pupil or corneal reflexes absent
1 = Pupil and corneal reflexes absent
0 = Absent pupil, corneal, or cough reflex

RESPIRATION
4 = Regular breathing pattern
3 = Cheyne-Stokes breathing pattern
2 = Irregular breathing
1 = Triggers ventilator or breathes above ventilator rate
0 = Apnea or breathes at ventilator rate

Figure 1 FOUR score (Wijdicks EF ,Bamlet WR, Maramattom BV,et al. Validation of a new coma scale: the FOUR score. Ann Neurol 2005; 58:585-593)

Figure 2. Conditions that affect Glasgow Coma scale [1]

Eye opening

- Periorbital edema
- Ocular trauma
- Cranial nerve injury
- Pain

Verbal response

- Endotracheal intubation/tracheostomy
- Laryngectomy
- Maxillary facial trauma
- Mutism
- Edematous tongue
- Hearing loss
- Aphasia
- Dementia
- Psychiatric disorder
- Inability to comprehend language spoken
- Medications (sedation, neuromuscular blockers, anesthetic)
- Development delay
- Alcohol and drug toxication

Motor response

- Spinal cord / peripheral nerve injury
- Extremity injury with immobilization
- Pain
- Inability to comprehend language spoken
- Dementia
- Psychiatric disorder
- Developmental delay
- Medication
- Alcohol and drug intoxication

1.2 Literature reviews :

Through " PUBMED " searching engine, the keyword (FOUR [ALL Fields] And GCS score [All Fields] and (" emergencies" [MeSH terms] or " emergencies " [All Fields] or " emergency" [All Fields] were searched. The articles which seemed to be well matched or related to the clinical questions were selected and reviewed as followed.

Fischer et al reviewed the implications for practice of the Glasgow coma scale [1]. The GCS was developed by Jennett and Trasdale in Glasgow, Scotland. It had been used in head injury patients initially and became widely accepted in a variety of neurological, neurosurgical and critically ill patients to assess the level of consciousness and predict functional outcome. This study summarized the components of the GCS, principles of scoring, the limitations, and enclosed with the case presentation exercise.

Wijdicks et al [6] devised a new score, the FOUR (Full Outline of UnResponsiveness) score. It consists of four component (eye, motor, brainstem, and respiration). They studied the FOUR score in 120 ICU patients and compared it with the GCS score using neuroscience nurses, neurology residents, and neurointensivists. They found good to excellent agreement among the raters with weighted kappa 0.82, (95% CI 0.77-0.88) and excellent correlation between the FOUR score and GCS score (Spearman's rank correlation coefficient = 0.92). This study show the advantage of FOUR score above GCS score due to the availability of brainstem reflexes, breathing patterns, and the ability to recognize different stage of herniation. Considering the total FOUR score, they also found that for every 1 point increase in total score, there is an estimated 20% reduction in the odds of in-hospital mortality (Odds ratio 0.80, 95% CI 0.72-0.88)

In Spain, Luis Idrovo et al [10], prospectively enrolled consecutive patients with acute strokes admitted to the stroke unit (60 patients) .They studied the inter-observer variability of the FOUR score in acute strokes. The patients were evaluated by neurology residents and nurses using the FOUR score and the GCS. For both scales, they obtained paired and total weighted kappa values (K_w) and intraclass correlation coefficients (ICC) .NIH (Nation Institutes of Health) strokes scales were also recorded on admission. They found that the overall rater agreement was excellent in the FOUR score (K_w 0.93; 95% CI 0.89-0.97) with an ICC of 0.94(95%CI 0.91-0.96) and in the GCS (K_w 0.96; 95%CI 0.94-0.98) with an ICC of 0.96 (95% CI 0.93-0.97). A good correlation was found between the FOUR score and the GCS (ρ0.83;$p<0.01$) and between the FOUR score and the NIH stroke scale (ρ -0.78; $p< 0.001$)

In 2009, Vivek N. Iyer et al [5], studied inter-observer agreement used by FOUR score compared to the Glasgow Coma Scale (GCS) score in 100 critically ill patients from May 1 , 2007 to April 30, 2008 at ICU. For each patient, the FOUR and GCS score were determined by a randomly selected staff pair (nurse/fellow, nurse/consultant, fellow/fellow or

fellow/consultant) .They were calculated for both scores for each observer pair by weighted kappa. They found that the inter-rater agreement with the FOUR score was excellent(K_w: eye response , 0.96 ; motor response , 0.97; brainstem reflex, 0.98 ; respiratory pattern, 1.0) and similar to that obtained with the GCS (K_w: eye response , 0.96 ; motor response , 0.97; verbal response, 0.98).The mortality rate for patients with the lowest FOUR score of 0 (89%) was higher than that for patients with the lowest GCS score of 3 (71%). This study concluded that the FOUR score is a good predictor of the prognosis of critically ill patients and has important advantage over the GCS in the ICU setting.

Chris A. Wolf et al [11], they study in ICU by using FOUR score compared with GCS to evaluated 80 patients with acute neurologic disease. This study chose raters from experienced and inexperienced neuroscience ICU nurse. Each patient was rated by 2 nurses, with the order randomly assigned. They found that the rater agreement was good to excellent with the FOUR score (Weighted Kappa; eye,0.84 ; respiration,0.92; brainstem, 0.89; and motor, 0.73) and similar to that for the GCS (Weighted Kappa; eye,0.85; verbal, 0.89; and motor, 0.74). Greater average experience in a year was associated with less disagreement, but the difference was not statistically significant. In conclusion of this study the FOUR score provides more neurologic information than the GCS. The FOUR score can be used by any ICU nurses, even those with minimal experience.

Latha G. Stead et al [8], sought to validate the use of FOUR score in the emergency department (ED) using non-neurology staff and they also compared its performance to the Glasgow Coma Scale (GCS) and correlated it to the functional outcome during hospital discharge and overall survival. The study was designed to enroll 120 patients sampled from all four alertness group categories-30 alert, 30comatose and 60 drowsy/ stuporous patients by using FOUR score and GCS for evaluated. But at the time limited total recruitment was 69 patients.

Total recruitment was evaluated by three different raters. The raters were selected from training groups of : ED physician, ED resident and ED nurse. They found that inter-rater reliability for FOUR score and GCS was excellent (respectively, K_w=0.8 and 0.86).This study concluded that the FOUR score can be reliably used in the ED by non-neurology staff. Both Four score and GCS performed equally well, but the neurological detail incorporated in the FOUR score makes it more useful in management and triage of patients.

In 2009, Jennifer Cohen [7], designed a study to compare the inter-rater reliability and predictive validity of the FOUR score and GCS score in pediatric patients. This study the sample of 60 neuroscience patients, ages 2 to 18 years, was recruited from the pediatric intensive care unit. To assess the use of the GCS and the FOUR score on a variety of patients, the participants were assigned by the principal investigator to one of four categories upon admission: alert (n=44), drowsy (n=10), stuporous (n=3), or comatose (n=3). Thirty-five pediatric critical care nurse raters participated in this study. This study found that the inter-rater reliability for the GCS was good (K_w=.738), and that the FOUR score was excellent (K_w = .951). Outcome prediction analysis showed that the FOUR score and the GCS are both able to predict in-hospital morbidity and poor outcome at the end of hospitalization. The results from this pediatric study were consistent with the adult studies which suggest that the FOUR score is a reliable and valid tool for use in a wide variety of neuroscience patients.

Phuping Akavipat [9], in 2009, led four evaluator groups to evaluate 64 neurosurgical patients for assessing the reliability of the FOUR score in comparison to the GCS score and to assess the practical feasibility of the FOUR score and the GCS. The patients were assigned to one of four categories: awake, drowsy, stuporous, and comatose. Results of this study show intraclass correlation in each group was over 0.9 and there were no difference between the scoring from expert and inexperienced rater. The scores' correlation was good (r=0.78). The feasibility of

FOUR score was lower than the GCS. The FOUR score is reliable and valid for consciousness evaluation with some sequences in practicability.

1.3 Research questions:

1.3.1 Primary question

- Is there any reliability between the FOUR score and the GCS to evaluate patients with intubation at emergency room?

1.3.2 Secondary question

- Can be used FOUR score compared with GCS in the emergency room to assess patients with intubation for predicted dead or alive?

1.4 Research objectives:

1.4.1 To evaluate the reliability between different observers: FOUR score compared GCS score at emergency room.

1.4.2. To predict dead or alive of patients with intubation by using FOUR score compared GCS score.

1.5 Research hypothesis:

The FOUR score is reliable and valid for evaluation in patients with intubation at emergency room.

1.6 Research design:

Descriptive observational study, diagnostic test on reliability and validity

CHAPTER II

METHODOLOGY

2.1 part 1 : Material and methods

2.1.1 Study population:

Target population is patients with intubation at Phramongkutklao hospital

Study population is patients with intubation at ER Phramongkutklao hospital

Sample is patients with intubation at ER Phramongkutklao hospital within 1 year and start study after approval by ethic committee.

2.1.1.1 Inclusion criteria:

2.1.1.1.1 Patients with intubation

2.1.1.1.2 Age over 18 years old

2.1.1.1.3 Thai language understandable

2.1.1.1.4 Visited to emergency room at Phramongkutklao hospital, the tertiary care or equal level hospital.

2.1.1.2 Exclusion criteria

2.1.1.2.1 Patients affected by sedative or neuromuscular blocking agents.

2.1.1.2.2 Patients with the after effect from anesthesia within 24 hours.

2.1.1.3 Sample size calculation

We used the PASS 2008 software to calculate the sample size for agreement between two raters.

Steps of calculation are as follow:

1. Choosing correlation and used kappa test for rater agreement
2. Selected power = 0.80 and Alpha = 0.05

3. Select K1(kappa |H1)=0.8 , K0 (kappa| H0)=0.5 and P(category frequencies) 0.2 ,0.3 and 0.5

The sample size for agreement between two rater is 45.

We used the PASS 2008 software to calculate the sample size for intraclass correlation. Steps of calculation are as follow:

1. Choosing correlation and used intra-class correlation
2. Selected power = 0.80 and Alpha = 0.05
3. Select R1 (Intra-class correlation 1)=0.9 and R0 (Intra-class correlation 0) = 0.5

The sample size for intraclass correlation is 50.

We used the PASS 2008 software to calculate the sample size for logistic regression. Steps of calculation are as follow:

1. Choosing correlation and used regression
2. Selected power = 0.80 and Alpha = 0.05
3. Select alternative hypothesis : two-tail

The sample size for logistic regression is 68.

From the calculations, the total sample sizes of this study are 68 and plus 10% equal about 80.

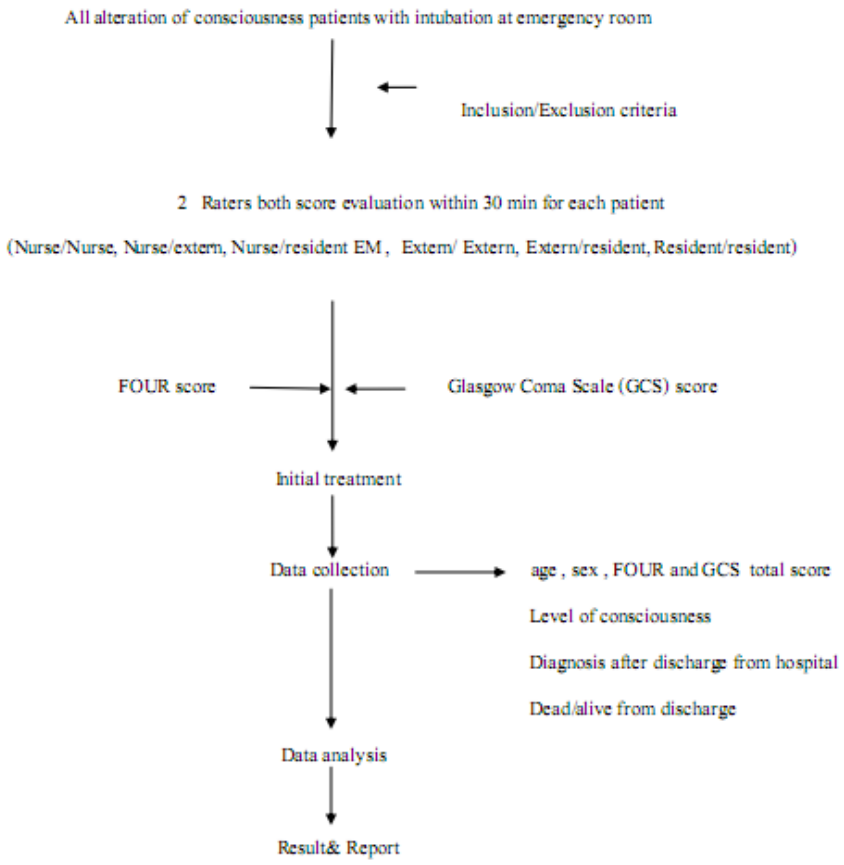
2.1.2 Methods:

The FOUR and GCS score would be assessed by three types of raters, each with two personnel i.e., emergency medicine residents (D), nurses (N) and externs (E). To protect patients from over-assessment, only 2 raters would independently examine and assign both FOUR and GCS score to each patient at ER within 30 min.

The raters all participated in education, provided by the investigator, related to use of the GCS and FOUR score assessment tool. Raters were given a copy of GCS and FOUR score instruction card for reference during the assessment patients.

To reduce bias, raters were blinded to other's score and were not aware of the diagnosis of the patients. A randomization sheet was used to select the rater pair (D/D, D/E, D/N, E/E, E/N or N/N) that would assess the patients. During the patients evaluation each rater would follow the instructions and complete the scoring sheet.

Figure 3 Flow Diagram



2.1.3 Operation definition :

2.1.3.1 Level of consciousness [12]

2.1.3.1.1 Alert - classified if the patients opened their eyes without prompting, looked about and conversed (if they are not aphasic)

2.1.3.1.2 Drowsiness - classified if the patients had their eyes closed but opened after conversational voice addressed or gently shaken, response with sensible speech, usually became sleepy within seconds after the conversation and had natural movements of the limbs on the side without hemiparesis.

2.1.3.1.3 Stuporous – classified if the patients maintained sleepiness for several minutes, closed their eyes, presented momentary or no arousal after shaking and yelling, mumbled, response with single word or no verbal reply and consistency push aside the examiner's prodding hand with their good arm.

2.1.3.1.4 Coma – classified if the patients had no speech, still closed their eyes even vigorous shaken and made no attempt to push away the examiner's hand.

2.1.3.2 Glasgow Coma Scale (GCS) was referred to Teasdale and Jennett's article in Lancet 1994 as followed (Figure 4). The impossible evaluation of every single component of eye opening, verbal or motor response such as severe eyelids swelling, intubation, tracheostomy, upper limb amputation, developmental delay, psychosis, etc. **would be scored 1 each**.

Figure 4 Glasgow Coma Scale score

Best Eye Response (4)

1=No eye opening

2=Eye opening to pain

3=Eye opening to verbal command

4=Eyes open spontaneously

Best Verbal Response (5)

1=No verbal response

2=Incomprehensible sounds

3=Inappropriate words

4=Confused

5=Orientated

Best Motor Response (6)

1=No motor response

2=Extension to pain

3=Flexion to pain

4=Withdrawal from pain

5=Localising pain

6=Obeys Commands

2.1.3.3 The FOUR (Full Outline of UnResponsiveness) score was referred to Wijdicks and colleague's article in Annals of Neurology 2005 (Figure 1). The impossible evaluation of every single component of eye response, motor response, brainstem reflex or respiration pattern such as severe eyelids swelling, upper limb amputation, developmental delay, psychosis, etc. **would be scored 0 each.**

Figure 5: **The Full Outline Of UnResponsiveness score (FOUR score)**

Eye response

4= eyelids open or opened, tracking, or blinking to command

3= eyelids open but not tracking

2= eyelids closed but open to loud voice

1= eyelids closed but open to pain

0= eyelids remain closed with pain

Motor response

4= thumbs-up, fist, or peace sign

3= localizing to pain

2= flexion response to pain

1= extension response to pain

0= no response to pain or generalized myoclonus status

Brainstem reflexes

4= papillary and corneal reflexes present

3= one pupil wide and fixed

2= papillary or corneal reflexes absent

1= papillary and corneal reflexes absent

0= absent papillary, corneal, and cough reflex

Respiratory pattern

4= not intubated, regular breathing pattern

3= not intubated, Cheyne-Stokes breathing pattern

2= not intubated, irregular breathing

1= breathes above ventilator rate

0= breathes at ventilator rate or apnea

2.1.3.4 Category of rater

2.1.3.4.1 Residents : Emergency medicine training at ER

2.1.3.4.2 Nurses : Nurses were nursing and practice at ER

2.1.3.4.3 Externs : Externs were rotated and working at ER

2.1.4 Outcome variables:

2.1.4.1 Demographic and baseline variables : age, gender, diagnosis, underlying disease

2.1.4.2 The total score of the FOUR and GCS score

2.1.4.3 Inter-observer reliability of the FOUR and GCS score

2.1.4.4 Functional outcome compare FOUR and GCS at hospital discharge : mention for dead/alive

2.1.5 Data Collection

2.1.5.1 Baseline characteristics of patients will be record in data extract forms

2.1.5.2 FOUR and GCS score were recorded in data extract forms

2.1.5.3 Medical record for diagnosis and status at hospital discharge

2.1.6 Data Analysis

2.1.6.1 Descriptive statistics for baseline data

- Continuous data: will be presented as mean, SD or median
- Categorical data: will presented as frequency (%)

2.1.6.2 Reliability

- Using data from all patients, inter-rater reliability of the FOUR and GCS would be determined for each pair of rater and all pair combined.

2.1.6.3 Functional outcome

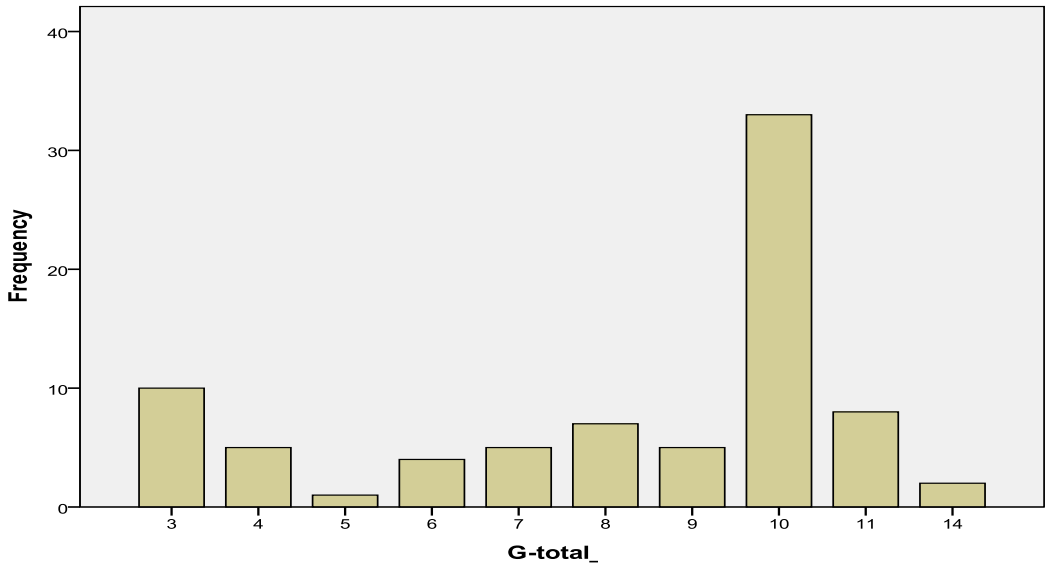
- Using logistic regression for analysis: dead/ alive at hospital discharge.

CHAPTER III

RESULTS

There were 80 patients enrolled and 160 data available for final analysis. The mean age of the study was 62.23±17.92 years with a range of 19-92 years. Fifty-six percent were male (45 patients) and forty-four percent were female (35 patients).The primary admittance diagnosis of 80 patients were neurology disorders [24%], cardiology disorders [23%], pulmonary disorders [25%], infectious diseases [16%], GI disorders [5%], trauma [4%], renal disorders [1%] and cardiac arrest 2%. All patients were intubated with mechanical ventilator and categorized into 3 stages of consciousness as followed; 64% drowsy, 10% stupor and 26% coma. The top three underlying diseases of patients were hypertension, diabetic mellitus and ischemic heart disease. Following the results of treatment at the hospital after discharge there 21 cases of patient who died. [table 1, 2; figure 6]

Figure 6 Frequency of rated categories for 80 patients in total GCS score and FOUR score



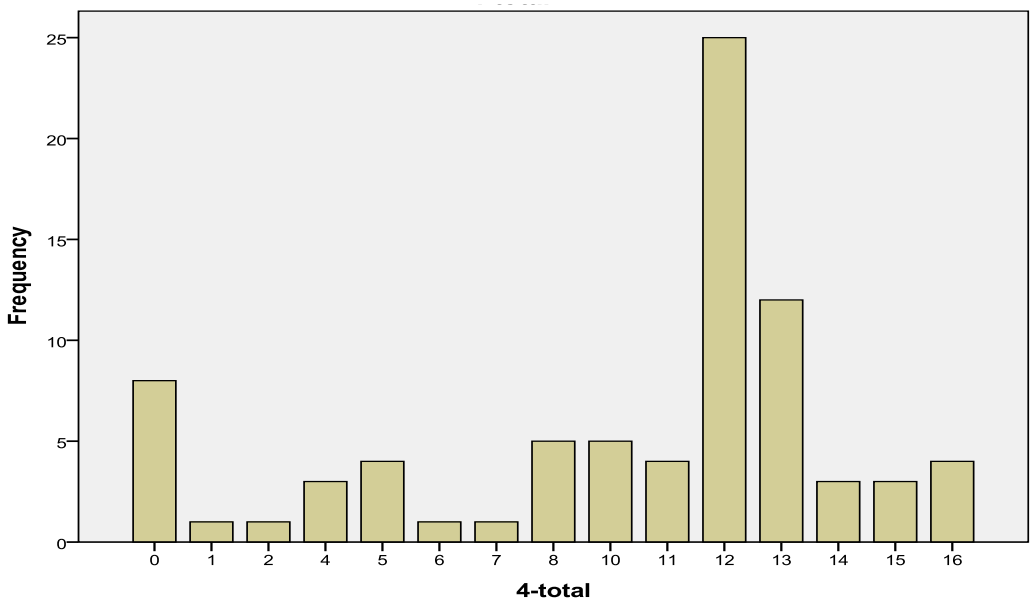


Table 1 Baseline characteristics of patients

Characteristic	N =80 (%)	Min.	Max.	Mean	SD
Age		19	92	62.23	17.92
Gender					
Male	45 (56.3)				
Female	35 (43.8)				
Level of consciousness					
Drowsiness	51 (63.8)				
Stuporous	8 (10)				
Coma	21 (26.3)				
Underlying diseases					
none	7 (8.8)				
1	33 (41.3)				
2	30 (37.5)				
>2	10 (12.5)				
Outcome (hospital discharge)					
death	21 (26.3)				
alive	59 (73.0)				

Min. = minimum, Max. = maximum, SD= standard deviation

Table 2 Primary admittance diagnoses of 80 patients undergoing scoring of GCS and FOUR score

Reason for admission	N (%)
Neurology disorders	19 (23.8)
Cardiology disorders	18 (22.5)
Pulmonary disorders	20 (25%)
Infectious diseases	13 (16.3)
GI diseases	4 (5)
Renal diseases	1 (1.3)
Trauma	3 (3.8)
Arrest	2 (2.5)

The overall rater agreement was good to excellent for both score. Inter-rater reliability using weight kappa (K_w) and intra-class correlation coefficient (ICC) for the FOUR score (K_w = 0.80, ICC = 0.96, 95% CI 0.93-0.97) and the GCS score (K_w = 0.83, ICC = 0.92, 95% CI 0.96-0.98) (Table 3)

Table 3 Inter-rater reliability using weighted kappa and intra-class correlation (ICC)

	FOUR						GCS			
	Eye	Resp	Brain	Motor	Total		Eye	Verbal	Motor	Total
Weighted kappa	0.88	0.57	0.83	0.81	0.8		0.84	0.81	0.87	0.83
ICC [95% CI]	0.95	0.77	0.94	0.95	0.96		0.94	0.96	0.97	0.92
	[0.93-0.97]	[0.65-0.85]	][0.92-0.96][	[0.92-0.97]	[0.93-0.97]		[0.92-0.97]	[0.93-0.97]	[0.96-0.98]	[0.96-0.98]

FOUR= Full Outline of Unresponsiveness, GCS= Glasgow Coma Scale

ICC= Intra-class correlation coefficient , CI = Confident Interval

Table 4 presents the FOUR score and GCS within subject differences by rater types (ED Resident, ED Nurse and Extern on duty at ER). Each pair of raters has

used both scores to evaluate each subject and present the mean differences. The mean differences of FOUR score ranging from 0.00 (Extern /Extern) to 1.15 (Resident/ Resident) and GCS ranging from 0.07 (Resident/Nurse) to 0.42 (Nurse/ Extern). There were no statistical significant differences between rater types.

Table 4 FOUR score and GCS within subject differences by rater type

	N	FOUR			GCS		
		Mean*	SD	p-value	Mean*	SD	p-value
Pair of rater							
Resident/Resident	13	1.15	2.54	0.13	0.15	0.90	0.55
Resident/Nurse	14	0.07	1.60	0.87	0.5	1.16	0.13
Resident/Extern	13	0.23	1.17	0.49	0.15	0.38	0.17
Nurse/Nurse	15	0.20	2.01	0.70	0.07	1.10	0.82
Nurse/Extern	12	0.50	1.93	0.40	0.42	1.50	0.36
Extern/Extern	13	0.00	0.58	1.00	0.15	0.38	0.17

*Mean differences between rater

Table 5 presents good to excellent internal consistency was found by measuring Cronbach's alpha for FOUR score and GCS between pair of rater (Cronbach's alpha $\geq$ 0.8). The Cronbach's alpha value $\geq$ 0.9 excellent internal consistency, 0.9 > α $\geq$ 0.8 good, 0.8> α $\geq$ 0.7 acceptable, 0.7> α $\geq$ 0.6 questionable, 0.6 > α $\geq$ 0.5 poor and unacceptable if $\alpha < 0.5$.

Table 5 Internal consistency of the FOUR and GCS score demonstrated in Cronbach's alpha value.

Raters	N	FOUR score	GCS score
Overall rater	160	0.73	0.81
Pair of rater			
Resident/Resident	13	0.87	0.97
Resident/Nurse	14	0.97	0.94
Resident/Extern	13	0.99	0.99
Nurse/Nurse	15	0.95	0.97
Nurse/Extern	12	0.93	0.90
Extern/Extern	13	0.99	0.99

Table 6 presents the correlation between the FOUR score and GCS witch measured by the rater. Total FOUR score and total GCS significantly intercorrelated (Spearman's rho = 0.82, Kendall's tau_b = 0.74 ; $p < 0.01$). Rater type correlation was highest among Extern and Extern for both score. Lowest correlation was Nurse and Extern group

Table 6 The correlation between the FOUR score and GCS which measured by the rater

Pair of rater	N	Spearman's rho		Kendall's tau_b		p-value
		FOUR	GCS	FOUR	GCS	
Resident/Resident	13	0.85	0.99	0.79	0.98	<0.01
Resident/Nurse	14	0.85	0.73	0.72	0.65	<0.01
Resident/Extern	13	0.84	0.95	0.78	0.92	<0.01
Nurse/Nurse	15	0.85	0.95	0.78	0.91	<0.01
Nurse/Extern	12	0.66	0.84	0.54	0.79	<0.01
Extern/Extern	13	0.92	0.99	0.88	0.99	<0.01
Total FOUR / Total GCS	**80**	**Spearman's rho = 0.82**		**Kendall's tau_b = 0.73**		**p<0.01**

Table 7 shows the relationship between total FOUR score and GCS with the outcome of in-hospital death .We found that the total FOUR score increase every 1-point will result in a 0.87 (95% CI 0.68-1.10) times lower risk of experiencing in –hospital mortality under the unadjusted model.

Table 7 FOUR score and GCS relation to In-hospital mortality

Outcome	N	Total FOUR		Total GCS	
(N=80)		OR	95%CI	OR	95%CI
In-hospital death	21	0.865	0.678-1.103	0.908	0.569-1.447

CHAPTER IV

DISCUSSION

4.1 Discussion

Glasgow Coma Scale is the worldwide tool used for evaluating the alteration of consciousness patients. The FOUR score has been developed to evaluate the alteration of consciousness patients to reduce the limitations of the GCS. [6] This is the inter-observer reliability study of the FOUR score in some limitations of GCS compare with GCS, patient with intubation, in critical setting.

The overall rater agreement in this study was good to excellent for both FOUR and GCS score by using weighted kappa (K_w) and intra-class correlation coefficient (ICC) analyzed. Subscale of FOUR score in the part of respiration has lowest score from K_w=0.57 and ICC = 0.77. Wijdicks et al [6] study found good to excellent agreement among the raters (neuroscience nurses, neurology resident and neurointensivists), Luis Idrovo et al [10] had reported in stroke unit care, Vivek et al [5] had reporedt in 100 critically ill patients, Chris A. Wolf et al [11] , Latha G. Stead et al [8] and Jenifer Cohen [7] were similar to our study findings. All of the studies found that the education and experience did not interference the agreement of the raters. The level of overall reliability is possibly caused by strong definitions as guidance, training and demonstration of the evaluation process in all raters.

The internal consistency for the FOUR score and GCS score between pairs of raters calculated by Cronbach's alpha in this study was good to excellent and the high scores's correlation between the FOUR score and GCS score had analyzed by Spearman's rho and Kendall's tau_b. The

result are similar to the prior study of Spearman's rho [3, 6, 9], on the other hand, this study shows good correlation by Kendall's tau_b too.

The FOUR score and GCS score used to evaluate within subject by rater type (table 4) showed no statistical significant difference of raters by compared with the mean differences. These results demonstrate that the FOUR score has no limitation of use and do not depend on the knowledge or expertise of the evaluators, as well as GCS score.

The total FOUR score can be predicted in-hospital mortality. We found that every 1- point increase in total FOUR score will result in a 0.87 time lower risk of experiencing in-hospital mortality unadjusted model. These results were similar in prior studies. [5, 6, 7]

In our study, all of the patients were alteration of consciousness with intubation. This may have improved rater agreement values in the GCS score but no interference with the FOUR score.

Following the research objective, the author has proposed that the FOUR score is reliable among the differences of the raters and powerful for predicted in-hospital mortality. Further study of FOUR score in varies situation should be done to verify the foregone conclusion of the new coma score instead of the GCS score in the near future.

4.2 Limitation:

There were several limitations to this study. An observation could introduce a variety of bias including those related to ascertainment. Intra-raters reliability had not been evaluated because it was impossible for the rater to score the same patient in such an abrupt time period without remembering the previous scores.

This study was produced by one center and time limited. Further study may be produced by multicenter to verify the results.

4.3 Ethical Consideration:

This study needs to be performed in human subjects. Therefore, the research proposal must be approved by the ethics committee before starting the study. Informed consent must be signed in every single case by the patients or the legal relatives

This study is an observational study. Therefore, the consciousness evaluation is the routine practice among the patients at ER but the caution must be used in applying painful stimulus and no intervention to take risk or any harm to patients.

CHAPTER V

CONCLUSION

The FOUR score is reliable for evaluating the alteration of consciousness patients with intubation at emergency room and can be used to predict the in-hospital mortality. The Four score can be an improvement in the emergency care system for triage, transportation and disaster or critical situations for evaluating the patients if the GCS is limited. The Four score may be used and applied in every emergency room for evaluating all patients.

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APPENDICES

APPENDIX A

Instruction for the assessment of the FOUR (Full Outline of UnResponsiveness) score

1. For eye response: grade the best possible response after at least three trial an attempt to elicit the best level of alertness.

   E4- indicates at least three voluntary excursions. Tracking with the opening of one eyelid will

   suffice in cases of eyelid edema. If tracking is absent horizontally, examine vertical tracking.

   Alternatively, two blinks on command should be documented.

   E3- indicates absence of voluntary tracking with open eyes.

   E2- indicates eyelids open to pain stimulus.

   E0- indicates no eyes opening to pain.

2. For motor response: grade the best response of the arms.

   M4- indicates that the patient demonstrated at least one of three hand position with ether hand.

   M3- indicates that the patient touched the examiner's hand after a painful stimulus.

   M2- indicates any flexion movement of the upper limbs.

   M1- indicates extensor response to pain.

   M0- indicates no motor response to pain, or myoclonus status epilepticus.

3. For brainstem reflexes: grade the best possible response; papillary and corneal reflexes, cough reflex to tracheal suctioning.

   B4- indicates papillary and corneal reflexes are present.

   B3- indicates one pupil wide and fixed.

   B2- indicates either papillary or corneal reflexes are absent.

B1- indicates both papillary and corneal reflexes are absent.

B0-indicates papillary ,corneal and cough reflexes are absent.

4. For respiratory : grade the best observed respiration.

R4- spontaneous breathing pattern in a nonintubated patient and grade simply as regular.

R3- spontaneous breathing pattern in a nonintubated patient and grade simply as Cheyne-stokes.

R2- spontaneous breathing pattern in a nonintubated patient and grade simply as irregular.

R1- indicates spontaneous respiratory pattern or self triggering of the ventilator in mechanically ventilated patients.

R0- indicates no patient-generated breaths on the ventilator.

Glasgow Coma Scale score

Best Eye Response. (4)

1=No eye opening.

2=Eye opening to pain.

3=Eye opening to verbal command.

4=Eyes open spontaneously.

Best Verbal Response. (5)

1=No verbal response

2=Incomprehensible sounds.

3=Inappropriate words.

4=Confused

5=Orientated

Best Motor Response. (6)

1=No motor response.

2=Extension to pain.

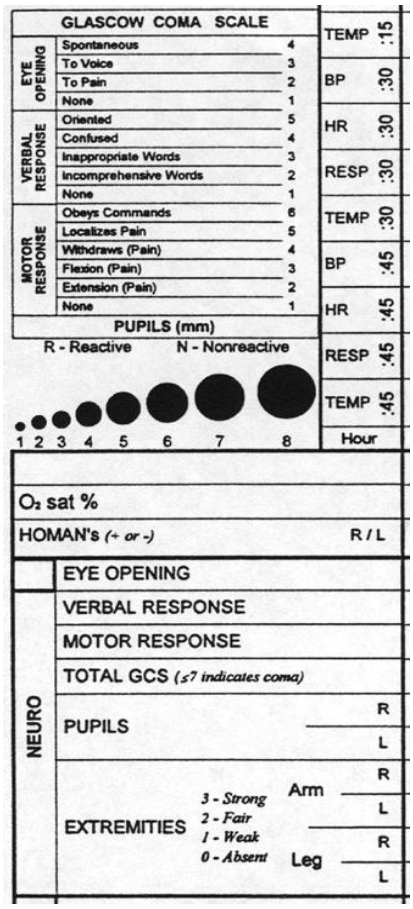
3=Flexion to pain.

4=Withdrawal from pain.

5=Localising pain.

6=Obeys Commands.

Glasgow coma score



http://www.coheadquarters.com/RefValues/GCS1.ht

APPENDIX B

Data extract form

ID_____ AGE_____Gender 1. Male ☐ 2.Female ☐

Status at discharge 1. Dead ☐ 2.Alive ☐

Diagnosis_____ ICD 10_____

Level of consciousness ☐ alert ☐ drowsiness ☐ stuporous ☐ coma date_____

FOUR score

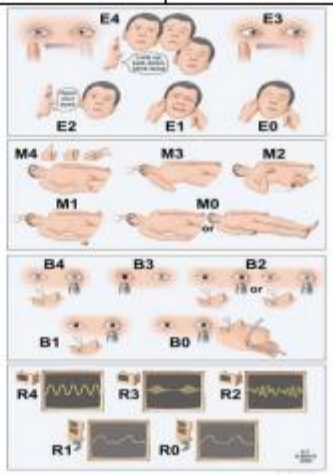
EYE RESPONSE
4 = Eyelids open or opened, tracking or blinking to command
3 = Eyelids open but not to tracking
2 = Eyelids closed but opens to loud voice
1 = Eyelids closed but opens to pain
0 = Eyelids remain closed with pain stimuli

MOTOR RESPONSE
4 = Thumbs up, fist, or peace sign
3 = Localizing to pain
2 = Flexion response to pain
1 = Extension response
0 = No response to pain or generalized Myoclonus status

BRAINSTEM REFLEXES
4 = Pupil and corneal reflexes present
3 = One pupil wide and fixed
2 = Pupil or corneal reflexes absent
1 = Pupil and corneal reflexes absent
0 = Absent pupil, corneal, or cough reflex

RESPIRATION
4 = Regular breathing pattern
3 = Cheyne-Stokes breathing pattern
2 = Irregular breathing
1 = Triggers ventilator or breathes above ventilator rate
0 = Apnea or breathes at ventilator rate

	FOUR score
Eye response	
Motor response	
Brainstem reflexes	
Total	



(Wijdicks EF ,Bamlet WR, Maramattom BV,et al. Validation of a new coma scale: the FOUR score.Ann Neurol2005; 58:585-593

Glasgow Coma Scale (GCS) score

Best Eye Response. (4)

1= No eye opening.

2= Eye opening to pain.

3= Eye opening to verbal command.

4= Eyes open spontaneously.

Best Verbal Response. (5)

1= No verbal response

2= Incomprehensible sounds.

3= Inappropriate words.

4= Confused

5= Orientated

Best Motor Response. (6)

1= No motor response.

2= Extension to pain.

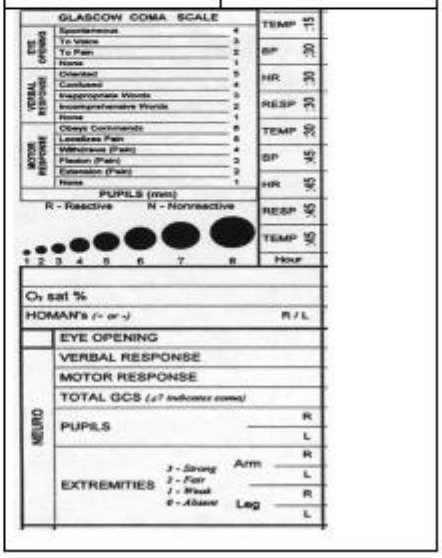
3= Flexion to pain.

4= Withdrawal from pain.

5= Localising pain.

6= Obeys Commands

	GCS score
Eye response	
Verbal response	
Motor response	
Total	



Evaluator 1.Nurse ☐ 2. Extern ☐ 3.Resident ☐

คู่มือการประเมินผู้ป่วยโดยการใช้ FOUR score

>>>

2.4 ตอบสนองในลักษณะการเหยียดแขนออกทั้งสองข้างแล้วข้อมือบิดออกจากแนวลำตัว เมื่อได้รับการกระตุ้นด้วยความเจ็บปวด จะได้คะแนน 1 คะแนน

2.5 ไม่มีการตอบสนองใดๆเมื่อได้รับการกระตุ้นด้วยความเจ็บปวด หรือมีอาการเกร็งทั้งตัว จะได้คะแนน 1 คะแนน

3. การประเมินในส่วนของ Brainstem reflexes

3.1 รูม่านตาและปฏิกิริยาตอบสนองของกระจกตาสามารถตอบสนองต่อแสงได้ปกติทั้งสองข้าง จะได้คะแนน 4 คะแนน

3.2 รูม่านตาหนึ่งข้างขยายตัวและคงสภาพไม่ตอบสนองต่อแสง จะได้คะแนน 3 คะแนน

3.3 ปฏิกิริยาตอบสนองของรูม่านตา หรือ กระจกตาไม่มีการตอบสนอง จะได้คะแนน 2 คะแนน

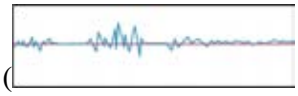
3.4 ปฏิกิริยาตอบสนองของรูม่านตาและกระจกตาไม่ตอบสนอง จะได้คะแนน 1 คะแนน

3.5 ไม่มีการตอบสนองต่อปฏิกิริยาของรูม่านตา กระจกตา และ การไอ

4. การประเมินในส่วนของ Respiration

4.1 มีการหายใจได้เองแบบปกติ จะได้คะแนน 4 คะแนน

4.2 มีการหายใจแบบ Cheyne-Stokes ( ) จะได้คะแนน 3 คะแนน

4.3 มีการหายใจไม่สม่ำเสมอ () จะได้คะแนน 2 คะแนน

4.4 สามารถหายใจได้โดยการกระตุ้นเครื่องช่วยหายใจก่อน หรือ มีการหายใจได้เร็วกว่าจังหวะที่เครื่องช่วยหายใจกำหนด จะได้คะแนน 1 คะแนน

4.5 ไม่หายใจ หรือหายใจตามจังหวะของเครื่องช่วยหายใจ จะได้คะแนน 0 คะแนน

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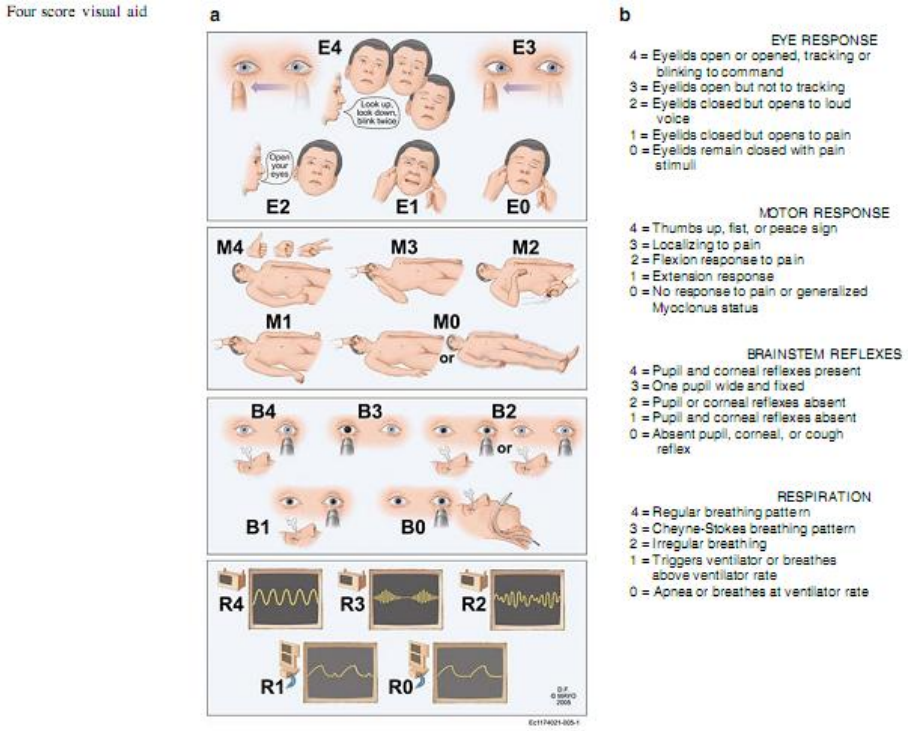
การกระตุ้นด้วยความเจ็บปวด: ให้กระตุ้นผู้ป่วดโดยการกดที่บริเวณกระดูกหน้าอกแล้วดูการตอบสนองโดยการขยับ ปัดป้อง งอแขน หรือเหยียดแขน

การทดสอบปฏิกิริยาของรูม่านตา : ใช้ไฟฉายส่องไปที่รูม่านตาทีละข้างโดยดูลักษณะการหด-ขยายของรูม่านตา ถ้ามีถือว่ามีการตอบสนอง

การทดสอบปฏิกิริยาของกระจกตา: ใช้ปลายสำลีเขี่ยที่กระจกตาแล้วดูการตอบสนองจากการกระพริบตา ถ้ามีการกระพริบตาถือว่ามีการตอบสนอง

การทดสอบการไอ : ใช้ไม้กดลิ้นกดที่บริเวณ 1/3 โคนลิ้น ดูการขย่อน หรือการไอ ถ้ามีการขย่อนหรือไอถือว่ามีการตอบสนอง



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Scholarships: -