A NEW APPROACH TO THE PERFORMANCE EVALUATION OF NEW BLOOD GLUCOSE MONITORING SYSTEMS IN THE HYPOGLYCAEMIC RANGE FOR REGULATORY APPROVAL

INTRODUCTION

The International Organisation for Standardisation ISO 15197:2015 (replacing 15197:2013 - In vitro diagnostic test systems for the monitoring of blood glucose) is the standard used to determine the performance of blood glucose monitoring systems (BGMS) to ensure safe and reliable patient care.

The ISO 15197:2015 standards clearly identify the performance criteria that BG systems need to fulfil for marketing approval. This involves systems achieving a standard deviation of the mean results across multiple patients of ±5% of the target glucose range. This precision testing of the BGMS whilst meeting the ISO 15197:2015 requirements is often a challenge.

To generate a patient-generated data set for the BGMS for marketing approval, manufacturers often need to perform a substantial number of BG measurements in a stable hypoglycaemic range in a controlled laboratory environment and consult with a study physician for any insulin dose adjustments required. Meticulous quality management of the glucose clamps is therefore of utmost importance.

RESULTS

A total of 19 patients successfully completed the hypoglycaemic glucose clamp to achieve a stable glucose level with no substantial instability of the blood glucose due to the natural counter regulatory responses to hypoglycaemia. The target blood glucose range was achieved as early as 1 hour following the start of the hypoglycaemic glucose clamp protocol. The achieved target glucose range was closely monitored for at least 1 hour to ensure the recommended safety level.

CONCLUSION

This study shows that the glucose clamp approach is successful for the evaluation of BGMS performance under controlled conditions at hypoglycaemic levels. This approach allows for the precision testing of the BGMS glucose data to be kept constant. The methodology in use, reproducibility and reliable performed over a short period of time.

REFERENCES

