Design of Non-invasive Multi-parameter Pain Monitoring System

C L Deepika* and D Brindha
Department of Biomedical Engineering, PSG College of Technology, Coimbatore, India

Received 6 December 2014; revised 27 April 2015; accepted 30 April 2015

Postoperative pain management of patients is a major medical and nursing challenge. Pain is still being measured in hospitals using Pain scales such as Faces scale. However this type of interpretation is not straightforward and management of postoperative pain using these methods continues to remain problematic and unsatisfactory. Poorly managed pain may interfere with postoperative complications, cause patient suffering and prolong recovery. In this paper, a multi-parametric method of objective pain monitoring using ECG, pulse rate and heart rate is proposed. The case of post-caesarean pain is taken up and the study showed that sympathetic tone increased, vagal tone decreased, heart rate and pulse rate increased during pain. A statistical ‘t’ test was performed on the data obtained from patients and the test results justified the conclusion.

Keywords: Pain, ECG, Sympathetic, Vagal, t-test.

Introduction

Inadequate pain relief in the postoperative phase is a well-known problem world-wide. Although there is a worldwide need for developing pain monitoring instruments, for application in Operation Theatre, Intensive Care Units, in Neonatal Intensive Care Units, Rehabilitation Centres, Pain Clinics and even at home, there is no affordable device available for effective pain monitoring allowing better pain management. The metrics currently available and being used in hospitals for monitoring the pain levels of patients are the Numerical Rating Scale (NRS), Verbal Rating Scale (VRS) and Faces Scale. However interpretation from pain scales is not as straightforward as it might appear and clinicians need to appreciate the potential for error within the tools. Further some patients cannot provide a self report of pain either verbally or even by pointing out at illustrations. This may lead to poor pain treatment and sometime excessive treatment for pain. In general, increase in heart rate, pulse rate and blood pressure are taken as indicators of fear, stress, pain and other emotional disturbances. However, heart rate and blood pressure can only be used as a clue for pain assessment and further appropriate assessment is needed for accuracy. So multiple parameters based objective pain measurement technique would be an invaluable tool in measuring pain for managing it effectively. The very few imported pain monitoring instruments available in our country are costly and not affordable by non-corporate hospitals. Hence there is a need for developing low cost, accurate and indigenous pain monitoring instruments. This paper analyses the accuracy with which certain parameters namely, sympathetic tone, vagal tone, sympathetic vagal balance, pulse rate and heart rate are capable of correctly indicating the presence or absence of pain. This analysis could serve as a basis for the development of a low cost non invasive multi-parameter pain monitoring system.

Materials and Methods

In human beings the autonomic nervous system involuntarily controls the functions of the body’s systems. Pain strongly influences the autonomic nervous system tone which leads to accelerated heart rates and increased oxygen consumption. Studies conducted on the heart rate variability due to pain, report an increase in sympathetic activity and a decrease in para-sympathetic activity. Studies have also shown that multi-parameter approaches could be investigated rather than testing a single parameter for pain assessment. Based on these clinically proven studies, the parameters identified for this study are Heart rate, Pulse rate, Vagal tone, Sympathetic tone and Sympathetic-vagal balance. The case of post operative pain in patients who have undergone a Cesarean procedure has been taken up. Pain may

*Author for correspondence
E-mail: cldeepika@yahoo.com
impair the mother’s ability to optimally care for her infant in the immediate postpartum period and may adversely affect early interactions between mother and infant\textsuperscript{9,10}.

Good pain relief will improve mobility, reduce recovery time and post operative complications. It can also reduce the risk of thrombo-embolic disease, which increases during pregnancy. The study on post-operative pain in Cesarean patients was conducted at PSG Institutions of Medical Sciences and Research, Coimbatore after appropriate and necessary Ethical Clearance. The approval from the Ethics committee is provided in Annexure I of this paper. The study was conducted on 40 subjects over a period of 6 months. An initial discussion was made with the patient before the cesarean surgery to know the patient’s willingness to participate in this study and also to check whether the patient satisfies the criteria for the study, namely the patient shall not have any other existing illness and is able to read and understand either English language or the local language. The need for development of a pain monitoring instrument was also briefly explained to the patient. A unique id was given to every patient who was willing to participate in the study. A protocol as in figure 1 was designed for collection of data, based on the advice from the doctors in the Department of Obstetrics and Gynecology at PSG Institute of Medical Sciences and Research. Data acquisition as per the protocol required a full fledged presence in the hospital nearby to the Gynecology department to be aware of admission of patients with an indication of cesarean. The day of surgery was taken as the 0\textsuperscript{th} day on which the first dose of analgesia was administered to the patient immediately after the surgery. After the patient was brought to the Post-operative ward, the Data Acquisition I was carried out. The heart rate, vagal tone, sympathetic tone, sympathetic-vagal balances were acquired using the Biopac Dual Channel Data Acquisition System while the pulse rate was acquired using a pulse sensor. The parameters were carefully recorded subject wise. Then the Faces Scale was shown to the patient and she was asked to indicate which illustration best described the pain she was experiencing and also recorded. The Data Acquisition II was done on the same day about two hours before the next dose of analgesia was given using both the data acquisition systems as well as the Faces Scale. The same procedure was repeated for the next day also. The trends of the data acquired during pain and without pain are shown in figure 2. The plots illustrate the parameter values vs. the patients, during two states of the patient, namely with pain and without pain. The dotted line in the plot in each graph depicts the data obtained under painful condition and the solid line in the plot shows the data obtained under the painless condition. It was observed from the plots that the heart rate, pulse rate, sympathetic tone and sympathetic-vagal balance acquired from patients with pain have values which are larger than those obtained during the no-pain condition; that is, these parameter values increases during pain, while the vagal tone decreases when the patient is in a painful state.

Results and discussion
The change in the parameters during pain is significantly consistent as may be observed from Figure 2. In order to further establish that the results obtained during pain are significantly different from the data obtained when there is no pain, statistical $t$-test was performed. The $t$-test is a statistical hypothesis test used to determine whether two sets of data are significantly different from each other. A null hypothesis is defined such that the means are equal for the two categories. i.e., there is no difference between the data obtained with pain and data without pain. The null hypothesis must be proved wrong to indicate the changes. A two tailed $t$-test detailed below is used for this purpose. The set of data obtained from patients without pain is called Dataset-I and the set of

![Fig. 1—Data Collection Process Flowchart](image)
data obtained from patients with pain is called Dataset-2. The ‘t’ values calculated using datasets (1) and (2) are given in Table 1.

\begin{align*}
S &= \left( \sum [x - \bar{x}]^2 / (n - 1) \right)^{1/2} \\
\bar{x} &= \text{mean} \\
n &= \text{total number of values} \\
t &= \left( \frac{\bar{x}_1 - \bar{x}_2}{s_1^2/n_1 + s_2^2/n_2} \right)^{1/2} \\
\bar{x}_1 &= \text{mean of 1st set values} \\
\bar{x}_2 &= \text{mean of 2nd set of values} \\
s_1^2 &= \text{standard deviation of 1st set of values} \\
s_2^2 &= \text{standard deviation of 2nd set of values} \\
n_1 &= \text{total number of values in 1st data set} \\
n_2 &= \text{total number of values in 2nd data set}
\end{align*}

For a level of significance of 0.01 and for Degrees of Freedom 60, the value obtained from standard \(t\)-Table is 2.660. If the calculated value exceeds 2.660, the null hypothesis will be rejected. The calculated values are summarized in table 1.  

The Dataset-1 refers to parameters acquired under

<table>
<thead>
<tr>
<th>Sl. No</th>
<th>Parameters</th>
<th>Metric</th>
<th>Dataset -1</th>
<th>Dataset -2</th>
<th>(t)-test value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(\bar{x})</td>
<td>Average</td>
<td>Average</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Standard</td>
<td>Deviation</td>
<td>Deviation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Variance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Sympathetic Tone</td>
<td>0.431</td>
<td>0.134</td>
<td>0.592</td>
<td>4.43</td>
</tr>
<tr>
<td>2</td>
<td>Vagal Tone</td>
<td>0.568</td>
<td>0.134</td>
<td>0.407</td>
<td>4.437</td>
</tr>
<tr>
<td>3</td>
<td>Sympathetic-Vagal Balance</td>
<td>0.859</td>
<td>0.621</td>
<td>1.934</td>
<td>4.145</td>
</tr>
<tr>
<td>4</td>
<td>Heart Rate</td>
<td>78</td>
<td>11.299</td>
<td>152.512</td>
<td>4.861</td>
</tr>
<tr>
<td>5</td>
<td>Pulse Rate</td>
<td>77.419</td>
<td>11.165</td>
<td>150.385</td>
<td>4.7</td>
</tr>
</tbody>
</table>

Fig. 2—Parameters acquired from patients; (a) Sympathetic Tone, Vagal Tone and Sympathetic-Vagal Balance; (b) Heart Rate and Pulse Rate
“Without Pain” conditions and Dataset-2 refers to parameters acquired under “With Pain” conditions. These calculated $t$-test values for all the parameters have exceeded the $t$-table value (2.660). Thus the null hypothesis is rejected implying that there is a significant difference for the ‘pain’ and ‘no pain’ condition and hence possible to predict pain.

**Conclusion**

A study on the influence of pain on five parameters has been done in this paper. The study carried out with the post-operative patients who have undergone a cesarean surgery has shown that during pain the sympathetic activity of the autonomic nervous system is increased, resulting in increase in the heart rate and sympathetic tone and decrease in para-sympathetic (vagal) tone. During pain the electrical activity of the heart increases due to the mechanical activity, namely the increased pumping action of the heart resulting in increase in the pulse rate of the patient. The consisteney in the nature of changes occuring in the different parameters during pain clearly establishes the feasibility of using these parameters to develop a multi-parameter pain monitoring system for monitoring the pain of post-operative patients.

**References**