Brain monitoring with information technology. The "Brain-IT" Group Experience

I. PIPER, C. F. CONTANT*, G. CITERIO**

Background. The Brain Monitoring with Information Technology "Brain-IT" network is a collaborative framework of basic scientists, clinicians and small enterprises working within the field of brain injury that have a specific interest in developing and assessing standardised methods for collection and analysis of neuro-intensive care monitoring information. *Methods.* The Brain-IT group has established an inter-net based infrastructure for accessing standardised patient data collection tools which can collect and quantify high resolution monitoring and treatment data. The network also provides a mechanism for stimulating and supporting links between neuroscience research groups. *Results.* This infrastructure has now been used in the assessment of a new form of brain monitoring: The Spiegelberg Brain Compliance Monitor. To date 75 patients have been recruited to the study. Data standardisation, accrual and analysis have been facilitated by this network. *Conclusions.* Continued use of this Internet based infrastructure will lead to the establishment of a large, standardised database of physiological monitoring data, demographic and patient treatment data which will provide a powerful tool for post-hoc development of new data analysis and hypothesis generation methodologies. This infrastructure is also an excellent resource for medical device manufacturers as a means of facilitating standardised multi-centre assessment of new technology. This infrastructure will also be of use in standardising the assessment of new therapy. To facilitate faster data accrual, more centres need to be recruited and installed with standardised hardware and software. Funding is being sought to expand the group and to improve the development of tools for access to the database.

Key words: **Brain injury - Brain monitoring.**

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The Brain Monitoring with Information Technology "Brain-IT" network is a collaborative framework of basic scientists, clinicians and small enterprises working within the field of brain injury that have a specific interest in developing and assessing standardised methods for collection and analysis of neuro-intensive care monitoring information.

The Brain-IT Group was set up in March 1998 by Ian Piper (Glasgow - Institute of Neurological Sciences) and Charles Contant (Houston - Baylor College of Medicine). The idea for the group came from discussions ari-

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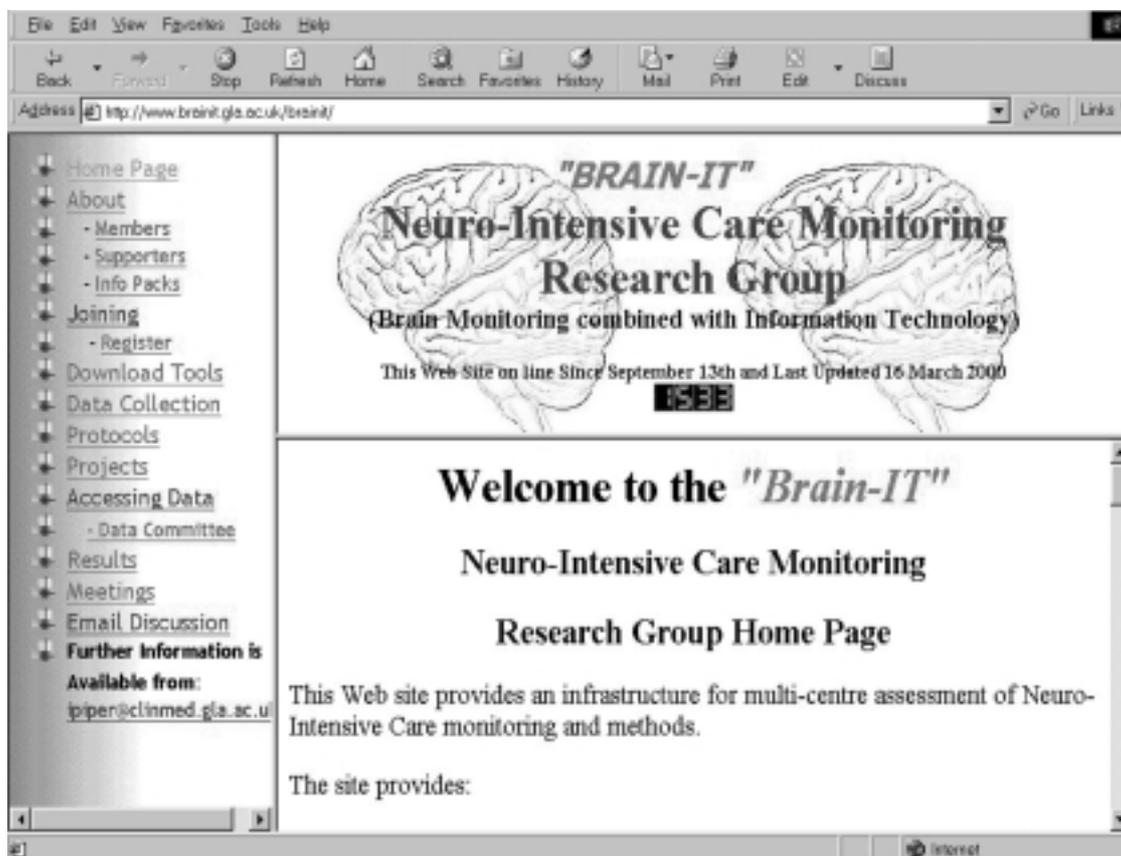
Fig. 1.—Screen shot of the "Brain-IT" Group Web Site Home Page.

sing during the 10th International Symposium on Raised Intracranial Pressure and Neuro-monitoring in Brain Injury held in Williamsburg, Virginia on May 25th-29th 1997.[1] A number of research groups present at the Richmond meeting were instrumental to the discussion underlying the development of a standardized multi-centre infrastructure for support of research into neuro-intensive care physiological monitoring.

The Brain-IT group has now established minimum monitoring data collection criteria through completion of a multi-centre survey of data collection methods.[2] Through seed funding from the Janssen Pharmaceutical company, in anticipation of assessment of a new treatment for head injury, the Brain-IT network established an FTP data server for download and archive of multi-centre data. The Brain-IT network has NIH funded travel support for a

statistician with considerable expertise in analysis of time-series patient monitoring data. The Brain-IT group is an Inter-net based research group linked by a Web-Site (http://www.brainit.gla.ac.uk/brainit) which provides on-line tools to support:

— Multi-centre collection of patient demographic data.

— Multi-centre collection of patient monitoring data.

— E-mail and mailbase access to an expanding research group with interests in assessment of neuro-intensive care health technology.

This paper describes the development of the Brain-IT group methods and the experience to date applying these methods in a multi-centre study of a new form of Brain-Monitoring technology.

Methods

Demographic data definition and collection

Multi-modality or multi-parameter minute-by-minute physiological monitoring is now common across many neuro-intensive care centres. However, there are no agreed standards for defining the collection, summary and analysis of monitoring data. As a consequence it is often difficult to compare even the most common forms of monitoring when data is presented at meetings. In order to define a basic data collection protocol, we carried out a survey of a number of centres to determine the existing range of physiological monitoring and data collection procedures currently in use. Eighteen centres were contacted and eleven returned completed survey forms. The forms consisted of 20 questions on monitoring (type of bedside monitors, transducer types, techniques for zero referencing transducers…) as well as information on the standard demographic information that is and can be collected from each centre. Full survey results and data collection protocols are available from the Brain-IT website: http://www.brainit.gla.ac.uk/brainit/ (see "Data Collection" Link).

Based upon the results of this survey, specially designed database software has been created which can be downloaded to each centre for collection of patient demographic data. The software was created by Davide Galli in Monza. The database design was based upon the Neurolink database but was expanded to allow collection of demographic data from patient groups other than head injured patients. Neurolink is a software tool which collects demographic data on head injured patients in a standard format with a very easy to use interface. It has been developed in Italy by Giuseppe Citerio & Manuela Cormio. The Brain-IT demographic data collection software package is free and can be accessed once a Brain-IT application form is completed. The package is downloaded from the Brain-IT website and allows local entry of patient data. When new patient data is entered, a facility is provided which exports the new data to an external file. This file is sent as an email attachment to the Brain-IT coordinating center in Glasgow where it is imported into the multi-centre database.

Monitoring data standardisation and collection

Some manufacturers of devices under test by the Brain-IT group provide free software designed specifically for collection of the continuous data from their monitors. The Spiegelberg data collection software (the device currently under assessment by the Brain-IT group) is an example. This software package is free and downloadable from the Brain-IT web site.: http://www.brainit.gla.ac.uk/brainit/ (see "Download Tools" Link).

There are now an increasing number of centres which use the "Edinburgh Secondary Insult Detection" software for collecting data. This suite of tools was developed by Dr Tim Howells, Universities of Edinburgh & Uppsala. These tools collect and analyse physiological data from patient monitors and both calculates and displays raw data and "Secondary Insult" data. These tools now have interfaces to a range of patient monitors and are ideal tools for generic collection of data for multi-centre trials. Monitors not supported can have new interfaces developed. Apart from physiological data, this tool also provides an excellent interface for collection of patient demographic and patient management data at the bed space. A demo version of this software package is downloadable from the Brain-IT web site.: http://www.brainit.gla.ac.uk/brainit/ (see "Download Tools" Link). By supporting access to these software packages, the Brain-IT group ensures hardware and software data collection standards between centers are improved.

Web based data transfer and analysis

Data collected by each centre is downloaded either as email attachments or by file transfer protocol (FTP) to the Brain-IT coordinating centre in Glasgow. The database is free of any patient information which might identify the patient. Demographic data is held

in a Filemaker Pro database format but can also be exported into other data formats. Physiological data is available in ASCII format but can also be viewed and analysed using the Edinburgh Browser Secondary insult software suite. All transferred data is accompanied by an ASCII coded file which describe centre specific "artefact codes" identifying potentially artefactual data. Transferred data is copied and reformatted into a standardised ASCII format. Reformatted data is copied by FTP to the data analysis server of the Brain-IT group Statistician in Houston, USA. Software tools are being developed which will allow Brain-IT members to search the common patient database, select sub-sets of patients and extract all demographic and monitoring data for those patients directly from the web-site.

Results

There are now 50 registered members of the Brain-IT group from 13 countries across Europe. Eight centers are actively recruiting and contributing data to the current Brain-IT project. Currently, due to the size of the group, there is only one Brain-IT project under multi-centre assessment, however, there are a number of protocols and project ideas being developed. As the Brain-IT group grows in size, it will be possible for multiple projects to be supported by sub-groups of members. Details of other project ideas can be viewed from the Brain-IT web site.: http://www.brainit.gla.ac.uk/brainit/ (see "Projects" Link).

The device currently under assessment is the Spiegelberg Compliance Monitor. This device is a new form of monitoring that measures craniospinal compliance continuously in patients who can have an intraventricular catheter placed for either drainage of CSF or measurement of intracranial pressure.[3] Continuous compliance measurement has not been previously possible. The purpose of this study is to define the inherent variability of compliance, using this method, in different populations of patients. Using this information, critical compliance thresholds for raised

ICP can be defined. These thresholds can then be tested in a subsequent prospective clinical trial. The Spiegelberg Compliance Study Protocol can be viewed from the Brain-IT web site.: http://www.brainit.gla.ac.uk/brainit/ (see "Projects" Link).

To date, 75 patients have been recruited to the Spiegelberg study. A recent power analysis of the database has determined that the device needs to be assessed in at least a further 70 head injured patients before a reliable estimate of a clinically relevant compliance threshold can be defined.[4] Once this is known, a future prospective trial can be designed to test whether treating compliance improves the incidence of raised ICP and patient outcome. Realistically, these numbers can best be achieved by expanding the number of centres actively assessing this device. Funding is being sought from a number of sources, including European funding, in an attempt to facilitate the expansion of this project. Project recruitment rates and all interim analysis results are viewable and downloadable from the Brain-IT web site.: http://www.brainit.gla.ac.uk/brainit/ (see "Results" Link).

The Brain-IT group meets at least once a year. Usually as a satellite meeting attached to a main neurosurgical or neurointensive care meeting. These informal meetings give the group the opportunity to openly discuss protocols, completed studies and any work in progress. In addition, these meetings will also provide a forum for discussion on how the management and organisation of the group and the group's data can be improved. The Brain-IT group is an independent research group. However, a number of non-academic organizations now support the Brain-IT group as a framework for the multi-centre approach to research into assessment of neuro-intensive care monitoring and methods. Supporting Organisations include the European Brain Injury Consortium (EBIC), a number of small medical device manufacturers and recently three pharmaceutical companies have registered an interest in the concept underlying the Brain-IT group infrastructure. Details can be obtained from the Brain-IT web site.:

http://www.brainit.gla.ac.uk/brainit/ (see "Supporters" Link).

Discussion and conclusions

The Brain-IT group has established an internet based infrastructure for accessing standardised patient data collection tools which can collect and quantify high resolution monitoring and treatment data. The network also provides a mechanism for stimulating and supporting links between neuroscience research groups. Continued use of this Internet based infrastructure will lead to the establishment of a large, standardised database of physiological monitoring data, demographic and patient treatment data which will provide a powerful tool for post-hoc development of new data analysis and hypothesis generation methodologies. This infrastructure is an excellent resource for medical device manufacturers as a means of facilitating standardised multi-centre assessment of new technology. This infrastructure will also be of use in standardising the assessment of new therapy.

To facilitate faster data accrual, more centres need to be recruited and installed with standardised hardware and software. Funding is being sought to expand the group and to improve the development of tools for access to the database.

Riassunto

Il Brain monitoring with information technology "Brain-IT" network é un framework collaborativo di ricercatori di base, clinici e di imprese che lavorano nel campo del danno cerebrale e che hanno uno specifico interesse nello sviluppare e sostenere metodi standardizzati per la raccolta e l'analisi del monitoraggio neuro-intensivo.

Viene riferito sullo stato dell'arte, sulla pagina web e sulle possibilità che il network propone.

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