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LETTER TO THE EDITOR

Effect of hydroxyethyl starch (Voluven® 6% 130/0.4) on blood glucose levels during orthopaedic lower limb surgery under spinal anaesthesia – a prospective, randomised controlled trial

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Hydroxyethyl starch (HES) is similar to glycogen as it is derived from amylopectin. It consists of ethylated polysaccharides and glucose polymers that are metabolised into smaller residues, including glucose, resulting in the potential to induce or potentiate hyperglycaemia. It was hypothesised that Voluven® 6% (130/0.4) – a third generation saline-based product with a lower molecular weight, molar substitution, and a C_2/C_6 ratio greater than eight compared to previous first and second generation HES – could be more easily hydrolysed by α-amylase and release glucose residues at a more rapid rate.

This study, conducted in East London, South Africa, aimed to investigate the impact of HES on blood glucose levels, comparing the basal to serial capillary blood glucose levels of patients receiving Voluven® to those receiving 0.9% saline. Ethical approval was obtained from the Walter Sisulu University Human Research Committee (027/2017). Written informed consent was obtained from all participants. Clinical data were analysed using Microsoft Office Excel 2007, using t-test, Mann-Whitney U and chi-square tests, with statistical significance determined by a *p*-value less than 0.05.

The study involved 134 non-diabetic patients, undergoing lower limb surgery under spinal anaesthesia, to alleviate the surgery-related hypermetabolic stress response and its hyperglycaemic effects. A calculated dose (7.5 ml/kg) of Voluven® (Voluven® group: 68 patients) or 0.9% saline (saline group: 66 patients) was administered over 30 minutes before the administration of spinal anaesthesia, with 0.9% saline as maintenance fluid. Blood glucose measurements were taken at 0 (basal), 15, 30, 60, and 120 minute intervals, with a mean time to surgical incision of 75 ± 19 minutes ($p = 0.57$).

The Voluven® group showed a statistically insignificant increase in glucose levels above the baseline of 5.0 ± 0.74 mmol/L to 5.09 ± 0.68 mmol/L at 15 minutes, 5.04 ± 0.66 mmol/L at 30 minutes, and subsequently decreased to 4.68 ± 0.79 mmol/L at 120 minutes (Figure 1). In the saline group, the mean blood glucose levels steadily declined from 5.03 ± 0.6 mmol/L at baseline to 4.73 ± 0.67 mmol/L at 120 minutes. When comparing serial differences in blood glucose levels from the basal value to those at the set time intervals, there was a statistically significant difference of 0.16 mmol/L at 15 minutes ($p = 0.011$, 95% confidence interval [CI] 0.00 to 0.19) between the two groups, with the Voluven® infusion preventing a decrease in blood glucose levels compared to the saline group (Table 1).

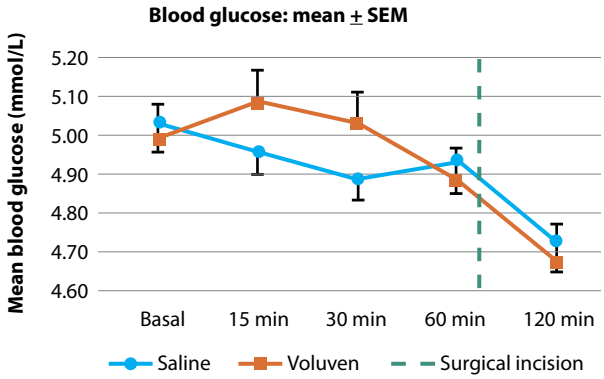

Figure 1: Mean blood glucose levels at set time intervals (basal = 0 minutes)
SEM – standard error of the mean

Table I: *p*-Values at set intervals

p-values at time interval	15 min	30 min	60 min	120 min
Saline vs. basal	0.083	0.002	0.128	< 0.001
Voluven® vs. basal	0.055	0.515	0.234	0.001
Saline vs. Voluven®	0.011	0.020	0.957	0.841

In conclusion, this study confirmed that Voluven® was associated with a statistically significant increase in blood glucose at specific time points compared to saline in this group of patients. However, all changes were within physiological norms and clinically insignificant.

Conflict of interest

The author declares no conflict of interest.

Funding source

The cost was calculated using government-issue prices. The estimated study cost above the standard of care was R2 270.41, which the investigator funded.

Ethical approval

Ethical approval was obtained from the Walter Sisulu University Human Research Committee review board (027/2017) before the study commenced.

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