Multi-Centre Assessment of the Spiegelberg Compliance Monitor: Interim Results

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SUMMARY

Analyses of a multi-centre database of 71 patients at risk of raised ICP showed that in head injured patients (n = 19) and tumour patients (n = 13) there were clear inverse relationships of ICP Vs compliance. SAH patients (n = 5) appear to exhibit a biphasic relationship between ICP and compliance, however greater numbers of patients need to be recruited to this group. Patients with hydrocephalus (n = 34) show an initial decrease in compliance while ICP is less than 20 mmHg, thereafter compliance does not show a dependence upon ICP. A power analysis showed sufficient numbers of patients have been recruited in the hydrocephalus group and a ROC analysis determined that a mean compliance value of 0.809 (lower and upper 95% CL = 0.725 & 0.894 resp.) was a critical threshold for raised ICP greater than 10 mmHg. Preliminary time-series analyses of the ICP and compliance data is revealing evidence that the cumulative time compliance is in a low compliance state (< 0.5 ml/mmHg), as a proportion of total monitoring time, increases more rapidly than the cumulative time ICP is greater than 25 mmHg. Before trials testing compliance thresholds can be designed, we need to consider not just the absolute threshold, but the duration of time spent below threshold. To identify this, a survey may be needed to identify a consensus of what is the minimum duration of raised ICP above 25 mmHg needed to instigate treatment.

INTRODUCTION

A multi-centre collaborative group (*Brain-IT Group*) has recently been formed and consists of basic scientists and clinicians with a specific interest in the development and assessment of new forms of intensive care monitoring for use in Brain Injured Patients. Each member of the group contributes data to a common database collected according to a standard protocol[1]. A Web-Page has been set up which describes the guidelines and procedures of the group:

http://www.brainit.gla.ac.uk/brainit. Currently the group is focused on assessing the ***Spiegelberg Compliance Monitor***. Raised intracranial pressure (ICP) remains a significant clinical problem in patients with brain trauma, mass lesions and disturbances to cerebrospinal fluid (CSF) dynamics. Measurement of craniospinal compliance offers the potential of earlier identification of processes which lead to raised ICP. In addition to predicting ICP, a measure of compliance in combination with other features of the ICP signal may aid in clinical decisions concerning definitive measures for CSF diversion. A new method for measurement of compliance on a continuous basis has been developed[2] and we report on analyses focused on studying the relationship between compliance and ICP data from 71 patients monitored with the Spiegelberg device.

METHODS

The Spiegelberg compliance monitor calculates intracranial compliance ($C = \Delta V/\Delta P$) from a moving average of small ICP perturbations (ΔP) resulting from a sequence of up to 200 pulses of added volume (ΔV = 0.1 ml, total V = 0.2 ml) made into a double lumen intraventricular balloon catheter. Once a stable average has developed, the device produces a minute by minute measure of intracranial compliance. Neuro-intensive care data collected from 8 centres (Glasgow, Edinburgh, Berlin, Monza, Uppsala, Hong Kong, Homburg, Birmingham) have been recruited to date which include a total of 55000 minutes (38 days) of paired ICP and compliance values. Collected data were grouped by patient type into 4 groups: a) Head Injury (HI) n = 19 patients, b) Hydrocephalus (HYDRO) n = 34 patients, c) Post-Operative tumour (TUMOUR) n = 13 patients, d) Post-Subarachnoid Haemorrhage (SAH) n = 5 patients. Summary statistics were produced for compliance data when grouped into 6 ICP bands and classed by patient type. A receiver-operator characteristic (ROC) analysis was performed to identify critical compliance thresholds for raised ICP. Disease state was defined as ICP > 25

mmHg (> 10 mmHg for the hydrocephalus group). The sensitivity and specificity was then calculated for compliance values predicting disease state when compliance was increased from 0.1 to 1.8 ml/mmHg in increments of 0.1. The crossover point of the sensitivity and 1-specificity curves was used as an estimate of an optimal threshold. To assess the temporal relationship between compliance and ICP, analyses were performed of the proportion of time spent, of total monitoring time, for compliance less than 0.5 ml/mmHg and ICP > 25 mmHg. All analyses were performed with S-Plus 2000.

RESULTS

TABLE 1 summarises the associated median compliance (± median absolute deviation) classed into 6 ICP bands. Head injured patients (n = 19) and patients after resection of tumours (n = 13) show clear inverse relationships of ICP Vs compliance. Patients with a subarachnoid haemorrhage (n = 5) appear to exhibit a biphasic relationship between ICP and compliance, however greater numbers of patients need to be recruited to this group. Patients with hydrocephalus (n = 34) show an initial decrease in compliance while ICP is less than 20 mmHg, however, above an ICP of 20 mmHg, compliance does not show a dependence upon ICP. FIGURE 1a shows the relative distribution of ICP between the patient groups and shows high ICP was predominantly found in the Head Injury, SAH and Tumour groups whereas there was proportionally very little raised ICP within the hydrocephalus group. FIGURE 1b shows the relative distribution of compliance between the patient groups, which demonstrates all groups showed episodes of lower compliance (<= 0.5 ml/mmHg) which can, in the case of the hydrocephalus group, occur in the absence of significantly raised ICP above 20 mmHg. This data supports the choice of a 10 mmHg ICP level, in this patient population, in the calculation of a critical compliance threshold.

TABLE 2 summarises the results of the ROC analyses expressed as mean and median compliance values (with upper and lower confidence limits). Note that only the hydrocephalus group has recruited sufficient numbers of patients according to an earlier performed power analysis. For the hydrocephalus group it was determined that a mean compliance value of 0.809 (lower and upper confidence limits = 0.725 and 0.894 resp) was a critical threshold for ICP > 10 mmHg.

FIGURE 2 is a line plot, for a single head injured patient's data, of the proportion of time spent (of total monitoring time) that compliance was less than 0.5 ml/mmHg and similarly the proportion of time spent with

ICP greater than 25 mmHg. Note that the cumulated time compliance is below threshold rises faster than the cumulative time ICP is greater than 25 mmHg.

DISCUSSION & CONCLUSIONS

In patient groups known to exhibit "tight brains", intracranial compliance, as measured continuously with the Spiegelberg device, shows the expected inverse relationship with ICP. All patient groups show significant periods of lower compliance (< 0.5 ml/mmHg) which, in the case of patients with hydrocephalus, are not necessarily associated with ICP > 20 mmHg. Systematic analyses for identification of compliance thresholds for raised ICP on a patient population basis has now identified a compliance threshold for patients with hydrocephalus, which may be used in a subsequent trial. However, time-series analyses are now revealing that it is not just the absolute compliance value that is critical but that the duration below threshold needs also to be considered. To achieve this and before a trial can be designed, a survey is warranted to identify a consensus of what is the minimum duration of raised ICP above 25 mmHg needed to instigate treatment.

REFERENCES

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2. Piper I, Spiegelberg A, Whittle I, Mascia L, Signorini D, Miller JD. (1999) A Comparative Study of the Spiegelberg Compliance Device with a Manual Volume-Injection Method: A Clinical Evaluation in Patients with Hydrocephalus. British Journal of Neurosurgery 13(6), 581-586, 1999.

Table 1
Associated Median Compliance (± median absolute deviation) classed into 6 ICP bands (mmHg).

Group	0-10	10+->20	20+->30	30+->40	40+->50	50+
HI (n = 19)	0.77 ±.42	0.62 ±.28	0.51 ±.22	0.44 ±.25	0.37 ±.39	0.03 ±0.03
SAH (n = 5)	0.53 ±.31	0.88 ±.61	0.43 ±.27	0.27 ±.06	0.25 ±.07	0.39 ±.33
Tumour (n = 13)	0.96 ±.37	0.79 ±.36	0.59 ±.24	0.59 ±.21	0.45 ±.21	--- ---
Hydrocep h (n=33)	0.88 ± .39	0.69 ±.30	0.85 ±.30	1.03 ±.32	0.78 ±.07	.92 ±.17

Table 2
Results of Receiver Operator Characteristic (ROC) Analysis Showing Mean and Median Compliance (Comp) with Confidence Limits for Predicting ICP > 25 mmHg (10 mmHg for Hydrocephalus Group)

Group	Power Analysis *(N Needed)*	N	ICP Cutoff *(mmHg)*	Comp Mean *(ml/mmHg)*	Comp Median *(ml/mmHg)*	Comp L95CL *(ml/mmHg)*	Comp U95CL *(ml/mmHg)*
HI	60-70	19	>25	0.641	0.561	0.424	0.857
Tumour	30-40	13	>25	0.785	0.671	0.538	1.032
SAH	30-40	5	>25	0.725	0.632	0.414	1.035
Hydro	30-40	34	>10	0.809	0.800	0.725	0.894

Figure Legends

Figure 1

a) Bar chart showing the relative distribution of ICP between the patient groups and shows high ICP was predominantly found in the head injury, SAH and tumour groups whereas there was proportionally very little raised ICP > 20 mmHg within the hydrocephalus group.
b) Bar chart showing the relative distribution of compliance between the patient groups, which demonstrates all groups showed episodes of lower compliance (<= 0.5 ml/mmHg) which can, in the case of the hydrocephalus group, occur in the absence of significantly raised ICP above 20 mmHg.

Figure 2

Plot for, a single head injured patient, of the proportion of time spent (of total monitoring time) that compliance was less than 0.5 ml/mmHg (diamonds) and similarly that ICP was greater than 25 mmHg (circles). Note that the time compliance is below threshold occurs sooner and rises faster than the time ICP is greater than 25 mmHg.

Figure 1A)

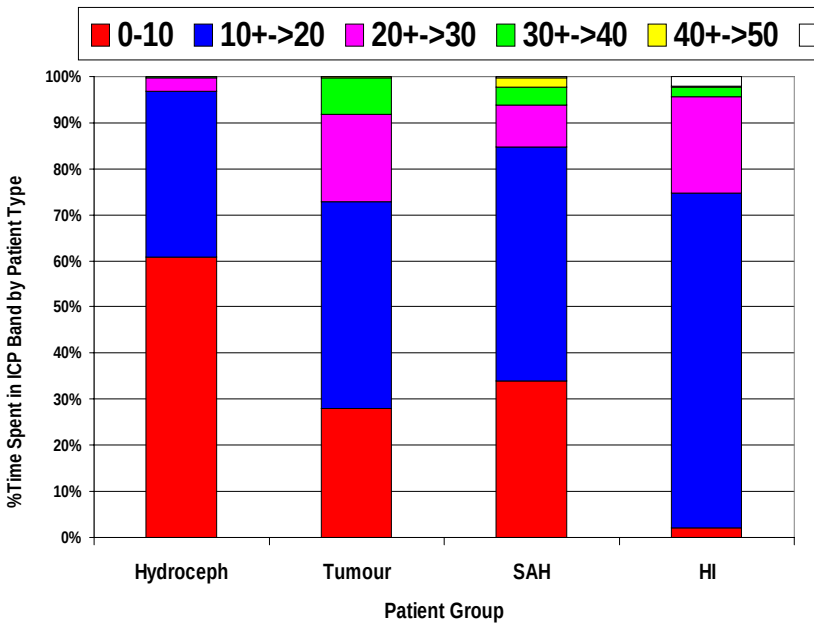


Figure 1B)

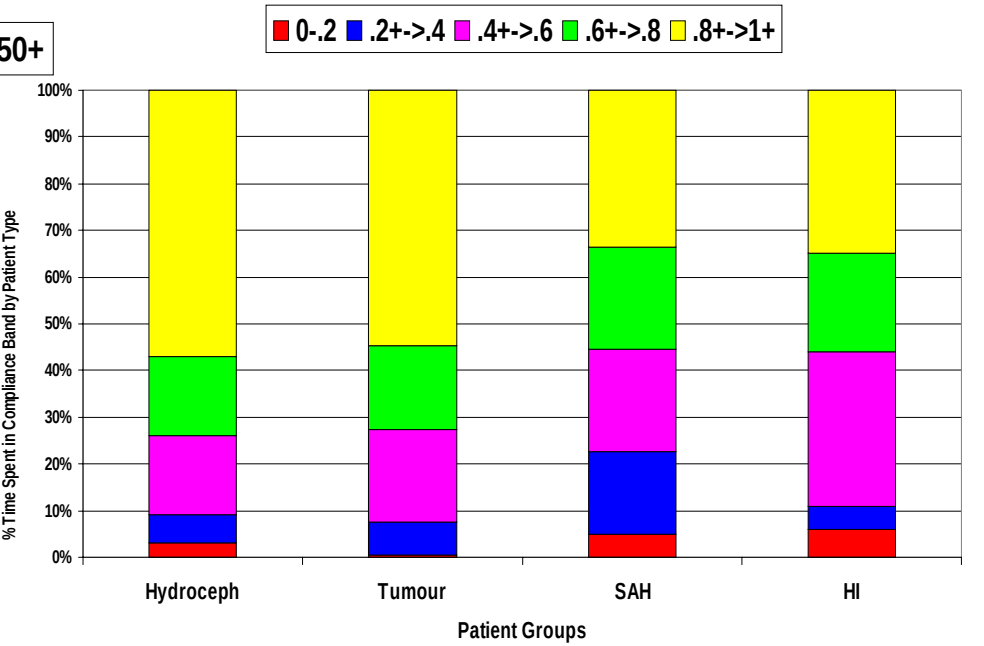
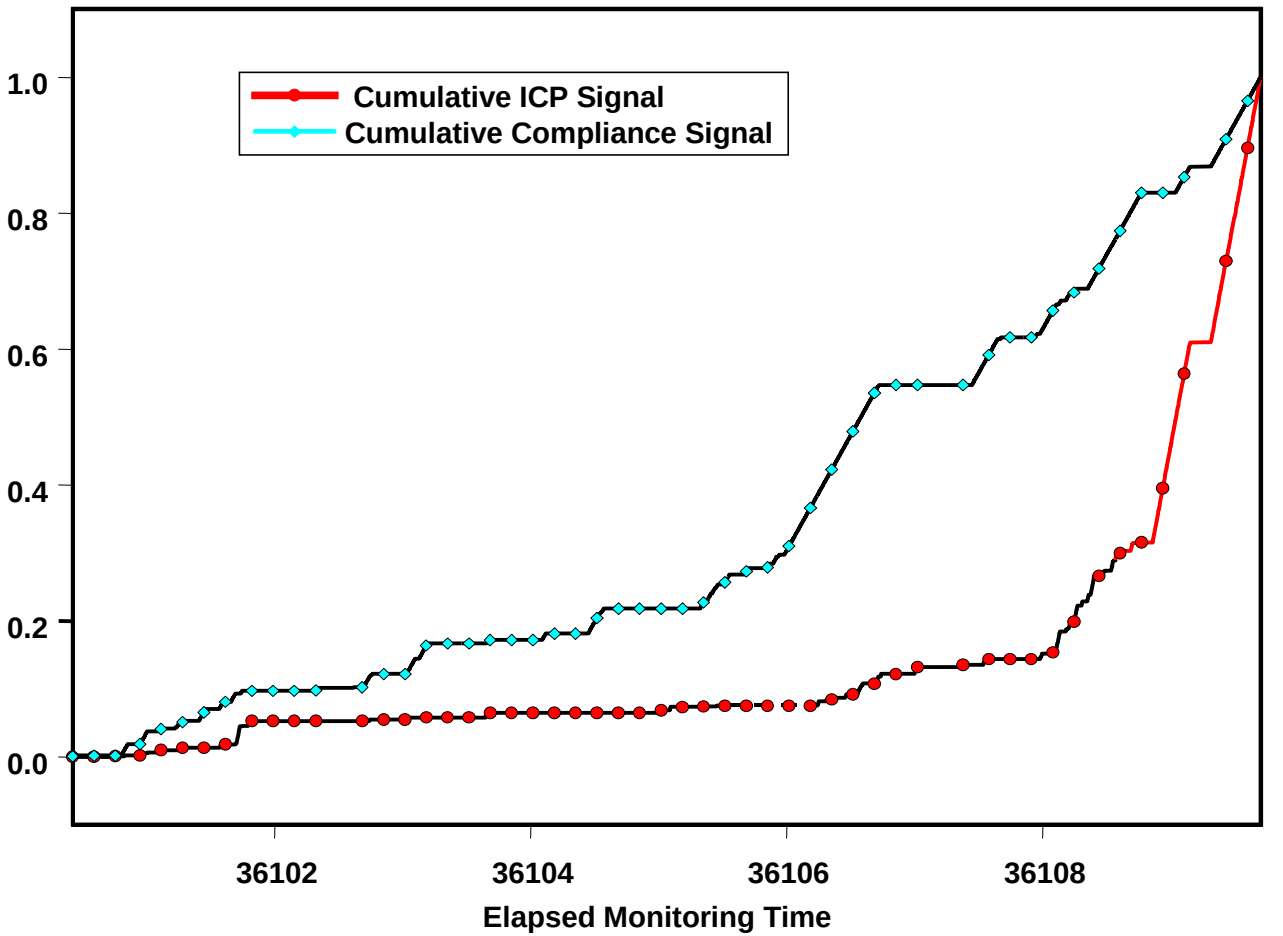


Figure 2


Cumulative ICP Signal
Cumulative Compliance Signal
1.0
0.8
0.6
0.4
0.2
0.0
36102
36104
36106
36108
Elapsed Monitoring Time