

Innovative technologies of head injury physiological monitoring

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Introduction

Head injury has devastating economic and social consequences both to the victim and to the society that supports the victim. The World Health Organisation estimate that by the year 2010, one in ten families will have a family member with a head injury. Since head injury is more prevalent in the young and the associated disability does not significantly reduce life expectancy, the result is that the social and economic costs incurred by health and welfare organisations are long term and substantial [1].

Direct measurement of intracranial pressure remains the mainstay of detecting brain swelling after the head injury before pressure rises to levels damaging the brain function. At present, the measurement techniques are invasive and require either the placement of a catheter-tip strain gauge device into the brain tissue directly or a fluid filled catheter placed into the cerebral spinal fluid space within the brain. The placement of these catheters damages the brain tissue through which they are placed and entails the risk of causing intracerebral bleeding if the blood vessels are damaged during the placement of the catheter. Due to these risks, intracranial pressure is usually monitored only in the severely head injured patients and only if there is clinical or CT or MRI - imaging evidence of the brain at risk of the raised pressure.

As a consequence, the actual incidence of the raised intracranial pressure (ICP) in the less severely head injured population is not well known. Certainly, there is significant morbidity associated with both moderate and minor head injury but to what degree that damage is due to the raised ICP or is it potentially treatable is unknown. Is it found that there is evidence that a significant proportion of patients for whose the computer tomography (CT) or magnetic resonance imaging (MRI) scan do not show the evidence of the raised pressure, subsequently go on to develop episodes of raised intracranial pressure. To define the clinical significance of the raised ICP in these patient groups, the non-invasive ICP monitoring technology is needed.

The ideas of the measurement of ICP non-invasively have been appearing since 1980. There are many patents, the authors of which attempt to find the objects or physiological characteristics of cerebrospinal system that would be related to the ICP and monitor them non-invasively (Table 1, Fig.1). Most of the proposed monitoring technologies are based on the ultrasound application and are capable of monitoring physiological properties such as blood flow in intracranial or intraocular vessels, pulsations of the cerebral ventricles, cranium diameter or acoustic properties of the cranium. However, there are a few main problems encountered by a lot of authors of these works:

- 1) Which biophysical parameter of a cerebrospinal system is a stable function of intracranial pressure or cerebral perfusion pressure (CPP)?
- 2) Is that function linear and more or less independent on such main influential factors as arterial blood pressure (ABP) and how it depends on the cerebral blood flow autoregulation?
- 3) How to calibrate non-invasively and individually the system "individual patient – non-invasive ICP or CPP meter"?

The general solution is to invent an absolute ICP or CPP non-invasive meter, the reliable and accurate enough for clinical practice, without the necessity of individual calibration.

Recently, a new method [2] for non-invasive measurement of intracranial volume or pressure has been created in Telematics Scientific Laboratory of Kaunas University of Technology (Lithuania) which uniquely purports to measure the intracranial pulsation of small intracranial blood vessels. This method may be of more clinical value as the microvasculature is the major source of cerebrovascular resistance which determines the intracranial cerebral blood flow and it is responsible for cerebral blood flow autoregulation. Another innovative method [3] includes a means based on the transcranial Doppler multi-depth technique for a non-invasive absolute ICP value measurement.

The new non-invasive devices are cost effective and have no competitors in the world market. The main market segments are:

- fast non-invasive diagnosing of brain injury during the first "golden hour" after the casualty case,
- non-invasive brain or spinal cord injury physiological monitoring during the intensive care,
- non-invasive diagnosing of brain physiological status during the rehabilitation period,
- diagnosing and monitoring of the reactions of cerebral blood flow autoregulation system and parenchymal blood volume/ICP on different pharmacological influences or physical loads (space medicine, sport medicine, battlefield casualty cases, etc.).

Methods

The background of the non-invasive intracranial volume or pressure measurement methodology is based on the idealized relationships between the ultrasound speed in the cerebral parenchymal acoustic path and blood volume inside the cerebral parenchyma (CBV), cerebrovascular resistance (CVR) and also CPP, ABP and ICP. These relationships could be explained by the changes of the diameter of cerebral arterioles as a result of cerebral blood flow autoregulation (Fig. 2).

Table 1. Patents of non-invasive ICP measurement methods.

Author and patent number,	Year	Object or characteristic related to ICP	Method
Allocca [6] US Pat. 4,204,547	1980	Blood flow in a jugular vein	Occlusion of blood flow in a jugular vein and the electromagnetic measurement of the change of blood flow within the jugular vein upstream of the occlusion
Rosenfeld et al. [7] US Pat. 4564022	1986	Electrical brain activity	Measurement of the changes of electrical brain activity after the light stimulus into the eyes
Kageyama [8] US Pat. 4,971,061	1990	Dura matter thickness	Amplitude measurement of ultrasound interference echoes reflected from dura matter
Kageyama [9] US Pat. 4,984,567	1991	Dura matter thickness	Cepstrum analysis of ultrasound interference echoes reflected from dura matter
Mick [10] US Pat. 5,117,835	1992	Sound attenuation in skull bones	Measurement of ultrasound attenuation in skull bones and signal spectrum analysis
Ragauskas et al. [2] US Pat. 5,388,583	1995	Acoustic properties of brain parenchyma tissue	Ultrasound pulse transmission through the intracranial media and signal time-of-flight measurement
Yost et al. [11] US Pat. 5,617,873	1997	Cranium diameter	Phase measurement of ultrasound signal reflected from the far side of the skull
Paulat [12] WO 97/30630	1997	Electrical resistance of the skull	Signal waveform analysis
Bridger et al. [13] US Pat. 5,919,144	1999	Acoustic impedance and resonance characteristics of the cranium	Low frequency acoustic signal transmission through the cranium and the application of the spectral analysis for a detected signal
Alperin [14] US Pat. 5,993,398	1999	Arterial and venous blood flow and the cerebrospinal fluid flow	Phase contrast magnetic resonance imaging
Denninghoff [15] WO 99/65387	1999	Eye vessels and intraocular pressure	Simultaneous measurement of the SrVO ₂ saturation in retinal vessels, intraocular pressure and cardiac cycle
Ragauskas et al. [3] US Pat. 5,951,477	1999	Blood flow in the eye artery	Ultrasonic two depth Doppler blood flow measurement technique
Madsen et al. [16] US Pat. 6,086,533	2000	Blood flow in the intracranial vessels	Ultrasonic Doppler blood flow measurement technique
Borchert et al. [17] US Pat. 6,129,682	2000	Parameters of an optic nerve of the eye	Optical coherence tomography
Sinha [18] US Pat. 6,117,089	2000	Stress level of skull bones	Generating and detecting standing waves in the skull bones and the measurement of phase difference between the transmitted oscillatory signal and the received signal
Michaeli [19] WO 0068467	2000	Third cerebral ventricle	Analysis of echo pulsogram waves

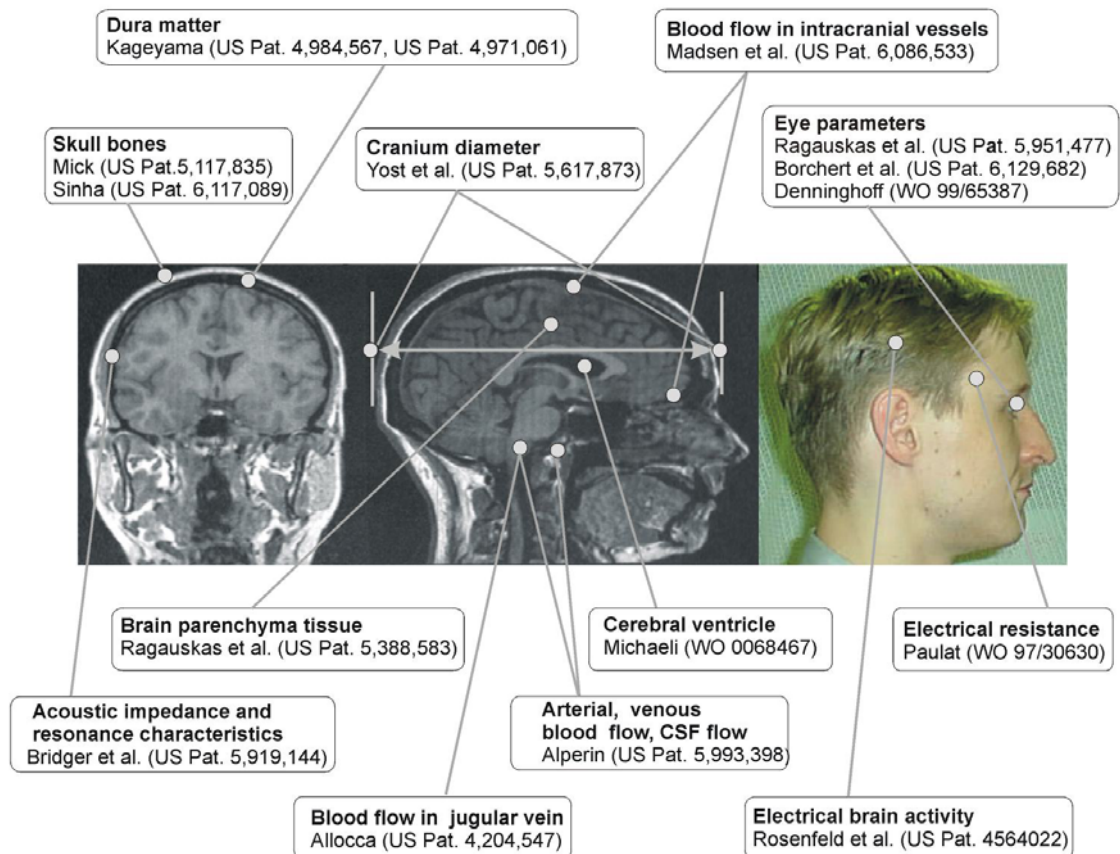


Fig. 1 Different methodologies for non-invasive ICP monitoring

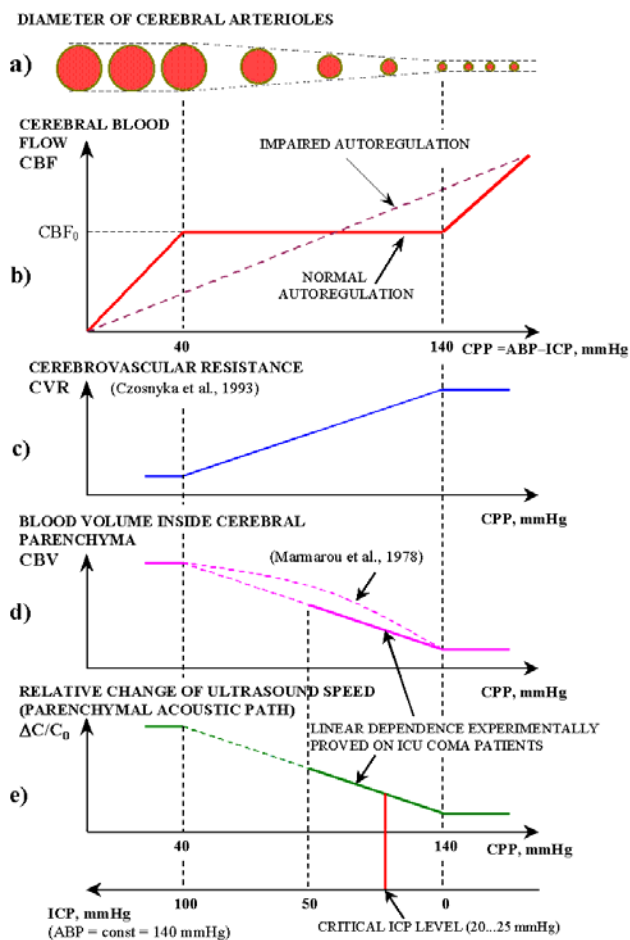


Fig 2. Relationships between ultrasound speed in cerebral parenchymal acoustic path and CBF, CPP, ICP, ABP, CVR and CBV

In the case of normal autoregulation (Fig. 2b) the diameter of cerebral arterioles decreases (Fig. 2a) when CPP increases within the linear range of CVR/ CPP dependence (Fig. 2c). The blood volume also changes inside the cerebral parenchymal acoustic path (Fig. 2d) as a result of the autoregulatory change of cerebral arterioles diameter. It was shown in our theoretical studies [4,5] that the relationship between ultrasound speed inside the transintracranial parenchymal acoustic path and the blood volume inside cerebral parenchyma is linear.

In the case when cerebral autoregulation is normal and ABP is stabilized the axis of CPP could be presented as the axis of ICP of the opposite direction (Fig. 2e). In Fig. 1e that situation is presented as an ideal case when ABP = 140 mmHg and ABP is stable. In that case the relative change of ultrasound speed linearly increases with the increment of ICP. In a more general case Fig. 1e when CPP is changing as a result of ABP and ICP changes, the relative change of ultrasound speed linearly decreases with the increment of CPP.

For the implementation of non-invasive ICP or CPP waves, ICP absolute value, cerebral parenchymal blood volume and cerebral blood flow autoregulation the continuous monitoring that is based on the dependence of ultrasound speed in cerebral parenchymal acoustic path on the blood volume inside cerebral parenchyma explained above the innovative concepts were proposed. These concepts are based on the following new ideas:

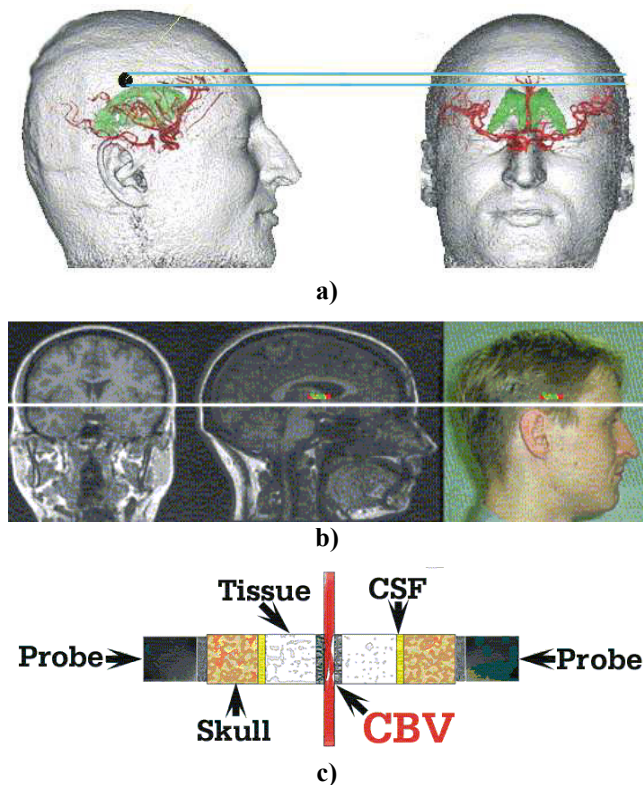


Fig.3 The correct positions of transintracranial supraventricular (a – black point and straight lines) and intraventricular (b - white line) parenchymal acoustic paths and structure of the microvascular acoustic path (c). The path consists of external tissues, skull bones and a transintracranial parenchymal acoustic path with the layers of blood, parenchyma tissue and CSF

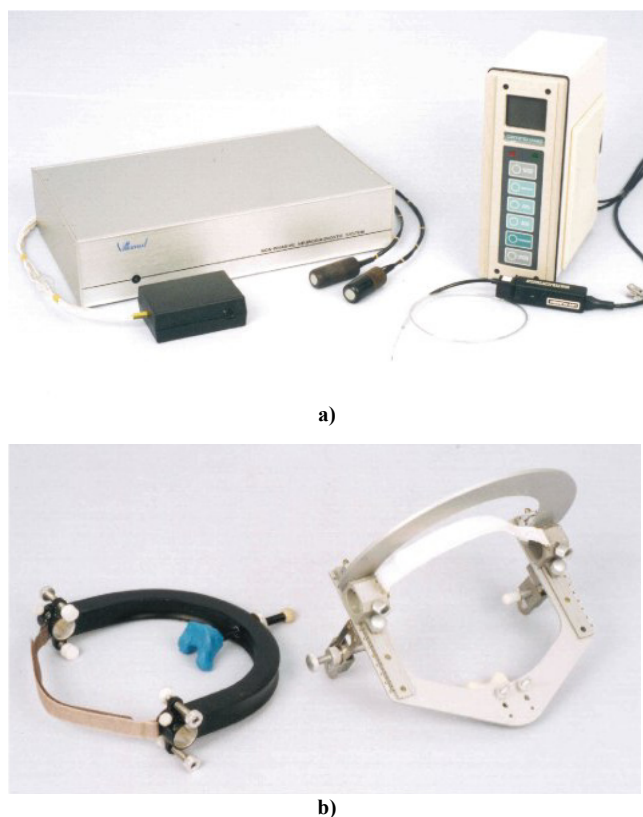


Fig 4. Non-invasive ICP monitor comparing with the invasive Camino V420 monitor in (a). Mechanical frames of non-invasive ICP monitor in (b)

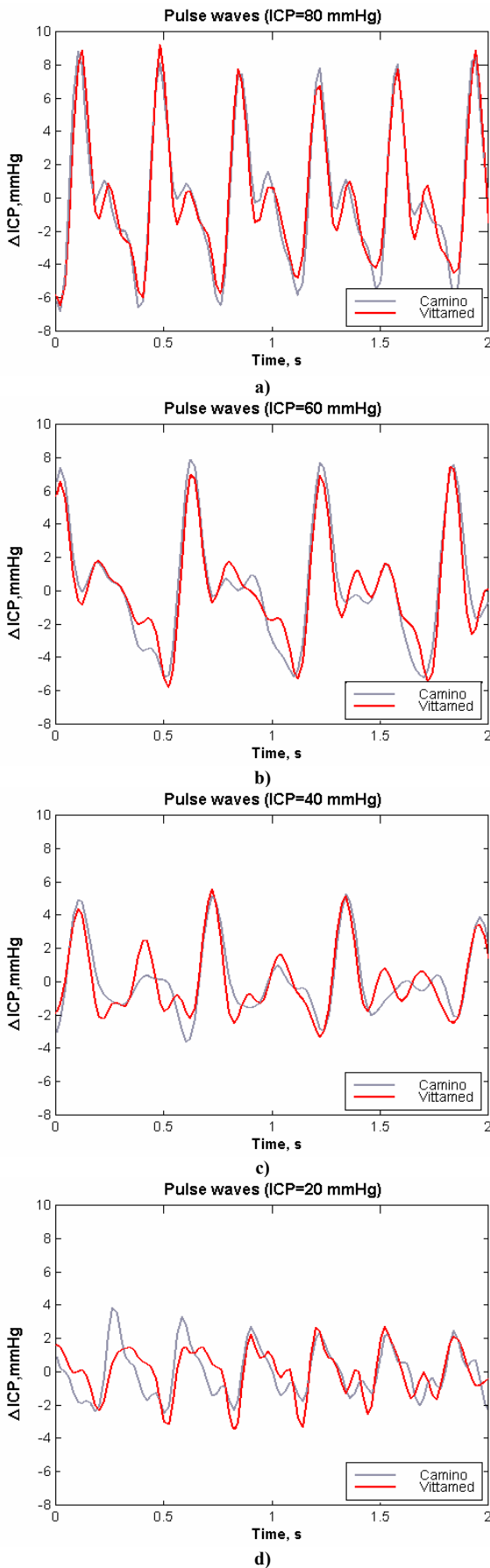


Fig. 5. Simultaneous invasive and non-invasive records of ICP pulse waves when ICP =80 mmHg (a), ICP=60 mmHg (b), ICP=40 mmHg (c) and ICP=20 mmHg (d) applying invasive Camino and non-invasive Vittamed devices (head injured patient in coma)

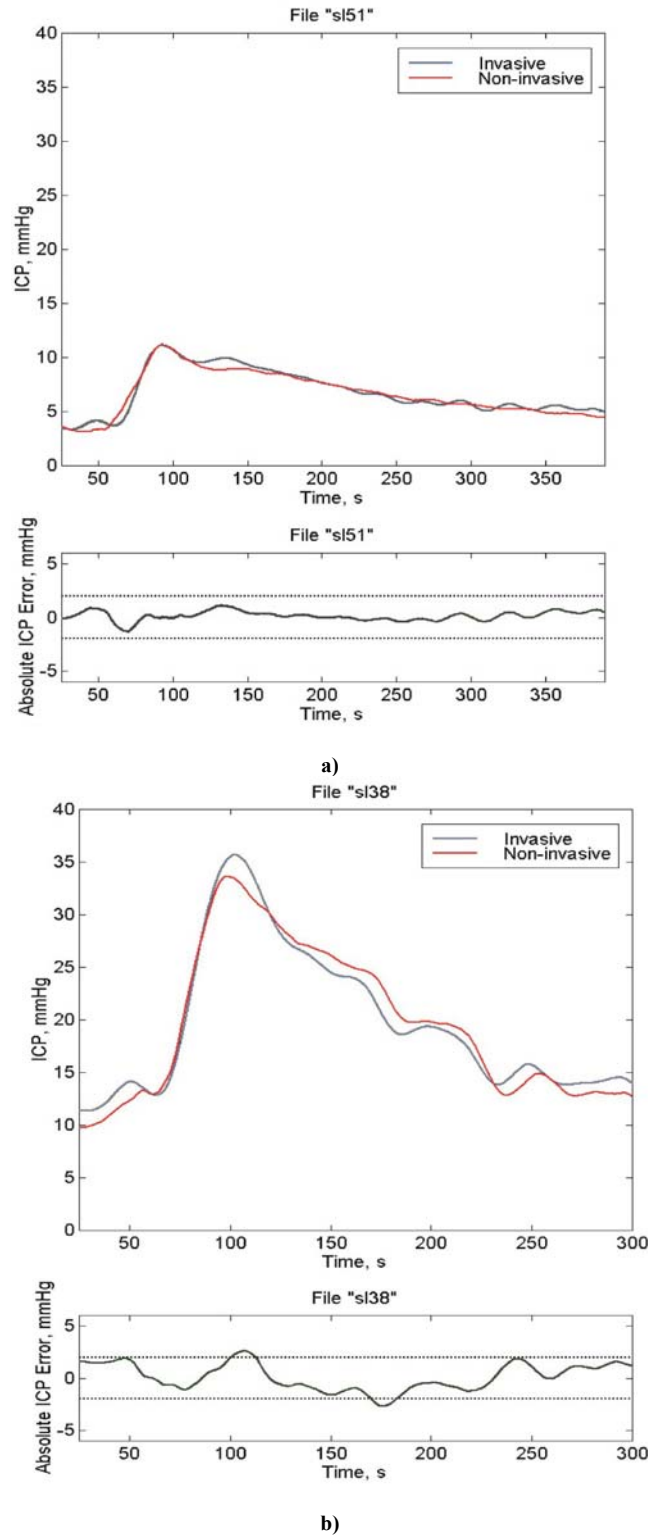


Fig. 6 Comparison of invasive and non-invasive ICP data during CO₂ reactivity tests. a) - minimal reaction, b) - maximal reaction

1. The concept of non-invasive cerebral blood volume/ICP/ CPP pulse waves, respiratory waves, slow waves and trends monitoring [2] is following as:

- the intraventricular or supraventricular parenchymal acoustic path which crosses the human head is used in this case (Fig 3a and b). The parenchymal acoustic path mainly consists of parenchymal tissue, relatively small blood vessels (arterioles, venules and capillary vessels) and a small amount of cerebrospinal fluid (CSF) (Fig. 3c). The

parenchymal arterioles are responsible for the cerebral blood flow autoregulation. The ultrasound speed inside the parenchymal acoustic path mainly depends on the blood volume inside this path. The ultrasound attenuation inside this path mainly depends on the volume of parenchyma tissue inside this path [4,5],

- to measure the relative value of ultrasound speed changes inside the parenchymal acoustic path, this path is insolated by supershort ultrasonic pulses, and the time-of-flight measuring method is used,

- to compensate in a real-time and *in situ* the influences of the human head external tissue hemodynamics on the results of such measurements, the same ultrasonic pulses and their echoes from internal surfaces of the skull are used,

- the specially designed software is used to convert the measured data into absolute or relative ICP or CPP values or into the cerebral blood flow autoregulation state estimating indices.

This is the only existing concept of non-invasive monitoring of cerebral parenchyma microvessel hemodynamics.

2. The concept of non-invasive ICP absolute value measurement [3] is following as:

- the eye artery is used as a natural "transducer" which has two segments - intracranial and extracranial. Intracranial segment is compressed by ICP. Extracranial segment can be compressed by the controlled external pressure applied to the eye ball surrounding tissues,

- the pressure balance can be achieved when the absolute value of external pressure is equal to the ICP. In the case of balance the blood flow parameters in the intracranial segment and extracranial segment of the eye artery are almost equal independently on the absolute value of arterial blood pressure, hydrodynamic resistance of the eye veins, the pressure inside the eye ball and the initial absolute values of the blood flow parameters in both segments of the eye artery,

- the especially designed two depth pulse wave transcranial Doppler device could be applied to identify this balance. The absolute value of external pressure reflects the absolute ICP value in the case of this balance.

This is the only existing concept of a non-invasive absolute ICP value measurement without the necessity of individual calibration of system "individual patient / non-invasive ICP meter".

Results

The new non-invasive ultrasonic Vittamed monitor based on the ultrasound speed in cerebral parenchymal acoustic path measurement and that includes a real-time and *in situ* compensation of the influence of the external tissue and skull bones to the measurement results was designed and tested in the intensive care units (ICU). The simultaneous ICP monitoring with a new non-invasive Vittamed monitor and Camino V420 invasive monitor (Fig. 4a) was performed for ICU coma patients after a closed head injury. The clinical results of simultaneous ICP pulse waves, ICP reactions on the CO₂ reactivity and mannitol tests and the long term ICP trends monitorings are shown in Fig. 5 - Fig.8.

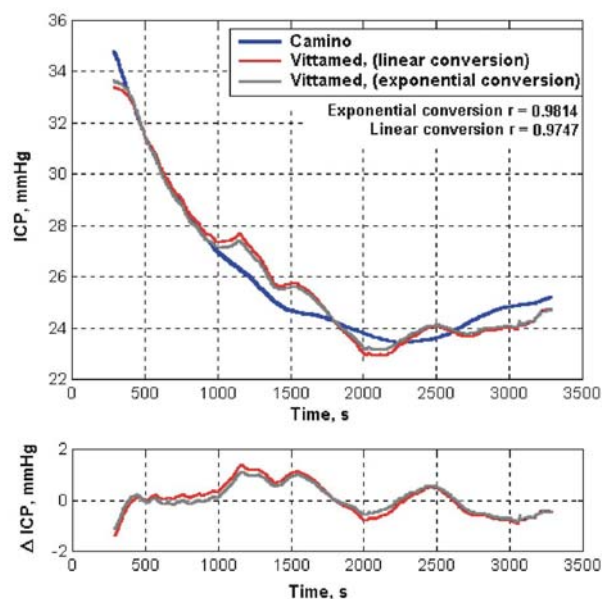


Fig. 7 Comparison of invasive and non-invasive ICP data during the mannitol infusion from 200s until 2000s

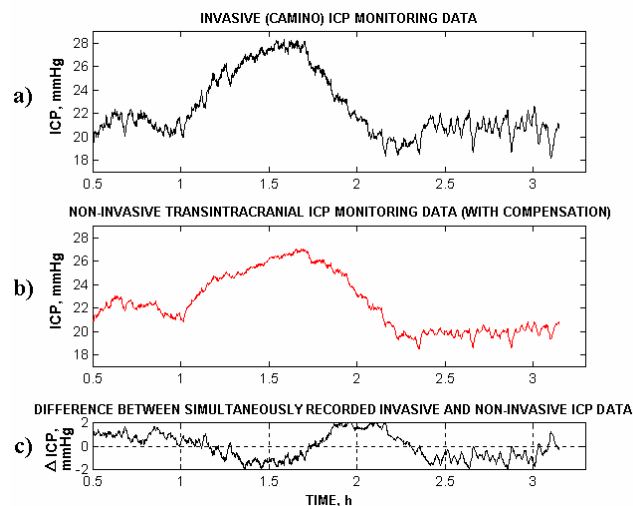


Fig. 8 Comparison of long term invasive and non-invasive ICP monitoring data in the intensive care unit (patient in coma after closed head injury)

While attempting to prove a linear relationship between the non-invasively measured ultrasound speed in a cerebral parenchymal acoustic path and ICP, the readings from the invasive ICP monitor were plotted against the readings of a non-invasive ICP monitor (18 head injured patients) Fig 9a. The non-invasive ICP data were calculated from the time-of-flight measured data using the linear functions after the real-time and *in situ* compensation of the influence of the external tissue and skull bones to the measured time-of-flight data. This experimental result shown in Fig 9a is the evidence that the ultrasound velocity changes are linearly dependent on the ICP as it was explained in Fig.2 and predicted during the theoretical modeling of time-of-flight and blood volume relationship inside the transintracranial parenchymal acoustic path [4,5]. It is also very important that this relationship is wide enough (0 to 50 mmHg) and this linear relationship is above and below the critical ICP level.

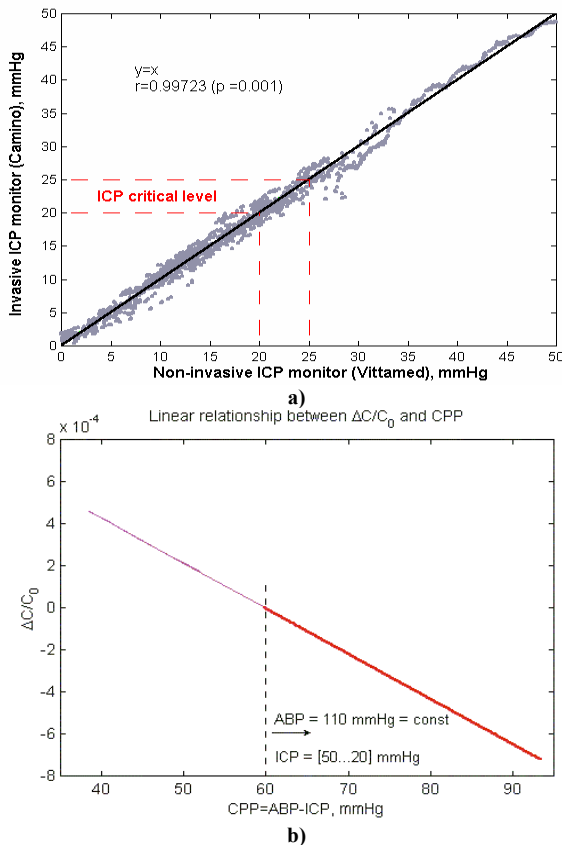


Fig 9. Readings from invasive ICP monitor plotted against readings of non-invasive ICP monitor (18 head injured patients) in (a). Relationship between the non-invasively measured ultrasound speed data and CPP in (b)

Another proof of the theoretical explanation presented in Fig.2 was performed in the next experiment, the results of which are shown in Fig. 10 and Fig.11. The ABP, ICP data were monitored with the invasive Datex Cardiocap II monitors and the ultrasound speed in the parenchymal acoustic path was measured simultaneously with the non-invasive time-of-flight monitor. In the first case of normal cerebral blood flow autoregulation (Fig. 10) the correlation factor between ICP and relative ultrasound speed was obtained $r = -0.51$ and the correlation factor between CPP and the sound speed data was $r = -0.64$. In the second case of the monitoring the patient with the impaired autoregulation (Fig. 11), the correlation factor between ICP and relative ultrasound speed was obtained $r = +0.26$ and the correlation factor between CPP and the ultrasound speed data was $r = +0.82$. These results show that in the case of the unstable arterial blood pressure, the correlation factor between the ultrasound speed and CPP is higher than the correlation factor between the ultrasound speed and ICP. That means that the relationship between the non-invasively measured ultrasound speed in the brain parenchymal acoustic path and the cerebral perfusion pressure with the negative slope (Fig. 9b).

Also, the correlation factor between the ABP and the relative ultrasound speed shows a normal cerebral blood flow autoregulation ($r = -0.64$) in the first case (Fig. 10) and an impaired autoregulation ($r = +0.81$) in the second case (Fig. 11) of the monitoring. The values of these factors show a good reliability of the non-invasive evaluation of the cerebral blood flow autoregulation.

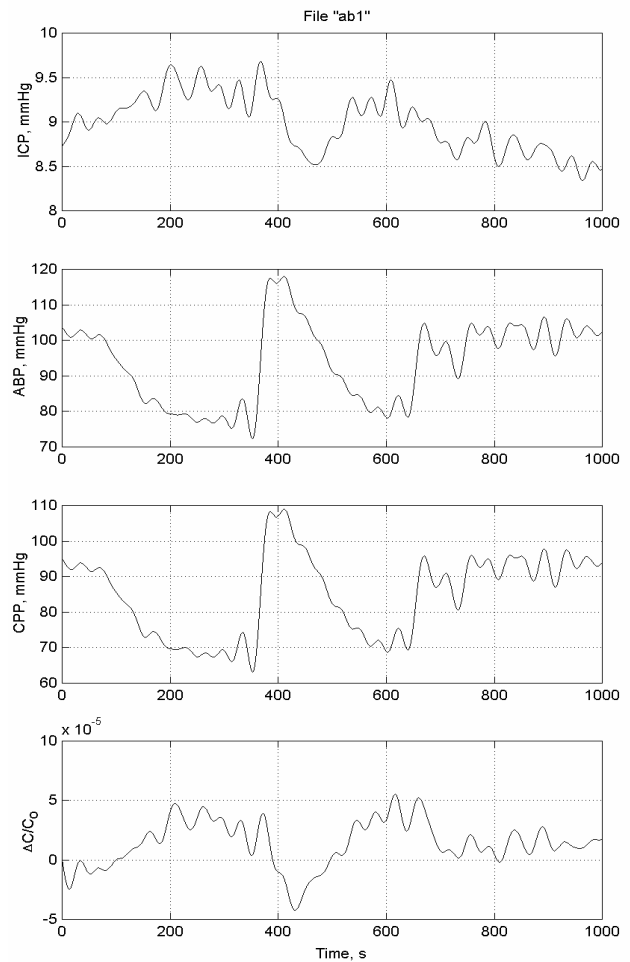


Fig 10. The simultaneous monitoring the changes of ABP, ICP (invasive monitors) and relative ultrasound speed in the parenchymal acoustic path (non-invasive monitor) for a patient with a normal cerebral blood flow autoregulation

Conclusions

1. The comparative studies of the new non-invasive ultrasonic Vittamed monitor based on the ultrasound speed in the cerebral parenchymal acoustic path measurement were performed for the first time in ICU. The results obtained show that by applying the real-time and *in situ* automatic compensation of the influence of the extracranial tissue and skull bones on the measured data it is possible to achieve the uncertainty better than ± 2 mmHg for the long term non-invasive ICP monitoring. The linear relationship between the ultrasound speed in the cerebral parenchymal acoustic path and the ICP was proved by calculating the ICP data from the non-invasively measured time-of-flight data. Such relationship was obtained for the first time during the long term monitoring in a wide range of ICP values from 0 mmHg to 50 mmHg and it confirms the results obtained by mathematical simulation. The performed simultaneous invasive and non-invasive monitoring of the ICP pulse waves shows a good agreement between the measured data. The application of the real-time and *in situ* automatic compensation of the influence of the extracranial tissue and skull bones on the measured data allows to reduce the significantly drift of the measurement data.

2. It is shown that in the case of intact cerebral blood flow autoregulation the ultrasound speed changes inside the parenchymal acoustic path reflect the CPP changes and waves. In the case of stabilized ABP the ultrasound speed changes reflect the ICP changes and waves.

In the case of intact cerebral blood flow autoregulation the correlation between ABP slow waves and non-invasively measured ultrasound speed slow waves in the cerebral parenchymal acoustic path is negative and high. This correlation technique could be applied for the first time for continuous non-invasive monitoring of cerebral blood flow autoregulation state.

3. The innovative method is proposed for ICP absolute value non-invasive measurement, which is only existing method without the necessity of individual calibration of the system "patient – non-invasive absolute ICP meter" [3].

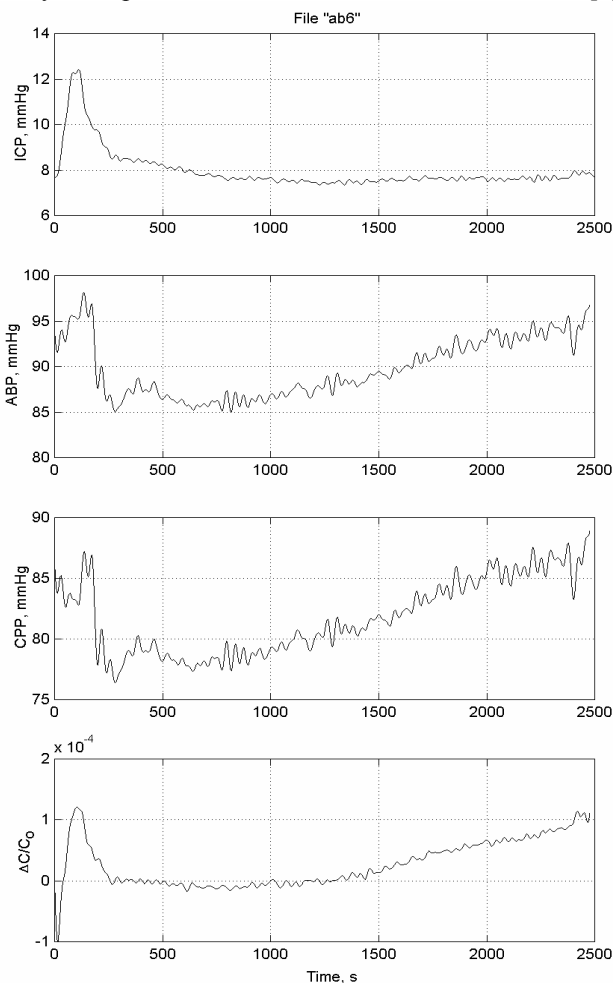


Fig 11. The simultaneous monitoring the changes of ABP, ICP (invasive monitors) and relative ultrasound speed in the parenchymal acoustic path (non-invasive monitor) for a patient with a impaired cerebral blood flow autoregulation

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Galvos smegenų traumos fiziologinio monitoringo inovacinės technologijos

Reziumė

Pasaulinės sveikatos organizacijos duomenimis 2010 metais išsivysčiusiose šalyse vienas iš kas 10-os šeimos narių turės galvos arba stuburo traumą. Galvos ir stuburo smegenų fiziologinio monitoringo sistemos ir traumotų pacientų gydymas pagal šių sistemų teikiamą diagnostinę informaciją leidžia sumažinti pacientų mirtinumą ir invalidumą po traumų. Tačiau esamos monitoringo technologijos yra invazinės. Šiame darbe analizuojama mokslinė ir patentinė informacija, skirta neinvazinėms fiziologinio monitoringo technologijoms kurti, taip pat susisteminti siūlomi technologiniai sprendimai. Darbe parodyta, kad smegenų kraujotakos autoreguliacijos būsenos, smegenų kraujotakos tūrio pulsinių ir lėtų bangų monitoringo bei reakcijų į neurodiagnostinius testus registravimo inovacinės neinvazinės technologijos gali būti sukurtos smegenų parenchimos ultragarsinių charakteristikų precizinio matavimo pagrindu. Pasiūlyti techniniai sprendimai ir sukurti tokių matavimų aparatūra, atlikti klinikiniai tyrimai, įrodantys pasirinktų koncepcijų teisingumą. Pirmą kartą pasiūlytas inovacinis neinvazinis metodas, skirtas galvosspūdžio absoliutinei reikšmei matuoti. Jį taikant nereikia individualiai kalibruoti sistemos "neinvazinis matuoklis - pacientas".

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