The main aim of the study was to determine how warm the solution in an elastomeric device becomes under various simulated conditions to inform future stability studies" van Der Merwe and Green (2016).

Abstract:

AIM: Outpatient parenteral antimicrobial therapy (OPAT), both in children and adults, is increasing in use as part of a cost saving measure for the NHS.1 However there is a general lack of stability data for antibiotics in elastomeric devices. The 'Yellow Covered Document'2 (YCD), as it is commonly known, specifies the storage conditions, under which stability testing should be carried out ranging from freezing to a worst case scenario of 37°C±2°C. It is assumed that a temperature of 37°C equates to wearing a device reservoir under clothing close to the body e.g. under a winter coat, however evidence supporting this assumption is lacking. The main aim of the study was to determine how warm the solution in an elastomeric device becomes under various simulated conditions to inform future stability studies.

METHOD: The study was conducted during the winter months. Miniature Type K Thermocouples, were inserted into 2 types of elastomeric devices: 240 ml Baxter Infusor LV 10 (BI) and 120 ml I-Flow Homepump Eclipse® C-Series (IFHE). The elastomeric devices were filled with sterile water to simulate the drug solution. Temperature data was collected from devices stored for 24 hrs in a fridge followed by a 24 hour period at ambient temperature, simulating patients going about their daily lives including wearing devices under clothing when it was cold.

RESULTS: The water in the BI took 4 hrs 0 min to decrease from 20°C (ambient temperature on the day) to 5°C when refrigerated, compared to 1 hr 22 min for the IFHE. After removal from the fridge the BI took an average of 6 hrs 12 min to reach 20°C compared to 2 hrs 28 min for the IFHE. The average maximum temperature if worn normally, therefore not under any clothing, was 23.3±0.8°C in the BI and 23.8±0.6°C in the IFHE. When worn under clothing the maximum temperature reached in the BI was 28.1°C and in the IFHE 23.4°C.

CONCLUSION: Since it is well known that an increase in temperature leads to an increase in drug degradation,3 the results of this study justifies stability testing in elastomeric

devices at a more realistic temperature, preventing antibiotics and other drugs potentially being excluded from outpatient parenteral administration. A temperature of 30°C is suggested allowing for slight body temperature variation between patients as well as allowing for warmer days during summer in the UK. It is hypothesised that the delay in temperature change observed for the BI is due to the protective casing around the balloon, acting as an insulator to the environment.

Reference:

van Der Merwe, S. and Green, H. (2016) What is the maximum temperature reached in elastomeric devices under simulated OPAT conditions? Archives of Disease in Childhood. 101(9), p.e2.

doi: 10.1136/archdischild-2016-311535.32.

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