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BrainIT collaborative network: analyses from a high time-resolution dataset of head injured patients

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Abstract
Background The BrainIT project was conceived in 1997 and has grown into an international collaboration with the purpose of gathering high time resolution data from head injured patients utilising standardised methodologies.

Materials and methods From 1998, 22 participating neuroscience centres collected three main types of information: demographic, physiological data and clinical treatment information. A data collection solution was provided for each centre dependent on their existing facilities and data

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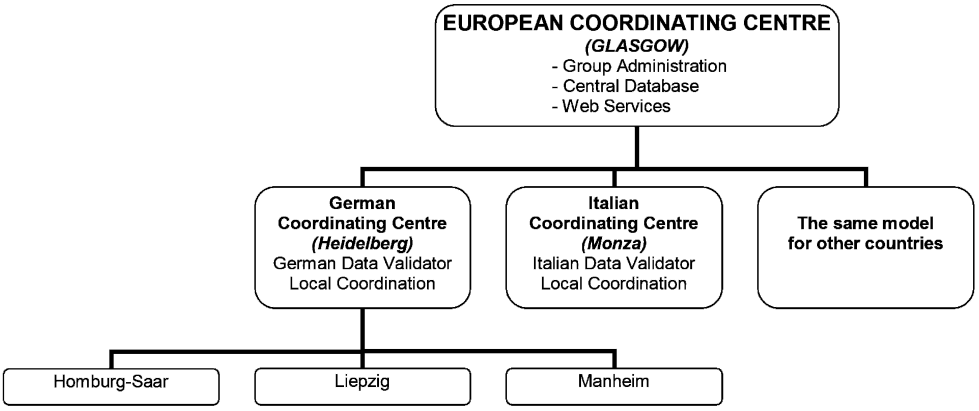

Fig. 1 Structure of the BrainIT group

were collected for the duration of monitoring as defined by the routine care in each centre. On completion of ICP monitoring all personal information was removed and then transferred to Glasgow via the internet where it was converted into a standard format and entered into a central database. Outcome was measured using the extended Glasgow Outcome Score using an interview questionnaire.
Findings Data has been obtained from a total of 349 patients (277 male and 72 female) The age of these patients ranged from 1 to 87 years (median 31); 145 had been involved in a traffic accident and 32 were pedestrians; 78 had suffered a fall; 24 were assaulted and the remaining 70 of other causes. A large amount of physiological data was collected (e.g. BP 2,531 days, ICP 2,212 days in total). This dataset has provided the opportunity to perform unique analysis and these include the statistical features of blood pressure, diurnal variations in ICP, optimal sampling rate determination and a comparison of summary measures of secondary insults.
Conclusions This challenging collaboration has brought together a large number of centres and developed a successful clinical research network focussed on improving the treatment of head injured patients. It has successfully collected a vast quantity of high quality data that provides a rich source for analysis and hypothesis testing.

Keywords Brain injury · Monitoring · Collaborative network · Information technology

Introduction

Head injured patients provide very rich but diverse data from physiological monitoring, patient demographics, treatment and imaging sources and with advances in technology the measurement and recording of high time resolution data as paper based methods is readily available. In comparison, paper based methods, often used in pharmacological studies, may underestimate the severity, length and frequency of secondary insults [7].

The increasing need to ensure that clinical practice is based upon a sound evidence base requires methods and analyses that are capable of replication. Research studies also need to be completed in a timely manner so that changes or improvements in aspects of care do not introduce confounding factors that might affect the analysis and results. In addition data are collected in different ways, formats and time resolution and can be described by different summary measures (e.g. 1 h reading, average over 1 h, rolling means etc.) and this can make it very difficult to compare studies from different centres. There is therefore a need to work collectively to ensure common standards and methods are employed for the collection of data.

In 1997 the BrainIT network evolved from discussions within a group of multi-disciplinary researchers working in the field of head injury. From the outset the underlying ethos was one of openness and collaboration: anyone can join, organisation was non-profit making and time was given voluntarily. All BrainIT studies contribute to a common database to which contributing members have free access. The primary objectives of the BrainIT group were defined as:

1. To develop and disseminate standards for the collection, analysis and reporting of intensive care monitoring data collected from brain injured patients.
2. To provide an efficient multi-centre infra-structure for generating evidence on the utility of new forms of invasive and non-invasive intensive care monitoring and methods for improving the care and outcome of brain-injured patients.
3. To develop and use a standardised database as a tool for hypothesis generation and the development, testing and validation of new data analysis methodologies.

Materials and methods

Three preliminary meetings brought European collaborators together to define the core dataset [6]. This described the

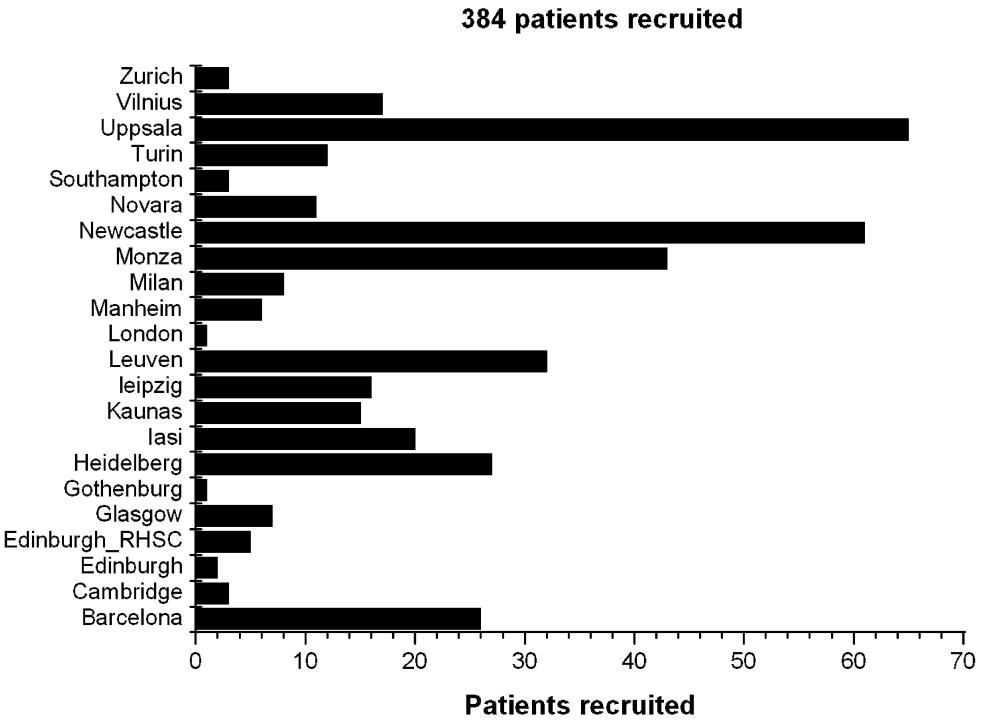

Fig. 2 Patient recruitment to date

format, frequency and units in which commonly measured variables should be stored. The minimum requirements were for invasive blood pressure and intracranial pressure to be monitored and recorded at a one-minute time resolution.

A European Union Framework V grant [3] provided the resources for a multi-centre pilot study to collect high resolution data from head injured patients. This required that equipment was deployed to participating sites for the

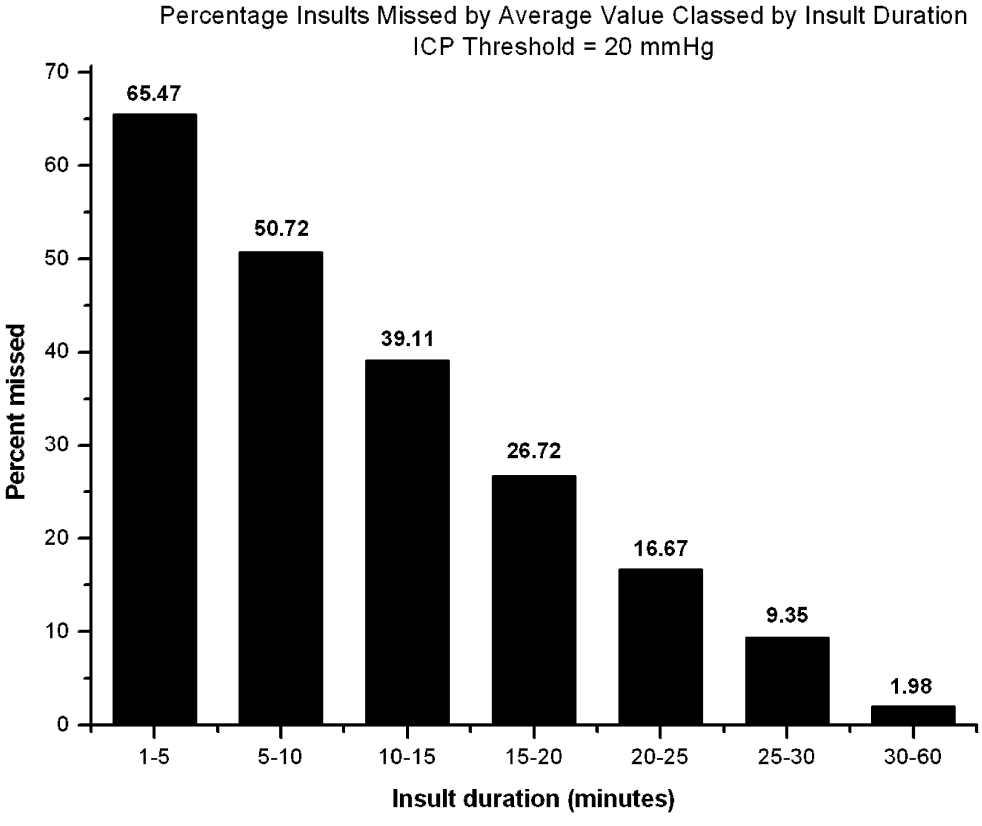

Fig. 3 Analysis of "missed" insults when using hourly averaged readings of ICP

collection of physiological, demographic and clinical information. The aim was to recruit and collect data from ten patients from each centre. Centres were coordinated, by a national validation centre where data validation staff were employed. The structure of the group is shown in Fig. 1 which depicts the way in which individual centres communicated with the national validation centres. There is both vertical and horizontal integration and individual centres are actively encouraged to communicate, participate and share information and resources with other centres.

Over the period between 1998 and 2006 data capture systems were deployed in high dependency and intensive care units in 21 participating neuroscience centres. The demographic information included age, cause, GCS, CT scan, pupil reaction and times of transfer; physiological data included minute by minute recording including ICP, CPP, MAP SaO2.

A web site (http://www.brainit.org) was designed and this provided several different functions:

1. Upload of data from centres
2. Requests for data validation and outcome assessment
3. Distribution information and results
4. Discussion forum for different groups (steering committee, data validators etc)

A data validation system was proposed so that data could be checked for accuracy. Firstly data from the acute phase was transmitted to Glasgow and inconsistencies identified. A request to correct any missing or out of range values was made. Then a request for validation of a 20% sample would be made to the data validator. Six months later a request for outcome assessment would be made, recorded and the validated data entered into the database.

Rules for publication of data were defined simply as publication can only be from validated data and manuscripts must be circulated to the Steering Group for comment prior to submission.

Results

At the end of the Framework V project, BrainIT had successfully collected and validated data from 200 head injured patients. This required the provision of data collection tools for the demographic, clinical management and physiological data. In collaboration with a commercial company (KelvinConnect Ltd, Glasgow) a PDA solution was produced to capture demographic and clinical data. A variety of different solutions to capturing physiological data were required as it was dependent upon the monitoring equipment used in each centre. Three main approaches were used, first a bedside computer running the Edinburgh Browser software [4], second a commercial product (ICUPilot, CMA Microdialysis AB) or thirdly an in-house solution that particular centres had already developed for other research works.

To date a total of 349 patients (277 male and 72 female) have now been transmitted to the coordinating centre in Glasgow (Fig. 2). The age of these patients ranged from 1 to 87 years (median 31). One hundred and forty-five had been involved in a traffic accident and 32 were pedestrians; 78 had suffered a fall and 24 were assaulted. A large amount of physiological data was collected (e.g. BP 2,531 days, ICP 2,212 days in total).

This dataset provides the opportunity to perform unique analyses and the statistical features of blood pressure have been described [5]. Further work related to the diurnal variations in ICP, optimal sampling rate determination and a comparison of summary measures of secondary insults are also underway. For example, Fig. 3 shows the percentage of insults that are missed when end hour averages are compared with minute-by-minute readings. Using a threshold of 20 mmHg the duration of missed insults was calculated for distinct 1-h periods. The percentage of ICP insults missed compared to the end hour value was highest with shorter duration insults although significant numbers of insults greater than 10 min in duration were still missed. The group has also been able to undertake a survey of traumatic brain injury management [2] and the evaluation of a new pressure monitoring device [1].

Discussion

This challenging collaboration has successfully developed a clinical research network focussed on improving the treatment of head injured patients. It has brought together a large number of centres capable and willing to undertake clinical research across the network. It has also successfully collected a vast quantity of high quality data that provides a rich source for analysis and hypothesis testing.

Clinical research networks such as BrainIT have the capacity to undertake research in a new way. The ethos of BrainIT is to foster an open collaboration, to data share and develop computer based data collection standards. The more members that join the BrainIT group, the more projects are formed. This will generate more data for the database and therefore generate more hypotheses. This will create more project ideas that will in turn generate more data. It is this cyclical process with an open collaborative approach which is at the heart of the BrainIT concept

The advantages are the ability to: standardise methods, store data in a compatible format and, because of the size of the network, studies can be done much quicker. There are benefits in bringing together different healthcare professionals who have a combined interest in a particular area to

produce a larger intellectual mass. These combine to produce benefits for the patient, the primary goal, but there are also advantages for the academic researchers and industry, both pharmaceutical and device manufactures.

The main disadvantages are that considerable time and effort are required to set up and maintain the network. There are resource implications in running the network by supporting centres and researchers and although considerable effort is made towards fully funding centre activities, during periods of low funding, centres may be required to absorb costs. On-going maintenance is required and individuals or groups may lose focus and/or interest particularly if regular meetings or projects of interest are not provided. Individual differences may surface so that the group is not always working together as a cohesive unit. If these barriers to progress are identified and the group are aware of them then strategies can be put in place to minimise their potential for creating a problem.

A good research network has the ability to answer important clinical questions that are beyond the capability of singles centres. They require a common enthusiasm and but the output from the group can be greater than the sum of the constituent parts.

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Conflict of interest statement We declare that we have no conflict of interest.

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