BrainIT: a trans-national head injury monitoring research network

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Summary

Background. Studies of therapeutic interventions and management strategies on head injured patients are difficult to undertake. BrainIT provides validated data for analysis available to centers that contribute data to allow post-hoc analysis and hypothesis testing.

Methods. Both physiological and intensive care management data are collected. Patient identification is eliminated prior to transfer of data to a central database in Glasgow. Requests for missing/ambiguous data are sent back to the local center. Country coordinating centers provide advice, training, and assistance to centers and manage the data validation process.

Results. Currently 30 centers participate in the group. Data collection started in January 2004 and 242 patients have been recruited. Data validation tools were developed to ensure data accuracy and all analysis must be undertaken on validated data.

Conclusion. BrainIT is an open, collaborative network that has been established with primary objectives of i) creating a core data set of information, ii) standardizing the collection methodology, iii) providing data collection tools, iv) creating and populating a data base for future analysis, and v) establishing data validation methodologies. Improved standards for multi-center data collection should permit the more accurate analysis of monitoring and management studies in head injured patients.

Keywords: Head injury; data collection; validation; analysis; network.

Introduction

There have been a number of projects that have collected high quality monitoring data from severely head injured patients. Patient recruitment to these projects can be restricted as the number of patients admitted to any one unit at any given time is limited. Collection of this data varies from hospital to hospital and there are no set standards; therefore, it is difficult to make comparisons of results from different centers. Physiological monitoring of these patients is essential so that the incidence and effects of secondary insults can be determined, as both play a significant role in patient recovery and outcome [1]. Accurate data collection is also required to detect subtle differences that new therapeutic and management strategies may produce in the care of these patients.

The aim of the BrainIT group is to coordinate with a number of European neurotrauma centers to collect high quality minute-by-minute physiological monitoring data and also clinical management data using a previously defined core data set [3] and standardized data collection equipment. The study started in September 2002 and the initial target for the group is to recruit 300 patients from 30 prospective centers. Data that is free of patient identification is then transferred over the internet to the BrainIT website where it is converted in a common format and entered into a database. Data is validated by country-specific data validators and only this data may be used in formative analysis. Data which has not been validated may be used for hypothesis testing. Anyone may register with the BrainIT website. Access to the database is permitted from those centers who recruit at least 5 patients per year.

Materials and methods

The BrainIT European Coordinating Center is located in Glasgow, Scotland, and a steering group of healthcare professionals leads and advises the group. There are currently 30 European centers participating, with 20 centers actively recruiting patients. Each country has a Country Coordinating Center, where a data validator assists and advises the centers taking part. The data validator's role is to assist in the training of nursing and/or medical staff who collect and transfer the data, and to act as the first point of contact for centers with any queries. A previously-defined core data set is used, of which there are 4 constituent parts: physiological monitoring data, demographic and clinical information, intensive care management data, and secondary insult management data. Minute-by-minute monitoring data are collected from the bedside monitors by either a bedside laptop computer using commercially developed software, or via a network and locally developed systems. Intensive care treatment and management data are collected using a handheld computer (personal digital assistant; PDA). Commercial software developed by Kelvin Connect Ltd. enables staff to collect demographic, clinical, and treatment data. Computed tomography (CT) data is also collected using the Traumatic Core Data Bank criteria (Marshall score) [2] and CT images devoid of patient identification are transferred to Glasgow via the BrainIT website for independent assessment.

Patients included in this project may be of any age as long as there is evidence of traumatic brain injury and the patient has both arterial and intracranial monitoring. Written consent is obtained from the relatives, although with agreement from the Multi-Research Ethics Committee in Scotland and local research ethics committees in the

U.K., data collection may begin before consent is formally obtained. If consent is not given, any data collected will not be retained, as is stated in information sheets provided to the relatives.

Patients are followed-up at 6 months post-injury using the Extended Glasgow Outcome Scale, either by face-to-face or telephone interview. Data is collected for as long as the intracranial pressure and arterial monitoring are in place. Daily intensive care management data are collected by nursing staff and entered into a PDA; the data is then transferred to a local computer where it is stored in a database. From this database, the patient files are exported to Glasgow via the BrainIT website. Patient confidentiality is ensured by removing patient identification data before the transfer occurs, which is in keeping with local and national data protection policies. Patient identification for local and coordinating center staff is by means of a unique 8-digit number, which is obtained from the BrainIT website and attached to the patient's file prior to sending the data. The same identification number is used for the physiological monitoring data, which is again sent via the internet. Once the data has been received in Glasgow, it is converted to a common file format and areas of missing or ambiguous data are highlighted. A missing data list is then created and sent back to the contributing center to look for the missing data, who attempts to complete the file as much as possible and return it to Glasgow. This process is repeated until as much of the data can be found as is possible.

A random sample of 20% of the data is then selected for validation against the available source documents (Fig. 1). The validation list may include any physiological, clinical, and treatment data. For example, a request may be sent for a record from the nursing chart or all of the blood pressure and cerebral perfusion pressure readings
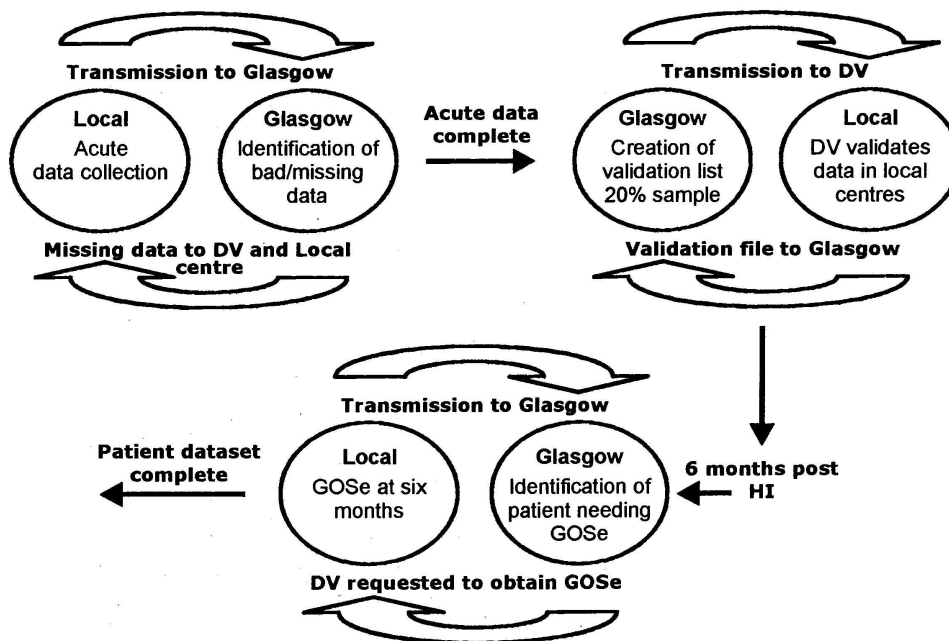

Fig. 1. Data validation cycle. *DV* Data Validator, *GOSe* Extended Glasgow Outcome Scale, *HI* Head Injury

from a 24-hour period. These readings are taken from the chart using the time nearest to that on the validation request. Simultaneously, a request is also sent for the actual number of specific episodic events during a known period; for example, the number of arterial blood gas samples taken in a given time span. A validation file is created for each patient using the BrainIT Core Data Collection tool and the file is then returned to Glasgow. The data validator is responsible for the validation of all the samples of data within a given country (Fig. 1).

Data validation is carried out following a set standard of procedures and can be done at 4 different levels. Only validated data is saved in the common database. This ensures that the 20% sample of data which is stored is the most accurate for each patient.

- Level 1 ensures the data conversion stage functions correctly; in particular, the time-stamp format (YYYY-MM-DD).
- Level 2 checks all non-numeric categorical core data set data for transcribing errors. This level of validation differs according to whether monitoring or non-monitoring data is being validated.
- Level 3 is the conversion of locally used units to BrainIT units.
- Level 4 requires intervention of the data validator.

There are 3 types of Level 4 data validation: Type 1 or self-validation where the principal investigator validates his own data; type 2 is cross-validation where local colleagues may validate each other's data; type 3 validation is where the data validator has no connection with the center from which the data has been collected.

Results

There are currently 30 centers participating in the group and 20 of these centers are actually recruiting

patients and supplying data. To date, 257 patients have been recruited to the study with monitoring data sent to Glasgow from 251 patients (Fig. 2). Of these, 53 patients have currently been validated.

There are several projects planned to make use of the data collected and stored in the database. Work is currently underway to assess intracranial pressure and cerebral perfusion pressure variability analysis, and to assess the frequency of missing data and ascertain which types of data are missing most frequently. Both quantitative and qualitative analysis methods will be used in this project. Another project for the future is the BrainIT network clinical evaluation of the Raumedic Neurovent intraparenchymal probe to test its long-term clinical performance.

Conclusion

BrainIT is an open, collaborative network and, thus far, the group has demonstrated that it is possible to standardize the collection methodology of high resolution neurointensive care data. By providing country-specific data validators who are responsible for staff coordination and training, the participating centers have been able to record intensive care treatment and
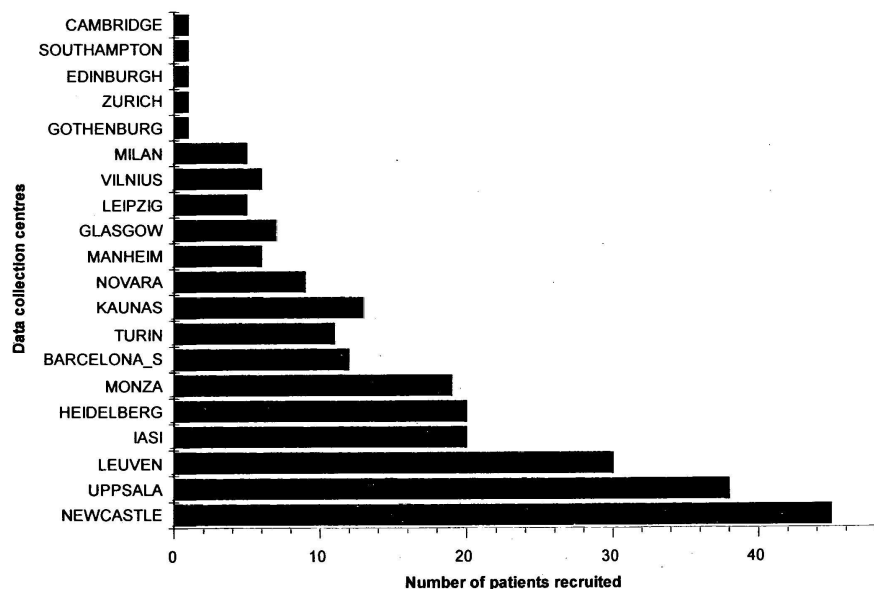
Fig. 2. Recruitment graph as at May 2005

management data using a defined core data set. The provision of standard equipment and assistance obtained from industry has enabled centers to collect data using standard data collection methods. Transfer of data has proven successful, and a populated database has provided data for future analysis by those who contribute data. A minimum of 5 patients per year is the requirement for those centers participating to have access to the data. Access to the data by personnel within the contributing centers is controlled by the principal investigator within each center. Development of software tools has enabled missing and ambiguous data to be selected from the data set, and data validators have collaborated with participating centers to find missing data. Data validation methodologies have been established and, with the help of the data validators, integrity of the data has been ensured.

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