The Accuracy of Commercial Blood Uric Acid Meters on Blood Uric Acid Level Measurement

Corresponding Author:
Dr. Tak S Ching,
Assistant Professor, Graduate Institute of Biomedicine and Biomedical Technology, National Chi Nan University,
No. 1, University Rd., Pulil, Nantou County, 54561 - Taiwan

Submitting Author:
Dr. Tak S Ching,
Assistant Professor, Graduate Institute of Biomedicine and Biomedical Technology, National Chi Nan University,
No. 1, University Rd., Nantou County, 54561 - Taiwan

Article ID: WMC001778
Article Type: Research articles
Article URL: http://www.webmedcentral.com/article_view/1778
Subject Categories: BIOMEDICAL ENGINEERING
Keywords: Blood, Uric Acid, Meter, Monitoring; Accuracy
Source(s) of Funding:
This work was supported by grants (98A032) from the National Chi Nan University and Puli Christian Hospital, Taiwan, Republic of China. This work was also partially supported by a grant (NSC 99-2221-E-260-004-) from the National Science Council, Taiwan, Republic of China and by an internal grant from the National Chi Nan University, Taiwan, Republic of China.

Additional Files:
References
The Accuracy of Commercial Blood Uric Acid Meters on Blood Uric Acid Level Measurement

Author(s): Hung Y L, Ching T S, Sun T P, Chien M Y, Chen C M, Jhan C W, Shieh H L

Abstract

High blood uric acid level is a risk factor for gout. To reduce the gout complications, patients need to measure their blood uric acid levels and take medication if necessary. Several commercial blood uric acid meters are available in the market. The aim of this study is to investigate the accuracy of two commercial blood uric acid meters, MultiSure and BeneCheck Pluse Meter, on blood uric acid level measurement. Eleven subjects participated in this study and their blood uric acid level is measured by the routine method in hospital and by the two commercial meters. Results showed that the two commercial meters always overestimates the situation of the user. Moreover, a fair correlation ($r^2 < 0.5$) between the blood uric acid level obtained by the routine method and by the two commercial meters was observed. In conclusion, the accuracy of the two commercial meters to reflect a user’s blood uric acid level is still questionable.

Introduction

Gout is a common form of arthritis [1]. It affects more than 700,000 adults in the UK [2] and nearly three million adults in the USA [3]. Moreover, it accounts for almost four million outpatient visits every year [4] and this causes a substantial economic burden [5]. Hyperuricemia, referring to the excessive amounts of uric acid, is one of most frequent metabolism disturbances. Clinically, hyperuricemia and high mean serum uric acid concentrations is a risk factors for gout [6]. Gouty arthritis is a rapid onset of joint inflammation and a complication of hyperuricemia. It is precipitated by deposits of uric acid crystals in the synovial fluid and synovial lining. Recently, lots of findings have shown that patients with hyperuricemia and gout are at increased risk of morbidity and mortality related to cardiovascular disease [7]. Therefore, blood uric acid monitoring is very important.

The routine method to determine blood uric acid level is achieved by blood sampling, with the extracted blood under colorimetric measurement for the blood uric acid level determination. In general, this is performed in hospital and causes so much inconvenience to patients. It is very luckily that there is commercial blood uric acid meter, just like blood glucose meter, available in the market. This allows patients to measure their blood uric acid level at home at any time. However, the accuracy of the commercial blood uric acid meter is questionable. Therefore, the aim of this study is to investigate the accuracy of commercial blood uric acid meters on blood uric acid level measurement.

Methods

Subjects

Eleven healthy and high blood uric acid level subjects (eight men and three women; mean age 42.8 ±11.7 years) were recruited in this study. The study was approved by The Institutional Review Board of National Chi Nan University. Informed consent was obtained from each subject before the experiment.

Equipments

Two commercial blood uric acid meters were used. They are MultiSure (S80014, ApexBio, Taiwan) and BeneCheck Pluse Meter (PD-G001-1, General Life Biotechnology Co., Taiwan).

Testing Procedures

Five mini-liter (i.e. 5cc) of blood was sampled from each subject every week for 4 consecutive weeks for the routine blood uric acid measurement (i.e. colorimetric measurement). The central laboratory of the Puli Christian Hospital, Taiwan was responsible for the above procedures.

At the same time of each blood sampling, subject’s blood uric acid level was determined immediately by the use of the two commercial blood uric acid meters following the instructions of their user manuals. In all cases, three separate sets of measurement were made in succession in order to check reliability of the measurements.

Statistical Analysis

Intraclass correlation coefficient (ICC) was used to evaluate intrarater reliability (ICC 3,1) of the two commercial blood uric acid meters on blood uric acid level determination. Also, paired-sample $t$ test was used to determine whether there were significant differences between the blood uric acid level obtained by the routine blood uric acid measurement and the blood uric acid level obtained by the two commercial
blood uric acid meters. Moreover, linear regression test was used to determine the relationship between the blood uric acid level obtained by the routine blood uric acid measurement and the blood uric acid level obtained by the two commercial blood uric acid meters. All statistical analyses were carried out using SPSS software with the level of statistical significance set at 0.05.

Results and Discussion

In this study, subjects participated every week for 4 consecutive weeks with the aim of increasing the data points for the linear regression test so as to facilitate the reliability of the linear regression test. The subject’s blood uric acid level obtained by the routine blood uric acid measurement in hospital and by the two commercial blood uric acid meters is shown in Table 1. It was found that there is significant difference (p=0.019) between the blood uric acid level obtained by the routine blood uric acid measurement and by the MultiSure commercial blood uric acid meter (see Table 2). As shown in Table 2, it was also observed that subject’s blood uric acid level obtained by the routine method is significant smaller (p=0.019) than that by the MultiSure commercial blood uric acid meter. This means that the blood uric acid level of a user is always overestimated by the use of the MultiSure commercial blood uric acid meter and this leads to the unnecessary medication treatment. On the other hand, subject’s blood uric acid level obtained by the routine method was found to be significantly smaller (p=0.022) than that by the BeneCheck Pluse Meter commercial blood uric acid meter (see Table 2). Again, this results in the same problem as the MultiSure commercial blood uric acid meter. In brief, the two commercial blood uric acid meters always overestimates the situation of the user leading to unnecessary medication treatment.

The intraclass correlation coefficient (ICC) is a measure used to quantify the reproducibility of a variable. ICC is also a measure of the homogeneity within groups of replicate measurements relative to the total variation between groups. In general, ICC values above 0.75 have been suggested for good reliability while ICC values below 0.75 have been suggested for poor to moderate reliability [8]. For many clinical measurements reliability should exceed 0.90 to ensure reasonable validity [9]. In this study, the ICC(3,1) values were above 0.90 (see Table 2) and this suggests that the two commercial blood uric acid meters have excellent reliability and validity. Although the two meters have excellent reliability and validity, its measured value is always significant larger (p<0.05)

On the other hand, linear regression test was performed to determine the relationship between the blood uric acid level obtained by the routine method and by the two commercial meters. Colton [10] state; "Correlation range from 0 to 0.25 indicates little or no relationship; those from 0.25 to 0.5 suggests a fair degree of relationship; values of 0.5 to 0.75 are moderate to good; and values above 0.75 are considered good to excellent.". Therefore, a fair correlation (r^2 < 0.5) between the blood uric acid level obtained by the routine method and by the two commercial meters was observed in this study (see Figure 1 and 2). Again, the accuracy of the two meters to reflect a user’s blood uric acid level is still dubious.

Conclusion(s)

The accuracy of the two commercial blood uric acid meters, MultiSure and BeneCheck Pluse Meter, to reflect a user’s blood uric acid level is questionable. Since the two meters always overestimate the situation of a user, this may lead to unnecessary medication treatment. Therefore, it is recommended to fully evaluate the meters in depth before putting them into the market.

Acknowledgement(s)

The authors would like to thank the eleven subjects who participated in this study. This work was supported by grants (98A032) from the National Chi Nan University and Puli Christian Hospital, Taiwan, Republic of China. This work was also partially supported by a grant (NSC 99-2221-E-260-004-) from the National Science Council, Taiwan, Republic of China and by an internal grant from the National Chi Nan University, Taiwan, Republic of China.
Illustrations

Illustration 1

Table 1: The subject's blood uric acid level obtained by the routine blood uric acid measurement in hospital and by the two commercial blood uric acid meters.

<table>
<thead>
<tr>
<th>Blood Uric Acid Meter</th>
<th>Patients</th>
<th>Subjects' Blood Uric Acid Level (mg/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Week 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Measured by routine method in hospital</td>
</tr>
<tr>
<td><strong>MultiSure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P1</td>
<td></td>
<td>8.5±0.2</td>
</tr>
<tr>
<td>P2</td>
<td></td>
<td>6.8±0.4</td>
</tr>
<tr>
<td>P3</td>
<td></td>
<td>7.8±0.5</td>
</tr>
<tr>
<td>P4</td>
<td></td>
<td>7.9±0.3</td>
</tr>
<tr>
<td>P5</td>
<td></td>
<td>5.4±0.4</td>
</tr>
<tr>
<td>P6</td>
<td></td>
<td>12.0±0.3</td>
</tr>
<tr>
<td>P7</td>
<td></td>
<td>11.2±0.5</td>
</tr>
<tr>
<td>P8</td>
<td></td>
<td>6.8±0.2</td>
</tr>
<tr>
<td>P9</td>
<td></td>
<td>9.9±0.1</td>
</tr>
<tr>
<td>P10</td>
<td></td>
<td>7.7±0.4</td>
</tr>
<tr>
<td>P11</td>
<td></td>
<td>3.3±0.5</td>
</tr>
<tr>
<td><strong>BeneCheck Pulse Meter</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P1</td>
<td></td>
<td>8.5±0.9</td>
</tr>
<tr>
<td>P2</td>
<td></td>
<td>6.8±0.2</td>
</tr>
<tr>
<td>P3</td>
<td></td>
<td>7.8±0.2</td>
</tr>
<tr>
<td>P4</td>
<td></td>
<td>7.9±0.3</td>
</tr>
<tr>
<td>P5</td>
<td></td>
<td>5.4±0.3</td>
</tr>
<tr>
<td>P6</td>
<td></td>
<td>12.0±0.5</td>
</tr>
</tbody>
</table>

**Notes:**
- **Week 1:** Measured by routine method in hospital.
- **Week 2:** Measured by routine method in hospital.
- **Week 3:** Measured by routine method in hospital.
- **Week 4:** Measured by routine method in hospital.
- **SD:** Standard Deviation
Illustration 2

Table 2: Estimation of intrarater reliability (ICC3,1) of the two commercial blood uric acid meters on subject's blood uric acid level determination and a comparison between the subject's blood uric acid level obtained by the routine blood uric acid measurement and by the two commercial blood uric acid meters.

<table>
<thead>
<tr>
<th></th>
<th>Intraclass Correlation Coefficient Test</th>
<th>Paired-Sample t Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ICC 3,1 value</td>
<td>Mean difference &lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>MultiSure</td>
<td>0.9751</td>
<td>-0.3121</td>
</tr>
<tr>
<td>BeneCheck Pluse Meter</td>
<td>0.9469</td>
<td>-0.2742</td>
</tr>
</tbody>
</table>

<sup>a</sup> Mean difference = Blood uric acid level obtained by routine method – Blood uric acid level obtained by the commercial blood uric acid meter.
Illustration 3

Figure 1: Comparison of the subject's blood uric acid level obtained by routine method in hospital and by a commercial blood uric acid meter, Multisure.
Illustration 4

Figure 2: Comparison of the subject's blood uric acid level obtained by routine method in hospital and by a commercial blood uric acid meter, BeneCheck.

\[
y = 0.6106x + 3.1827 \\
R^2 = 0.4349
\]
Disclaimer

This article has been downloaded from WebmedCentral. With our unique author driven post publication peer review, contents posted on this web portal do not undergo any prepublication peer or editorial review. It is completely the responsibility of the authors to ensure not only scientific and ethical standards of the manuscript but also its grammatical accuracy. Authors must ensure that they obtain all the necessary permissions before submitting any information that requires obtaining a consent or approval from a third party. Authors should also ensure not to submit any information which they do not have the copyright of or of which they have transferred the copyrights to a third party.

Contents on WebmedCentral are purely for biomedical researchers and scientists. They are not meant to cater to the needs of an individual patient. The web portal or any content(s) therein is neither designed to support, nor replace, the relationship that exists between a patient/site visitor and his/her physician. Your use of the WebmedCentral site and its contents is entirely at your own risk. We do not take any responsibility for any harm that you may suffer or inflict on a third person by following the contents of this website.