Evaluation of a Revised Scale for the Prediction of Long-Term Outcome in Poor-Grade Aneurysmal Subarachnoid Hemorrhage Undergoing Operative Repair

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A. Study Purpose and Rationale

Aneurysmal subarachnoid hemorrhage (aSAH) is a devastating neurological condition credited with a 30 day mortality of 30 to 40% with 10 to 15% of patients dying before they reach medical care.[1] Of those patients that survive, 30% will have moderate to severe disability.[2] To differentiate patients on admission and communicate clinical severity, Hunt and Hess devised a rating scale based on the neurologic exam at the time of admission that continues to aid prognosis and decision making.[3] Patients with poor-grade (Hunt and Hess Grades IV and V) aSAH comprise 20-30% of patients admitted to the hospital after aSAH. In a study of 98 poor-grade patients from Columbia University between 1998 and 2002, a mortality rate of 35% and a moderately severe to severe disability rate of 26% were observed at 1 year.[4] Recent studies have shown that aggressive management, including early surgical clipping or endovascular coiling, can benefit a subset of these poor-grade patients.[5,6]

Numerous studies have attempted to identify prognostic indicators in poor grade patients to better inform operative decision making and prognosis. Certain groups have focused on radiologic features, such as intraventricular hemorrhage, ventriculomegaly, and cerebral low density.[7] Other investigators have shown that basic demographic information or clinical variables can be used, such as age greater than 65, hyperglycemia on admission, and aneurysm size of at least 13mm.[4] Even genetics makeup has been shown to have an important effect on outcome, such as current work showing the negative effect of the apoE ε4 isoform of apolipoprotein E on outcome after neurologic injury.[8] Mocco et al. recently used a subarachnoid hemorrhage database of poor grade patients to build a multivariate model that could be used to determine a "Prognosis Score" to separate poor and favorable outcome patients and aid operative decision making.[4]

Efforts have been made to devise a new grading scale on admission that would better reflect outcome predictions under current management strategies, which have dramatically changed since 1964 when Hunt and Hess originally proposed their grading scale. It has also been suggested that other existing scales, such as the Glasgow Coma Scale (GCS) be combined with the Hunt Hess grade. This was because other scales, like the GCS, have better inter- and intraobserver reliability than the Hunt and Hess scale.[9]

Members of the neurosurgical team at Columbia suspect that they have made medical decisions and developed expectations pertaining to aSAH patients based on a combination of the GCS and Hunt and Hess grading scales throughout this period of time. We propose to retrospectively analyze poor grade patients admitted to this hospital over a ten year period with the intention a) to test the hypothesis that the decision to operate has been based on a specific grading scale including the GCS in combination with the standard Hunt and Hess grading scale and b) to test the hypothesis that this new scale is a better predictor of outcome than the Hunt Hess alone.

B. Study Design and Statistical Analysis

We propose to perform a retrospective chart analysis of all patients who were admitted to this hospital from 1996 to 2005 with the diagnosis of aSAH who have consented to have their information analyzed under the Subarachnoid Hemorrhage Outcomes Project (SHOP) protocol, which is a prospectively collected database maintained by the Neurologic Intensive Care Unit at Columbia Presbytarian Medical Center. It is necessary to analyze patient charts as well as gather data through SHOP because one of the parameters that will be used to grade patients on admission, the specific components of the GCS score, was not included in the SHOP database. Also, there was a lapse in the SHOP protocol throughout 2003 during which patient data was not collected. Patient data from 2003 will be collected from charts obtained through medical records. From 1997 to 2005 (excluding 2003), 99% of patients presenting with aSAH consented to have data gathered under SHOP. Of these 698 patients included in the database, 232 were Hunt and Hess grade IV or V on admission. Previous analysis of hospital databases has shown that there were 48 poor grade aSAH patients in 2003. In total there were 280 poor grade patients who will be included in this study. Of this total number of patients, 142 (51%) were grade IV on admission and 138 (49%) were grade V. Of those 142 grade IV patients, 136 underwent an operation.

From data collected on the GCS score on admission, a patient will be assigned a "good" or "bad" rating for each Hunt and Hess grade. Specifically, all grade IV patients will be divided into either a good or bad prognostic group depending on their motor and eye exam components of the GCS score. All grade V patients will also be divided into either a good or bad prognostic group depending also on their GCS motor and eye exams on admission. It is highly unlikely, but possible, that an individual may have a combination of GCS motor and eye exam scores that do not allow it to fit into any category. In this case, the eye GCS score will be ignored and the motor GCS score will be used to assign the patient to the appropriate group. A GCS score is assigned to patients by the nurses in the Neurologic Intensive Care Unit (NICU) every 3 hours. It is therefore possible that a patient may be assigned different GCS scores throughout the first day of admission. In this case, the worst GCS score on the day of admission will be included in the database for separate analysis as past studies have shown that the worst neurologic exam on admission is a better predictor of outcome.[5]

Assigned to the appropriate groups, a concordance table will then be constructed to determine the consistency of the decision to operate with this grading scale in grade V patients. Previously collected data for prior research projects suggests that the concordance table will show that this scale has been used regularly over the last 10 years.

If found to be concordant with management decisions, this scale will then be evaluated for predictive value among grade IV patients using a neurologic examination performed at 1 year. Most previous studies use 3 or 6 month time points to evaluate outcome, but it is felt that the patient status at 1 year will provide a more accurate characterization of long-term prognosis. The scale that will be used to evaluate outcome is the Modified Rankin Scale (mRS), which is the standard of care for the evaluation of long-term outcome in neurologic patients and is available both through the SHOP protocol and patient charts. There will be a significant number of patients who die within 1 year following their aSAH presentation and there will be others that were lost to follow-up at either 3 months and/or 1 year. In the case that a patient dies, a score of 6, the worst possible score, is assigned under the mRS. When a patient is lost to follow-up, the most recent mRS score will be used. Based on the mRS, patients will be dichotomized to have

either a “favorable” or “unfavorable” outcome, which is a commonly accepted method of outcome analysis in the neurology literature.[4]

A chi-square analysis will be performed on all grade IV patients, who will be divided into either a “good” or “bad” prognostic group and a “favorable” or “unfavorable” outcome group. A chi-square power analysis shows that with a population of 136 patients, we will be able to detect a 20% or more difference in the good and bad groups. For example, of the 136 patients included in the study, we already know that 55 (40%) had a favorable outcome at 1 year.

Because this exam on admission is attempting to categorize patients, we will also consider analyzing its effectiveness using epidemiologic outcomes including positive predictive value (ability to predict good outcome) and negative predictive value (ability to predict poor outcome).

Hunt and Hess grading scale[3]

I	asymptomatic, or mild headache and slight nuchal rigidity
II	cranial nerve palsy, moderate to severe headache, nuchal rigidity
III	mild focal deficit, lethargy, or confusion
IV	stupor, moderate to severe hemiparesis, early decerebrate rigidity
V	deep coma, decerebrate rigidity, moribund appearance

Glasgow coma scale[10]

Points	Best eye opening	Best verbal	Best motor
6	-	-	obeys
5	-	oriented	localizes pain
4	spontaneous	confused	withdraws to pain
3	to speech	inappropriate	flexion (decorticate)
2	to pain	incomprehensible	extensor (decerebrate)
1	None	None	None

Combined Hunt Hess and Glasgow for poor grade patients

Combined	**Hunt Hess**	**Glasgow coma scale**
Good IV	IV	localizing or withdrawing (4-6 motor), eye-opening (2-4 eyes)
Bad IV		does not withdraw to pain (1-3 motor), nonspontaneous eye-opening (1-3 eyes)
Good V	V	decerebrate or better (2-6 motor), eye opening to pain only (1-2 eyes)
Bad V		flaccid (1 motor), no eye opening (1 eyes)

Management and prognosis by the combined scale

Combined scale	**Management and prognosis**
Good IV	treat and expect the best
Bad IV	treat but expect the worst
Good V	treat only if young and or family very aggressive
Bad V	conservative

Modified Rankin Scale

0	no symptoms at all
1	no significant disability despite symptoms: able to carry out all usual duties and activities
2	slight disability: unable to carry out all previous activities. Able to look after own affairs without assistance
3	moderate disability: requiring some help, but able to walk without assistance
4	moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance
5	severe disability: bedridden, incontinent, and requiring constant nursing care and attention
6	death

C. Study Procedure

A retrospective chart review will be performed to obtain data on the GCS motor and eye exam on the day of admission for all patients as well as to obtain outcome data on all patients admitted throughout 2003. For all other years, outcome data will be obtained from the SHOP database. For all patients, the GCS score will be obtained from the NICU flowsheet, which is a datasheet completed by nurses on a continuous basis throughout the hospital day. From 1997 to July of 2004, these flowsheets are available in paper form in the charts in medical records. After July of 2004, they are computerized and accessible through the program Eclipses. It should be noted that the SHOP database is maintained by individuals uninvolved in the care of the patient, which will eliminate bias in evaluating outcome.

D. Study Drugs

No drugs will be administered during the course of this study.

E. Medical Devices

No medical devices are under investigation in this study.

F. Study Questionnaires

No questionnaires will be utilized during the course of this study. All questionnaires used in the SHOP database are approved under that protocol.

G. Study Subjects

Study subjects will include all patients who were admitted to this hospital from 1997 to December of 2005 with the diagnosis of aneurysmal subarachnoid hemorrhage. This group has previously been shown to have an average age in the range of 55-60 and to be predominantly women at a ratio of 2:1.

H. Recruitment of Subjects

No recruitment of subjects will be necessary for the completion of this study.

I. Confidentiality of Study Data

Confidential medical information will be reviewed and recorded only if necessary to accomplish study goals. All recorded and compiled confidential information will be deidentified via removal of personal information such as subject name, hospital unit number, social security number, telephone number(s), and

J. Potential Conflict of Interest

There are no potential conflicts of interest.

K. Location of the Study

The study will be performed at Columbia Presbytarian Hospital.

L. Potential Risks

There are no potential risks to the patients involved in this study.

M. Potential Benefits

The potential benefit of this study is that it will contribute to the prognoses of poor grade patients with aSAH and assist clinicians in making medical decisions.

N. Alternative Therapies

No therapies are being offered in this study.

O. Compensation to Subjects

There will be no compensation to the patients whose medical data is analyzed in this study.

P. Costs to Subjects

There will be no costs to the patients involved in this study.

Q. Minors as Research Subjects

All patients included in the study will be over the age of 18.

R. Radiation of Radioactive Substances

There is no radiation and there are no radioactive substances used in this study.

S. References

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